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 Action Titled, "Pesticide Registration Review; Proposed Interim Decision And Draft Risk Assessment Addendum For Ethylene Oxide; Notice Of Availability" (DOCKET ID NO. EPA-HQ-OPP-2013-00244)

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 interim registration review decision (PID) and draft risk assessment addendum for ethylene oxide (EtO) (Draft RA).

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 PID, "EtO is used to sterilize 50 percent of all sterilized medical devices, or 20 billion devices, annually. EPA has investigated alternatives to EtO for sterilizing medical devices, including engaging in discussions with FDA about pursuing alternatives to EtO. EPA understands that, while there are alternative sterilization methods for some medical devices, there are currently no available alternatives—pesticidal or non-pesticidal—for some devices due to challenges such as material compatibility, scalability, and capacity. Therefore, if commercial sterilization and healthcare facilities no longer had access to EtO to sterilize medical devices, the result would likely be a disruption to the medical device supply chain, which could in turn result in a nationwide public health crisis."[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.

[1] PID page 69.

Currently, the notice published in the Federal Register on April 13, 2023, gives 60 days for public comment, closing on June 12, 2023. The PID and Draft RA together include over 100 pages of technical discussion and support documents. A 60-day comment period will not provide adequate time for HIDA to thoroughly evaluate the impact of these new regulations 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 "National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review" (EtO Commercial Sterilizer NESHAP). This proposal also has a direct impact on EtO commercial sterilizers and has the same 60-day comment period as the EtO PID and Draft RA. 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 Commercial Sterilizer NESHAP.

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 PID and Draft RA. 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