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 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:

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 interim registration review decision (PID) and draft risk assessment addendum for ethylene oxide (EtO) (Draft RA). 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 public health by decreasing risk for workers who use EtO to sterilize products. 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. 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.

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]

HIDA would like to offer comments on the proposed interim registration review decision and draft risk assessment addendum for EtO that will address the following:

1. Requiring all-in-one sterilization systems
2. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) compliance timeline
3. Challenges of employee monitoring

Requiring All-In-One Sterilization Systems
In all-in-one systems, sterilization and aeration occur in the same chamber, rather than two separate chambers. This is intended to prevent worker exposure to off-gassing EtO from treated product during the transfer from sterilization chamber to aeration room. However, all-in-one sterilization can damage some products due to pressure sensitivity and creation of excess condensation. These systems also require more overall time than traditional sterilization. Currently, the use of all-in-one systems is not required by the EPA.

Since the cycles for all-in-one sterilization are 30-50% longer than traditional methods, the overall supply of medical products would decrease considerably, straining the healthcare supply chain that is still recovering from the COVID-19 pandemic. To change to all-in-one systems, commercial sterilizers would be required to re-configure current chambers and/or install new chambers, requiring significant investments in both time and resources.

HIDA Recommends

- That commercial sterilizers not be required to implement all-in-one sterilization systems.

FIFRA Compliance Timeline
EPA provides a five-year compliance timeline for sterilizers to reduce EtO used in existing products, and a two-year compliance deadline for new products. The new rules would require:

- Installation of new indoor air monitoring systems
- Installation of new emission controls
- Installation of automated transfer equipment
- Performance testing of control equipment and total enclosure
- Development and validation of new optimized cycles

It is unreasonable to expect all commercial sterilizers to be able to achieve these requirements in the proposed timeframe. Some requirements, such as automation, may work for newly-built facilities but are not feasible for existing facilities. For cycle optimization, developing and obtaining FDA approval for new products is not attainable in two years. As facilities work to fulfilling these new requirements, the

[1] PID page 69.

resulting delays would lead to lost capacity and lack of necessary medical products in the healthcare supply chain.

HIDA Recommends

- EPA not require automation for existing sterilization facilities.

Challenges Of Employee Monitoring

EPA's proposed standard for EtO concentrations inside sterilization facilities is 100 times lower than the current Occupational Safety and Health Administration (OSHA) EtO standard. As proposed, if EtO concentrations inside a sterilization facility exceed 10 parts per billion (ppb), the following is required:

- Workers either wear self-contained breathing apparatus, use supplied respirators, or evacuate the facility until concentrations of EtO drop below 10 ppb
- All EtO areas of sterilization (processing and non-processing) must be monitored using advanced technology systems
- Monitoring system to include visual and audio alarms to alert employees when 10 ppb is exceeded

These new requirements are unnecessary as commercial sterilizers currently adhere to strong employee protections that are already in place. Implementing this type of employee monitoring is technologically challenging, if not impossible, at current proposed levels. For example, an alarm system that continuously (and accurately) monitors EtO at 10 ppb is not technologically feasible. It is also unlikely that an employee will want to work a full day wearing a self-contained breathing apparatus.

HIDA Recommends

- That commercial sterilization facilities continue to operate under established OSHA standards regarding permissible exposure limits for EtO.

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. Thank you for considering HIDA's comments 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