Federation of American Hospitals®

Charles N. Kahn III
President and CEO

June 27, 2023

The Honorable Michael S. Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Mail Code: 4607M
Washington, D.C. 20460

RE: Pesticide Registration Review: Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide; Docket ID No. EPA-HQ-OPP-2013-0244; 88 Fed. Reg. 22,447 (April 13, 2023)

Dear Administrator Regan:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable health care in both urban and rural areas across 46 States, Washington DC, and Puerto Rico. These members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals, and together they provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services to patients in diverse communities across the country.

On behalf of its members, the FAH appreciates this opportunity to submit comments to the U.S. Environmental Protection Agency (EPA or Agency) regarding the Pesticide Registration Review: Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide (EtO) (Docket ID No. EPA-HQ-OPP-2013-0244, published in the *Federal Register* on April 13, 2023 (Proposed Interim Decision).[1] The FAH supports the EPA's efforts to protect workers, the public, and the environment from harmful emissions associated with EtO sterilization processes. However, the FAH is concerned with the immediate implications that the Proposed Interim Decision may have on the healthcare sector if implemented as proposed, which could have detrimental effects on patient care and safety.

[1] 88 Fed. Reg. 22,447 (Apr. 13, 2023).

Our member hospitals and healthcare systems rely heavily on a steady and uninterrupted supply of essential supplies, including medical equipment, devices, and other critical technologies necessary to deliver effective and timely healthcare services. Reliance on these technologies being unquestionably sterile is a vital part of our members' ability to deliver quality and life-saving healthcare. Approximately 50% of all medical devices in the United States, including an estimated 95% of all surgical kits, are sterilized using EtO sterilization – ranging from surgical gowns and dressings to specialized devices such as stents and catheters.[2] Sterilization of medical devices using EtO is a "well-established and scientifically-proven method of preventing harmful microorganisms from reproducing and causing infections."[3] For many medical devices, EtO sterilization may be the only method that completely sterilizes the device without damaging its structural integrity. While the industry is working on developing additional technology to replace EtO sterilization or to dramatically reduce emissions associated with current sterilization processes, which the FAH supports, this technology does not yet exist on a market-wide basis. Without a sufficient number of operable EtO sterilization facilities, there may be some medical devices that can no longer be used in healthcare. Such devices could include surgical kits used in emergency procedures or feeding tube devices often used in neonatal intensive care units. This is a very practical concern that we urge the EPA to consider during this rulemaking process. While FAH members understand and support the need to reduce exposure to EtO emissions in the long-term, our members are concerned about the immediate short-term consequences of working toward this laudable long-term goal too rapidly – a balance is needed to ensure hospital patient safety.

The Proposed Interim Decision, as it currently stands, poses several challenges that could threaten the stability of the hospital supply chain and could impede hospitals' ability to provide adequate healthcare to their patients. First, the Proposed Interim Decision will almost certainly cause a dramatic decrease in the number of medical devices that can be sterilized in order to meet timely demand due to the Proposed Interim Decision's recommended rate reductions for EtO use and cycle calculation validations, both of which will increase the number of sterilization cycles necessary in order to process the same quantity/quality of medical devices. Secondly, the Proposed Interim Decision may require healthcare and sterilization facilities to undergo timely and resource-intensive modifications in order to meet the Proposed Interim Decision's proposed engineering controls. While some facilities will be able to meet these control standards, the small number of hospital facilities sterilizing with EtO will likely discontinue EtO sterilizations onsite and some commercial sterilization facilities may effectively need to shut down – either temporarily or permanently.

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[2] FDA Continues Efforts to Support Innovation in Medical Device Sterilization (Aug. 3, 2022), https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization.

[3] FDA Statement on Concerns with Medical Device Availability Due to Certain Sterilization Facility Closures (Oct. 25, 2019), https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures.

I. The Proposal Could Dramatically Decrease the Availability of Sterilized Medical Devices Required to Meet Care Needs

The Proposed Interim Decision is proposing to reduce the EtO concentration for new cycles to less than or equal to 500 mg/L. For some sterilization processes this is an unattainably low number under currently available technology. Further, the Proposed Rule will likely require current sterilization validation processes to be re-reviewed by the U.S. Food and Drug Administration (FDA). Introducing stringent revalidation requirements without adequate time for compliance could disrupt the supply chain and create delays in accessing essential medical products.

For nearly all sterilization facilities, it is anticipated that this proposal may result in having to revalidate sterilization procedures for every medical device sterilized using EtO. Revalidation is a time and resource intensive undertaking that will result in a reduction of medical devices available to hospitals and healthcare professionals. There is also no clear data on how many medical devices will need to be revalidated or how long this process will take. Some facilities will likely be unable to sustain these revalidation requirements and will be forced to decrease sterilization activities for multiple products and possibly close due to added costs, further exacerbating the decreased availability of sterilized medical devices.

The EPA acknowledges in the Proposed Interim Decision that methods to reduce the rate of EtO use concentration while ensuring adequate sterilization and availability of medical devices are still being developed.[4] Without adequate methods to ensure sterilization of medical devices to meet current and future demands, EtO sterilizers will be forced to wait until these new methods are developed, approved, and implemented – adding to the burden and delay of meeting demand. The FAH emphasizes that it is critical that healthcare workers and patients can depend on medical devices being 100% sterilized when they arrive at hospitals for use.

II. The Proposed Interim Decision Will Require Healthcare and Sterilization Facilities to Undergo Timely and Resource-Intensive Modifications or Will Force the EtO Sterilization Industry Overseas

The Proposed Interim Decision will likely require existing EtO sterilization facilities to retrofit their operations with new technology in order to comply with the rule. It is also likely that some existing EtO sterilization facilities will not be able to afford such retrofits or that the resulting increased costs they will pass along to hospitals will be difficult for the healthcare system to absorb. The Proposed Interim Decision's potential to increase costs and create supply chain disruptions may force hospitals to seek alternative suppliers or products. This could also lead to medical device sterilization using EtO being outsourced overseas. This shift in procurement practices could introduce new risks and challenges maintaining consistent quality and an adequate supply chain for healthcare systems, similar to the recent supply chain shortages with infant formula.

[4] See Proposed Interim Decision at P 50, FDA and industry continue to research and implement additional methods for use rate reductions through reduced concentrations that use a more conservative ISO 11135 approach while optimizing cycle designs."

Given the critical importance of timely and reliable access to high-quality medical equipment and supplies, it is essential that the Agency consider the potential consequences of the Proposed Interim Decision on hospitals' ability to treat patients.

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The FAH is concerned that without coordinated efforts among the EPA, FDA, manufacturers, and sterilizers, the Proposed Interim Decision will cause a domino effect of EtO sterilization facility closures that could have dramatic consequences for the healthcare system nationwide. The FAH encourages the EPA to consider the impact of facility closures by either allowing sterilization facilities more time to comply with the Proposed Interim Decision as it currently standards, or gradually increase the stringency of the Proposed Interim Decision's standards over a period of time to avoid existing facilities not being able to meet the proposed requirements. With greater coordination and implementation time, the EPA can ensure a sustainable healthcare system that prioritizes patient safety and care while simultaneously protecting the public and the environment.

The FAH appreciates this opportunity to submit these comments. If you have any questions, or if there is any other way that we can assist the EPA as it considers the Proposed Interim Decision, please contact me or any member of my staff at (202) 624-1534.

Sincerely,