Ethylene Oxide NESHAP Proposed Rule

OMB REVIEW WITH STERIGENICS

JANUARY 30, 2023

Overview

- Sterigenics is a leading provider of medical device sterilization services, committed to emissions reductions and employee protection, and uniquely qualified to offer input and guidance for new rules
- Ethylene Oxide sterilization is essential to U.S. public health and global capacity is limited
- Sterigenics is many years into proactive emission control enhancements, and has gained experience with implementation challenges and trade-offs
- Our lessons learned inform our recommendations for proposed EtO rules
- Impacts of NESHAP and FIFRA PID must be evaluated together when considering feasibility of rule proposals
- Reliance on flawed IRIS risk assessment creates serious industrywide issues

Sterigenics is a Leading Provider of Comprehensive Sterilization Solutions

Sterigenics
A Sotera Health company

*Our mission is **Safeguarding Global Health**, and we take our responsibility seriously because we know that we play a critical role in making the world a safer place for our **employees**, the **communities** in which we operate, and the **customers & patients** we serve.*

Comprehensive Sterilization Solutions & Expert Advisory Services

- Provider of mission-critical and government mandated sterilization services
  - 48 facilities in 13 countries
  - 16 ethylene oxide locations globally
  - 8 Ethylene oxide locations in US
- Offers all major sterilization technologies: gamma irradiation, ethylene oxide processing and electron beam irradiation, as well as X-ray and nitrogen dioxide
- End markets include Medical Device, Pharmaceutical/BioPharma, Food Safety and Advanced Applications
- 2,800+ customers in 52 countries including virtually all leading medical device OEMs

Ethylene Oxide is Essential to the U.S. Health Care System

20+ Billion
devices sold in the U.S. every year are sterilized with ethylene oxide

~50%
of medical products that require sterilization in the U.S. are sterilized using EtO

- Hospitals and patients depend on sterilization for critical and lifesaving products
- EtO is the only sterilization method that satisfies FDA-approved sterility validations for many critical medical devices
- Per the FDA, for many medical devices, sterilization with EtO is the only method that effectively sterilizes and does not damage the device during the sterilization process
- **EtO sterilization capacity in the United States is very limited, cannot count on foreign capacity in times of crisis**
- **Any loss of capacity will affect the resiliency of the supply chain for sterilized medical devices, potentially leading to shortages and endangering public health**

Sterigenics Emission Control Enhancements

- **Since 2018, Sterigenics has been proactively installing state-of-the-art emission controls and technologies to capture and control all process and fugitive EtO emissions at its US facilities**
- **While all facilities are in compliance with existing standards, voluntary emission reduction enhancements are being made based on best available control technology, including:**
  - **PTE Negative Pressure System:** New ventilation system that captures all internal facility air and routes it to a new emissions control system
  - **Double Scrub Process:** Routes EtO captured by the primary emissions control device through a secondary emission control system to achieve the highest technologically achievable level of EtO control
  - **Optimized Discharge Point:** Seals off facility from the outside and creates central discharge point(s) to further control the very small emissions that remain after treatment through the emission control systems
- Cost of enhancements per facility = $8 to $20 million
- Time to complete enhancements per facility = 2-3 years w/ some overlap

Challenges to Facility Enhancements

Sterigenics has experienced several challenges while implementing enhancements:

- Each facility is completely different, requiring unique designs and solutions
- Implementation of PTE negative pressure systems to capture fugitive emissions necessitates enhancements elsewhere in the facility to increase air flow and reduce temperatures for employee protection
- Availability of new equipment, technology and contractor services is limited, and costs have increased dramatically over the past 5 years
- Installation, validation and operation of new or unproven technology has resulted in mixed results and some lengthy delays
- State and local permitting requirements can cause unanticipated delays
- Superficial levels of knowledge on EtO across local regulators, elected officials, communities, and media - must be clear and balanced in communications

Key Recommendations for Proposed EtO Rules

- **What should be included in all proposed EtO rules:**
  - **Performance standards only -** Control efficiencies, worker exposure limits, negative pressure guidelines and EtO cycle concentration limits.
  - **Realistic implementation timelines -** Limited availability of new technology and equipment will delay compliance with new rules.
  - **Lessons learned –** Rules should reflect and be based on experience gained by Sterigenics and other sterilizers through their voluntary enhancements to existing facilities.

- **What should not be included in the proposed EtO rules:**
  - **Specific mandated engineering controls and technologies** --Existing EtO sterilization facilities are unique in design and need flexibility to comply with performance standards.
  - **Specific mandated EtO cycle designs or validation methods** -- EtO sterilization cycles are uniquely designed for the products' intended use. Single, industry wide requirements are not feasible.
  - **Specific mandated mass limits on volumes of EtO used --** All facilities' products and devices have unique properties that require their own levels of usage of EtO.
  - **Reliance on ambient air monitoring** – Technology cannot accurately measure or distinguish between background levels of EtO

Impacts of NESHAP and FIFRA PID Must Be Evaluated Together

- EPA is concurrently considering an update to NESHAP requirements and a revision of FIFRA registration requirements (currently at Proposed Interim Decision (PID) stage). Industry does not know the details of either of these proposed rules
- **A full regulatory review of both proposals should be required *prior to* public release, including how various control technologies can have different impacts on facilities and EtO concentrations**
- For example, implementation of certain control equipment (e.g., PTE negative pressure systems to capture fugitive emissions) could increase EtO levels and temperatures within a facility, and implicate other equipment that might be required to increase air flow and lower temperatures for employee protection
- OMB should review the FIFRA PID as it meets Ex Order 12866's definition for a significant regulatory action
  - Significant potential to "adversely affect . . . the economy [or] a sector of the economy [and] public health or safety [and] raise novel or legal policy issues." Ex. Order 12866, Sec. 3(d), (f).
  - Potentially inconsistent with policy for resilient, diverse, and secure domestic supply chains to address pandemic and other risks -- See Ex. Order 14017 Feb 24, 2021

Lack of Updated Standards and Reliance on IRIS Risks Assessment Creates Serious Issues

- **EPA's continued reliance on the flawed and outdated 2016 IRIS risk assessment has resulted in unfounded consequences negatively impacting the medical device industry and the resiliency of the public health care supply chain**
- EPA's proposed rules could also greatly exaggerate the risks from low-level exposure to EtO resulting in required mitigation measures that cannot be addressed by technologies currently available
- Tort litigation fueled by misapplications of the 2016 IRIS risk assessment is undercutting the industry's ability to serve public healthcare needs, including raising capital for continued investment in operational enhancements at essential sterilization facilities
- Continued EPA reliance on the IRIS risk assessment without adequate context regarding the evolving science of EtO (e.g. background and endogenous levels of EtO) or levels of exposure has given rise to communications exaggerating the actual risk to the public and employees presented by sterilization facilities
- **The industry needs and supports updates to existing rules and requirements that are well-founded, evidence-based and grounded in peer-reviewed science and literature**

Key Takeaways

- **EtO remains essential to public health** and regulation of its use requires a balanced approach that ensures the needs of communities, workers, and patients are all considered
- **Industry desperately needs updated rules** that are performance based and that adequately consider best available technology and realistic implementation timelines
- **The NESHAP and FIFRA PID must be analyzed together** to ensure feasible rules that protect the availability of medical devices, and resiliency of the public health supply chain, and mitigate potential risks for employees and communities
- Reliance on the outdated and overly conservative **IRIS risk assessment has exaggerated risk levels** presented by EtO facilities
- Failure to properly **address these considerations at a senior government-wide level** could jeopardize the US medical sterilization industry and lead to **shortages of sterilized medical products** in the US


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