Ethylene Oxide Commercial Sterilizer NESHAP

OMB REVIEW OF FINAL RULE

FEBRUARY 2024

Overview

- Sterigenics is a leading provider of medical device sterilization services, fully committed to achieving emissions reductions and to protecting its employees and the surrounding community
- The concerns OMB will hear from Sterigenics and other commenters regarding the potential for facility shutdowns and increased reliance on foreign supplies of medical devices are real
- But there is viable path to a protective NESHAP Final Rule by using:
  - Permanent Total Enclosure (PTE)
  - Appropriate destruction limits with maximum concentration limits (not mass limits)
  - Realistic timelines consistent with the Clean Air Act provisions allowing 3 or more years
- OMB should ensure that a balanced view of all risks and benefits is part of the final rule and evaluate impacts of the FIFRA ID scheduled for later this year

Sotera Health Overview

- Sterigenics is one of three businesses of Sotera Health which operate with one common mission, Safeguarding Global Health®.
- Sterigenics is a leading global provider of comprehensive sterilization solutions and expert advisory services.

Sotera Health

Safeguarding Global Health®

Sterigenics
A Sotera Health company

Comprehensive Sterilization Services

- Provider of mission-critical and government mandated sterilization services
  - » 48 facilities in 13 countries
  - » 8 EtO facilities within the United States
- Offers all major sterilization technologies: Gamma Irradiation ("Gamma"), Ethylene Oxide ("EtO") & Electron Beam ("E-Beam")
- End markets include Medical Devices, Pharma, and Food
- 2,000+ customers in 52 countries including virtually all leading medical device OEMs, served via multi-year contracts

Safeguarding Global Health – with every product we sterilize.

Nelson Labs
A Sotera Health company

Expert Lab Testing and Advisory Services

- Provider of microbiology and biopharma testing services
  - » State-of-the-art facilities across 13 global lab locations
- Offers 900+ tests across the product lifecycle, from initial product validation to ongoing quality control and extractables and leachables testing
- End markets include Medical Devices, Pharma and Tissue
- 3,000+ active customers including leading medical device and pharma manufacturers

Safeguarding Global Health – with every test we complete.

Nordion
A Sotera Health company

Gamma Technologies

- Global leader in Cobalt-60 ("Co-60") supply
  - » Co-60 is the key input for Gamma sterilization
- Long-term Co-60 supply contracts with nuclear reactors at multiple reactor sites
- 40 active customers including contract sterilizers and medical device manufacturers, served via multi-year agreements

Safeguarding Global Health – with every critical isotope we supply.

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
- 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
- Sterigenics has experienced significant technical challenges, equipment/permit lead times, and costs while installing these new enhancements
  - Costs per facility far exceed EPA estimates

Final NESHAP Rule Concerns and Recommendations

- Some proposed requirements are not achievable with current technology:
  - Mass limits /Volumetric limits - Many facilities cannot meet proposed limits
  - Destruction Removal Efficiency (DRE) Limits - Proposed DREs are not achievable and higher than pollution control manufacturer guarantees
  - Lack of maximum concentration limits – Such limits are needed for emission streams with low EtO concentrations
  - Compliance Timeline - Industry needs maximum time allowed by Clean Air Act (3 years with potential for extensions)
- Sterigenics recommends the following highly-protective limits in Final Rule:

Emission Source	DRE (%)	Max. Conc. (ppm)
Sterilizer Chamber Vent (SCV)	99.9%	0.3
Aeration Room Vent (ARV)	99%	0.3
Chamber Exhaust Vent (CEV)	99%	0.3
Fugitives (Group 1 and 2)	80%	0.3

- Any new requirements in Final Rule need to be achievable and EPA may provide compliance flexibility in final rule (e.g., facility-wide limits)

Ethylene Oxide is Essential to the U.S. Health Care System – Concerns Over Additional Capacity Loss Are Real

- EtO is the only sterilization method that satisfies FDA-approved sterility validations for many critical medical devices
- Any loss of capacity will affect the resiliency of the supply chain for sterilized medical devices, potentially leading to shortages and endangering public health
- EtO sterilization capacity in the United States is very limited, cannot count on foreign capacity in times of crisis
  - » Many companies have already started sterilizing products in other countries because of the concerns of the NESHAP rule
  - » There are limited to no current US sterilization capacity expansions or greenfield projects underway
  - » Implementation of new requirements will reduce operating capacity within existing facilities
  - » There could be additional facility closures based on costs of upgrades

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

All Costs and Benefits Must Be Considered in Final Rulemaking

- We recognize need to be cautious in protecting public health, but risks must be properly balanced with potential reduction in domestic sterilization capacity
- EPA has not quantified the impacts to human health and relies on numerous conservative estimates:
  - Person living outdoors for 70 years
  - Person located where worst case of modeled air impact occurs
  - Modeling uses peak 1 hour emissions data and upper bound estimates of health risk
- EPA analysis disregards data that endogenous levels of EtO and levels in ambient air are greater than levels used to calculate EtO emissions risks
- EPA's economic and capacity analysis is flawed
  - EPA claims capacity reductions will be transitory and costs passed on to customers, but does not consider shift of capacity to non-US markets or capacity loss created by facility enhancements
  - Costs of implementation, including high cost to public health of medical product shortages, are greatly underestimated

Impacts of FIFRA ID Must Also Be Evaluated by OMB

- EPA is concurrently considering a revision of FIFRA registration requirements (Interim Decision (ID) stage)
- Sterigenics has filed comments noting:
  - Fundamental incompatibility of proposed NESHAP/PID control measures
  - Use of an environmental exposure model for occupational exposures
  - Unachievability of automation for existing facilities
  - Inability to monitor down to 10 ppb in real time
- The FIFRA ID is focusing on EtO levels within the sterilization facility; many NESHAP final rule requirements (e.g., PTE negative pressure systems to capture fugitive emissions) could *increase* EtO levels within a facility
- EPA needs to review carefully the FIFRA ID and, consistent with a final NESHAP, fully assess potential impacts of *both actions* on US sterilization capacity
- Given the scope of E.O. 12866 with regard to agency statements of "general applicability and future effect" including those that can "adversely affect . . . a sector of the economy" OMB has ample authority to review the FIFRA ID before it is finalized

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 supports updated rules** that are achievable and that adequately consider available technology and realistic implementation timelines
- **EPA must ensure all costs are analyzed and the actual benefits are properly reflected** in the final NESHAP rulemaking
- **The NESHAP and FIFRA ID 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
- **Failure to properly address both actions** could jeopardize the U.S. medical sterilization industry and lead to **shortages of sterilized medical products** in our country


Sterigenics®