Final Amendments to Air Toxics Standards for Ethylene Oxide Commercial Sterilization Facilities FACT SHEET

- On March 14, 2024, the U.S. Environmental Protection Agency (EPA) announced final amendments to Clean Air Act standards for ethylene oxide (EtO) emitted from commercial sterilization facilities, also called commercial sterilizers.
    - Commercial sterilizers are one of the nation's leading sources of EtO, a potent cancer-causing air pollutant.
    - Commercial sterilizers that use EtO must follow the National Emission Standards for Hazardous Air Pollutants (NESHAP). EPA is significantly strengthening this regulation based on our updated understanding of risk from EtO exposure, as well as available technologies to control emissions.
    - This rule will reduce EtO emissions by over 90 percent, reducing cancer risk in dozens of communities nationwide. It will enable cost-effective compliance, mitigating and managing any potential risks to the supply chain.

Key Information:

- **Slashes emissions of toxic air pollution:** Based on feedback and public comment, EPA strengthened the standards from proposal to final resulting in reduced EtO emissions to the outdoor air. Using proven and achievable air pollution controls, the result is an over 90 percent reduction in EtO emissions from commercial sterilizers nationwide.
- **Significantly reduces cancer risks**: Finalizing this rule is one of the most important measures EPA is taking to reduce emissions of EtO. Once implemented, this rule will reduce the lifetime cancer risk from EtO exposure for people living near commercial sterilization facilities.
- **Requires accountability and transparency:** Continuous emissions monitoring and quarterly reporting for most commercial sterilizers will provide EPA and communities with data to ensure EtO emissions are controlled and not entering the outdoor air before being captured and controlled.

Quick Facts

- This action will result in an over 90 percent reduction in EtO emissions nationwide from commercial sterilizers.
- These reductions in EtO are critical for communities that have suffered disproportionately from toxic air pollution for far too long.
- Once the rule is in full effect, no individual will be exposed to EtO at levels that correspond to a lifetime cancer risk of greater than 100-in-1 million.
- The number of people with a potential risk of greater than or equal to 1-in-1 million will be reduced by approximately 92 percent.
- There are currently 88 commercial sterilizers in the U.S., with two facilities under construction.

- **Ensures a safe supply of medical devices for patients and hospitals:** Building on extensive engagement with communities, as well as industry and federal partners with expertise in medical supply chain issues, the rule lays out a process that safeguards our nation's critical supply of sterilized medical equipment.

Ensuring a Safe Supply of Sterilized Medical Devices:

- In developing this final rule, EPA was mindful of the vital role that commercial sterilizers play in supplying the nation with sterile medical devices. The Agency carefully evaluated the feasibility and cost of compliance and any potential implications for the medical supply chain.
- This final rule provides sufficient time and flexibility for facilities to come into compliance, simultaneously providing strong public health protection for nearby communities while minimizing any potential impacts to the medical device supply chain.
- A number of facilities covered by this final rule have already implemented one or more of the controls that will be needed for compliance.
- The final rule provides a timeline for compliance that ensures that facilities using larger amounts of EtO must comply sooner than other facilities because they pose the greater risk:

Facility EtO Use	**Compliance Timeframe**[1]	**Number of Facilities**
Over 60 tons per year	Two years	28
1-60 tons per year	Two to three years	39
Less than 1 ton per year	Three years	21

- EPA's own experience working with facility owners, as well as state and local agencies that have regulated EtO emissions from these facilities, confirms that it is feasible for individual facilities to install the required controls within the deadlines provided in this rule. This rule offers cost-effective compliance options and mitigates and manages any potential risks to the supply chain. It ensures that these standards reduce cancer risks for communities exposed to EtO emissions.
- Among other things, the final rule extends the compliance deadlines to provide the maximum compliance time allowed by law. It provides sufficient compliance time to enable facilities to continue sterilizing essential products while installing and testing new control systems and associated equipment that will provide ample protection for nearby communities.

Details:

[1] Facilities will have an additional 180 days to demonstrate compliance. Also, the Clean Air Act provides that under certain standards (i.e., those established under section 112(d)), facilities can apply for a 1-yr extension. The 1-year extension is not available for standards issued under section 112(f)to reduce risk.

- This final rule requires facilities to install available and proven technologies, practices, and procedures which have been demonstrated to significantly reduce EtO emissions.
- Ethylene oxide is a significant contributor to air toxics risk, and reducing the cancer risk posed by this chemical is a major priority for EPA.
- EPA's analysis for this rule examined the risks posed by commercial sterilizers to those living around the facilities. Once the rule is in full effect, no person will be exposed to EtO at levels that correspond to a lifetime cancer risk of greater than 100-in-1 million, which is an important Clean Air Act metric for elevated cancer risk. The number of people with a potential risk of greater than or equal to 1-in-1 million will be reduced by approximately 92 percent.
- EPA estimates that the capital costs for the final rule would be $313 million and would reduce emissions by 21 tons per year, which will lower the risk of adverse health effects, including cancer, for individuals in communities near commercial sterilization facilities.
- Commercial sterilizers use EtO to sterilize devices that cannot be sterilized using steam or radiation, such as some medical and dental equipment. According to the Food and Drug Administration (FDA), approximately 50 percent of sterile medical devices in the United States - approximately 20 billion devices each year -- are sterilized with EtO.
- Medical sterilization is a critical function that ensures a safe supply of medical devices for patients and hospitals. This final rule reflects robust engagement with the public, industry, and our federal partners.
- Based on extensive input and our review, EPA is finalizing the following amendments to the NESHAP:
    - Establish standards for currently unregulated emissions, such as building leaks ("room air emissions") and chamber exhaust vents, to reduce risk and account for technological developments.
    - Strengthen standards that are on the books for sources such as sterilization chamber vents and aeration room vents.
    - Strengthen compliance by requiring the use of continuous emissions monitoring systems, which will provide much-needed assurance to nearby communities.
    - Include definitions for affected sources.
    - Ensure that sterilizers are subject to emission standards during periods of startup, shutdown, and malfunction.
    - Other clarifying items including electronic reporting and technical revisions.
- The final rule will address emissions at nearly 90 commercial sterilization facilities that are owned and operated by approximately 50 companies.
- In this final rule, EPA is addressing the second Risk and Technology Review for the EtO NESHAP, which was initially promulgated in 1994 and last amended in 2001. EPA last reviewed the rule in 2006.
- In the coming weeks, EPA will also finalize an action that will reduce outdoor emissions of EtO from the chemical sector under the Clean Air Act. The chemical sector rule is expected to reduce EtO-related cancer risks in communities surrounding the facilities it covers.
- EPA's Office of Pesticide Programs (OPP) is also working on a comprehensive set of new mitigation

measures for workers who use EtO to sterilize products and for other people in communities near sterilization facilities.

TECHNOLOGY AND RESIDUAL RISK REVIEW:

- The Clean Air Act requires EPA to assess, review, and revise air toxics standards, as necessary, taking into account developments in practices, processes, and control technologies, every eight years.
    - Although risk review is a one-time obligation, which EPA completed along with a technology review (RTR) in 2006, the Clean Air Act does not limit EPA's discretion or authority to conduct another risk review should EPA consider that such review is warranted.
    - Due to changes in our understanding of the health effects of ethylene oxide, EPA has conducted a second residual risk review for commercial sterilization facilities using ethylene oxide in order to ensure that the standards provide an ample margin of safety to protect public health.

BACKGROUND:

- The Clean Air Act requires EPA to regulate hazardous air pollutants, also known as air toxics, from categories of industrial facilities in two phases.
- The first phase is "technology-based," where EPA develops standards for controlling the emissions of air toxics from processes and equipment in an industry group or "source category." These standards reflect application of the maximum achievable control technology (MACT) and are based on emissions levels that are already being achieved by the best-controlled and lower-emitting sources in an industry. For commercial sterilizers that emit smaller amounts of air toxics, also known as area sources, EPA has the option of setting standards based on generally available control technology (GACT).
- Within eight years of setting the MACT standards, the Clean Air Act directs EPA to assess the remaining health risks from each source category to determine whether the MACT standards protect public health with an ample margin of safety and protect against adverse environmental effects. This second phase is a risk-based approach called "residual risk review." Here, EPA must determine whether more health-protective standards are necessary.
- Every eight years after setting technology-based standards, the Act requires EPA to review and revise the standards, if necessary, to account for improvements in air pollution controls and/or prevention.

FOR MORE INFORMATION:

- To read a copy of the final rule, visit: https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities

- Today's action and other background information are also available either electronically at https://www.regulations.gov/, EPA's electronic public docket and comment system, or in hardcopy at the EPA Docket Center's Public Reading Room.
    - The Public Reading Room is located at EPA Headquarters Library, room number 3334 in the WJC West Building, 1301 Constitution Ave., NW, Washington, DC. Hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time, Monday through Friday, excluding federal holidays.
    - Visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor materials will be processed through an X-ray machine as well. Visitors will be provided a badge that must be visible at all times.
    - Materials for this final action can be accessed at https://www.regulations.gov/ using Docket ID No. EPA-HQ-OAR-2019-0178.