United States Environmental Protection Agency

FACT SHEET

EPA Issues Proposed Actions to Reduce Ethylene Oxide Exposures under the Nation's Pesticide Control Law

Action

- On April 11, 2023, the U.S. Environmental Protection Agency (EPA) used its authority under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to propose increased protections for workers and community members exposed to ethylene oxide (EtO) when it's used to sterilize products.
- EPA has been evaluating EtO as part of the registration review process. This review process requires the Agency to re-evaluate pesticides every 15 years to ensure that risk assessments and decisions reflect the best available science, and that they appropriately address identified risks.
- As part of that review, EPA has proposed new actions to protect both workers that are exposed to EtO on the job as well as people who live, work, or go to school or daycare near sterilization facilities that emit EtO.
- Facilities are already using some of EPA's proposed protections to reduce exposures. EPA's proposal would apply these controls nationally to all facilities that use EtO as a sterilant. This includes commercial sterilizers and some healthcare facilities.
- EPA is proposing to update protections to reflect our new understanding of risk from EtO and technologies available to reduce this risk. The proposal would cancel certain EtO uses where alternatives exist, and require engineering controls and other technologies, practices, and procedures that would dramatically reduce risks from EtO emissions inside commercial sterilizers and healthcare facilities. Reducing emissions will help to reduce risks for workers and community members who live or spend significant time near facilities that use EtO.
- The actions EPA has proposed are driven by the latest available science, including a new agency analysis showing that risks to workers who sterilize products over the course of a 35-year career are more significant than we had previously thought.
- This proposal is part of a comprehensive series of actions to address health risks from EtO. In addition to the proposal under FIFRA, EPA is proposing actions under the Clean Air Act that would 1) cut emissions from commercial sterilizing facilities by 80 percent; and 2) significantly reduce emissions of EtO from chemical manufacturing facilities.

Details on Proposal

- EPA has proposed new actions to protect both workers that are exposed to EtO on the job as well as people who live, work, or go to school or daycare near sterilization facilities that emit EtO.

- EPA's proposal would prohibit the use of EtO where it's not needed because effective alternatives exist, which includes uses in museums, archival settings, beekeeping equipment, cosmetics, and musical instruments.
- EtO fills a critical need in sterilizing medical devices used for lifesaving care and other items that can't be sterilized using alternatives such as steam or radiation and EPA has developed a set of proposed protections for workers in these facilities who are at risk for higher exposure to the chemical because of their proximity to it.
- The proposal would reduce the amount of EtO that's used to sterilize medical devices, while still making sure that Food and Drug Administration requirements for sterility are met.
- The proposal includes requiring engineering controls, like automation or emissions capture technology to reduce exposures to workers during the sterilization process.
- The proposal would expand personal protective equipment (PPE) requirements by requiring employees in sterilization facilities to wear PPE during certain tasks of the sterilization process when EtO exposures could be higher.
- EPA has also proposed a new requirement that all workers in a facility wear personal protective equipment when EtO concentrations exceed 10 parts per billion (ppb) based on real-time monitoring, including employees that aren't directly working with EtO. 10 ppb is the lowest real-time concentration of EtO that can be quantified in commercial sterilization facilities using today's technology.
- EPA proposed new engineering controls for healthcare facilities that sterilize medical equipment, such as negative air pressure in rooms containing EtO sterilization devices and the use of abatement devices that will remove EtO from the exhaust air and reduce discharge to the environment.
- The proposal includes new data collection and reporting requirements in commercial sterilization facilities that would help identify and improve protective monitoring technologies and assess the effectiveness of the proposed mitigation measures in the future. Based on the data the EPA receives, the Agency intends to initiate the next round of registration review for EtO earlier than the typical 15-year timeframe so that we can take faster action to incorporate any needed additional protections or any advances in technology.
- Some commercial sterilization facilities have already successfully implemented some of these measures, including reducing the amount of EtO used for sterilization and installing engineering controls that reduce worker and community exposures.
- The proposal includes different timelines for controls depending on their complexity and feasibility. For example, workers can use respirators far more quickly than it takes to reengineer control systems.
- EPA will accept comment on this proposal for 60 days in docket EPA-HQ-OPP-2013-0244 at http://www.regulations.gov.

Details on Risk

- EPA is moving urgently to advance these new protections based on the Agency's latest assessment of cancer risks from EtO exposure in occupational settings, which are more significant than previously understood.
- EPA has found that routine exposure to EtO from these facilities do not cause short-term or acute health risks.
- EPA's new analysis estimates the following risks for workers who handle EtO. Actual risks may vary depending on the types of controls used at facilities, the amount of time spent working around EtO, and other factors. These risks can be reduced through measures that have already been taken or can be taken quickly.
    - Without the new, proposed practices or engineering controls in place to protect them, we would expect that if 17 workers who apply EtO to medical devices in commercial sterilization facilities are exposed to EtO over the course of their entire career (8 hours per day, for 240 days a year, for 35 years) then one of those 17 workers would develop cancer from this work.
    - Without the proposed practices or engineering controls in place to protect them, we would expect that if 25 workers who apply EtO in healthcare facilities are exposed to EtO over the course of their entire career (8 hours per day, for 240 days a year, for 35 years) then one of those 25 workers would develop cancer from this work.
    - Without the new, proposed practices or engineering controls in place to protect them, we would expect that if 36 workers who apply EtO to spices in commercial sterilization facilities are exposed to EtO over the course of their entire career (8 hours per day, for 240 days a year, for 35 years) then one of those 36 workers would develop cancer from this work.
- In commercial sterilization facilities, EPA also found that continuous, long-term exposure to EtO could lead to elevated cancer risk for workers who do not directly handle EtO but work in other areas of these facilities. EPA's proposed mitigations will reduce risk for people who may be exposed to EtO in or near these settings and many facilities are already taking these measures or can take additional measures quickly. Note that EPA expects risks to be much lower to those near hospital sterilization settings than those near commercial sterilization facilities. That is because the amount of EtO applied in healthcare facilities is significantly less than the amount of EtO applied in commercial sterilizing facilities.
- In addition, EPA's assessment found that there may be risks to residents near commercial sterilizers. Risk levels for those who live near commercial sterilization facilities may be over one in one million if they are exposed over the course of a lifetime.
- Furthermore, EPA's assessment found that there may be risk for children who go to school or daycare near commercial sterilizers. Risk levels for certain children may be over one in one million. If one million of these children were exposed for the entirety of the time they spend in a school or daycare, at least one of them would be expected to get cancer from that exposure.
- EPA is proposing robust, unprecedented controls to reduce risks for those who work at EtO sterilization facilities and for those who live, attend school, go to daycare, or otherwise

spend significant amounts of time near EtO sterilization facilities that emit EtO into the outdoor air.

Ethylene Oxide (EtO)

- Ethylene oxide (EtO) is a colorless gas used to sterilize medical equipment and spices. It is also used to make other chemicals that are used in making a range of products, including antifreeze, textiles, plastics, detergents, and adhesives.
- According to the Food and Drug Administration, EtO is used to treat approximately 50 percent of sterile medical devices, which is about 20 billion medical devices annually. Sterile medical equipment is necessary to ensure that surgeries and other medical procedures are safe for patients and healthcare providers.
- Commercial sterilization is one of the main sources (along with chemical manufacturing and hospital sterilizers) of ethylene oxide emissions.
- Additionally, EtO is a fumigant and sterilant registered for use on dried herbs and spices, dried vegetables, and other seasoning materials to prevent serious food-borne illnesses such as *Salmonella* or *E. Coli*. Alternatives for this use may not be viable for every situation, pathogen, or consumer market.
- EtO causes cancer in humans. Scientific evidence in humans indicates that exposure to EtO for many years increases the risk of cancers of the white blood cells, including non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia. Studies also show that long-term exposure to EtO increases the risk of breast cancer in women.

Background

Certain products containing EtO are considered pesticides under federal law because they are used to kill microorganisms such as viruses and bacteria. Pesticide labels, which are part of a pesticide registration and are legally binding under FIFRA, carry directions and precautions that define who may use a pesticide, as well as where, how, how much, and how often it may be used. Failure to follow the label is a violation of federal law.

EtO is currently undergoing registration review, a process EPA conducts for all currently registered pesticides every 15 years to ensure that products can carry out their intended function without creating unreasonable risks to human health and the environment. EtO is currently at the Proposed Interim Decision (PID) phase of registration review, which is the stage in which EPA proposes mitigations, as necessary, to reduce the potential risks of a pesticide.

In November 2020, EPA issued a draft human health and ecological risk assessment (2020 DRA) for ethylene oxide as part of the registration review process. The EtO 2020 DRA has been revised for the human health inhalation risk assessment using EPA's 2016 IRIS assessment to characterize the cancer risk from inhalation exposure.

For more information, please visit https://epa.gov/ethylene-oxide