United States Environmental Protection Agency

News Releases from Headquarters › Air and Radiation (OAR)

EPA Moves Forward on Suite of Actions to Address Ethylene Oxide

11/06/2019

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WASHINGTON (Nov. 6, 2019) — Today, the U.S. Environmental Protection Agency (EPA) continued its progress on a suite of actions to address ethylene oxide by announcing proposed amendments to the Miscellaneous Organic Chemical Manufacturing National Emission Standards for Hazardous Air Pollutants (NESHAP), known as MON, to reduce hazardous air pollutants, including ethylene oxide. EPA is also continuing work to address ethylene oxide from commercial sterilizers; working closely with other federal partners such as the Food and Drug Administration (FDA) to address medical device supplies; and providing an update on its work to better understand ethylene oxide – in particular, work to characterize air concentrations of this chemical.

"EPA's actions underscore the Trump Administration's commitment to addressing and reducing hazardous air pollutants, including ethylene oxide emissions, across the country," **said EPA Administrator Andrew Wheeler.** "The proposed MON amendments represent the first regulatory action that EPA is taking to address ethylene oxide under our two-pronged approach to reduce emissions. This proposal would reduce other hazardous air pollutants from our nation's air, while providing improved compliance measures for industry."

Proposed MON Amendments

The proposed MON amendments are expected to reduce emissions of hazardous air pollutants from the source category by 116 tons per year, which includes a 93 percent reduction in ethylene oxide emissions from covered facilities. The

proposal addresses EPA's obligation under the Clean Air Act to conduct the residual risk and technology (RTR) review for the miscellaneous organic chemical manufacturing source category. EPA has evaluated the risks posed by air toxics from this source category and has determined cancer risks for this source category to be unacceptable. To reduce risks to an acceptable level, EPA is proposing additional requirements for process vents, storage tanks, and equipment in ethylene oxide service. In addition to reducing ethylene oxide emissions, the MON amendments would include updates to requirements for flares, heat exchange systems, and equipment leaks. These proposed requirements would further reduce emission of air toxics for these covered facilities. EPA is taking comment on all aspects of this proposal and will hold public hearings in early December in Washington, DC and Houston, TX. A separate notice will provide details on the hearings shortly.

To further explain the uncertainties in the estimated cancer risks from ethylene oxide, EPA is also posting the *Memorandum: Sensitivity of ethylene oxide risk estimates to dose-response model selection*, which explores the various dose-response models evaluated in the ethylene oxide carcinogenicity assessment. This information provides important context for interpreting the risk results from the Residual Risk Assessment developed in support of this proposal.

EPA's Two-Pronged Approach to Ethylene Oxide

EPA has been taking steps to address ethylene oxide emissions after EPA's National Air Toxics Assessment, issued in 2018, found that ethylene oxide emissions may be contributing to potentially elevated cancer risk in some areas around the country. Since then, EPA has been taking a two-pronged approach to evaluate these emissions. First, the agency is reviewing existing Clean Air Act regulations for industrial facilities that emit ethylene oxide. Second, because the process for revising our regulations takes time, EPA is gathering additional information on ethylene oxide emissions and is working with state and local air agencies to determine whether more immediate emission reduction steps may be warranted. By working with our state and local partners, we seek to identify opportunities to achieve early emission reductions.

Upcoming review of standards for commercial ethylene oxide sterilization facilities

In addition to the proposed RTR for the MON, EPA is also reviewing the NESHAP for Ethylene Oxide Commercial Sterilization and Fumigation Operations. EPA intends to issue an Advance Notice of Proposed Rulemaking (ANPRM) to outline potential approaches and gather comments and data. The ANPRM will seek information on several key topics, including possible approaches to calculate and control fugitive emissions; potential improvements to EtO monitoring technologies; and process differences between types of sterilization facilities. EPA also will issue a survey under Clean Air Act section 114 to gather information from several commercial sterilization companies on facility characteristics, control devices, work practices and costs for emission reductions. Our efforts are intended to inform a potential future proposed rule for ethylene oxide commercial sterilizers in the coming months.

Federal Partnerships

EPA is also working with our federal partners to better understand ethylene oxide, including participating in an FDA advisory committee meeting November 6-7, 2019, to discuss how best to advance innovations in medical device sterilization. FDA is actively working with sterilization experts, medical device manufacturers, and other government agencies to advance innovative ways to sterilize medical devices with lower levels of currently used agents, and employ new agents or alternatives, while maintaining device safety and effectiveness. In addition, FDA released a statement regarding "concerns with medical device availability due to certain sterilization facility closures" on October 25, 2019.

Work to Characterize Air Concentrations of Ethylene Oxide

EPA is also beginning to examine the question of whether ethylene oxide is present more broadly in the air in the U.S., and if so, at what levels. As part of this work, the agency has begun to analyze available air quality samples from a subset of existing, longstanding monitors in the National Air Toxics Trends Stations (NATTS) network and the Urban Air Toxics Monitoring Program (UATMP) network to determine whether ethylene oxide was present in the air at those locations. These networks, which are not focused on specific industrial sources, are designed to help track progress in reducing air toxics across the country. They include monitoring locations in both urban and rural areas. EPA analyzed samples from the subset of these monitors that send samples to EPA's national contract laboratory for analysis. The results confirmed the presence of ethylene oxide, with six-month averages ranging from about 0.2 to about 0.4 micrograms per cubic meter. We believe that there is no immediate, short-term risk from the levels of ethylene oxide found in these limited air monitoring data. There is a need to better understand low levels of ethylene oxide over a longer-term period. EPA will continue to collect information from its existing air monitoring networks and share data as it becomes available. To this end, EPA has added ethylene oxide to the list of air toxics that will be routinely monitored at all 34 sites in the NATTS and UATMP networks.

Background on Ethylene Oxide

Ethylene oxide is one of 187 hazardous air pollutants regulated by the EPA. Ethylene oxide is a flammable, colorless gas used to make other chemicals that are used in making a range of products, including antifreeze, textiles, plastics, detergents, and adhesives. Ethylene oxide also is used to sterilize equipment and plastic devices that cannot be sterilized by steam, such as medical equipment. In 2016, EPA updated its risk value for ethylene oxide. The agency is working with state, local and tribal air agencies to address this chemical.

More information on the MON can be found at: https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission

More information about the NATTS and UATMP data posting, can be found at: https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-updates

General information about the air toxic ethylene oxide, can be found at: https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide

LAST UPDATED ON NOVEMBER 6, 2019