

To fight cancer, EPA wants sterilizer companies to emit less

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A syringe is prepared at a clinic in Norristown, Pa., Dec. 7, 2021. The Environmental Protection Agency proposed Tuesday, April 11, 2023, to limit the use of the chemical ethylene oxide after finding higher than expected cancer risk at facilities that use it to sterilize billions of medical devices each year. Credit: AP Photo/Matt Rourke, File

The Environmental Protection Agency on Tuesday proposed limiting the use of the chemical ethylene oxide after finding a higher than expected cancer risk at facilities that use it to sterilize billions of medical devices each year.

The EPA says its proposal will reduce ethylene oxide emissions by roughly 80% by targeting 86 medical sterilization facilities across the United States. The companies will also have to test for the antimicrobial chemical in the air and make sure their pollution controls are working properly.

"EPA's number one priority is protecting people's health and safety," EPA Administrator Michael Regan said in a statement. The agency's proposals "would significantly reduce worker and community exposure to harmful levels of ethylene oxide," he said.

Darya Minovi, a senior research analyst with the Union of Concerned Scientists, called the action overdue by "almost a decade" and said it should have gone further to require monitoring at facility fence lines so people know what is entering their neighborhoods.

"I'm relieved and pleased that the EPA has finally issued proposed standards that are based on their own scientists' recommendations on an updated, higher cancer risk value," Minovi said in a statement.

The tightened safeguards are driven by the EPA's better understanding that ethylene oxide's threat is severe. The chemical is classified as a pesticide. A worker in a medical sterilizing plant, over the course of a career, could see their risk shoot up by as much as one extra case of cancer for every 10 people exposed. The EPA's generally acceptable increase in lifetime cancer risk is 1 in 10,000.

Ethylene oxide is a gas used to sterilize roughly half of all medical

devices and is also used to ensure the safety of certain spices and other food products. It is used to clean everything from catheters to syringes, pacemakers and plastic surgical gowns. Brief exposure isn't considered a danger, but breathing it long term elevates the risk of breast cancer and lymphoma, according to the agency.

In 2016, the EPA updated its assessment of ethylene oxide's danger based on information about exposed workers at sterilizing facilities, finding the chemical was many times more threatening than previously known. Analysis released by the agency two years later found that cancer risk was too high near some medical sterilization plants and some other facilities that release ethylene oxide.

"That set off a regulatory alarm bell," said Marvin Brown, an attorney at the environmental group Earthjustice.

Public concern grew. Sterigenics shuttered a medical sterilization plant in a Chicago suburb after monitoring found emissions spikes in nearby neighborhoods. They eventually settled numerous lawsuits.

In 2022, the EPA laid out the risk faced by residents who live near medical sterilization facilities. In Laredo, Texas, for example, residents and activists fought to clean up a sterilization facility run by Missouri-based Midwest Sterilization Corp. It was one of 23 sterilizers in the United States that the EPA said posed a risk for people nearby.

"This, for us, feels like a win," said Sheila Serna, the climate science and policy director at the environmental group Rio Grande International Study Center. She said despite improvements at the Laredo facility, the risk is still too high. Her group sued the EPA in December, pushing it to tighten ethylene oxide protections. She agreed with Minovi that the proposal should require fence line monitoring as well as protections at warehouses where sterilized products are temporarily stored.

Midwest Sterilization said the company's work helps provide life-saving medical care.

"Most of the changes proposed by the EPA have already been achieved by Midwest, or are currently being implemented," the company said in a statement.

The EPA said many facilities have already sharply reduced emissions, but those that haven't will now have to meet stricter requirements.

Scott Whitaker, president and CEO of the Advanced Medical Technology Association, said medical sterilizers provide a vital service and many devices "cannot be sterilized by another method." He said the EPA's risk assessment overstates the threat employees face and undervalues the protections they are already provided.

He added that the facilities are already at capacity and if some close, it could delay medical care. The 18-month time frame for installing technology to reduce emissions after the final rule is issued is "much too short," Whitaker said in a statement. "It could take many months for abatement equipment to arrive. Supply chains and manufacturing are still recovering from the pandemic."

Susan Buchanan, an environmental and occupational health physician at the University of Illinois Chicago School of Public Health, said ethylene oxide is a "potent carcinogen" that is also very good at sterilizing medical equipment. She rejects arguments that the EPA overstated ethylene oxide's risks.

"The EPA is full of really smart, diligent, nonaligned scientists," she said. "If anything, the EPA is sometimes not protective enough."

The EPA also wants to require protective vapor masks for people who

work with high amounts of ethylene oxide and says some workplaces, including museums, should stop using it altogether because safer alternatives exist.

Tuesday's proposal follows the EPA's directive last week to [cut emissions from chemical plants](#) in general to reduce cancer risk. In part, that rule targeted manufactures of ethylene oxide. Tuesday's proposal targets those who use it.

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