**11 states ask EPA to crack down on ethylene oxide emissions**

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*Ethylene oxide*

Eleven state attorneys general are urging the U.S. Environmental Protection Agency to impose stricter regulations over commercial operations that emit ethylene oxide (EtO), a widely used medical device sterilant gas.

The EPA, which considers EtO a carcinogen, has been fielding comments on it in light of public outcry over emissions from medtech sterilization plants during the past year.

Illinois attorney general Kwame Raoul ordered a Sterigenics EtO plant in Willowbrook closed one year ago because of concerns over emissions. The plant used EtO to sterilize millions of devices annually, beginning in 1984. Willowbrook area residents and workers have filed more more than 76 lawsuits against the company claiming EtO exposure caused cancer and other health problems. Citizens, local and state officials in Georgia and Michigan, which have EtO plants operated by companies such as Sterigenics and BD, have also been clamoring for tighter regulations.

Raoul and 10 other attorneys general signed a comment letter arguing that the EPA’s current National Emission Standards for Hazardous Air Pollutants (NESHAP) fail to adequately protect workers and communities from the harmful effects of EtO.

The AGs also call on the EPA to work with the FDA to support research into effective alternatives to EtO sterilization and end over-reliance on the practice. In January, the FDA asked the EPA to leave it out of its new proposed regulations and the EPA complied.

“Illinois has already acted to significantly reduce EtO emissions, but there is an urgent need for the EPA to strengthen national EtO standards to protect communities throughout the country,” Raoul said in a news release. “The EPA has a responsibility to protect the health and safety of residents by adequately regulating hazardous air pollutants. I urge the EPA to live up to this responsibility and implement the standards needed to address the severe risks to public health and the environment posed by EtO emissions.”

EtO emissions from commercial operations such as sterilization plants are subject to NESHAP, which the EPA is required to review every eight years. The EPA last reviewed the NESHAP for commercial sterilizers in 2006 . The current NESHAP allows commercial sterilizers to emit tens of thousands of pounds of EtO annually.

Raoul and the coalition propose the EPA make several changes to the NESHAP, including extending it to include facilities that use one ton or more of EtO in any consecutive 12-month period. The group also asked the EPA to require commercial sterilizers to:

* Reduce emissions to the atmosphere from each exhaust point by at least 99.9%.
* Capture 100% of all generated EtO emissions.
* Conduct all required emissions testing under operating conditions that represent maximum emissions.
* Install, operate, calibrate and maintain a continuous emissions monitoring system.
* Submit dispersion modeling that demonstrates its EtO emissions achieve the reductions necessary to protect human health.

The coalition also includes the attorneys general of Delaware, Iowa, Maryland, Massachusetts, Michigan, Minnesota, New Jersey, New York, Rhode Island and Vermont.

More than 288,000 people live in areas across the country that the EPA identified to be at elevated risk of EtO exposure, and there are more than 100 commercial sterilization facilities subject to the NESHAP, according to Raoul’s office. These facilities are located in 36 states. The attorneys general claim that the EPA’s failure to update the NESHAP to reflect current science has led state regulators to step in and do it themselves. The Illinois legislature in 2019 enacted the strictest EtO emissions regulations in the nation.

The Willowbrook plant shutdown prompted the first in a series of FDA warnings about possible device shortages. Other shutdowns followed in Georgia. State and local scrutiny of EtO emissions and public outcry may lead to what one industry advocate called a “rolling effect” of plant shutdowns and device shortages nationwide.

EtO sterilization works at low temperatures — between 90°F and 135°F — making it a viable option for devices made of multiple components and materials, including plastics, polymers, metals and glass, as well as coatings, bonds and packaging from damage. It can also penetrate different types of device packaging, enabling sterilizers to process truckloads’ worth of devices simultaneously.

The EPA accepted public comments until Feb. 10. Medtech trade group AdvaMed, which has been working with the FDA and the EPA on the EtO issue, took the opportunity to get in one more public comment.

AdvaMed urged the EPA to reassess its risk assessment value for EtO, arguing that the threshold is neither practical nor based on the latest science. Pursuing it could pose an increased risk to public health through what the group termed “supply chain and distribution threats.”

“EtO is vital to the continued availability of tens of billions of safe and effective medical devices every year, and the medical technology industry is committed to its safe and responsible use as we look for alternatives and ways to reduce EtO emissions,” said AdvaMed president and CEO Scott Whitaker in a news release. “The agency’s failure to address these valid scientific concerns surrounding their value threatens not only the medical technology supply chain but the tens of millions of American patients that rely on EtO-sterilized devices. We ask the agency to follow its own scientific recommendations and develop a revised EtO risk assessment standard that will effectively protect the public health and not disrupt patient access to needed medical technology.”

AdvaMed argues that the EPA’s 2016 Integrated Risk Information System (IRIS) value for EtO should not be used for regulatory purposes, because it:

* Is inconsistent with a variety of recommendations made by the National Academy of Sciences and by EPA’s own risk assessment guidance.
* Defies science and common sense in the context of everyday human exposures, both endogenous and exogenous.
* Poses unacceptable public health risk-risk tradeoffs.

The EPA is due to come out with its new proposed rule covering commercial EtO operations in May 2020. The agency accepted public comments until Feb. 10. You can read its advance notice of the proposed rule and all of the public comments [here](https://www.regulations.gov/document?D=EPA-HQ-OAR-2019-0178-0001).