

CLIENT ALERT

Agencies, Plaintiffs Target Ethylene Oxide

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Both the United States Environmental Protection Agency (EPA) and plaintiff's lawyers have been targeting the chemical ethylene oxide in recent months. In December 2019, EPA published an [advance notice of proposed rulemaking](#) to gather information about the use of ethylene oxide in commercial sterilization and fumigation businesses for future Clean Air Act regulations. One week later, EPA published a [proposed rule](#) under the Clean Air Act that would seek to reduce emissions of ethylene oxide from storage tanks, process vents and equipment leaks at manufacturing facilities. These actions followed on the heels of two class action lawsuits filed in a West Virginia federal court on behalf of individuals who lived in the vicinity of two different facilities that manufactured ethylene oxide and, according to the complaint, emitted the chemical into the environment, allegedly causing harm to the plaintiffs. These actions may lead to additional interest in ethylene oxide among plaintiff's lawyers and state regulators.

Ethylene oxide (EtO) is a flammable, colorless gas with a faint ether-like odor. EtO is used mainly as a chemical intermediate in the manufacture of ethylene glycol (antifreeze), textiles, detergents, polyurethane foam, solvents, medicine, adhesives, and other products. Ethylene glycol, in turn, is used in the manufacture of carpets, upholstery, plastics, PVC piping, and other products. EtO is also used as a fumigant, as a sterilant for food and cosmetics, and in sterilization of surgical equipment and plastic devices. Some amount of EtO is also present in cigarette smoke. EtO production is mostly, but not exclusively, concentrated in the Gulf Coast region in Texas and Louisiana. EtO can be released into the environment through manufacturing and industrial operations, sterilizing equipment, and cigarette smoke.

EPA regulates EtO as a hazardous air pollutant and has concluded that ethylene oxide is carcinogenic to humans by the inhalation route of exposure, although the basis for that conclusion has been challenged by industry. EtO has been linked in animal studies to various forms of cancer, and occupational studies have shown elevated levels of lymphoid and breast cancers in humans exposed to EtO. Some studies also suggest that inhalation of EtO is linked to an increased rate of miscarriages. Acute inhalation exposure of workers to high levels of ethylene oxide has resulted in nausea, vomiting, neurological disorders, bronchitis, pulmonary edema, and emphysema. Dermal or ocular contact with solutions of ethylene oxide has caused irritation of the skin and eyes in humans.

Recent Regulatory Actions

On December 12, 2019, EPA published an advance notice of proposed rulemaking, seeking information and comment on proposed control measures for reducing EtO emissions from commercial sterilization and fumigation facilities. 84 Fed. Reg. 67889. EPA has also announced plans to issue information requests under section 114 of the Clean Air Act to gather information directly from facilities about how EtO emissions are controlled. Some of the control measures under consideration for these facilities include controls for fugitive emissions of EtO, safety measures for the chamber exhaust vents (CEVs), process equipment improvements, and advances in add-on control technologies for point sources. Focus on sterilization facilities may have been prompted, to some extent, by scrutiny from members of Congress and a number of lawsuits brought against

healthcare product sterilization provider Sterigenics for alleged EtO releases from the company's Willowbrook, Illinois facility in 2018. Shortly thereafter, the Illinois Attorney General's Office filed suit against Sterigenics for violation of air pollution laws and public nuisance. *People v. Sterigenics U.S., LLC*, No. 2018CH001329 (DuPage County, IL). On February 15, 2019, the Illinois Environmental Protection Agency (IEPA) issued a "seal order" that effectively shut down operations at the facility. Illinois also enacted a new statute, The Matt Haller Act, 415 ILCS 5/9.16, setting the strictest emission standards in the nation for EtO sterilization facilities. In September 2019, Sterigenics announced that the facility would not be reopening. The decision was made after the IEPA approved the company's permit to install additional control measures at its Willowbrook facility and court approval of a consent order ending all litigation between the State and Sterigenics without penalties or finding of fault. But under the circumstances, according to a company press release, Sterigenics could not reach an agreement to renew its lease on the facility.

On December 19, 2019, EPA published a proposed rule to address emissions from EtO manufacturing facilities. 84 Fed. Reg. 69182. The rule seeks to reduce emissions of EtO by 10 tons annually. EPA identified nine facilities with ethylene oxide emissions from processes that fall within the Miscellaneous Organic Chemical Manufacturing National Emissions Standards for Hazardous Air Pollutants (MON). According to EPA, two of these facilities have unacceptable cancer risks driven by EtO emissions. The other seven have cancer risks of less than 100 in 1,000,000. EPA has proposed ethylene oxide-specific requirements for storage tanks, process vents, and equipment leaks. These requirements are expected to impact eight of the nine facilities. The ninth facility is expected to fall below applicability thresholds that would require control, due to very low concentrations of ethylene oxide in their process. If EPA's proposed requirements are implemented, the risks would be acceptable and provide an ample margin of safety to protect public health.

Given the historical role that EtO has played in sterilizing medical devices, the recent closures of sterilization facilities and scrutiny of EtO has raised concerns within the medical device industry. The Food and Drug Administration, which regulates medical devices, has announced steps to reduce the use of EtO through development of safer alternatives. For example, the FDA has announced an innovation challenge to identify new sterilization methods and technologies. In the meantime, the FDA continues to monitor the closure of sterilization facilities and the impact on the supply chain for medical devices that require sterilization.

Class Action Litigation

Government agencies are not the only ones showing interest in EtO. In December 2019, two class action lawsuits were filed in the U.S. District Court for the Southern District of West Virginia, each alleging claims on behalf of residents living near Union Carbide facilities in West Virginia that manufactured EtO and allegedly released it into the air around the plant for several decades. *Letart v. Union Carbide Corp.*, Case No. 2:19-cv-00877 (S.D.W.Va.); *Sommerville v. Union Carbide Corp.*, Case No. 2:19-cv-00878 (S.D.W.Va.).

The *Letart* case involves a Union Carbide plant in Institute, WV; *Sommerville* arises from Union Carbide's South Charleston plant. The allegations of the two complaints are virtually identical. Both allege that residents of various census blocks near the Union Carbide plants have been exposed to EtO emissions over a lengthy period of time, and claim that they are at an increased risk of cancer due to those exposures. The complaints seek to represent classes of residents who live in various census tracts around the plants, and they assert claims for negligence, strict liability for ultrahazardous activity, medical monitoring, willful and

wanton conduct, and public nuisance. The complaints seek compensatory and punitive damages, a medical monitoring program, and other injunctive and declaratory relief.

Conclusion

EPA's activity and more stringent regulations governing EtO emissions are likely to draw additional attention to the chemical from plaintiff's attorneys. Even though EPA has found that most EtO manufacturing facilities do not present an unacceptable risk to the public, such determinations may not deter lawsuits alleging exposure to EtO. Likewise, sterilization and fumigation facilities face the likelihood that they will be required to install more stringent control devices to address EtO emissions and, like Sterigenics's Willowbrook facility, their operations may draw attention from regulators and the plaintiff's bar.

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