

# D.C. Circuit Court Upholds EPA's Assessment of Cancer Risk from Ethylene Oxide

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## **Background**

Ethylene Oxide (EtO) is a reactive chemical widely used as a sterilizing agent for medical equipment that cannot otherwise be sterilized by heat/steam. EtO may also be used as a component for producing other chemicals, including glycol and polyglycol ethers, emulsifiers, detergents, and solvents. Allegations that exposure to EO may increase the risk of certain cancers has resulted in litigation in a number of states across the country, including Illinois, California, Georgia, and New Mexico, against companies that own and operate sterilizations facilities that utilize EtO. The claimants are nearby residents of these plants who allege that their cancers were caused by EtO emissions.

## **EtO Litigation**

The first ethylene oxide trial went to verdict in September 2022, and a Cook County (Illinois) jury awarded \$363 million to a plaintiff who alleged that she developed breast cancer as a result of ethylene oxide emissions from the Sterigenics Willowbrook plant. This was the Kamuda case and was the first ethylene oxide personal injury case to go to trial. It was followed by a second trial involving the same defendant and in the same court though with a different type of cancer at issue. That trial, Fornek, resulted in a defense verdict. In January 2023, Sterigenics, the defendant in the three trials noted above and in another 870 or so cases arising from the Willowbrook plant, announced a settlement of its pending cases in the amount of \$408 million. The cases were pending in state and federal court in Illinois. The settlement was recently agreed to by all but three of the plaintiffs.

In October 2023, Sterigenics settled 79 claims for \$35 million. The claims arose from claimants alleging cancer as a result of their proximity to a plant in Smyrna, Georgia that utilizes EtO. Other claims are still pending in that jurisdiction.

On March 18, 2024, a 49 page Complaint was filed in Superior Court, County of Los Angeles, on behalf of approximately 15 plaintiffs who live or lived near the Sterigenics sterilization facility in Vernon, California (actually two adjacent facilities). The Complaint alleges that the plaintiffs developed various types of cancer due to their proximity to the facility. Notably, the Complaint in the

## **EPA Involvement**

The EPA, as well as various state environmental protection agencies, has been involved for years in monitoring EtO emissions and issuing regulations concerning same. In late 2022, the EPA affirmed its cancer risk assessment for ethylene oxide emissions from facilities in the miscellaneous organic chemical manufacturing source category. Based on this, the EPA determined the EtO emissions presented an unacceptable risk to human health. This designation then triggered stricter emissions standards with respect to the approximately 200 EtO facilities that comprise this miscellaneous category.

## **Judicial Review of EPA's EtO Regulations**

Last week, a three-judge panel of the D.C. Circuit upheld the EPA's assessment of the cancer risk from exposure to EtO emissions, holding that the risk assessment was neither arbitrary nor capricious as a chemical company and two chemical company associations had unsuccessfully argued. The panel held that in "the case of EPA's evaluation of scientific data within its area of expertise, we accord an 'extreme degree of deference'" and that this "is particularly true for statistical and modeling analysis."

## **Analysis**

The EPA's tougher EtO emission regulations now have the imprint of judicial approval. Presumably, industry will continue to challenge these regulations. In the meantime, though, the companies that own plants which utilize EtO and release same into the environment will need to determine whether they can retro fit their facilities to come into compliance (if they have not done so already) or whether to simply shutter their operations.

Hand in hand with EPA regulations with respect to EtO are suits filed against the plant owners/operators by nearby residents alleging cancer. We anticipate that the EtO litigation will continue to spread across the country, albeit at a slower pace than previously anticipated, particularly in light of this judicial decision upholding the EPA's regulations which significantly tighten permissible levels of EtO emissions by sterilization plants.

## **What Measures Can Your Company Take To Minimize Risk?**

What measures should companies take to minimize the risk of being sued by private parties or by regulatory agencies? For one, retaining an expert to review whether the facility is emitting EtO unknowingly (or in excess of allowable regulatory levels) is recommended. If a problem is identified, consider purchasing (or upgrading) equipment that will bring the facility into compliance. Be proactive with respect to potential litigation. Is your facility in a community that is concerned with environmental justice? Are you in compliance with all state and federal regulations, particularly the new EPA rules? The best litigation strategy is to ensure you avoid litigation in the first place.

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