LITIGATION MINUTE: ETHYLENE OXIDE—COULD YOUR COMPANY BE A LITIGATION TARGET?

ETHYLENE OXIDE SERIES: PART TWO OF FOUR

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WHAT YOU NEED TO KNOW IN A MINUTE OR LESS

Based largely on publicly available data from the U.S. Environmental Protection Agency (EPA), plaintiffs have been filing an increasing number of personal-injury and class-action claims related to alleged exposures to ethylene oxide (EO). These claims often relate to alleged cancers associated with EO, but have also included claims for medical monitoring where no physical injury has occurred.

While many cases have focused on emissions from facilities using EO as a commercial sterilizer, claims have expanded to those using EO as constituent in the manufacture of other products, and any company emitting any level of EO could become the target of a lawsuit.

In a minute or less, here is what you need to know about understanding and addressing EO litigation.

NATA and AirToxScreen Typically Underlie Allegations

On 22 August 2018, the EPA released its 2014 National Air Toxics Assessment (NATA) as a screening tool to help state and local air agencies identify emission sources for further study.[1] NATA incorporated the EPA's 2016 Integrated Risk Information System (IRIS) Assessment for EO, in which the agency found EO to be 60 times more toxic than previous estimates and "carcinogenic to humans."[2] This resulted in the EPA classifying EO as a "regional cancer risk driver," designating a number of census tracts as potentially having increased cancer risks due to EO emissions.

The EPA has routinely acknowledged, however, that NATA does not estimate actual risk and that the information reported should only be used as starting point for further investigation of cancer risks in any specific location.[3] Despite these limitations, NATA provided a simple tool for plaintiffs' counsel to leverage as a foundation for civil tort claims.

On 2 March 2022, the EPA released NATA's successor, the 2017 Air Toxics Screening Assessment (AirToxScreen), operating similarly to NATA, with estimated risk levels orders of magnitude lower in some locations due to updates in methods and data.[4] AirToxScreen remains a public mapping tool that can be queried by location, specific air emissions, and specific facilities to identify census tracts with potentially elevated cancer risks associated with EO and other chemicals.[5] The simplicity of this tool and the information it provides have resulted in its continued featured prominence in support for plaintiffs' claims.[6]

Sterilizers Targeted—For Now

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Since EO's most publicized application is sterilization, many EO lawsuits have targeted commercial sterilizers that use EO to treat medical devices where steam cannot be used.[7] EO is a versatile compound with a wide variety of applications, however—including the fumigation of spices and production of ethylene glycol, polyurethanes, and household cleaners, among many other products. Non-sterilizer defendants are already seeing EO claims and the scope of defendants targeted is likely to continue to expand as the litigation matures. Any business reporting environmental emissions of EO—regardless of volume or permit status—may find itself at risk of becoming a target.

Individual and Class Claims

While most EO lawsuits present as typical toxic torts, in which an individual plaintiff alleges that an exposure caused a manifested injury (such as breast or lymphatic cancer), defendants are also seeing EO suits in the form of medical-monitoring class actions.

In a putative medical-monitoring class action, the class is typically defined to exclude any individuals with a presently manifested injury. Instead, the alleged harm is generally a purported increased risk of developing an injury in the future, for which the proposed class seeks significant damages to fund a “monitoring” program for thousands of putative class members. While some jurisdictions have recognized medical-monitoring claims absent any physical injury, a number of jurisdictions have refused them outright, with recent U.S. Supreme Court precedent signaling that an increased risk of future harm may not be a sufficient injury-in-fact for Article III standing purposes.[8]

Any company facing claims regarding EO emissions must also be familiar with the applicable causation standards, as different jurisdictions accept different types of proof, and the science regarding EO's carcinogenicity remains unsettled. Moreover, any company facing a medical-monitoring claim should examine whether the law of the jurisdiction governing the claims actually recognizes medical monitoring as a cause of action and, if so, under what circumstances.

Considerations for Mitigating Risk

Since NATA and AirToxScreen use the EPA's National Emission Inventory (NEI) as a starting point, companies with facilities that have emissions tied into NEI should examine their emissions and control technologies. They should also be mindful of the evolving scientific and regulatory landscape surrounding EO and should consult counsel to evaluate strategies for minimizing litigation risks in their specific situation.

With regulatory developments driving the litigation landscape, our next edition will focus on EO regulation and where the EPA is directing its focus.

FOOTNOTES

[1] *See* U.S. ENV'T PROT. AGENCY, National Air Toxics Assessment.

[2] U.S. ENV'T PROT. AGENCY, EPA/635/R-16/350FA, EVALUATION OF THE INHALATION CARCINOGENICITY OF ETHYLENE OXIDE (2016); U.S. ENV'T PROT. AGENCY, FREQUENT QUESTIONS ABOUT ETHYLENE OXIDE (ETO) (last updated Jan. 13, 2023).

[3] *See* U.S. ENV'T PROT. AGENCY, 2014 NATIONAL AIR TOXICS ASSESSMENT: FACT SHEET.

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[4] *See* U.S. ENV'T PROT. AGENCY, AIR TOXICS SCREENING ASSESSMENT.

[5] *See* U.S. ENV'T PROT. AGENCY,AIRTOXSCREEN MAPPING TOOL.

[6] *See* Fact Sheet, *supra* note 3.

[7] For a discussion regarding the lawsuits regarding medical sterilizer Sterigenics, see our prior publications:

- Litigation Minute: Ethylene Oxide—What It Is and Why You Should Care
- The $363 Million Dollar Question: Are Your Ethylene Oxide Emissions A Litigation Target?

[8] For more on the U.S. Supreme Court's recent cases calling into doubt the viability of an alleged increased risk of future harm as the basis for Article III standing, see our prior publications:

- Where's the Harm in Class Certification? The United States Supreme Court Confirms: It Must Be in Plaintiffs' Evidence
- Litigation Minute: Has the Supreme Court Left ESG Class Actions a Leg to Stand On?

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