LITIGATION MINUTE: ETHYLENE OXIDE—WHAT IT IS AND WHY YOU SHOULD CARE

ETHYLENE OXIDE SERIES: PART ONE OF FOUR

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WHAT YOU NEED TO KNOW IN A MINUTE OR LESS

Ethylene oxide (EO) is a versatile compound used to make ethylene glycol and numerous consumer products, including household cleaners and personal care items. Also used to sterilize medical equipment and other plastics that are sensitive to heat or steam, it has gained increased regulatory scrutiny and has been the focus of recent multimillion-dollar lawsuits and settlements. Given this attention, any company emitting any level of ethylene oxide could become the target of a lawsuit or regulatory agency. This encompasses a range of companies, as EO has applications in the building and construction, transportation, health and safety, and manufacturing sectors, and is used as an intermediate in the manufacture of numerous downstream products.

The first edition in this four-part series introduces the risks inherent in EO litigation through the prism of two recent trials that were followed by a $408 million settlement, along with the hotly debated science underlying the carcinogenic risk driving the recent EO litigation wave.

Subsequent editions will cover the litigation landscape, the state of EO regulation, and insurance-coverage considerations.

EO in the News: Sterigenics Trials and Settlements

Two Illinois trials against medical sterilizer Sterigenics and its parent, Sotera Health Company, reached opposite jury verdicts. Those verdicts were then followed by a US$408 million settlement.

On 19 September 2022, a Chicago jury awarded US$363 million (including US$325 million in punitive damages) to a single plaintiff who alleged that Sterigenics's EO emissions caused her to develop breast cancer and that Sterigenics failed to implement measures to reduce its emissions.[1] Less than two months later, a different Chicago jury returned a defense verdict against a plaintiff who alleged that Sterigenics's EO emissions from the same facility had caused her acute T-cell lymphoblastic leukemia. These differing jury verdicts illustrate both the risk inherent in EO litigation—an immature and developing tort—and the upside for plaintiffs' counsel driving the uptick in litigation.

Following these trials, Sterigenics and Sotera Health announced a US$408 million settlement to resolve more than 870 EO-related claims filed against the companies in the Circuit Court of Cook County, Illinois and in the

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United States District Court for the Northern District of Illinois.[2] While the settlement is not yet completed—requiring that substantially all plaintiffs opt in and dismiss their claims with prejudice, as well as court approval—a settlement averaging more than US$450,000 per plaintiff will likely embolden future claimants.

EO in the Courts: Regulatory Battles on the Science

Law is typically downstream of science, and EO litigation is no exception. The recent litigation focus on EO has been largely driven by battles between state and federal regulators, regarding the science surrounding EO's carcinogenic risk.

In 2016, the U.S. Environmental Protection Agency (EPA) released its Integrated Risk Information System (IRIS) Assessment, where the agency found that EO was 60 times more toxic than previous estimates and "carcinogenic to humans."[3] While the EPA recognized that its assessment included a number of uncertainties—such as the retrospective exposure assessment for its lone human cohort study, the exposure-response modeling of its data, and its low-dose extrapolation—the EPA maintained relatively high confidence in its assessment.

Separately, the Texas Commission on Environmental Quality (TCEQ) released its own EO Carcinogenic Dose Response Assessment that criticized the EPA's IRIS Assessment. Among other things, the TCEQ concluded that the EPA overestimated EO's carcinogenic risk by a factor of 2400.[4] To support its critiques of the EPA, the TCEQ's analysis included data from an additional human cohort and post-2016 data, applying modeling and methods it deemed more appropriate.[5]

Despite the TCEQ's findings and various other criticisms from industry and scientific communities, the EPA reaffirmed its decision on 21 December 2022 to use the 2016 IRIS assessment value in its future EO regulations.[6] This decision will affect not only future regulations, but also EO litigation that is largely based the 2016 IRIS assessment. A more detailed review of the EO litigation will be covered in our next Litigation Minute in this series.

FOOTNOTES

[1] For more on the first Sterigenics verdict, see our prior alert: The $363 Million Dollar Question: Are Your Ethylene Oxide Emissions A Litigation Target?

[2] *See* Sotera Health, Sotera Health Announces Settlement of Ethylene Oxide Litigation in Illinois

[3] 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), EPA.GOV (last updated 13 January 2023).

[4] *See* TEX. COMM'N ENV'T QUALITY, ETHYLENE OXIDE CARCINOGENIC DOSE-RESPONSE ASSESSMENT (15 May 2020).

[5] *Id.*

[6] U.S. ENV'T PROT. AGENCY, Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review, FED'L REG. (21 December 2022).

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