

THE \$363 MILLION DOLLAR QUESTION: ARE YOUR ETHYLENE OXIDE EMISSIONS A LITIGATION TARGET?

Date: 26 September 2022

U.S. Litigation and Dispute Resolution Alert

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On 19 September 2022, a Cook County, Illinois jury awarded US\$363 million¹ to a plaintiff who alleged that her breast cancer was caused by emissions of ethylene oxide (EtO) from a Sterigenics facility in Willowbrook, Illinois. The plaintiff alleged that Sterigenics, which used the flammable, colorless gas in the sterilization of medical supplies, knew for decades of the health risks created by EtO exposure but failed to control its emissions or notify members of the neighboring community of the risks.

Despite its regulation as a hazardous air pollutant under the Clean Air Act (CAA) since 1990,² and as we discussed in a prior alert,³ the recent public attention given to EtO emissions largely stems from the United States Environmental Protection Agency's (USEPA) December 2016 EtO cancer risk assessment update.⁴ In that update, the USEPA concluded that EtO is considerably more dangerous than previously believed and that the inhalation of EtO is associated with an increased risk of breast cancer and lymphohematopoietic cancers. The USEPA's assessment is not without criticism, however, and there remains significant debate in the scientific community regarding the level at which EtO emissions present a human health hazard. For example, a 2020 Texas Commission on Environmental Quality (TCEQ) assessment noted that even certain background EtO concentrations across the country would present an increased risk using the USEPA's 2016 risk estimate.⁵ TCEQ's own assessment concluded that that available science indicated that the actual risk from exposure to EtO was 2,400 times less than the USEPA's estimate.⁶

Medical device sterilizers, like Sterigenics, have been the primary target of EtO-related regulatory scrutiny and civil litigation.⁷ But EtO's widespread use suggests that the number of impacted industries will only continue to increase. For instance, EtO is used not only to sterilize medical supplies⁸ but also to sterilize certain consumer goods including spices and cosmetics.⁹ EtO is further used as a constituent in the manufacture of numerous products, such as antifreeze, textiles, plastics, detergents, and adhesives.¹⁰ Indeed, chemical and industrial manufacturers are already facing litigation for EtO-related claims. Likewise, on the regulatory front, beginning in 2018, the USEPA initiated a review of CAA regulations related to EtO for certain industry sectors, including the following:

- Commercial Sterilizers (review to be completed in 2022);
- Hospital Sterilizers (review to be completed in 2023);
- Group 1 Polymers and Resins (Neoprene) (review to be completed in 2024);
- Synthetic Organic Chemicals Manufacturing Industry (review to be completed in 2024);

- Polyether Polyols Production (review to be completed in 2024); and
- Chemical Manufacturing Area Sources (review to be completed in 2024).¹¹

Looking ahead, the large Sterigenics verdict will undoubtedly generate an increase in litigation across the many industries where EtO is utilized. As a result, any company utilizing EtO in its operations should evaluate whether its operations could result in alleged exposures to employees or the community. For many, this investigation should start with a review of their emissions reporting to identify EtO emissions that may present a risk for future litigation. It is important to recognize, however, that current trends indicate that even EtO emissions in compliance with the CAA and state regulations may still lead to civil tort litigation with the potential for significant consequences to defendants.

FOOTNOTES

¹ The plaintiff requested US\$21 million in compensatory damages and \$325 million in punitive damages; the jury awarded all of the punitive damages along with a \$38 million in compensatory damages.

² See 42 U.S.C. § 7412(b)(1).

³ See David A. Fusco et al., *Ethylene Oxide: The Litigation Risks And Regulatory Issues Ahead*, K&L GATES HUB (July 26, 2021), <https://www.klgates.com/Ethylene-Oxide-The-Litigation-Risks-and-Regulatory-Issues-Ahead-7-26-2021>.

⁴ U.S. ENV'T PROT. AGENCY, EPA/635/R-16/350FA, *EVALUATION OF THE INHALATION CARCINOGENICITY OF ETHYLENE OXIDE* (2016).

⁵ See TEX. COMM'N ENV'T QUALITY, *ETHYLENE OXIDE CARCINOGENIC DOSE-RESPONSE ASSESSMENT* (May 15, 2020).

⁶ See *id.*

⁷ See, e.g., *Hazardous Air Pollutants: Ethylene Oxide, Ethylene Oxide Risk from Commercial Sterilizers*, EPA.GOV, <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/forms/ethylene-oxide-risk-commercial-sterilizers> (last visited Sept. 23, 2022).

⁸ EtO is used as a medical sterilizer both by commercial sterilization facilities, such as Sterigenics, as well as hospitals. See AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, *TOXICOLOGICAL PROFILE FOR ETHYLENE OXIDE* (2022) (noting approximately 1,900 hospitals in the United States have EtO sterilization chambers).

⁹ See *Hazardous Air Pollutants: Ethylene Oxide (EtO), Our Current Understanding of the Human Health and Environmental Risks of Ethylene Oxide*, EPA.GOV, <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/our-current-understanding-human-health-and-environmental> (last visited Sept. 23, 2022); see also AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, *TOXICOLOGICAL PROFILE FOR ETHYLENE OXIDE* (2022).

¹⁰ See *id.*

¹¹ See U.S. ENV'T PROT. AGENCY, *SLIDE SHOW FOR THE REGION 6 WEBINAR ON ETHYLENE OXIDE* 101

(2021); see also *Hazardous Air Pollutants: Ethylene Oxide, What EPA Is Doing to Address Ethylene Oxide and to Learn More About the Chemical*, EPA.GOV, <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/what-epa-doing-address-ethylene-oxide-and-learn-more-about#:~:text=After%20conducting%20a%20%E2%80%9Crisk%20and,by%20multiple%20air%20toxics%20rules> (last visited Sept. 23, 2022).

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