King & Spalding
Client Alert

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Emerging Regulation, Enforcement, and Litigation Involving Ethylene Oxide, a Critical Substance for Sterilizing Medical Products and Devices

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Ethylene oxide ("EtO"), one of the most widely used and effective substances for sterilizing medical products and devices, has come under intense scrutiny by the Environmental Protection Agency ("EPA"), the Food and Drug Administration ("FDA"), state and local agencies, environmental groups, and others. Given its importance, the increased focus on EtO affects a wide range of parties, from chemical manufacturers, to medical device manufacturers and sterilizers, to hospitals and health care providers.

EtO. A flammable colorless substance used to make many common consumer and industrial products, EtO is also one of the most widely used substances to sterilize medical equipment and devices that cannot be sterilized by steam, radiation, or other methods. EtO naturally occurs in ambient air from a variety of sources. In 2018, after EPA released its most recent National Air Toxics Assessment ("NATA"), almost every aspect of EtO management is now being reconsidered, including the continued use of EtO.

State Regulation. Following the release of EPA's 2018 NATA, numerous state environmental agencies initiated review of their own past regulation of EtO, and a few have already announced a desire for more stringent requirements for EtO management. In a few instances, states have negotiated with facilities to install additional EtO controls and make process changes designed to reduce certain EtO emissions. In many states, legislators are proposing legislation that will significantly limit EtO emissions. As the regulatory requirements continue to tighten, air quality and other health, safety, and environmental approvals will receive increased scrutiny by regulators and third parties, including environmental and other non-governmental organizations.

EPA Regulation. EPA regulates EtO under the Clean Air Act.[1] On December 17, 2019, EPA published a proposed rule to address ethylene oxide emissions from producers.[2] As part of that effort, EPA is proposing additional requirements for equipment, including controls for fugitive emissions, as well as work practices and related processes.[3] On December 12, 2019, EPA also issued an Advance Notice of Proposed Rulemaking outlining potential regulatory changes for commercial sterilization and fumigation operations and seeking comment and information on methods to monitor, calculate, and control EtO emissions, including fugitive emissions, from sterilization facilities.[4]

Congressional Action. In addition to EPA's regulatory agenda, EtO has also caught the attention of Congress. Members recently launched the Bipartisan Congressional Task Force on Ethylene Oxide, a task force to consider future improvements to EtO regulation. This Task Force has requested that EPA issue a proposed rule for commercial sterilizers by the end of February 2020.[5]

Worker Safety. In the workplace, EtO exposure is regulated by the Occupational Safety and Health Administration ("OSHA") and, potentially, state counterparts. Depending on the specific features and operations at a facility, employers may be required to monitor ambient air levels, conduct medical surveillance of employees, and implement other measures to address worker exposure to EtO.[6] In addition, as the case for many facilities, OSHA standards may apply to multiple operations at one facility.

FDA Concerns. As the FDA recently noted, a safe and reliable supply of EtO is critical to ensure the continued supply of sterile medical devices and products critical to patient health throughout the world. Thus, for the FDA, rising concerns over EtO create a different public health concern: a potential shortage of critical medical devices sterilized with EtO. Recognizing the supply chain vulnerabilities, FDA established two public innovation challenges to encourage the development of new sterilization methods and the development of strategies to reduce EtO emissions.[7] FDA also recently instituted a pilot program to expedite approvals of certain changes to EtO sterilization processes for commercial sterilizers and device manufacturers.[8] In addition, FDA is urging manufacturers to modify packaging, to reduce paper, so that less EtO can be used to sterilize devices.[9] FDA and EPA are closely coordinating their regulatory activities relating to EtO.

Continuing EtO Litigation. Litigation involving EtO, both individual and class actions, is increasing. In these lawsuits, plaintiffs frequently seek to recover personal injury and property devaluation damages and, in a few cases, medical monitoring for non-injured parties. In one state, an EtO facility has been the target of at least 70 individual lawsuits and several putative class action lawsuits. Similarly, administrative litigation over permit reissuance and new regulatory requirements is expected to track the increased focus on EtO.

Long known for its expertise in regulatory compliance, toxic torts, and environmental litigation, King & Spalding advises clients on a wide range of risks and potential liabilities related to regulated chemical substances, including extensive experience in EtO compliance and litigation. Our Environmental, Health and Safety team regularly provides counseling on the most challenging environmental, health, and safety issues, and often works closely with the FDA and Life Sciences team on EtO issues. We regularly develop risk communication and incident response strategies for engaging legislators, regulators, and affected communities. For decades, the Trial and Global Disputes lawyers have litigated toxic torts, mass torts, permit challenges, and environmental liabilities involving hundreds of different kinds of chemicals, including EtO emissions in several states.

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[1] 42 U.S.C. § 7412.
[2] EPA, National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review, 84 Fed. Reg. 69,182, 69,213 (proposed Dec. 17, 2019).
[3] *Id.* at 69,235–69.
[4] EPA, National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations, 84 Fed. Reg. 67,889 (Dec. 12, 2019).
[5] *See* Bradley Schneider and Jody Hice, Letter to Andrew Wheeler, EPA (Dec. 18, 2019), available at https://schneider.house.gov/sites/schneider.house.gov/files/Letter%20to%20EPA%20Administrator%20Wheeler%20-%2012.18.19.pdf.
[6] *See* 29 C.F.R. § 1910.1047.
[7] FDA, Ethylene Oxide Sterilization for Medical Devices, https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices.
[8] FDA, Statement on new steps to advance innovation in medical device sterilization with ethylene oxide (Nov. 25, 2019), available at https://www.fda.gov/news-events/press-announcements/statement-new-steps-advance-innovation-medical-device-sterilization-ethylene-oxide.
[9] *Id.*