Legal Backgrounder

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Ethylene Oxide: How Dubious Regulatory Science Has Fueled Vicious Cycle of Litigation and Overregulation

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In 2016, the Environmental Protection Agency ("EPA") issued its Integrated Risk Information System ("IRIS") Assessment for ethylene oxide ("EtO"). In that assessment, which applied new modeling approaches to existing data, the agency concluded that environmental exposure to EtO carries substantially more cancer risk at lower levels than previously thought.[1] The news about the dramatic change in EPA's risk assessment prompted concerns and protests in communities located near EtO sterilization facilities about whether environmental EtO exposures from these facilities were the cause of health problems. Predictably, the plaintiffs' bar quickly latched on to this community unease and began filing personal injury suits, arguing that the "regulatory science" set forth in the 2016 IRIS Assessment establishes that environmental exposures to EtO caused a variety of cancers and other maladies. Hundreds of cases have been filed around the country against EtO sterilizers and manufacturers.

Last year, two trials involving such alleged exposures reached wildly disparate verdicts within 60 days of each other in the same courthouse in Chicago. The first trial resulted in a record-setting verdict for a single plaintiff in Cook County, Illinois; the second in a complete defense verdict. In the wake of these two trials, EPA has proposed new regulations based on the 2016 IRIS Assessment that would limit permissible levels of EtO emissions dramatically, not only encouraging additional litigation but also providing the impetus for plaintiffs to claim that alleged historical exposures were unsafe. This Legal Backgrounder explores the regulatory science of EtO, its role in generating the pending litigation, its use by plaintiffs to counter scientific studies that demonstrate that safe exposure levels to EtO are significantly higher than the new regulatory assumption, and its use by EPA as a basis to propose significant new regulatory restrictions on emissions.

What is EtO?

EtO is a naturally occurring gas that results from the combustion of wood, tobacco, and certain carbon-based fuels; it is also formed naturally in the human body when bacteria in the intestines break down ethylene. EtO is also manufactured as a component in the production of ethylene glycol, which is used to make antifreeze, detergents, plastics and other products, and for use in the sterilization of medical equipment that is sensitive to heat or steam and as a fumigating agent for spices. Roughly 50% of all medical devices used in the United States are sterilized with EtO, including surgical kits, catheters, stents, artificial knees, and wound dressings. According to the U.S. Food and Drug Administration ("FDA"), EtO sterilization is "a safe and effective method that helps ensure the safety of medical devices and helps deliver quality patient care."[2]

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[1] U.S. Environmental Protection Agency, EPA/635/R-16/350FA, *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide* (2016).

[2] U.S. Food and Drug Administration, *Statement from FDA Commissioner Scott Gottlieb, M.D., on Steps the Agency is Taking to Prevent*

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EtO Scientific Studies

Since the 1960s, scientific researchers have conducted epidemiological studies of employees that worked in EtO manufacturing and medical device sterilization facilities. Because some early, small European studies suggested a possible link between EtO exposure and Leukemia, the National Institute of Occupational Safety and Health ("NIOSH") began a study in the mid-1980s that observed workers at EtO sterilization facilities over several decades. That study, the largest examination of EtO occupational exposures, was specifically designed to identify any connection between EtO exposure and Leukemia and other cancers. In 2004, NIOSH concluded that "[t]here was little evidence of any excess cancer mortality for the cohort as a whole, with the exception of bone cancer based on small numbers."[3] NIOSH accompanied its study conclusions with a Worker Notification aimed at educating workers on EtO exposure, which stated that occupational exposure to EtO posed "[n]o overall elevated risk for any type of cancer or other diseases as compared to the general U.S. population."[4]

The EtO Regulatory Framework

EtO has been subject to federal regulations for decades. In 1977, NIOSH recognized "the continued use of ETO as a gaseous sterilant [a]s highly desirable," and concluded that a long-term 50 parts per million ("ppm") permissible exposure limit ("PEL") was necessary to protect workers.[5] In 1985, the Occupational Safety and Health Administration ("OSHA") published a final rule setting an occupational exposure limit for EtO of 1 ppm over an eight-hour period without the use of personal protective equipment.[6] That standard remains in effect today.[7] FDA regulates EtO sterilization through robust requirements ensuring that sterility methods comport with international standards.[8] In addition to recognizing the indispensable need for EtO, FDA has raised concerns "about the potential impact of shortages of sterilized medical devices that would result from disruptions in commercial sterilizer facility operations."[9]

In 1985, EPA issued its first upper-level inhalation unit risk[10] estimate for EtO.[11] In 1990, Congress included EtO as a "hazardous air pollutant" under the Clean Air Act ("CAA").[12] In 1994, the EPA published the first National Emissions Standards for Hazardous Air Pollutants ("NESHAP") for EtO applicable to commercial sterilization. The 1994 Final Rule required that emissions controls be implemented for sterilization chambers, chamber exhaust

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Potential Medical Device Shortages and Ensure Safe and Effective Sterilization Amid Shutdown of a Large Contract Sterilization Facility (Mar. 26, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-steps-agency-taking-prevent-potential-medical-device.

[3] Kyle Steenland, et al., *Mortality Analyses in a Cohort of 18,235 Ethylene Oxide Exposed Workers: Follow Up Extended from 1987 to 1998*. Occup. Environ Med. 2004;61(1):2-7.

[4] Centers for Disease Control and Prevention, *Worker Health Study Summaries – Ethylene Oxide* (Apr. 2004), https://www.cdc.gov/niosh/pgms/worknotify/ethyleneoxide.html.

[5] Zorach R. Glaser, *Special Occupational Hazard Review with Control Recommendations for the Use of Ethylene Oxide as a Sterilant in Medical Facilities*. U.S. Department of Health, Education and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, DHEW (NIOSH) Publication No. 77-200, 58 pp. (1977).

[6] Occupational Exposure to Ethylene Oxide, Final Standard, 49 Fed. Reg. 25734, 25796 (1984) (codified at 29 CFR § 1910.1047 (1985)).

[7] 29 CFR 1910.1047 (2019).

[8] Center for Devices and Radiological Health, *Sterilization For Medical Devices*, U.S. Food and Drug Administration (Apr. 11, 2023), https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#how.

[9] Office of the Commissioner, *FDA Continues Efforts to Support Innovation in Medical Device Sterilization*, U.S. Food and Drug Administration (Aug. 3, 2022), https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization.

[10] An Inhalation Unit Risk ("IUR") is an estimate of the increased cancer risk from inhalation exposure to a concentration of 1 $\mu g/m^3$ for a lifetime. The IUR can be multiplied by an estimate of lifetime exposure (in $\mu g/m^3$) to estimate the lifetime cancer risk. U.S. EPA, *Basic Information about the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system (last accessed June 13, 2023).

[11] Gray, D., B. Harris, S. Bosch, and J. Santodonato, *Health Assessment Document for Ethylene Oxide*, U.S. Environmental Protection Agency, Washington, D.C., EPA/600/8-84/009F (NTIS PB86102597), 1985 at p. 1-8 (establishing an "upper-limit incremental unit risk estimate of 1.0×10^{-4}, for lifetime cancer risk resulting from continuous exposure to air that contains an ethylene oxide concentration of 1 $\mu g/m^3$").

[12] 42 U.S.C. § 7412, p. 6262.

vents (also called "back vents"), and aeration rooms within three years of the effective date of the regulation.[13] In December 1997, EPA issued an Interim Final Rule deferring the effectiveness of these regulations until December 1998,[14] and subsequently deferred for an additional year certain requirements for emission controls.[15] As of December 2000, controls were required to be applied to aeration room emissions but not back vent emissions.[16] EPA subsequently determined in 2006 that control of back vent emissions would not improve cancer risk, stating "that the maximum individual cancer risk…already meets the level [it] generally consider[ed] acceptable, and that further control requirements would achieve, at best, minimal emission and risk reductions at a very high cost...."[17]

Later in 2006, EPA's IRIS program released a draft report for EtO that radically departed from the status quo, stating that there were high cancer risks associated with low environmental exposures to EtO.[18] This reporting was not finalized, however, because EPA's own Science Advisory Board criticized the report's conclusions, finding that they did not meet the "necessary level of rigor and balance," failed to take into account epidemiology beyond the NIOSH studies, and failed to consider whether it was appropriate to apply a linear low-dose risk model or a non-linear model that assumes greater risk at lower doses when applied to the NIOSH study data showing limited cancer associations at only very high occupational exposure levels, among other criticisms.[19]

EPA issued an updated EtO IRIS report in 2016.[20] Following the same methodology it relied on in the 2006 draft report, EPA concluded that there are elevated risks of cancer at levels of exposure thousands of times lower than what had been shown in the NIOSH study. EPA's 2016 IRIS announced that the safe level of environmental exposure to EtO was 30 times less than what the EPA had determined in 1985—which had provided the basis for EPA regulation of EtO emissions (and with which the EtO industry historically complied) for decades. Based on IRIS, exposure to EtO at a concentration of 0.1 part per trillion ("ppt") poses a one-in-a-million lifetime cancer risk—a concentration orders of magnitude below the levels of EtO produced by the human body and what is normally present in ambient air—and labeled EtO as one of the most powerful carcinogens known to man.[21] EPA's 2016 IRIS Assessment also enhanced the risk descriptor for EtO from "probably carcinogenic to humans" to "carcinogenic to humans."[22]

EtO Sterilization Litigation

EtO litigation presents a familiar battleground to those experienced in litigation over injuries arising from environmental exposures to chemicals. On the one hand, plaintiffs argue that any exposure to the chemical at issue in the environment causes the alleged malady—citing regulatory conclusions that the chemical is "carcinogenic," regulatory pronouncements based on the precautionary principle,[23] and employing modeling

[13] 59 Fed. Reg. 62585 (Dec. 6, 1994); 40 CFR part 63, subpart O.

[14] 62 Fed. Reg. 64736 (Dec. 9, 1997).

[15] 63 Fed. Reg. 66990 (Dec. 4, 1998).

[16] *See* 66 Fed. Reg. 55577 (Nov. 2, 2001).

[17] 71 Fed. Reg. 17712 (Apr. 7, 2006).

[18] U.S. Environmental Protection Agency (U.S. EPA), Office of Research and Development (ORD), *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide*, External Review Draft. EPA/635/R-06/003, 2006.

[19] U.S. Environmental Protection Agency (U.S. EPA). *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Appendices). Appendix H, Summary of 2007 External Peer Review and Public Comments and Disposition*. EPA/635/R-16/350Fb, 2016. *See also* U.S. Environmental Protection Agency (U.S. EPA), Science Advisory Board (SAB). *Review of Research and Development (ORD) Draft Assessment entitled, "Evaluation of the Carcinogenicity of Ethylene Oxide."* EPA-SAB-08-004, 2007.

[20] *Supra*, note 1.

[21] *Supra*, note 1, at 4-90–4-96; Kenneth T. Bogen et al., *Reevaluation of Historical Exposures to Ethylene Oxide Among U.S. Sterilization Workers in the National Institute of Occupational Safety and Health (NIOSH) Study Cohort.*, Int'l. of Environ. Research and Pub. Health, 2019 (citing the EPA IRIS Assessment).

[22] *Supra*, note 1, at 3-70.

[23] Principle 15 of the 1992 Rio Declaration states that "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." United Nations Conference on Environment and Development, *The Rio Declaration on Environment and Development* (June 3-14, 1992).

based on regulatory assumptions to urge that there is "scientific" proof of general and specific causation. On the other hand, the defendants point to scientific studies, some sponsored by industry and often in the context of occupational exposures, to show that the low levels of exposure that could be experienced environmentally do not cause the malady.

In the 2022 Cook County EtO trials, plaintiffs relied on conclusions reached by EPA in 2016 and the International Agency for Research on Cancer to argue that "science" proves that any exposure to emitted EtO in the environment can cause cancer—even though plaintiffs were exposed to levels of EtO thought "safe" under regulatory assumptions that governed prior to 2016. The defendants sought to rely on the scientific studies conducted by epidemiologists under the auspices of NIOSH to demonstrate that plaintiffs could not prove that their cancers were caused by EtO, particularly the low-level environmental exposure to defendants' emissions of EtO alleged by plaintiffs.

In the first Cook County case, plaintiff Susan Kamuda alleged that EtO emitted from a medical device sterilization facility caused her breast cancer.[24] Plaintiff's counsel were permitted to present the full regulatory record leading to EPA's 2016 conclusions regarding safe levels of environmental exposure to EtO. Plaintiff argued that the 2016 IRIS Assessment demonstrated retroactively that defendants' regulatorily compliant, pre-2016 emissions were unsafe and that communities in the vicinity of EtO sterilization facilities had actually been cancer "hot spots" for decades. The court was not troubled by the fact that many courts have rejected plaintiffs' efforts to rely exclusively on environmental regulatory action to establish causation.[25] In contrast, the defense was not permitted to show or even describe to the jury the conclusions of the scientific papers that the defense contended demonstrated that there is no risk of cancer arising from environmental exposure to EtO. The defense was also not permitted to tell the jury that EtO occurs naturally in the environment and the human body, facts that help put ambient EtO levels into perspective. The *Kamuda* trial resulted in a $363-million verdict for plaintiff, a large part of which was punitive damages.[26]

The defense prevailed in the second trial, *Fornek v. Sterigenics U.S. LLC, et al*., No. 2018-L-10744, 2018 Ill. Cir. Ct. (Oct. 4, 2018), which commenced in the same Cook County courthouse less than a month after the verdict was rendered in the *Kamuda* case. Plaintiff Teresa Fornek claimed that defendants caused her Acute Lymphoblastic Leukemia—a type of blood cancer—and miscarriage. In *Fornek*, the defense was permitted to show the jury scientific studies finding no association between EtO exposure and the plaintiff's cancer. The jury also heard evidence showing that EtO arises naturally in the environment and the human body and that the exposure levels calculated by plaintiff's own experts were only slightly above the background levels of EtO in the plaintiff's area. Some have suggested that this more complete approach to science is what turned the tide in the second case.[27]

After the complete defense verdict in the second trial, the defendants were able to reach a comprehensive settlement with both trial plaintiffs and more than 870 other plaintiffs who had sued based on allegations that EtO emissions from the Sterigenics sterilization facility in Illinois caused various types of cancers and reproductive harms.[28]

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[24] *Kamuda v. Sterigenics U.S. LLC, et al*., No. 2018-L-010475, 2018 Ill. Cir. Ct. (Sept. 26, 2018).

[25] *See Parker v. Mobil Oil Corp*., 857 N.E.2d 1114, 1121–22 (N.Y. 2006) ("[S]tandards promulgated by regulatory agencies as protective measures are inadequate to demonstrate legal causation."); *see also Rider v. Sandoz Pharms. Corp*., 295 F.3d 1194, 1201 (11th Cir. 2002) (rejecting FDA findings as proof of causation because agency's "risk-utility analysis involves a much lower standard than that which is demanded by a court of law"); *Hollander v. Sandoz Pharms. Corp*., 289 F.3d 1193, 1215 (10th Cir. 2002) (rejecting "a state agency's classification of a substance as a carcinogen" because "[t]he agencies' threshold of proof is reasonably lower than that appropriate in tort law" (internal quotation marks omitted) (citation omitted).

[26] Some have suggested that plaintiff's emphasis in the first trial on an unpopular former Republican governor's private equity stake in the sterilization company inflamed the jury into awarding a large verdict. Jenkins, H., *Opinion | Forget AI: The Administrative State Is a Bad Algorithm*, Wall St. J. (Apr. 28, 2023, 5:08 PM), https://www.wsj.com/articles/forget-ai-the-administrative-state-is-a-bad-algorithm-microsoft-ftc-ethylene-oxide-chicago-355dc0a4. While this and other evidentiary issues may have also influenced the verdict, this paper is focused on the scientific issues in the case.

[27] *Id.*

[28] On January 9, 2023, the cases pending against Sterigenics U.S., LLC and Sotera Health LLC in the Circuit Court of Cook County, Illinois,

Regulatory Initiatives and Litigation Outlook

While the Cook County lawsuits have garnered the most media attention so far, hundreds of other EtO lawsuits remain pending against EtO manufacturers and users in various jurisdictions throughout the United States.[29] Since issuance of the 2016 IRIS assessment, six state-level environmental regulators have conducted studies near EtO sterilization facilities in search of evidence of cancer clusters and consistently found none.[30] New testing and environmental monitoring funded by EPA found that natural levels of EtO in the body and in ambient air, unrelated to any industrial use, are much higher than the level of EtO deemed unsafe in the EPA's 2016 IRIS assessment.[31] Meanwhile, in 2020, the Texas Commission on Environmental Quality concluded that the EPA overestimated EtO's carcinogenic risk by a factor of 2400, applying modeling and methods it deemed more appropriate than those used by EPA in its 2016 IRIS assessment.[32] Despite these developments, litigation over environmental EtO exposure will continue. The panoply of new EtO regulations proposed by EPA in April 2023 are based on EPA's 2016 IRIS assessment.[33]

EPA has continued to move forward with proposing regulations that implement the 2016 IUR.[34] On April 6, 2023, EPA proposed a package of New Source Performance Standards amendments to reduce emissions of six air toxins, including EtO, from chemical-manufacturing facilities.[35] The regulatory package proposes new provisions to restrict EtO emissions by establishing a fence-line monitoring program and enhanced flaring requirements. EPA's Proposed Rule has received 34,491 comments, which stress the necessity of EtO sterilization and raise numerous concerns, including EPA's inaccurate EtO IRIS value, an unrealistic compliance deadline, and that certain requirements exceed the agency's CAA statutory authority.[36] On April 11, 2023, EPA proposed revisions to the NESHAP to regulate EtO emissions from commercial sterilizer facilities by imposing numeric emission limits,

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and U.S. District Court for the Northern District of Illinois settled for $408 million. *See Sotera Health Announces Settlement of Ethylene Oxide Litigation in Illinois*, Sotera Health (Jan 9, 2023), https://investors.soterahealth.com/news-releases/news-release-details/sotera-health-announces-settlement-ethylene-oxide-litigation.

[29] *See, e.g.,* Lotshaw, T., *Ga. Judge Sends Ethylene Oxide Cases Back to State Court*, Law360 (Mar. 13, 2023, 11:52 PM), https://www.law360.com/articles/1585350/ga-judge-sends-ethylene-oxide-cases-back-to-state-court; Chad Pradelli & Cheryl Mettendorf, *Federal Agency Fails To Notify Allentown Residents About Their Increased Cancer Risk*, 6ABC Philadelphia (Feb. 11, 2022), https://6abc.com/bbraun-allentown-cancer-lawsuit-ethylene-oxide-eto-environmental-protection-agency/11552914/.

[30] *Community risk assessment of ethylene oxide near Terumo BCT in Lakewood, Colorado*, Colorado Department of Public Health (Dec. 2018); *Cancer Incidence Data Review - Area Surrounding Viant Medical, Inc. Grand Rapids, MI.*, Michigan Department of Health and Human Services; *Cancer Incidence near Two Facilities Utilizing Ethylene Oxide, Lake County, Ill.*, 1998-2017, Illinois Department of Public Health (Nov. 2021); *Community Cancer Incidence Data Review, B. Braun Medical Sterilization Facility, Allentown, Leigh County, Pennsylvania*, Pennsylvania Department of Health (May 2022); *Risk Assessment Report for the Sterigenics Facility in Willowbrook, Illinois*, EPA's Office of Air Quality Planning and Standards Office of Air and Radiation (Aug. 2019); *Cancer Incidence Assessment near Sterigenics in Willowbrook, IL, 1995-2015*, Illinois Department of Public Health (Mar. 2019).

[31] On March 2, 2022, the EPA released the 2017 Air Toxics Screening Assessment ("AirToxScreen"), a successor to the 2014 National Air Toxics Assessment ("NATA"), estimated risk levels orders of magnitude lower in some locations due to updates in methods and data. U.S. EPA, 2019 AirToxScreen: Assessment Results, https://www.epa.gov/AirToxScreen/2019-airtoxscreen-assessment-results (last accessed May 9, 2023).

[32] *Ethylene Oxide Carcinogenic Dose-Response Assessment*, Texas Commission on Environmental Quality (May 2020).

[33] U.S. EPA, *EPA's Proposal to Reduce Toxic Air Pollution from the Synthetic Organic Chemical Manufacturing Industry and the Polymers and Resins Industry: Overview*, https://www.epa.gov/system/files/documents/202304/PROPOSED.%20HON.PR_OVERVIEW.Fact%20Sheet.FINAL_.4.6.23_0.pdf (last accessed May 9, 2023).

[34] EPA, *News Release: EPA Proposes New Standards to Protect Public Health, Reduce Exposure to Ethylene Oxide Pollution* (Apr. 11, 2023), https://www.epa.gov/newsreleases/epa-proposes-new-standards-protect-public-health-reduce-exposure-ethylene-oxide. EPA's proposals were informed by collaboration with the FDA, the U.S. Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry, and OSHA. *Id*.

[35] *See* New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry, 88 Fed. Reg. 25080 (Apr. 25, 2023).

[36] Comments, New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry, 88 Fed. Reg. 25,080, https://www.regulations.gov/document/EPA-HQ-OAR-2022-0730-0001 (last visited July 19, 2023).

operating limits, and management practices.[37] EPA seeks to establish standards for certain currently unregulated emission sources, including but not limited to, sterilization chamber vents, aeration room vents, chamber exhaust vents, and room air emissions. Further, EPA seeks to toughen EtO monitoring requirements by mandating that facilities either conduct initial and annual performance tests with continuous parameter monitoring or implement EtO Continuous Emissions Monitoring Systems. According to the EPA, "these requirements, if implemented, will reduce the amount of EtO that comes out of commercial sterilizers by 80 percent and will reduce risk in nearby communities."[38]

On March 28, 2023, EPA also published the Proposed Interim Registration Review under the Federal Insecticide, Fungicide, and Rodenticide Act, which stiffens control measures on the use of EtO, such as prohibiting certain uses of EtO where alternatives exist, including use in museums, archival settings, beekeeping, cosmetics, and musical instruments.[39] It will mandate personal protective equipment in sterilization facilities where EtO in the air is at or above 10 parts per billion ("ppb")—notably, 10 ppb is the lowest level at which current technology can detect EtO in the workplace.[40] Additionally, EPA has proposed new engineering controls that would necessitate the physical transformation of facilities, such as automating the transport of sterilized and aerated materials to remove humans from potential exposure during transport, separating HVAC systems between offices and EtO sterilization areas to prevent EtO circulation in office spaces, and installing emissions capture technology to reduce discharge to the environment.[41]

The proposed new requirements—which will be in addition to existing regulations—would be time-consuming, costly to implement, and would require substantial dislocation and downtime in a medical device sterilization industry that is already operating at full capacity to provide an indispensable service. The new proposed regulations also will give ammunition to plaintiffs' lawyers to argue that these preventative measures should have been taken already, in many instances years before the issuance of the new regulations. Thus, EtO facilities that have historically been given a clean bill of health by their regulators will again be accused of causing cancer and potentially other ailments for not implementing such preventative measures sooner.

While EtO finds itself on the cutting edge of regulatory change, EPA's regulatory approach to EtO will likely soon be applied to other chemicals and industries. EPA's proposals for EtO are part of the current review for all air pollutants regulated under the NESHAP, which establishes emission limits and work practice standards for many hazardous air pollutants other than ethylene oxide, including toluene, methanol, xylene, hydrogen chloride, and methylene chloride. Given the recent significant changes in the traditional regulatory approach to EtO and other air pollutants like benzene (for which a dramatic reduction in the permissible exposure limit has been recommended by some organizations),[42] manufacturers and users of such chemicals can expect increased regulatory scrutiny in the future, along with a litigation arc likely to mirror that currently being experienced by the EtO industry.

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[37] 88 Fed. Reg. 22790 (Apr. 13, 2023).

[38] Proposal to Reduce Ethylene Oxide Emissions from Commercial Sterilization Facilities, *Hazardous Air Pollutants: Ethylene Oxide*, https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/proposal-reduce-ethylene-oxide-emissions-commercial (last visited May 9, 2023).

[39] U.S. EPA, *Ethylene Oxide Proposed Interim Registration Review Decision Case Number 2275, Docket ID: EPA-HQ-OPP-2013-0244*, https://www.regulations.gov/document/EPA-HQ-OPP-2013-0244-0045 (Mar. 28, 2023).

[40] *Id*. at 59-62. EPA also "determined [the OSHA PEL of 1 ppm] is not protective based on the Agency's updated risk analysis, and thus are not sufficient to ensure that the use of EtO will not cause unreasonable adverse effects to workers." *Id.* at 60. EPA states that it will work with OSHA to revise its limits to be consistent with the dramatically lower levels proposed by EPA. *Id.* at 37.

[41] *Id.* at 54-57.

[42] The American Conference of Governmental Industrial Hygienists ("ACGIH") recently published a Notice of Intended Change to dramatically reduce its recommended benzene threshold limit values and its short-term exposure limit. ACGIH, *2023 Notice of Intended Changes List (NICs)*, https://www.acgih.org/science/tlv-bei-guidelines/documentation-publications-and-data/notice-of-intended-changes/ (last accessed May 9, 2023).

