Comments of the Attorneys General of
Illinois, Colorado, Connecticut, Maryland, Massachusetts, Michigan, New Jersey, New York, Oregon, Pennsylvania, Rhode Island, Vermont, and Wisconsin

June 27, 2023

Via electronic submission to www.regulations.gov

U.S. Environmental Protection Agency
Office of Air and Radiation, 6101A
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

Re: Docket ID No. EPA-HQ-OAR-2019-0178; Multistate Comments in Response to the U.S. Environmental Protection Agency's Proposed National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review

Dear Administrator Regan:

The undersigned State Attorneys General of Illinois, Colorado, Connecticut, Maryland, Massachusetts, Michigan, New Jersey, New York, Oregon, Pennsylvania, Rhode Island, Vermont, and Wisconsin ("Attorneys General") respectfully submit these comments supporting the U.S. Environmental Protection Agency's ("EPA") proposed amendments to the National Emission Standards for Hazardous Air Pollutants ("NESHAP") for Ethylene Oxide ("EtO") Emissions from Sterilization Facilities. 88 Fed. Reg. 22,790 (Apr. 13, 2023) (the "Proposal" or "Proposed Rules").

The Attorneys General strongly support EPA's Proposal to reduce harmful EtO emissions from sterilization facilities across the country and urge EPA to promptly finalize the Proposal. In addition, the Attorneys General offer recommendations to further strengthen the Proposal based on several states' experiences regulating commercial sterilizers. Among other recommendations offered below, this comment urges EPA to evaluate the potential harms of fugitive emissions released from storage sites holding items sterilized by EtO.

The Proposal addresses many of the concerns that a multistate coalition of Attorneys General, including many of the undersigned, raised in prior correspondence with EPA.[1] As reflected in those letters, the existing EtO standards fail to adequately protect workers and communities from ethylene oxide, a highly toxic chemical for which acute exposure risks include respiratory irritation and lung injury, nausea, shortness of breath, and cyanosis (a decreased

[1] Letter from the Attorneys General of Illinois, California, Connecticut, Delaware, the District of Columbia, Iowa, Maryland, Massachusetts, Minnesota, New Mexico, New York, North Carolina, Rhode Island, Vermont, Virginia, and Wisconsin to the Honorable Andrew Wheeler, *available at* https://ag.state.il.us/pressroom/2019_10/Letter_to_US_EPA_re_Ethylene_Oxide.pdf. (Oct. 10, 2019); Comment on EPA Advance Notice of Proposed Rulemaking for National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations, 84 Fed. Reg. 67,889 (Dec. 12, 2019) from Illinois, Maryland, Rhode Island, Massachusetts, Iowa, New Jersey, New York, Delaware, Minnesota, Vermont, and Michigan (Feb. 10, 2020), *available at* https://www.regulations.gov/comment/EPA-HQ-OAR-2019-0178-0115.

oxygen level in the blood, characterized by a blueish discoloration of the skin or mucous membranes). Chronic exposure risks include cancer, reproductive effects, mutagenic changes, and neurotoxicity.[2] EPA's Proposal provides critical protections to limit the adverse effects. We urge EPA to promptly adopt the Proposed Rule to protect public health and the environment from the well-documented risks posed by EtO emissions in our communities.

I. Legal and Factual Background

A. Statutory and Regulatory Framework

Section 112 of the Federal Clean Air Act establishes a comprehensive regulatory process to address emissions of hazardous air pollutants ("HAP")—like EtO[3]—from stationary (non-vehicle) sources of air pollution.[4] In implementing this statutory process, EPA must identify categories of sources emitting one or more of the HAP listed in Section 112(b)(1) of the Clean Air Act.[5] Section 112(d) requires EPA to promulgate national technology-based emission standards for sources within those categories that emit or have the potential to emit any single HAP at a rate of 10 tons or more per year or any combination of HAP at a rate of 25 tons or more per year (known as "major sources").[6] These technology-based national emission standards for major sources of HAP (such standards, "NESHAP") must reflect the maximum reductions of HAP achievable in light of cost, energy requirements, and non-air health and environmental impacts and are commonly referred to as maximum achievable control technology, or MACT standards.[7]

For new major sources, the MACT standard must be at least as stringent as the emission control achieved in practice by the best controlled similar source.[8] For existing sources in a category with 30 or more such sources, the maximum achievable reduction in emissions must be at least as stringent as the average emission limitation achieved by the 12% best-performing sources in that category.[9] These standards are known as the "MACT floor." Once the "floor" has been determined for new or existing major sources for a category or subcategory, EPA must set a MACT standard that is no less stringent than the floor. Such standards must be met by all major sources within the category or subcategory.

If a source emits HAP but is not a "major source," it is an "area source."[10] EPA is also required to promulgate technology-based standards for area sources of HAPs. For area sources,

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[2] Occupational Safety and Health Administration, Ethylene Oxide Overview, *available at* www.osha.gov/ethylene-oxide.
[3] *See* 42 U.S.C. § 7412(b)(1).
[4] *See id*. at § 7412 *et seq.*
[5] *Id.* at §§ 7412(c), 7412(b)(1).
[6] *Id.* at § 7412(d).
[7] *Id.* at § 7412(d)(2).
[8] *Id.* at § 7412(d)(3).
[9] *Id.* at § 7412(d)(3)(A).
[10] *Id.* at § 7412(a)(1). "'Major source' means any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants" or a lesser threshold set by EPA "on the basis of the potency of the air pollutant, persistence, potential for bioaccumulation, other

Section 112(d)(5) provides that in lieu of MACT, EPA may elect to promulgate standards or requirements which provide for the use of generally available control technologies, or GACT standards.[11] These standards are known as the "GACT floor," and likewise for new or existing area sources, EPA must set a GACT standard no less stringent than the floor. All area sources within the category or subcategory must meet these standards.

Section 112(d)(6) requires EPA to review these technology-based standards every eight years.[12] In these reviews, EPA is to review standards set under section 112 and revise them as necessary, "taking into account developments in practices, processes, and control technologies."[13]

In addition to the technology-based regime, the Clean Air Act requires EPA to review any residual health risks that have not been eliminated by the initial technology-based standards.[14] This second stage is described as "risk based" or "health-based" because it requires EPA to set a standard based on a medical assessment of a given pollutant's health risks, rather than the current state of control technology. EPA must complete one risk review for major sources subject to MACT standards but may use its discretion to perform additional risk reviews.[15] Risk review is not required for area sources subject to GACT standards, but EPA likewise has discretion to do so.[16]

B. History of Regulation of the Commercial Sterilization Industry under § 112

Under the Clean Air Act, listed HAPs—like EtO—are those pollutants that are known or suspected to cause cancer or other serious health effects, such as reproductive effects or birth defects, or adverse environmental effects.[17] On July 16, 1992, EPA published a list of major and area sources of EtO for which it would promulgate a NESHAP.[18] EPA listed EtO commercial sterilization and fumigation operations as a category of major sources and area sources.[19] Commercial sterilizers use EtO to sterilize a range of products including medical equipment, spices, and cosmetics.

On March 7, 1994, EPA first published proposed standards in the *Federal Register* to limit emissions of EtO from existing and new commercial EtO sterilization and fumigation operations designated as subpart O of part 63 of the Code of Federal Regulations.[20] On December 6, 1994, EPA promulgated final standards (the "1994 Rule").[21] In the 1994 Rule, EPA set technology standards for major sources under Section 112(d)(2). As for area sources, EPA

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characteristics of the air pollutant, or other relevant factors." 42 U.S.C. § 7412(a)(2) An "area source" is "any stationary source ... that is not a major source."

[11] *Id.* at § 7412(d)(5).

[12] *Id.* at § 7412(d)(6).

[13] *Id.*

[14] *Id.* at § 7412(f)(2).

[15] *Id*.

[16] *Id.* at § 7412(f)(5).

[17] *Id.* at § 7412(b)(1).

[18] 57 Fed. Reg. 31, 576 (July 16, 1992).

[19] *Id.* at 31,592.

[20] 59 Fed. Reg. 10,591 (Mar. 7, 1994).

[21] 59 Fed. Reg. 62,585 (Dec. 6, 1994).

established technology standards for certain emission points pursuant to Section 112(d)(2) and technology standards for other emission points pursuant to Section 112(d)(5).

The 1994 Rule addressed three emission points: (1) the sterilization chamber vent ("Sterilization Vent" or "SCV"), (2) the chamber exhaust vent ("Exhaust Vent" or "CEV"), and (3) the aeration room vent ("Aeration Vent" or "ARV"). The Sterilization Vent is the emission point out of the facility and into the air for EtO evacuated from a facility's sterilization chamber via a series of air washes. The emissions from any pump used to evacuate the chamber during these air washes is an element of this emissions point. Next, prior to unloading the chamber, the chamber door is automatically opened a crack and the chamber exhaust is activated. The chamber exhaust evacuates EtO-laden air out of the chamber through the Exhaust Vent prior to unloading and while the chamber is being unloaded. Finally, aeration rooms are used to allow further diffusion of residual EtO from the sterilized products prior to shipping. Exhaust from aeration rooms is emitted through the Aeration Vent. The 1994 Rule does not address fugitive emissions that occur from (1) off-gassing associated with the handling of EtO prior to its use in the sterilizer chamber; (2) off-gassing of sterilized product following product transfer from the sterilizer chamber to the aeration room; (3) off-gassing from uncontrolled and under-controlled aeration rooms; and (4) any off-gassing that may occur after product is removed from the aeration room.

In the 1994 Rule, EPA required that emissions from the Sterilization Vent be controlled by at least 99% at facilities using one or more tons of EtO per year. For Aeration Vents at sources using 10 or more tons of EtO per year, EPA required a 99% emission control or a one part per million (ppm) concentration limit for EtO in emissions. The 1994 Rule also set requirements for the Exhaust Vent. Sources using between 1 and 10 tons of EtO were required to lower the EtO concentration in the chamber to at least 5,300 ppm, whereas sources using more than 10 tons of EtO were required to reduce emissions by 99%.

The 1994 Rule also required initial performance testing to demonstrate that the source is meeting the emissions standards. Specifically, for the Sterilization Vent, the rule required a one-time test on an empty sterilization chamber, filled with a typical amount of EtO, for the duration of the first evacuation under "normal" operation conditions.

Affected sources had up to three years to comply with the 1994 Rule. However, the month the standards were to take effect, EPA suspended all rule compliance dates for one year until December 6, 1998.[22] EPA attributed the delay to explosions at facilities subject to the NESHAP.[23] Although the precise cause of the explosions was uncertain, EPA delayed the rule to investigate whether the emission control equipment required by the 1994 Rule was in any way associated with the explosions. In December 1998, the requirements for the Sterilization Vents went into effect; however, EPA further delayed the requirements for the Aeration Vents and Exhaust Vents.[24]

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[22] 62 Fed. Reg. 64,736 (Dec. 9, 1997).
[23] *Id*. at 64,737.
[24] 63 Fed. Reg. 66,990 (Dec. 4, 1998).

On November 29, 1999, EPA issued a rule suspending the 1994 Rule's requirements for Exhaust Vents and Aeration Vents until December 6, 2001 and December 6, 2000, respectively.[25] The Aeration Vent requirements went into effect on December 6, 2000. However, on November 2, 2001, EPA finalized a rule that removed MACT and GACT requirements for Exhaust Vents.[26] To date, commercial sterilization facilities are not required by federal regulations to control EtO emissions from Exhaust Vents.

In 2006, EPA conducted a residual risk analysis and technology review required by Clean Air Act Sections 112(f)(2) and 112(d)(6).[27] No changes were made to the requirements as part of that action. EPA did not conduct any further risk or technology reviews until publishing the Proposed Rules, despite the statutory requirement to conduct a technology review every eight years.[28]

EPA took no further rulemaking action on these standards until December 9, 2019, when EPA issued an Advance Notice of Proposed Rulemaking for National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations ("ANPRM").[29] The ANPRM solicited information from stakeholders on a potential future rulemaking to revise the EtO NESHAP. Specifically, the ANPRM sought comment on available control technologies for reducing emissions of EtO and developments in measuring, monitoring, processes, and control technologies, particularly with respect to fugitive emissions and Exhaust Vent controls.[30] A multistate coalition of attorneys general—including many of the undersigned—responded to the ANPRM, urging EPA to quickly adopt stronger standards to reduce harmful EtO emissions.[31]

EPA subsequently released an information collection request in 2020 to require responses to various questions about EtO sterilization equipment from a broader range of sources than the 2019 ANPRM.[32] EPA released a second notice of its information collection request in 2021.[33]

C. Current Proposed Rules for the Commercial Sterilizers under § 112

The Proposed Rules, published on April 12, 2023, updates EPA's standards for EtO emissions from commercial sterilization operations.[34] The Proposal would, if adopted, increase the stringency of the standards promulgated in the 1994 Rule and impose new standards on several currently unregulated sources of EtO emissions at commercial sterilizers. The currently unregulated sources that would be subject to the Proposed Rule include (1) Sterilization Vents, Aeration Vents, and Exhaust Vents at facilities using less than 1 ton per year ("tpy") of EtO; (2) Aeration Vents and Exhaust Vents at facilities using at least 1 tpy but less than 10 tpy of EtO; (3) Exhaust Vents at facilities using at least 10 tpy of EtO,

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[25] 64 Fed. Reg. 67,789 (Dec. 3, 1999).
[26] 66 Fed. Reg. 55,577 (Nov. 2, 2001).
[27] 71 Fed. Reg. 17,712 (Apr. 7, 2006).
[28] *See* 88 Fed. Reg. at 22,794, *citing* 42. U.S.C. § 7412(d)(6).
[29] 84 Fed. Reg 67,889 (Dec. 12, 2019).
[30] *Id*. at 67,894.
[31] *See* supra at n.1.
[32] 85 Fed. Reg. 35,931 (June 12, 2020).
[33] 86 Fed. Reg. 24,862 (May 10, 2021).
[34] 88 Fed. Reg. 22,790 (Apr. 12, 2023).

and (4) room air emissions (*i.e.*, fugitive emission).[35] The Proposal would regulate both room air emissions generated before the sterilization process, such as during storage of EtO, and room air emissions generated after sterilization, such as off-gassing from sterilized equipment awaiting shipment.

As part of the Proposal, EPA conducted an appropriate and scientifically sound risk and technology review for EtO emissions from commercial sterilizers. The risk review takes into account updated scientific understanding concerning the health impacts of EtO emissions, particularly studies that formed the basis of EPA's updated Integrated Risk Information System ("IRIS") draft risk assessment.[36] The technology review evaluated new practices, processes, and control technologies to limit EtO emissions that have been developed since EPA's last review.[37]

EPA also justifiably proposed updated monitoring requirements. The Proposal would require sources to either use a continuous emissions monitoring system ("CEMS") for EtO emissions or an annual compliance demonstration and operating limits.[38]

Overall, EPA reasonably estimates that the Proposal would reduce the risk of exposure to dangerous levels of EtO to 100-in-1 million or lower.[39] The cost of compliance with the proposal, according to EPA estimates, are roughly $220 million of capital investment and about $39 million of annual operation and maintenance costs.[40] Regulated sources would be required to come into compliance within 18 months of the final rule's effective date.[41]

II. EtO Emissions Endanger Public Health and Welfare

A. Scientific Studies on Public Health Harms of EtO

EtO was listed in the *Fourth Annual Report on Carcinogens* in 1985 as *reasonably anticipated to be a human carcinogen* based on limited evidence of carcinogenicity from human studies and sufficient evidence of carcinogenicity from studies in experimental animals.[42] That same year, the EPA Office of Health and Environmental Assessment released a publication that classified EtO as "probably carcinogenic to humans."[43] In 1987, California declared EtO a human carcinogen.[44] And in 2000, the *Ninth Report on Carcinogens* listed EtO as a *known human carcinogen.*[45]

Studies since the 2000 *Ninth Report* confirm the findings that EtO is a potent carcinogen. One of the chief studies of EtO's cancer risks to date involved more than 18,000

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[35] *Id*. at 22,793.
[36] *Id*. at 22,802; IRIS updates discussed in section II.A, *infra*.
[37] *Id*. at 22,800-801.
[38] *Id*. at 22,843.
[39] *Id*. at 22,794-95.
[40] *Id*. at 22,794.
[41] *Id*. at 22,852.
[42] Report on Carcinogens, Fifteenth Edition, National Toxicology Program, U.S. Departments of Health, *available at* https://ntp.niehs.nih.gov/sites/default/files/ntp/roc/content/profiles/ethyleneoxide.pdf
[43] 50 Fed. Reg. 40,286 (Oct. 2, 1985).
[44] California Office of Environmental Health Hazard Assessment, https://oehha.ca.gov/proposition-65/chemicals/ethylene-oxide
[45] Report on Carcinogens, Fourteenth Edition, *supra* n. 42, at 1.

workers at sterilization plants working in 13 sterilizing facilities.[46] Researchers for the National Institute for Occupational Safety and Health ("NIOSH") found that the workers suffered worrisome rates of breast cancer and lymphomas. This 2004 study provided the foundation of an IRIS draft risk assessment issued in August 2006 by EPA which concluded that EtO is a "known human carcinogen."[47]

In December 2016, EPA released its final evaluation of EtO's inhalation carcinogenicity ("Integrated Risk Information System" or "IRIS").[48] The conclusions were largely the same as the 2006 draft. In 2016, EtO officially joined six other chemicals on EPA's "Group A" list of known carcinogens. In addition to elevating EtO to a known carcinogen, the IRIS increased the adult-based inhalation cancer risk estimate for EtO, called the "unit risk estimate," from 0.0001 per microgram per cubic meter ("µs/m^3") to 0.003 per µg/m^3, which equates to a 30-fold cancer potency increase. Toxicologists at the Michigan Department of Environment Great Lakes and Energy ("EGLE") have since reviewed the 2016 IRIS "unit risk estimate" and determined that it is "appropriate," "defensible," and "reflects a rigorous development and peer review process."[49]

EPA used the revised IRIS risk estimate in its most recent National Air Toxics Assessment (the "NATA"), released in August 2018. The NATA shows that EtO is among the most hazardous air pollutants posing the greatest health risks in the largest number of urban areas in the country. Alarmingly, the NATA shows 58 census tracts in 18 different counties across 12 states that had EtO air emissions at levels that pose cancer risks higher than EPA's "upper bound" of 100 in 1,000,000 cancer risk.[50] Over 288,000 people live in these high risk areas across the country.[51] According to EPA, "further investigation on the NATA inputs and results led to the EPA identifying commercial sterilization using EtO as a source category contributing to some of these risks, which has led the EPA to evaluate, in greater depth, the potential health risks associated with emissions of EtO."[52]

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[46] Center for Disease Control and Prevention, Worker Health Study Summaries, Sterilization of Medical Instruments and Treatment of Spices (Ethylene Oxide), April 2004, *available at* https://www.cdc.gov/niosh/pgms/worknotify/ethyleneoxide.html#Updated%20EtO%20Mortality%20Study.

[47] U.S. EPA, Evaluation of the Carcinogenicity of Ethylene Oxide External Review Draft, *available at* *https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryId=157664*.

[48] U.S. EPA. Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Final Report). U.S. Environmental Protection Agency, Washington, DC, EPA/635/R-16/350F, 2016, *available at* https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryId=329730

[49] State of Michigan Department of Environmental Quality, Air Quality Division, Response to Comments for Ethylene Oxide (CAS # 75-21-8), July 31, 2017, *available at* https://www.deq.state.mi.us/aps/downloads/ATSL/75-21-8/75-21-8_RTC.pdf

[50] Letter from Natural Resources Defense Council ("NRDC"), *et al.*, Public Hearing Request on HC1 and EtO Risk Factor, *available at* https://www.nrdc.org/sites/default/files/public_hearing_request_docket_id_no._epa-hq-oar-2018-0417.pdf

[51] Natural Resources Defense Council, Action Needed to Protect Americans from Toxic EtO Pollution, https://www.nrdc.org/bio/dan-west/action-needed-protect-americans-toxic-eto-pollution

[52] 84 Fed. Reg at 67,893.

B. State Responses to Harms from EtO: Illustrative Examples

Recognizing the harms to their communities left by the gaps in federal regulation, states began to step in to rein in EtO emissions from commercial sterilization facilities. In this section, the experience of two states—Illinois and Michigan—are briefly discussed to provide context for how EPA's Proposal also would improve on existing federal regulations.

1. Commercial Sterilization Facilities in Illinois

i. Sterigenics Facility in Willowbrook, Illinois

Several states' experiences with addressing risks presented by commercial sterilization facilities in their jurisdictions demonstrate the importance of promulgating strong and effective regulations to reduce EtO emissions. A recent EPA investigation into a commercial sterilizer in Willowbrook, Illinois revealed that these facilities are posing a hazard to workers and nearby residents.

Due to EtO emissions from the commercial sterilizer in Willowbrook (operated by the company Sterigenics, U.S., LLC), the cancer risk for Willowbrook residents was 300 per one million according to the NATA. [53] Over 19,000 people lived within a mile of Sterigenics' facility and many others worked at the facility. The facility's air permit—issued by the Illinois Environmental Protection Agency ("Illinois EPA") and reviewed by the federal EPA—allowed the facility to use up to 542.1 tons of EtO and emit approximately 18.2 tons of EtO every year.[54] Consistent with the 1994 Rule, the permit did not require controls for fugitive emissions or emissions from the Exhaust Vent. Between 1995 and 2017, emissions at the facility ranged between 4,200 to 35,400 pounds per year.[55]

In June 2018, EPA provided sampling data to the Agency for Toxic Substances and Disease Registry ("ATSDR") and asked whether modeled and measured EtO concentrations at the Willowbrook sterilization facility, if representative of long-term conditions, would "pose a public health problem for people living and working in Willowbrook."[56] On July 26, 2018, ATSDR concluded that, assuming the data is representative, "an elevated cancer risk exists for

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[53] The 2014 NATA identified seven census tracts near Sterigenics Willowbrook as having a cancer risk greater than EPA's "upper bound" of 100 in 1,000,000 cancer risk. From May 16-18, 2018, following EPA's receipt of the 2014 NATA results for the area surrounding Sterigenics Willowbrook, EPA collected 39 ambient air samples at 26 discrete locations near the facility. Some of the samples were "grab samples" (a short "grab" of air that is analyzed) and some were "12-hour samples" (average concentration of EtO over 12 hours). The sample results ranged from 0.162 $\mu g/m^3$ to 9.09 $\mu g/m^3$. The highest concentration of EtO detected near a residence was 2.12 $\mu g/m^3$. EPA utilized these samples to model short- and long-term ambient EtO concentrations to evaluate the impact of emissions from the facility.

[54] Clean Air Act Permit Program Permit No. 95120085, originally issued on June 30, 2006. On September 20, 2019, Illinois EPA issued a construction permit to Sterigenics to install additional controls at the facility. The construction permit modified the emission limit contained in the CAAPP Permit.

[55] *Id.* (35,400 pounds in 1998 and 4,200 pounds in 2016).

[56] ATSDR, *Letter Health Consultation*, "Evaluation of Potential Health Impacts from Ethylene Oxide Emissions" Sterigenics International, Inc. Willowbrook, Illinois, *available at* https://www.atsdr.cdc.gov/HAC/pha/sterigenic/Sterigenics_International_Inc-508.pdf.

residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility."[57]

Later in July 2018, controls for emissions from the Willowbrook facility's Exhaust Vent were added. In November 2018, EPA began to monitor for ambient levels of EtO near the facility, collecting samples at eight sites within a two miles radius.[58] Samples ranged from non-detect to 26.4 $\mu g/m^{3.}$ EPA concluded that although there was "considerable day-to-day variation in measured EtO concentrations . . . [the Willowbrook facility was] responsible for [a] significant amount of [the] measured EtO concentrations."[59] Therefore, even after the facility installed Exhaust Vent controls, EPA believed that "estimated risks" still required regulatory action and that those "risks could be reduced if the facility was more highly controlled."[60]

In August 2019, EPA released a risk assessment for EtO emissions from the Willowbrook facility.[61] Using a reference scenario of approximately 4,000 pounds of annual EtO emissions, EPA wrote that approximately 60 people were estimated to have cancer risks equal to 1,000 per one million and 11,500 people were estimated to have cancer risks greater than or equal to 100 per one million. In total, EPA estimated that the facility's emissions would lead to roughly 0.3 excess cancer cases per year, *i.e.*, one additional cancer victim every three years.[62]

ii. Illinois' Regulatory Response

In response, the State of Illinois enacted legislation to dramatically reduce EtO emissions from commercial sterilization facilities in Illinois. Illinois has among the most stringent laws regulating commercial sterilization facilities in the country.

The Matt Haller Act ("Haller Act") significantly strengthens the current regulatory framework for EtO in Illinois—far exceeding the requirements of the 1994 Rule.[63] The Haller Act requires that commercial sterilizers in Illinois (a) capture 100% of EtO emissions (including fugitive and Exhaust Vent emissions) and (b) reduce EtO emissions to the atmosphere from each exhaust point at the EtO sterilization source by at least 99.9% or to 0.2 ppm.[64]

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[57] *Id*.
[58] U.S. EPA, Full Data Table: Ethylene Oxide Concentrations in Outdoor Air - 24-hour averages, *available at* https://www.epa.gov/sites/default/files/2019-03/documents/copy_of_031519_willowbrook_eto_master_data_table_for_web.pdf.
[59] Overview of Current Information, Michael Koerber, Deputy Director, Office of Air Quality Planning & Standards, Office of Air and Radiation U.S. EPA, *available at* https://www.epa.gov/sites/default/files/2019-05/documents/epa-overview-current-information.pdf.
[60] *Id*.
[61] Risk Assessment Report for the Sterigenics Facility in Willowbrook, Illinois, EPA's Office of Air Quality Planning and Standards Office of Air and Radiation, August 2019, *available at* https://www.epa.gov/sites/default/files/2019-08/documents/risk_assessment_for_sterigenics_willowbrook_il.pdf.
[62] *Id*.
[63] Illinois Public Act 101-22, amends the Illinois Environmental Protection Act to add a new Section 9.16
[64] 415 ILCS 5/9.16(b).

Additionally, the Haller Act requires limits on EtO usage,[65] continuous emissions monitoring,[66] and dispersion modeling.[67] Importantly, the Haller Act also requires a testing protocol that is representative of maximum emissions from each of the 3 cycles of operation (chamber evacuation, back vent, and aeration).[68] Each of these requirements help limit EtO emissions from commercial sterilizers in Illinois.

Medline Industries owns a commercial sterilizer in Illinois using EtO. The Medline facility is also located near residential areas and raises the same health concerns as did the Willowbrook facility. Indeed, the NATA showed a risk of 123-in-1 million around the Medline facility based on annual emissions of 3,040 pounds—an amount that did not include thousands of pounds emitted uncontrolled through the Exhaust Vent. On February 14, 2019, Medline applied to the Illinois EPA for a construction permit to modify its facility to reduce EtO emissions. On May 30, 2019, Illinois EPA issued a final construction permit to Medline Industries to implement the requirements contained in the Haller Act.[69] Under the construction permit, the facility's allowable emissions were reduced from 10,780 pounds to 150 pounds annually—a 98.6% reduction in allowable emissions.

2. Commercial Sterilization Facilities in Michigan

Two commercial sterilization facilities in Michigan were subject to the existing NESHAP. One ceased sterilization operations in January 2020, and the other ceased sterilization operations in October 2021. The history of both facilities demonstrates both the importance and practicability of the EPA adopting more stringent EtO control measures.

Centurion ("Centurion") Medical Products, (operated by Medline Industries, Inc.) formerly known as Tri-State Hospital Supply Corporation, ceased sterilization operations in late October 2021 at the Howell facility that had been in operation for almost 30 years. Their facility had three EtO sterilization chambers, an EtO aeration room, and an associated product transfer corridor at its Howell location. Once sterilized, parts were transferred through the product transfer corridor into an aeration room. Each Sterilization Vent was controlled by a thermal oxidizer (TO) and each Exhaust Vent and Aeration Vent were controlled by a dry bed scrubber. Stack test results from 2019 indicated that the thermal oxidizer had a destruction efficiency of 99.9% and that the dry bed scrubber had an emission reduction efficiency of 99.9%. At an inspection on November 1, 2018, the facility was found in compliance with the NESHAP. However, EGLE determined additional work was needed to determine the potential impact of EtO emissions on nearby residents.

In March 2021, EtO sampling was conducted, and results identified elevated concentrations of EtO in the air around Centurion. These elevated concentrations along with a

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[65] *Id.* at 5/9.16(j).
[66] *Id.* at 5/9.16(d).
[67] *Id.* at 5/9.16(f).
[68] *Id.* at 5/9.16(b)(1)(A)(iii).
[69] Illinois EPA, Construction Permit No. 19020013, *available at* https://epa.illinois.gov/content/dam/soi/en/web/epa/topics/community-relations/sites/ethylene-oxide/documents/medline-industries-19020013-final.pdf.

subsequent modeling study indicated non-compliance with Michigan's Air Pollution Control Rules. As such, EGLE issued a Violation Notice for Rule 336.1901(a) (Rule 901a). Rule 901a states, "A person shall not cause or permit the emission of an air contaminant that causes injurious effects to human health or safety, animal life, plant life of significant economic value, or property." In August 2021 EGLE commenced escalated enforcement, however these proceedings were discontinued when the sterilization chambers were rendered inoperable, and sterilization ceased at the facility.

Viant Medical Inc. ("Viant") ceased sterilization operations in January 2020 at a Grand Rapids facility that had been in operation for almost 30 years. Their facility had five sterilization chambers controlled by two acid scrubbers operated in series. The sterilization chambers and aeration room vented directly to an acid scrubber and the Exhaust Vent was controlled by a small acid scrubber ducted to the larger scrubber operating in series. In early June 2018, EGLE discovered that the Viant facility was not complying with the NESHAP. EGLE performed a joint inspection at the facility in October of 2018 and collected information to perform dispersion modeling to estimate outdoor air concentrations near the facility and in the nearby residential areas. The final modeling report in early November 2018 estimated that EtO levels in residential areas may be as high as 0.3 ug/m^3 as a long-term average.[70] The lifetime additional cancer risk associated with that exposure level is 15 in 10,000. This is substantially higher than EPA's NATA estimate for the census tract, and higher than EPA's 100 in 1,000,000 "upper bound". The estimated concentration of 0.3 ug/m^3 is also far higher than the health-based screening levels of 0.0002 and 0.002 ug/m^3 that EGLE utilizes to determine acceptably low risks during review of air permit applications. After EGLE shared this information with Viant, the company voluntarily eliminated a process that was believed to be a significant EtO emission source.

EGLE also used the modeling study to calculate fugitive emissions. The quantity of fugitive emissions used in the report was calculated using the in-plant gas chromatograph technology designed for employee safety, along with engineering calculations to convert to pounds of emissions. Using this information in conjunction with the use of EtO, the Air Quality Division ("AQD") was able to calculate the percentage of EtO emitted as fugitive emissions since 2017. These values range from the maximum of 5.0% to a low (outlier) of 0.006%. These calculations underscore the importance of controlling fugitive emissions of EtO from commercial sterilization facilities.

III. Responses to Solicited Comment Topics

The Attorneys General strongly support EPA's proposed rules to significantly increase the stringency of limits on EtO emissions from commercial sterilizers through implementing new limits on emissions from sources that are currently not regulated and increasing stringency on some emissions sources regulated under the existing rules. These standards appropriately reflect the recent scientific studies showing the harmful health effects of EtO and would implement

[70] Michigan Department of Environmental Quality, Viant Medical Inc. – Modeling Summary, *available at* https://www.michigan.gov/documents/deq/deq-aqd-viant_modeling_summary_638133_7.pdf.

reasonable steps to limit these impacts. The Attorneys General also support the provisions to enhance monitoring requirements to ensure that facilities are meeting the applicable standards.

The Attorneys General suggest some areas to improve the stringency and effectiveness of the Proposal. Among other things, the Attorneys General request EPA consider EtO emissions from warehouses that hold EtO-sterilized equipment, consider implementing EtO management practices along with emissions control technology, and to more quickly require compliance with these rules. The Attorneys General also suggest that EPA quickly making monitoring data available to the public.

The preamble to EPA's Proposal solicits responses to specific numbered questions. The Attorneys General list their responses` below along with a reference to the question number in the preamble.

A. Environmental Justice (C-41 through C-46)

The Attorneys General share EPA's concern that commercial sterilizers emitting EtO disproportionately impose adverse health effects on communities of color, low-income populations, and indigenous peoples. EPA's analysis examines the "population with risks greater than 100-in-1 million living within 10 km of a commercial sterilizer" and finds that environmental justice communities bear a disproportionate risk under the existing rules.[71] EPA's analysis predicts that after applying technology-based limits to EtO facilities, the remaining risk is less disproportionate;[72] after applying residual risk-based controls, risk is further lowered.[73] After considering disproportionate impact, the Proposal further revises the standards, increasing stringency at certain Sterilization Vents and Aeration Vents.[74]

The Attorneys General support EPA's approach to examining the environmental justice impacts of the existing rules and comparing it to expected outcomes from the proposed rules. However, the Attorneys General urge EPA to consider the cumulative effects of pollution on populations exposed to EtO emissions from commercial sterilizers. EPA claims that assessments of the cumulative effects of pollution to these populations are "too unreliable." [75] The Attorneys General urge EPA to find methods to more reliably assess these effects.

B. Definition of Affected Sources (C-1)

EPA is proposing to add definitions for affected sources: the individual vents for Sterilization Vents, Aeration Vents, and Exhaust Vents (referred to in the Proposal as SCVs, ARVs, and CEVs, respectively); and all room air emissions for Group 1 and Group 2 emissions.[76] The Attorneys General support these definitions for affected sources.

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[71] 88 Fed. Reg. at 22,833.
[72] *Id*. at 22,834.
[73] *Id*. at 22,837-39.
[74] *Id*. at 22,839-41.
[75] *Id*. at 22,799.
[76] *Id.* at 22,807.

However, we urge EPA to consider including as a source the warehouses where EtO-sterilized materials are held after being treated at a sterilizing facility. Significant quantities of EtO can be emitted from warehouses that hold materials that have been sterilized with EtO. For instance, in 2019 the Georgia Environmental Protection Division issued a notice of violation for operating a warehouse that emitted EtO without a permit and ordered air monitoring at another warehouse.[77] Given that sterilized materials can continue to off-gas significant quantities of EtO even when moved to a warehouse, EPA should consider regulating sources at these facilities.

EPA has already recognized these concerns with storage of EtO-sterilized materials in several ways. First, EPA requested the names and addresses of any non-colocated warehouse, manufacturer, or hospital that holds sterilized products in its information collection request.[78] Furthermore, EPA recognizes that materials can off-gas after sterilization, therefore requiring emissions controls on Group 2 emissions.[79]

In addition to listing warehouses as sources of EtO, EPA should identify and publicly list all warehouses and hospitals that are storing sterilized supplies. EPA should also affirm that this information, which is crucial for the public to understand the risk of exposure to EtO, is not confidential business information.

C. Proposed Technology-Based and Risk-Based Standards (C-2 through C-40)

EPA's proposal sets forth technology-based standards for currently unregulated sources of EtO emissions under sections 112(d)(2), 112(d)(3), and 112(d)(5) of the Clean Air Act, as appropriate. These currently unregulated sources include room air emissions and emissions from Sterilization Vents, Aeration Vents, and Exhaust Vents at certain levels of EtO use. (For example, Sterilization Vents at facilities that use less than 1 tpy of EtO are currently unregulated.[80]) EPA also proposes to revise standards for certain EtO sources that were regulated under the 1994 Rule, reflecting changes in technology.

After establishing technology-based standards, EPA considers any remaining risks to human health. Determining that risks exist from Sterilization Vents and Group 2 room air emissions, risk-based standards for those sources are proposed under section 112(f).

Establishing these standards will help reduce harmful emissions, especially from sources that the existing rules do not regulate. For reasons further detailed below, the Attorneys General strongly support these standards, especially for the sources that were left unregulated under the 1994 rule, such as Exhaust Vents and room air emissions. The Attorneys General further support EPA's proposal to strengthen standards that were first established by the 1994 rule.

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[77] Georgia Environmental Protection Division, https://epd.georgia.gov/press-releases/2019-12-20/statement-georgia-epd-regarding-bd-notice-violation (Dec. 20, 2019).
[78] Information Collection Request, 86 Fed Reg. 24,862 (May 10, 2021), Section L, Table 2 to the Main Questionnaire, *available at* www.regulations.gov/document/EPA-HQ-OAR-2019-0178-0148.
[79] 88 Fed. Reg. at 22,818.
[80] *Id*. at 22,807.

The Attorneys General also urge EPA to consider requiring that facilities use both control technology and pollution-reduction management practices simultaneously, rather than evaluating these options separate from each other.

1. Technology Standards for Sterilization Vents (SCVs) and Aeration Vents (ARVs) (C-2 through C-18)

Existing regulations apply no emission standards to Sterilization Vents at existing or new facilities using less than 1 tpy of EtO.[81] However, as EPA notes in its proposal, 19 of 20 existing facilities of this type are presently using emissions control technology.[82] The proposed rules would set forth technology requirements for existing and new facilities using less than 1 tpy EtO to achieve 99% emission reduction from the Sterilization Vent at existing and new facilities.[83]

For Aeration Vents, the current regulations do not require any controls for facilities that use less than 10 tons of EtO in any consecutive 12-month period.[84] Of facilities with Aeration Vents using less than 10 tpy but at least 1 tpy of EtO, 9 out of 10 facilities are using control technology to limit emissions from Aeration Vents.[85] For existing facilities with Aeration Vents using less than 1 tpy EtO, two of four currently use control technology. The proposal would require these facilities to reduce emissions by 99% at existing and new Aeration Vents using less than 10 tpy EtO.

For facilities using more than 10 tons of EtO, the current NESHAP requires facilities to control the Aeration Vent emissions to one part-per-million by volume ("ppmv") or 99% emission reduction.[86] The Proposal strengthens the requirements for ARVs at facilities using more than 10 tpy EtO by removing the alternative 1 ppmv limit.[87] EPA argues that this revision is necessary because sources can comply with the existing MACT standard for this emissions source either by achieving a 99% emissions reduction or a 1 part-per-million by volume, "whichever is less stringent".[88] A MACT standard may not include a less stringent alternative standard, so EPA proposes to remove the 1 ppmv standard from the MACT for Aeration Vents using more than 10 tpy EtO.

The Attorneys General support these proposals to require use of control technology at many facilities whose Sterilization Vent and Aeration Vent emissions are currently unregulated.

2. Technology Standards for Exhaust Vents (CEVs) (C-19 through C-27)

EPA delayed and eventually removed the requirement that facilities control emissions from the Exhaust Vent due to possible safety issues. Therefore, to date, facilities are not required by EPA to control these emissions. However, EPA had determined that the MACT floor for

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[81] *Id*. at 22,808.
[82] *Id*.
[83] *Id*.
[84] 40 C.F.R. § 63.362(a).
[85] 88 Fed. Reg. at 22,811.
[86] 40 C.F.R. § 63.362(d).
[87] 88 Fed. Reg. at 22,811.
[88] *Id*. at 22,810-11.

Exhaust Vents at existing and new sources, for sources using 10 tpy or more of EtO, is routing emissions from the Exhaust Vent such that they are combined with a stream that is already being routed to a control device that achieves 99% emissions reduction.[89]

As noted in the Proposal, even absent legal requirements, facilities have begun to safely control EtO from the Exhaust Vent by revising their operating procedures to reduce potential safety issues. Among the 40 facilities with Exhaust Vents using over 10 tpy EtO, 34 facilities safely control Exhaust Vent emissions.[90] Not only are facilities controlling Exhaust Vent emissions without safety concerns, stack testing shows that emissions from the Exhaust Vent can be controlled beyond the 99% requirement contained in the original standards.

Because facilities are demonstrating emissions reductions from Exhaust Vent using control technology, EPA has strengthened the standards that apply for Exhaust Vent using more than 10 tpy EtO. For both existing and facilities, the standard is 3.2E-4 lb/hr.[91] EPA claims that this standard is the lowest level at which compliance can be consistently demonstrated with existing CEMS technology.[92] The proposal would establish this emissions rate at the MACT for these major sources.

The 1994 Rule does not include standards for Exhaust Vents at facilities using less than 10 tpy EtO. Noting that Exhaust Vent emissions can be controlled safely, as described above, EPA proposes a 99 percent reduction in EtO emissions by use of control technology for Exhaust Vents at new and existing facilities that use either between 10 tpy and 1 tpy EtO, as well as facilities that use less than 1 tpy EtO. EPA states that three out of six facilities with Exhaust Vents using between 10 tpy and 1 tpy EtO are using emission control technology, justifying the requirement that all facilities apply controls to Exhaust emissions.[93]

Controlling Exhaust Vent emissions nationwide would be one of the single most effective methods of reducing EtO emissions from commercial sterilization facilities, and leaving this emissions source unregulated has led to significant harms to human health. The Attorneys General strongly support implementing these technology-based limits.

3. Technology Standards for Room Air Emissions (C-28 through C-35)

As discussed above, the 1994 Rule does not regulate room air emissions, *i.e.*, fugitive emissions. The Proposal would regulate these emissions and categorize them into two groups: Group 1 room air emissions "include indoor EtO storage, EtO dispensing, vacuum pump operation, and pre-aeration handling of sterilized materials."[94] Group 2 air emissions "include post-aeration handling of sterilized material."[95]

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[89] *See supra* at I.B.
[90] 88 Fed. Reg. at 22,814.
[91] *Id*. at 22,815.
[92] *Id*.
[93] *Id*.
[94] *Id.* at 22,818.
[95] *Id*.

Room air emissions, EPA notes, "tend to have . . . lower EtO concentrations compared to point sources."[96] However, these emissions are still potentially dangerous and should be controlled. According to the Proposal, an analysis of the Willowbrook commercial sterilizer facility indicated that the fugitive component of the emissions accounted for approximately 0.6% of the total EtO usage at that facility.[97] In 2018, that facility reported using 270,181 pounds of EtO. Thus, the facility released approximately 1,621 pounds in fugitive emissions that year. This represents a dangerous amount of EtO emissions that must be controlled.

The Proposal's standards for room air emissions are based on "complete capture of emission" for most types of fugitive emissions—a Permanent Total Enclosure (PTE)—that limits room air emissions to 1.3E-3 lb/hr for Group 1 emissions and 2.8E-3 lb/hr for Group 2 emissions.[98] One exception to this standard is for group 2 air emissions at existing area source facilities. For these, the Proposal would adopt best management practices to reduce EtO use.[99] EPA argues that the economic impact of installing controls at these nine specific source facilities could damage availability of certain medical devices. For that reason, EPA did not require controls in this instance.

These standards generally follow the lead of legislation at the state level that has taken a similar approach to controlling fugitive emissions. For example, under Illinois' Haller Act, all EtO commercial sterilization facilities in Illinois must "capture . . . 100% of all ethylene oxide emissions."[100] To comply with this provision, a facility in Illinois has received a construction permit to install a PTE.[101] Under the terms of its permit, "[t]he Permittee shall operate the affected facility with [PTE] for all areas of the facility in which ethylene oxide is used or may be released, including the storage and handling of bulk ethylene oxide and the storage and handling of sterilized material prior to loadout from the facility."[102]

We strongly support EPA's proposal to require PTE to control fugitive emissions to further reduce the risk of cancer to those living and working near EtO sterilization facilities.

4. Best Management Practices Considered to Reduce Emissions

In the process of determining its proposed technology-based standards, EPA also in many instances considered Best Management Practices (BMP) to reduce EtO emissions—essentially requiring reduced EtO usage rather than implementing control technology. EPA states that use of control technology is their preferred option in most instances because control technology typically achieves greater emission reductions at a lower cost to the facility.[103]

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[96] *Id*.
[97] *Id.* at 22,801.
[98] *Id*. at 22,819-23 (requirements for Group 1 room air emissions at existing and new major and area source facilities, Group 2 room air emissions at existing and new major source facilities, and Group 2 room air emissions at new area source facilities).
[99] *Id*. at 22,823.
[100] 40 C.F.R. § 63.362(c).
[101] Medline Construction Permit, *supra* note 69, at 4.
[102] *Id.*
[103] *E.g.*, 88 Fed. Reg. at 22,818 (EPA states that technology controls for Exhaust Vents at new sources is more cost-effective than BMP).

The Attorneys General recommend that EPA consider not only to require either control technologies or BMP, but rather whether there are instances that using technology and pollution prevention in conjunction would be appropriate to prevent harms to human health from EtO emissions.

5. Risk-Based Standards (C-36 through C-40)

The Proposal sets forth a "determination of risk acceptability." This level of risk that is found to be acceptable is then used by EPA when evaluating the residual risk of EtO emissions after implementation of the technology-based standards. For the Commercial Sterilization Facilities source category, EPA establishes the "presumptive limit on [maximum individual lifetime cancer risk ("MIR")] of approximately one in 10 thousand."[104]

EPA's analysis showed that even after implementing the technology-based standards at commercial sterilization facilities, the risks to human health from EtO emissions remain above this MIR limit due to emissions from Sterilization Vents and Group 2 room air emissions at existing sources.[105] To reduce this risk, the Proposal considers requiring Sterilization Vents at facilities using at least 20 tpy EtO to reduce emissions from individual Sterilization Vents by 99.94 percent and management practices at facilities using at least 20 tpy EtO to limit Group 2 air emissions to 2.8E-3 lb/hr.[106] The Proposal then evaluates whether the standards are protective within an ample margin of safety.

The final product of the Proposal's risk analysis would increase the stringency of standards for emissions from Sterilization Vents at several sizes of new and existing facilities beyond 99 percent and implement a standard that reflects use of emission controls at most existing Group 2 air emissions at area sources using at least 20 tpy at a rate of 2.8E-3 lb/hr.[107]

D. Startup, Shutdown, and Malfunction Requirements (C-47, C-48)

The Proposal discusses the appellate decision "holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the [startup, shutdown, and malfunction (SSM)] exemption violates the CAA's requirement that some CAA section 112 standards apply continuously.[108] Accordingly, the Proposal would eliminate the existing SSM exemption and require compliance at all times.

EtO, as discussed, is an extremely hazardous form of pollution, and the Attorneys General support removing these exemptions that could result in unregulated, risky, emissions, as well as violations of court rulings on SSM exemptions.

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[104] *Id*. at 22,826, *citing* 54 Fed. Reg. 38,045 (Sept. 14, 1989).
[105] *Id*. at 22,826.
[106] *Id*.
[107] *Id*. at 22,831-32.
[108] *Id*. at 22,481, *citing Sierra Club v. EPA*, 551 F.3d 1019 (D.C. Cir. 2018).

E. Monitoring, Recordkeeping, Reporting and Testing Requirements (C-49 through C-69)

1. Performance Testing Methods and Procedures (C-49 through C-60)

The Proposal would update regulatory requirements for monitoring, recordkeeping, reporting, and testing at commercial sterilization facilities. The testing method required under the 1994 Rule, which allows facilities to test the first evacuation of an empty chamber,[109] is not representative of maximum emissions. During actual operations, multiple chambers are often running simultaneously. In addition, EtO accumulates in product during the sterilization process, making it more difficult for the vacuum pump to evacuate the EtO from the chamber. The methodology allowed under the 1994 Rule does not reflect these actual operating conditions and overestimates the amount of EtO that the vacuum pump evacuates, artificially increasing the control efficiency.

The Proposal recognizes these concerns with testing in circumstances that are not representative of normal operation.[110] Illinois' Haller Act requires EtO sterilization facilities to be tested every year under conditions that are representative of maximum emissions from each of the three cycles of operation (Sterilization Vent, Exhaust Vent, and Aeration Vent).[111] This method of testing provides an accurate assessment of the effectiveness of the pollution control equipment in limiting EtO emissions to the surrounding communities. The Proposal updates its requirements to provide a more accurate assessment of operation, so the Attorneys General support the proposal's intention to revise test methods on the pollution control equipment that limits EtO.

2. Continuous Emissions Monitoring System (C-61 through C-67)

The Attorneys General support EPA's proposal to replace the existing monitoring requirements with a requirement to demonstrate continuous compliance by using a CEMS to monitor EtO emissions or an annual compliance demonstration with operating limits.[112] Continuous emissions monitoring can provide information on the effectiveness of pollution controls on a daily basis, ensuring that sterilizers, regulators, and the public have certainty about the emission of this carcinogen. Illinois has already begun requiring that EtO sterilizers continuously collect emissions information.[113]

We also support EPA's proposal to add test methods that can continuously measure stack emissions of the affected facility at concentrations in parts per billion (ppb). Specifically, we support addition of EPA Method 320 for Fourier Transform Infrared Spectroscopy (FTIS).[114]

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[109] 40 C.F.R. § 63.365(b)(1).
[110] 88 Fed. Reg. at 22,844.
[111] 415 ILCS 5/9.16(b).
[112] 88 Fed. Reg. at 22,843.
[113] 415 ILCS 5/9.16(d).
[114] 88 Fed. Reg. at 22,843.

3. Fenceline Monitoring (C-68)

EPA's proposal declines to require that commercial sterilizers' EtO emissions be tracked through fenceline monitoring. The proposal argues that "EPA does not believe that a fenceline monitor would measure a significant quantity of residual EtO emissions, or identify a compliance issue that has not already been detected through the continuous monitoring requirements . . ."[115] Furthermore, EPA questions whether fenceline monitoring is technically feasible.[116]

The Attorneys General urge EPA to include fenceline monitoring requirements in the final rule. This safeguard will further ensure the safety of local communities and workers, as fugitive emissions can still occur even when a facility is using a PTE. As EPA recognizes, many commercial sterilization facilities are located near residences, schools, and other public facilities.[117] Fenceline monitoring is needed to inform communities as to whether this cancer causing gas is continuing to enter their neighborhoods, even after EPA's proposed measures are implemented.

For example, in New York, Sterigenics US LLC operates at 84 Park Road in Kingsbury.[118] The facility uses ethylene oxide to sterilize medical devices. [119] The nearby community consists of numerous residences, with an estimated 1,375 people living within one mile.[120] Most of the houses on Dean Road are within a half mile of the facility. Dean Road is also east of Sterigenics and since the wind comes predominantly from the north, parts of Dean Road are in the path of wind. Additionally, a daycare center is only 0.57 miles from Sterigenics and also in the path of wind.

Based on an examination using EPA EJSCREEN, the New York Disadvantaged Communities' map, and the Agency for Toxic Substances and Disease Registry's Environmental Justice Index, the community within one mile of the Sterigenics facility has several health and socioeconomic vulnerabilities, including high air toxics cancer risk (99th percentile, state), high percentage of children under age 5 (93rd percentile, state), high percent of low-income households (65th percentile, state), high levels of respiratory-related emergency department visits (asthma and chronic obstructive pulmonary disease (COPD) (77th percentile, state and 72nd percentile, state)), and lower levels of formal education. Members of this community have expressed their serious concerns regarding emissions of EtO from the facility and justifiably believe that fenceline monitoring is necessary to protect their health. Indeed, EPA received "a substantial number of comments from front-line communities supporting the use of fenceline measurements[.]"[121]

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[115] *Id*. at 22,847-48.
[116] *Id*.
[117] *Id.* at 22,792.
[118] EPA Kingsbury NY EtO Community Meeting Presentation (Feb. 16, 2023), https://www.epa.gov/system/files/documents/2023-02/Kingsbury%20NY%20EtO%20Community%20Meeting%20Presentation.pdf.
[119] *Id.*
[120] EPA EJSCREEN Census 2010 Summary Report.
[121] *Id.* at 22,847.

Despite EPA's statements that fenceline monitoring is infeasible, it has been used to detect EtO emissions in Illinois.[122] In addition, EPA's Office of Research and Development has significant experience regarding monitoring of ethylene oxide.[123] Furthermore, EPA has received funds under the Inflation Reduction Act that can and should be used to assure fenceline monitoring methods are available for ethylene oxide.[124] EPA should consult with the Office of Research and Development as well as state and local governments such as California's South Coast Air Quality Management District that have implemented ethylene oxide fenceline monitoring.[125]

4. Ambient Monitoring (C-69)

EPA states that it is considering ambient monitoring "as part of a work practice standard . . . or as an additional measure to assure additional compliance . . ."[126] The States support adding ambient monitoring to the Proposed Rule. Illinois has required a six-month monitoring period for ambient air monitoring of EtO at six locations across the state, which provided useful information for the protection of its residents from EtO pollution.[127]

5. Title V Permitting (C-74)

In 2005, EPA promulgated a rule that exempted area source EtO commercial sterilizers from Title V permitting.[128] This rule found that requiring area sources to comply with Title V permitting requirements would be "unnecessarily burdensome" for area sources.[129] The Proposal would reverse this finding and require area source EtO commercial sterilizers to comply with Title V permitting requirements. In support of this decision, EPA cites new information on the harms to human health posed by EtO emissions and more information about the cost of complying with these requirements for area sources.[130]

The Attorneys General strongly support this measure in EPA's proposal. As EPA notes, there are significant public participation and compliance benefits that EPA cites in support of its proposed action.[131] Furthermore, this action is appropriate because of the manner in which EPA has defined the effective source in these rules. The proposed rule would define sources at the level of an individual vent, so there could potentially be very large sources with a variety of emission points that would still be classified as a synthetic area source depending on how much EtO is emitted from any individual vent. It is important for these sources to be covered by Title V permitting requirements.

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[122] *See supra*, n.53.
[123] *See* Comments of Earthjustice regarding *Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act; Safer Communities by Chemical Accident Prevention; Proposed Rule*, 87 Fed. Reg. 53,556 (Aug. 31, 2022), at 91, https://www.regulations.gov/comment/EPA-HQ-OLEM-2022-0174-0460.
[124] *Id.*
[125] South Coast AQMD, Ethylene Oxide (EtO) Emissions Investigation, https://www.aqmd.gov/home/eto.
[126] 88 Fed. Reg. at 22,848.
[127] 35 Ill. Adm. Code 429 (Ethylene Oxide Ambient Air Monitoring).
[128] 70 Fed. Reg. 57,320 (Dec. 19, 2005), *citing* 42 U.S.C. 7661a(a). *See also* 40 CFR 70.3(a), 71.3(a).
[129] *Id*.
[130] 88 Fed. Reg. at 22,850-51.
[131] *Id*. at 22,851.

6. Compliance Deadlines (C-80)

EPA proposes that all existing affected sources come into compliance with the amended rule within 18 months after the effective date of the final rule.[132] The Attorneys General urge EPA to require compliance within a shorter time frame, provided that facilities have enough time to obtain the necessary permits, hire contractors, and complete the work necessary to comply with the proposed rule. The harms presented by currently unregulated EtO emissions from commercial sterilizers present a serious risk to human health and urgently need to be addressed.

IV. Conclusion

The Proposed Rules, if adopted, would, for the first time, limit EtO emissions from all emission sources within a commercial sterilizing facility. The weight of scientific evidence shows that human exposure this extremely hazardous, carcinogenic chemical substance must be strictly limited, and the Proposal will help lower risks to human health. Furthermore, the increased quantity and quality of data reporting on EtO emissions required by the Proposal will provide the public with important information about potential exposure pathways and the ability to understand the risks posed by EtO emissions in their neighborhoods.

For these reasons, the Attorneys General strongly support adoption of the Proposed Rules as quickly as feasible. The Attorneys General also urge EPA to further strengthen the Proposal by incorporating our recommendations herein based on the experience of several states that regulate EtO emissions from facilities in their own communities.

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[132] *Id*. at 22,852.

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