Attorneys General of Illinois, Maryland, Rhode Island, Massachusetts, Iowa, New Jersey, New York, Delaware, Minnesota, Vermont, and Michigan

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Via Electronic Transmission

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U.S. Environmental Protection Agency
Mail Code 28221T
1200 Pennsylvania Avenue, NW
Washington, DC 20460
a-and-r-Docket@epa.gov

RE: Comments on National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations, 84 Fed. Reg. 67,889 (Dec. 12, 2019)

Attention: Docket ID No. EPA-HQ-OAR-2019-0178

Dear Administrator Wheeler,

The undersigned Attorneys General of Illinois, Maryland, Rhode Island, Massachusetts, Iowa, New Jersey, New York, Delaware, Minnesota, Vermont, and Michigan respectfully submit these comments in response to the U.S. Environmental Protection Agency's ("EPA") advance notice of proposed rulemaking entitled "National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations," 84 Fed. Reg. 67,889 (Dec. 12, 2019) ("ANPRM").

These comments expand on concerns a coalition of 16 Attorneys General, including many of the undersigned, raised in an October 10, 2019 letter[1] regarding EPA's current national emission standards for the hazardous air pollutant ethylene oxide ("EtO"). We are concerned that the standards for EtO, a flammable and highly reactive gas, fail to adequately protect workers and communities from this toxic chemical for which acute exposure risks include respiratory irritation and lung injury, headache, nausea, vomiting, diarrhea, shortness of breath, and cyanosis, and chronic exposure risks include cancer, reproductive effects, mutagenic changes, and neurotoxicity.[2] We urge EPA to propose revised standards that adequately protect public

[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* http://www.illinoisattorneygeneral.gov/pressroom/2019_10/Letter_to_US_EPA_re_Ethylene_Oxide.pdf.
[2] Occupational Safety and Health Administration, Ethylene Oxide Overview, *available at* https://www.osha.gov/SLTC/ethyleneoxide/index.html.

health and the environment from the well-documented risks posed by EtO emissions. We also call on the EPA to work with the U.S. Food and Drug Administration (FDA) to support research into effective alternatives to EtO sterilization and end the over-reliance on the practice.

I. LEGAL AND FACTUAL BACKGROUND

A. Statutory and Regulatory Framework

Section 112 of the Clean Air Act establishes a comprehensive regulatory process to address emissions of hazardous air pollutants ("HAP") from stationary (non-vehicle) sources of air pollution.[3] 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.[4] 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").[5] These technology-based national emission standards for 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.[6] If a source emits HAP but is not a "major source," it is an "area source".[7] For area sources, 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.[8]

For new sources, the MACT standard must be at least as stringent as the emission control achieved in practice by the best controlled similar source.[9] 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.[10] These standards are known as the "MACT floor". Once the "floor" has been determined for new or existing 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 sources within the category or subcategory.

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[3] *See* 42 U.S.C. § 7412 *et seq.*
[4] *Id.* §§ 7412(c), 7412(b)(1).
[5] *Id.* § 7412(d).
[6] *Id.* § 7412(d)(2).
[7] *Id.* § 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 characteristics of the air pollutant, or other relevant factors").
42 U.S.C. § 7412(a)(2) ("area source" is "any stationary source ... that is not a major source").
[8] 42 U.S.C. § 7412(d)(5).
[9] *Id.* § 7412(d)(3).
[10] *Id.*

Section 112(d)(6) requires EPA to review technology-based standards every 8 years.[11] 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)."[12]

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.[13] 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.

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

EtO is a listed HAP.[14] On July 16, 1992, EPA published a list of major and area sources for which it would promulgate a NESHAP.[15] EPA listed EtO commercial sterilization and fumigation operations as a category of major sources and area sources.[16]

On March 7, 1994, EPA first proposed standards to limit emissions of EtO from existing and new commercial EtO sterilization and fumigation operations in the *Federal Register* as subpart O of part 63 of the Code of Federal Regulations.[17] On December 6, 1994, EPA promulgated final standards ("December 1994 Rule").[18] In the December 1994 Rule, EPA set MACT for major sources under Section 112(d)(2). As for area sources, EPA established MACT standards for certain emission points pursuant to Section 112(d)(2) and GACT standards for other emission points pursuant to Section 112(d)(5).

The December 1994 Rule addressed three emission points: (1) the sterilization chamber vent ("SCV"), (2) the aeration room vent ("ARV"), and (3) the chamber exhaust vent ("CEV"). The SCV is the emission point for EtO evacuated from the sterilization chamber via a series of air washes. A component of this emission point is the emissions from any pump used to evacuate the chamber during these air washes. Prior to unloading the chamber, the chamber door is automatically cracked, and the chamber exhaust is activated. The chamber exhaust evacuates EtO-laden air out of the chamber through the CEV prior to unloading and while the chamber is being unloaded. 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 ARV. The standards do not address fugitive emissions that occur from (1) off-gassing associated with the handling of EtO prior its use in the sterilizer chamber; (2) off-gassing of sterilized product

[11] *Id.* § 7412(d)(6).
[12] *Id.*
[13] *Id.* § 7412(f)(2).
[14] *Id.* § 7412(b)(1).
[15] 57 Fed. Reg. 31, 576 (July 16, 1992).
[16] *Id.* at 31, 592.
[17] 59 Fed. Reg. 10,591 (Mar. 7, 1994).
[18] 59 Fed. Reg. 62,585 (Dec. 6, 1994).

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.[19]

In the December 1994 Rule, EPA required that emissions from the SCV be controlled by at least 99% at facilities using 1 or more tons of EtO per year. For ARVs at sources using 10 or more tons of EtO per year, EPA required a 99% *or* a 1 part per million (ppm) concentration limit. The December 1994 Rule also set requirements for the CEV. 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 December 1994 Rule also required initial performance testing to demonstrate that the source is meeting the emissions standards. Specifically, for the SCV, 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 December 1994 Rule. However, the month the standards were to take effect, EPA suspended all rule compliance dates for one year until December 6, 1998.[20] EPA attributed the delay to explosions at facilities subject to the NESHAP.[21] Although the precise cause of the explosions was uncertain, EPA delayed the rule to investigate whether the emission control equipment required by the December 1994 Rule was in any way associated with the explosions.[22] In December 1998, the requirements for the SCV went into effect; however, EPA further delayed the requirements for the ARVs and CEVs.[23]

On November 29, 1999, EPA issued a rule suspending the December 1994 Rule's requirements for CEV and ARV until December 6, 2001 and December 6, 2000, respectively.[24] The ARV requirements went into effect on December 6, 2000, however on November 2, 2001, EPA finalized a rule that removed MACT and GACT requirements for the CEVs.[25] To date, commercial sterilization facilities are not required to control EtO emissions from the CEV.

In 2006, EPA conducted the residual risk analysis and technology review required by Clean Air Act Sections 112(f)(2) and 112(d)(6).[26] No changes were made to the requirements as part of that action. EPA is now more than five years late in conducting the next required 8-year technology review.

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[19] ANPRM at 67,894.
[20] 62 Fed. Reg. 64,736 (Dec. 9, 1997).
[21] *Id.* at 64,737.
[22] *Id.*
[23] 63 Fed. Reg. 66,990 (Dec. 4, 1998).
[24] 64 Fed. Reg. 67,789 (Dec. 3, 1999).
[25] 66 Fed. Reg. 55,577 (Nov. 2, 2001).
[26] 71 Fed. Reg. 17,712 (Apr. 7, 2006).

C. Ethylene Oxide Emissions from Commercial Sterilization Operations Endanger Public Health and Welfare

EtO was first 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 in animal studies.[27] That same year, the EPA Office of Health and Environmental Assessment released a publication that classified EtO as "probably carcinogenic to humans."[28] In 1987, California declared EtO a human carcinogen.[29] In 2000, the *Ninth Report on Carcinogens* listed EtO as a *known human carcinogen*.[30]

Studies since the 2000 Ninth Report confirm that EtO is a potent carcinogen. One of the chief studies of EtO's cancer risks to date involved more than 18,000 workers at sterilization plants.[31] 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 Integrated Risk Information System ("IRIS") draft risk assessment issued in August 2006 by EPA which concluded that EtO is a "known human carcinogen."[32] A panel of independent scientists agreed with the draft's conclusion but advised that EPA make improvements to its risk assessment. This process took nine years to complete. In December 2016, EPA released its final evaluation of EtO's inhalation carcinogenicity ("December 2016 IRIS").[33] 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 December 2016 IRIS increased the adult-based inhalation cancer risk estimate for EtO, called the "unit risk estimate," from 0.0001 per microgram per cubic meter ("$\mu g/m^3$") to 0.003 per $\mu g/m^3$, 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 IRIS "unit risk estimate" and determined that it is "appropriate," "defensible," and "reflects a rigorous development and peer review process."[34]

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[27] Report on Carcinogens, Fourteenth Edition, National Toxicology Program, U.S. Departments of Health, *available at* https://ntp.niehs.nih.gov/ntp/roc/content/profiles/ethyleneoxide.pdf.
[28] 50 Fed. Reg. 40,286 (Oct. 2, 1985).
[29] California Office of Environmental Health Hazard Assessment, https://oehha.ca.gov/chemicals/ethylene-oxide.
[30] Report on Carcinogens, Fourteenth Edition, *supra* note 27, at 1.
[31] 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.
[32] Evaluation of the Carcinogenicity of Ethylene Oxide External Review Draft, *available at* https://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=458625.
[33] 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/ncea/iris_drafts/recordisplay.cfm?deid=329730.
[34] 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.

EPA used the revised IRIS risk estimate in its most recent National Air Toxics Assessment (the "2014 NATA"), released in August 2018. The 2014 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 2014 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.[35] Over 288,000 people live in these high risk areas across the country.[36] According to EPA, '[f]urther 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."[37]

D. Sterigenics Facility in Willowbrook, Illinois

The health risks of EtO emissions from commercial sterilization facilities may have been significantly underestimated for years. As an EPA investigation into one company in Willowbrook, Illinois shows, these facilities are very likely under-reporting actual emissions and so obscuring the true extent of the hazard posed by their operations to workers and residents in neighboring communities. And there are similar facilities that may pose a similar risk in many of the undersigned states.[38]

As but one example of the types of EtO exposure risks in many of the undersigned states, according to the 2014 NATA, residents of Willowbrook, Illinois had an estimated cancer risk of 300 in 1 million, due to exposure to reported EtO emissions from a commercial sterilization facility operated by Sterigenics U.S., LLC ("Sterigenics Willowbrook"). Sterigenics Willowbrook operated from 1984 to 2019 in a densely populated area with more than 19,000 people living within a mile and many additional people working there.[39] On January 30, 2006, the Illinois Environmental Protection Agency ("Illinois EPA") issued Clean Air Act Permit Program Permit No. 95120085 to Sterigenics Willowbrook, which Illinois EPA renewed on June 8, 2015 ("CAAPP Permit").[40] The CAAPP Permit includes the NESHAP for EtO emissions from sterilization facilities, 40 C.F.R. Part 63, Subpart O. As with all CAAPP permits issued by Illinois EPA, EPA reviewed the permit for compliance with the applicable requirements of the

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[35] Public Hearing Request on HCl 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.
[36] NRDC, Action Needed to Protect Americans from Toxic EtO Pollution, https://www.nrdc.org/experts/dan-west/action-needed-protect-americans-toxic-eto-pollution.
[37] ANPRM at 67,893.
[38] These include many of the facilities listed in the docket at EPA-HQ-OAR-2019-0178-0013.
[39] On February 15, 2019, Illinois EPA issued an order to Sterigenics that effectively prohibited Sterigenics Willowbrook from using EtO for sterilization. On September 30, 2019, Sterigenics announced that it would not seek to reopen the facility because it could not renew the lease.
[40] Clean Air Act Permit Program (CAAPP) Permit No. 95120085, *available at* https://www2.illinois.gov/epa/topics/community-relations/sites/sterigenics/Documents/Sterigenics%20CAAPP%20Permit.pdf.

Clean Air Act.[41] Under the current NESHAP, the CAAPP Permit for Sterigenics Willowbrook allowed[42] the facility to utilize up to 542.1 tons (1,084,200 pounds)—and emit approximately 18.2 tons (36,400 pounds)—of EtO per year. Consistent with the NESHAP, the permit did not require that Sterigenics Willowbrook control fugitive emissions, or emissions from the CEV. In 2015, Sterigenics Willowbrook sent its Annual Emissions Report to Illinois EPA, reporting 5,080 pounds of EtO emitted at the Willowbrook facility in 2014.[43] Between 1995 and 2017, emissions at the facility ranged from 4,200 pounds (2016) to 35,400 pounds (1998).[44]

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 .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.

In June 2018, EPA provided the analytical data from the May 2018 sampling event to the U.S. Department of Health and Human Services Agency for Toxic Substances and Disease Registry ("ATSDR") and asked that ATSDR review air measurements of EtO and modeling results of EtO emissions from Sterigenics Willowbrook and to answer the question: "If modeled and measured EtO concentrations represent long term conditions, would they pose a public health problem for people living and working in Willowbrook?"

On July 26, 2018, ATSDR sent EPA a "Letter Health Consultation"[45] that answered the above question. On August 21, 2018, EPA released the letter to the public, which concluded as follows:

> It is ATSDR's conclusion that the data U.S. EPA provided suggests that residents and workers are exposed to elevated airborne EtO concentrations from facility emissions. It is difficult to assess long-term public health implications from facility emissions because there has been no historical air monitoring in the community. ATSDR assumed that these data represent long term exposures for area residents and workers. Specifically, ATSDR

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[41] *See* 42 U.S.C. § 7661d.
[42] On September 20, 2019, Illinois EPA issued a construction permit to Sterigenics to install additional controls at the facility. *See infra*, note 60. The construction permit modified the emission limit contained in the CAAPP Permit.
[43] Sterigenics Willowbrook Annual Emissions Reports, 1995-2017, *available at* https://www2.illinois.gov/epa/topics/community-relations/sites/sterigenics/Documents/043110AAC%20-%20AERs%201995-2017.pdf.
[44] *See id.*
[45] 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.

concludes the following:

> 1) If measured and modeled data represent typical EtO ambient concentrations in ambient air, an elevated cancer risk exists for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility. These elevated risks present a public health hazard to these populations.
>
> 2) Measured and modeled ethylene oxide concentrations in ambient air indicate that non-cancer health effects are unlikely for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility.

In June 2018, Sterigenics Willowbrook applied to the Illinois EPA for a construction permit to control emissions from the CEV at the facility. Illinois EPA issued the construction permit on June 26, 2018, and Sterigenics Willowbrook ducted the CEV to existing controls on July 27, 2018. According to Sterigenics, controlling the CEV led to a "90% decrease" in overall EtO emissions from Sterigenics Willowbrook.[46]

In November 2018, EPA announced a monitoring program to assess ambient levels of EtO surrounding Sterigenics Willowbrook. On 49 days between November 13, 2018 and March 31, 2019, EPA collected samples at 8 sites within two miles of Sterigenics Willowbrook.[47] Samples ranged from non-detect to 26.4 $\mu g/m^3$.[48] Following the monitoring program, EPA concluded that although there was "considerable day-to-day variation in measured EtO concentrations . . . [Sterigenics Willowbrook was] responsible for [a] significant amount of [the] measured EtO concentrations."[49] Additionally, EPA noted that although "background levels of EtO exist," they are "much lower" than the contributions from Sterigenics Willowbrook.[50] According to EPA, the main takeaways from the monitoring program were that (1) "estimated risks" from the facility after it controlled the CEV still required "regulatory action;" and (2) those "risks could be reduced if the facility was more highly controlled."

At a community meeting in Illinois on May 29, 2019, EPA informed the audience that it planned to propose a revised NESHAP for commercial sterilizers in "summer 2019."[51]

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[46] Sterigenics FAQ, *available at* https://www.sterigenicswillowbrook.com/faqs.
[47] Full Data Table: Ethylene Oxide Concentrations in Outdoor Air - 24-hour averages, *available at* https://www.epa.gov/sites/production/files/2019-03/documents/copy_of_031519_willowbrook_eto_master_data_table_for_web.pdf.
[48] *Id.*
[49] Overview of Current Information, Michael Koerber Deputy Director, Office of Air Quality Planning & Standards, Office of Air and Radiation U.S. Environmental Protection Agency, *available at* https://www.epa.gov/sites/production/files/2019-05/documents/epa-overview-current-information.pdf.
[50] *Id.*
[51] *Id.*

In August 2019, EPA released a risk assessment for Sterigenics Willowbrook.[52] The assessment focused only on the *risk from EtO emissions from Sterigenics Willowbrook*.[53] 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-in-1 million, 11,500 people were estimated to have cancer risks greater than or equal to 100-in-1 million, 230,000 people were estimated to have cancer risks greater than or equal to 10-in-1 million, and 6.5 million people were estimated to have cancer risks greater than or equal to 1-in-1 million.[54] The total estimated cancer incidence from the Sterigenics facility was 0.3 excess cancer cases per year, or one excess case in every three years.[55]

E. Illinois' Regulatory Response

In June 2019, responding to both the ATSDR Letter Health Consultation and the alarming sampling results from EPA's monitoring program around Sterigenics Willowbrook, the State of Illinois enacted legislation to dramatically reduce EtO emissions from commercial sterilization facilities in Illinois. Illinois currently has the most stringent laws regulating commercial sterilization facilities in the country.

The Matt Haller Act ("Haller Act"), attached to this comment as Attachment 1, which was enacted as Illinois Public Act 101-22, amends the Illinois Environmental Protection Act to add a new Section 9.16. The Haller Act significantly strengthens the current regulatory framework for EtO in Illinois—far exceeding the requirements of the NESHAP. Most significantly, the Haller Act requires that commercial sterilization sources in Illinois (a) capture and demonstrate that they capture 100% of all EtO emissions (including fugitive and CEV 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.[56] These capture and control requirements will result in a dramatic reduction in EtO emissions at facilities in Illinois. As noted in the ANPRM,[57] the 100% capture requirement has resulted in the implementation of permanent total enclosure ("PTE") at facilities in Illinois, which will eliminate hundreds of pounds of fugitive emissions from entering Illinois' communities.

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[52] 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/production/files/2019-08/documents/risk_assessment_for_sterigenics_willowbrook_il.pdf.
[53] *Id.* at 4.
[54] *Id.*
[55] *Id.*
[56] 415 ILCS 5/9.16(b).
[57] ANPRM at 67,894-95.

Additionally, the Haller Act requires a limit on EtO usage,[58] continuous emissions monitoring,[59] ambient air testing,[60] and dispersion modeling.[61] 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).[62] Each of these requirements will help ensure that EtO emissions from Illinois facilities will not pose a threat to neighboring communities.

In its August 2019 risk assessment, EPA evaluated an "illustrative future scenario" in which Sterigenics Willowbrook implemented the kinds of controls required by the Haller Act and reduced its emissions to only 26 pounds per year.[63] Under this scenario, EPA estimated the maximum lifetime (residential) individual cancer risk to be 1-in-1 million, which occurred at a single residential grid receptor. All cancer risks at census blocks were less than 1-in-1 million. The total estimated cancer incidence was 0.002 excess cancer cases per year, or one excess case in every 700 years within the entire modeling domain.

On September 20, 2019, Illinois EPA issued a final construction permit for Sterigenics Willowbrook, based on a permit application submitted by the company on June 24, 2019 in response to the passage of the Haller Act.[64] Taking into account the requirements in the Haller Act, the construction permit limited the facility's EtO emissions to 8.5 pounds per month and 85 pounds per year, a drastic 99.76% reduction from the 36,400 pounds of EtO allowed under the current NESHAP. In its August 2019 Risk Assessment, EPA estimated that these emissions result in a "1- to 10-in-1 million cancer risk"—well below EPA's "upper bound" of 100 in 1,000,000 cancer risk.[65]

A second commercial sterilizer using EtO in Illinois is owned by Medline Industries. The Medline facility is also located near residential areas and raises the same health concerns as did Sterigenics Willowbrook. Indeed, the 2014 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 CEV. 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.[66] Under the construction

[58] 415 ILCS 5/9.16(j).
[59] *Id.* 5/9.16(d).
[60] *Id.* 5/9.16(e).
[61] *Id.* 5/9.16(f).
[62] *Id.* 5/9.16(b)(1)(A)(iii).
[63] Risk Assessment Report for the Sterigenics Facility in Willowbrook, *supra* note 52, at 3.
[64] Construction Permit No. 19060030, *available at* https://www2.illinois.gov/epa/topics/community-relations/sites/ethylene-oxide/Documents/19060030%2009-20-2019.pdf.
[65] Risk Assessment Report for the Sterigenics Facility in Willowbrook, *supra* note 52, at 8 note 5.
[66] Construction Permit No. 19020013, *available at* https://www2.illinois.gov/epa/topics/community-relations/sites/ethylene-oxide/Documents/Medline%20Industries%2019020013%20FINAL.pdf.

permit, the facility's allowable emissions were reduced from 10,780 pounds to 150 pounds annually—a 98.6% reduction in allowable emissions.[67]

F. Commercial Sterilization Facilities in Michigan

Two commercial sterilization facilities in Michigan are or were subject to the existing NESHAP. One has ceased operations, and the other remains in operation. The history of both facilities demonstrates both the importance and practicability of the EPA adopting more stringent EtO control measures.

Centurion Medical Products, formerly known as Tri-State Hospital Supply Corporation, is a medical product manufacturer that has three EtO sterilization chambers, an EtO aeration room, and an associated product transfer corridor at its location. Once sterilized, parts are transferred through the product transfer corridor into an aeration room. Each SCV is controlled by a thermal oxidizer (TO) and each CEV and ARV are controlled by a dry bed scrubber. Records from the facility indicate that the thermal oxidizer has a destruction efficiency of 99.985% and that the dry bed scrubber has an emission reduction efficiency of 99.95%. As of the last inspection on November 1, 2018, the facility was in compliance with the NESHAP.

Viant Medical Inc. (Viant) very recently ceased sterilization operations 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 CEV 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.[68] 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

[67] *Id.*
[68] 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.

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.

II. EPA MUST ADOPT STANDARDS THAT REDUCE RISK AND PROTECT HUMAN HEALTH

In this ANPRM, EPA is soliciting information and requesting comment on potential control measures for reducing EtO emissions from commercial sterilization facilities. As outlined above, the control measures in Subpart O are not sufficiently protective of human health in light of new, compelling information since the 2006 the residual risk analysis and technology review about EtO's carcinogenic risks—most notably the agency's 2016 IRIS assessment. As EPA itself stated in May 2019, "risks could be reduced" if commercial sterilization facilities were more highly controlled.[69]

Higher SCV and ARV Control Efficiencies

In consideration of the carcinogenic potency of EtO, and of the availability of improved control technology that can further reduce SCV and ARV emissions, EPA should propose revisions to the current NESHAP.

The current NESHAP requires that facilities using one ton or more of EtO in any consecutive 12-month period control emissions from the SCV by 99%.[70] However, as EPA recognizes in the ANPRM, "testing has revealed emission control performance that is significantly superior to the current standard."[71] For ARVs, the current NESHAP does not require any controls for facilities that use less than 10 tons of EtO in any consecutive 12-month period.[72] For facilities using more than 10 tons of EtO, the NESHAP requires facilities to control the ARV emissions to one ppm maximum outlet concentration or 99% emission reduction.[73] In Illinois and California, however, EtO sterilization facilities using one ton or more of EtO in any consecutive 12-month period must control emissions from the SCV by at least 99.9%, or to 0.2 ppm in Illinois.[74] For facilities using more than 10 tons of EtO, Illinois requires facilities to control ARV emissions by at least 99.9% or to 0.2 ppm.[75]

Consistent with Congress' mandate in Section 112(f)(2) to ensure an ample margin of safety, we recommend that EPA adopt a similarly restrictive approach for the rest of the country to control emissions of this known carcinogen and protect communities located near EtO sterilization facilities.

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[69] Overview of Current Information, *supra* note 49.
[70] 40 C.F.R. § 63.362(c).
[71] ANPRM at 67,897; *see supra* p. 11 (noting 99.9% efficiency at Centurion Medical Products in Michigan).
[72] 40 C.F.R. § 63.362(a).
[73] *Id.* § 63.362(d).
[74] 415 ILCS 5/9.16(b); Cal. Code Regs. tit. 17, § 93108.5.
[75] 415 ILCS 5/9.16(b).

Reinstate the Chamber Exhaust Vent Control Requirement

As noted above, EPA delayed and eventually removed the requirement that facilities control emissions from the CEV. Thus, to date, federal law does not require facilities to control these emissions. This is despite the fact that the MACT floor for CEVs at existing and new sources, for sources using 10 tons per year or more of EtO, is routing emissions from the CEV such that they are combined with a stream that is already being routed to a control device that achieves 99% emissions reduction.[76]

As noted by EPA in the ANPRM, facilities have begun to control EtO from the CEV, and multiple facilities currently control the CEV.[77] Not only are facilities controlling CEV emissions without safety concerns, stack testing shows that emissions from the CEV can be controlled beyond the 99% requirement contained in the original standards. Stack testing of the CEVs at Sterigenics Willowbrook in September 2018 demonstrated a control efficiency of greater than 99.61%.[78] Controlling the CEV at this efficiency led Sterigenics to claim a "90% decrease" in emissions from the facility.[79] Controlling CEV emissions nationwide would be one of the single most effective methods of reducing EtO emissions from commercial sterilization facilities. Thus, at minimum, EPA should require that CEV emissions be controlled, and we recommend that EPA adopt control efficiency standards above 99%.

Permanent Total Enclosure ("PTE") to Control Fugitive Emissions

According to the ANPRM, an analysis of Sterigenics Willowbrook indicated that the fugitive component of the emissions accounted for approximately 0.5% of the total EtO usage at that facility.[80] In 2018, that facility reported using 270,181 pounds of EtO. Thus, EPA now estimates that the facility released 1,350 pounds in fugitive emissions that year. This represents a 47% increase over what the facility reported that year, and is a potentially dangerous amount that can and should be controlled.

The Haller Act, and the permits issued to in-state facilities by Illinois, provides a model for how EPA should regulate fugitive emissions for this category of facilities. Pursuant to the terms of the Haller Act, all EtO commercial sterilization facilities in Illinois must "capture . . . 100% of all ethylene oxide emissions."[81] In response to this requirement, multiple facilities in

[76] D.Haerne and K. Schmidtke, MRI, to D. Markwordt, U.S. EPA. October 24, 1994. Revised Calculation of MACT Floors for Major Source Chamber Exhaust Vents at Ethylene Oxide Commercial Sterilization and Fumigation Operations; National Emissions Standards for Hazardous Air Pollutants (NESHAP) (Legacy Docket ID No. A-88-03, Docket Entry IV-B-02).
[77] ANPRM at 67,896.
[78] Report of Air Pollution Source Testing of an Ethylene Oxide Emission-Control System Operated by Sterigenics, U.S., LLC in Willowbrook, Illinois on September 21, 2018, *available at* https://www2.illinois.gov/epa/topics/community-relations/sites/sterigenics/Documents/WBI%20rev1.pdf.
[79] Sterigenics FAQ, *supra* note 46.
[80] ANPRM at 67,894.
[81] 40 C.F.R. § 63.362(c).

Illinois have received construction permits to install a permanent total enclosure system (PTE).[82] Under the terms of these permits, "[t]he Permittee shall operate the affected facility with permanent total enclosure (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. The PTE shall be designed and operated to comply with the criteria for PTE in Section 6 of Method 204 in 40 CFR Part 51 Appendix M . . . so that 100 percent of the emissions of ethylene oxide of the facility are captured and ducted to control device(s)."[83]

EPA should require PTE to control fugitive emissions to further reduce the risk of cancer to those living and working near EtO sterilization facilities.

Representative Testing Method

The testing method required under the current NESHAP, which allows facilities to test the first evacuation of an empty chamber,[84] 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 current NESHAP method does not reflect these actual operating conditions and overestimates the amount of EtO that the vacuum pump evacuates, artificially increasing the control efficiency.

All required emissions testing in the revised NESHAP should be conducted under operating conditions that are representative of maximum emissions. For the gas stream from the sterilization chambers, the duration of each test run should be sufficient to span the "middle portion" of the sterilization cycle for all chambers that are in operation during the period of testing. For this purpose, the middle portion of the sterilization cycle should begin with the initial evacuation of EtO-laden air from a chamber and end 60 minutes after the sterilized material from that chamber is transferred to an aeration room.

The 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 (SCV, CEV, and ARV).[85] This method of testing provides an accurate assessment of the effectiveness of the pollution control equipment in limiting EtO emissions to the surrounding communities. While we believe that EPA should adopt stricter standards for EtO emissions, at a minimum, demonstrating compliance should be based on actual operating conditions, rather than a non-representative scenario that fails to provide accurate information.

[82] Sterigenics Construction Permit, *supra* note 64, at 5; Medline Construction Permit, *supra* note 66, at 4.
[83] *Id.*
[84] 40 C.F.R. § 63.365(b)(1).
[85] 415 ILCS 5/9.16(b).

Continuous Emissions Monitoring

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,[86] and EPA should adopt a similar requirement.

Specifically, EPA should require that all commercial sterilization facilities install, operate, calibrate and maintain a continuous emissions monitoring system (CEMS) on the stack of the affected facility to measure the concentration of EtO in the exhaust stream in parts per billion (ppb). The required monitoring system should be designed and operated to meet the requirements in EPA's Performance Specification 15 (PS-15) for Extractive Fourier Transform Infrared Spectroscopy (FTIR).

Also, EPA should require that all commercial sterilization facilities install, operate, calibrate and maintain a continuous monitoring system (CMS) on the stack of the affected facility to measure the gas flow rate in the stack to track mass emissions of the affected facility in pounds per hour. This CMS should be located in the same area as the required CEMS and be designed and operated to meet the requirements in EPA's Performance Specification 6, "Specifications and Test Procedures for Continuous Emission Rate Monitoring Systems in Stationary Sources," 40 CFR Part 60, Appendix B, PS-6.

Dispersion Modeling

The Haller Act requires that commercial sterilization facilities in Illinois perform dispersion modeling that demonstrates the appropriate manner of retrofitting a facility to achieve emissions reductions necessary to protect human health.[87] EPA, too, should require that each commercial sterilization facility submit dispersion modeling that demonstrates that its EtO emissions after implementation of the above emission reduction measures, will approach as near as possible a lifetime cancer risk of one in 1,000,000 people.

[86] 415 ILCS 5/9.16(d).
[87] 415 ILCS 5/9.16(f).

III. CONCLUSION

The undersigned Attorneys General appreciate the opportunity to submit these comments and urge the Administrator to propose a rule that adequately addresses the severe risks to public health and the environment posed by EtO emissions from commercial sterilization facilities.

Respectfully submitted,

KWAME RAOUL
Attorney General of Illinois

/s/ Daniel I. Rottenberg
Matthew J. Dunn
Chief, Environmental Enforcement/
Asbestos Litigation Division
Elizabeth Wallace
Chief, Environmental Bureau
Daniel I. Rottenberg
Assistant Attorney General
69 W. Washington St., 18th Floor
Chicago, IL 60602
(312) 814-3816
drottenberg@atg.state.il.us

BRIAN E. FROSH
Attorney General of Maryland

/s/ Steven J. Goldstein
Steven J. Goldstein
Special Assistant Attorney General
Office of the Attorney General
200 Saint Paul Place, 20th Floor
Baltimore, MD 21202
(410) 576-6414
sgoldstein@oag.state.md.us

PETER F. NERONHA
Attorney General of Rhode Island

/s/ Gregory S. Schultz
Gregory S. Shultz
Special Assistant Attorney General
Environmental Unit, Civil Division
Office of the Attorney General
150 South Main Street
Providence, RI 02903
(401) 274-4400
gschultz@riag.ri.gov

MAURA HEALEY
Attorney General of Massachusetts

/s/ I. Andrew Goldberg
I. Andrew Goldberg
Assistant Attorney General
Environmental Protection Division
Office of the Attorney General
One Ashburton Place, 18th Floor
Boston, Massachusetts 02108
(617) 963-2429
andy.goldberg@mass.gov

TOM MILLER
Attorney General of Iowa

/s/ Jacob J. Larson
Jacob J. Larson
Assistant Attorney General
Environmental Law Division
Hoover State Office Building
1305 E. Walnut St., 2nd Floor
Des Moines, IA 50319
(515) 281-5341
jacob.larson@ag.iowa.gov

GURBIR S. GREWAL
Attorney General of New Jersey

/s/ Aaron A. Love
Aaron A. Love
Deputy Attorney General
New Jersey Division of Law
25 Market St., P.O. Box 093
Trenton, NJ 08625
(609) 376-2762
aaron.love@law.njoag.gov

LETITIA JAMES
Attorney General of New York

/s/ Sarah Kam
Sarah Kam
Special Assistant Attorney General
New York State Office of the Attorney General
Environmental Protection Bureau
28 Liberty Street, 19th Floor
New York, NY 10005
(212) 416-8465
sarah.kam@ag.ny.gov

KATHLEEN JENNINGS
Attorney General of Delaware

/s/ Christian Douglas Wright
Christian Douglas Wright
Director of Impact Litigation
Valerie S. Edge
Deputy Attorney General
Delaware Department of Justice
102 W. Water Street
Dover, DE 19904
(302) 257-3219
Christian.Wright@delaware.gov
Valerie.Edge@delaware.gov

KEITH ELLISON
Attorney General of Minnesota

/s/ Peter N. Surdo
Peter N. Surdo
Special Assistant Attorney General
445 Minnesota St., Ste. 1400
St. Paul, Minnesota 55101
(651) 757-1061
peter.surdo@ag.state.mn.us

THOMAS J. DONOVAN, JR.
Attorney General of Vermont

/s/ Nicholas F. Persampieri
Nicholas F. Persampieri
Assistant Attorney General
Office of the Attorney General
109 State Street
Montpelier, VT 05609
(802) 828-3171
nick.persampieri@vermont.gov

DANA NESSEL
Attorney General of Michigan

/s/ Elizabeth Morrisseau
Elizabeth Morrisseau
Assistant Attorney General
Environment, Natural Resources, and Agriculture Division
G. Mennen Williams Building
525 W. Ottawa Street, 6th Floor
P.O. Box 30755
Lansing, MI 48909
(517) 335-7664
morrisseaue@michigan.gov