Comments of the Attorneys General of Illinois, Arizona, California, Colorado, Delaware, the District of Columbia, Maryland, Massachusetts, Michigan, Minnesota, New Jersey, New Mexico, New York, Oregon, Vermont, and Virginia and the California Air Resources Board

on

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 Reconsideration,"
91 Fed. Reg. 12,700 (Mar. 17, 2026), Docket ID No. EPA-HQ-OAR-2019-0178

May 15, 2026

The Attorneys General of Illinois, Arizona, California, Colorado, Delaware, the District of Columbia, Maryland, Massachusetts, Michigan, Minnesota, New Jersey, New Mexico, New York, Oregon, Vermont, and Virginia and the California Air Resources Board ("States") respectfully submit these comments on the Environmental Protection Agency's ("EPA" or the "Agency") proposal entitled "National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review Reconsideration" ("Proposal").[1] The Proposal is the result of EPA's review of its Clean Air Act ("CAA" or the "Act") section 112 emission standards for hazardous air pollutants ("HAPs") promulgated through EPA's 2024 "residual risk and technology review ("2024 Rule").[2]

The States oppose the Proposal and urge EPA to retain the emission standards that exist in its 2024 Rule, which was based on updated scientific understanding of the serious health harm to our residents from ethylene oxide emissions. EPA's Proposal inverts the purpose of the Clean Air Act, claiming that the statute requires the Agency to ignore these scientific advances. The States request that EPA withdraw its Proposal.

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 HAPs 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 HAPs listed in section 112(b)(1) of the 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 HAPs at a rate of 25 tons or more per year (known as "major sources").[5] These technology-based national emission standards for major sources of HAPs ("NESHAPs") must reflect the maximum reductions of HAPs achievable and are commonly referred to as maximum achievable control technology ("MACT") standards.[6]

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[1] 91 Fed. Reg. 12,700 (Mar. 17, 2026).
[2] 89 Fed. Reg. 24,090 (Apr. 5, 2024).
[3] *See* 42 U.S.C. § 7412.
[4] *Id.* at §§ 7412(c), 7412(b)(1).
[5] *Id.* at § 7412(d).
[6] *Id.* at § 7412(d)(2).

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.[7] 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 best-performing sources in that category.[8] These minimum stringencies are known as the "MACT floor." If EPA determines that even greater levels of reduction are achievable, considering the relevant statutory factors, EPA must set even more stringent standards, sometimes referred to as "beyond the floor" standards. Whether the standards EPA sets are at the level of the "MACT floor" or "beyond the floor," such standards must be met by all major sources within the category or subcategory.

If a source emits HAPs but is not a "major source," it is an "area source."[9] EPA is also required to promulgate technology-based standards for area sources of HAPs. For area sources, section 112(d)(5) provides that, in lieu of MACT, EPA may elect to promulgate standards or requirements that provide for the use of generally available control technologies, or GACT standards.[10] 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 and revise them as necessary, "taking into account developments in practices, processes, and control technologies."[11]

In addition to the technology-based regime, section 112(f)(2) of the Act requires EPA to review any residual health risks that remain after implementing the initial technology-based standards (the Administrator shall promulgate standards for a source category if required "in order to provide an ample margin of safety to protect public health").[12] This second stage is described as "risk based" or "health-based" because it requires EPA to set a standard based on a

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[7] *Id.* at § 7412(d)(3).
[8] *Id.* at § 7412(d)(3)(A).
[9] *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 characteristics of the air pollutant, or other relevant factors."); *Id*. at § 7412(a)(2) (An "area source" is "any stationary source . . . that is not a major source").
[10] *Id*. at § 7412(d)(5).
[11] *Id.* at § 7412(d)(6).
[12] *Id*. at § 7412(f)(2).

scientific assessment of a given pollutant's health risks, rather than the current state of control technology. EPA must complete at least one risk review for sources subject to MACT standards and may use its discretion to perform additional risk reviews, as further described below.[13] EPA also has discretion to conduct risk reviews for area sources subject to GACT standards.[14] The Act also adopts a presumptive limit on lifetime excess cancer risks at 100 in 1,000,000, that is to say, risk above this level is legally defined as unacceptable.[15]

B. Health Hazards Related to EtO

Ethylene oxide ("EtO") is one of the most toxic hazardous air pollutants regulated under the Clean Air Act. It is one of only seven HAPs classified as a "Group A" known human carcinogen.[16] Short-term exposure to high levels of EtO has harmful effects on people that include memory loss, headache, dizziness, numbness, and other neurological impacts, respiratory irritation, and eye and skin irritation.[17] People who were exposed to lower levels of EtO over a multiple year period experienced cognitive and motor impairment, changes to the composition of their blood, and DNA damage.[18] Long-term cumulative exposure, even to smaller amounts of EtO, significantly increases the risk of developing lymphohematopoietic cancers and, for women, the risk of developing breast cancer.[19] Finally, children are particularly vulnerable to

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[13] *Id.*
[14] *Id.* at § 7412(f)(5).
[15] *Id.* at § 7412(f)(2)(B), *citing* 54 Fed. Reg. 38,044 (Sept. 14, 1989) ("a presumptive limit on maximum individual lifetime risk (MIR) of approximately 1 in 10 thousand," is the first step in determining acceptable risk of exposure to HAPs).
[16] EPA, *Risk Assessment for Carcinogenic Effects* (last updated Oct. 9, 2025), https://www.epa.gov/fera/risk-assessment-carcinogenic-effects (identifying "Group A" agents as those "with adequate human data to demonstrate the causal association of the agent with human cancer").
[17] Agency for Toxic Substances and Disease Registry ("ATSDR"), *Clinician Brief: Ethylene Oxide,* ATSDR Environmental Health and Medicine Education (Jan. 9, 2024), https://www.atsdr.cdc.gov/environmental-medicine/hcp/clinicianbriefeto/index.html.
[18] *Id.*
[19] *Id.*; Kyle Steenland et al., *Mortality Analyses in a Cohort of 18,235 Ethylene Oxide Exposed Workers: Follow Up Extended from 1987 to 1998*, 61 Occup. & Enviro. Med. 2, 6–7 (2004), *available at* https://pmc.ncbi.nlm.nih.gov/articles/PMC1757803/; Kaitlin Kelly-Reif et al., *Exposure to Ethylene Oxide and Relative Rates of Female Breast Cancer Mortality: 62 Years of Follow-Up in a Large US Occupational Cohort*, 133 Enviro. Health Perspectives 057013-1, 057013-6–7 (2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12097532/pdf/ehp15566.pdf; Kyle Steenland et al., *Ethylene Oxide and Breast Cancer Incidence in a Cohort Study of 7576 Women (United States)*, 14 Cancer Causes & Control, 531–39 (2003), https://link.springer.com/article/10.1023/A:1024891529592; *see also* Center for Disease Control and Prevention ("CDC"), *Worker Health Study Summaries, Sterilization of Medical Instruments and Treatment of Spices (Ethylene Oxide)* (Apr. 8 2020), *archived at* https://web.archive.org/web/20230607134136/https://www.cdc.gov/niosh/pgms/worknotify/ethyleneoxide.html#Updated%20EtO%20Mortality%20Study (archived on June 7, 2023).

ethylene oxide, which can cause DNA mutations.[20] In 2016, EPA found that EtO is 60 times more toxic than previously known, with children particularly susceptible.[21] Recognizing the importance of protecting the young, the longstanding Executive Order 13045, *Protection of Children from Environmental Health Risks and Safety Risks*, requires EPA to identify and "ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks."[22]

EtO's cancer-causing properties have been known or suspected for more than half a century, with recent studies confirming that it is powerfully carcinogenic. The U.S. Dept. of Health and Human Services' National Toxicology Program listed EtO in the Fourth Annual Report on Carcinogens in 1985 as reasonably anticipated to be a human carcinogen.[23] That same year, the EPA Office of Health and Environmental Assessment classified EtO as "probably carcinogenic to humans."[24] By 1987, California had listed EtO as a known carcinogen.[25] And in 1999, the National Toxicology Program's Ninth Report on Carcinogens ("Ninth Report") listed EtO as a known human carcinogen.[26]

Numerous studies conducted since the publication of the *Ninth Report* confirm its findings that EtO is a potent carcinogen. One of the chief studies of EtO's cancer risks to date involved more than 17,000 workers from 13 sterilizing facilities, including commercial sterilizers.[27] In 2004, researchers for the National Institute for Occupational Safety and Health ("NIOSH") found that the workers exposed to EtO suffered increased rates of breast cancer and lymphoid cancers. In 2025, a follow-up study on the more than 7,000 female workers included in

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[20] EPA, *Our Current Understanding of Ethylene Oxide (EtO)* (Mar. 17, 2025), *archived at* https://web.archive.org/web/20260217053202/https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/our-current-understanding-ethylene-oxide-eto (archived on Feb. 17, 2026); Darya Minovi, *Invisible Threat, Inequitable Impact: Communities Impacted by Cancer-Causing Ethylene Oxide Pollution*, Union of Concerned Scientists (Feb. 7, 2023), https://www.ucs.org/resources/invisible-threat-inequitable-impact.

[21] EPA, *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Final Report)* (Dec. 16, 2016), https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryId=329730 ("2016 IRIS Report").

[22] Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks, 62 Fed. Reg. 19,885 (Apr. 23, 1997), https://www.epa.gov/children/executive-order-13045-protection-children-environmental-health-risks-and-safety-risks.

[23] National Toxicology Program, U.S. Dept. of Health & Human Services, *Report on Carcinogens, Fifteenth Edition*, (Dec. 2021), ntp.niehs.nih.gov/sites/default/files/ntp/roc/content/profiles/ethyleneoxide.

[24] 50 Fed. Reg. 40,286 (Oct. 2, 1985).

[25] California Office of Environmental Health Hazard Assessment ("OEHHA"), *Ethylene Oxide* (2026), https://oehha.ca.gov/proposition-65/chemicals/ethylene-oxide.

[26] National Toxicology Program, *Report on Carcinogens, Ninth Edition* (1999) at 8, ntrl.ntis.gov/NTRL/dashboard/searchResults/titleDetail/PB2000107509.

[27] Steenland et al., *Mortality Analyses in a Cohort of 18,235*, *supra* note 19, at 6–7; *see also* CDC, *supra* note 19.

the original NIOSH study found that cumulative exposure to EtO was associated with elevated rates of breast cancer mortality, with the most exposed workers dying at three times the rate of their unexposed peers.[28]

The 2004 NIOSH 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."[29] In December 2016, EPA released its final IRIS evaluation of EtO's inhalation carcinogenicity, confirming that it is a known human carcinogen.[30] Thereafter, 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 evaluation 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. In other words, EPA concluded that the risk from adult exposure was 30 times greater than the Agency previously believed. When factoring in childhood exposure, the lifetime unit risk estimate increases 60-fold.

EPA relied on the 2016 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 identifies 58 census tracts in 18 different counties across 12 states with EtO air emissions at levels that pose cancer risks higher than EPA's "upper bound" of 100 in 1,000,000 cancer risk.[31] Over 288,000 people live in these high risk areas across the country.[32] 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 just over six years ago led the EPA to evaluate, in greater depth, the potential health risks associated with emissions of EtO."[33] More recent evidence has only increased and

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[28] Kelly-Reif et al., *supra* note 19, at 057013-6–7; Steenland et al., *Mortality Analyses in a Cohort of 18,235*, *supra* note 19, at 531–39.
[29] EPA, *Evaluation of the Carcinogenicity of Ethylene Oxide (2006 External Review Draft)* (Sept. 24, 2006), https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryId=157664.
[30] 2016 IRIS Report, *supra* note 21.
[31] Letter from Natural Resources Defense Council ("NRDC"), *et al*., Re: Public Hearing Request on HC1 and EtO Risk Factor, to EPA Acting Administrator Wheeler (Feb. 11, 2019), https://www.nrdc.org/sites/default/files/public_hearing_request_docket_id_no._epa-hq-oar-2018-0417.pdf.
[32] Dan West, *Action Needed to Protect Americans from Toxic EtO Pollution*, NRDC (Feb. 14, 2019), https://www.nrdc.org/bio/dan-west/action-needed-protect-americans-toxic-eto-pollution.
[33] 84 Fed. Reg at 67,893.

further substantiated concerns about the potential health impacts of EtO, potentially affecting even those who do not live near EtO sterilization facilities. An October 2025 study, analyzing nationwide data from 2018 to 2024, indicates that EtO emissions can be transported via air currents across state borders, meaning that downwind residents are vulnerable to EtO from poorly controlled upwind sources.[34] Further, primary industrial EtO emissions become relatively well-mixed in the troposphere, and thus, long-range transport of EtO is a major component of background concentrations nationwide.

C. Rulemaking History for EtO Emissions from Commercial Sterilizers under Section 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.[35] On July 16, 1992, EPA published a list of major and area sources of EtO for which it would promulgate a NESHAP.[36] EPA listed EtO commercial sterilization and fumigation operations as a category of major sources and area sources.[37] Commercial sterilizers use EtO to sterilize a range of products including medical equipment, spices, and cosmetics. EPA has identified 102 commercial sterilizers subject to this NESHAP located in 32 states across all regions of the continental United States and Puerto Rico.[38]

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.[39] On December 6, 1994, EPA promulgated final standards (the "1994 Rule").[40] In the 1994 Rule, EPA set technology standards for major sources under section 112(d)(2). As for area sources, EPA 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).

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[34] Ellis Robinson et al., *Analysis of Ambient Ethylene Oxide Mixing Ratios in the United States*, 2 ACS ES&T Air (11) 2467–2480 (2025), https://pubs.acs.org/doi/10.1021/acsestair.5c00186.
[35] 42 U.S.C. § 7412(b)(1).
[36] 57 Fed. Reg. 31,576 (July 16, 1992).
[37] *Id.* at 31,592.
[38] EPA, 2024 Facility List, EPA-HQ-OAR-2019-0178 (Mar. 17, 2026), https://www.regulations.gov/document/EPA-HQ-OAR-2019-0178-1610. EPA relied on this 2024 list in its 2026 proposal. 91 Fed. Reg. at 12,708.
[39] 59 Fed. Reg. 10,591 (Mar. 7, 1994).
[40] 59 Fed. Reg. 62,585 (Dec. 6, 1994).

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 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.

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%. Additionally, the 1994 Rule required initial performance testing to demonstrate that the source is meeting the emissions standards. However, the 1994 Rule did 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.

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.[41] EPA attributed the delay to explosions at facilities subject to the NESHAP.[42] 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

[41] 62 Fed. Reg. 64,736 (Dec. 9, 1997).
[42] *Id.* at 64,737.

went into effect; however, EPA further delayed the requirements for the Aeration Vents and Exhaust Vents.[43]

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.[44] 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.[45] Until the 2024 Rule, commercial sterilization facilities were 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).[46] No changes were made to the requirements as part of that action. EPA did not conduct any further risk or technology reviews until 2019, despite the statutory requirement to conduct a technology review every eight years.[47]

EPA took no further rulemaking action on EtO emission 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").[48] 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.[49] 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.[50]

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[43] 63 Fed. Reg. 66,990 (Dec. 4, 1998).
[44] 64 Fed. Reg. 67,789 (Dec. 3, 1999).
[45] 66 Fed. Reg. 55,577 (Nov. 2, 2001).
[46] 71 Fed. Reg. 17,712 (Apr. 7, 2006).
[47] *See* 88 Fed. Reg. at 22,794, *citing* 42 U.S.C. § 7412(d)(6).
[48] 84 Fed. Reg 67,889 (Dec. 12, 2019).
[49] *Id.* at 67,894.
[50] 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 (Oct. 10, 2019), https://ag.state.il.us/pressroom/2019_10/Letter_to_US_EPA_re_Ethylene_Oxide.pdf; 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), https://www.regulations.gov/comment/EPA-HQ-OAR-2019-0178-0115.

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.[51] EPA released a second notice of its information collection request in 2021.[52]

D. State Responses to the Dangers of EtO

Despite these clear dangers posed by EtO, federal regulations prior to 2024 had not been sufficient to protect human health. Recognizing the significant harms to their communities, states, including Illinois, Michigan, and California have stepped in to rein in EtO emissions from commercial sterilization facilities and safeguard against insufficiently protective federal regulation.

1. Illinois' Regulatory Response

In 2019, EPA investigated a commercial sterilizer operated by Sterigenics U.S., located in Willowbrook, Illinois. The investigation revealed that the facility posed a hazard to workers and nearby residents. Based on sampling data provided by EPA,[53] the Agency for Toxic Substances and Disease Registry ("ATSDR") concluded that the data, if representative, showed than "an elevated cancer risk exists for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility."[54]

The cancer risk for Willowbrook residents was 300 per one million according to the NATA.[55] 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.[56] Consistent with the 1994 Rule, the

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[51] 85 Fed. Reg. 35,931 (June 12, 2020).
[52] 86 Fed. Reg. 24,862 (May 10, 2021).
[53] ATSDR, *Letter Health Consultation: Evaluation of Potential Health Impacts from Ethylene Oxide Emissions, Sterigenics International, Inc., Willowbrook, Illinois, to EPA Air and Radiation Division* (July 26, 2018), https://www.atsdr.cdc.gov/HAC/pha/sterigenic/Sterigenics_International_Inc-508.pdf.
[54] *Id*.
[55] 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.
[56] Clean Air Act Permit Program ("CAAPP") 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.

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.[57]

After EPA conducted its sampling, the Willowbrook facility added emissions controls to the exhaust vent. In November 2018, EPA began to monitor 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]

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

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[57] *Id.* (35,400 pounds in 1998 and 4,200 pounds in 2016).
[58] EPA, *Full Data Table: Ethylene Oxide Concentrations in Outdoor Air- 24-hour averages* (March 2019), https://www.epa.gov/sites/default/files/2019-03/documents/copy_of_031519_willowbrook_eto_master_data_table_for_web.pdf; *see also* EPA, *Outdoor Air Monitoring Data in the Willowbrook Community* (Aug. 7, 2025), https://www.epa.gov/il/outdoor-air-monitoring-data-willowbrook-community.
[59] Michael Koerber, EPA, *Overview of Current Information* (May 29, 2019), https://www.epa.gov/sites/default/files/2019-05/documents/epaoverview-current-information.pdf; *see also* EPA, *Sterigenics Willowbrook Facility: Community Meeting Presentations* (Aug. 7, 2025), https://www.epa.gov/il/sterigenics-willowbrook-facility-community-meeting-presentations.
[60] Koerber, *supra* note 59.
[61] EPA Office of Air Quality Planning and Standards, Office of Air and Radiation, *Risk Assessment Report for the Sterigenics Facility in Willowbrook, Illinois* (August 2019), https://www.epa.gov/sites/default/files/2019-08/documents/risk_assessment_for_sterigenics_willowbrook_il.pdf; *see also* EPA, *Risk Assessment Report for the Sterigenics Facility in Willowbrook, IL* (July 28, 2025), https://www.epa.gov/il/risk-assessment-report-sterigenics-facility-willowbrook-il.
[62] EPA Office of Air Quality Planning and Standards, *supra* note 61.

The Matt Haller Act ("Haller Act") significantly strengthened the 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]

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 helps limit EtO emissions from commercial sterilizers in Illinois.

Medline Industries, owner of a different commercial sterilizer in Illinois using EtO located near residential areas, presented the same health concerns. Indeed, the NATA showed a risk of 123 per one million around the Medline facility based on annual emissions of 3,040 pounds—an amount that did not include thousands of pounds of EtO emitted uncontrolled through the exhaust vent. On February 14, 2019, in cooperation with regulatory authorities, 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 installed control technology to reduce allowable emissions from 10,780 pounds to 150 pounds annually—a 98.6% reduction in allowable emissions. Since installing new control technology, Medline's facility has continued to demonstrate reduced emissions: in 2025, Medline's facility emitted 116.1283 pounds of ethylene oxide, well below its annual limit of 150 pounds.[70]

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[63] Illinois Public Act 101-22, amended the Illinois Environmental Protection Act to add a new Section 9.16 addressing ethylene oxide emissions.
[64] 415 ILCS 5/9.16(b).
[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, epa.illinois.gov/content/dam/soi/en/web/epa/topics/community-relations/sites/ethyleneoxide/documents/medline-industries-19020013-final.pdf.
[70] Medline Industries Q4 2025 quarterly emissions data reporting to Illinois EPA (Jan. 15, 2026). *See also* Medline Industries, Quarterly emissions data reporting to Illinois EPA for Q2 2020 through Q4 2024, https://epa.illinois.gov/topics/community-relations/sites/ethylene-oxide.html.

2. Michigan's Regulatory Response

Prior to 2021, two commercial sterilization facilities in Michigan were subject to the existing NESHAP. Centurion Medical Products, operated by Medline Industries, Inc., (formerly known as Tri-State Hospital Supply Corporation) ("Centurion"), ceased sterilization operations in late October 2021 at a facility in Howell, Michigan that had been in operation for almost 30 years. That facility had three EtO sterilization chambers, an EtO aeration room, and an associated product transfer corridor. 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, Michigan's Department of Environment, Great Lakes, and Energy ("EGLE") determined additional work was needed to determine the potential impact of EtO emissions on nearby residents.

In March 2021, EtO sampling results identified elevated concentrations of EtO in the air around Centurion. These elevated concentrations along with a 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 $\mu g/m^3$as a long-term average.[71] 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 $\mu g/m^3$ is also far higher than the health-based screening levels of 0.0002 and 0.002 $\mu g/m^3$ 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 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.

3. California's Regulatory Response

According to the facility list accompanying the Proposal, 14 commercial sterilization facilities in California are subject to the 2024 Rule.[72] The State of California has long regulated EtO air emissions from commercial sterilizers. The California Air Resources Board ("CARB") identified EtO as a toxic air contaminant in 1987 and subsequently, in 1990, adopted an airborne toxic control measure to reduce EtO emissions from commercial and non-commercial sterilizers and aerators in California, which was revised in 1999.[73] CARB's EtO regulation requires 95-to-99.9 percent control efficiency technologies to cover all but one component within facilities more than 25 pounds but using less than 2,000 pounds of EtO annually, and requires facilities using over 2,000 pounds of EtO annually to meet similar control rates.[74] Facilities in California

[71] Michigan Dept. Enviro. Quality, *Viant Medical Inc. (N0795) - Modeling Summary* (Nov. 5, 2018), *archived at* https://web.archive.org/web/20191017092819/https://www.michigan.gov/documents/deq/deq-aqd-viant_modeling_summary_638133_7.pdf (archived on Oct. 17, 2019).
[72] 2024 facility list, *supra* note 38.
[73] Cal. Code Regs., tit. 17, §§ 93108, 93108.5 ("CARB's EtO regulation").
[74] *Id.*

using less than or equal to 25 pounds of EtO annually are exempt from CARB's control requirements.[75]

Local air quality management districts in California, including the South Coast Air Quality Management District ("SCAQMD"), also regulate EtO emissions from commercial sterilizers. SCAQMD originally adopted regulations titled Rule 1405 in 1990, which requires large facilities—those using more than 4,000 pounds of EtO annually—to use 99 to 99.9% control technologies.[76] SCAQMD also imposes 95 to 99.8% control requirements on smaller facilities that use less than 4,000 pounds and 400 pounds of EtO annually, respectively.[77] But following EPA's reconsideration of EtO's potential toxicity in 2022, SCAQMD conducted an extensive investigation, including evaluations and air sampling at local facilities that are permitted to use EtO, to ensure compliance at sterilization facilities in its jurisdiction.[78] SCAQMD found elevated ambient air monitoring results near three major sterilization facilities located in Carson, Vernon and Ontario and determined that these facilities needed stronger controls and more stringent regulation.[79]

Accordingly, in December 2023, SCAQMD amended Rule 1405 to further protect public health and the environment by requiring facilities to reduce 99% of emissions from stacks, further control fugitive emissions, establish continuous monitoring protocols, and adopt controls for warehouses storing EtO-treated items.[80] SCAQMD's regulation requires new and existing facilities to construct permanent total enclosures ("PTE") to prevent and contain fugitive emissions from whole facility sections, adopt leak detection and repair protocols, and implement mobile and fenceline monitoring followed by permanent continuous monitors placed in facility stacks to ensure controls are properly working.[81] Additionally, warehouses that receive sterilized

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[75] *Id.* at § 93108, subd. (f)(1).
[76] SCAQMD, Rule 1405: Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes, subd. (d) (Jan. 4, 1991), https://www.aqmd.gov/docs/default-source/rule-book/reg-xiv/rule-1405.pdf?sfvrsn=4.
[77] *Id.* at subds. (d)(1), (d)(2).
[78] SCAQMD compiled an extensive set of ambient air monitoring data from sterilization facilities and made that information publicly available at https://www.aqmd.gov/home/eto.
[79] For example, SCAQMD's ambient air monitoring near these three facilities yielded multiple 24-hour time integrated sample results above 80 parts per billion of EtO, which is high for facilities with annual EtO usage that is comparatively low on a national basis.
[80] SCAQMD, Preliminary Draft Staff Report: Proposed Amended Rule 1405—Control of Ethylene Oxide Emissions from Sterilization and Related Operations at 1-4 (March 2023), http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_pdsr_031723_draftfinal.pdf?sfvrsn=8.
[81] *Id.* at 2-9 to 2-17.

products are required to monitor emissions at the fenceline to identify the level of EtO off-gassing from the materials to determine whether and what controls are needed to reduce this potential release of emissions.[82] After all requirements are in place, if ambient monitoring shows EtO levels exceed 3 parts per billion, the facility must curtail operations and if a facility has repeated exceedances of the threshold, SCAQMD may temporarily shut down the facility.[83]

E. EPA's 2024 Regulations Strengthening the EtO Sterilizer NESHAP

On the federal level, in 2023, EPA also began a process to improve the federal regulations. On April 13, 2023, EPA published a proposed rule for the EtO NESHAP, proposing a risk and technology review and changes to the requirements for EtO emissions monitoring and reduction.[84] EPA based its authority to conduct an additional residual risk and technology review on Clean Air Act sections 112(d)(6) and 112(f)(2).[85] Pursuant to section 112(d)(6) of the Clean Air Act, EPA is required to conduct a technology review every eight years. The most recent technology review for the EtO NESHAP was conducted in 2006, more than a decade overdue upon publication of the 2023 proposed rule. EPA also conducted a residual risk review according to Clean Air Act section 112(f)(2). EPA noted that although section 112(f)(2) affirmatively requires a one-time residual risk review within eight years of the initial promulgation of NESHAP standards, it does not limit EPA's power to conduct discretionary additional reviews.

EPA exercised its discretion to conduct an additional residual risk review for two reasons. First, the Agency's understanding of the health risks of EtO had improved in the nearly two decades since the 2006 residual risk and technology review. Specifically, the most recent IRIS cancer unit risk estimate for EtO was 60 times higher than the risk estimate in 2006.[86] Second, area sources subject only to the GACT standards were not evaluated in the 2006 review. Therefore, EPA exercised its discretion to conduct another residual risk review in order both to take into account scientific developments and to evaluate GACT sources for the first time.

Following a robust comment period, EPA issued the final rule on April 5, 2024 (the "2024 Rule").[87] The 2024 Rule improves the health and safety of Americans by requiring continuous emissions monitoring for most commercial sterilization facilities and significantly reducing EtO

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[82] *Id*.
[83] SCAQMD Rule 1405, subd. (q).
[84] 88 Fed. Reg. 22,790 (Apr. 13, 2023).
[85] 89 Fed. Reg. 24,094 (Apr. 5, 2024).
[86] *Id.; see* 2016 IRIS Report, *supra* note 21.
[87] 89 Fed. Reg. at 24,090.

emissions at regulated facilities.[88] Notably, the 2024 Rule requires commercial sterilization facilities to reduce fugitive EtO emissions for the first time in the history of the EtO NESHAP.[89] The 2024 Rule also imposes stricter emissions standards for the largest facilities.[90] Further, the 2024 Rule creates emissions standards for EtO emitted from Aeration Vents and Exhaust Vents at all facilities.[91] Finally, the 2024 Rule sets EtO emission standards for facilities that emit less than 1 ton per year of EtO.[92] Prior to the 2024 Rule, those facilities were subject only to reporting and recordkeeping requirements.[93] The 2024 Rule also modifies the procedures for periods of startup, shutdown, and malfunction, including removing exemptions for those periods.[94] The 2024 Rule went into effect for all new facilities on April 5, 2024.[95] Existing facilities had until April 6, 2026, to comply with most provisions of the 2024 Rule, and have until April 5, 2027, to comply with the provisions of the 2024 Rule requiring more substantial changes.[96] EPA's 2024 Rule made essential updates to the preexisting regulations, taking into account new scientific evidence showing EtO emissions are far more harmful than previously recognized.

Environmental and industry groups both filed petitions for review of the 2024 Rule shortly after its issuance.[97] The environmental groups, headed by California Communities Against Toxics, challenged the 2024 Rule's compliance timelines and permitting exemptions.[98] The industry groups, headed by the Ethylene Oxide Sterilization Association, challenged EPA's decision to conduct another residual risk review and the compliance and monitoring standards required by the 2024 Rule.[99] EPA initially defended the 2024 Rule in briefing before the D.C. Circuit.[100] However, that litigation is currently in abeyance following EPA's announcement that it planned to reconsider the 2024 Rule.[101]

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[88] *Id.*
[89] *Id.* at 24,099.
[90] *Id.* at 24,093.
[91] *Id.* at 24,100.
[92] 89 Fed. Reg. at 24,092–93, 24,099.
[93] *Id.*
[94] *Id.* at 24,100–01.
[95] *Id.* at 24,101–02.
[96] *Id.*
[97] *California Communities Against Toxics v. EPA*, Docket No. 24-1178 (D.C. Cir. June 3, 2024).
[98] *Id.*
[99] *Id.*
[100] *See* Final Answering Br., *California Communities Against Toxics v. EPA*, No. 24-1178 (D.C. Cir. Feb. 24, 2025) (arguing "EPA's actions [in the 2024 Rule] are well within the authority granted by [CAA] Section 7412, whose goal is to reduce emissions of air toxics to, among other things, provide an ample margin of safety to protect public health").
[101] 91 Fed. Reg. 12,700 (Mar. 17, 2026).

On top of the litigation challenging the 2024 Rule, President Biden issued a proclamation allowing facilities to request Presidential exemptions to the 2024 Rule, in accordance with Clean Air Act section 112(i)(4).[102] To qualify for a limited exemption, a facility would have to demonstrate that despite "due diligence and best efforts" compliance was not possible "due to the unavailability of control technology[,]" leading to likely facility shutdown and "serious disruption to the supply of medical products."[103] The Biden Proclamation created an orderly process by which facilities could request a waiver, and was designed "[t]o achieve the EtO Rule's critical health protections as soon as practicable, while safeguarding the supply of safe medical products from disruption that would compromise the health and welfare of the American people."[104]

By contrast, the Trump Administration has actively solicited regulated facilities to request a Presidential exemption via an electronic mailbox.[105] The American Chemistry Council submitted a request for two-year exemptions for all its members, which include all 88 facilities regulated under the EtO NESHAP.[106] Just a few months later, the Trump Administration granted mass exemptions for 41 facilities from the requirements of the 2024 Rule in just five sparse pages and including no justification tailored to individual facilities.[107] In response, two coalitions of environmental and public health organizations sued the Trump Administration, arguing that the President exceeded his authority in granting the exemptions.[108] On March 17, 2026, the two cases were consolidated.[109] And, on March 23, 2026, the Ethylene Oxide Sterilization

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[102] Joseph R. Biden, Jr., *Memorandum on the Orderly Implementation of the Air Toxics Standards for Ethylene Oxide Commercial Sterilizers* (Jan. 16, 2025) ("Biden Proclamation").
[103] *Id*.
[104] *Id.*
[105] EPA, *Clean Air Act Section 112 Presidential Exemption Information* (Mar. 12, 2026), https://www.epa.gov/stationary-sources-air-pollution/clean-air-act-section-112-presidential-exemption-information.
[106] Letter from American Chemistry Council, Re: Powering the Great American Comeback Fact Sheet, Request for two-year compliance exemption pursuant to Clean Air Act Section 112(i)(4) for New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Synthetic Organic Chemical Manufacturing Industry (SOCMI) and Group I & II Polymers and Resins Industry, to U.S. EPA (Mar. 31, 2025), *available at* https://library.edf.org/AssetLink/imiyhj203d5nni5g1nkh7hmsmk5ymw44.pdf?gl=1*1rxgqvi*gclau*MTQ2OTk3MzkzNS4xNzM4MDE2MjM0*ga*MTcyODQ0MDU1Ni4xNzM4MDE2MjM0*ga2B3856Y9QW*MTc0NDIyNTE4My4xNS4xLjE3NDQyMjcxMDYuNDEuMC4w; *see also* Enviro. & Energy Law Program, Harvard Law School, *Ethylene Oxide (EtO) Emissions Standards for Commercial Sterilizers*, (Mar. 17, 2026), *available at* https://eelp.law.harvard.edu/tracker/ethylene-oxide-eto-emissions-standards-for-commercial-sterilizers/.
[107] 90 Fed. Reg. 34,747 (July 17, 2025).
[108] *Texas Env't Just. Advocacy Servs. v. Trump*, No. 25-03745 (D.D.C. Oct. 22, 2025); *CleanAIRE NC v. Trump*, No. 26-00233 (D.D.C. Jan. 28, 2026).
[109] *CleanAIRE NC v. Trump*, No. 26-00233 (D.D.C. Jan. 28, 2026).

Association filed a Motion to Intervene on behalf of the defendants.[110]

F. EPA's Current Proposal to Weaken the Commercial Sterilizer NESHAP

On March 17, 2026, EPA published the Proposal, which proposes to repeal the 2024 Rule.[111] Specifically, the Proposal seeks to rescind or revise amendments made to the Commercial Sterilization Facilities NESHAP in the 2024 Rule to implement what EPA now, and contrary to its prior positions, asserts is the best reading of the Clean Air Act.[112] EPA asserts that Clean Air Act section 112(f)(2) only authorizes a single residual risk review of the MACT standards within eight years of establishing the emission standard, but that EPA may review and revise the standards "as necessary" through a technology review at least every eight years under Clean Air Act section 112(d)(6).[113] EPA also proposes to find that "significant uncertainties regarding the magnitude of EtO's carcinogenic potency, particularly at low concentrations, would be an additional reason for rescinding the EtO standards[.]"[114]

In the Proposal, EPA seeks to rescind the tighter risk-based emissions standards imposed by the 2024 Rule on the basis that section 112(f)(2) did not allow EPA to perform a new residual risk review in 2024. Additionally, the Proposal revises the EtO emission standard promulgated under section 112(d)(6) of the Act for new facilities using at least 10 tons per year of EtO, amends the compliance demonstration requirements to allow facilities to choose between parametric monitoring or continuous emissions monitoring system ("CEMS"), and rescinds the requirement that PTE be used to ensure complete capture of EtO.[115]

II. Comments

EPA conducted the EtO residual risk review in 2006. Research into the health harms of EtO has since advanced, including that conducted by EPA. Yet the Proposal ignores these decades of progress and improved understanding, thereby undermining the scientific integrity of EPA's emissions standards process. As discussed above, the scientific evidence irrefutably demonstrates that EtO is more dangerous than the 2006 risk review indicated, with even small quantities presenting significant risks. The 2024 Rule, based on current science, understood these risks and adjusted the emission standard accordingly. The 2024 Rule found that its required

[110] *Id.*
[111] 91 Fed. Reg. 12,700 (March 17, 2026).
[112] *Id.*
[113] *Id.*
[114] *Id*.
[115] *Id.* at 12,709

emissions reductions would reduce the overall risk of cancer from covered emissions from 1 cancer case every 1.1 years to 1 cancer case every 5 to 10 years.[116]

Despite this evidence, based solely on a strained statutory interpretation, the current proposal would eliminate those health benefits without even acknowledging the significant risks of doing so. In fact, the proposal barely considers the risks to human health, contrary to the Act's directive to reduce HAP emissions to the "maximum degree" and up to complete elimination.[117] Instead of directly acknowledging the carcinogenic potency and other health harms from EtO, the Proposal instead obliquely refers to the "[n]on-monetized health *disbenefits* [that] are expected under this proposed reconsideration."[118] The Proposal then simply redirects the reader to the Regulatory Impact Analysis ("RIA") for further information. Mere recitation of the potential health "disbenefits" does not satisfy EPA's duty to protect human health,[119] which is the paramount purpose of section 112. The RIA does not provide further information assessing the Proposal's health harms. [120]

Simply put, EPA's Proposal will increase emissions of EtO, a HAP that recent studies have shown is among the most toxic pollutants regulated under the Clean Air Act, creating immense public health harms to the residents of our States, all without any meaningful discussion or analysis of those harms.

A. EPA's proposal erroneously concludes the Agency lacks authority to promulgate new or revised emission standards under section 112(f)(2)

In its 2024 rulemaking, EPA appropriately exercised authority under CAA section 112(f)(2) to reconsider and update its dangerously obsolete 2006 residual risk review, including by considering its 2016 IRIS assessment.[121] But EPA has now abruptly changed course and rejects its authority to update obsolete risk reviews, and it does so despite available new science that has dramatically improved the Agency's understanding of the serious risks posed by EtO emissions from commercial sterilizers. EPA's proposed misinterpretation is badly misplaced—it

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[116] 89 Fed. Reg. at 24,139.
[117] 42 U.S.C. § 7412(d)(2).
[118] 91 Fed. Reg. at 12,734 (emphasis added).
[119] *See* Michael B. Gerrard, *Bad Faith Disregard of Benefits and Science in Federal Environmental Deregulation*, N.Y.L.J. (Apr. 22, 2026), https://scholarship.law.columbia.edu/faculty_scholarship/4790/.
[120] EPA, Regulatory Impact Analysis for the Proposed National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emission Standards for Sterilization Facilities Residual Risk and Technology Review Reconsideration (Mar. 11, 2026), https://www.epa.gov/system/files/documents/2026-03/eto_commericial_sterilizers_proposal_ria_memo-2026-03.pdf ("RIA").
[121] *See* 89 Fed. Reg. at 24,091.

fails to comport with either the statute's text, structure, or purpose. Contrary to EPA's apparent policy preference, section 112(f)(2) does not condemn the public to perpetually inadequate health protection.

In proposing to conclude otherwise, EPA fails to apply a plausible, much less "best," reading of the Act.[122] EPA's interpretive Proposal conflicts with EPA's own prior positions, distorts clear indicia of Congress' intent, and contravenes basic precepts of administrative law.

Repealing the section 112(f)(2) standards established in 2024 would not only misapply the statute Congress enacted, but it would also result in seriously harmful consequences. It would subject communities near sterilization facilities to unacceptable levels of cancer risk and thereby likely result in avoidable cancer fatalities. EPA should fully retain the section 112(f)(2) standards promulgated in 2024.

1. The statutory language does not support EPA's interpretation

Section 112(f)(2) directs EPA, in relevant part, to conduct a residual risk review of potential public health harms remaining after implementation of section 112(d) technology standards. Section 112(f)(2) then directs EPA to establish risk-based standards where required to protect public health with an ample margin of safety, including directing that EPA "shall" promulgate section 112(f)(2) standards where technology standards "do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than one in a million."[123]

Section 112(f)(2) imposes a duty on EPA to complete a residual risk review and to promulgate appropriate standards within eight years of promulgation of technology standards. But the existence of this nondiscretionary initial obligation is accompanied by the implicit granting of authority to EPA to reconsider its section 112(f)(2) standards in appropriate circumstances.

Proposing to abruptly abandon its position in the 2024 Rule that the Agency holds such presumptive discretionary reconsideration authority, EPA now suggests that it cannot reconsider an initial decision under section 112(f)(2). EPA does so despite how dramatically available new science has improved the Agency's understanding of the serious risks currently posed by EtO

[122] *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 400 (2024).
[123] *See Nat. Res. Def. Council v. Regan*, 67 F. 4th 397 (D.C. Cir. 2023) ("the word 'shall' generally indicates a command that admits of no discretion on the part of the person instructed to carry out the directive") (cleaned up).

emissions from commercial sterilizers. But EPA's proposed reinterpretation is badly misplaced—it fails to comport with either the statute's text, structure or purpose. Contrary to EPA's apparent policy preference, section 112(f)(2) does not condemn the public to perpetually inadequate health protection.

Indeed, not only does EPA have discretionary authority under section 112(f)(2) to revise an obsolete risk review, but under these facts it would have been wholly arbitrary for EPA to have declined to do so. EPA in 2006 concluded—based on the limited available science at that time—that the cancer risk associated with remaining ethylene oxide emissions after implementation of technology standards would not impair public health. However, subsequent scientific developments proved EPA's initial risk assessment to be wrong. A rigorous peer-reviewed scientific risk assessment established that the risks associated with ethylene oxide exposure were approximately *60 times greater* than EPA originally understood, rendering EPA's 2006 risk review obsolete and dangerous in its continued application.[124]

Having become aware through completion of a robust peer-reviewed risk reassessment that actual cancer risks posed by ethylene oxide were some 60 times greater than originally believed, EPA quite properly elected to reconsider and update its section 112(f)(2) residual risk review to ensure public health protection. Had EPA declined, as it now proposes, to reconsider that outdated risk review where it had undervalued risk by such a large magnitude, it could not have rationally defended that choice.[125] Indeed, EPA projected in the 2024 Rule that, without the Rule's more stringent standards, approximately 19,000 people would be exposed to ethylene oxide from commercial sterilizers at levels corresponding with a lifetime cancer risk of greater than 100-in-1 million, EPA's presumptive upper bound threshold for acceptable cancer risk, and that when considering allowable emissions, this number increased to 260,000 people.[126]

In its Proposal, EPA agrees that section 112(f)(2) provides the Agency with authority to conduct an initial residual risk review, but EPA suggests that this authority is strictly cabined to

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[124] *See* 89 Fed. Reg. at 24,094.

[125] In this scenario, the public would have been able to enforce EPA's obligation to update its residual risk review. For example, the public could have filed a petition for rulemaking and challenged as arbitrary any denial of that petition. *See* 5 U.S.C. § 553(e) (agencies must provide right to petition for amendment or a rule); *Citizens for Pennsylvania's Future v. Wheeler*, 469 F. Supp. 3d 920, 931 n.2 (N.D. Cal. 2020) (persons may petition for revision of section 112(f)(2) standards and contest EPA's action on such petition).

[126] 89 Fed. Reg. at 24,095. *Cf.* 42 U.S.C. § 7412(f)(2) (directing that EPA "shall" promulgate section 112(f)(2) standards where technology standards "do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than one in a million").

one initial action. Accordingly, EPA asserts that it has no ability to update and correct a defective initial residual risk review, no matter how flawed the review may be and no matter how many people will die of cancer as a result. But this sort of "our hands are tied to prevent deaths" construction of section 112(f)(2) is not the best reading of the statute; indeed, it does not land anywhere close to faithfully implementing Congress' intent. The Agency should therefore return to its previous correct and longstanding interpretation and retain the 112(f)(2) standards that were promulgated in 2024.

The best reading of the statute is not difficult to divine. To reiterate, the starting point is the foundational administrative law principle that when a statute authorizes an agency to decide a matter, that authority is implicitly "accompanied by the power to reconsider" that decision.[127] As EPA itself recently put it, the "revision and reconsideration of rules, after notice and comment, is part of the basic architecture of administrative law."[128] That principle is reflected in the Clean Air Act's provisions for reconsideration of promulgated rules in light of new information.[129]

EPA claims that a limitation on its authority may be "inferred" from the structure of Section 112 and surrounding statutory language.[130] However, EPA's effort to draw such an inference is deeply flawed. To the extent that indicia of Congress' intent can be drawn from the structure of Section 112 and surrounding statutory language, those indicia all point in the other direction and *support* EPA's authority to revise a prior Section 112(f)(2) review.

2. EPA's interpretation distorts Congressional intent

Fundamentally, EPA's contextual analysis goes far astray because EPA fails to give any apparent weight to the most important contextual factor: the statutory objectives identified by Congress. Fulfillment of statutory objectives are always a good starting point for any sound "contextual" analysis; yet, any effort to secure the fulfillment of Congress' stated objectives is wholly missing from EPA's interpretive analysis.

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[127] *Nat. Res. Def. Council v. Regan*, 67 F.4th at 401; *accord Ivy Sports Med. v. Burwell*, 767 F.3d 81, 86 (D.C. Cir. 2014).
[128] *See* EPA Final Brief at 30, *California Communities Against Toxics v. EPA* (D.C. Cir. 24-1178), filed Feb. 24, 2025. Ironically, EPA itself is simultaneously invoking and relying upon this very principle in this rulemaking for purposes of locating some authority to propose withdrawing the 2024 standards. *See* 91 Fed. Reg. at 12,705.
[129] *See* 42 U.S.C. § 7406(d)(7)(B); *Clean Air Council v. Pruitt*, 862 F.3d 1, 14 (D.C. Cir. 2017) (affirming "EPA's authority to reconsider the final rule" and noting reconsideration is available where "the new policy is permissible under the statute …, there are good reasons for it, and … the agency *believes* it to be better.." *citing FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)).
[130] 91 Fed. Reg. at 12,712–13.

To state the obvious, the principal objective of the Clean Air Act is not to consign the public to unacceptable levels of exposure to toxic air pollution; it is rather to "promote the public health and welfare[.]"[131] And the specific objective of section 112(f)(2), in particular, is to ensure hazardous air pollutant emission standards "provide an ample margin of safety to protect public health."[132] Focusing on these fundamental purposes, there is no reason to believe that Congress—when it substantially amended Section 112 to *strengthen* the Act's regulation of air toxics—intended to create a system that would potentially condemn the public to excessive health risks, in perpetuity.

Under the carefully drawn scheme created by the 1990 amendments, technology-based standards are the starting point, but residual risk-based standards play a critically important role as well should technology-based standards prove inadequate to protect public health. Thus, the core residual risk directive in Section 112(f)(2) is a requirement that EPA "tighten emission standards if it determines that certain emissions pose an unacceptable risk to public health."[133] That core directive in Section 112(f) fully applied to the situation here and warranted EPA's invocation of discretionary reconsideration authority.

3. EPA's rationale for cabining its risk review authority is unavailing

Nor does the statute contain ambiguity as to whether EPA may exercise section 112(f)(2) reconsideration authority following an initial defective residual risk review. The statute provides, in no uncertain terms, that EPA may amend its section 112(f)(2) standards. Specifically, in the Act's administrative proceedings and judicial review provision, 42 U.S.C. § 7607(d)(1)(C), Congress specifies that the "revision of" section 112(f) standards will be subject to the special rulemaking procedures in section 307(d). If Congress had intended to preclude reconsideration of section 112(f) standards, then it surely would not have specified the rulemaking procedures that should be applied to such a proceeding. In short, this situation is not even one where EPA's revision authority can be described as only implicit; it is actually quite explicit.

EPA tries to construe that reference as being intended to apply only to revisions made "as the result of an adverse judicial decision" or mandatory "administrative reconsideration under CAA section 307(d)(7)(B)."[134] But EPA is trying to conjure a limitation in the section 112(f)

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[131] 42 U.S.C. § 7401.
[132] *Id.* at § 7412(f)(2).
[133] *Huntsman Petrochemical LLC v. EPA*, 114 F.4th 1127 (D.C. Cir. 2024).
[134] 91 Fed. Reg. at 12,713.

reference that Congress did not include. Moreover, in the hypothetical scenario where a court voided promulgated section 112(f)(2) standards, that would then mean there would be no standards in place that could be "revised." Further, to the extent it is conceivable that EPA could revise standards after a mandatory section 307(d)(7)(B) reconsideration proceeding, that possibility just reinforces that Congress was fully comfortable with reconsideration. There is no reason to believe that Congress would have *required* reconsideration based on new information brought to EPA's attention within the judicial review period, while intending to disable any reconsideration based on similar information brought to EPA's attention subsequently.

Indeed, the one judicial precedent that has examined the precise interpretive question presented has confirmed this understanding of EPA's reconsideration authority and of the meaning of the reference to the revision of section 112(f) standards in section 307(d)(1)(C).[135] There, the court observed that while EPA did not have a *nondiscretionary* duty to conduct a second residual risk review after modifying technology standards, EPA still undoubtedly retained the *discretion* to do so. As the court explained:

> [T]he Clean Air Act expressly contemplates that EPA might revise its risk-based standards. *See 42 U.S.C.* § 7607(d)(1) (C) (referring to "the promulgation or revision of ... any standard under section 7412(f)"). But Congress—wisely or foolishly, by compromise or by oversight—did not establish a clear-cut duty to review risk-based standards for potential revision when technology-based standards are revised . . . . That said, the plaintiffs are not left entirely without recourse. Out-of-date risk-based standards can be challenged by a petition for rulemaking under the Clean Air Act, and EPA's action on any such petition would be subject to judicial review. 42 U.S.C. § 7607(b)(1); *cf. Massachusetts v. EPA*, 549 U.S. 497, 533 (2007).[136]

EPA's assorted justifications for abandoning its longstanding prior understanding of its reconsideration authority are all wholly misplaced. EPA observes that it has a one-time nondiscretionary duty to conduct a risk review within eight years of promulgating technology

[135] *See Citizens for Pennsylvania's Future v. Wheeler*, 469 F. Supp. 3d 920 (N.D. Cal. 2020). The proposed rule fails to cite to the decision in *Citizens*, so it appears the Agency did not consider it.
[136] *Id*. at 931 & n.2 (emphasis in original).

standards. But, as discussed above, the fact that EPA has a *nondiscretionary* duty to complete a risk review within eight years says nothing about whether EPA retains customary implicit *discretionary* authority to reconsider that initial required risk review in appropriate circumstances.

EPA places significant weight on the fact that section 112(d)(6) requires periodic eight-year nondiscretionary technology standard reviews, without imposing the same nondiscretionary duty to repeatedly review residual risk. Again, however, the fact that Congress placed a recurring nondiscretionary duty on EPA to conduct periodic technology reviews, without imposing the same duty within section 112(f)(2), says nothing about whether or when EPA should exercise *discretionary* reconsideration authority to review residual risk. Further, there are reasons why Congress would have elected solely to impose a recurring nondiscretionary duty on EPA to conclude technology reviews (e.g., because technologies generally change and evolve quite rapidly), without signifying any intent by Congress to disable EPA from being able to reconsider an obsolete residual risk review.

EPA additionally points to the eight-year time frame for conducting the required nondiscretionary residual risk review and suggests that the imposition of this time frame implicitly precludes any reconsideration after eight years. The imposition of an eight-year deadline reflects that Congress did not intend for EPA to unreasonably delay completing a residual risk review, but it does not convey that Congress intended to disable EPA from being able to respond to subsequent scientific developments bearing on risk. Nor would applying presumptive implicit reconsideration authority "effectively gut Congress's carefully articulated existing system."[137] To the contrary, the application of such authority very clearly *enhances* fulfillment of Congress' stated objectives. Again, the core objective set forth in section 112(f)(2) is for EPA to secure protection of public health with an ample margin of safety, not to preclude EPA from conducting more than one risk review at all costs. Put simply, there is no basis for believing that Congress wanted to assure public health protection, but only for eight years.[138]

EPA contends that enabling additional risk reviews under section 112(f)(2) could disrupt the statutory scheme "by eliminating the finality of residual risk reviews, undermining certainty

[137] 91 Fed. Reg. at 12,713.

[138] Further, to the extent EPA is suggesting that it can never promulgate standards after the expiration of the eight-year period for conducting an initial review, that is belied by EPA's past practice, where EPA has often gone far past the eight-year deadline before promulgating section 112(f) standards.

for regulated industry and the public."[139] But the statute is not designed to provide regulated industry with "certainty" that emission standards will forever remain the same. As EPA itself emphasizes, it has a nondiscretionary section 112(d)(6) obligation to review and revise technology standards as necessary every eight years—thus, the statute envisions frequent revision of standards, and there is no certainty or long-term stability associated with existing standards that could be undermined through the exercise of discretionary reconsideration authority. Moreover, in this case, EPA efficiently completed its residual risk review at the same time it completed a required section 112(d)(6) technology review, so EPA's reconsideration proceeding did not even entail an additional rulemaking beyond what would have otherwise occurred.[140]

EPA further claims that a second risk review is problematic because section 112(f)(2) purportedly fails to provide any applicable "standard" for such a review.[141] But there clearly is a standard to be applied: namely, the same standard that is applied when EPA conducts its initial residual risk review. The standard for protecting public health does not change just because EPA is engaged in a reconsideration proceeding.

EPA further suggests that a second risk review is inconsistent with the requirement in section 112(f)(1) that the Agency prepare a report to Congress on residual risk by November 15, 1996, while placing an obligation on EPA to promulgate standards under section 112(f)(2) where Congress does not act on recommendations for further legislation.[142] But Congress has not acted on recommendations for further legislation or stripped EPA of its authority to promulgate standards under section 112(f)(2). Thus, the report requirement in section 112(f)(1) has no remaining application or relevance.

Finally, because EPA's proposed interpretation is novel and runs counter to its longstanding prior contrary interpretation, it is entitled to particularly minimal "respect."[143] And to be clear, EPA's 2024 rulemaking was not, in fact, "the first time" EPA "implemented" its former longstanding interpretation that CAA section 112(f)(2) allows the Agency to reconsider a

[139] 91 Fed. Reg. at 12,713.
[140] EPA's professed interest in regulatory stability also rings hollow where EPA is within this very Proposal unnecessarily reopening standards it promulgated just two years ago.
[141] 91 Fed. Reg. at 12,713.
[142] *Id*.
[143] *Loper Bright*, 603 U.S. at 386.

previous risk review.[144] That interpretation had been articulated and applied previously. For example, as EPA stated in its 2006 action establishing ethylene oxide emission standards:

> We disagree with the commenter's assertion that there is no mechanism to revisit risks from the source category, and that, therefore, the risk assessment must include consideration of foreseeable changes that may occur in the future. We have the authority to revisit (and revise, if necessary) any rulemaking if there is sufficient evidence that changes within the affected industry or significant improvements to science suggest the public is exposed to significant increases in risk as compared to the risk assessment prepared for the rulemaking (*e.g.*, CAA section 301).[145]

4. EPA's Proposal to withdraw both the 2024 risk-based standards and the new area source standards is arbitrary and capricious

A second, and entirely independent fatal flaw undermining the Proposal is EPA's arbitrary and capricious proposed revocation of the risk-based standards established in 2024 based on its consideration, in that rulemaking, of an updated assessment of residual risk. Under EPA's new interpretation, residual risk may be considered during a technology standard review evaluating whether it is "necessary" to revise those standards, but only residual risk assessed in the Agency's initial review conducted eight years after standards are promulgated.[146]

At the outset, EPA is wrong that residual risk may be considered in setting technology-based standards under section 112(d)(6). Risk-based concerns are appropriate to consider when setting risk-based standards under section 112(f)(2); they cannot be considered during section 112(d)(6) technology reviews.[147] Applying EPA's new interpretation would inappropriately

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[144] 91 Fed. Reg. at 12,712.

[145] 71 Fed. Reg. 17,712, 17,715 (Apr. 7, 2006). *See also* National Emission Standards for Gasoline Distribution Facilities, 71 Fed. Reg. 17,352, 17,354 (Apr. 6, 2006) (similarly asserting authority to revise 112(f) standards if improvements to science suggest the public is exposed to increased risk as compared to the risk assessment prepared for rulemaking); National Air Emission Standard for Hazardous Air Pollutants: Halogenated Solvent Cleaning, 72 Fed. Reg. 25,138, 25,147 (May 3, 2007) (same).

[146] *See* National Emission Standards for Hazardous Air Pollutants: Coal-and Oil-Fired Electric Units Final Repeal, 91 Fed. Reg. 9088, 9092 (Feb. 24, 2026) (the results of a prior residual risk review under CAA section 112(f)(2) can be relevant under certain circumstances when evaluating whether it is "necessary" to revise standards under CAA section 112(d)(6).

[147] *See* Comments of the Attorney General of Illinois et al. on proposed repeal of amendments to hazardous air pollutant emission standards for coal- and oil-fired electric generating units, Docket No. EPA-HQ-OAR-2018-0794, at 42–43.

conflate these two processes, which case law makes clear are two "distinct, parallel analyses" that are undertaken "[s]eparately."[148]

Additionally, however, if EPA follows its own interpretation to its logical conclusion, then EPA would be required to consistently account for unacceptable risk levels when setting all section 112(d)(6) standards. If that is the case here, then EPA must *retain* the 2024 risk-based standards as necessary to protect public health. Thus, at a minimum, EPA's failure to consider and evaluate the possibility of retaining its existing standards—applying the authority it purports to have under section 112(d)(6)—constitutes the failure to examine an important aspect of the problem.[149]

Again, putting aside EPA's erroneous interpretation, EPA is proposing to withdraw risk-based standards for certain area sources based on its 2006 risk review, even though that risk review omitted those area sources. As EPA explained in its 2024 rule, EPA's updated residual risk review encompassed those area sources whose risk EPA did *not* evaluate in its 2006 rulemaking.[150] By withdrawing the 2024 standards, EPA is returning to standards that fail to account for all current area sources. The 2024 standards for these are sources should be retained under EPA's statutory obligation to conduct at least one residual risk review under section 112(f)(2).

B. EPA's evaluation of the risk to health from EtO is arbitrary and capricious

1. EPA's rejection of the 2016 cancer-risk assessment for EtO as a basis for rescinding the 2024 Rule is arbitrary and capricious

In the Proposal, EPA now cites "significant uncertainties regarding the magnitude of EtO's carcinogenic potency, particularly at low concentrations," as an additional reason for rescinding the 2024 Rule.[151] Specifically, EPA calls into question the 2016 EtO cancer-risk assessment or "IRIS value"[152] used by EPA in the 2024 Rule and now asserts that "it would not be appropriate to rely on the 2016 EtO IRIS value in setting standards."[153] EPA's rejection of the

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[148] *Nat'l Ass'n for Surface Finishing v. EPA*, 795 F.3d 1, 5 (D.C. Cir. 2015).
[149] *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co*, 463 U.S. 29, 43 (1983) (agency action is arbitrary and capricious when the agency "entirely failed to consider an important aspect of the problem").
[150] 89 Fed. Reg. 24,094. In 2006, EPA undertook a CAA section 112(f)(2) residual risk analysis only for area source emissions standards that were issued as maximum achievable control technology (MACT) standards and did not do a section 112(f)(2) analysis for those emission points for which generally available control technology standards were established. 88 Fed. Reg. at 22,794.
[151] 91 Fed. Reg. at 12,714.
[152] 2016 IRIS Report, *supra* note 21.
[153] *Id*. at 12,714.

2016 EtO IRIS value in the Proposed Rule therefore represents a reversal of EPA's "former views as to the proper course."[154] Accordingly, EPA must show that there are "good reasons" for the reversal and demonstrate that its new position is "permissible under the statute."[155] When "new policy rests upon factual findings that contradict those which underlay its prior policy," an agency must "provide a more detailed justification than what would suffice for a new policy created on a blank slate."[156]

EPA has not met any of these requirements. As stated, EPA cannot show that the Proposal is permissible under the Clean Air Act. Further, EPA has not provided "good reasons" to abandon the 2016 EtO IRIS value. EPA and the broader scientific community have long affirmed the 2016 EtO IRIS value as the gold standard of toxicity reviews, developed through an extensive public peer-reviewed process based on the best available science on the risk presented by EtO. Contrary to EPA's assertions now, the model selection in the 2016 EtO IRIS value was scientifically supportable, and EPA cannot point to any basis now for choosing an alternative to modeling that has undergone as rigorous a peer review process as the 2016 EtO IRIS Value.

EPA must provide a reasoned explanation for its decision to abandon scientifically sound data and reintroduce data that it previously rejected. EPA fails to do so here.

2. EPA cannot merely reject the 2016 EtO IRIS value based on uncertainty; it must assess risk based on the best scientific evidence

EPA's primary assertion—that scientific uncertainties exist that undermine the 2016 EtO IRIS value so the 2024 Rule must be rescinded—is unsupportable. Courts have consistently held that agency analyses that ignore or fail to adequately account for important considerations are improper.[157] As the Supreme Court has held, "reasonable regulation ordinarily requires paying attention to the advantages and the disadvantages of agency decisions."[158] The mere fact that

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[154] *See Pub. Citizen v. Steed*, 733 F.2d 93, 98 (D.C. Cir. 1984).
[155] *Fox*, 556 U.S at 515; *see also Lone Mountain Processing, Inc. v. Secretary of Interior*, 709 F.3d 1161, 1164 (D.C. Cir. 2013) ("[A]n agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored. Failing to supply such analysis renders the agency's action arbitrary and capricious.").
[156] *Fox*, 556 U.S at 515.
[157] *Bus. Roundtable v. SEC*, 647 F.3d 1144, 1148–49 (D.C. Cir. 2011); *Pub. Citizen, Inc. v. Mineta*, 340 F.3d 39, 58 (2d Cir. 2003); *Sierra Club v. Sigler*, 695 F.2d 957, 979 (5th Cir. 1983); *Getty v. Fed. Savs. & Loan Ins. Corp*., 805 F.2d 1050, 1055, 1057 (D.C. Cir. 1986); *Sierra Club v. U.S. Dep't of Interior*, 899 F.3d 260, 293 (4th Cir. 2018).
[158] *Michigan v. EPA*, 576 U.S. 743, 753 (2015).

uncertainties exist does not exempt an agency from the obligations to consider relevant factors and reach reasonable conclusions.[159]

Further, Section 112 requires EPA to address and regulate all emitted HAPs. It is unlawful under Section 112(f)(2) for EPA not to assess risk at all from any HAP, thereby ignoring risks EPA knows exist and which led Congress to list that pollutant under Section 112(b)(1). Just as *National Lime Association* requires EPA to set emission limits for all HAPs, EPA must assess the health risk for all listed HAPs.[160] EPA may not, as it proposes to do here, simply ignore health risks associated with a highly dangerous pollutant because purported "uncertainties" exist. To the extent EPA believes there is no reference dose currently available here, EPA must, at minimum, add an uncertainty factor to account for the additional risk that a HAP likely causes, until such time as EPA does have a reference value to use. Using a protective uncertainty factor—developed based on the best available science—would allow EPA to satisfy its legal duty under Section 112(f)(2) to prevent unacceptable health risk and ensure an "ample margin of safety to protect public health."[161] As such, the Proposal's lack of even a "minimal level of analysis" supporting its decision to abandon the 2016 IRIS value due to "uncertainties" renders the action arbitrary and capricious.[162]

3. EPA's 2016 EtO IRIS value remains the best understanding of EtO carcinogenic potency

The record clearly demonstrates that the 2016 EtO IRIS value is the best understanding of the effect of EtO on the human body and "that 'strong evidence' supported the conclusion that inhalation of ethylene oxide increases the risk of certain kinds of cancer."[163] As the Court noted in *Huntsman*, "EPA generated that cancer-risk assessment in an extensive, eighteen-year process that began in 1998, involved rounds of public comment and peer review by EPA's Science Advisory Board, and concluded in 2016 when EPA issued a comprehensive report on the subject."[164]

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[159] *Pub. Citizen v. Fed. Motor Carrier Safety Admin*., 374 F.3d 1209, 1219 (D.C. Cir. 2004); *see also Lead Indus. Ass'n, Inc. v. EPA,* 647 F.2d 1130, 1153, 1154 (D.C. Cir. 1980) (recognizing Clean Air Act's "precautionary nature" requires the EPA to "err on the side of caution").
[160] *National Lime Ass'n v. EPA*, 233 F.3d 625 (D.C. Cir. 2000).
[161] 42 U.S.C. § 7412(f)(2).
[162] *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016).
[163] *Huntsman*, 114 F.4th at 733.
[164] *Id*.

To create the 2016 EtO IRIS value, EPA used high-quality data from a large-scale NIOSH study to develop a dose-response model to calculate cancer risk.[165] The NIOSH study was considered "high-quality" because it was by far the largest of the available human studies, examining over 17,000 workers at 13 sterilization facilities.[166] Further, about 55% of the workers in the study were women, a group often underrepresented in industrial studies.[167] The NIOSH study followed its participants for over 25 years (a period long enough to detect cancer), and the participants were exposed only to EtO, not other occupational carcinogens.[168] Finally, the study used internal comparisons which takes into account the healthy-worker effect, a phenomenon often observed in occupational epidemiology in which a population of workers is healthier than the general public.[169] The NIOSH study found that sterilizer workers exposed to EtO faced higher risks of lymphoid and breast cancer.[170]

EPA then used this high-quality epidemiological data in the analyses to estimate cancer risk and develop the 2016 EtO IRIS value. EPA reasonably organized voluminous data to characterize the relationship between exposure and risk. "EPA focused on the risk faced by members of the public from low environmental exposures because of [Section 112's] focus on 'public,' rather than occupational, health."[171] Accordingly, EPA chose a dose-response model with two distinct slopes that capture the two distinct dose-response relationships, fitting the data well overall, including at low exposures. As shown in Figure 1, the linear two-piece linear spline model used by EPA in the developing the 2016 IRIS EtO value better fits the data compared to the model being advanced by industry stakeholders at the time and subsequently used by the TCEQ 2020 assessment.

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[165] Steenland (2003), *supra* note 19, Steenland (2004), *supra* note 19.
[166] *Id.* at *17.
[167] *Id.*
[168] *Id.*
[169] *Id.*
[170] *Huntsman*, 2024 WL 181598, at *5 (EPA *Huntsman* Brief)
[171] *Huntsman*, 114 F.4th at 734.

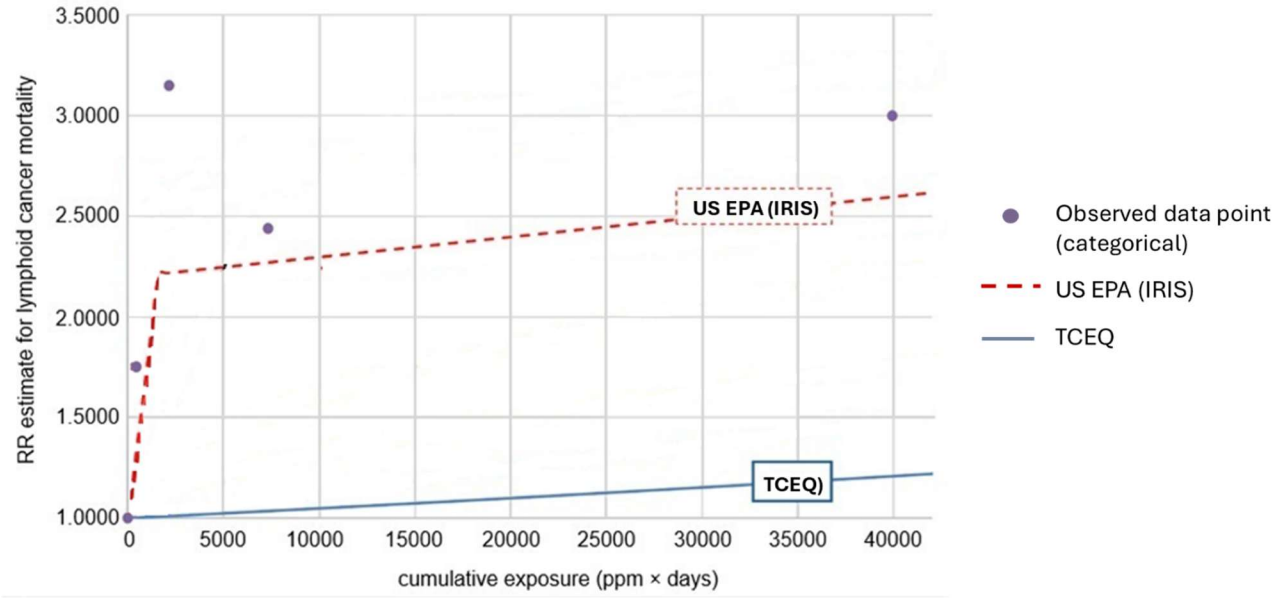

Figure 1. Two exposure-response models for lymphoid cancer mortality versus occupational cumulative exposure in the NIOSH cohort, in males and females combined, 15-year exposure lag. Observed data points are shown as categorical, plotted at the mean cumulative EtO exposure for the group of study participants.(taken from USEPA 2016 with modifications to remove additional models).

And finally, EPA used its chosen model to perform additional statistical analyses to estimate the cancer risk from EtO exposure at low environmental exposure levels.[172]

EPA submitted drafts of the 2016 IRIS value twice for external peer review by EPA's Science Advisory Board, which provided an additional round of external review than is typically received by IRIS assessments.[173] EPA's IRIS assessment methods and conclusions directly relied on detailed recommendations presented by EPA's Science Advisory Board.[174] EPA invited and responded to public comments repeatedly and extensively on its use of the 2016 EtO IRIS value in the MOCM Rule, EPA's 2022 reconsideration of the MOCM Rule, [175] and the 2024 Rule. During EPA's 2022 MOCM Reconsideration, EPA specifically solicited public comment on the use of the TCEQ 2020 assessment as an alternative to the 2016 EtO IRIS value.[176] EPA

[172] *Huntsman,* 114 F.4th at 733–34 (citation modified).
[173] EPA's Science Advisory Board was established by Congress in 1978, pursuant to the Environmental Research, Development, and Demonstration Authorization Act to provide scientific advice to the EPA Administrator. 42 U.S.C. § 4365.
[174] 2016 IRIS assessment at 2-2, https://iris.epa.gov/static/pdfs/1025tr.pdf.
[175] Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review, 87 Fed. Reg. 77,985 (Dec. 21, 2022) ("2022 MOCM Reconsideration").
[176] *Id*.

subsequently affirmed its decision to use the 2016 EtO IRIS value for the MOCM Rule and explained its rejection of TCEQ's 2020 assessment, concluding that "EPA is not aware of new epidemiological, toxicological, or basic scientific studies that suggest the [2016 EtO IRIS] value is no longer appropriate or that could fundamentally alter the basis for the current ethylene oxide IRIS assessment."[177]

EPA's robust explanation regarding how and why it decided to use the 2016 EtO IRIS value is reflected in its Response to Comments for the MOCM Rule, 2022 MOCM Reconsideration, and 2024 Rule and those documents are hereby incorporated by reference into these comments. Indeed, EPA vigorously defended the 2016 EtO IRIS value in those rulemakings, stating that the assessment:

- "…underwent an extensive peer and public review process that adhered to the guidelines in EPA's Peer Review Handbook for peer review of highly influential scientific assessments"[178] that "was an integral part of the development of the final assessment."[179]
- "…continues to provide sound scientific conclusions that are consistent with the latest scientific knowledge."[180]
- "…is scientifically sound and robust and represents the best estimate of the increased cancer risk posed by inhalation exposure to ethylene oxide for use in a risk assessment.
- "…underwent extensive internal EPA review, as well as external review by other federal agencies.
- "…[was] reviewed by a wide range of EPA scientists, interagency reviewers from other federal agencies and the Executive Office of the President, the public, and independent scientists external to the EPA."[181]

[177] *Id.*
[178] 2022 MOCM Reconsideration at 77,989.
[179] *Id.* at 77,990.
[180] *Id.*
[181] *Id.*

As EPA recognizes in the Proposal, EPA vigorously defended its use of the 2016 EtO IRIS value in *Huntsman Petrochemical*.[182] In that case, petitioners raised myriad technical and legal challenges to EPA's reliance on the 2016 EtO IRIS value.[183] The D.C. Circuit Court of Appeals found that EPA sufficiently addressed and rejected petitioners' arguments in detail during the rulemaking, and that petitioners failed to show that in doing so, EPA acted arbitrarily, capriciously, or otherwise contrary to law. Specifically, the Court held that EPA adequately explained its modeling approach and decisions, including EPA's use of the NIOSH data, its selection of the two-piece linear spline model, and its rejection of the model used in the TCEQ 2020 assessment. In sum, the 2016 EtO IRIS value represents the gold standard of scientific analysis. Moreover, the 2016 EtO value and EPA's prior rejection of the TCEQ 2020 assessment were upheld by a federal appellate court in the face of attacks regarding the 2016 IRIS value's validity.

4. EPA's newfound acceptance of TCEQ's 2020 assessment represents an arbitrary change in position

EPA also points to a risk assessment it previously found unreliable, conducted by the Texas Commission on Environmental Quality ("TCEQ") in 2020, that estimates an EtO cancer risk about 3,000 times lower than the 2016 EtO IRIS value.[184] EPA has already identified deficiencies in the TCEQ 2020 assessment, which were also identified by the National Academies of Sciences, Engineering, and Medicine ("NASEM"), and other scientific peers.[185] EPA also fails to explain how it believes the Proposal is "better" because of "new studies" that could change its understanding of EtO's carcinogenic potency—EPA does not actually engage

[182] *Huntsman*, 114 F.4th at 727.
[183] Among its many challenges, Petitioners argued that: (1) EPA's Science Advisory Board commented that certain of the pre-1978 exposure levels estimated in the NIOSH study were "unlikely" and "surprising;" (2) EPA ignored a 2019 study that, according to petitioners, called the NIOSH data's pre-1978 exposure levels into question; (3) the NIOSH study and EPA ignored other evidence suggesting that exposure levels early in the study period would have been much higher than what NIOSH estimated; (4) using categorical averages was an oversimplification that led EPA to choose the wrong model; (5) that EPA's approach ran contrary to EPA's Science Advisory Board's feedback; (6) EPA's process was "simply eyeballing" the data and relying solely on visual fit to select the model it wanted; (7) EPA should have counted the knot of its spline model as a third estimated parameter; and (8) EPA misused one of its own figures in assessing the potential models.
[184] Texas Commission on Environmental Quality, *Ethylene Oxide Carcinogenic Dose-Response Assessment: Development Support Document.* 75-21-8 (2020), https://www.tceq.texas.gov/toxicology/ethylene-oxide/ (TCEQ 2020 assessment).
[185] *See also* 87 Fed. Reg. 77,985, 77,991 (Dec. 21, 2022) (EPA determination that "the TCEQ risk value is unsuitable for use as an alternative to the IRIS value for [EtO] in assessing cancer risk under CAA section 112(f)" in reconsidering its Miscellaneous Organic Chemical Manufacturing NESHAP).

with these studies, much less explain how they justify its sweeping change in position. Finally, as EPA acknowledges, the D.C. Circuit recently upheld EPA's use of the 2016 EtO IRIS value — and EPA's rejection of the TCEQ model—in setting updated emission standards for the Miscellaneous Organic Chemical Manufacturing source category ("MOCM Rule").[186] Given EPA's history of "forcefully" defending the 2016 EtO IRIS value in rulemakings and litigation, a mere acknowledgement of a change in position will not suffice.[187]

Nonetheless, in the Proposal, EPA now points to the TCEQ 2020 assessment, which estimates EtO cancer risk about 3,000 times lower than the 2016 EtO IRIS value,[188] and seeks comments on that assessment's modeling calculations and assumptions, which EPA previously rejected as unreliable. EPA cannot justify its adoption of the TCEQ assessment over the 2016 EtO IRIS value nor explain what "good reasons" exist to make this drastic change from its prior, successfully defended, position. Specifically, in 2022 when EPA granted reconsideration of the MOCM Rule, EPA concluded that the TCEQ 2020 assessment was "unsuitable for use as an alternative to the IRIS value for ethylene oxide in assessing cancer risk."[189] EPA disagreed with "TCEQ's decision to exclude breast cancer in women as an endpoint for [EtO] dose response assessment," which was "not scientifically sound," because "the available epidemiological evidence for a causal relationship between ethylene oxide exposure and breast cancer in women was strong" and "[n]o substantial studies challenge this conclusion."[190] EPA also found that TCEQ's dose-response model "is unsupported by the underlying epidemiological data" and that the analyses used to justify the model choice were "erroneous and relied on flawed assumptions."[191]

Indeed, EPA rejected the TCEQ model because it was inconsistent with the underlying epidemiological exposure-response data and mischaracterized risk at lower exposure levels.[192] In the 2022 MOCM reconsideration, EPA found that "TCEQ supported their model choice using flawed calculations and inappropriate assumptions."[193] EPA found that TCEQ's chosen model did not fit the lower-exposure data, which is especially important because the lower exposure

[186] *Huntsman*, 114 F.4th at 727.
[187] *See MISO Transmission Owners v. FERC*, 45 F.4th 248, 264 (D.C. Cir. 2022).
[188] *Huntsman* at 734.
[189] 2022 MOCM Reconsideration, at 77991.
[190] *Id*. at 77991–92.
[191] *Id*. at 77991.
[192] 2022 NESHAP Reconsideration at 77993.
[193] 2022 MOCM Reconsideration at 77991.

data is "the range representing potential general population exposures," rather than the higher exposures likely to be found only in an occupational setting.[194] Instead of selecting a model that accounted for all the data, TCEQ chose a linear curve influenced by the highest exposures and underestimated the "risk for points below the highest exposure levels."[195] EPA examined TCEQ's inferences and calculations and identified problems with:

> "(1) TCEQ's assumption that national lymphoid cancer *mortality* rates equal rates of cancer mortality for members of the NIOSH cohort in the absence of ethylene oxide exposures; (2) TCEQ's calculation of projected cancer rates; and (3) the statistical confidence intervals TCEQ developed for the 'predicted' numbers of cancers." [196]

EPA criticized the errors that TCEQ made in its cancer rate projections and in the "reality check" calculations it used to justify its model choice. EPA explained that TCEQ's "reality check" calculations were "not statistically appropriate" and did "not support TCEQ's claims."[197]

NASEM, a 162-year-old institution that provides "independent, trustworthy advice and facilitate[s] solutions to complex challenges by mobilizing expertise, practice, and knowledge in science, engineering, and medicine,"[198] evaluated the TCEQ 2020 assessment and determined in a consensus report that there were multiple major flaws that would need to be remedied before it could be relied upon in risk assessments.[199] NASEM's review raised "significant concerns regarding the overall methodology" of the TCEQ 2020 assessment.[200] NASEM found basic problems with both TCEQ's Hazard Assessment and Dose Response in that they suffered from numerous flaws and did not adhere to best practices.[201] Specifically, TCEQ relied on "narrative reviews without … using established tools to assess quality and rigor."[202] NASEM criticized

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[194] *Id.*
[195] *Id.* at 77993.
[196] *Id*. (emphasis in the original).
[197] *Id*.
[198] NASEM, Purpose, *last accessed* May 12, 2026, https://www.nationalacademies.org/purpose.
[199] NASEM, *Review of Texas Commission on Environmental Quality's Ethylene Oxide Development Support Document.* Washington, DC: The National Academies Press, (2025) https://doi.org/10.17226/28592. (NASEM Report)
[200] NASEM, *Review of Texas Commission on Environmental Quality's Ethylene Oxide Development Support Document, Consensus Study Report Highlights* at 3 (2025), https://nap.nationalacademies.org/resource/28592/Highlights_Review_of_Texas_Commission_on_Environmental_Quality.pdf. (NASEM Report Highlights).
[201] *Id.* at 2.
[202] *Id.*

TCEQ's hazard assessment for failing to provide "a credible basis for its hazard conclusions."[203] NASEM found that TCEQ inappropriately excluded evidence related to the hazard assessment for breast cancer.[204] NASEM also concluded that TCEQ did not appropriately account for data biases like the healthy-worker effect, "leading to the reliance on an inappropriate external reference group, which may have contributed to the exclusion of breast cancer as an endpoint."[205]

With regard to the Dose Response, NASEM criticized TCEQ for developing a unit risk factor for cancer mortality rather than cancer incidence.[206] NASEM explained that mortality rates poorly reflect lymphoid cancer incidence rates; because lymphoid cancer mortality rates are far lower than incidence rates, unit risk factor for mortality will be much lower than unit risk factor for incidence.[207] NASEM found TCEQ did not appropriately consider alternative nonlinear models, like the one EPA chose for the 2016 EtO IRIS value and suggested by TCEQ's own guidance. Thus, TCEQ did not "prioritize selection of a model that best fits the dose-response curve at the lowest end of the exposure distribution."[208] NASEM faulted TCEQ for relying on "unpublished, non-peer-reviewed data" to validate its models.[209] NASEM concluded that TCEQ's "methodological deviations underscore the need for a more rigorous and comprehensive approach in future assessments."[210]

Overall, the NASEM committee found that "[t]he lack of application of systematic review methods, the exclusion of critical epidemiological data, the limitations in the modeling approach and use of unpublished validation data all contribute to a lack of confidence in TCEQ's risk assessment of [EtO]."[211] Notably, TCEQ has not updated its assessment to address the significant recommendations by NASEM and it would be arbitrary and capricious for EPA to rely on the facially flawed report of another agency.[212] Thus, EPA cannot reasonably rely on the 2020 TCEQ assessment in the Proposal.

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[203] *Id.*
[204] *Id.*
[205] *Id.*
[206] *Id.*at 3.
[207] NASEM Report at 24.
[208] NASEM Report Highlights at 3.
[209] *Id.*
[210] *Id.*
[211] *Id*.
[212] *See Ergon-West Va., Inc. v. EPA*, 896 F.3d 600, 610 (4th Cir. 2018).

5. Recent studies neither support the Proposal nor change the conclusion that the 2016 EtO IRIS value represents the best available science

Beyond the 2020 TCEQ assessment, EPA cites a mere two studies to support its claim that "new scientific evidence has continued to emerge" that "could change the EPA's understanding of EtO's carcinogenic potency."[213] EPA does not assess these studies, however, much less explain how they could justify the Agency's sweeping claims regarding uncertainty.

The first study is an update of the NIOSH cohort study.[214] This is the same cohort used by EPA for its 2016 EtO IRIS value calculations. As with an earlier report from this cohort, this updated report presented strong evidence of an association between EtO and breast cancer mortality. This study is important because it provides additional evidence that EtO causes breast cancer and thus supports the inclusion of breast cancer in calculating the 2016 IRIS value. However, this study is based on breast cancer mortality and would therefore not directly alter an inhalation unit risk based on cancer incidence. Information on cancer incidence is usually preferred for inhalation unit risk derivation over data on cancer mortality since the former is generally considered a better indicator of overall cancer response.

The second recent study cited in the Proposal is an updated analysis of EtO and cancer in the Union Carbide Corporation (UCC) cohort.[215] As with earlier publications from this cohort, this updated report did not find strong evidence of an association between EtO and cancer. Importantly though, the major problems seen in the earlier publications from this cohort were also present in this update. These included concerns about the accuracy of the EtO exposure data, the exclusion of female participants, concerns about the effects of other chemical exposures in the UCC facilities, and the relatively small number of cancer cases. Based on these problems, the 2025 UCC update is not informative for assessing the risks of EtO.

Also, the Proposal fails to mention a 2026 study analyzing the healthy worker survivor effect in the NIOSH cohort performed by academic researchers.[216] The healthy worker effect can occur when cohorts of exposed workers are compared to the general U.S. population. The

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[213] 91 Fed. Reg. at 12,715.
[214] Kelly-Reif et al., *supra* note 19.
[215] Ciriaco Valdez-Flores et al., *Use of Updated Mortality Study of Ethylene Oxide Manufacturing Workers to Inform Cancer Risk Assessment*, 45 Risk Anal. 2822 (2025), https://pubmed.ncbi.nlm.nih.gov/40458005/.
[216] Sally Picciotto et al., *How to Identify the Healthy Worker Survivor Effect Empirically and How to Interpret Results from Published Studies: The NIOSH Ethylene Oxide Cohort as a Case Study*, Am. J. Epidemiol. (Mar. 2026), https://pubmed.ncbi.nlm.nih.gov/41800785/.

healthy worker effect includes two aspects: the healthy hire effect and healthy worker survivor effect. Both can bias the relative risks in exposed workers towards the null since working people are generally healthier than the U.S. population as a whole (which includes some people who are too ill to work). This issue is particularly relevant since the 2020 TCEQ assessment relied heavily on the assumption that the healthy worker effect is minimal in the NIOSH cohort. However, the 2026 study not mentioned in the Proposal demonstrates that TCEQ erred in its assumption and that the healthy worker survivor effect likely had some effect on the NIOSH cohort study. The 2026 study demonstrated that at least some healthy worker survivor effect exists in the NIOSH cohort results and that this effect most likely biased relative risk estimates towards the null and not towards creating false associations. Overall, the 2026 study is useful because it highlights yet another flaw in the Proposal's purported reliance on the 2020 TCEQ assessment.

For all the foregoing reasons, these recent studies fail to support the Proposal change or change the conclusion that the 2016 EtO IRIS value represents the best available science.

6. EPA cannot reject the 2016 IRIS value based on endogenous EtO exposure

The Proposal also attempts to undermine the 2016 EtO IRIS value and the 2024 Rule by emphasizing that endogenous production, non-industrial background contributions, and voluntary behaviors (like smoking) contribute to EtO levels, thereby downplaying the significant cancer risks from inhaling EtO emissions. However, any background or endogenous contributions to EtO levels do not negate EPA's responsibility to control exposures.

EtO emitted from commercial sterilizers is an independent and involuntary exogenous exposure that adds to a person's exposure above and beyond background and endogenous EtO concentrations. A recent analysis of nationwide EtO measurements at regulatory monitoring sites reported to the EPA's Air Quality System found that near-source monitoring sites (those within 2 km of a high-emitting source) had substantially higher EtO measurements than other sites, including low-emitting near-source sites and mid-range sites (2 to 10 km from any emission source), and urban, suburban, and rural sites.[217] In addition, annual average emissions at industrial monitoring sites were three times those at rural sites.[218] A smaller, more limited, study also found that while smokers had significantly higher EtO biomarker levels overall, non-

[217] Robinson et al., *supra* note 34.
[218] *Id*.

smokers living within a half mile of an EtO-emitting facility had significantly higher EtO levels than nonsmokers living elsewhere.[219] Thus, EtO-emitting facilities put everyone in nearby communities at greater risk of cancer and related health outcomes, regardless of pre-existing endogenous EtO levels.

Further, recent literature review and pharmacokinetic analysis by EPA-affiliated scientists concluded that more research is needed to assess the contribution of endogenous EtO relative to other sources.[220] These research gaps highlight the need for public health measures to consider cumulative exposure with an ample margin of safety, which the 2024 Rule and 2016 IRIS value provides.

Accordingly, the fact that humans endogenously produce EtO is not a justification to question the well-known, added exposure and health risks from exogenous EtO contributions from commercial sterilizers. Thus, EPA's decision to abandon the 2016 IRIS value due to "endogenous production" also renders the action arbitrary and capricious.[221]

7. State agencies support EPA's continued reliance on the 2016 EtO IRIS value

Our respective states support EPA's continued reliance on the 2016 EtO IRIS value for setting risk-based standards and reject the TCEQ 2020 assessment as an alternative value.[222]

For example, the California Office of Environmental Health Hazard Assessment ("OEHHA") is legislatively mandated to develop guidelines for conducting health risk assessments under the California Air Toxics Hot Spots Program.[223] In response to this requirement, OEHHA develops inhalation unit risk factors for carcinogens, such as EtO, which

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[219] Emily Szwiec et al., *Levels of Ethylene Oxide Biomarker in an Exposed Residential Community*, 17 Int'l J. Envtl. Rsch. & Pub. Health 8646 (2020), https://pubmed.ncbi.nlm.nih.gov/33233319/.
[220] Yu-Sheng Lin et al., *Uncovering the Connection: Ethylene Exposure and Endogenous Ethylene Oxide Levels in Humans*, 36 J. Exposure Sci. & Envtl. Epidemiol. 361 (2026), https://www.nature.com/articles/s41370-025-00826-7.
[221] *Encino Motorcars,* 579 U.S. at 221.
[222] Outside of the Proposal, the EPA continues to claim uncertainty with the IRIS value for EtO. On April 27, 2026, EPA sent a memorandum titled "Future Development and Use of Risk Assessments" to the Inspector General, general counsel, chief officers, and associate and regional administrators of the EPA discussing the "need for EPA to provide more clarity as to how the Agency should develop and utilize information to inform scientific risk assessments," arguing that "programmatic shortcomings . . . have not advanced the original goal of the IRIS program[,]" directly citing the Agency's conclusion in the Proposal that "EtO is five times safer than the IRIS value provided[.]" Memorandum from David Fotouhi, Deputy Adm'r, EPA, to Assistant Adm'rs, Directive on the Utilization of Independent Toxicity Assessments (Apr. 27, 2026), *as published in* Emma Gardner and Maria Hegstad, *EPA Launches Agency-Wide Overhaul of Risk Methods Amid IRIS Shutdown*, Inside EPA (May 4, 2026). However, as discussed at length in Section II(D), the IRIS assessment remains the best understanding of EtO carcinogenic potency and, indeed, has fostered consistency in all chemical toxicity evaluations across EPA programs and a range of federal, state, and local agencies for the past 40 years.
[223] Cal. Health & Safety Code § 44360(b)(2).

are used to estimate lifetime cancer risks associated with inhalation exposure to carcinogens.[224] On May 14, 2026, OEHHA released a draft update to its cancer risk value for EtO that corresponds to EPA's adult-based unit risk estimate in the 2016 IRIS value for lymphoid and breast cancers combined.[225]

Illinois also extensively relies on IRIS assessments when regulating toxics[226] and specifically when regulating toxic air contaminants: Illinois regulations classify a contaminant as a carcinogen when IRIS lists it as such.[227] Furthermore, when the Illinois Environmental Protection Agency proposed new regulations for ethylene oxide emissions from commercial sterilizers under the Haller Act, it directly cited the 2016 IRIS report.[228]

Additionally, toxicologists at the Michigan Department of Environment Great Lakes and Energy ("EGLE") have concluded that the 2016 IRIS "unit risk estimate" is "appropriate," "defensible," and "reflects a rigorous development and peer review process."[229]

C. EPA's failure to quantify the health harms from allowing an increase of EtO emissions is arbitrary and capricious

As discussed above, the Regulatory Impact Analysis that EPA conducted to support its proposal fails to adequately examine the health harms that would result from allowing an increase in EtO emissions. In particular, EPA vaguely alludes to "methodological and data limitations" to excuse the Agency from quantifying human health impacts.[230] Yet EPA does not actually identify any such data limitations and did not take any action to fill an alleged data gap or limitation before proposing to rescind the 2024 Rule. EPA does begrudgingly admit that "[s]hould the impacts from increased EtO exposure be monetized, they would reduce the overall monetized benefits relative to the anticipated cost savings." But if EPA cannot quantify health impacts, then it also cannot conclude that the proposal will merely reduce benefits. Rather, the monetized harms from increased EtO exposure could potentially exceed reduced costs to

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[224] OEHHA, Air Toxics Hot Spots Program, Ethylene Oxide Cancer Inhalation Unit Risk Factor, Technical Support Document for Cancer Potency Factors Appendix B, Public Review Draft (May 2026), https://oehha.ca.gov/sites/default/files/media/2026-05/EtOIURpcDraft051426.pdf.
[225] *Id*.
[226] *E.g.*, Illinois' Tiered Approach to Corrective Action Objectives, 35 Ill. Adm. Code 742, lists IRIS as a top-tier source for information when setting cleanup standards for contaminated soil and groundwater.
[227] 35 Ill. Adm. Code 232.320.
[228] Illinois EPA, Statement of Reasons, Illinois Pollution Control Board Rulemaking, R20-18, (Dec. 17, 2019).
[229] State of Michigan Dept. Enviro. Quality, Air Quality Division, *Response to Comments for Ethylene Oxide (CAS # 75-21-8)*, July 31, 2017, https://www.egle.state.mi.us/aps/downloads/ATSL/75-21-8/75-21-8_RTC.pdf.
[230] RIA at 10.

industry, resulting in a rule with net negative benefits. This is a central issue that EPA fails to address.

This unexplained change in approach conflicts with three decades of Agency practice, including analysis supporting the 2024 Rule that quantified health benefits. This practice was consistent with Executive Order 12866 of 1993, which provides:

> In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. **Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated)** and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider.[231]

Indeed, EPA followed this Executive Order's directive in the 2024 Rule, quantifying the expected benefits from the rule as reducing estimated cancer incidence due to EtO emissions "from 0.9 to between 0.1 to 0.2, or from 1 cancer case every 1.1 years to 1 cancer case every 5 to 10 years."[232]

The RIA for the Proposal also cites the IRIS study, despite discrediting and discarding it in the preamble. The IRIS study quantifies the inhalation unit risk, which may translate to 500 excess cancer cases over a lifetime.[233] EPA also calculates that "there is an estimated EtO emissions increase of 7.8 tons per year ("tpy") for the total source category" because of the proposal.[234] That increase will eliminate over a third of the 21 tpy reductions the 2024 Rule would produce. Even if EPA chooses not to fully monetize the health impacts, EPA has an established track record of rigorous, peer-reviewed methodologies that would allow the Agency to translate the quantified emission increase into an analysis of tangible health impacts. EPA fails to confront the voluminous scientific evidence and guidelines underlying its past practice, including the available quantitative methods to characterize the risk, as the 2024 Rule did.

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[231] *See* Exec. Order No. 12866, 58 Fed. Reg. 51,735 (Oct. 4, 1993) (emphasis added).
[232] Notably, EPA quantifies risk in this way despite lacking "sufficient methods to monetize benefits associated with HAP, HAP reductions, and risk reductions for this rulemaking." 89 Fed. Reg. at 24,139.
[233] *See supra* note 21.
[234] 91 Fed. Reg. at 12,732.

Instead, EPA makes only vague references to methodological and data limitations, failing to explain why it can no longer conduct this kind of quantitative analysis.

This unexplained change in position and refusal to analyze the impact of the Proposal are the hallmarks of arbitrary agency action under the Administrative Procedure Act.[235] To the extent that some amount of uncertainty is inherent in quantifying health benefits, EPA cannot simply disregard health benefits entirely. Rather, courts have held that when the data is uncertain, "the agency's job is to exercise its expertise to make tough choices about which of the competing estimates is most plausible, and to hazard a guess as to which is correct, even if . . . the estimate will be imprecise."[236]

It is also arbitrary and capricious not to quantify public health benefits based on concerns about uncertainty while continuing to quantify regulatory costs when such costs are also uncertain and rely on assumptions and estimates. In the RIA's analysis of how the Proposal would reduce compliance costs for industry, "cost impacts were estimated," "assumed configurations were applied for some facilities," and EPA "estimated costs for 89 commercial EtO sterilization facilities," all while acknowledging that "this analysis may overestimate the cost savings of the rule" and, when estimating compliance costs through 2045, that "more uncertainty is introduced when impacts are estimated this far into the future."[237] By precisely calculating compliance costs in the face of this uncertainty while declining to quantify benefits, EPA arbitrarily elevates industry interests over other interests.[238]

EPA's new practice of systematically declining to quantify public health benefits from emission reductions while continuing to monetize compliance costs—costs that EPA itself admits are uncertain and based on various estimates and assumptions—prioritize industry interests over public health. In rejecting past practice without explanation, EPA obscures from the public

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[235] *See* 5 U.S.C. § 706(2)(a).
[236] *Pub. Citizen v. Fed. Motor Carrier Safety Admin*., 374 F.3d 1209, 1221 (D.C. Cir. 2004). *See also Mont. Wilderness Ass'n v. McAllister*, 666 F.3d 549, 559 (9th Cir. 2011) ("[T]he proper response to [uncertainty] is for the Service to do the best it can with the data it has, not to ignore [it].").
[237] RIA at 6, 15–16. Furthermore, EPA made assumptions concerning capital costs, stream of cost savings for facilities covered under the Proclamation, and interest rates. *Id*. at 7–8.
[238] *See Ctr. for Biological Diversity*, 538 F.3d at 1198 (holding that an agency "cannot put a thumb on the scale by undervaluing the benefits and overvaluing the costs of more stringent standards" when conducting cost-benefit analysis).

significant health harms from rolling back EtO emissions reductions and, doing so, fails to account for an important aspect of EtO regulation.[239]

D. EPA fails to adequately consider States' reliance interests

As stated, a few states have their own regulations to protect their residents from EtO's significant health harms. But most states have not and instead rely on EPA to establish and enforce national standards pursuant to its statutory obligations under the Clean Air Act and using its scientific expertise. And even states with their own regulations rely on a national regulatory floor, standardized testing protocols, and source categorization. Thus, EPA's decision to roll back the standards in the 2024 Rule that incorporated the latest in scientific research and understanding for this highly carcinogenic substance impairs those states' reliance interests. Where an agency's "prior policy has engendered serious reliance interests that must be taken into account," "the agency 'must' provide 'a more detailed justification' for" its change in policy, including "a rational connection between the facts found and the choice made."[240] EPA's Proposal fails to justify its weakening of the 2024 Rule in relation to the serious reliance interests that states without their own EtO regulations have in protecting their residents from the harmful consequences of EtO exposure. Environmental justice communities in our States who already experience disproportionate cumulative pollution exposure risks are particularly harmed by the weakening of this standard.

States have relied for decades on EPA's position that EPA could, and would, later revisit health risks associated with EtO sterilizers as needed, which it explained in its 2006 residual risk review rule when it decided not to revise the EtO standards. At that time, EPA explained that it was developing an updated cancer assessment for ethylene oxide that would consider all relevant literature and studies, but that the study was not yet complete.[241] EPA indicated that because it could later revisit its risk assessment, it need not correct its 2006 section 112(f) residual risk review to account for reasonably foreseeable changes that could result in increased risk, such as

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[239] *See State Farm,* 463 U.S. at 43; *Michigan v. EPA*, 576 U.S. at 753 (explaining that "reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions"); *Bus. Roundtable v. SEC*, 647 F.3d 1144, 1148–1149 (D.C. Cir. 2011) (explaining that an agency acted arbitrarily and capriciously when it "inconsistently and opportunistically framed the costs and benefits of the rule" and "failed to adequately quantify the certain costs or to explain why those costs could not be quantified").

[240] *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 719 (D.C. Cir. 2016) (quoting *Fox*, 556 U.S. at 515 and *State Farm*, 463 U.S. at 43).

[241] 71 Fed. Reg. at 17,716.

new residences being built closer to the facility, or increases in actual emissions within the current permit limitations.[242] EPA explained this in its response to comments:

"We disagree with the commenter's assertion that there is no mechanism to revisit risks from the source category, and that, therefore, the risk assessment must include consideration of foreseeable changes that may occur in the future. We have the authority to revisit (and revise, if necessary) any rulemaking if there is sufficient evidence that changes within the affected industry or significant improvements to science suggests the public is exposed to significant increases in risk as compared to the risk assessment prepared for the rulemaking (*e.g.*, CAA section 301)."[243]

Furthermore, as set forth above, the period from 2019 to 2024 saw extensive regulatory efforts at the state and federal level to strengthen regulations to protect the public from EtO emissions. These regulatory efforts in many ways culminated in the adoption of the 2024 Rule. Many states observed the federal movement towards a tighter regulatory framework and opted not to pursue their own regulations on EtO, relying instead on the tighter regulations adopted at the federal level.

The proposed rollback of the more stringent controls required by the 2024 Rule particularly impacts those states that rely on nationwide federal HAP standards to protect their citizens' health while allowing the states to otherwise allocate their limited resources towards protecting public health of their citizens. If EPA adopts the Proposal, states that relied on the more protective emission standards required by the 2024 Rule will be individually burdened to fill in the regulatory gap caused by EPA's retreat from protecting public health and will spend limited state agency time and resources to spend limited state agency resources to enact sufficiently protective standards. Each state will need to do so through independent rulemaking procedures, requiring significant staff time and agency resources already dedicated to other important state priorities, and all redundant of the effort already expended by EPA (twice over) at the federal level.[244] Even if states without stringent standards for EtO began a rulemaking process today, the expectation is that the adoption of stringent state rules would take 1-2 years,

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[242] *Id*.
[243] *Id*. at 17,715–17,716.
[244] *See, e.g.*, Minnesota Pollution Control Agency ("MPCA"), *Proposed rules*, https://www.pca.state.mn.us/get-engaged/proposed-rules; Minnesota Department of Health, *Minnesota Rulemaking Manual* (Feb. 2026), https://www.health.state.mn.us/data/rules/manual/docs/manual.pdf.

years during which their citizens would be left without necessary protection from an extremely dangerous hazardous air pollutant.

States have also taken regulatory action in related areas that rely on or integrate with the more stringent EtO controls of the 2024 Rule. For example, Minnesota has incorporated by reference the federal EtO emissions standards into its sterilizers' emissions regulations.[245] Minnesota therefore relies on the stringency of the federal standards to protect its residents from EtO emissions. Minnesota has clusters of EtO-emitting facilities, particularly in the northwest suburbs of the Twin Cities, which pose cumulative exposure risks.[246] Stronger federal regulations protect communities in these areas from the dangerous health risks associated with EtO exposure. Minnesota also adopted rule amendments in 2024 to increase stringency of its air emissions reporting program.[247] In adopting those rules, Minnesota relied on the 2024 Rule's more stringent standards for EtO.[248]

The 2024 EtO sterilizer regulation's stringent standard protects communities with environmental justice concerns that are already burdened by the cumulative effects of pollution and other burdens. In the United States over 14.2 million people live within five miles of an EtO-emitting facility.[249] The average risk of cancer from air toxics is nearly three times the national average in communities located near EtO-emitting facilities.[250] And according to a 2021 EPA study, nearly two-thirds of the EtO-emitting facilities contributing to cancer risks of 100 in one million or more are in census block groups that are at least 50 percent minorities or low-income households.[251]

As demonstrated above, EtO regulations can dramatically reduce EtO emissions in communities surrounding emitting facilities. EPA's 2024 EtO sterilizer regulation offered similar protection to communities across the nation, meeting EPA's duty to set national emission

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[245] *See* Minn. R. 7011.7140.
[246] Darya Minovi, *Invisible Threat, Inequitable Impact: Communities Impacted by Cancer-Causing Ethylene Oxide Pollution*, UNION OF CONCERNED SCIENTISTS (Feb. 7, 2023), https://www.ucs.org/resources/invisible-threat-inequitable-impact?read-online-content=1.
[247] MPCA, *Statement of Need and Reasonableness: In the Matter of Proposed Revisions of Minnesota Rule Chapters 7002, 7005, 7007, and 7019, Revisor ID No. RD-4599*, ENVIRONMENTAL ANALYSIS AND OUTCOMES DIVISION (Nov. 2024) https://www.pca.state.mn.us/sites/default/files/aq-rule2-02h.pdf.
[248] *Id.* at 50.
[249] Logan Malik, *Ethylene Oxide Emissions Standards for Commercial Sterilization Facilities*, HARVARD LAW SCHOOL ENVIRONMENTAL AND ENERGY LAW PROGRAM (May, 2025), https://eelp.law.harvard.edu/wp-content/uploads/2025/05/Ethylene-Oxide-Rule-for-Commercial-Sterilizers-FINAL.pdf.
[250] *Id*.
[251] *Id*.

standards that protect all people from the harmful effects of hazardous air pollutants. The Proposal's weakening of the 2024 federal EtO standard will once again reduce the protection available to communities in states relying on the 2024 Rule for protection from this dangerous toxin. EPA's failure to consider these reliance interests accordingly renders the Proposal arbitrary and capricious.[252]

E. The Proposal arbitrarily and capriciously rescinds standards that were adopted under section 112(d)

1. EPA fails to explain its revised cost-effectiveness calculation for new aeration vents at major sources

The 2024 Rule set a new technology-based standard of 99.9% EtO reduction for new aeration vents at facilities using at least 10 tpy of EtO, finding it cost-effective at $2.2 million per ton of EtO reduced, while the previous 99.6% reduction standard cost $2.6 million per ton reduced. EPA's Proposal would rescind the updated standard, allowing significantly more EtO emissions because the prior regulation did not accurately account for the costs of installing controls for new ARVs installed at existing facilities, where companies could use existing ductwork, control devices, and other equipment to lower the cost of emissions reduction.[253]

That argument is flawed on numerous levels. First, EPA does not provide any detail on how it conducted its revised cost-effectiveness calculation. The Agency asserts that sharing existing infrastructure would reduce the cost to comply with a 99.6% reduction standard, but does not provide an actual dollar value to compare with the 2024 Rule's findings on cost-effectiveness. And although the RIA mentions the proposed revision,[254] it also does not provide any calculations to support the revision. EPA must explain how it arrived at the conclusion that 99.6% reduction is more cost effective than 99.9% reduction. Absent these details, the Proposal is arbitrary and capricious.

Second, EPA also fails to explain why the 99.6% standard is more cost-effective for new ARVs at new facilities. The Proposal justifies the rollback by alleging the 2024 Rule ignored information about new ARVs at existing facilities. However, the Proposal does not demonstrate, much less assert that a 99.6% reduction would be more cost-effective for new ARVs at new

[252] *See Fox*, 556 U.S. at 515.
[253] 91 Fed. Reg. at 12,714–716.
[254] RIA at 2.

facilities, indicating that for entirely new EtO sterilizers, the 2024 Rule's cost-effectiveness calculation presumably holds. Therefore, EPA's failure to consider whether separate standards should be used for new ARVs at new facilities versus existing facilities is arbitrary and capricious.

Most importantly, EPA does not consider how much additional EtO emissions will be created by this regulatory change. EPA previously chose a 99.9% emission reduction standard not only because it would be more cost-effective, but also because it "would achieve greater emission reductions[.]"[255]Even if EPA concludes that 99.6% emission reduction is more cost-effective, it must weigh whether the minor gain in cost-effectiveness is outweighed by the harms from increased emissions. EPA is not tasked with choosing the most cost-effective emissions reduction standard; rather, it must evaluate whether the cost-effectiveness gain justifies a large increase in harmful emissions.[256]

2. EPA fails to justify rescinding monitoring and compliance assurance requirements from the 2024 Rule

EPA proposes to remove the requirement that facilities using at least 100 lb/yr of EtO demonstrate compliance with applicable standards by using a CEMS.[257] Instead, the Proposal would allow all facilities to demonstrate compliance using parametric monitoring and performance testing.[258] The States oppose these proposed changes.

At base, EPA argues that because the CEMS requirement in the 2024 Rule was "based on facility risks" which were "based on the results of an unauthorized second residual risk assessment and risk-based standards setting," the CEMS requirement is also illegitimate.[259] But as explained above, EPA's new interpretation of its authorities and obligations under section 112(f)(2) is not the best reading of the Clean Air Act. Because EPA offers no justification for removing the existing CEMS requirement other than an erroneous statutory interpretation, both the rollback to numeric emission limits that flow from that misinterpretation as well as its proposed change to compliance assurance that rely on that erroneous interpretation cannot be maintained.

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[255] 88 Fed. Reg. at 22,841.
[256] *See U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 640 (D.C. Cir. 2016) ("Congress required the EPA to *consider* a variety of factors without telling the EPA how to weigh them").
[257] 91 Fed. Reg. at 12,716.
[258] *Id*.
[259] *Id*.

However, EPA's Proposal leaves several strengthened standards in place from the 2024 Rule that it enacted under section 112(d) but fails to explain why CEMS should not be required for these emissions.[260]

Second, EPA mischaracterizes its prior analysis of CEMS-based monitoring of EtO emissions. The Proposal states that the 2024 Rule found that parametric monitoring is "used to good effect" to meet emissions reduction requirements.[261] But EPA omits is that the 2024 Rule also found that "parametric monitoring alone will not be sensitive enough to detect very small fluctuations in EtO concentration,"[262] and that multiple parameter collection and processing increases system complexity and leads to process problems.[263] Where, as in the Proposal, EPA would retain certain regulatory provisions that would require EtO reductions as low as 99.94%, EPA must consider the effects of such flaws in parametric monitoring. This is especially true when regulating HAPs like EtO, which is extremely harmful in very small quantities. In other words, the very small fluctuations that parametric monitoring, unlike CEMS, cannot readily detect can lead to significant health harms for our States' residents. EPA's failure to justify this change beyond relying on its flawed interpretation of Section 112(f)(2) is arbitrary and capricious.

F. The 2024 Rule's permanent total enclosure requirement is technologically feasible and should not only be implemented on a case-by-case basis

EPA also proposes to rescind the 2024 Rule's requirement to use PTE to ensure complete capture of EtO, addressing potential sources for fugitive emissions, in compliance with the standards.[264] EPA puts forward two distinct, record-based rationales and one legal rationale to support this proposed recission. The record-based reasons are arbitrary, and the legal reason is contrary to law under controlling D.C. Circuit precedent.

1. EPA's selective reading of the 2024 Rule's administrative record does not support rescinding the permanent total enclosure requirement

First, the Proposal justifies rescinding the PTE requirement because sterilizer facility design varies and "some [state] permits require PTE while others do not" (Proposal at 12,718),

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[260] 91 Fed. Reg. at 12,710.
[261] 91 Fed. Reg. at 12,716, *citing* 89 Fed. Reg. at 24,132.
[262] 89 Fed. Reg. at 24,101.
[263] *Id*. at 24,131.
[264] 91 Fed. Reg. at 12,718.

undermining the 2024 Rule's reliance on state permit conditions that included PTE.[265] However, the 2024 Rule cited state permit conditions as just one means of support to determine that all facilities with room air emissions can use a PTE to capture emissions. Furthermore, the 2024 Rule acknowledged that "configuration and design of sterilization facilities vary widely." *Id*. In fact, the 2024 Rule cited the versatility of EPA Method 204's PTE requirements as a strength of the requirement, not a flaw.[266] In sum, EPA's primary justification for rescinding the PTE requirement faults the 2024 Rule for failing to address conditions that the 2024 Rule actually considered. The Proposal thus reaches a different conclusion without any explanation of why EPA's view has changed. This unexplained change in view is arbitrary and capricious.

Second, EPA proposes, in the alternative, to rescind the PTE requirement because the 2024 Rule "did not account for the impacts of facilities shutting down due to [] variation" in facility design and configuration, seeking comment on the feasibility of PTE.[267] However, the 2024 Rule "accounted for the cost to retrofit facilities" and found that the EPA Method 204 design requirements have successfully been applied in many other source categories.[268]

Additionally, Illinois' Haller Act requires EtO sterilizers to capture "100% of all ethylene oxide emissions[.]"[269]After adopting this statute, a regulated sterilizer in Illinois installed two PTEs at its facility to capture and contain all EtO emissions for discharge through a control device, demonstrated under EPA Method 204.[270] Likewise, facilities in California subject to SCAQMD's recently amended Rule 1405 are required to install and operate PTEs to contain, capture, and reduce fugitive EtO emissions.[271] These facilities have seen an overall downward trend in ambient EtO concentrations. For example, one of the sterilization facilities located in Carson, California installed PTE in 2022 to reduce EtO emissions.[272] Since PTE installation and operation, measurements of the ambient air in the nearby community have been consistently at or

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[265] *Id*., citing 88 Fed. Reg. at 22,819.
[266] Emphasizing how PTE can be applied to a wide variety of sources with various designs, EPA stated that "[t]he design requirements of EPA Method 204 are agnostic to the industry it is applied. It has been applied widely to any industrial processes that need to control VOC emissions[.]" 89 Fed. Reg. at 24,114.
[267] 91 Fed. Reg. at 12,718.
[268] 89 Fed. Reg. at 24,114.
[269] 415 ILCS 5/9.16(b).
[270] https://epa.illinois.gov/content/dam/soi/en/web/epa/topics/community-relations/sites/ethylene-oxide/documents/pte-report-200323.pdf
[271] SCAQMD Rule 1405, https://www.aqmd.gov/docs/default-source/rule-book/reg-xiv/rule-1405.pdf?sfvrsn=4.
[272] SCAQMD, Parter Emissions Investigation in Carson, *last accessed* May 12, 2026, https://www.aqmd.gov/home/news-events/community-investigations/parter.

near typical background EtO levels for the area.[273] The experiences in Illinois and California in implementing this requirement shows that the 2024 Rule's PTE requirement is feasible.

Finally, the 2024 Rule did not include a requirement for fenceline monitoring because it found fenceline monitoring only useful for emission sources where PTE is *not* feasible. 2024 Rule at 24,131. So, not only has EPA failed to explain its rationale in the Proposal, but if it actually conducts the research and concludes that PTE is not cost effective, then EPA must consider applying fenceline monitoring requirements instead.

2. EPA misinterprets *Louisiana Envt'l Action Network v. EPA* to rescind permanent total enclosure requirements

EPA also relies on a misinterpretation of t *Louisiana Env't Action Network v. Env't Prot. Agency* ("*LEAN*"), a 2020 D.C. Circuit case, to support its proposal to rescind the PTE standard. As stated above, the Clean Air Act requires EPA to promulgate "emission standards" for each category of "major sources" of hazardous air pollutants.[274] The CAA establishes the method by which EPA must calculate source-specific limits for each air toxic.[275] To ensure that emission standards are updated considering technological developments and scientific advances, EPA is also required to revisit these emission standards. No less than every eight years, EPA must "review, and revise as necessary (taking into account developments in practices, processes, and control technologies), emission standards promulgated under this section."[276]

In *LEAN*, the D.C. Circuit addressed whether EPA was required, when conducting a review under 112(d)(6), to promulgate emissions standards for hazardous air pollutants that were not regulated under the initial rulemaking.[277] The Circuit found that "EPA's section 112(d)(6) review of a source category's emission standard must address all listed air toxics the source category emits."[278]

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[273] *Id*.
[274] 42 U.S.C. § 7412(d)(1).
[275] *Id.* § 112(d)(2)–(3).
[276] *Id.* § 112(d)(6).
[277] *Louisiana Env't Action Network v. Env't Prot. Agency*, 955 F.3d 1088 (D.C. Cir. 2020) ("*LEAN*").
[278] *LEAN*, 955 F.3d at 1091. *See also Blue Ridge Env't Def. League v. Regan,* No. 22-CV-3134 (APM), 2024 WL 5093495, at *2 (D.D.C. Dec. 12, 2024) ("As part of the technology review required under § 7412(d)(6), the EPA also must establish technology-based standards for listed HAPs that are emitted by the source category but that are not regulated by the existing standards under review.") (citing *LEAN*).

While acknowledging that EPA has in the past stated that the D.C. Circuit's decision in *LEAN* requires it to address additional emissions points,[279] EPA now proposes to revise its interpretation. Specifically, EPA now proposes that when conducing a 112(d)(6) review, "the EPA is not obligated to prescribe particular standards for emission points with respect to pollutants already regulated under the NESHAP."[280] EPA's proposal is contrary to law.

LEAN held that "because the Act necessitates section 112-compliant emission standards for each source category, and section 112(d)(6) requires EPA at least every eight years to review and revise emissions standards 'as necessary,' EPA's section 112(d)(6) review of a source category's emission standard must address all listed air toxics the source category emits."[281] The Proposal identifies that *LEAN* specifically regarded unregulated *pollutants*, and not emissions points, but the Clean Air Act dictates that EPA must remedy these missing standards just as it must address missing pollutants.

For its holding, *LEAN* cites to section 112(d)(2)-(3), and the requirement that "EPA must 'require the maximum degree of reduction in emissions' by the particular source category that the Agency 'deems is achievable."[282] The court went on to explain that the purpose of review under section 112(d)(6) is to "ensure[] that, over time, EPA maintains source standards compliant with the law and on pace with emerging developments that create opportunities to do even better."[283] And "the 'standards' to which section 112(d)(6) refers—are statutorily defined are *comprehensive controls* for each source category that must include limits on each hazardous air pollutant the category emits."[284] Based upon this language, the court concluded that "as used in section 112(d), an emission standard includes *as many limits as needed* to control all the emitted air toxics of a particular source category."[285] Accordingly, those "emissions standards" "are not

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[279] EPA very recently acknowledged this position during the current Presidential Administration, *see* National Emission Standards for Hazardous Air Pollutants: Integrated Iron and Steel Manufacturing Facilities Technology Review, 90 Fed. Reg. 55,681, 55,683 (Dec. 3, 2025) (acknowledging that EPA "set standards for previously unregulated sources of air toxics pursuant to our interpretation of the D.C. Circuit's decision in [*LEAN*]."), and has held this position since the *LEAN* decision, *see* National Emissions Standards for Hazard Air Pollution: Carbon Black Production and Cyanide Chemicals Manufacturing, 86 Fed. Reg. 66,096, 66,106 (November 19, 2021) ("The expansion to cover all process vents under the Carbon Black Production MACT standard is in accordance with *LEAN*.").
[280] 91 Fed. Reg. at 12,718.
[281] *LEAN,* 955 F.3d at 1091.
[282] *Id.* at 1093 (quoting 42 U.S.C. § 7412(d)(2)).
[283] *Id.*
[284] *Id.* at 1096 (quoting 42 U.S.C. § 7412(d)(1)–(3), (6)) (emphasis added).
[285] *Id.* at 1097.

constrained by past, potentially flawed and underinclusive agency action"; section 112(d)(6) "is a mandate to address the adequacy of each emission standard on the books against the statutory demand of section 112(d)(2)."[286]

The D.C. Circuit's logic—that it is "necessary" under section 112(d)(6) for EPA to "address the adequacy of each emission standard on the books" and ensure that its section 112 standards "include as many limits as needed"—applies to standards for additional emission points in addition to standards for additional pollutants. In other words, as EPA has said time and again, under *LEAN*, it must address regulatory gaps—logically including emissions points that do not have emissions standards. This best reading also aligns with Congress's purpose in section 112. It is implausible to suggest that a statutory provision intended to achieve the "maximum degree of reduction in emissions" would grant the Agency discretion to leave emissions points without any standards.

And even if EPA's new interpretation of *LEAN* were correct (it is not), EPA's proposal to remove the PTE limit is *still* arbitrary and capricious on this record because it would leave an unjustified control gap. While acknowledging EPA's earlier finding that many commercial sterilizers have installed PTEs, the proposal asserts (without any factual support) that some permits do not require PTE and configuration and design varies between facilities. Based on these unsubstantiated asserts, the proposal muses that these observations "*suggest* that whether PTE would be necessary … *could* depend on a facility's design and configuration."[287] It is unreasonable for EPA to provide mere conjecture when withdrawing a health-protective standard under section 112—it must at a minimum substantiate its claims and explain why they outweigh the benefits of leaving a source of toxic pollution uncontrolled.

The underlying history of the EtO standards at issue here illustrate the purpose of 112(d)(6) review. The initial rulemaking was "flawed and underinclusive";[288] it failed to set MACT standards for several significant sources of EtO, the danger of which was confirmed by subsequent research. Fortunately, EPA was required to conduct a 112(d)(6) review; when conducting this review, it identified the significant gaps in EtO regulations and, adhering to the principles laid out in *LEAN*, proposed new regulations to ensure that EtO was appropriately

[286] *Id.*
[287] 91 Fed. Reg. at 12,718 (emphasis added).
[288] *LEAN*, 955 F.3d at 1097.

limited to protect human health. In short, it remedied the oversights in the original rulemaking; the process worked as described in *LEAN*.

For these reasons, the States urge EPA to reconsider its approach to section 112(d)(6) review and return to its prior practice of comprehensive review that ensures adequate controls are in place for each source and each air toxic.

III. Conclusion

EPA's proposal misinterprets CAA 112 in order to avoid adequately considering the ample scientific evidence showing the immense harms to human health presented by higher EtO emissions. EPA ignores both the successes of states who have regulated EtO emissions as well as the reliance interests of states without EtO regulations. Not only do EPA's flawed legal interpretations increase risk from EtO sterilizer emissions but they will also lead to harms to human health and the environment in several other Clean Air Act regulations. The States urge that EPA not adopt its Proposal.

Respectfully,

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