Ethylene Oxide Emissions Standards for Commercial Sterilization Facilities

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Overview

On April 5, 2024, EPA finalized a rule to significantly reduce the emissions of ethylene oxide (EtO) from commercial sterilization facilities under Section 112 of the Clean Air Act (CAA). The rule was immediately challenged by both environmental groups and industry.[1] The Trump administration has said it will reconsider the 2024 rule,[2] and invited industry to seek exemptions from the rule.[3] As of this writing, two chemical industry associations requested an exemption for all their member companies.[4]

EtO is a potent carcinogen. While EtO emissions from sterilization facilities have been regulated since 1994, prior requirements did not apply to several significant sources of EtO, including fugitive emissions (also called "room air emissions").[5] As a result, communities who live near these facilities — who are disproportionately low-income and communities of color — have suffered from a significantly higher rate of cancer than the rest of the country.[6] If the 2024 final rule were to take effect, EPA anticipated it would reduce annual EtO emissions from commercial sterilizers 90% by 2027 by increasing the stringency of emissions standards, regulating fugitive emissions, and requiring consistent monitoring to ensure compliance with the new standards.

In this piece, I summarize EPA's EtO final rule for sterilization facilities, discuss the significance of regulating EtO emissions for fenceline communities, and look at how the pollutant has historically been regulated. I describe the rule's requirements, including changes to prior regulations. I conclude by discussing the litigation challenging the rule and the Trump administration's anticipated effort to roll back the rule.

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[1] *The Ethylene Oxide Sterilization Association, Inc. v. EPA, et al.*, Docket No. 24-1180 (D.C. Cir. Jun 04, 2024).
[2] Press Release, EPA, Trump EPA Announces Reconsideration of Air Rules Regulating American Energy, Manufacturing, Chemical Sectors (NESHAPs) (March 12, 2025), https://www.epa.gov/newsreleases/trump-epa-announces-reconsideration-air-rules-regulating-american-energy-manufacturing.
[3] *Clean Air Act Section 112 Presidential Exemption Information*, EPA (Mar. 24, 2025), https://www.epa.gov/stationary-sources-air-pollution/clean-air-act-section-112-presidential-exemption-information?source=email
[4] Letter from Brendan Mascarenhas, Senior Dir. Am. Chem. Council & Leslie Bellas, Vice President, Am. Fuel & Petrochem. Mfr., *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*, (Mar. 31, 2025), https://www.edf.org/media/new-analysis-shows-extensive-number-facilities-across-us-could-get-trump-epa-pollution-pass.
[5] Defined in this paper in the section "Overview of EPA's 2024 final rule setting EtO emissions standards for chemical sterilizers."
[6] 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.

Background on Ethylene Oxide

Ethylene Oxide (EtO) is a flammable, colorless gas that is used primarily as a sterilizer for medical devices.[7] Chronic exposure to EtO has been linked to irritation of the eyes, skin, and respiratory passages; reproductive and developmental effects, including an increased risk of miscarriage; and an increased risk of several different types of cancer, including lymphoid and breast cancer.[8]

The primary source of exposure to EtO is through air.[9] As a result, people most at risk from EtO are those who live, work, or attend school near facilities that use EtO, such as commercial sterilizers.[10] Children and babies are more susceptible to harm from the chemical.[11]

Over 14.2 million people live within five miles of an EtO-emitting facility in the United States.[12] A 2023 study found that the average risk of cancer from air toxics was nearly three times the national average in communities located near EtO-emitting facilities.[13] Moreover, they found that a large proportion of the increased cancer risk was a result of EtO emissions, compared to over 130 other air pollutants that were also assessed.[14]

EtO emissions disproportionately impact low-income communities, communities of color, and communities in which English is not the primary language. Of the 14.2 million people living near EtO-emitting facilities, 8.5 million identified as people of color, 4.8 million identified as low-income, and 1.2 million identified as having limited English language proficiency.[15] These disparities are even more pronounced near facilities with the highest risk of cancer in nearby communities. According to a 2021 EPA study, nearly two-thirds of the EtO-emitting facilities contributing to cancer

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[7] *Id.* See *Ethylene Oxide*, Environmental Protection Agency, 1, (Dec. 2018) www.epa.gov/sites/default/files/2016-09/documents/ethylene-oxide.pdf (EtO is also used to as a pesticide, as a fumigating agent for spices, and as an intermediate in the production of chemicals used in antifreeze and polyester); See Genna Reed, *What is Ethylene Oxide? Answers to Your Questions about the Cancer-Causing Chemical*, Union of Concerned Scientists (Oct. 6, 2022), https://bit.ly/3Ya69hN.

[8] *Ethylene Oxide*, *supra* note 7 at 2.

[9] See *Ethylene Oxide*, National Cancer Institute (June 10, 2024) www.cancer.gov/about-cancer/causes-prevention/risk/substances/ethylene-oxide. According to the EPA, there is no indication of risk from soil or water pollution, or from consumer use of products made with or sterilized with EtO. See *What is EtO? What are the Risks?*, 1, Environmental Protection Agency (Nov. 2023) www.epa.gov/system/files/documents/2023-11/final-virtual-eto-2-pager-mb.mn-changes-incorporated-v10-002.pdf

[10] *Invisible Threat, Inequitable Impact*, *supra* note 6.

[11] *Our Current Understanding of Ethylene Oxide (EtO)*, United States Environmental Protection Agency (Apr. 3, 2024), www.epa.gov/hazardous-air-pollutants-ethylene-oxide/our-current-understanding-ethylene-oxide-eto

[12] *Invisible Threat, Inequitable Impact*, *supra* note 6.

[13] *Id.* (information generated from *AirToxScreen*, Environmental Protection Agency, 2022. "AirToxScreen Mapping Tool (based on 2018 emissions)")

[14] *Id.*

[15] *See Invisible Threat, Inequitable Impact*, *supra* note 6, at Table 2. Environmental Injustice of Commercial Sterilizers and MON-related EtO Emissions www.ucsusa.org/sites/default/files/2023-02/table-2_0.pdf

risks of 100 in one million or greater are located in census block groups that are at least 50 percent people of color or low-income households.[16]

EPA's History of Regulating Ethylene Oxide

In 1990, Congress amended Section 112 of the Clean Air Act to authorize EPA to regulate hazardous air pollutants (HAPs)[17] — pollutants that are known or suspected to cause cancer or other serious health effects, or adverse environmental effects.[18] Sections 112(d)(2) and 112(d)(3) require EPA to establish emissions standards for HAPs that reflect "the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts)."[19] EPA currently regulates the emissions of 188 HAPs from major and minor sources across 28 source categories that emit, or have the potential to emit, these toxic pollutants.[20] After EPA establishes an emission standard for a HAP generated from a particular source, EPA must "review, and revise as necessary (taking into account developments in practices, processes, and control technologies), emission standards . . . no less often than every 8 years."[21]

In 1994, EPA established EtO emissions standards for commercial sterilizer facilities and fumigation operations.[22] Notably, the rule only set emissions standards for three sources: (1) sterilization chamber vents (SCVs) — the vent through which EtO emissions flow following sterilization of the device or materials,[23] (2) aeration room vents (ARVs) — a room where sterilized products go to off-gas EtO,[24] and (3) chamber exhaust vents (CEVs) — a vent to prevent exposing workers to EtO when they open SCVs to transfer sterilized products.[25] As part of these standards, commercial sterilizers and fumigator facilities using between one and 10 tons of EtO and facilities

[16] Bao Chuong, et. al, *EPA Should Conduct New Residual Risk and Technology Reviews for Chloroprene and Ethylene Oxide-Emitting Source Categories to Protect Human Health Report No. 21-P-0129*, 25, United States Environmental Protection Agency Office of the Inspector General (May 6, 2021) www.epa.gov/sites/default/files/2021-05/documents/_epaoig_20210506-21-p-0129.pdf
[17] 42 U.S.C. § 7412(d).
[18] *What are Hazardous Air Pollutants?*, United States Environmental Protection Agency (Dec. 7, 2023) www.epa.gov/haps/what-are-hazardous-air-pollutants
[19] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations, 84 Fed. Reg. 67889, 67892 (advance notice of proposed rulemaking Dec. 12, 2019)
[20] *Clean Air Act Overview,* Environmental Compliance Information for Energy Extraction (accessed 4/2/24) www.eciee.org/caa-gt.php
[21] 42 U.S.C. § 7412(d)(6)
[22] *See* National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations, 59 Fed. Reg. 29823 (Dec. 6, 1994) (codified at 40 C.F.R. pts 9 and 63).
[23] *Presentation for State, Local, and Tribal Air Agencies – Ethylene Oxide Commercial Sterilizers: Clean Air Act National Emission Standards for Hazardous Air Pollutants (NESHAP)*, United States Environmental Protection Agency, 6, (May 12, 2022) www.4cleanair.org/wp-content/uploads/EtO-Sterilizer-National-Webinar-for-SLTs-Part-2_May-12-2022_FINAL_.pdf
[24] *Id.*
[25] *Presentation for State, Local, and Tribal Air Agencies*, *supra* note 23 at 7; CEV standards were eliminated in 2001 due to safety concerns (*See* Ethylene Oxide Emissions Standards for Sterilization Facilities, 66 Fed. Reg. 55577, 55577 (Nov. 2, 2001) (codified at 40 CFR Part 63).

using more than 10 tons of EtO were required to reduce their emissions by 99% from each sterilization chamber vent.[26] Facilities using 10 tons or more were also required to reduce EtO emissions from ARVs to either a maximum concentration of one part per million by volume (ppmv) or a 99 percent reduction, whichever is less stringent.[27] Initially, commercial sterilizers emitting more EtO were also required to reduce emissions from CEVs.[28] However, those standards were eliminated in 2001 due to safety concerns.[29] No reductions were required for facilities emitting less than one ton of EtO,[30] but those facilities were required to keep records of EtO emissions.[31] [See Table 1 in the Appendix].

Notably, the 1994 rule did not impose any standards or regulatory requirements to limit fugitive emissions,[32] and the monitoring requirements focused strictly on the performance of the emissions control technology in the chamber vents.[33] No requirements were established to monitor overall emissions by facilities into the neighboring environment.

Despite the 1994 EtO rule's limited scope and new science on the adverse health effects of EtO,[34] in 2006, as part of the required review and revision under the CAA,[35] EPA decided not to revise the rule for EtO emissions from commercial sterilization facilities.[36] EPA stated that "further control requirements would achieve, at best, minimal emission and risk reductions at a very high cost."[37]

Ten years later, in 2016, EPA updated the Integrated Risk Information System (IRIS) value associated with EtO, increasing the unit risk estimate for EtO by nearly 60 times.[38] In 2018, EPA

[26] *Id.* Table 1 of § 63.362
[27] National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations, 59 Fed. Reg. 29823, 63.362(d) (Dec. 6, 1994) (codified at 40 C.F.R. pts 9 and 63).
[28] *Presentation for State, Local, and Tribal Air Agencies*, *supra* note 23 at 7; CEV standards were eliminated in 2001 due to safety concerns (*See* Ethylene Oxide Emissions Standards for Sterilization Facilities, 66 Fed. Reg. 55577, 55577 (Nov. 2, 2001) (codified at 40 CFR Part 63).
[29] *See* Ethylene Oxide Emissions Standards for Sterilization Facilities, 66 Fed. Reg. 55577, 55577 (Nov. 2, 2001) (codified at 40 CFR Part 63).
[30] National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations, 59 Fed. Reg. 29823, Table 1 of § 63.362, (Dec. 6, 1994) (codified at 40 C.F.R. pts 9 and 63).
[31] *Id.* § 63.367 Recordkeeping requirements
[32] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations, 84 Fed. Reg. 67889, 67892, (advance notice of proposed rulemaking Dec. 12, 2019) (codified at 40 CFR Part 63)
[33] National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations, 59 Fed. Reg. 29823, § 63.364 (Dec. 6, 1994) (codified at 40 C.F.R. pts 9 and 63).
[34] Ethylene Oxide Emissions Standards for Sterilization Facilities, 71 Fed. Reg. 17712, 17715 (Apr. 7, 2006) (codified at 40 C.F.R. pt 63)
[35] Four years after § 112(d)(6) mandated that the standard be reviewed
[36] Ethylene Oxide Emissions Standards for Sterilization Facilities, 71 Fed. Reg. 17712, 17712 (Apr. 7, 2006) (codified at 40 C.F.R. pt 63)
[37] *Id.* at 17713
[38] U.S. EPA. Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (2016 Interagency Science Discussion Draft). U.S. Environmental Protection Agency, Washington, DC, EPA/635/R-16/284a-b, 2016.

released its National Air Toxics Assessment which "identified EtO emissions as a potential concern in several areas across the country" and estimated that "EtO significantly contributes to potential elevated cancer risks in some census tracts across the U.S."[39] In 2019, EPA published an advance notice of proposed rulemaking and solicited information to support future revisions to EtO emission standards for commercial sterilization facilities.[40] EPA issued two more information collection requests in June of 2020[41] and May of 2021.[42] In April 2023, EPA proposed new EtO emissions standards for sterilization facilities,[43] and finalized those standards on April 5, 2024, discussed in detail below.[44]

Notably, on April 9, 2024, EPA also finalized EtO emissions standards for the synthetic organic chemical manufacturing industry and the polymers and resins industries.[45] While not covered in this overview, EPA stated that, if implemented, those standards will further reduce the emissions of both EtO and chloroprene – another toxic air pollutant, and "dramatically reduce lifetime air toxics-related cancer risks for people living in communities near chemical plants that emit EtO and chloroprene."[46]

Overview of EPA's 2024 final rule setting EtO emissions standards for chemical sterilizers

The 2024 EtO final rule for sterilization facilities takes several important steps to reduce EtO emissions, improve monitoring, and improve the health and safety of nearby communities. The rule applies to 88 sterilization facilities that are currently operating as well as two planned facilities.[47] Under the final rule, existing facilities are required to comply by April 2026 or April 2027, depending on the applicable standard and the extent of technical changes required for facilities to be in compliance. EPA estimated that once fully implemented, the final rule will reduce annual

[39] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations, 84 Fed. Reg. 67889, 67893 (advance notice of proposed rulemaking Dec. 12, 2019) (codified at 40 CFR Part 63)
[40] *Id.* at 67889
[41] Proposed Information Collection Request; Comment Request; Information Collection; Effort for Ethylene Oxide Commercial Sterilization Facilities, 85 Fed. Reg. 35931 (notice Jun. 12, 2020).
[42] Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Ethylene Oxide Commercial Sterilization Facilities National Emission Standards for Hazardous Air Pollutants (NESHAP) Technology Review, 86 Fed. Reg. 24862 (notice May 10, 2021).
[43] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 88 Fed. Reg. 22,790 (proposed Apr. 13, 2023).
[44] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 89 Fed. Reg. 24090 (Apr. 5, 2024) (codified at 40 C.F.R. pts. 60, 63).
[45] *Final Rule to Strengthen Standards for Synthetic Organic Chemical Plants and Polymers and Resins Plants*, Environmental Protection Agency (May 16, 2024), www.epa.gov/hazardous-air-pollutants-ethylene-oxide/final-rule-strengthen-standards-synthetic-organic-chemical
[46] *Factsheet: EPA Issues Final Rule to Reduce Toxic Air Pollutants on from the Synthetic Organic Chemical Manufacturing Industry and the Polymers and Resins Industries*, Environmental Protection Agency www.epa.gov/system/files/documents/2024-04/chem-sector-final-rule.-overview-fact-sheet_0.pdf
[47] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 89 Fed. Reg. 24090, 24094 (Apr. 5, 2024) (codified at 40 C.F.R. pts. 60, 63).

nationwide EtO emissions from commercial sterilizers by 90%.[48] According to EPA, "under the final rule, no individual will be exposed to EtO at levels that correspond to a lifetime cancer risk of greater than 100-in-1 million, and the number of people with a potential risk of greater than or equal to 1-in-1 million will be reduced by approximately 92 percent."[49]

The final rule also requires continuous emissions monitoring and quarterly reporting for most commercial sterilizers, enabling EPA to "ensure EtO emissions are controlled and not entering the outdoor air before being captured and controlled."[50]

To achieve these EtO emissions reductions, the 2024 rule makes five changes: (1) regulating fugitive EtO emissions from chemical sterilizers for the first time; (2) imposing more stringent emissions standards for larger facilities; (3) expanding the sources of emissions that are covered, and the stringency of those standards; (4) setting emissions standards for facilities emitting lower levels of EtO; and (5) imposing continuous monitoring requirements. These changes are summarized below.

1. The 2024 final rule addresses fugitive EtO emissions for the first time

For the first time, the 2024 EtO final rule requires commercial sterilization facilities to reduce fugitive EtO emissions. The rule establishes two types of fugitive, or "room air emissions," called Group 1 and Group 2. Group 1 room air emissions are "emissions from indoor EtO storage, EtO dispensing, vacuum pump operations, and pre-aeration handling of sterilized material."[51] Group 2 room air emissions are "emissions from post-aeration handling of sterilized material."[52] For each group, the rule establishes emissions standards based on the amount of EtO that facilities use per year and whether it is a new or existing facility. The required emissions reductions are outlined in Table 2 in the Appendix.

As fugitive emissions are the primary source of EtO emissions that were left unaddressed by the 1994 EtO rule, this improvement is perhaps the most significant step that the 2024 rule takes to reduce emissions and improve community health.

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[48] *Factsheet: Final Amendments to Air Toxics Standards for Ethylene Oxide Commercial Sterilization Facilities*, Environmental Protection Agency, 1, www.epa.gov/system/files/documents/2024-03/factsheet_etosterilizers_final_3-14-24.pdf

[49] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 89 Fed. Reg. 24095 (Apr. 5, 2024) (codified at 40 C.F.R. pts. 60, 63).

[50] *Factsheet: Final Amendments to Air Toxics Standards for Ethylene Oxide Commercial Sterilization Facilities*, *supra* note 48 at 1.

[51] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 89 Fed. Reg. 24095, 24099 (Apr. 5, 2024) (codified at 40 C.F.R. pts. 60, 63).

[52] *Id.*

2. The 2024 rule imposes more stringent emissions standards for larger facilities.

The 2024 final rule also increases the number of distinctions among sterilization facilities and the stringency of EtO emissions standards for larger facilities. For example, both new and existing facilities that use at least 30 tpy (tons per year) are required to reduce EtO emissions from SCVs and ARVs by 99.99%. More stringent emissions standards also apply to CEVs at major and area source facilities based on the amount of EtO used.[53] These increased standards for larger facilities are an important step to ensure that the most harmful facilities are taking additional steps to mitigate their emissions of EtO into neighboring communities. More details on how the new rule increases emissions stringency for larger facilities can be found in Table 3 in the Appendix.

3. The 2024 rule covers more sources of EtO emissions and increases the stringency of EtO emissions standards.

In 2001, EPA removed the 1994 rule's EtO emissions standards for CEVs due to safety concerns.[54] Similarly, the 1994 rule did not set emissions standards for the ACVs of commercial sterilizers that had lower levels of EtO emissions. Under the 2024 rule, all commercial sterilization facilities have emissions standards for EtO emitted from ACVs and CEVs. Requirements for reductions differ depending on the amount of EtO the facility emits. More details on new emissions standards for CEVs and ACVs can be found in Table 3.

4. The 2024 rule imposes new emissions standards for smaller sources of EtO.

The 2024 EtO rule includes, for the first time, EtO emissions standards for facilities that emit less than 1 tpy. Under the 1994 and 2006 EtO rules, these sources were only subject to reporting and recordkeeping requirements. The 2024 rule requires both new and existing sterilization facilities that use less than 1 tpy of EtO to reduce EtO emissions from SCVs and ARVs by 99%.[55] The 2024 rule also regulates ARVs at facilities where EtO usage is at least 1 tpy but less than 10 tpy. More details on emissions standards for facilities emitting lower levels of EtO can be found in Table 3.

5. The 2024 rule imposes continuous emissions monitoring requirements.

The 2024 rule requires all facilities with annual EtO usage of 100 pounds per year or greater to demonstrate compliance by monitoring EtO using a continuing emissions monitoring system (CEMS). Data from the CEMS must be reported to the EPA at least quarterly.[56]

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[53] *Id.* at 24,093–94 (Translated from Table 1 — Summary of Standards After Taking Actions Pursuant to CAA Sections 112(d)(2), 112(d)(3), 112(d)(5), 112(f)(2), and 112(d)(6))

[54] Regulatory Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations, EPA 1–5 (March 2024), https://www.epa.gov/system/files/documents/2024-03/final-ethylene-oxide-commercial-sterilization-neshap-ria.pdf.

[55] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 89 Fed. Reg. 24095, 24099 (Apr. 5, 2024) (codified at 40 C.F.R. pts. 60, 63).

[56] *Id.*

Implementation, Litigation and Exemptions

The 2024 rule went into effect for all new facilities in April 2024 and requires existing facilities to comply with most provisions by April 2026. Existing facilities have until April 2027 to comply with standards that require more significant facility redesigns and/or installation of more substantial equipment.[57]

Following the promulgation of the 2024 rule, two groups, led by the California Communities Against Toxics and the Ethylene Oxide Sterilization Association, submitted petitions for review to the D.C. Circuit. Litigation is held in abeyance while EPA reconsiders the rule.[58] EPA "anticipates" that reconsideration of the rule will result in further rulemaking to revise or rescind the rule.[59]

In March 2025, the Trump administration announced a process to provide a presidential exemption from nine Biden EPA Clean Air Act regulations, including this rule.[60] Clean Air Act section 112(i)(4) permits a president to exempt a stationary source from compliance with a Clean Air Act standard for two years if the president finds that the technology to comply is not available and it is in the national security interest of the United States to provide an exemption.[61] The American Chemistry Council & American Fuel & Petrochemical Manufacturers requested an exemption for all member companies.[62]

EELP will continue to monitor the rule's implementation, exemptions, and related litigation on our Regulatory Tracker.

[57] *Id.* at 24102, 24187.
[58] *Ethylene Oxide Sterilization Association, Inc. v. EPA*, et al, Docket No. 24-01180 (D.C. Cir. Jun 04, 2024).
[59] EPA's Mot. for Voluntary Remand and Renewed Mot. to Hold Case in Abeyance, *Ethylene Oxide Sterilization Association, Inc. v. EPA*, et al, Docket No. 24-01180, 4-5 (D.C. Cir. Mar. 25, 2025).
[60] *Clean Air Act Section 112 Presidential Exemption Information*, EPA (Mar. 24, 2025), https://www.epa.gov/stationary-sources-air-pollution/clean-air-act-section-112-presidential-exemption-information?source=email
[61] 42 U.S.C. § 7412(i)(4).
[62] Letter from Brendan Mascarenhas, Senior Dir. Am. Chem. Council & Leslie Bellas, Vice President, Am. Fuel & Petrochem. Mfr., *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*, (Mar. 31, 2025), https://www.edf.org/media/new-analysis-shows-extensive-number-facilities-across-us-could-get-trump-epa-pollution-pass.

Appendix 1

Table 1: EtO Standards for Commercial Sterilizers prior to 2024 rule

Existing and New Sources Subcategory (in any consecutive 12-month period)[i]	Sterilization chamber vent (SCV)	Aeration room vent (ARV)	Chamber exhaust vent (CEV)[ii]
Sources using 10 tons or more of EtO	99 percent emission reduction (see 40 CFR 63.362(c)).	1 part per million (ppm) maximum outlet concentration or 99 percent emission reduction, whichever is less stringent (see 40 CFR 63.362(d)).	No control.
Sources using 1 ton or more of EtO but less than 10 tons of EtO.	99 percent emission reduction (see 40 CFR 63.362(c)).	No control.	No control.
Sources using less than 1 ton of EtO	No control required; minimal recordkeeping requirements apply (see 40 CFR 63.367(c)).	No control required; minimal recordkeeping requirements apply (see 40 CFR 63.367(c))	No control required; minimal recordkeeping requirements apply (see 40 CFR 63.367(c))

[i] Determined on a rolling 12-month basis.
[ii] The CEV emission source was included in the original standard but was later eliminated from the 40 CFR part 63, subpart O, regulation in 2001.

Table 2: Emissions reduction requirements for fugitive EtO emissions under the 2024 rule

Emissions source[63]	New or existing	EtO Use	Emissions Standard	Existing Facility Compliance Date[64] [65]	New Facility Compliance Date[66] [67]
Group 1 Room Air Emissions					
Major sources*	Existing and New	No required output	97% reduction	April 5, 2027	April 5, 2024 (or upon startup)
Area sources**	Existing and New	≥40 tons per year (tpy)	98% reduction	April 6, 2026	
		<40 tpy	80% reduction	April 5, 2027	
Group 2 Room Air Emissions					
Major sources	Existing and New	No required output	86% reduction	April 5, 2027	N/A
Area sources	Existing	≥20 tpy	98% reduction	April 6, 2026	N/A
		≥4 tpy but <20 tpy	80% reduction	April 6, 2026	
		<4 tpy	Reduce EtO in each chamber to 1 ppm before opening chamber.	April 5, 2027	
	New	≥20 tpy	98% reduction	N/A	April 5, 2024 (or upon startup)
		<20 tpy	80% reduction		

[63] *Id.* at 24093-94 (Translated from Table 1 — Summary of Standards After Taking Actions Pursuant to CAA Sections 112(d)(2), 112(d)(3), 112(d)(5), 112(f)(2), and 112(d)(6))
[64] *Id.* at 24194 (Translated from Table 4 to Subpart O of Part 63 — Standards for Group 1 Room Air Emissions)
[65] *Id.* at 24195 (Translated from Table 5 to Subpart O of Part 63 — Standards for Group 2 Room Air Emissions)
[66] *Id.* at 24194 (Translated from Table 4 to Subpart O of Part 63 — Standards for Group 1 Room Air Emissions)
[67] *Id.* at 24195 (Translated from Table 5 to Subpart O of Part 63 — Standards for Group 2 Room Air Emissions)

Table 3: New emissions reduction requirements for EtO from SCVs, ARVs, and CEVs

Emissions source[68]	New or existing	EtO Use (tpy)	Emissions Standard	Existing Facility Compliance Date[69] [70] [71]	New Facility Compliance Date[72] [73] [74]
SCV	Existing and New	≥ 30 tpy	99.99% reduction	April 6, 2026	April 5, 2024 (or upon startup)
		≥10 tpy but <30 tpy	99.99% reduction	April 6, 2026	April 5, 2024 (or upon startup)
		≥1 tpy but <10 tpy	99.98% reduction	April 6, 2026	April 5, 2024 (or upon startup)
		< 1 tpy	99% reduction	April 5, 2027	April 5, 2024 (or upon startup)
ARV	Existing	≥ 30 tpy	99.90% reduction	April 6, 2026	N/A
		≥10 tpy but <30 tpy	99.60% reduction	April 6, 2026	N/A
		≥1 tpy but <10 tpy	99% reduction	April 6, 2026	N/A
		< 1 tpy	99% reduction	April 5, 2027	N/A
	New	≥ 30 tpy	99.90% reduction	N/A	April 5, 2024 (or upon startup)
		≥ 10 tpy	99.90% reduction	N/A	April 5, 2024 (or upon startup)

[68] *Id.* at 24093-94 (Translated from Table 1 — Summary of Standards After Taking Actions Pursuant to CAA Sections 112(d)(2), 112(d)(3), 112(d)(5), 112(f)(2), and 112(d)(6))
[69] *Id.* at 24192-93 (Translated from Table 1 to Subpart O of Part 63 — Standards for SCVs)
[70] *Id.* at 24193 (Translated from Table 2 to Subpart O of Part 63 — Standards for ARVs)
[71] *Id.* (Translated from Table 3 to Subpart O of Part 63 — Standards for CEVs)
[72] *Id.* at 24192-93 (Translated from Table 1 to Subpart O of Part 63 — Standards for SCVs)
[73] *Id.* at 24193 (Translated from Table 2 to Subpart O of Part 63 — Standards for ARVs)
[74] *Id.* (Translated from Table 3 to Subpart O of Part 63 — Standards for CEVs)

Emissions source[68]	New or existing	EtO Use (tpy)	Emissions Standard	Existing Facility Compliance Date[69 70 71]	New Facility Compliance Date[72 73 74]
		≥1 tpy but <10 tpy	99% reduction	N/A	April 5, 2024 (or upon startup)
		< 1 tpy	99% reduction	N/A	April 5, 2024 (or upon startup)
CEVs at major sources	Existing and new	N/A	99.94% reduction	April 5, 2027	April 5, 2024 (or upon startup)
CEVs at area sources	Existing and new	≥400 tpy	99.94% reduction	April 6, 2026	April 5, 2024 (or upon startup)
		≥60 tpy by <400 tpy	99.90% reduction	April 6, 2026	April 5, 2024 (or upon startup)
		<60 tpy	99% reduction	April 5, 207	April 5, 2024 (or upon startup)