EPA Proposed Rescinding Ethylene Oxide Emissions Standards for Commercial Sterilizers

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On March 17, 2026, EPA proposed rescinding several ethylene oxide (EtO) emissions standards for commercial sterilizers it finalized in 2024.[1]

EtO is a flammable, colorless gas used to sterilize medical devices and some foods.[2] It is a potent carcinogen when inhaled.[3] Communities living near commercial sterilization facilities that use EtO, which are disproportionately low-income and communities of color, have suffered from a significantly higher rate of cancer than the rest of the country.[4] As explained in EELP's full analysis, EPA updated EtO emissions standards in 2024 for commercial sterilizers by tightening standards for large sterilization facilities, requiring continuous emissions monitoring systems, and regulating fugitive emissions for the first time. EPA projected that, if implemented, the 2024 Rule would reduce annual EtO emissions from commercial sterilizers by 90 percent.[5]

EPA now proposes to rescind several aspects of the 2024 Rule, asserting that the rule relied on misinterpretations of law, unreliable data, and faulty analyses. In this quick take, I explain EPA's four main rescissions and their asserted legal bases.

EPA's proposed rule would rescind all risk-based standards set by the 2024 Rule

EPA first proposes rescinding all "risk-based standards promulgated in 2024" pursuant to Clean Air Act (CAA) section 112(f)(2).[6] EPA offers two independent bases for this action: (1) section 112(f)(2) does not allow the agency to perform discretionary risk reviews such as the one that underpins the 2024 rule's risk-based standards, and (2) EPA should not have relied on the 2016 EtO Integrated Risk Information System (IRIS) value when setting the 2024 Rule's risk-based standards.

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[1] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review Reconsideration, 91 Fed. Reg. 12700, 12706 (March 17, 2026). EPA will accept public comments on its proposed rule until May 1, 2026.
[2] 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.
[3] *Id.*
[4] *Id.*
[5] EPA, *Final Amendments to Air Toxics Standards for Ethylene Oxide Commercial Sterilization Facilities Fact Sheet* (last visited April 15, 2026), https://www.epa.gov/system/files/documents/2024-03/factsheet_etosterilizers_final_3-14-24.pdf.
[6] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review Reconsideration, 91 Fed. Reg. 12700, 12712 (March 17, 2026).

EPA now asserts that CAA section 112(f)(2) permits only one residual risk review

Under CAA section 112, EPA sets technology- and risk-based emissions standards for regulated source categories using a two-phase process. First, the agency sets technology-based standards for a regulated source category. These standards "reflect application of the maximum achievable control technology (MACT) and are based on emissions levels that are already being achieved by the best-controlled and lower-emitting sources in an industry."[7]

Second, within eight years of first setting MACT standards, EPA must (1) conduct a "residual risk review" to determine whether stricter risk-based standards are needed to protect public health with an ample margin of safety, and (2) perform a "technology review" to determine whether advances in emission reduction technology warrant updating the MACT standards. The CAA requires EPA to repeat the technology review and update the MACT standards at least every eight years, and it requires EPA to complete the residual risk review within eight years of first promulgating the MACT standards.[8]

When developing the 2024 Rule, EPA completed a second residual risk review for EtO emissions from commercial sterilizers. The 2024 Rule states that while section 112(f)(2) "requires only a one-time risk review," the provision does not "limit [the agency's] discretion or authority" to conduct additional risk reviews if the agency finds them warranted.[9] EPA determined that a second residual risk review was warranted because a 2016 EPA toxicological assessment for EtO indicated that the "IRIS cancer unit risk estimate for EtO" was "approximately 60 times greater" than the value EPA used for its first residual risk assessment in 2006.[10] Based on this new information, EPA's 2024 Rule set new risk-based EtO emissions standards for larger commercial facilities that were more stringent than the technology-based standards it set for smaller facilities.[11]

In the 2026 Proposed Rule, EPA asserts that its 2024 approach violated CAA section 112(f)(2) because that section does not allow EPA to conduct discretionary risk reviews.[12] EPA claims this "limitation on authority" must be inferred from section 112's language and structure. As EPA notes, CAA section 112(d) expressly requires EPA to revisit its technology-based standards at least every eight years, but "CAA section 112(f) sets out a *one-time* obligation and authority to conduct a risk review for each source category."[13] From this, EPA

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[7] EPA, *Final Amendments to Air Toxics Standards for Ethylene Oxide Commercial Sterilization Facilities Fact Sheet* (last visited April 14, 2026), https://www.epa.gov/system/files/documents/2024-03/factsheet_etosterilizers_final_3-14-24.pdf.

[8] *See* 42 U.S.C. § 7412(d)(6) (requiring the EPA to review and revise technology-based standards "no less often than every 8 years"); *Id.* § 7412(f)(2)(A) (requiring EPA to perform set risk-based standards within eight years of first setting technology-based standards).

[9] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 89 Fed. Reg. 24090, 24093 (April 5, 2024).

[10] *Id.*

[11] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review Reconsideration, 91 Fed. Reg. 12700, 12707-12708 (March 17, 2026) (cataloging the emissions standards set by the 2024 Rule and each standard's statutory basis).

[12] *Id.* at 12712-12715.

[13] *Id.* at 12712 (emphasis added).

argues that "one can infer that Congress did not authorize multiple risk reviews under section 112(f)(2)."[14] EPA further asserts that "allow[ing] more than one residual risk review . . . long after the statutory deadline . . . 'would effectively gut Congress's carefully articulated existing system'" for setting hazardous air pollutant (HAP) standards.[15] Accordingly, EPA asserts, it must rescind these risk-based standards.

If finalized (and courts agree in any challenge that follows), EPA's new interpretation of section 112(f)(2) would not just invalidate the risk-based standards of the 2024 Rule but would also bar the agency from conducting discretionary risk reviews on any HAP after it completes the one mandatory residual risk review, even if new toxicological data emerges.

EPA states that the 2016 EtO IRIS value was an unreliable basis for regulation

In the alternative, EPA proposes rescinding the 2024 Rule's risk-based standards because they relied on the agency's 2016 IRIS value for EtO's cancer risk.[16] EPA states that the 2016 IRIS value suffers from "significant uncertainties," justifying repeal of the risk-based standards for two main reasons. First, EPA states the 2016 EtO IRIS value was calculated using a dose-response model and statistical upper confidence limit that was overly conservative.[17] Second, EPA states that new scientific evidence that emerged since 2016 "could change the EPA's understanding of EtO's carcinogenic potency."[18]

Notably, EPA successfully defended its use of the 2016 EtO IRIS value in the D.C. Circuit in 2024 after industry groups challenged "numerous technical decisions" underlying the IRIS value, including the choice of model and the epidemiological studies and exposure data that supported it.[19] EPA now distances itself from this case by asserting that the agency has consistently acknowledged "significant uncertainties . . . regarding the magnitude of EtO's carcinogenic potency" and that "[s]ince the EPA defended the use of the 2016 EtO IRIS value . . . new scientific evidence has continued to emerge" that justifies revisiting its toxicological assessment.[20]

EPA's proposed rule would relax the more stringent technology-based standards that apply to new aeration room vents at larger-emitting facilities

For sterilization facilities that use at least 10 tons of EtO per year, the 2024 Rule set different technology-based emission standards for existing and new aeration room vents

[14] *Id.* at 12712-13.
[15] *Id.* at 12713 (citing *Loving v. I.R.S.*, 742 F.3d 1013, 1020 (D.C. Cir. 2014)).
[16] *Id.* at 12714-15.
[17] *Id.* at 12714 (suggesting that a different dose-response model and statistical upper confidence limit could have resulted in an EtO IRIS value up to "five times safer than the 2016 EtO IRIS value provided[.]")
[18] *Id.* at 12715.
[19] *See id.* at 12714-15 (citing *Huntsman Petrochemical LLC v. EPA*, 114 F.4th 727 (D.C. Cir. 2024)) (noting the agency defended the 2016 IRIS value from challenges to numerous technical decisions "including but not limited to, model selection and choice of underlying epidemiological studies and exposure estimates.").
[20] *Id.*

(ARVs). The 2024 Rule requires existing ARVs in this category to achieve a 99.6 percent reduction in EtO emissions; new ARVs must achieve a 99.9 percent reduction.[21]

EPA now proposes to loosen the standard for new ARVs to 99.6 percent to match the standard for existing ARVs.[22] EPA states that this change will allow facilities that use both existing and new ARVs to "share infrastructure, streamline facility operations, and reduce costs" — cost savings the agency asserts the 2024 Rule did not consider.[23]

EPA's proposed rule would rescind continuous emissions monitoring systems requirements

Facilities can monitor air pollutant emissions in several ways. In parametric monitoring, facilities measure emissions indirectly by tracking parameters that correlate with emissions, such as temperature, pressure, or flow rate.[24] Facilities using continuous emissions monitoring systems (CEMS), however, "measure[] *actual* emission levels from a stationary source."[25]

The 2024 Rule allows commercial sterilization facilities that use less than 100lb of EtO per year to use parametric monitoring to demonstrate compliance with EtO emissions standards. All other facilities have to use CEMS.[26] EPA explained in 2024 that "small amounts [of EtO] can have large risk impacts," and thus, "parametric monitoring alone will not be sensitive enough to detect very small fluctuations in EtO concentration."[27]

EPA now proposes to rescind the CEMS requirement and allow all facilities to choose "using either parametric monitoring and performance testing or CEMS to demonstrate compliance."[28] EPA proposes this recission "[b]ecause the EtO CEMS requirement was based on the results of [the] unauthorized second residual risk assessment and risk-based standards" that the agency now proposes to rescind (discussed above).[29]

EPA's proposed rule would rescind the requirement that facilities use permanent total enclosures to address fugitive EtO emissions

The 2024 Rule regulated fugitive EtO emissions (also called "room air emissions") from commercial sterilizers for the first time by requiring facilities to use permanent total enclosures (PTE) to comply with EtO emissions standards.[30] A PTE is a "permanently

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[21] *See id.* at 12710 (cataloging the standards set for ARVs in the 2024 Rule).
[22] *Id.* at 12716.
[23] *Id.*
[24] EPA, *Basic Information about Air Emissions Monitoring* (last updated July 9, 2025), available at https://perma.cc/QBD5-DEPV.
[25] *Id.* (emphasis added).
[26] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 89 Fed. Reg. 24090, 24101 (April 5, 2024).
[27] *Id.*
[28] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review Reconsideration, 91 Fed. Reg. 12700, 12716 (March 17, 2026).
[29] *Id.*
[30] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 89 Fed. Reg. 24090, 24099-24100 (April 5,

installed enclosure that completely surrounds a source of emissions such that all VOC emissions are captured and contained for discharge to a control device."[31]

EPA now proposes to rescind the 2024 Rule's PTE requirements. EPA states that "whether PTE would be necessary to assure compliance with an emission standard could depend on a facility's design and configuration," and that "EPA has historically left such case-by-case reviews of facility design to the states to decide as part of their permitting process."[32] EPA thus proposes rescinding the nationwide PTE requirement and allowing state permitting authorities to require PTE for fugitive EtO emissions on a case-by-case basis.

In the alternative, EPA proposes rescinding the PTE requirements because: (1) the 2024 Rule "did not account for the impacts of facilities shutting down" due to the PTE requirement, or (2) EPA has discretion to remove the PTE requirement and believes it prudent to do so.[33]

Estimated Emission Implications of EPA's Proposed Actions

EPA estimates that, combined, its proposed rescissions will increase ethylene oxide emissions by 7.8 tons per year compared to the baseline set by the 2024 Rule.[34] EPA did not break down the impact of each of the four rescissions on annual EtO emissions. It did, however, provide a breakdown of how rescinding the risk-based standards, the PTE requirement, and the CEMS requirement will reduce engineering costs for affected facilities.[35] EPA also did not quantify the potential human health impacts caused by its proposed rescissions "[d]ue to methodological and data limitations."[36]

EPA will accept public comments on its proposed rule until May 1, 2026. EELP will continue to monitor the rule's implementation, exemptions, and related litigation in our Regulatory Tracker.

2024) ("[W]e are finalizing, as proposed, a requirement that facilities operate all areas with room air emissions subject to an emission standard in accordance with the PTE requirements of EPA Method 204, irrespective of which CAA section 112 authority is invoked.").

[31] EPA, *Method 204 – Criteria For and Verification Of a Permanent or Temporary Total Enclosure* at 1 (Jan. 14, 2019), https://www.epa.gov/sites/default/files/2019-06/documents/method_204_0.pdf.

[32] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review Reconsideration, 91 Fed. Reg. 12700, 12718 (March 17, 2026).

[33] *Id.*

[34] EPA, *Regulatory Impact Analysis for the Proposed Reconsideration of the 2024 National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations* at 10 (March 11, 2026), https://www.epa.gov/system/files/documents/2026-03/eto_commericial_sterilizers_proposal_ria_memo-2026-03.pdf.

[35] *Id.* at 6-10 (calculating the annual engineering cost savings that would result from its proposed rescissions).

[36] *Id.* at 10.