May 15, 2026

ELECTRONIC SUBMISSION

Attn: EPA-HQ-OAR-2019-0178

Brian Langloss
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20004

RE: National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review Reconsideration

Dear Mr. Langloss:

On March 17, 2026, the U.S. Environmental Protection Agency (EPA) published the proposed rule, "National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review Reconsideration"[1] (Proposed Rule). In it, EPA proposes to rescind its 2024 Final Rule establishing National Emissions Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide emissions from sterilization facilities,[2] and in addition proposes various technical corrections and clarifications. The comments were initially due on May 1, 2026, but EPA published an extension to allow a later deadline of two weeks later, on May 15, 2026.[3]

The 2024 Final Rule was not in accordance with the provisions of the Clean Air Act (CAA), and exceeded EPA's statutory authority. Moreover, the 2024 Final Rule represented terrible public policy, in undermining economically important U.S. medical supply chains for dubious, likely nonexistent benefits. Accordingly, we welcome this Proposed Rule, and are grateful for the opportunity to comment.

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[1] U.S. Environmental Protection Agency, "National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review Reconsideration," *Federal Register,* Vol. 91, No. 51 (March 17, 2026), p. 12,700.
[2] U.S. Environmental Protection Agency, "National Emissions Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review," *Federal Register,* Vol. 89, No. 67 (April 5, 2024), p. 24,090.
[3] U.S. Environmental Protection Agency, "National Emissions Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review Reconsideration; Extension of Comment Period," *Federal Register,* Vol. 91, No. 84 (May 1, 2026), p. 23,382.

Discussion

1) The 2024 Final Rule has Not Generated Reliance Interests to Prevent EPA from Adopting the Proposed Rule.

For the following reasons, there are no justifiable reliance interests on the part of any relevant parties that would prevent EPA from promulgating its Proposed Rule and rescinding the 2024 Final Rule.

First, leaving aside for a moment the statutory weaknesses underlying the 2024 Final Rule, that Final Rule relied extensively on EPA's 2016 Integrated Risk Information System (IRIS) assessment for Ethylene Oxide.[4] This IRIS assessment, by its nature, is a scientific finding. Unlike statutory authorities, which only update when Congress enacts new statutory amendments, scientific determinations are inherently subject to reconsideration and potential revision or revocation to the extent that the most current scientific understanding of the underlying matter evolves. As a result, it would be inappropriate for any party to view the 2024 Final Rule as a permanent, unchanging feature of the regulatory landscape.

In the decade since EPA published the 2016 IRIS assessment for ethylene oxide, more recent reports have criticized the assessment and raised questions about its methodology. In 2019, just three years after the publication of the assessment on which EPA relied, a peer-reviewed article appeared in the *International Journal of Environmental Research and Public Health*,[5] finding that the methodology that EPA used to estimate the cancer risk of ethylene oxide should be reexamined (attached as "Exhibit A"). A separate article, a systematic review of the scientific evidence of Ethylene Oxide as a human carcinogen, published three years later in 2022, which integrated epidemiological, animal, and mechanistic literature, suggested evidence of no association for all cancers at current human exposures (attached as "Exhibit B").[6]

These are merely two examples of academic articles published since 2016, which directly undercut the findings of EPA's 2016 IRIS assessment. It is a truism that scientific observations are continually updated to account for new evidence. As a result, it would simply be unjustifiable for any governmental or nongovernmental entity to assume that scientific findings, unlike underlying statutory authorities, will remain undisturbed indefinitely.

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[4] *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide*, December 2016, EPA/635/R-16/350Fc.
[5] Bogen, K.T.; Sheehan, P.J.; Valdez-Flores, C.; Li, A.A. Reevaluation of Historical Exposures to Ethylene Oxide Among U.S. Sterilization Workers in the National Institute of Occupational Safety and Health (NIOSH) Study Cohort. *Int. J. Environ. Res. Public Health* **2019**, *16*, 1738. https://doi.org/10.3390/ijerph16101738
[6] Heather N. Lynch, Jordan S. Kozal, Anthony J. Russell, William J. Thompson, Haley R. Divis, Rachel D. Freid, Edward J. Calabrese, Kenneth A. Mundt, Systematic review of the scientific evidence on ethylene oxide as a human carcinogen, *Chemico-Biological Interactions*, Volume 364, 2022, 110031, ISSN 0009-2797, https://doi.org/10.1016/j.cbi.2022.110031

Second, administrative agencies possess inherent authority to reconsider their previous decisions, within the bounds of the relevant enabling statute.[7] Indeed, the 2024 Final Rule itself represents a reversal from EPA's initial stance that the agency would not regulate Ethylene Oxide submissions from sterilizers of medical equipment. It would be odd, and would go against the entire spirit and purpose of reliance interests, for EPA to find or for anybody to argue that reliance interests first did not protect the expectation of the sterilizers to remain unregulated Section 112 of the CAA after 30 years of such treatment, only to then argue that reliance interests would require such regulations to remain in place, a mere two years after EPA reversed its 30-year stance. Provided that EPA acknowledges and explains the change in its position, as is being done here, gives commenters the opportunity to articulate any reliance interests in the prior position and addresses them, EPA is well within its discretion to reverse the interpretation that guided the 2024 Final Rule.[8]

Third, and relatedly, this Proposed Rule is a liberalizing measure, permissive rather than prescriptive in nature. Nobody will be required to change their behavior or their plans as a result of this rulemaking action. Moreover, the requirements of the 2024 Final Rule have never gone into effect. The compliance date was initially set for April of 2026,[9] but was extended out two years by Presidential Proclamation on national security grounds,[10] as authorized by Section 112(i)(4) of the CAA.[11] To the extent that any industry members have taken measures to comply with the requirements promulgated in the 2024 Final Rule, they would be free either to continue those measures or abandon them. Yet it would be nonsensical for any industry members, or anybody in the vicinity of any of the medical sterilization facilities in question, to claim reliance interests based on standards that never took effect.

This is particularly true given that the 2024 Final Rule has been subject to consolidated legal challenges in the U.S. Court of Appeals for the D.C. Circuit, making it unclear pending the outcome of litigation whether the rule could ever take effect, even if EPA ultimately makes the decision to retain the 2024 Final Rule.

In fact, in the long term this Proposed Rule would actually promote the reliance interests of the sterilizers, as well as the medical providers who rely on the sterilizers, and the patients who rely on those medical providers. Removing the sterilizers from these regulations, which

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[7] *See, e.g.*, *Spanish Int'l Broadcasting Co. v. FCC*, 385 F.2d 615, 621 (D.C. Cir. 1967); *Sierra Club v. Antwerp*, 560 F. Supp. 2d 21, 23 (D.D.C. 2008); *ConocoPhillips Co. v. EPA*, 612 F.3d 822, 832 (D.C. Cir. 2010).
[8] *See FDA v. Wages & White Lion Investments, LLC*, 604 U.S. 542 (2025); *Clean Air Council v. Pruitt*, 862 F.3d 1, 8 (D.C. Cir. 2017) ("Agencies obviously have broad discretion to reconsider a regulation at any time").
[9] 89 *Fed. Reg.* at 24,101-03.
[10] Proclamation 10,959, "Regulatory Relief for Certain Stationary Sources to Promote American Security with Respect to Sterile Medical Equipment," *Federal Register*, Vol. 90, No. 139 (July 17, 2025), p. 34,747.
[11] 42 U.S.C. 112(i)(4).

come with mandatory 8-year review periods for potential regulatory revision, would help protect the sterilizers against unanticipated regulatory change in future, thus allowing more stable expectations and behavior among participants in the market for medical devices that rely on these sterilization processes.

Fourth, the Government has discretion "to conclude that reliance interests it views as unlawful are entitled to no or diminished weight."[12] Given that EPA's reconsideration of the 2024 Final Rule is not motivated by a mere policy reversal, but by a reasoned determination that the 2024 Final Rule was actually unlawful, EPA has, if anything, enhanced discretion to discount reliance interests claimed on the 2024 Final Rule.

Fifth, in the 2024 Final Rule, EPA relied on a provision of the CAA that explicitly envisions that the resulting regulations would change. Specifically, EPA relied on language in Section 112(d)(6) of the CAA, requiring technology reviews no less than once every eight years.[13] As EPA noted in the Proposed Rule at hand, the 2024 Final Rule relied on an inappropriate blurring of Section 112's provisions requiring the risk review at the outset, and the recurring technology reviews afterward. Nonetheless, to the extent that any standards promulgated in the 2024 Final Rule are justified by this language, any stakeholder would be warned by the specific terms of the statute that the provisions are subject to regular change, at least every eight years but potentially more often.

Sixth, and finally, even when an agency "ultimately concludes that reliance interests rank as serious, they are but one factor to consider."[14] Balancing the totality of considerations, along with the factors that weigh against reliance as listed above, EPA should find that there are no reliance interests sufficient to bar the proposed rescission of the 2024 Final Rule.

2) <u>EPA is Correct to Rescind the 2024 Final Rule on the Proposed Grounds that the Discretionary Second Risk Review was Not Authorized by the CAA.</u>

Although EPA promulgated the 2024 Final Rule just over two years ago, the world of administrative law underwent seismic change in the intervening time. EPA issued the 2024 Final Rule on April 5th of 2024. At that time, courts still reviewed agency decisions under the review standard of *Chevron* deference, as they had for the previous 40 years. Specifically, under *Chevron* the courts deferred to agencies that made a "reasonable" or "permissible" choice when interpreting an ambiguous statute.[15] Effectively, this approach gave agencies broad discretion to

[12] *DHS v. Regents of the University of Cal.*, 591 U.S. 1, 32 (2020).
[13] 42 U.S.C. 7412(d)(6).
[14] *DHS v. Regents*, 591 U.S. at 32.
[15] *See Chevron U.S.A., Inc. v. Natural Resources Defense Counsel, Inc.*, 467 U.S. 837, 842-43 (1984).

select any preferred policy options when faced with statutory language that the agency deemed ambiguous.

Yet toward the end of June 2024, the Supreme Court replaced the *Chevron* standard, requiring instead that courts and agencies find and apply the "best reading" of the statute. As the Court found in *Loper Bright Enters. v. Raimondo*:

> "When the best reading of a statute is that it delegates discretionary authority to an agency, the role of the reviewing court under the APA is, as always, to independently interpret the statute and effectuate the will of Congress subject to constitutional limits. The court fulfills that role by recognizing constitutional delegations, fixing the boundaries of the delegated authority, and ensuring the agency has engaged in reasonable decisionmaking within those boundaries. By doing so, a court upholds the traditional concept of the judicial function that the APA adopts."[16]

This marked a dramatic departure from the *Chevron* approach that applied when EPA promulgated the 2024 Final Rule, less than three months previously. Instead of empowering agencies to choose any plausible policy option from the menu of possible interpretations of an ambiguous statute, *Loper Bright* requires agencies (and the courts that review agency determinations) to discern and apply the "single, best meaning"[17] of the statute. In so deciding, the Supreme Court gave new life to the Administrative Procedure Act (APA) and its sensible allocations of standards of review based on the comparative advantages of agencies and courts. Specifically, under *Loper Bright*, the Court recognized that courts are empowered to determine what the law is, whilst agencies are entitled to deference on questions of policy and factfinding.[18]

It is both responsible and correct for EPA to acknowledge the change that has occurred since the publication of the 2024 Final Rule, and to seek to apply this updated understanding of agency powers and discretion to its regulations, including the CAA regulations governing ethylene oxide.[19] Moreover, EPA's explanation of how the structure of Section 112 of the CAA informs its determination that the 2024 Final Rule exceeded EPA's statutory authority is both well-reasoned and persuasive, and we agree with EPA's analysis entirely. We only seek to bring further insights, based on the language of the statute and the regulatory history, to further reinforce EPA's Proposed analysis that the 2024 Final Rule indeed exceeded EPA's statutory authority, and that the Proposed Rule restores EPA to the correct path.

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[16] *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 395 (2024) (internal citations and quotations omitted).
[17] *Loper Bright*, 603 U.S. at 400.
[18] *Loper Bright*, 603 U.S. at 392.
[19] 91 Fed. Reg. at 12,703.

Section 112 of the CAA contains three separate review processes: first, to establish technology-based standards that reflect the maximum achievable control technology (MACT) or a reasonable alternative;[20] second, a risk review to determine within 8 years afterwards whether additional standards are needed to address any remaining risk (the risk review);[21] and third, to update any standards imposed as a result of the residual risk review, to "revise as necessary" in such a way as to account for "developments in practices, processes, and control technologies" (the technology review).[22] These are three separate statutory review processes, yet in establishing standards for sterilizers in the 2024 Final Rule, EPA improperly blurred the line between the risk and technology reviews. This is clear, not only from the structure of the statute, which EPA discussed at length in the Proposed Rule, but from the very language of these provisions.

EPA Inappropriately Revisited the Risk Review in the 2024 Final Rule

To begin with, the statutory language establishing the process for the technology review makes clear that this is a one-time review, set forth at the outset of the statutory process. Specifically, statutory section establishes, "The Administrator shall determine whether or not to promulgate such standards and, if the Administrator decides to promulgate such standards, shall promulgate the standards 8 years after promulgation of the standards under subsection (d) for each source category or subcategory concerned."[23]

This establishes a two-step process for the technology review. First, the Administrator (or EPA, effectively) makes the determination whether to set standards for the source category in question. Then, the eight-year review timeline applies, only if EPA actually promulgates standards under this section. Thus, the 8-year review is couched in conditional language, specifically that the 8-year review period only applies *if* EPA decides to set standards in the first place. In 2006, EPA carried on a Risk and Technology Review. For the residual risk review, EPA determined that the existing Maximum Available Control Technology (MACT) standards first implemented in 1994 protected health and public safety by reducing health risks below the levels that Section 112(f)(2) of the CAA required,[24] and concluded in the technology review that any further reductions "would achieve, at best, minimal emission and risk reductions at a very high cost."[25]

[20] 42 U.S.C. 7412(d)(1)-(3).
[21] 42 U.S.C. 7412(f)(2).
[22] 42 U.S.C. 7412(d)(6).
[23] 42 U.S.C. 7412(f)(2)(C).
[24] U.S. Environmental Protection Agency, "Ethylene Oxide Standards for Sterilization Facilities," *Federal Register*, Vol. 71, No. 67 (April 7, 2006), p. 17,712 at 17,713.
[25] 71 Fed. Reg. at 17,714.

Under the provisions of Section 112(f)(2), EPA thus made its determination under the residual risk review, and it was inappropriate for EPA to revisit that determination 20 years later. Nothing in this language envisions a process whereby EPA could choose to revisit its conclusions on the residual risk review, and to the extent that EPA unilaterally creates such a process, they would effectively undermine the finality for the potentially regulated industries, which Congress safeguarded with these timelines. In fact, the statute set a deadline for EPA to regulate all identified air pollutants, emitted by any covered source, within 10 years of the Act's effective date, or in other words, by November 15, 2000.[26]

In *Loper Bright*, the Department of Commerce (DoC) had interpreted Congressional silence as permission to charge regulated stakeholders for the costs of carrying Federal monitors aboard the regulated fishing boats. Congress had not authorized such charges to be passed on to the regulated fishing companies, but DoC decided that Congress's silence created an ambiguity, which DoC treated as allowing them to pass the cost on to the regulated businesses. In using this case as an opportunity to overturn *Chevron*, the Supreme Court made clear that such silence should not be interpreted as authorization absent, well, a clear authorization in the statute.

Given that EPA, in the 2024 Final Rule and in the 2023 Notice of Proposed Rulemaking that preceded it, used exactly such silence as its opportunity to revisit this determination, *Loper Bright* is directly on point here; such silence should not be interpreted as Congressional authorization, particularly where, as here, such an interpretation would go against the structure and language of the statute.

The Eight-Year Technology Review does Not Authorize EPA to Revisit Previous Determinations Not to Cover the Residual Risk in the First Place

The full language of the statutory provision establishing the technology review reads: "The Administrator shall review, and revise as necessary (taking into account developments in practices, processes, and control technologies), emission standards promulgated under this section no less often than every 8 years."[27]

In the context of the 2024 Final Rule, two major items jump out. Structurally, this provision is entirely separate from the residual risk review laid out in CAA Section 112(f)(2), which makes it odd for EPA to have used this timeline as an opportunity to review the 2006 residual risk determination. Moreover, this structural intuition is supported by the language of this provision. Specifically, this provision empowers EPA to revisit "emission standards promulgated under this section no less often than every 8 years." The provision does *not*, by its terms, empower EPA to determine a decision *not* to impose emission standards in the first place.

[26] 42 U.S.C. 7412(e)(1)(E).
[27] 42 U.S.C. 7412(d)(6).

Thus, in both cases, the language of the provisions in question confirm EPA's structural analysis as set forth in the Proposed Rule, namely, that the provisions of Section 112 of the CAA do not support EPA's decision, as explained in the 2024 Final Rule, to revisit the residual risk determination that the agency had made close to 20 years previously, and on which the entire ethylene oxide sterilization industry had come to rely.

11 and 13) The Permanent Total Enclosure Requirements in the 2024 Final Rule are Unduly Expensive and Prescriptive, and EPA is Correct to Propose Removal of this requirement.

EPA is correct to acknowledge in its proposed rule that the Permanent Total Enclosure (PTE) requirements in the 2024 Final Rule are unduly prescriptive, overly expensive, and infeasible, and is therefore correct to propose removal of the PTE requirements.

A simple overview of EPA's air pollution control technology fact sheet[28] for PTEs reveals how outdated EPA's study of PTEs in fact is. The references all date from 1997 to 2002, more than two decades ago now, and lists the application as "commonly used in flexographic printing, rotogravure printing, coating (paper, film, fabric, and metal), laminating, screen printing, can coating, and plastic card coating."[29] The cost estimates (expressed in 1997 dollars, so almost 30 years old) cover an enclosure with five pieces of equipment.[30]

These common applications reflect the origin of the PTE method, in the world of food (and especially candy) packaging and wrappers. Yet these facilities typically work at a much smaller scale than sterilizers of medical equipment, which typically use ethylene oxide over spaces that amount to tens of thousands of square feet, rather than single rooms with only five pieces of equipment. It is thus inappropriate for EPA simply to assume that a PTE method that works in the initial context would necessarily translate to sterilizers of medical equipment, without any further study.

Indeed, the difficulties, and even the unfeasibility, of mandating the PTE method in the context of medical sterilizers is well-documented. Many in the medical sterilizer industry have pointed out how the PTE method, in the context of food packaging, typically takes place in an area roughly the size of a living room, compared to the sterilizer facilities that span tens of thousands of square feet. Indeed, it has not even been proven that a PTE could successfully

[28] "Air Pollution Control Technology Fact Sheet: Permanent Total Enclosures (PTEs). EPA.gov. EPA-452/F-03-033. https://www.epa.gov/sites/default/files/2016-05/documents/fpte.pdf
[29] *Id.*
[30] *Id.*

reduce the emissions in a sterilizing facility, to the extent that EPA envisions. For an article discussing these issues at length,[31] please see "Exhibit C" in the attached.

Facilities that have considered the possibility of implementing these systems have found that, even where PTE might be technically possible, it would be prohibitively costly to implement, and at this point only hypothetical at the scale that EPA envisioned in 2024 for medical sterilizer facilities. In this context, it is worth reviewing a memorandum, from the South Coast Air Quality Management District, detailing the technical challenges inherent in applying PTE requirements to a local sterilizer facility, and recommending an exemption.[32] Implementing these requirements would at a minimum require a full redesign of existing facilities, accompanied by at least months of construction work, which would at a minimum disrupt existing supply chains for sterilizers of medial equipment. At worst, these requirements would effectively suffocate a truly essential industry, by imposing a prohibitively expensive compliance burden.

12) EPA's Interpretation of its Responsibilities, as Set Forth in the Proposed Rule, Fall Well Within the Scope of EPA's Discretion and Obligations as Laid Out by the D.C. Circuit in *Louisiana Environmental Action Network v. EPA*.[33]

The D.C. Circuit decision in *Louisiana Environmental Action Network (LEAN)* does not prevent EPA from promulgating the Proposed Rule. Any argument that *LEAN* somehow would foreclose EPA's action here would necessarily be undergirded by the same erroneously blurred distinction between CAA Sections 112(d) and (f), discussed above, which underlay the 2024 Final Rule. In fact, the D.C. Circuit was explicit in *LEAN*, that "[p]etitioners here do not challenge EPA's section 112(f)(2) risk assessment."[34] Thus, in *LEAN*, the D.C. Circuit went out of its way to recognize the distinction between the analysis under CAA Sections 112(d)(6) and (f)(2), and was explicit that the analysis within *LEAN* only applied to the technology assessment within Section 112(d)(6), and not to the risk assessment within section 112(f)(2).

In *LEAN*, EPA had already recognized that the pulp mills in question were sources of emissions for hazardous air emissions; the recognition of pulp mills as a source of such emissions was not in dispute. Rather, *LEAN's* analysis revolved around the fact that EPA had, even while recognizing pulp mills as regulated emissions sources, neglected to set limits for

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[31] Sadasivam, N., Younes, L., & Rosado Lebrón, J.A. (2024, August 22). Why the EPA is relying on uproven technology to stop cancer-causing emissions. *Grist.* https://grist.org/accountability/epa-ethylene-oxide-permanent-total-enclosure-pte-solution/

[32] S. Coast Air Quality Mgmt. Dist., Proposed Amended Rule 1405 – Control of Ethylene Oxide Emissions from Sterilization and Related Operations, Agenda No. 25 (Dec. 1, 2023), https://www.aqmd.gov/docs/default-source/Agendas/Governing-Board/2023/2023-dec1-025.pdf

[33] *Louisiana Environmental Action Network v. EPA*, 955 F.3d 1088 (D.C. Cir. 2020).

[34] *LEAN*, 955 F.3d at 1093.

hazardous air pollutants that Congress had explicitly listed in the statute to be regulated, and which EPA itself acknowledged a statutory responsibility to regulate, even while failing to do so.[35]

Here, the situation is exactly reversed. Nobody contests EPA's statutory obligation to regulate emissions of ethylene oxide. In the statute, Congress specifically listed ethylene oxide as a hazardous air pollutant that EPA is required to regulate under this program.[36] Unlike the hazardous pollutants in *LEAN*, EPA has been regulating ethylene oxide emissions as early as 1994.[37] However, EPA had already determined, in its 2006 rulemaking project, that sterilization facilities were not a significant source of ethylene oxide emissions. The relevant issue here is not whether EPA is required to promulgate regulations for the hazardous pollutants that Congress required EPA to regulate; EPA already has issued such regulations, and rescinding the 2024 Final Rule would not change that. Rather, the issue here is whether EPA is allowed to add new sources of pollutants, nearly 20 years after concluding that the source in question was not a major source of emissions for the pollutant in question, and nearly 25 years after the Congressional deadline for regulating such sources.

This distinction is further reflected in the language throughout *LEAN*, which consistently speaks of the pollutants being regulated, not the sources being regulated, which, as noted above, was not in dispute. Yet, given that the pollutants in question had been listed in the schedule of hazardous air pollutants that EPA was required to regulate, the intervenors in that case "[did] not deny that EPA has authority separately to promulgate new rules to set the missing emission limits for regulated sources."[38] EPA similarly accepted that they had the authority (and indeed, ultimately, the obligation) to do so. This is a very different posture from the situation at hand, where EPA likely does not even have that statutory discretion.

Given that the very problem with the 2024 Final Rule is the way in which it blurred the distinction between EPA's authorities under CAA Sections 112(d) and (f), it would be very odd for EPA to conclude that *LEAN* requires a certain result under Section 112(f), when the parties themselves specifically restricted their arguments to Section 112(d), and where the court itself took special pains to note that EPA's authorities under Section 112(f) were not part of the case.

Seeing the analysis in *LEAN* through this light further emphasizes the analytical errors that EPA made in justifying its promulgation of the 2024 Final Rule. In particular, it is not clear what relevance, if any, the 2016 IRIS assessment that EPA cited would have for its analysis

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[35] *See LEAN*, 955 F.3d at 1095.
[36] 42 U.S.C. 7412(b)(1).
[37] U.S. Environmental Protection Agency, "National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations," *Federal Register*, Vol. 59, No. 233 (December 6, 1994), p. 62,585.
[38] *LEAN*, 955 F.3d at 1099 (*citing* 42 USC 7412(d)(1)).

under Section 112(f). Congress had recognized the potential harm in ethylene oxide emissions as early as 1990, when Congress passed the Clean Air Act amendments, and already mandated the regulation of ethylene oxide in that statute, and EPA had already concluded that sterilizers (which make up at most 3 percent of ethylene oxide consumption in the United States)[39] was not a significant source of these emissions, even while regulating other sources.

Even leaving aside the subsequent reports that undermined EPA's 2016 IRIS assessment,[40] it is not clear why EPA's 2016 IRIS assessment would cause EPA, in 2024, to revisit the basis of its source determinations in the 2006 rule. The potential health concerns surrounding ethylene oxide emissions were already apparent when Congress enacted its amendments to the Clean Air Act in 1990, as illustrated by the fact that Congress included ethylene oxide in the list of pollutants to be regulated. EPA did not question these harms in the 1994 or 2006 rules regulating ethyl oxide emissions, but merely found that sterilizers were not a significant source of these emissions. Nothing in the 2016 IRIS assessment pertains to this finding, and it is only by blurring the distinction between CAA sections 112(d) and (f) that EPA could (improperly) justify using the 2016 assessment to overturn that finding.

Given how explicitly the *LEAN* analysis was restricted to CAA Section 112(d), and how the language of *LEAN* makes clear that the analysis does not apply to any EPA findings under CAA Section 112(f), nothing in the *LEAN* holding requires, or even contemplates, EPA revisiting its previously, timely settled finding under CAA Section 112(f).

The Policy Implications Support EPA's Analysis that the Proposed Rule Should Supplant the 2024 Final Rule

The 2024 Final Rule also reflects a broader cost-benefit imbalance. EPA previously concluded that existing standards had already reduced risks below statutory thresholds and that further reductions would provide only minimal additional benefit at very high cost.[41] Imposing significant new regulatory burdens to achieve marginal or speculative risk reductions is economically inefficient, particularly when those costs fall on critical healthcare infrastructure.

These burdens would not be limited to sterilization facilities themselves. They would increase costs throughout the healthcare system and risk exacerbating existing supply-chain

[39] Swift, T.K., Moore, M.G., Rose-Glowacki, H.R., & Sanchez, E. (2019). *The Economic Benefits of Ethylene Oxide*. American Chemistry Council. P.3, Fig. 1. https://www.americanchemistry.com/industry-groups/ethylene-oxide/resources/the-economic-benefits-of-ethylene-oxide
[40] *See* Attachments, *supra* n. 5 and 6.
[41] 71 Fed. Reg. at 17,714.

constraints.[42] In addition, large fixed compliance costs along with a strict regulatory system, tend to favor larger incumbent firms, and can reduce the ability of smaller firms to innovate and compete. Currently a quarter of the Ethelene oxide facilities parent companies are classified as small entities, and implementing the 2024 Final rule would increase their compliance costs to an excessive degree.[43] Implementing the 2024 Final Rule poses significant risks to the ethylene oxide sterilization industry by reducing economic competitiveness and driving up costs for manufacturers that rely on commercial sterlizers.

The 2024 Final Rule also raises broader concerns regarding regulatory overreach and economic centralization. Expanding agency authority beyond clear statutory limits reduces accountability and creates uncertainty for private-sector decision-making. Competitive markets function best under stable, predictable legal frameworks rather than constantly shifting regulatory interpretations.

The Rule also risks undermining domestic manufacturing competitiveness. Excessive regulatory burdens on sterilization facilities may incentivize firms to relocate operations abroad, weakening U.S. industry without meaningfully reducing global emissions. President Trump has issued an Executive Order, "Regulatory Relief for Certain Stationary Sources to Promote American Security with Respect to Sterile Medical Equipment", and has classified commercial sterilization facilities that use ethylene oxide as "essential to ensuring that our Nation provides its sick and injured with the best outcomes possible" and indicated that having a thriving domestic medical device sterilization industry is essential for national security. In order to have a strong domestic sector, overly burdensome regulations must be removed and domestic industries placed in a position to compete. The 2024 Final Rule risks driving medical device sterilization companies aborad to places where they can perform their work at a lower cost. Requiring companies to implement Permanent Total Enclosures at large scale within the next three years would increase compliance costs by requiring redesign of existing facilities such that it would be "a de facto prohibition on these [Ethelene Oxide] appliances."[44]

Had the 2024 Final Rule taken effect, those costs would have propagated throughout the healthcare system, increasing prices and constraining access to medical goods. Based on an analysis by the Small Business Administration, the medical device sterlization industry would

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[42] U.S. EPA, *Ethylene Oxide Commercial Sterilizers Proposal Regulatory Impact Analysis Memorandum* (March 2026), https://www.epa.gov/system/files/documents/2026-03/eto_commericial_sterilizers_proposal_ria_memo-2026-03.pdf

[43] U.S. Small Business Administration. (2022). Table of Small Business Size Standards. Found at https://www.sba.gov/document/support-table-size-standards.

[44] Office of Advocacy, *Advocacy comments on EPA's proposals to limit ethylene oxide emissions from commercial sterilizers,* U.S. Small Business Administration, June 2023, https://advocacy.sba.gov/wp-content/uploads/2023/06/Comment-Letter-EtO-NPRM-6.23.23-508c.pdf.

experience a capacity reduction of over 20% meaning that some devices would not be able to be sterilized in America as domestic facilities shut down.[45]

Effectively prohibiting the use of Ethelene Oxide sterilization appliances would smother domestic industry and expose U.S. medical supply chains to unnecessary risks. The Proposed Rule avoids these outcomes by restoring a more restrained and textually grounded interpretation of EPA's authority under the Clean Air Act.

Conclusion

This shift in the world of administrative law also brings economic implications. Stable economic growth and efficient private investment depend upon predictable legal rules and low compliance costs. Expansive agency interpretations untethered from clear congressional authorization undermine that predictability by subjecting major sectors of the economy to shifting regulatory obligations driven by administrative preference rather than a clear interpretation of the statute. When agencies operate within clearly defined statutory limits, regulated entities can plan and invest with greater confidence. This increases the uncertainty firms face regarding future compliance obligations, which functions as a deterrent to investment and economic growth. Remaining at the 2019 regulatory threshold for Ethelene Oxide emissions would generate cost savings of between $500 and $600 million over the next 20 years. This is largely due to keeping compliance costs at their current levels and encouraging continued investment by maintaining a stable legal framework for the medical device sterilization industry to operate under.[46]

Stable regulatory expectations are particularly important for capital-intensive industries such as medical device manufacturing. Firms in these sectors make investment decisions over long time horizons and depend on stability to make the best choice possible. By restoring a clearer and more predictable regulatory framework, the Proposed Rule would support long-term investment and encourage innovation in the medical field.

Finally, the structure of Section 112 reflects an implicit recognition that regulatory interventions are subject to diminishing returns. Since EPA previously concluded that additional controls beyond existing standards would produce only minimal additional risk reduction at

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[45] Office of Advocacy, *Advocacy comments on EPA's proposals to limit ethylene oxide emissions from commercial sterilizers,* U.S. Small Business Administration, June 2023, https://advocacy.sba.gov/wp-content/uploads/2023/06/Comment-Letter-EtO-NPRM-6.23.23-508c.pdf.

[46] U.S. Environmental Protection Agency, " 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, Docket No. EPA-HQ-OAR-2019-0178, https://www.epa.gov/system/files/documents/2026-03/eto_commericial_sterilizers_proposal_ria_memo-2026-03.pdf.

substantial cost, revisiting that determination 20 years later, without clear statutory authorization, risks encouraging a regulatory framework in which agencies continually impose escalating compliance obligations despite increasingly marginal public-health gains.

For the reasons that go to the structure, interpretation, and intent of the Clean Air Act, along with the resulting policy implications, EPA is correct to propose the rescission of its 2024 Final Rule. We appreciate the opportunity to comment.

Respectfully yours,

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[48] *Id.*