UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review Reconsideration, 91 Fed. Reg. 12700 (March 17, 2026)	**Docket ID No. EPA-HQ-OAR-2019-0178** Via regulations.gov May 15, 2026

COMMENTS OF PUBLIC HEALTH AND ENVIRONMENTAL ORGANIZATIONS

The undersigned organizations [1] respectfully submit these comments on the Environmental Protection Agency's proposed rule: National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review Reconsideration, 91 Fed. Reg. 12700 (March 17, 2026). For the reasons below, it would be unlawful and arbitrary and capricious for EPA to finalize the Proposed Rule. EPA must withdraw the Proposed Rule and leave the 2024 update of the Commercial Sterilization Facilities NESHAP unchanged or strengthened.

[1] The undersigned organizations are California Communities Against Toxics, CleanAIRE NC, Comité Diálogo Ambiental, Earthjustice, Environmental Defense Fund, Natural Resources Defense Council, Rio Grande International Study Center, Sierra Club, Southern Environmental Law Center, Sustainable Newton, and Union of Concerned Scientists ("Commenters").

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INTRODUCTION

Over 13 million people in the United States live less than just a few miles from a commercial sterilization facility and inhale its ethylene oxide (EtO) emissions. These facilities sterilize various products, including medical equipment and culinary spices. Commenters have members and constituents who live on or near the fenceline of one or more commercial sterilization facilities and have grave concerns about their and their families' exposure to toxic EtOH pollution.

For the communities that surround commercial sterilization facilities, and for the workers inside these facilities, the health risks posed by inhaling EtO emissions are exceptionally high. EPA's "upper bound threshold for acceptable health risks" from a hazardous air pollutant like EtO is a lifetime cancer risk of 100-in-1 million. 2024 Commercial Sterilization Facility NESHAP, 89 Fed. Reg. 24090, 24095 (Apr. 5, 2024) ("2024 Rule"). But when EPA analyzed the cancer risk posed by commercial sterilizers' allowable emissions, the agency found that "the maximum lifetime individual cancer risk could be as high as 8,000-in-1 million"—eighty times EPA's upper bound threshold—"with EtO driving the risk." *Id.* at 24118. This translates to "1 excess [cancer] case in every 1.5 months." *Id*. For workers in commercial sterilization facilities, the risk caused by inhaling EtO is even higher: Without new protections, 1 in 17 workers at a commercial sterilization facility could develop cancer over the course of their career. Ethylene Oxide (EtO) Risks and Your Health, EPA-HQ-OAR-2019-0178-1564, at 3.

The Clean Air Act requires EPA to reduce the public health threat posed by EtO emissions from commercial sterilization facilities by setting national emission standards for hazardous air pollutants (NESHAPs), and then revising those standards "as necessary" to incorporate technological developments, 42 U.S.C. § 7412(d)(6), and to provide "an ample margin of safety," *id.* § 7412(f)(2)(A).

EPA first set national emission standards for commercial sterilizers under 42 U.S.C. § 7412(d)(2)–(3) in 1994 in a fatally deficient rule that illegally set emission limits for only some emissions sources.[2] Within eight years of promulgating a NESHAP, sections 112(d)(6) and (f)(2) of the Clean Air Act required EPA to perform a community health risk and technology review (RTR) and set revised standards if necessary. EPA did not complete this review until 2006, when it decided not to revise the 1994 standards.[3] As a result, until the 2024 Rule, commercial sterilization facilities operated based on outdated emission limits set nearly 30 years earlier—standards that allow these facilities to operate without any controls on multiple sources of EtO emissions. That was flatly illegal and long overdue for correction.

Moreover, in 2016, EPA's understanding of the health impacts of EtO emissions dramatically changed, finding it to be a much more dangerous pollutant than it had previously recognized. EPA's Integrated Risk Information System (IRIS) program finalized and published

[2] National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations, 59 Fed. Reg. 62585 (Dec. 6, 1994).
[3] Ethylene Oxide Emissions Standards for Sterilization Facilities, 71 Fed. Reg. 17712 (Apr. 7, 2006).

its toxicological review of EtO cancer risk.[4] IRIS, an independent and impartial research office housed in EPA's Office of Research and Development, employed a multi-year systematic peer-review process that ultimately resulted in recognizing EtO as definitively "carcinogenic to humans" based on strong evidence of cancer development in both epidemiological and toxicological studies.[5] EPA established a cancer risk factor for EtO of 3.0 x 10^{-3} per $\mu g/m^3$ for adult exposure, or 5.0 × 10^{-3} per $\mu g/m^3$ over a lifetime, accounting for increased vulnerability from early-life exposure—or 60 times more toxic than previously understood.[6] In 2018, EPA's air office applied the new IRIS risk value to the 2014 National Air Toxic Assessment and found that ethylene oxide contributed to a cancer risk equal to or greater than 100-in-one million, EPA's benchmark for "unacceptable cancer risk," in 58 census tracts across the United States.

Based on the IRIS assessment and emissions from commercial sterilization facilities, EPA's Inspector General urged EPA in 2021 to fulfill its overdue duty to complete a new rulemaking that would protect "people in some areas of the country" from "unacceptable health risks from … ethylene oxide emissions."[7] The OIG report warned that "[i]n the absence of updated reviews for [four source categories, including commercial sterilizers], the Agency cannot provide assurance that its current [NESHAPs] are protective" of public health.[8] These sentiments were echoed in Congress, when members of the House of Representatives' bipartisan Congressional Ethylene Oxide Task Force stated: "The first priority of any rule, in both substance and process, must be assuring the people in neighboring communities that the air they breathe is safe." EPA-HQ-OAR-2019-0178-0139, at 1 (March 27, 2020).

In addition to its improved understanding of the health harms of EtO, EPA's understanding of the emissions from commercial sterilization facilities also advanced. As EPA eventually acknowledged, the agency had wrongly "assumed there were no room air (i.e., fugitive) emissions, and no EtO remaining in the sterilized product and packaging."[9] This faulty assumption has had grave consequences for communities nationwide, as it has severely undercounted the risks posed by sterilization facilities to the communities surrounding them. And as the agency has further acknowledged, over a quarter of the commercial sterilization facilities in the country "pose elevated lifetime cancer risks to [their] surrounding communities, some of which are exceptionally high."[10] Even with this new analysis, as Commenters outline below, EPA still severely underestimates the risks posed by commercial sterilizers.

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[4] IRIS Review of Ethylene Oxide, EPA-HQ-OAR-2019-0178-0477, at 1-1 (Dec. 2016) [hereinafter "2016 IRIS Assessment"].
[5] *Id.* at 1-7.
[6] *Id.*
[7] EPA OIG, *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 at 1 (May 6, 2021), https://www.epa.gov/sites/default/files/2021-05/documents/_epaoig_20210506-21-p-0129.pdf (attached) [hereinafter "EPA OIG Report"].
[8] *Id.* at 21.
[9] Development of Ethylene Oxide Usage Fractions for Ethylene Oxide Commercial Sterilization, EPA-HQ-OAR-2019-0178-0480, at 2 (Nov. 3, 2022).
[10] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review Proposed Rule, 88 Fed. Reg. 22792 (April 13, 2023) [hereinafter "2023 Proposed Rule"].

In 2024, after years of advocacy and a lawsuit brought by environmental and public health groups, including many Commenters, EPA finally revised its NESHAP for commercial sterilization facilities and issued 112(d) and 112(f)(2) standards. The 2024 Rule requires (1) controlling pollution from previously unregulated sources of fugitive emissions, (2) more stringent standards for capturing and controlling EtO emissions, and (3) continuous emissions monitoring systems, among other requirements. EPA estimates that the 2024 Rule would eliminate about 90% of EtO emissions, reduce the number of people exposed to unacceptable cancer risk from sterilizers' EtO emissions from 85,000 to 0, and reduce the number of people exposed to a cancer risk greater than 1-in-1-million by 92%.[11] The number of excess cancer cases would decrease from 8 every year to 1 every 5 years.[12]

The 2024 Sterilizers Rule is based on an extensive legal and factual record and is legally required under the Clean Air Act. EPA nevertheless proposes to revisit and withdraw the vast majority of the 2024 Rule, including the entire section 112(f)(2) risk review. EPA proposes to return to outdated standards that, by the agency's own admission, do not protect public health from unacceptable cancer risk and do not incorporate technological developments in pollution control. To justify this proposal, EPA adopts extreme legal positions on its section 112(f)(2) duties and seeks to undermine the best available science on ethylene oxide.

For the reasons explained in these comments, prior comments on the 2023 Proposed Rule, and briefing by EPA and environmental and public health organizations in defense of the 2024 Rule, finalizing the Proposed Rule would be unlawful and arbitrary and capricious, and EPA must withdraw it.[13]

All sources cited to in this comment are incorporated by reference into this rulemaking docket. For convenience, we also attach most documents cited to in this comment that are not part of this rulemaking docket.

I. EPA's Proposed Rescission of the Risk Review is Unlawful. (Response to Question 2)

EPA proposes to rescind the entire section 112(f)(2) risk review based on its new and incorrect interpretation of section 112(f)(2), under which EPA is barred from conducting additional risk reviews for a source category: "[T]he EPA now proposes to interpret CAA section 112(f)(2) as setting out a one-time authority and obligation to assess the residual risk remaining for the source category at issue within eight years of promulgating MACT standards." 91 Fed. Reg. at 12705.

EPA's proposed reading is incorrect. Section 112(f)(2) of the Clean Air Act requires EPA to conduct a residual risk review within eight years of promulgating standards under any

[11] Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2024 Risk and Technology Review Final Rule, EPA-HQ-OAR-2019-0178-1576, at 6, [hereinafter "2024 RRA"].
[12] *Id.*
[13] *See* Comments of Environmental and Community Groups on 2023 Proposed Rule, EPA-HQ-OAR-2019-0178-0634 (June 27, 2023).

provision of section 112(d), not only after promulgating the first-ever standards for that source category under section 112(d)(2)–(3). *See id.* at 12712. That is the "best reading" of the Act, for it is the only proffered interpretation consistent with the Act's text, structure, and purpose (Sections I.A–D). *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024) ("[C]ourts use every tool at their disposal to determine the best reading of the statute."). The absurdity of EPA's new interpretation of section 112(f)(2) in the Proposal is thrown into even sharper relief when coupled with its interpretation of 112(d)(6) in the 2026 Mercury and Air Toxics Standards Rule, 91 Fed. Reg. 90888 (Feb. 24, 2026) (Section I.E). Beyond ignoring the plain text, structure, and purpose of section 112, as well as EPA's longstanding practice, EPA's other reasons for proposing a new interpretation of section 112(f)(2) fail (Section I.F.).

When EPA issued new standards for commercial sterilization facilities under section 112(d) in 2024, it triggered a legal duty to undertake a residual risk review of the section 112(d) standards within eight years. 89 Fed. Reg. at 24099–101; 42 U.S.C. § 7412(f)(2). EPA fulfilled this duty in the 2024 Rule by conducting a residual risk review of the standards promulgated under section 112(d) in the same rulemaking. Because the statute requires additional risk reviews, EPA's one-and-done rationale is unlawful and cannot support repeal of section 112(f) standards promulgated in the 2024 Rule.

Independent of requiring EPA to conduct a section 112(f)(2) review within eight years of promulgating section 112(d) standards, section 112(f)(2) also requires EPA to promulgate residual risk standards "if promulgation of such standards is required in order to provide an ample margin of safety." 42 U.S.C. § 7412(f)(2)(A). Such was the case here, where EPA concluded that the 2024 section 112(d) standards did not provide an ample margin of safety. By rescinding the 2024 section 112(f)(2) standards, EPA would, by its own admission, fail to provide the statutorily required "ample margin of safety" and leave the public exposed to unacceptable cancer risk, in violation of section 112(f)(2)'s mandate *Id.* EPA unlawfully and arbitrarily fails to address or justify the health harms its proposal will cause to public health (Section I.G.), in particular to children's health (Section I.H). Neither of EPA's alleged reasons for rescinding the 112(f)(2) review—its incorrect legal reading or the alleged uncertainty in the IRIS value—override the mandate to provide an ample margin of safety. Congress did not authorize EPA to indefinitely delay health protections due to uncertainties—quite the opposite, Congress specifically designed the ample margin of safety requirement to operate under conditions of scientific uncertainty, not to be suspended because of it. Congress knew uncertainty would always attend risk assessment for carcinogens, and nonetheless required EPA to provide "an ample margin of safety to protect public health." *Id.* Section II of this comment discusses the IRIS value further.

Even if EPA did not have the obligation to conduct an additional risk review, it retains authority to do so and reasonably used its discretion in promulgating the 2024 112(f)(2) standards (Section I.I). EPA has discretion to conduct and revise standards based on a subsequent risk review, particularly in circumstances like those presented here, where the Agency's understanding of the risks associated with ethylene oxide emissions has significantly changed since its last (f)(2) review. EPA appropriately exercised its discretion under (1) section 112(f)(2), (2) section 301(a)(1), and (3) "the basic architecture of administrative law" in conducting the risk review in 2024. EPA Br. at 30, *Cal. Cmtys. Against Toxics v. EPA*, Nos. 24-1178/1180

(consolidated) (D.C. Cir. Feb. 24, 2025), Doc. #2102382 (attached). Thus, whether section 112(f)(2) mandates or merely authorizes the 2024 risk review, rescinding the 2024 risk review would not survive judicial review under the Clean Air Act.

A. The Plain Language of Section 112(f)(2) Requires EPA to Conduct a Health Risk Review Within Eight Years of Promulgating Section 112(d) Standards.

The plain language of section 112(f)(2) requires EPA to conduct a health risk review within eight years of promulgating section 112(d) standards, which EPA did here in 2024. 89 Fed. Reg. at 24090. First, we discuss the well-established background of section 112 and the 1990 amendments and then discuss the plain text.

Congress enacted the Clean Air Act "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population." 42 U.S.C. § 7401(b). The Clean Air Act originally relied on EPA to identify which pollutants are "hazardous" and then set risk-based standards for these pollutants. *See Cement Kiln Recycling Coal. v. EPA*, 255 F.3d 855, 857–58 (D.C. Cir. 2001). That law "worked poorly." *Nat'l Lime Ass'n v. EPA*, 233 F.3d 625, 634 (D.C. Cir. 2000). In the first eighteen years after enactment, the agency "regulated only some sources of only seven chemicals." *Id.* (quoting S. Rep. No. 101-228, at 128 (1989), *as reprinted in* 1990 U.S.C.C.A.N. at 3513). So Congress rewrote the Clean Air Act in 1990 "to require EPA to set the most stringent standards achievable" by eliminating much of the agency's discretion. *Cement Kiln Recycling Coal.*, 255 F.3d at 857; *see also Sierra Club v. EPA*, 551 F.3d 1019, 1028 (D.C. Cir. 2008) ("[T]he text, history and structure of section 112," 42 U.S.C. § 7412, show Congress intended to "[e]liminat[e] much of EPA's discretion.").

The Clean Air Act Amendments of 1990, Pub. L. No. 101-549, 104 Stat. 2399 (1990), aimed to remedy section 112's flaws by, among other changes, supplementing the risk-based standard-setting approach with a mandate for EPA to require reductions "based on the maximum reduction in emissions which can be achieved by application of best available control technology." *Sierra Club v. EPA*, 353 F.3d 976, 980 (D.C. Cir. 2004) (citation omitted).

Emission standards may differ depending on whether a source category is a "major source" or an "area source." 42 U.S.C. § 7412(a)(1)–(2) (defining major source and area source). A "major source" is a source 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." *Id.* § 7412(a)(1). Emission standards for major sources, referred to as "maximum achievable control technology" standards, must require "the maximum degree of reduction in emissions of … hazardous air pollutants … [that] is achievable" considering various factors. *Id.* § 7412(d)(2). The standards must be at least as stringent as the "floor," defined as the average emission limitation that the relevant best controlled or best performing sources have "achieved." *Id.* § 7412(d)(3).

The Act then requires EPA to review and, if necessary, revise them by issuing two different sets of standards—technology-based standards under section 112(d)(6) and health-based standards under section 112(f)(2). The Clean Air Act establishes different

schedules and conditions for when and how EPA must update each set of standards. These standards are put in place over time, as technology and scientific understanding of human health harms evolve.

For all HAP emission source categories, EPA must "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." 42 U.S.C. § 7412(d)(6). These are known as technology-based standards *See* 42 U.S.C. § 7412(d). An "emission standard" is "a requirement … which limits the quantity, rate, or concentration of emissions of air pollutants on a continuous basis, including any requirement relating to the operation or maintenance of a source to assure continuous emission reduction, and any design, equipment, work practice or operational standard promulgated under this chapter." *Id.* § 7602(k). The "emission standards" that section 112 directs EPA to promulgate—and that section 112(d)(6) requires EPA to review and revise—are emission standards for source categories. *See id*. § 7412(c)(2), (d)(1); *Louis. Environmental Action Network v. EPA*, 955 F.3d 1088, 1096 (D.C. Cir. 2020) ("*LEAN*"). When conducting a section 112(d)(6) review of these standards, EPA must revise them "as necessary" to bring them into compliance with the Clean Air Act, including section 112(d)(2)'s requirement to assure the maximum achievable degree of emission reduction. 42 U.S.C. § 7412(d)(2).

Pursuant to the plain language of the statute, within eight years of promulgating standards under section 112(d), EPA must review the health and environmental risk—also known as the "residual risks"—that the emissions remaining under the existing technology-based standards might pose to the public's health. If EPA's technology-based standards do not remove all unacceptable risk and provide an "ample margin of safety to protect public health," then EPA is required to promulgate "residual risk" standards that do. 42 U.S.C. § 7412(f)(2)(A); *see also id.* ("If standards promulgated pursuant to subsection (d) … [of] a pollutant (or pollutants) classified as a known, probable or possible human carcinogen 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 one million, the Administrator shall promulgate standards under this subsection for such source category."). The plain language provides:

> [T]he Administrator shall, <u>within 8 years after promulgation of standards for each category or subcategory of sources pursuant to subsection (d)</u>, promulgate standards for such category or subcategory <u>if promulgation of such standards is required in order to provide an ample margin of safety to protect public health</u> in accordance with this section (as in effect before November 15, 1990) or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

42 U.S.C. § 7412(f)(2)(A) (emphasis added).

EPA's duty to conduct a section 112(f)(2) review is therefore triggered by EPA's "promulgation of standards … pursuant to subsection (d)," *id.* § 7412(f)(2)(A), unlike

section 112(d)(6), which is a time-based requirement to "review, and revise as necessary" emission standards "no less often than every 8 years," *id.* § 7412(d)(6).

Section 112(d) standards are a "standard" for purposes of section 112(f)(2) because they are a "criterion for measuring acceptability." STANDARD, Black's Law Dictionary (11th ed. 2019). That ordinary meaning also comports with the Act's more specific definition of an "emission standard." 42 U.S.C. § 7602(k) (defining an "emission standard" as "a requirement established by … the Administrator which limits the quantity, rate, or concentration of emissions of air pollutants on a continuous basis, including…any design, equipment, work practice or operational standard promulgated under [the Act].").

EPA "promulgates" standards by publishing them in the Federal Register and in the Code of Federal Regulations as the consummation of a rulemaking process; the plain meaning of the word "promulgate" extends beyond the setting of initial standards. *See* PROMULGATE OR PROMULGATION, Black's Law Dictionary 1214 (6th ed. 1990) ("To publish; to announce officially; to make public as important or obligatory. The formal act of announcing a statute or rule of court. An administrative order that is given to cause an agency law or regulation to become known and obligatory."); *see also Horsehead Res. Dev. Co. v. EPA*, 130 F.3d 1090, 1092–93 (D.C. Cir. 1997) ("'[P]romulgation' is accorded its 'ordinary meaning'—i.e., publication in the Federal Register." (internal citations removed)). EPA's own practice is consistent with the plain meaning of the word "promulgate" and extends beyond the setting of an initial set of standards. Even "as EPA reads [the Clean Air Act]" in its own rulemakings, "promulgate" refers to the agency's "oblig[ation] to conduct a rulemaking." *Nat. Res. Def. Council v. EPA*, 529 F.3d 1077, 1083 (D.C. Cir. 2008) (holding that EPA "promulgated" a standard when it simply "readopted," verbatim, an existing regulation in a subsequent rulemaking). In its own rulemakings, including this one, EPA recognizes that it *promulgates* standards under multiple paragraphs of section 112(d). 91 Fed. Reg. at 12732 ("The 2024 Final Rule includes standards promulgated under CAA section 112(d)(2) and (3), (d)(5), and (d)(6).").

Thus, if EPA promulgates standards under section 112(d)(2)–(3) or (d)(6), it must then conduct a residual risk review of these standards. [14]

The *Russello* canon supports this straightforward interpretation: Congress purposefully did not base the risk review on the <u>initial</u> promulgation of section 112(d) standards. *See Russello v. United States*, 464 U.S. 16, 23 (1983). Congress expressly considered whether to limit risk reviews to the "initial promulgation" of standards and did not adopt that version of the law. Unlike the enacted version of section 112, an early Senate bill stated that the obligation to conduct a residual risk rulemaking was contingent on the "initial promulgation" of standards:

> (7)(A) Not later than three years after the <u>initial promulgation</u> of emissions standards for a category or subcategory of sources pursuant to subsection (d), the Administrator shall commence an evaluation of the risks to human health and the environment

[14] Under section 112(f)(5), EPA is not required to conduct a residual risk review for standards promulgated under section 112(d)(5), but it may do so under its own discretion. 42 U.S.C. § 7412(f)(5).

> resulting from emissions of hazardous air pollutants by sources in the category or subcategory remaining after application of such standards.

S. Rep. No. 101–228, at 522 (1989), reprinted in 1990 U.S.C.C.A.N. 3385 (emphasis added).

This drafting history demonstrates that Congress considered limiting residual risk rulemakings to the "initial" promulgation of standards, but then deleted that limitation from the statute it enacted. "Where Congress includes limiting language in an earlier version of a bill but deletes it prior to enactment, it may be presumed that the limitation was not intended." *Russello*, 464 U.S. at 23–24; *Plata v. Schwarzenegger*, 603 F.3d 1088, 1096 (9th Cir. 2010) (same). Additionally, elsewhere in the Act, Congress did limit EPA's obligations to revise standards only on "initial promulgation"—conditioning EPA's review of incinerator standards on the "initial promulgation" of standards, *e.g.*, 42 U.S.C. § 7429(a)(5)—confirming that Congress did not intend to do so here. *Russello*, 464 U.S. at 23 ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (citation omitted)).

Thus, the plain language of section 112(f)(2) requires EPA to conduct a residual risk review any time it promulgates standards "pursuant to subsection (d)." 42 U.S.C. § 7412(f)(2)(A). By requiring EPA to conduct a residual risk review within eight years of the promulgation of section 112(d) standards, the Clean Air Act ensures that EPA will eventually verify that its technology-based standards, even its updated standards, are protective of public health.

B. The Structure of the Clean Air Act Confirms EPA's Obligation to Conduct Additional Health Risk Reviews.

The structure of section 112 confirms that EPA is required to conduct additional risk reviews after promulgating subsection 112(d) standards, not just once after promulgating initial MACT standards. *See United States v. Wilson*, 290 F.3d 347, 355 (D.C. Cir. 2002) ("It is 'a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'") (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000)). In particular, the provisions contemplating the listing of new HAPs confirm that risk reviews are not simply one-time per source category. EPA's arguments that the statutory scheme somehow limits its authority to issue multiple health risk reviews thus fail. *See* 91 Fed. Reg. at 12713–14.

The provisions contemplating the listing of new HAPs confirm that risk reviews are not simply one-time per source category. If they were, EPA would never be required to conduct a health risk review that incorporates HAPs newly listed after EPA performs a risk review for a source category. Such a reading of the statute illegally renders "superfluous, void, [and] insignificant" the Act's mandates for EPA to ensure that standards for newly listed HAPs protect human health against unsafe health risks that may remain after EPA promulgates technology-based standards. *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is a cardinal principle of

statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.") (cleaned up); *see Wagner v. Fed. Election Comm'n*, 717 F.3d 1007, 1014 (D.C. Cir. 2013) (rejecting interpretation as contrary to the structure of the statute because courts "cannot interpret federal statutes to negate their own stated purposes." (quoting *N.Y. Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 419–20 (1973))).

The Clean Air Act requires EPA to "periodically review" its list of regulated HAPs and to add pollutants to the list that, like the congressionally listed ones, "are known to be, or may reasonably be anticipated to be" severe threats to human health, like carcinogens and mutagens. 42 U.S.C. § 7412(b)(2) (directing EPA to consider whether substances are "carcinogenic, mutagenic, teratogenic, neurotoxic, … cause reproductive dysfunction, or … are acutely or chronically toxic"). If a petition to EPA shows that emissions of the pollutant are known to cause or may reasonably be anticipated to cause adverse human health or environmental effects, then EPA must add the pollutant to the list within 18 months of receiving the petition. *Id.* § 7412(b)(3)(A)–(B).

The addition of a pollutant to the list triggers the regulatory process to reduce its emissions to protect public health. After EPA lists a new HAP, EPA has a mandatory duty to establish emission standards for that pollutant, even when it is emitted by an existing source category with emission standards for other pollutants. *LEAN*, 955 F.3d at 1096 ("There is no dispute that the Act requires EPA to have in place emission standards to control all the listed pollutants that a source category emits."). EPA has a "clear statutory obligation to set emission standards for each listed [hazardous air pollutant]," *Nat'l Lime Ass'n*, 233 F.3d at 634, and that duty includes "a mandate to add missing limits" for a newly listed hazardous air pollutant in existing source categories, *LEAN*, 955 F.3d at 1096.

Thus, EPA's reading of its section 112(f)(2) duties in the Proposed Rule would illegally render "superfluous, void, [*and*] insignificant" the Act's mandates for EPA to ensure that standards for newly listed HAPs protect human health against unsafe health risks that may remain after EPA promulgates technology-based standards. *TRW Inc.*, 534 U.S. at 31. It would require EPA to conduct a residual risk review only for the initial set of standards in a source category and create a significant loophole that would interfere with the requirement for EPA to regulate newly recognized HAPs, thereby leaving public health unprotected from such pollutants. *See Wagner*, 717 F.3d at 1014. Given that Congress expected that EPA would complete risk reviews for all source categories no later than November 15, 2008, [15] that means every new HAP listed after that date would be relegated to second class status: Newly listed pollutants would never be subject to section 112's full requirements. As the D.C. Circuit held in *LEAN*, EPA's reading fails because it would "effectively … deprive of practical effect the Act's specified processes for adding to or subtracting from the statutory list of hazardous air pollutants." *LEAN*, 955 F.3d at 1098.

[15] The Act required EPA to establish initial standards for all source categories by November 15, 2000. 42 U.S.C. § 7412(e)(1). Therefore, the first risk review for every source category should have been completed within eight years of that date. *Id.* § 7412(f)(2).

Indeed, EPA's interpretation leads to outcomes Congress could not have intended. The whole point of requiring EPA to act within 18 months of receiving a petition to list a pollutant "is to ensure that emission standards timely reflect new information about hazards." *Id.* But after adding a new HAP and setting standards for it, if EPA was barred from conducting an additional residual risk review for those standards, then "the Agency could choose to ignore [the pollutant's health effects] indefinitely, even as EPA updates other features of standards governing the very source categories known to emit it." *Id.* If EPA's reading of the Clean Air Act—that EPA may conduct only one residual risk review per source category—were correct, then no matter how dangerous the pollutant, no matter how high the resulting cancer risk, EPA could never conduct a residual risk review of a newly listed pollutant in an existing source category and set health-protective standards. *See King v. Burwell*, 576 U.S. 473, 492–93 (2015) (rejecting an interpretation of a statute that would "likely" lead to an outcome "that Congress designed the Act to avoid"). The text of the Clean Air Act avoids this result by requiring EPA to conduct a residual risk review based on the promulgation of any section 112(d) standards, not just the initial promulgation of standards in a source category.

EPA listing new HAPs is not a hypothetical situation. In 2022, EPA added its first ever new hazardous air pollutant, 1-bromopropane ("1-BP"), to its list of regulated hazardous air pollutants in response to a petition. *See* 87 Fed. Reg. 393 (Jan. 5, 2022). And since then, EPA has been systematically reviewing each source category under section 112(d)(6) to see whether to add emission standards for 1-BP to it. *See, e.g.*, 89 Fed. Reg. 55,684, 55,690 (July 5, 2024) ("[A]s each NESHAP is reviewed, the EPA is evaluating whether the addition of 1-BP to the CAA section 112 HAP list impacts the source category."). When a residual risk review is eventually triggered for these existing source categories due to the promulgation of section 112(d) standards, the Clean Air Act ensures that EPA will be required to review the health risk posed by 1-BP emissions for the first time. And in requiring EPA to do so, the Clean Air Act ensures that EPA will review whether the standards for these source categories protect public health.

While 1-BP is the first newly listed hazardous air pollutant, more listing petitions are pending. In August 2024, North Carolina, New Jersey, and New Mexico filed a petition with EPA to list four per- and polyfluorinated substances ("PFAS") as hazardous air pollutants under the Clean Air Act.[16] These chemicals, colloquially known as "forever chemicals," have been shown to have "effects on the immune system, the cardiovascular system, human development (like decreased birth weight), and cancer," as well as effects on the liver and kidney. 87 Fed. Reg. 36848, 36849 (June 21, 2022). Recognizing these chemicals harm human health, EPA has taken steps in recent years to regulate these chemicals under other authorities, including by issuing a Health Advisory for these chemicals under the Safe Drinking Water Act. *Id.* EPA has also confirmed that "[a]ir emissions of PFAS from industrial sources is now recognized as a significant route for PFAS releases to the environment."[17] Indeed, state officials have already found them to be emitted by facilities that are regulated by standards for existing source

[16] Multistate Petition to Add PFAS Compounds to List of Clean Air Act Hazardous Air Pollutants (Aug. 29, 2024), https://www.deq.nc.gov/air-quality/pfas-hap-petition/open (attached).
[17] Ryan, J., EPA PFAS Air Emission Measurements: Activities and Research. Presented at EPA Region 9 Laboratory Technical Information Group Meeting, San Francisco, CA (June 2019) https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NRMRL&dirEntryId=345762 (attached).

categories, like the Miscellaneous Organic Chemicals ("MON") NESHAP.[18] EPA was required to act on the multistate petition for listing these PFAS under section 112 by March 2026. And should EPA list those pollutants, section 112(f)(2) provides that EPA must ensure, through a residual risk review, that the technology-based standards it will set for these newly listed chemicals are protective of public health. *See PDK Laboratories, Inc. v. U.S. DEA*, 362 F.3d 786, 796 (D.C. Cir. 2004) ("The words of the statute should be read in context … and the problem Congress sought to solve should be taken into account.").

C. Any Other Reading of EPA's Risk Review Obligations Would Undermine the Purpose of the Clean Air Act.

The purpose of section 112 is "to provide an ample margin of safety to protect public health," including by minimizing the number of people who face excessive cancer risk, and "to prevent … an adverse environmental effect." 42 U.S.C. § 7412(f)(2). EPA can achieve this purpose only by conducting additional health risk reviews after promulgating section 112(d) standards. EPA's reading of the statute, on the other hand, requires freezing health protections based on a snapshot of risk and undermines core purposes of the Act.

Section 112(f)(2)(A) of the Act provides that EPA must conduct risk reviews and promulgate standards if they are:

> required <u>in order to provide an ample margin of safety to protect public health</u> in accordance with this section … or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. If standards promulgated pursuant to subsection (d) and applicable to a category or subcategory of sources emitting a pollutant (or pollutants) classified as a known, probable or possible human carcinogen 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 one million, the Administrator shall promulgate standards under this subsection for such source category.

42 U.S.C. § 7412(f)(2) (emphasis added). EPA must go beyond what is found to be safe, and ensure not just a minimal "margin" beyond that, but an "ample" one. *See, e.g.*, *Sierra Club v. EPA*, 895 F.3d 1, 13 (D.C. Cir. 2018) (holding that "EPA did not meet the CAA requirement to include an ample margin of safety in the health threshold" under CAA section 112(d)(4)). Using the term "ample" demonstrates that EPA is required to do more than just set a minimum level of protection, and that it must take a "generous," health-protective approach to setting a margin of safety that is "copious" and "abundant." *NRDC v. EPA*, 824 F.2d 1146, 1153 (D.C. Cir. 1987) (applying similar language in the pre-1990 version of section 112 stating that "Congress used the modifier 'ample' to exhort the Administrator not to allow 'the public [or] the environment … to be exposed to anything resembling the maximum risk' and, therefore, to set a margin 'greater

[18] Air Quality Permit No. 03735T48, Chemours Company – Fayetteville Works (May 13, 2020), https://www.deq.nc.gov/coastal-management/gis/data/air-quailty-emissions-testing/final-permitno48-chemours-ves-sw-cas-1/download (attached).

than normal or adequate'") (quoting *EDF v. EPA*, 598 F.2d 62, 81 (D.C. Cir. 1978) (interpreting identical language in the Clean Water Act). EPA considers cancer risk greater than 100-in-1 million presumptively unacceptable [19] "while adopting the one-in-one million standard as an aspirational goal." *NRDC*, 529 F.3d at 1080. [20]

Independent of the requirement to conduct a section 112(f)(2) review within eight years of promulgating section 112(d) standards, in text that also implements this statutory purpose, *see infra* Section I.G, section 112(f)(2) also requires EPA to promulgate residual risk standards "if promulgation of such standards is required in order to provide an ample margin of safety to protect public health" or to prevent adverse environmental effects "taking into consideration costs, energy, safety, and other relevant factors." 42 U.S.C. § 7412(f)(2)(A). EPA's duty to promulgate protective standards is mandatory once it finds that 112(d) standards are insufficient. *See NRDC*, 529 F.3d at 1080.

Adopting EPA's one-and-done interpretation of section 112(f)(2) would freeze public health protections, limiting them to the science available to EPA when it first conducted a residual risk rulemaking for a source category. Given that EPA's own understanding of risk is constantly advancing, freezing health protections based on a snapshot of risk would undermine core purposes of the Act, including the goal of minimizing the number of people who face excessive cancer risk. *See also infra* Section I.G (EPA's interpretation would contravene a textual mandate to EPA that implements this purpose). In EPA's own words before the D.C. Circuit, section 112(f)(2) authorizes multiple risk reviews because "[t]he public is not condemned to inadequate protection based on obsolete science." EPA Br. at 31, *Cal. Cmtys. Against Toxics v. EPA*, Nos. 24-1178/1180 (consolidated) (D.C. Cir. Feb. 24, 2025), Doc. #2102382 (attached).

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[19] EPA must update its outdated assumption that 100-in-1 million is an acceptable risk level. Commenters have previously challenged EPA's continued reliance on a 100-in-1 million acceptability benchmark, given the lack of supporting evidence that such risk is acceptable and its direct contradiction of the Clean Air Act's directive to provide an ample margin of safety. The 100-in-1 million level was not based on the science of health risk to begin with. EPA based this benchmark not on science about health risk, but rather on a 1988 study of people's perceptions of their own various risks. Survey of Risks, Benzene Rule Legacy Docket ID No. OAQPS 79-3, Part I, Docket Item X-B-1. EPA looked to other types of perceived risk, such as perceived risk of being in a car accident, and found that "the presumptive level established for [maximum individual risk of cancer] of approximately 1-in-10 thousand is within the range for individual risk in the survey, and provides health protection at a level lower than many other risks common 'in the world in which we live.'" Benzene NESHAP, 54 Fed. Reg. 38046, 38046 (Sept. 14, 1989). In other words, because a perceived risk of 1- in-10 thousand, or 100- in-1 million was within the realm of other perceived daily risks, EPA deemed it "acceptable." EPA must recognize that no level of cancer risk is "acceptable," and set a benchmark for presumptively unacceptable risk that is based on the science of health harms from toxic air pollution. Since EPA adopted this flawed 100-in-1 million risk benchmark, significant advances in scientific understanding (including in understanding early-life exposure and vulnerability and in understanding socioeconomic disparities) and in technologies to analyze and control the impacts of pollutants on human health, support a lower benchmark.

[20] In 2008, the *NRDC* court, 529 F.3d at 1083, upheld EPA's determination on cancer risk there due to its conclusion that EPA's interpretation of section 112(f)(2) "although not an inevitable one, … is, at least, a reasonable construction of the statute," relying on *Chevron v. NRDC*, 467 U.S. 837, 843 (1984), which was reversed by the Supreme Court in 2024 in *Loper Bright Enterprises*, 603 U.S. 369 (2024).

Congress could not have meant that EPA "shall" promulgate (f)(2) standards *only* based only on the understanding of risk at one moment of time, regardless of whether the science later evolved to show that the HAP was more toxic, as was the case with EtO. (Indeed, under EPA's interpretation, if one source's (f)(2) review were conducted before a crucial study or analysis, and another was after, it would leave two categories that emit the same pollutant subject to very different levels of stringency, regardless of the pollutant's impact on public health.).

There are many reasons why existing standards might no longer adequately protect public health, including that the old 112(f)(2) review and standards might be outdated or incorrect. For example, EPA would need to update a risk review standard to incorporate a newly regulated HAP. *See* 42 U.S.C. § 7412(b)(3)(A)–(B). If previous risk reviews were insufficient, EPA would need to correct them. Additional risk reviews also ensure that EPA can incorporate new updates to the science on the health harms of a HAP. Ethylene oxide and chloroprene make that clear—in both cases, EPA determined the HAPs are significantly more carcinogenic than it had understood when it had conducted the last section 112(f)(2) review.[21]

The pre-1990 Clean Air Act directed EPA to "'establish any such standard at the level which in his judgment provides an ample margin of safety to protect the public health from such hazardous air pollutant.'" *NRDC v. EPA*, 489 F.3d 1250, 1254 (D.C. Cir. 2007) (quoting the 42 U.S.C. § 7412(b)(1)(B) (1990)). Congress had given EPA broad discretion to set standards based on health risk considerations alone, without reference to technology performance or industrial practice. Critically, the pre-1990 statute contained no provision mandating periodic or recurring review of standards once promulgated.

Congress rewrote section 112 in the 1990 amendments and "require[d] EPA to set the most stringent standards achievable" by eliminating much of the agency's discretion. *Cement Kiln Recycling Coal.*, 255 F.3d at 857; *see also Sierra Club*, 551 F.3d at 1028 ("[T]he text, history and structure of section 112," 42 U.S.C. § 7412, show Congress intended to "[e]liminat[e] much of EPA's discretion."). The 1990 amendments replaced the former risk-based NESHAP framework with a technology-based regime in section 112(d) and a risk-based backstop in section 112(f)(2). Specifically, Congress required EPA to enact MACT standards, discussed above, under section 112(d)(1)–(3). It mandated recurring eight-year reviews under section 112(d)(6), a requirement to account for the inherently dynamic nature of what is technologically achievable by the best performing sources. Congress envisioned continuous tightening of technology-based standards which would be periodically reviewed every eight years.[22] *See LEAN*, 955 F.3d at 1093 (the recurring 112(d)(6) review "ensures that, over time, EPA maintains source standards compliant with the [Clean Air Act] and on pace with emerging developments that create opportunities to do even better").

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[21] *See* EPA, Toxicological Review of Chloroprene, EPA-HQ-OAR-2022-0730-0078, at 92, 96 (Sept. 2010); EPA, Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide, EPA-HQ-OAR-2022-0730-0040, at 1-1 to 1-7 (Dec. 2016) (attached).

[22] Waxman, H., *An Overview of the Clean Air Act Amendments of 1990*, 21 Envtl. L. 1721, 1775–76 & n.256 (1991) (Congress intended that: "the continual tightening of existing source standards will be assured") (attached).

It maintained a risk-based backstop in the form of section 112(f). As explained above, Congress considered limiting residual risk rulemakings to the "initial" promulgation of standards, but then deleted that limitation from the statute it enacted. S. Rep. No. 101–228, at 522 (1989), *reprinted in* 1990 U.S.C.C.A.N. 3385 (emphasis added). *See supra* Section I.A (citing *Russello*, 464 U.S. at 23–24). By tying risk reviews to technology-based and other section 112(d) updates, it ensured that every time there were new standards, EPA would also make sure that health is adequately protected. In particular, Senator Durenberger noted that the new Clean Air Act Amendments included a "mechanism" to ensure that there would be "a second tier of standards, if they are necessary to protect public health." 136 Cong. Rec. S16895, S16932, 1990 WL 164490. It would be incongruous for Congress to express the need for EPA to verify the health-protectiveness of its standards but to then limit EPA's ability to complete that task, and EPA's interpretation wrongly adopts this illegal reading.

D. EPA's Longstanding Practice Confirms Its Authority to Conduct Additional Health Risk Reviews.

"[T]he longstanding practice of the government—like any other interpretive aid—can inform a court's determination of what the law is." *Loper Bright*, 603 U.S. at 386 (cleaned up). As EPA represented before the D.C. Circuit, it "has consistently interpreted Section 7412(f)(2) as providing [] authority" to update section 112(f)(2) reviews and "consistently stated that a change in a pollutant's cancer-risk estimate could require revisiting a prior risk review." EPA Br. at 29, *Cal. Cmtys. Against Toxics v. EPA*, Nos. 24-1178/1180 (consolidated) (D.C. Cir. Feb. 24, 2025), Doc. #2102382. EPA's assertion in the Proposed Rule that this approach is "novel" contradicts its representations before the D.C. Circuit and the record. *See* 91 Fed. Reg. at 12713 (the "novelty of this approach presents an additional reason to proceed with caution"); *see id.* at 12712 (this is the "first time" EPA concluded it had this authority). EPA has acknowledged that "[t]he Clean Air Act entrusts EPA with discretion to update risk reviews, especially when warranted by changed circumstances, such as an updated understanding of ethylene oxide's significant cancer risks." EPA Br. at 29, *Cal. Cmtys. Against Toxics v. EPA*, Nos. 24-1178/1180 (consolidated) (D.C. Cir. Feb. 24, 2025), Doc. #2102382; *see, e.g.*, National Emission Standards for Gasoline Distribution Facilities (Bulk Gasoline Terminals and Pipeline Breakout Stations), 71 Fed. Reg. 17352, 17354 (Apr. 6, 2006) ("We disagree with the commenter's assertions that there is no mechanism to revisit risks from the source category and that 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)."); Ethylene Oxide Emissions Standards for Sterilization Facilities, 71 Fed. Reg. 17712, 17715 (Apr. 7, 2006) (risk review for commercial sterilization facilities) (same); NSPS for Synthetic Organic Chemical Manufacturing Industry and NESHAP for Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry, 89 Fed. Reg. 42932, 42934 (May 16, 2024) (conducting additional risk review due to include updated IRIS value). In the Halogenated Solvent Cleaning risk review, EPA explicitly cited an ongoing assessment of the cancer-risk estimate as a reason that it might need to revisit and revise the standards. National Air Emission Standards for Hazardous Air Pollutants: Halogenated Solvent Cleaning, 72 Fed. Reg. 25138, 25147 (May 3, 2007).

EPA has acknowledged its authority and need to update the risk assessment for this category in particular since at least 2006, when EPA conducted its last risk review. 71 Fed. Reg. at 17715. EPA based its 2006 risk review on its 1985 health assessment for ethylene oxide and determined that no risk-based standards were required. *Id.* Key here, however, EPA cautioned that it was in the process of updating its cancer assessment for ethylene oxide, that it would receive external peer review until after the promulgation of the residual risk review, and that it therefore may need to revisit the risk review should the science suggest that the public is exposed to greater risk. *Id*. EPA explicitly acknowledged its "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." *Id.*

Based on this understanding of EPA's authority, in 2021, EPA's Inspector General filed a report urging EPA to fulfill its overdue duty to complete a new rulemaking that would protect "people in some areas of the country" from "unacceptable health risks from … ethylene oxide emissions."[23] In 2016, EPA finalized its updated cancer-risk estimate for ethylene oxide and found ethylene oxide poses about 60 times higher cancer risk than known in 2006. Based on that assessment and emissions from these facilities, EPA's Inspector General's report warned that "[i]n the absence of updated reviews for [four source categories, including commercial sterilizers], the Agency cannot provide assurance that its current [NESHAPs] are protective" of public health.[24] It explained that EPA should conduct additional risk reviews "whenever new data or information indicates an air pollutant is more toxic than previously determined,"[25] and that conducting an additional review "to account for new risk information would best ensure public health is protected with an ample margin of safety that is consistent with the Clean Air Act."[26] In its response to the OIG's report, EPA's Office of Air and Radiation "note[d] that the CAA provides more than one authority that EPA can use to reduce risks to public health by establishing emission standards for hazardous air pollutants … and in light of the CAA's multiple options to review risk, we are expeditiously evaluating" conducting an additional review.[27] OAR specified that a "basic trigger in our internal control process for determining whether and when to re-examine risk in further reviews of existing NESHAP is the issuance of an updated or new IRIS value that shows a pollutant to be more toxic than previously understood or provides a first-time health benchmark for assessing risk," as was the case with ethylene oxide.[28]

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[23] EPA OIG Report at 1 (attached).
[24] *Id.* at 21.
[25] *Id.* at 22.
[26] OIG Response to Planed Corrective Actions at 1 (June 7, 2022), https://www.epa.gov/system/files/documents/2022-06/_epaoig_21-P-0129_IG_Comment_on_Response2.pdf (attached).
[27] OAR Response #2 to OIG Report No. 21-P-0129 at 3 (July 7, 2021), https://www.epa.gov/system/files/documents/2021-08/_epaoig_21-p-0129_agency_response.pdf (attached).
[28] OAR Response #3 to OIG Report No. 21-P-0129 at 2 (June 1, 2021), https://www.epa.gov/system/files/documents/2022-06/_epaoig_21-P-0129_Agency_Response2.pdf (attached).

Because of the Act's eight-year technology review cycle—coupled with EPA's history of extensive delays in meeting its statutory obligations[29] and the agency's own prior statutory interpretation (i.e., that it had authority to update the health risk standards based on new scientific information, for example, but that it was not required to do so)—it is hardly surprising that EPA would only in recent years have gotten around to undertaking a new residual risk review. *See Hoopa Valley Tribe v. FERC*, 629 F.3d 209, 212 (D.C. Cir. 2010) (finding that it was not unreasonable for an agency to apply a long existent authority to a new situation when "there have not been many cases with circumstances like those present here"); *see also* EPA Br. at 32, *Cal. Cmtys. Against Toxics v. EPA*, Nos. 24-1178/1180 (consolidated) (D.C. Cir. Feb. 24, 2025), Doc. #2102382 ("EPA has consistently interpreted Section 7412(f)(2) as authorizing it to update risk-based standards.").

EPA asserts that the 2024 Rule "did not account for the mine run of consistent regulatory practice," but it cites to no such practice to support that contention. 91 Fed. Reg. at 12713. Instead, it mischaracterizes some of EPA's citations in the Response to Comments ("RTC"). *See id.* n.45 (addressing citations in 2024 Rule RTC at 229–33). There, EPA cited to other actions to show that "EPA's discretion to revise prior standards where the statute does not contain limiting language, and where the statute also does not explicitly tell us to periodically revise standards, has been implemented without controversy," RTC at 229–30. EPA ultimately fails to engage with the above past practice, representations it has made before federal courts, or conclusions by its General Counsel's Office.

E. EPA's New Interpretation of Section 112(f)(2), Coupled With Its New Interpretation of Section 112(d)(6) in the Proposed Repeal of the Mercury and Air Toxics Standards, Is Unlawful.

The irrationality and illegality of EPA's new interpretation of section 112(f)(2) in the Proposal is thrown into even sharper relief when coupled with its interpretation of 112(d)(6) in the 2026 Mercury and Air Toxics Standards Rule, 91 Fed. Reg. 90888 (Feb. 24, 2026). In this Proposed Rule for the commercial sterilizers source category, EPA asserts that the appropriate mechanism by which it could evaluate new information on health risk is not in the context of an additional section 112(f)(2) review, but rather in a section 112(d)(6) review—by "evaluating the cost-effectiveness of potential developments by reference to the nature of the risk posed by the particular HAP at issue (*i.e.*, by accepting higher values or cost-per-ton of emission reduction for extremely dangerous HAP)." 91 Fed. Reg. at 12713. Not only does that ignore the textual differences between subsections (d)(6) (focused on technological developments) and (f)(2) (focused on health risk), but it also ignores the position EPA took in the MATS Rule that its

[29] *See, e.g.*, *LEAN*, 955 F.3d at 1099 (noting that EPA was still failing to meet its obligation to set technology-based emission limits for the pulp mill combustion source category "almost twenty years after the final statutory deadline … and ten years since [a petition] for a rulemaking."); *Comty. In-Power & Dev. Ass'n v. Pruitt*, 304 F. Supp. 3d 212, 217, 218 & n.3 (D.D.C. 2018) (Jackson, K.B., J.) (listing nine source categories for which EPA was seven to eight years overdue in completing first-time reviews under sections 112(d)(6) and (f)(2), and that EPA had been overdue to complete such reviews for at least 35 other source categories).

assessment of risk under (d)(6) would rely on the (f)(2) review—which EPA now proposes would only ever happen *once.* MATS Repeal Rule, 91 Fed. Reg. at 9095. 91 Fed. Reg. at 12703.

In the MATS Repeal Rule, EPA asserts that it can consider the results of the (f)(2) residual risk review in determining whether there is sufficient public health benefit to make revising technology-based standards "necessary." EPA's Final MATS Repeal asserts, for the first time, that where prior section 112 standards have "lowered the maximum individual [] cancer risk" from a particular set of air toxics to "below one-in-one-million for every" source in a category, section 112(d)(6) requires "a greater emphasis on cost" such that "additional controls would generally only be 'necessary' when the costs are on the lower end of what has been found acceptable" in prior actions under section 112. 91 Fed. Reg. at 9095. But in this Proposed Rule on sterilizers, EPA insists that it may conduct only *one* (f)(2) residual risk review—and may not "revisit" its residual risk reviews to respond to developments in our understanding of hazardous air emissions' public health risks. So "all subsequent 112(d)(6) reviews" can consider the residual risk review, but *only* the residual risk review that will grow increasingly outdated as the years pass. *Id.*

EPA cannot square that arbitrary and capricious circle. On the one hand, if EPA cannot update its risk reviews to assess whether existing 112 standards for a source category continue to "provide an ample margin of safety to protect public health," 42 U.S.C. § 7412(f)(2)(A), but *can* consider the (f)(2) review under (d)(6), then the Agency yokes itself to an outdated risk assessment for "all subsequent 112(d)(6) reviews," 91 Fed. Reg. at 9095. Indeed, in the MATS Repeal Rule, EPA stated that comments that attempted to bring EPA's attention to errors in the 2020 MATS risk review—on which EPA's alternative basis for rescinding the fPM standards is based—were outside the scope of the Agency's action. EPA thus constructs a framework for section 112 reviews that leaves the Agency willfully blind twice over: It will neither conduct a formal review of residual risk under (f)(2) nor informally consider risk information raised by public commenters.

The Act does not authorize EPA to consider the 112(f)(2) assessment of residual risk or other risk reductions as part of a 112(d)(6) technology review. Because the statutory text and structure and D.C. Circuit precedent preclude all consideration of risk under section 112(d), consideration of the one-in-one million cancer risk test is also necessarily precluded. *Id.* Section 112(d)(2)—whose criteria govern revisions pursuant to section 112(d)(6)—establishes a technology-based, not a risk-based—standard. *See Sierra Club*, 353 F.3d at 990. The plain text of section 112(d)(6) confirms that the agency must review and revise the technology-related standards set out under section 112(d)(2) as "necessary," instructing EPA to "tak[e] into account developments in practices, processes, and control technologies." 42 U.S.C. § 7412(d)(6). "[N]othing" in that "text suggests that EPA must consider such factors" as "risk reduction." *Battery Recyclers v. EPA*, 716 F.3d 667, 672 (cleaned up) (D.C. Cir. 2013). And EPA may not decline to make otherwise "necessary" revisions based on its appraisal of risk reduction. Where the Act allows EPA to depart from enumerated criteria based on its view of a standard's efficacy, it does so explicitly. *See, e.g.*, 42 U.S.C. § 7411(b)(1)(B) ("Notwithstanding the requirements of the previous sentence, [EPA] need not review any such standard if [EPA] determines that such review is not appropriate in light of readily available information on the efficacy of such standard.").

The statutory history confirms that EPA may not alter the statutory standards based on its own appraisal of the risks and benefits associated with reducing hazardous air pollution. In 1990, Congress amended section 112 to eliminate the stasis produced by the prior risk-balancing regime by requiring standards "based not on an assessment of the risks posed by [air toxics], but instead on the maximum achievable control technology." *Sierra Club*, 353 F.3d at 980. Those amendments reflected "Congress' understanding that fully characterizing the risks posed by HAP emissions was exceedingly difficult." National Emission Standards for Hazardous Air Pollutants; Coal- and Oil-Fired Electric Utility Steam Generating Units—Revocation of the 2020 Reconsideration and Affirmation of the Appropriate and Necessary Supplemental Finding, 88 Fed. Reg. 13956, 13963 (March 6, 2023). Based on that understanding, "Congress purposefully replaced a regime" dependent upon EPA's "assessment of risk in the first instance, with one in which Congress determined risk existed and directed the EPA to make swift and substantial reductions based upon the most stringent standards technology could achieve." *Id.* at 13963–64 (also noting that "[t]he statutory design and direction also repeatedly emphasize that the EPA should regulate with the most exposed and most sensitive members of the population in mind"). Importing risk-based considerations to those set out in section 112(d)(2) when EPA conducts the periodic reviews of MACT standards required by section 112(d)(6) "would collapse the technology-based/risk-based distinction at the heart of the Act, undermining the central purpose of the 1990 Amendments," thereby "reintroduc[ing] the very problem Congress sought to exorcize" through those Amendments. *Sierra Club,* 353 F.3d at 990 (cleaned up).

Because EPA's interpretation does not represent the best reading of either section 112(f)(2) or 112(d)(6), it must fail. *Loper Bright*, 603 U.S. at 400.

F. EPA's Other Reasons for Proposing a New Interpretation of Section 112(f)(2) Fail.

For the reasons below, EPA's other arguments in support of its incorrect interpretation of section 112(f)(2) fail.

First, EPA argues that because section 112(d)(6)'s language requires EPA to conduct technology reviews on a recurring basis and that language does not appear in section 112(f)(2), the agency must not have authority or obligation to conduct additional reviews. *See* 91 Fed. Reg. at 12712–13. But EPA's juxtaposition is inapt: Congress chose to have the provisions serve different purposes and accordingly be triggered in different ways. Technology reviews under section 112(d)(6) occur on an 8-year timeline 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." *LEAN*, 955 F.3d at 1093. By contrast, Congress chose to have the residual risk review requirement be triggered only "after promulgation of standards … pursuant to subsection (d) of this section" because the whole purpose of a residual risk review is to ensure that the technology-based standards promulgated under section 112(d) provide an "ample margin of safety to protect public health." 42 U.S.C. § 7412(f)(2)(A). Thus, Congress did not place residual risk reviews on an automatically-recurring basis because residual risk reviews are entirely dependent on verifying the health protectiveness of EPA's promulgated technology-based standards.

Second, EPA asserts that because "Congress stated twice in section 112(f)(2) that any required standard must be promulgated within 8 years of promulgating section 112(d) standards," reading it to allow more than one residual risk review "could result in additional risk standards long after the eight-year statutory deadline, in this case twenty years after section 112(d) standards were promulgated in 1994, 'would effectively gut Congress's carefully articulated existing system.'" 91 Fed. Reg. at 12713. This argument is based on a flawed reading of the statute. As discussed above, *see supra* Section I.A (*Russello* canon), Congress intentionally omitted the word "initial" before "section 112(d) standards" because it intended for the 112(f)(2) duty to be triggered when EPA promulgates standards under any section of 112(d), and not only the first time. EPA's argument is also circular: EPA asserts that the duty cannot be recurring because, if it were, it would lead to recurring reviews. But that is precisely Congress' intent: The purpose of section 112 is to establish and periodically update technology-based and health risk-based standards. A recurring duty will necessarily continue recurring long after initial standards were set.

Contrary to EPA's assertion, section 112(e) does not undermine EPA's recurring duties under section 112(d) and (f). *See* 91 Fed. Reg. at 12713 n.43. EPA is correct that Congress "enacted the detailed regulatory scheme in CAA section 112 with the express goal of achieving rapid regulation." *Id.* at 12713. Section 112(e) sets a "schedule for standards and review," including requiring EPA to set emissions standards for all categories and subcategories by November 15, 2000. *See* 42 U.S.C. § 7412(e)(1)(E). As EPA acknowledges, that means that it was required to conduct risk reviews on those standards by 2008, given section 112(f)(2)'s 8-year deadline. *See* 91 Fed. Reg. at 12713 n.43. None of this undermines Congress's express requirement for EPA to conduct recurring reviews under the plain text of section 112(d)(6) or 112(f)(2). Congress imposed coherent, fully consistent obligations on EPA when it required EPA both to regulate quickly and to update its regulations into the future. *See Friends of the Earth v. EPA*, 440 F.3d 140, 145 (D.C. Cir. 2006) ("The existence of two conditions does not authorize EPA to disregard one of them.").

EPA also claims that "[a]n implied authority to conduct discretionary risk reviews on an ad hoc basis disrupts the statutory scheme by eliminating the finality of residual risk reviews, undermining certainty for regulated industry and the public." 91 Fed. Reg. at 12713. This argument is also circular: EPA presumes that the statutory scheme allows only one risk review, but that is precisely the question at issue. This circular argument misunderstands the plain text, structure, and purpose of section 112. Congress did not intend for section 112 standards to be permanent and unchangeable: If that were the case, it would not have required recurring technology or health reviews under the plain text of section 112(d)(6) or (f)(2). Quite the opposite, it required recurring reviews precisely for the purpose of incorporating new technology and health risk information. Technology reviews under section 112(d)(6) occur on an 8-year timeline 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." *LEAN*, 955 F.3d at 1093; *see Nat'l Ass'n for Surface Finishing v. EPA*, 795 F.3d 1, 5 (D.C. Cir. 2015) (This provision requires EPA to conduct a "technology review" to determine "whether standards [for an industry] should be tightened in view of developments in technologies and practices since the standard's promulgation or last revision."). The fact that standards are explicitly designed to

change indicates that Congress was not concerned with finality for industry at all, and thus that EPA's reliance on that consideration here "relies upon improper factors" that Congress did not intend for it to consider and is arbitrary and capricious. *NRDC v. EPA*, 822 F.2d 104, 111 (D.C. Cir. 1987).

If complied with, section 112 indeed provides certainty for regulated industry and the public: It provides a clear trigger (promulgation of standards under subsection (d)), a deadline (within eight years of promulgation), and a substantive requirement (it must "provide an ample margin of safety to protect public health … or to prevent … an adverse environmental effect). 42 U.S.C. § 7412(f)(2). Any uncertainty regarding the Sterilizers NESHAP is EPA's own making, as EPA decided to reconsider this Rule a mere few weeks before the facilities are required to comply with the 2024 Rule. As for EPA's complaint that the statute does not "provid[e] a standard for the use of such implied discretion," 91 Fed. Reg. at 12713, EPA is wrong: (f)(2) calls for risk based standards that supply an ample margin of safety against effects on public health and welfare, and it requires risk-based standards if cancer risks exceed 1-in-1 million.

As for EPA's concern that doing more than one health risk review would "plac[e] certain source categories on a different trajectory from the rest," the Clean Air Act necessarily puts source categories on different trajectories to some extent by requiring EPA to issue standards by source category. *See* 42 U.S.C. § 7412(c)(1) (requiring the Administrator to publish and revise a list of "all categories and subcategories of major sources and area sources … of the air pollutants listed pursuant to subjection (b)); *see id.* § 7412(d)(1) ("The Administrator shall promulgate regulations establishing emission standards for each category or subcategory of major sources and area sources of [HAPs] listed for regulation pursuant to subsection (c)); *see* § 7412(c)(2) (same). In fact, EPA "may distinguish" between facilities in the same source category based on their "classes, types, and sizes" when setting standards. 42 U.S.C. § 7412(d)(1); *see Sierra Club*, 895 F.3d at 15 ("EPA has the authority to 'distinguish among classes, types, and sizes' of emissions sources and set separate MACT floors for each."). In any event, EPA asserts no reason as to why placing source categories on "a different trajectory" is inconsistent with the text, structure, or purpose of section 112.

EPA asserts that this interpretation is inconsistent with CAA section 112(f)(1) because that section "envisions potential further action from Congress to address residual risk." 91 Fed. Reg. at 12713. EPA's argument finds no support in the text of the Act. Subsection (f)(1) indeed contemplates that Congress *may* take further action to address residual risk; however, it also contemplates that it may not. And when Congress takes no further action, the Act *requires* action from EPA. Specifically, section 112(f)(1) requires EPA to submit to Congress a one-time report on (a) methods calculating the risk to public health remaining after application of 112(d) requirements; (b) the public health significance of the estimated remaining risk, and methods and cost of reducing it; (c) the health effects on fenceline communities, among other information; and, key to EPA's argument here, (d) "recommendations as to legislation regarding such remaining risk." 42 U.S.C. § 7412(f)(1)(D). But "[i]f Congress does not act on any recommendation submitted under paragraph (1), the Administrator shall … promulgate standards" under section 112(f)(2). *Id.* at § 7412(f)(2)(A). EPA submitted the "Residual Risk

Report to Congress,'' EPA–453/R–99–001, in March 1999.[30] EPA made no legislative recommendations to Congress because it "believe[d] that the regulatory approach embodied in the CAA is adequate for maintaining the goal of protecting the public health and environment, and, therefore, is not recommending any legislative changes."[31] As EPA acknowledged in its 2005 Sterilizers Rule, "Congress did not act on any of the recommendations in the report, triggering the second stage of the standard-setting process, the residual risk phase." 70 Fed. Reg. 61404, 61405 (Oct. 24, 2005). Thus, under the plain text of section 112(f)(2), EPA must issue a residual risk review.

Third, EPA now asserts that section 307(d) authorizes revision of section 112(f)(2) standards in certain circumstances only, like in the case of adverse court decision or mandatory administrative reconsideration under section 307(d)(7)(B). 91 Fed. Reg. at 12713. EPA finds no support in the text of section 307(d), or any other authority, which simply does not include the qualifications EPA would insert into the broader language Congress actually chose to enact. Furthermore, EPA cannot rationally have it both ways—that is, it cannot claim that it has authority to reconsider rules only to weaken standards, as it attempts here by proposing to undermine the IRIS value, and not to strengthen them. Regardless, EPA generally retains authority to revisit rules under "the basic architecture of administrative law," even when the rules are part of mandatory reconsideration, and that general proposition holds for EPA's NESHAPs governing commercial sterilizers, as EPA explained before the D.C. Circuit regarding the 2024 Rule. EPA Br. at 30, *Cal. Cmtys. Against Toxics v. EPA*, Nos. 24-1178/1180 (consolidated) (D.C. Cir. Feb. 24, 2025), Doc. #2102382.

G. Rescinding the Section 112(f)(2) Standards Would Violate the Statute's Mandate to Provide an Ample Margin of Safety to Protect Public Health.

Independent of the requirement to conduct a section 112(f)(2) review within eight years of promulgating section 112(d) standards, section 112(f)(2) also requires EPA to promulgate residual risk standards "if promulgation of such standards is required in order to provide an ample margin of safety to protect public health" or to prevent adverse environmental effects, "taking into consideration costs, energy, safety, and other relevant factors." 42 U.S.C. § 7412(f)(2)(A). EPA's duty to promulgate protective standards is therefore mandatory once it finds that 112(d) standards are insufficient. Section 112(f)(2)(A) also includes a heightened mandatory duty for carcinogens: "If standards promulgated pursuant to subsection (d) and applicable to a category or subcategory of sources emitting a pollutant (or pollutants) classified as a known, probable or possible human carcinogen 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 one million, the Administrator shall promulgate standards under this subsection for such source category." *Id.* (emphasis added); *see NRDC*, 529 F.3d at 1083.

Here, the record evidence is clear. As EPA has acknowledged multiple times in its OIG Reports and responses, in the 2024 Rule, and elsewhere, the 2006 standards do not provide an ample margin of safety because they were based on an old IRIS assessment, in which EPA

[30] EPA, *Residual Risk Report to Congress* EPA-453/R-99-001 (March1999), https://www.epa.gov/sites/default/files/2013-08/documents/risk_rep.pdf (attached).
[31] *Id.* at PDF 32.

thought that EtO was far less carcinogenic than the agency concluded in the 2016 IRIS assessment.[32] EPA also concluded that the 2024 section 112(d) standards did not provide an ample margin of safety, 89 Fed. Reg. at 24100, which is why the 2024 section 112(f)(2) standards were necessary. EPA's 2024 residual risk assessment found that 6000-in-1 million cancer risks from actual emissions, or 8000-in-1 million for allowed emissions—or 60 to 80 times EPA's own 100-in-one-million benchmark. 2024 RRA, EPA-HQ-OAR-2019-0178-1576, at 6. And that assessment actually underestimated risk. *See* Comments of Environmental and Community Groups on 2023 Proposed Rule, EPA-HQ-OAR-2019-0178-0634, at 5–8; 2023 Sahu Expert Report, EPA-HQ-OAR-2019-0178-0634, at 91–103. Additionally, EPA now proposes to rescind even some of the 2024 section 112(d) standards, leaving the public subject to an even higher cancer risk than that which EPA already concluded was unacceptable. By rescinding the 2024 section 112(f)(2) standards, EPA would, by its own admission, fail to provide the statutorily required "ample margin of safety" and leave the public exposed to unacceptable cancer risk, in violation of section 112(f)(2)'s mandate *Id.* EPA cannot rescind the risk review without violating its legal obligations and harming the health of millions of people.

Neither of EPA's explanations for the proposed rescission can override section 112(f)(2)'s mandate that EPA promulgate standards when necessary to provide an ample margin of safety. As explained above, EPA's new proposed interpretation of section 112(f)(2) is incorrect. The second justification is alleged uncertainty in the IRIS value. But Congress did not authorize EPA to indefinitely delay health protections due to uncertainties—quite the opposite, **Congress specifically designed the ample margin of safety requirement to operate under conditions of scientific uncertainty, not to be suspended because of it. Congress knew uncertainty would always attend risk assessment for carcinogens, and it nonetheless required EPA to provide "an ample margin of safety to protect public health,"** so that scientific uncertainties did not lead to dangerous gaps in health protection. 42 U.S.C. § 7412(f)(2)(A). The ample margin of safety framework's core logic is precautionary. Rescinding a completed residual risk standard on the basis of alleged IRIS uncertainty would effectively convert the ample margin of safety requirement into an obstacle to public health protection, standing the statutory scheme on its head.

The D.C. Circuit has addressed the role of uncertainty in what is now section 112(f)(2) and firmly resolved it in the opposite direction from the one EPA proposes to adopt:

> Congress recognized in section 112 that the determination of what is 'safe' will always be marked by scientific uncertainty and thus exhorted the Administrator to set emission standards that will provide an 'ample margin' of safety. This language permits the Administrator to take into account scientific uncertainty and to use expert discretion to determine what action should be taken in light of that uncertainty. *See Environmental Defense Fund,* 598 F.2d at 83 ('by requiring EPA to set standards providing an "ample margin of safety," Congress authorized and, indeed, required EPA to protect against dangers before their extent is conclusively ascertained"); *Hercules,* 598 F.2d at 104 ('Under the "ample margin of safety" directive, EPA's standards must protect

[32] *See, e.g.*, EPA OIG Report at 1; 2024 RRA, EPA-HQ-OAR-2019-0178-1576, at 6.

> against incompletely understood dangers to public health and the environment, in addition to well-known risks.').

NRDC, 824 F.2d at 1165. "In determining what is an 'ample margin' the Administrator may, and perhaps must, take into account the inherent limitations of risk assessment and the limited scientific knowledge of the effects of exposure to carcinogens at various levels, and may therefore decide to set the level below that previously determined to be 'safe.'" *Id.* Thus, Congress addressed uncertainty not by permitting the agency to avoid regulation when uncertainty exists, but rather to use uncertainty as a reason to be more protective, not as a ground to abandon regulation.

This framework applies directly to post-1990 section 112(f)(2). The D.C. Circuit explained in its 2008 *NRDC v. EPA* decision that "the phrase 'this section (as in effect before November 15, 1990)' is certainly broad enough to encompass EPA's prior interpretations of 'this section' as well as the text itself." *NRDC*, 529 F.3d at 1082. Congress also rejected the Senate version of the 1990 amendments—which would have mandated a bright-line standard for carcinogens—in favor of the House version, which preserved more EPA discretion under the "ample margin of safety" standard. *See id.* 1081 n.4; *compare* A Legislative History of the Clean Air Act Amendments of 1990, at 4445, *with id.* at 2139–40.

EPA's own cancer risk guidelines acknowledge that health-protective assumptions (also known as scientific "defaults") and uncertainties are always present in risk assessment where the goal is to attempt to predict and prevent future harm. The guidelines acknowledge that "a high level of uncertainty does not imply that a risk assessment or a risk management action should be delayed" and recommend that "[a]ssessments should discuss the significant uncertainties encountered in the analysis."[33] EPA's own risk assessment policy and guidelines also recognize that carcinogenic risk adds up with each increment of exposure and that there is no safe level of exposure.[34] EPA conducts a risk analysis and acknowledges that the total risk exceeding 100-in-1 million level is presumptively unacceptable. Benzene NESHAP, 54 Fed. Reg. 38044, 38045 (Sept. 14, 1989). EPA guidelines direct that "the primary goal of EPA actions is protection of human health; accordingly, as an Agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective."[35]

H. EPA Unlawfully and Arbitrarily Fails to Justify the Health Harms Its Proposal Will Cause to Children.

Section 112(f)(2) requires EPA to promulgate standards that "provide an ample margin of safety to protect public health." 42 U.S.C. § 7412(f)(2)(A). Children's health is an important part of the "public health" that EPA must protect under section 112(f)(2), and thus EPA must consider

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[33] EPA, Guidelines for Carcinogen Risk Assessment (March 2005), EPA-HQ-OAR-2019-0178-1517, at 3-29 [hereinafter "2005 Carcinogen Risk Assessment Guidelines"].
[34] *See id.* at 3-26; NIOSH, Current Intelligence Bulletin 68: NIOSH Chemical Carcinogen Policy 20 (July 2017) ("for most carcinogens"—i.e., those with a linear dose response, like ethylene oxide—"there is no known safe level of exposure"), https://www.cdc.gov/niosh/docs/2017-100/default.html (attached).
[35] *See* 2005 Carcinogen Risk Assessment Guidelines, at 1-7.

greater early-life susceptibility as part of deciding whether to weaken the standards. Moreover, section 112(f)(2) requires EPA to focus in particular on "the individual most exposed to emissions from a source" in the category. *Id.* § 7412(f)(2)(A). Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks, 62 Fed. Reg. 19885 (Apr. 23, 1997), and EPA policy also require EPA to protect children from environmental health risks.[36]

EPA's proposal fails to meet the ample margin of safety requirement under section 112(f)(2) because EPA does not show how it will provide this required health protection for children—who are among the individuals most exposed to sterilizers' EtO emissions. EPA does not assess the particular risk to children in its proposal to rescind the 2024 risk review standards.

Children are among the individuals most exposed and vulnerable to EtO emissions from this source category for at least two reasons that EPA has already acknowledged. First, many commercial sterilization facilities are located near residences and schools. 89 Fed. Reg. 24091. Second, "EtO is a mutagen, meaning it acts directly on DNA and causes chromosome damage. Children may be particularly susceptible to the harmful effects of mutagenic substances." EPA, Regulatory Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations, EPA-HQ-OAR-2019-0178-1557 (March 2024), at 4-2 [hereinafter "2024 Rule RIA"]. As explained in Section II of these comments, the best available science shows that EtO poses disproportionately high cancer risks to children under age 16. IRIS Assessment at 1-3 ("Because the weight of evidence supports a mutagenic mode of action for EtO carcinogenicity, … increased early-life susceptibility should be assumed."); *see Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*, EPA (March 2005), EPA/630/R-03/003F. In particular, "very young children might have a decreased capacity to detoxify EtO compared to adults" because detoxifying enzymes that enable clearance of EtO from the body do not develop until after birth.[37] When applying EPA's age-dependent adjustment factors and comparing to people aged 16 and up, children aged 2 to 16 face unit risks that are 3 times higher, and children aged 0 to 2 face risks that are 10 times higher, which reflects greater early-life susceptibility to EtO carcinogenicity.[38] To meet its mandate under section 112(f)(2), EPA must consider these significant health risks to children in its revision to the commercial sterilizer standards.

In addition to being unlawful, EPA's failure to consider the impacts of the Proposed Rule on children's health is arbitrary and capricious and contradicts Executive Order 13045 and EPA's Policy on Children's Health.[39] EPA's failure to assess the impacts of the proposal on children's health "fail[s] to consider an important aspect of the problem" and its conclusion that section 112(d) standards sufficiently protect children is unsupported and "runs counter to the evidence" in the record. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("*State Farm*").

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[36] *U.S. Environmental Protection Agency Policy on Children's Health* (March 2026), https://www.epa.gov/system/files/documents/2026-03/children-s-health-policy-march-2026.pdf [hereinafter "EPA Policy on Children's Health"] (attached).
[37] 2016 IRIS Assessment, EPA-HQ-OAR-2019-0178-0477, at 3-71.
[38] *Id.* at 4-89.
[39] EPA Policy on Children's Health (attached).

Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks, requires federal agencies to "make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children" and to "ensure that its … standards address disproportionate risks to children that result from environmental health risks or safety risks." EO 13045, Sec. 1, 62 Fed. Reg. 19885, 19885 (Apr. 23, 1997). In the 2024 Rule, EPA's analysis pursuant to EO 13045 noted that "because EtO is mutagenic, emission reductions in this preamble will be particularly beneficial to children. In addition, children are at increased risk if they live, play, or attend school in close proximity to a commercial sterilization facility, of which there are many cases noted by the public to be the case." 89 Fed. Reg. at 24149. EPA acknowledges that EO 13045 applies to the Proposed Rule. 91 Fed. Reg. at 12735. EPA further acknowledges that "[t]he environmental health and safety risks addressed by this action present a disproportionate risk to children due to EtO being mutagenic." *Id.* Yet, EPA does not explain at all how it can still be lawful and reasonable to rescind these protections, and admits it "did not conduct a new analysis of children's environmental health for this action." *Id.* EPA's action plainly contradicts EO 13045.

EPA's proposal also acknowledges and contradicts the agency's Policy on Children's Health. *See* 91 Fed. Reg. at 12736. That policy states that "it is EPA's policy to protect children from environmental exposures by consistently and explicitly considering early life exposures and potential lifelong health impacts in all human health decisions."[40]

EPA attempts to justify the impact of its proposal on children's health by pointing to the remaining standards promulgated under section 112(d) that it proposes to keep. *See* 91 Fed. Reg. 12735–36. But EPA completely ignores its previous conclusion that even after application of standards finalized under sections 112(d)(2), (d)(3), and (d)(5), risks remain unacceptable. *See* 89 Fed. Reg. at 24119. EPA's assertion that any remaining standards promulgated under those sections "will continue to apply and protect children's health" is unsupported and plainly contradicted by the evidence before the agency and by EPA's previous conclusions. 91 Fed. Reg. at 12736.

I. Even if EPA Did Not Have the Obligation to Conduct an Additional Health Risk Review, the Agency Retains Authority to do so Here and Reasonably Used its Discretion in 2024.

As explained, reading the statute to merely authorize, rather than require, new health risk reviews is inconsistent with the Act's plain text, structure, purpose, and history. *Cf. LEAN*, 955 F.3d at 1099 ("EPA's reading of the Act to allow but not require the Agency to address previously uncontrolled air toxics during a scheduled section 112(d)(6) review implausibly leaves no statutory prompt for the completion of statutorily deficient controls."). But even assuming, arguendo, that section 112(f)(2) did not require EPA to conduct risk reviews within eight years of promulgating section 112(d) standards, the Act certainly authorizes EPA to conduct additional risk reviews using its discretion. Indeed, this is the position that EPA has taken until now. Nothing in section 112 or elsewhere in the Clean Air Act prohibits EPA from updating its section 112(f)(2) risk reviews, as EPA now argues. For the same reasons explained above, *see supra* Section I.A–D, such a prohibition would be inconsistent with the Act's text, structure, purpose,

[40] EPA Policy on Children's Health (attached).

and history. Thus, under either reading of the statute—that it requires or merely authorizes EPA to conduct additional health risk reviews—EPA's claim here that the 2024 risk review was barred is wrong and cannot support repeal.

In conducting the 2024 risk review, EPA appropriately exercised its discretion under (1) section 112(f)(2), (2) section 301(a)(1), and (3) "the basic architecture of administrative law." EPA Br. at 30, *Cal. Cmtys. Against Toxics v. EPA*, Nos. 24-1178/1180 (consolidated) (D.C. Cir. Feb. 24, 2025), Doc. #2102382. As EPA explained before the D.C. Circuit in defense of the 2024 Rule, "[w]hen a statute authorizes an agency to decide a matter, that authority is implicitly 'accompanied by the power to reconsider' that decision." *Id.* (quoting *NRDC v. Regan*, 67 F.4th 397, 401 (D.C. Cir. 2023)); *accord Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81, 86 (D.C. Cir. 2014) (explaining that the "power to reconsider is inherent in the power to decide"). To be sure, Congress "can limit an agency's discretion to reverse itself." *New Jersey v. EPA*, 517 F.3d 574, 583 (D.C. Cir. 2008). But where Congress has not barred revisions or reconsideration or curtailed such actions, such as by providing a "mechanism capable of rectifying mistaken actions," *Am. Methyl Corp. v. EPA*, 749 F.2d 826, 835 (D.C. Cir. 1984), an agency need not identify explicit reconsideration authority to revisit or revise a prior action. EPA's reading of section 112(f)(2) and its administrative rulemaking authority—that they authorize EPA to weaken, but not strengthen, risk reviews based on new information—finds no support in the Clean Air Act or general principles of administrative law. EPA cannot have it both ways. That is, it cannot assume it has authority to only weaken or rescind standards and not to strengthen them when there is lawful grounds to do so. Here, as EPA correctly concluded in the 2024 Rule, the 112(f)(2) review was necessary "in order to ensure that the standards provide an ample margin of safety to protect public health." 89 Fed. Reg. at 24094.

Under either interpretation of section 112(f)(2) (whether it mandates or merely authorizes the 2024 risk review), rescinding the 2024 risk review would not survive court review under the Clean Air Act. *See Loper Bright*, 603 U.S. at 395 ("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 … fix[] the boundaries of the delegated authority, and ensur[e] the agency has engaged in reasoned decisionmaking within those boundaries.") (internal citations and quotations omitted)); *see* 5 U.S.C. § 706(2); 42 U.S.C. § 7607(d)(9); *supra* Section I.A–D, F, G.

II. EPA's Proposed Rescission of the Risk Review Is Arbitrary and Capricious.

EPA provides two justifications for proposing to rescind the section 112(f)(2) review and standards. First, EPA asserts (1) an erroneous view of its obligations under section 112(f)(2); and (2) alleged uncertainty in the 2016 EtO IRIS value. For the reasons below, both of these justifications are arbitrary or otherwise unlawful in violation of the Clean Air Act and the Administrative Procedure Act. 42 U.S.C. § 7607(d)(9)(A); 5 U.S.C. § 706(2)(A).

EPA's proposed rescission of the section 112(f)(2) standards is based on an erroneous view of the law and therefore cannot be upheld (Section II.A). *See Sea-Land Serv., Inc. v. Dep't of Transp.*, 137 F.3d 640, 646 (D.C. Cir. 1998).

EPA fails to sufficiently explain its change in position on the EtO IRIS value and ignores evidence that the agency and the D.C. Circuit have already addressed EPA's alleged uncertainties (Section II.B). *See State Farm*, 463 U.S. at 42 ("[A]n agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance."). EPA also fails to sufficiently explain its departure from longstanding policies on developing IRIS values and using them in section 112(f)(2) risk reviews (Section II.C). *See id.*

EPA states that "new scientific evidence has continued to emerge" since it defended the 2016 EtO IRIS value in *Huntsman Petrochemical v. EPA*, 114 F.4th 727 (D.C. Cir. 2024), but it does not explain what those studies say or how they support EPA's action, 91 Fed. Reg. at 12715. By claiming such "significant uncertainties" without any evidentiary support, 91 Fed. Reg. at 12714, and by fishing for such evidence from commenters, EPA admits that its uncertainties with the EtO IRIS value are unsupported and that its proposal is "based on speculation" (Section II.D), *Delaware Dep't of Nat. Res. & Env't Control v. EPA*, 785 F.3d 1, 11 (D.C. Cir. 2015) (citation omitted).

Critically, EPA proposes no alternative assessment of the risks of ethylene oxide emissions from commercial sterilization facilities, which EPA had concluded pose as high as 6000-in-1 million cancer risks from actual emissions, or 8000-in-1 million for allowed emissions. 2024 Rule RIA at 4-3 to -4. EPA mentions the TCEQ EtO factor but does not explicitly propose to rely on it. Both EPA and the National Academy of Sciences agree that it is a scientifically and procedurally flawed factor, and the D.C. Circuit has already upheld EPA's judgment on precisely this point; it would be arbitrary and capricious for EPA to rely on the TCEQ EtO factor (Section II.E).

Without providing an alternative assessment of the risks, rescinding the 112(f)(2) standards in their entirety is necessarily arbitrary and capricious. EPA cannot indefinitely abdicate its statutory obligations due to alleged uncertainty (Section II.F). "[T]he mere invocation of 'substantial uncertainty'" is not a sufficient basis to reject its detailed risk assessment and abdicate its mandate to protect human health with an adequate margin of safety. *Murray Energy Corp. v. EPA*, 936 F.3d 597, 619 (D.C. Cir. 2019) (quoting *State Farm*, 463 U.S. at 52).

EPA's proposal also arbitrarily fails to consider the forgone health benefits of the 112(f)(2) standards (Section II.H). In doing so, EPA "fail[s] to consider an important aspect of the problem"—the core purpose of section 112(f)(2), which is to address public health and environmental risk. *State Farm*, 463 U.S. at 43. To the extent EPA receives any new information not in the record in response to its questions on the IRIS value (Questions 3–5)—such as new or updated information relevant to dose-response model selection, studies, factual data, methodology used to analyze that data, or quantitative assumptions or determinations not currently in the record—the agency may not rely on that information in the final rule without providing an additional opportunity for public comment through mandatory reconsideration of the rule (Section II.H). *See* 42 U.S.C. § 7607(d)(7)(B).

A. EPA's Proposed Rescission of the Section 112(f)(2) Standards Is Based on an Erroneous View of the Law.

"An agency action, however permissible as an exercise of discretion, cannot be sustained 'where it is based … on an erroneous view of the law.'" *Sea-Land Serv., Inc.*, 137 F.3d at 646 (quoting *Prill v. Nat'l Labor Relations Bd.*, 755 F.2d 941, 947 (D.C. Cir. 1985)). Legal error infects and invalidates the agency action regardless of factual support. *See Chen v. GAO*, 821 F.2d 732, 739 (D.C. Cir. 1987). EPA's rescission is based on two erroneous views of the law. First, the view that the CAA bars another risk review is erroneous for the reasons explained in Section I of this comment. Second, the view that EPA may withdraw the entire section 112(f)(2) standards based on alleged uncertainty in the IRIS value is erroneous for the reasons explained in Section II.F of this comment. *See* 91 Fed. Reg. at 12713–14.

B. EPA Fails to Sufficiently Explain Its Change in Position on the EtO IRIS Value and Ignores Evidence That the Agency and D.C. Circuit Have Already Addressed EPA's Alleged Uncertainties. (Response to Questions 3–6)

Beyond its (incorrect) position on its legal authority, EPA points to alleged "uncertainty" in the IRIS value on which EPA's risk assessment relied. *Id.* at 12714. "[A]n agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance." *State Farm*, 463 U.S. at 42. When an agency's "new policy rests upon factual findings that contradict those which underlay its prior policy," it must provide a "detailed justification" for its change. *FCC v. Fox Television Stations*, 556 U.S. 502, 515 (2009) ("*Fox*"). EPA's proposal to reverse its well-supported 2024 section 112(f)(2) standards on the basis of alleged uncertainties with the EtO IRIS value does not begin to meet these heightened standards.

EPA's call to uncertainty is not an adequate basis for rescinding the standards for several reasons. First, the 2016 EtO IRIS value remains the best available science on the toxicity of ethylene oxide. EPA fails to explain how or why its assessment of the very same facts about ethylene oxide risks, including uncertainty, changed between 2024 and the Proposed Rule. EPA previously acknowledged the same questions regarding dose selection and upper confidence limit, and it concluded that the IRIS assessment is the best available science. The agency repeatedly defended the IRIS value in the Miscellaneous Organic NESHAP ("MON") reconsideration process and before the D.C. Circuit—and won. *See* MON Rule, 85 Fed. Reg. 49084, 49097 (Aug. 12, 2020) (addressing model selection); Reconsideration of the 2020 MON Rule, 87 Fed. Reg. 77985, 77991 (Dec. 21, 2022) (finalizing MON Rule with 2016 EtO IRIS value and explaining rejection of TCEQ value); *Huntsman*, 114 F.4th 727. Second, EPA's alleged uncertainties do not undermine the IRIS value as the best available science. Third, recent studies do not undermine the IRIS value as the best available science.

i. The IRIS value is based on a decades-long systematic and peer review process.

EPA's Integrated Risk Information System ("IRIS") Program "provide[s] an internal database of human health assessments for chemicals found in the environment."[41] The goal of the IRIS Program is to foster impartiality and consistency in the evaluation of chemical toxicity across the Agency using the best available scientific and health information.[42] The program involves an extensive peer review and data evaluation process involving multiple EPA offices to ensure scientific rigor and reliability in its assessments.[43] The IRIS Program was intentionally placed in EPA's Office of Research and Development, a separate scientist-led office, to insulate it from regulatory processes and to ensure a health-protective and science-based (not a political or policy preference) approach.[44] As EPA's guidelines explain: "IRIS is a critical resource for risk assessors because the database contains toxicity information that reflects a consensus among EPA program offices."[45] "Because the IRIS process is so rigorous, IRIS assessments are considered the gold standard for toxicity values."[46]

The ethylene oxide IRIS assessment was developed in accordance with EPA's robust peer-review requirements and after a ten-year process involving internal technical review, external peer review, and the opportunity for public comment.[47] In EPA's own words, the 2016 IRIS assessment went through "unusually extensive processes for the consideration of public comment and external peer review" and is considered by EPA's ORD to be the "best available scientific information regarding cancer risks from EtO."[48] "In developing the 2016 IRIS assessment, ORD 'utilized extensive advice' from the Science Advisory Board (SAB) and incorporated recommendations from the SAB into the 2016 IRIS assessment to address

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[41] EPA, *Basic Information about the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process (Oct. 1, 2025) (attached).
[42] *Id.*
[43] *See, e.g.*, EPA, *ORD Staff Handbook for Developing IRIS Assessments* at 1-4, EPA 600/R-22/268 (Dec. 2022), https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=356370 (attached).
[44] EPA, *Basic Information about the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process (Oct. 1, 2025).
[45] EPA, *Air Toxics Risk Assessment Reference Library*, Vol. 1 Tech. Res. Manual, EPA-453-K-04-001A at 3-9 (Apr. 2004), https://www.epa.gov/sites/default/files/2013-08/documents/volume_1_reflibrary.pdf (attached); *id.* at 12-25 ("Dose-response assessments that have achieved full intra-agency consensus are incorporated in the Integrated Risk Information System (IRIS), which is regularly updated and available on-line (www.epa.gov/iris).").
[46] GAO, *Chemical Assessments: Annual EPA Survey Inconsistent with Leading Practices in Program Management* at 9 (Dec. 2020), https://www.gao.gov/assets/d21156.pdf (attached).
[47] EPA IRIS, *Ethylene Oxide, Background, History, and Other Supporting Documents*, https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=329730 (last updated Aug. 2, 2023) (attached).
[48] Memo from Timothy Dole (Senior Scientist, CIH) to Jessica Bailey (Chemical Review Manager, Antimicrobials Division) at 2 (March 27, 2023), https://www.epa.gov/system/files/documents/2023-04/eto-rtc.pdf (attached) (citing Memo from W. Cascio (ORD) to J. Goffman (OAR), ORD Review of Comments on the IRIS Ethylene Oxide Assessment Contained in the ACC Request for Correction Submitted Regarding EPA's National Air Toxics Assessment, Aug. 25, 2021, Page 1) (attached)).

uncertainties identified by the SAB. Further, since the publication of the 2020 DRA, the EPA has repeatedly expressed favorable views of the 2016 IRIS assessment, including comparison to the other EtO cancer inhalation risk characterization approaches cited in the 2020 [Draft Risk Assessment]."[49]

Ethylene oxide is a known carcinogen that increases risk of breast cancer and lymphoid cancer, and causes acute health impacts to the eyes, skin, nose, throat, and lungs.[50] Particularly, EPA found that it is "carcinogenic to humans" through inhalation.[51] Other scientists and health experts have independently confirmed this finding, including the National Toxicology Program, the International Agency for Research on Cancer, and the Occupational Safety and Health Administration.[52] IRIS determined that the risk across a lifetime of breathing just one microgram of ethylene oxide per cubic meter of air was 0.005.[53] Consistent with EPA's ORD Handbook and Supplemental Cancer Guidelines, this factor included age-adjustment factors due to increased susceptibility to cancer resulting from exposure during childhood.[54] IRIS described a "relatively high" confidence in the factor, and a "particularly high" confidence for breast cancer, "based on strong epidemiological evidence supplemented by other lines of evidence," including "a large, high-quality epidemiology study with individual worker exposure estimates" and over 200 breast cancer incident cases.[55] IRIS also explained that the method of linear low-exposure extrapolation used "is strongly supported."[56]

All available peer-reviewed scientific evidence—as cited by the 2016 IRIS value and as scientists' comments and testimony have emphasized[57]—show that this value is robust and the best available reflection of cancer risk caused by ethylene oxide. EPA and independent scientists and health experts have repeatedly confirmed that the 2016 EtO IRIS value is the best available

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[49] *Id.* (citation omitted).
[50] EPA, *Ethylene Oxide 75-21-8* (2016), EPA-HQ-OAR-2019-0178-0459, at 1.
[51] 2016 IRIS Assessment, EPA-HQ-OAR-2019-0178-0477, at 1-1.
[52] National Toxicology Program, *Ethylene Oxide*, Report on Carcinogens (2016), https://ntp.niehs.nih.gov/ntp/roc/content/profiles/ethyleneoxide.pdf (attached); International Agency for Research on Cancer, *Chemical Agents and Related Occupations: Volume 100 F A Review of Human Carcinogens* 379–400 (2012), https://publications.iarc.who.int/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Chemical-Agents-And-Related-Occupations-2012 (attached); Occupational Safety and Health Administration, OSHA Fact Sheet Ethylene Oxide (2002), https://www.osha.gov/OshDoc/data_General_Facts/ethylene-oxide-factsheet.pdf (attached).
[53] 2016 IRIS Assessment, EPA-HQ-OAR-2019-0178-0477, at 1-1.
[54] *Id.* at 4-89; *see* EPA, *Handbook for Developing IRIS Assessments* at 8–11 (Dec. 2022), https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=356370 (requiring application of age-dependent adjustment factors to cancer risk values "to account for the fact that early life exposures to mutagens increase the risk for cancer") (attached); EPA, *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* EPA/630/R-03/003F (March 2005), https://www.epa.gov/risk/supplemental-guidance-assessing-susceptibility-early-life-exposure-carcinogens (attached).
[55] 2016 IRIS Assessment, EPA-HQ-OAR-2019-0178-0477, at 1-1, 1-4.
[56] *Id.* at 1-4.
[57] *See, e.g.*, Letter from Scientists to EPA (Apr. 26, 2019) (filed by J. Sass, NRDC), EPA-HQ-OAR-2018-0417-0132 (attached).

science on the toxicity of ethylene oxide. Industry's repeated attempts to undermine this value have all been rejected by EPA and the D.C. Circuit. *See* MON Rule, 85 Fed. Reg. 49084, 49097 (Aug. 12, 2020); Reconsideration of the MON Rule, 87 Fed. Reg. at 77991 (finalizing MON Rule with 2016 EtO IRIS value and explaining rejection of TCEQ value); *Huntsman*, 114 F.4th at 734.

ii. EPA's alleged uncertainties in the IRIS value do not undermine it.

EPA now asserts that alleged uncertainties with the IRIS value—the dose-response model selection and the statistical upper confidence limit—justify undermining the 2016 IRIS value and withdrawing the entire 112(f)(2) review for this source category. EPA and the D.C. Circuit addressed and put these uncertainties to rest years ago, and rightly so. For the reasons below, neither of these alleged uncertainties undermine the IRIS value as the best available science. The mere existence of those same uncertainties, without more, cannot justify EPA's shift in the Proposed Rule. A departure from such a consistent, robust record in which EPA has already addressed these uncertainties in the IRIS assessment, MON reconsideration, and before the D.C. Circuit in *Huntsman* requires a robust explanation, and EPA has failed to provide it. *See Fox*, 556 U.S. at 515. EPA does not explain how "uncertainties" change its risk assessment: Does the Agency believe there are no residual risks (and if so, how does it reach that conclusion)? Does the Agency believe the risks are still present, but less than it identified in 2024 (and if so, what risks will commercial sterilization facilities present if EPA finalizes this Proposal)? Without even an attempt to answer these questions, EPA's proposed action is arbitrary and capricious. EPA's attempts to distance itself from its representations before the D.C. Circuit in *Huntsman* fail. EPA cites to one source: a memorandum, "Sensitivity of ethylene oxide risk estimates to dose-response model selection" ("White Memo") (attached), but the White Memo in fact reaffirms EPA's ultimate model selection. Thus, EPA's conclusion "runs counter to the evidence" in the record, and EPA cannot rationally rely on that memo as a reason to undermine the model selection. *State Farm*, 463 U.S. at 43. Additionally, EPA states that "new empirical data may trigger a need to reevaluate toxicity values." 91 Fed. Reg. at 12715. Merely citing to two studies—without explaining their conclusions or how those conclusions support EPA's proposed action—is insufficient. *See Fox*, 556 U.S. at 515. Furthermore, these studies do not undermine the IRIS value as the best available science. Thus, EPA cannot rationally rely on the cited studies as a reason to undermine the model selection.

The IRIS value is based on the best model. The 2016 ethylene oxide IRIS assessment considered multiple lymphoid cancer models (including models not included in the White Memo) and rejected alternative models while affirming that "the lymphoid cancer estimate is considered a reasonable estimate from the available data, and overall, there is relatively high confidence in the total cancer unit risk estimate."[58] EPA repeatedly defended its model selection and rejection of certain endogenous and background levels of EtO in the MON reconsideration process and before the D.C. Circuit—and won. For the reasons below, reliance on the White Memo to question EPA's model selection is irrational because that Memo in fact supports EPA's model selection.

[58] 2016 IRIS Assessment, EPA-HQ-OAR-2019-0178-0477, at 1-5.

In the MON reconsideration, EPA addressed public comments on model selection and upper confidence limit, and it reaffirmed its reliance on the 2016 EtO IRIS value in the final rule. *See* Proposed MON Rule, 69182, 69218 (Dec. 17, 2019); Final MON Rule, 85 Fed. Reg. 49084, 49097–98 (Aug. 12, 2020); Responses to Comments (Aug. 12, 2020), EPA-HQ-OAR-2018-0746-0200, at 84–99 (responding to comments on dose-response model development and evaluation). When ORD reviewed comments on the IRIS Ethylene Oxide assessment contained in the American Chemistry Council's Request for Correction submitted regarding dose model selection and endogenous exposure, it concluded that the Request for Correction did not demonstrate any errors in the IRIS assessment and stated that "ORD notes that the EtO IRIS Assessment was appropriately conducted with unusually extensive processes for the consideration of public comment and external peer review. ORD considers the 2016 assessment to still represent the best available scientific information regarding cancer risks from EtO."[59] EPA ultimately finalized the MON Rule with the 2016 EtO IRIS value. Reconsideration of the MON Rule, 87 Fed. Reg. at 77991.

In *Huntsman*, EPA again defended its model dose selection, the 2016 EtO IRIS value, and its rejection of the TCEQ EtO factor. 114 F.4th at 734; EPA Br., *Huntsman*, No. 23-1085 (D.C. Cir. Jan. 16, 2024), Doc. # 2035712 (attached). The D.C. Circuit upheld the validity of EPA's model selection for 2016 EtO IRIS and its rejection of studies on endogenous and background levels of EtO. *See Huntsman*, 114 F.4th at 737. In holding that EPA's decisions were not arbitrary or capricious, the Court explained that EPA had "extensively explained why it chose the NIOSH study as the basis for its risk assessment," adequately explained its use of categorical averages when assessing visual fit of potential statistical models, did not run contrary to feedback from EPA's Science Advisory Board, and that its selection of statistical model using a two-piece linear spline was not arbitrary and capricious." *Id.*; *see id.* at 735–38.

Now, EPA alleges that its uncertainty in the dose model justifies rescinding the entire section 112(f)(2) risk review in this rule. To justify this new position, EPA cites to the White Memo, which addressed alternative cancer dose-response models. EPA mischaracterizes the White Memo by suggesting it supports using some alternative to the IRIS factor. It does not. Quite the opposite, the memo explains that, like any risk assessment, the 2016 IRIS factor exists in the context of some uncertainty regarding the communities' full real-world risk from exposure to ethylene oxide. It describes the models that IRIS, in consultation with the Science Advisory Board, considered and rejected, explains why, and acknowledges that the IRIS factor is not the most conservative value that IRIS considered. The White Memo ultimately reconfirms that the 2016 IRIS value is the best and the only available science that is health protective and satisfies EPA's own principles of scientific integrity. Thus, EPA's conclusion on the White Memo and alleged uncertainty regarding the model selection "run[] counter to the evidence." *State Farm*, 463 U.S. at 43.

In 2019, the Office of Air and Radiation "inquired" to the Office of Research and Development about the "uncertainties" in the 2016 IRIS value. The Director of the Office of

[59]EPA, ORD Review of Comments on the IRIS Ethylene Oxide Assessment Contained in the ACC Request for Correction submitted regarding EPA's National Air Toxics Assessment (Aug. 25, 2021), EPA-HQ-OAR-2018-0746-0264_attachment_1 [hereinafter "ORD Review of Comments"] (attached).

Research and Development responded with an accompanying "analysis, developed by Paul White [that] synthesizes the information on the range of model forms evaluated in the IRIS assessment, and considering statistical and biological factors, identifies additional models examined that can reasonably contribute to quantitatively characterizing model and statistical uncertainty in the risks of cancer associated with environmental exposures to [ethylene oxide]."[60]

The White Memo explains that, to determine the most appropriate modeling approach, "EPA conducted extensive statistical modeling to examine multiple approaches to represent the risk information" from "human data from a large, high-quality, occupational epidemiology study." White Memo at 2. "[T]he IRIS assessment examined a large number of potentially applicable models," and SAB "offered advice on several aspects of model choice that the EPA considered in completing the assessment…." *Id.* Specifically, the SAB:

> - Recommended prioritizing functional forms of the exposure that allow regression models with more local fits in the low exposure range (e.g., spline models)
> - Preferred the use of continuous individual-level exposure data over the use of categorical results
> - Advised that any model that is to be considered reasonable for risk assessment must have a dose-response form that is both biologically plausible and consistent with the observed data.
>
> These considerations led the IRIS assessment to select the 2-piece linear spline models for dose- response assessment for both lymphoid and female breast cancers. Spline models were the only models identified that were fully consistent with SAB's advice.

Id.

Among the spline models EPA evaluated, the linear 2-piece spline model fit those considerations most strongly. EPA did consider alternative spline models, including a log-linear spline, but none fit the SAB criteria as well as the selected model. Even the next best-performing alternative, the log-linear spline, yielded an upper bound risk estimate nearly three times lower than the selected model, which highlights that the model selection rather than statistical conservatism was the primary driver of differences between EPA's risk estimate and those derived using alternative approaches.

Importantly, IRIS ensured that the parameters outlined above and advised by the SAB were taken into full consideration in selecting the final dose-response model for the 2016 ethylene oxide toxicological assessment. These considerations led the IRIS assessment to select

[60] Letter from ORD to OAR Re: IRIS EtO Assessment - Modeling Comparisons and Assessment of Uncertainty 1 (Oct. 18, 2019), https://www.epa.gov/sites/default/files/2019-11/documents/memo_sensitivity_of_ethylene_oxide_risk_estimates_to_dose-response_model_selection_c_.pdf (attached).

the 2-piece linear spline models for dose response assessment for both lymphoid and female breast cancers. The 2-piece linear spline model was the only model identified that was fully consistent with SAB's advice listed above.

EPA previously determined that other models were not good fits for the dose-response data. In other words, they are not the best available models when compared to the model chosen in the IRIS assessment. For each alternative dose-response model, the memo provides sound reasons why each alternative model was flawed and why "IRIS/SAB modeling goals were robustly met by the fitted two-piece spline model." *Id.* at 4. Importantly, White also highlights that the other models and estimates presented in his memo, which IRIS soundly rejected, "are not adjusted for [Age Dependent Adjustment] factors for early life sensitivity to mutagenic carcinogens." *Id.* at 6. That is, in addition to failing to meet IRIS and the SAB's scientific principles, they fail to account for increased risk to children, and to the increased risk to people for cancer at some point in their lifetime from exposure during childhood. And the alternative back-of-the envelope calculations regarding potentially lower risks cannot be relied on or used in any way for regulatory purposes because they have not gone through the rigorous systematic and peer reviews within the IRIS process, including the basic and necessary step to apply such factors to account for the increased vulnerability of children.

White notes that the IRIS value "should not be considered a worst-case analysis. Higher estimates of risk were obtained using some other models providing statistically appropriate fits to the data.... [I]t is likely that a comprehensive analysis of alternative models ... would likely include some risk estimates higher than the IRIS unit risk." *Id.* Importantly, while IRIS properly considered childhood vulnerability, it placed no factor on the increased cancer risk due to *in utero* exposure, to the developing fetus. OEHHA does just that. EPA scientists pointed out years ago that this is an important way to address impacts that can begin at that stage of development. The scientific evidence showing the need to account for impacts of toxic chemicals like ethylene oxide to the developing fetus and during pregnancy as well as in childhood, has only continued to develop and deepen since the IRIS value.[61] So, in addition to not being the "worst-case" or most conservative value, the IRIS factor itself also likely underestimates the real-world cancer risk for people whose exposure began before birth.

The White Memo confirms this issue by pointing out "[h]igher estimates of risk were obtained using some other models providing statistically appropriate fits to the data. While there were limitations with these models, and we have not used them in this analysis, it is likely that a comprehensive analysis of alternative models (for example considering other spline models with knots somewhat lower than the selected values) would likely include some risk estimates higher than the IRIS unit risk." White Memo at 6. The explanation provided in the White Memo reaffirms that these alternative models were considered but not relied upon following an extensive and all-inclusive analysis of available alternative dose-response models and due to the

[61] Dzubow, R. et al., *Comparison of Carcinogenic Potency Across Life Stages: Implications for the Assessment of Transplacental Cancer Risk*, 82 J. Toxicol. & Envtl. Health A 769 (2019) (attached); Cal. EPA, Air Toxics Hot Spots Program Risk Assessment Guidelines: Technical Support Document for Exposure Assessment and Stochastic Analysis at 1-6 to 1-7 (Aug. 27, 2012), https://oehha.ca.gov/air/crnr/notice-adoption-technical-support-document-exposure-assessment-and-stochastic-analysis-aug-2012.

selected model having the best fit to the SAB's factors of model choice.

The use of the upper confidence limit is scientifically sound and EPA's standard protocol. EPA's discussion of the central estimate in the Proposed Rule is inconsistent with EPA's own definition of the unit risk estimate and principles espoused in the 2005 Guidelines for Carcinogen Risk Assessment. EPA-HQ-OAR-2019-0178-1517 [hereinafter "2005 Guidelines"]. EPA fails to support its change in course on this protocol with a "a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance." *State Farm*, 463 U.S. at 42; *see Fox*, 556 U.S. at 515.

A unit risk estimate is defined as "the upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 µg/m^3 in air…. [Unit risk estimates] are considered upper-bound estimates, meaning they represent a plausible upper limit to the true value. (Note that this is usually not a true statistical confidence limit.) The true risk is likely to be less, but could be greater."[62] In a risk assessment, the central estimate is defined as "the mean or average of the distribution; or a number which contains multiple estimates of risk based on different assumptions, weighted by their relative plausibility; or any estimate judged to be most representative of the distribution."[63] Importantly, "[t]he central estimate should neither understate nor overstate the risk, but rather, should provide the risk manager and the public with the expected risk."[64] IRIS, in its 2016 ethylene oxide assessment, appropriately provided the central estimate along with the upper-bound and lower- bound risk estimates and chose the UCL to derive its unit risk estimate based on the guidance outlined in the 2005 Guidelines.[65]

Using the UCL for known carcinogens and mutagens, like EtO, is standard protocol in EPA IRIS assessments. The 2005 Guidelines support this approach by stating "to the extent practicable, such assessments should provide central estimates of potential risks in conjunction with lower and upper bounds (e.g., confidence limits) and a clear statement of the uncertainty associated with these estimates."[66] The 2016 IRIS assessment provides this information. Indeed, EPA, in its response on the use of upper and lower confidence limits, stated: "In both the 2006 and revised drafts of the [ethylene oxide] assessment, the EPA presents 95% (one-sided) lower bounds and central estimates ... as well as standard errors for the regression coefficients used in the modeling, which provide information about the variability in the modeled slope estimate. The

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[62] *See* EPA, NATA Glossary of Terms "unit risk estimate" (updated Dec. 26, 2016), https://19january2017snapshot.epa.gov/national-air-toxics-assessment/nata-glossary-terms_.html (attached).

[63] *See, e.g.*, C.A. Holloway, *Decision Making Under Uncertainty: Models and Choices* 76, 91–127, 214 (1979); Theodore Colton, *Statistics in Medicine* 28–31 (1974).

[64] Nat'l Research Council, *Science and Judgment in Risk Assessment* 170–75 (Nat'l Acad. Press 1994), https://pubmed.ncbi.nlm.nih.gov/25032408/.

[65] *See* Nat'l Acad. of Scis., *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Mgmt. & Budget* app. B (2007), https://www.nap.edu/read/11811/chapter/11#139 ("When there is uncertainty in estimates of risk, presentation of single estimates of risk is misleading and provides a false sense of precision. Presenting the range of plausible risk estimates, along with a central estimate, conveys a more objective characterization of the magnitude of the risks. Influential risk assessments should characterize uncertainty by highlighting central estimates as well high-end and low-end estimates of risk. The practice of highlighting only high-end or only low-end estimates of risk is discouraged.") (attached).

[66] 2005 Guidelines, EPA-HQ-OAR-2019-0178-1517, at 25.

EPA's Guidelines for Carcinogen Risk Assessment also recommend the calculation of a 95% upper bound on the central estimate ... related to the [point of departure] 'to the extent practicable.'"[67] Contrarily, each aforementioned Guideline supports selecting the most health protective factor, as IRIS has done in the final ethylene oxide toxicological assessment.

Although EPA finds the 2016 IRIS value is health protective, it proposes that risk could be lower. Lowering the value contradicts EPA's 2005 Guidelines for Carcinogenic Risk Assessment, which direct that, "the primary goal of EPA actions is protection of human health; accordingly, as an Agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective."[68]

iii. Recent studies do not undermine the IRIS value.

When an agency's "new policy rests upon factual findings that contradict those which underlay its prior policy," it must provide a "detailed justification" for its change. *Fox*, 556 U.S. at 515. In the Proposed Rule, EPA states: "Since the EPA defended the use of the 2016 EtO IRIS value in *Huntsman,* new scientific evidence has continued to emerge." 91 Fed. Reg. at 12715. To support this point, EPA merely cites to two studies in footnotes. *Id.* at 12715 nn. 55, 56. These studies were authored and submitted by industry to call into question the 2016 EtO value. First, merely citing to these studies without explanation of what they conclude, or how that conclusion supports EPA's action, is arbitrary and capricious. Second, EPA's characterization of these papers as introducing "significant uncertainties" in the 2016 IRIS value misrepresents both their scope and their findings. Neither study adds any uncertainty to the IRIS value nor undermines it as the best available science—one study, in fact, reinforces it. Thus, EPA cannot rationally cite to them as supporting its proposed action.

The 2016 IRIS assessment derived its inhalation unit risk by combining lymphoid cancer mortality from the NIOSH cohort (contributing approximately 87% of the final IUR) and breast cancer incidence from the same cohort (contributing the remaining approximately 13%).[69] EPA selected breast cancer incidence as the more sensitive endpoint given that breast cancer is not a rapidly fatal cancer, with Kelly-Reif et al. (2025) noting that the U.S. five-year survival rate now exceeds 90%, meaning the use of mortality data would systematically undercount incident cases and underestimate exposure-associated risk.[70] Both papers cited in the reconsideration evaluate breast cancer mortality, which is a less sensitive measure of EtO-attributable breast cancer burden than incidence. Importantly neither paper addresses the endpoint that EPA used to derive the breast cancer component of the IRIS IUR and therefore do not undermine the 2016 value.

Critically, Kelly-Reif et al. (2025) strengthens the scientific foundation underlying the IRIS assessment. The 62-year NIOSH cohort follow-up finds a supralinear exposure-response

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[67] EPA, Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide APPENDICES (Dec. 2016), EPA-HQ-OAR-2019-0178-0477_attachment_2 [hereinafter "2016 IRIS Appendices"].
[68] 2005 Guidelines, EPA-HQ-OAR-2019-0178-1517, at 1-7.
[69] 2016 IRIS Assessment, EPA-HQ-OAR-2019-0178-0477, at 4-84.
[70] *Id.* at 1-2; Kelly-Reif, K. et al., *Exposure to Ethylene Oxide and Relative Rates of Female Breast Cancer Mortality: 62 Years of Follow-Up in a Large U.S. Occupational Cohort*, 133 Env't Health Persp. 057013 (2025) (attached).

relationship between cumulative EtO exposure and breast cancer mortality, with substantially elevated relative rates even in the lowest exposure categories.[71] The authors note that because mortality studies underestimate incidence risks, their mortality findings should be understood as a lower bound on the true breast cancer risk, which suggests that the IRIS incidence-based estimate remains appropriately conservative rather than overstated.[72]

Valdez-Flores et al. (2025) challenge the shape of the dose-response model for lymphoid cancer mortality using the updated Union Carbide Corporation ("UCC") cohort and argue that the standard Cox proportional hazards model is more plausible than EPA's two-piece linear spline.[73] This methodological dispute is not new, and it restates the same TCEQ position that EPA and the SAB have already evaluated and rejected.[74] More importantly, the paper analyzes lymphoid cancer mortality in an all-male chemical manufacturing cohort, a population structurally distinct from the male and female sterilant worker NIOSH cohort that underlies the IRIS value. Furthermore, it does not address the breast cancer incidence endpoint at all. The UCC cohort also cannot address female cancers by design, which is a critical limitation given that female lymphoid cancers in the NIOSH study contribute to the combined-sex analysis EPA used.

EPA's characterization of these papers as introducing "significant uncertainties" in the 2016 IRIS value misrepresents both their scope and their findings. The Kelly-Reif et al. (2025) study reinforces a core tenet of the IRIS value, which is that breast cancer is a critical health endpoint to consider, while the Valdez-Flores et al. (2025) study relies on a study that lacks the statistical power and population characteristics to displace the primary NIOSH analysis. Neither paper provides a scientific basis for reconsideration of the 2024 Rule.

Some studies call into question the appropriateness of the IRIS EtO unit risk and, subsequently, the relative importance of exogenous EtO exposures in cancer incidence by comparison of endogenous and exogenous exposures.[75] However, these studies are based on an unvalidated method using a hemoglobin biomarker as a proxy to measure EtO exposure. As EPA previously explained, that method "was not valid to assess the low environmental exposures that EPA was examining." *Huntsman*, 114 F.4th at 741. Additionally, EPA has noted that biomonitoring data such as National Health and Nutrition Examination Survey (NHANES) "provides cross-sectional data representing a snapshot in time of exposure and health outcome and is not designed to establish temporal causality between chemical exposure and cancer outcomes."[76] Therefore, contextualizing exogenous exposures with endogenous exposures using

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[71] Kelly-Reif et al., *Exposure to Ethylene Oxide*, 133 Env't Health Persp. 057013.
[72] *Id.*
[73] Valdez-Flores, C. et al., *Use of Updated Mortality Study of Ethylene Oxide Manufacturing Workers to Inform Cancer Risk Assessment*, 45 Risk Analysis 2822 (2025) (attached).
[74] 2016 IRIS Assessment, EPA-HQ-OAR-2019-0178-0477, at 4-3 to 4-4 and 4-60 to 4-61.
[75] Kirman, C.R. et al., *Ethylene Oxide Review: Characterization of Total Exposure via Endogenous and Exogenous Pathways and Their Implications to Risk Assessment and Risk Management*, 24 J. Toxicol. & Envtl. Health B 1 (2021); Sheehan, P.J. et al., *Ethylene Oxide Exposure in U.S. Populations Residing Near Sterilization and Other Industrial Facilities: Context Based on Endogenous and Total Equivalent Concentration Exposures*, 18 Int'l J. Envtl. Res. & Pub. Health 607 (2021) (attached).
[76] 87 Fed. Reg. at 77992.

this method does not change the conclusions of the IRIS assessment or have any effect on the unit risk itself.

Three studies, all fully authored by consultants from Cardno ChemRisk, provide their own systematic review and meta-analysis.[77] However, these studies have multiple shortfalls and are insufficient to reverse the findings from EPA or support a weaker cancer risk value. For example, the meta-analysis in these studies can dilute the findings from more high-quality, occupational exposure scenarios from cohorts such as in the NIOSH study which was ranked by EPA as "high-quality" due to its large size and validated exposure model. These meta-analyses often combine high-power study data with data from smaller studies with indirect exposure measurements and limited statistical power. This can result in ignoring statistically significant exposure-response findings in robust individual studies, such as the NIOSH study, and replaces these nuanced internal findings with an overall finding based on comparisons between diverse studies with varying designs and populations. Findings from these limited studies from the same industry consultants are not strong enough to refute the strengths of the IRIS assessment—including reliance on high-quality primary data (such as the NIOSH cohort data), controlling for factors such as the healthy worker effect, and undergoing an extensive systematic and peer review process.

In contrast, multiple studies published recently support EPA's conclusions on EtO's association with blood and breast cancers,[78] as previously discussed in comments on the Chemical Manufacturing Area Sources NESHAP (Docket Number EPA-HQ-OAR-2024-0303).[79] For example, a reanalysis of the 1991 NIOSH study of occupational EtO exposure[80] that included a "duration of employment" adjustment strengthened positive associations between estimated EtO exposure and lung and breast cancer in women, and hematopoietic cancer in Black workers.[81] Additionally, a study found that living under 10 km from an EtO-emitting Toxic Release Site increased likelihood of lymphoma and breast cancer.[82]

Overall, the presence of industry-led peer-reviewed journal articles that attempt to undermine EPA's findings in the IRIS assessment are not sufficient to support a weaker cancer value for EtO. The findings of the industry studies are often based on unvalidated biomarker methods and flawed meta-analyses, and multiple other lines of new evidence support EPA's

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[77] Marsh et al., *Ethylene Oxide and Risk of Lympho-Hematopoietic Cancer and Breast Cancer: A Systematic Literature Review and Meta-Analysis* (May 2019) (attached), https://link.springer.com/article/10.1007/s00420-019-01438-z [hereinafter "Marsh (2019)"]; Vincent et al., *Ethylene Oxide: Cancer Evidence Integration and Dose-Response Implications* (Dec. 2019), https://journals.sagepub.com/doi/full/10.1177/1559325819888317 [hereinafter "Vincent (2019)"].

[78] O'Kelley, L. et al., *Integrative Literature Review: Ethylene Oxide Exposure Signs and Symptoms*, 40 Public Health Nurs. 790–809 (2023).

[79] Union of Concerned Scientists Comments, EPA-HQ-OAR-2024-0303 (Apr. 14, 2025) (attached) https://www.regulations.gov/comment/EPA-HQ-OAR-2024-0303-0061.

[80] Steenland, K. et al., *Mortality Among Workers Exposed to Ethylene Oxide*, 324 N. Engl. J. Med. 1402–07 (1991) (attached).

[81] Park, R.M., *Associations Between Exposure to Ethylene Oxide, Job Termination, and Cause-Specific Mortality Risk*, 63 Am. J. Ind. Med. 577–88 (2020) (attached).

[82] Jones, R.R. et al., *Ethylene Oxide Emissions and Incident Breast Cancer and Non-Hodgkin Lymphoma in a U.S. Cohort*, 115 J. Nat'l Cancer Inst. 405–12 (2023) (attached).

original findings. Critically, these individual studies are not comparable to the extensive and rigorous systematic review and peer review performed by EPA in the EtO IRIS assessment and cannot serve as the basis for a new cancer value.

Critically, "[i]n its updated literature search and systematic review, [the California Office of Environmental Health Hazard Assessment] did not identify any new scientific information that would necessitate a change to US EPA's basic IUR approach (e.g., study and model evaluation and selection). As such, the present update of OEHHA's existing EtO IUR (CDHS, 1987) is consistent with US EPA's analysis of the EtO exposure-response relationship and the combined IUR for breast cancer and lymphoid cancer. Overall, OEHHA concludes that the IUR value of 3.0 × 10–3 (µg/m3) –1 or 5.5 × 10–3 (ppb) –1 is a scientifically sound and reliable estimate of the cancer risks of EtO." [83]

C. EPA Fails to Rationally Explain Its Departure From Its Longstanding Policies on Developing IRIS Values and Using Them in Health Risk Reviews.

EPA has specific policies and protocols for how it conducts IRIS assessments and incorporates them into section 112(f)(2) reviews. EPA now proposes to depart from those longstanding practices and policies in several ways, including by seeking new scientific information on the toxicity of EtO to undermine the IRIS value, without subjecting that information to the standard peer review process. Refusing to use the 2016 IRIS value would represent a significant backward step by EPA, away from well-developed scientific policy and methods, and EPA's own practices. These scientific policies and practices are based on years of evaluation and have gone through extensive peer review by the Science Advisory Board (SAB)—a statutorily established committee mandated to "provide advice and recommendations EPA, Science and Technology Policy Council Peer Review Handbook, 4th edition (2015) to the Agency on scientific and technical matters." [84] EPA's proposal arbitrarily and capriciously fails to "display awareness that it is changing position" on these longstanding policies for developing IRIS assessments and using them in 112(f)(2) review, and EPA fails to offer "good reasons for the new policy." *Fox*, 556 U.S. at 515.

EPA's ORD Handbook for Developing IRIS Assessments "provide[s] operating procedures for the development of Integrated Risk Information System (IRIS) assessments to promote consistency and ensure all contributors understand the methods used to develop the assessments, which include systematic review, dose-response, and application of [EPA] human health guidelines." [85]

The IRIS Assessment process is a 7-step process. The first step is to draft an IRIS assessment according to the following sub-steps, shown in the figure below: EPA must (1) scope

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[83] Cal. Off. of Env't Health Hazard Assessment, *Ethylene Oxide Inhalation Unit Risk Proposed Draft Technical Support Document*, 82 (May 14, 2026), https://oehha.ca.gov/sites/default/files/media/2026-05/EtOIURpcDraft051426.pdf (attached).

[84] EPA, *Science and Technology Policy Council Peer Review Handbook* (4th ed. 2015), https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf (attached).

[85] *See, e.g.*, EPA, *ORD Staff Handbook for Developing IRIS Assessments* at xvi.

and formulate the problem and develop an IRIS Assessment Plan and Systematic Review Protocol; (2) conduct a literature search, screening, and inventory; (3) refine the problem formulation and specify assessment approach; (4) evaluate studies; (5) extract and display study results from epidemiological and toxicological studies; (6) synthesize and integrate evidence; (7) consider hazard and study selection for deriving toxicity values; and (8) derive toxicity values. [86]

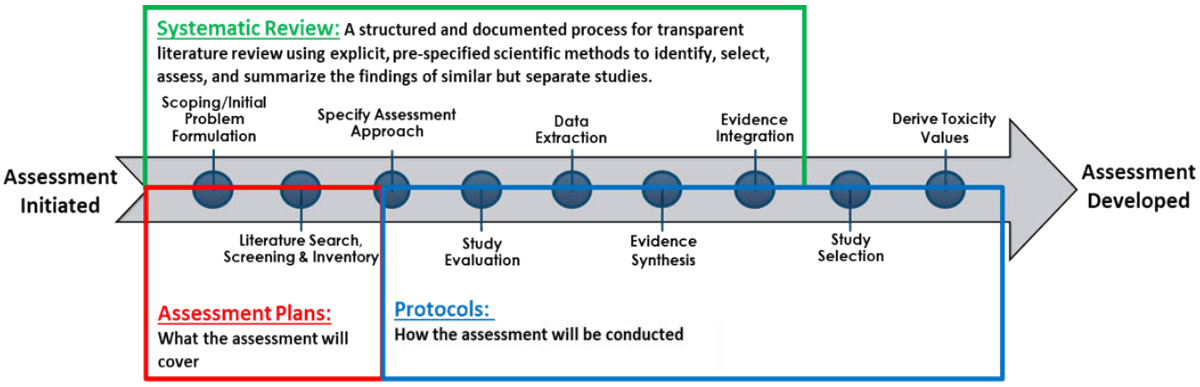
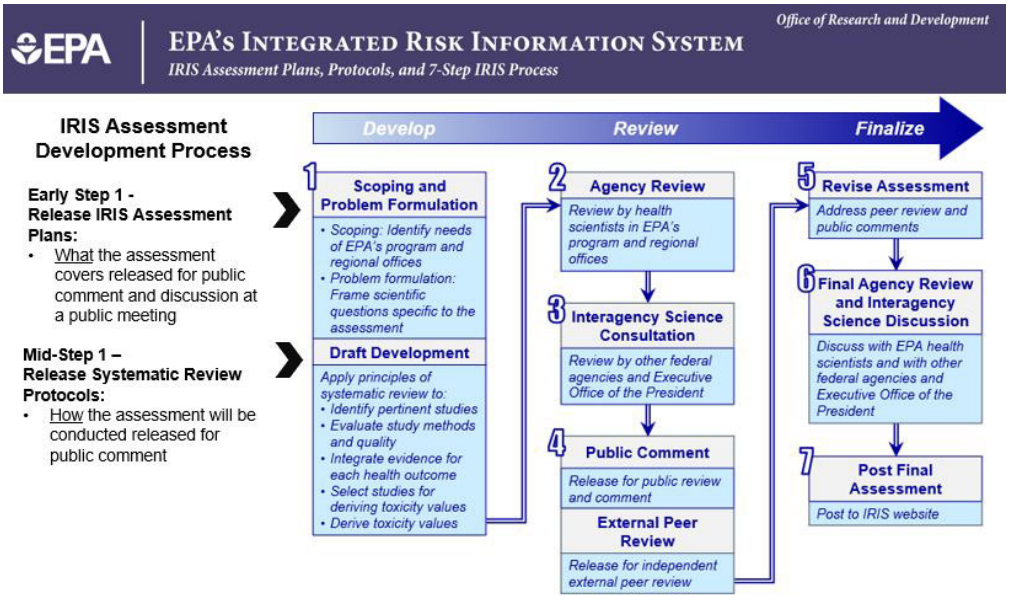


Figure O-2. Stages in Integrated Risk Information System (IRIS) assessment development process. [87]

Then, EPA proceeds to step 2 through 7 below: [88]



[86] *Id.* at 2-1.
[87] *Id.* at xix.
[88] EPA, *Basic Information about the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process (Oct. 1, 2025).

EPA conducted the 2016 EtO IRIS assessment in compliance with its longstanding policies and practices, as outlined in its Residual Risk Report to Congress, EPA-453/R-99-001 (March 1999); Peer Review Policy Statement (2006), EPA-HQ-OAR-2014-0828-0978; Science and Technology Policy Council Peer Review Handbook, 4th edition (2015); and SAB Review of EPA's Methodologies. It conducted a robust, 10-year long, scientific, and peer-reviewed toxicological review to finalize a health-protective cancer risk value for ethylene oxide. As explained in more detail above, the value is the best available science. It is "based on strong epidemiological evidence supplemented by other lines of evidence" on lymphoid and breast cancers.[89] And EPA has "relatively high" confidence in its value as an estimate of the upper bound on risk from lifetime exposure, with "particularly high" confidence for its breast cancer component.[90]

Because setting standards under section 112(f)(2) requires using the best available science to protect public health, and consistent with the agency's longstanding policies and practices, EPA also correctly used the IRIS value as part of its section 112(f)(2) review. For section 112(f)(2) reviews and other regulations, EPA's scientific method is to consult and rely on IRIS's toxicity database as "the preferred source of toxicity information used by EPA," due in part to the high level of peer review and EPA's robust IRIS process.[91] If EPA is attempting to create a new IRIS value, it cannot do that through the rulemaking process; it must go through the IRIS assessment process discussed above.

If a chemical does not have an IRIS value—which is not the case here—EPA may consider "publicly available assessments that have been developed by other government agencies in a manner that is conceptually similar to the EPA's approach. This includes consistency with the EPA's risk assessment guidelines, incorporation of an independent external peer review, inclusion of a public review period, and use of the best available science with respect to dose-response information."[92] That means EPA prioritizes its own risk value and may "consider" other sources only "if they have undergone adequate and rigorous scientific peer review"[93] and satisfy "consistency" with EPA's guidelines and if there has been sufficient "peer review received."[94] California's OEHHA values are the only non-federal source that meets EPA's scientific principles and that EPA's policies have allowed it to use for this kind of risk assessment. After conducting its own robust analysis of the literature, spanning from January 2016 through April 2026, California OEHHA recently released a draft assessment that reached

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[89] 2016 IRIS Assessment, EPA-HQ-OAR-2019-0178-0477, at 1-4.
[90] *Id.*
[91] EPA, *Basic Information about the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process (Oct. 1, 2025) (attached).
[92] Proposed MON Rule, 87 Fed. Reg. 6466, 6471 & n.13 (Feb. 4, 2022) (citing Recommendations of the SAB Risk and Technology Review Methods Panel are provided in their report, Review of EPA's draft entitled, "Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing," EPA–HQ–OAR–2018–0746).
[93] *Id.* (citing SAB Recommendations at 5).
[94] *See* 2024 RRA, EPA-HQ-OAR-2019-0178-1576, at 25 (EPA follows a "periodization process was aimed at incorporating into our assessments the best available science with respect to dose-response information.").

the same IUR value for EtO as EPA's 2016 IRIS: 3.0 × 10–3 (µg/m^3) –1 or 5.5 × 10–3 2106 (ppb).[95].

EPA's Peer Review Policy Statement (2006) states:

> Peer review of all scientific and technical information that is intended to inform or support Agency decisions is encouraged and expected. Influential scientific information, including highly influential scientific assessments, should be peer reviewed in accordance with the Agency's *Peer Review Handbook*. All Agency managers are accountable for ensuring that Agency policy and guidance are appropriately applied in determining if their work products are influential or highly influential, and for deciding the nature, scope, and timing of their peer review. For highly influential scientific assessments, external peer review is the expected procedure. For influential scientific information intended to support important decisions, or for work products that have special importance in their own right, external peer review is the approach of choice. Peer review is not restricted to the nearly final version of work products; in fact, peer review at the planning stage can often be extremely beneficial.

EPA, Science and Technology Policy Council Peer Review Handbook, 4th edition (2015). The 2016 EtO IRIS assessment qualifies as influential scientific information ("ISI") under EPA's Peer Review Handbook because it introduced a cancer risk value that established significant methodological precedent and application across EPA's national air toxics programs, including the final and current commercial sterilizers rule. Additionally, the risk value has been adopted by state environmental agencies and has been incorporated into ATSDR guidance, which demonstrates the cross-agency and interagency implications that further confirm the assessment as ISI and satisfies a number of criteria defined in the Peer Review Handbook.[96]

EPA's Peer Review Handbook goes further to state: "For work products that are intended

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[95] Cal. Off. of Env't Health Hazard Assessment, *Ethylene Oxide Inhalation Unit Risk Proposed Draft Technical Support Document*, 82 (May 14, 2026), https://oehha.ca.gov/sites/default/files/media/2026-05/EtOIURpcDraft051426.pdf (attached).

[96] EPA, *Science and Technology Policy Council Peer Review Handbook* 42–43 (4th ed. 2015), https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf ("At EPA, scientific and technical work products that will have or do have a clear and substantial impact on important public policies or private-sector decisions would be considered influential. Decision Makers (DMs) should consider the following factors when determining whether a product is likely to be influential: Establishes a significant precedent, model or methodology; is likely to have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or state, tribal or local governments or communities; addresses significant controversial issues; focuses on significant emerging issues; has significant cross-agency and/or interagency implications; involves a significant investment of agency resources; considers an innovative approach for a previously defined problem, process, or methodology; satisfies a statutory or other legal mandate for peer review.").

to support important public policy or private sector decisions, external peer review is the approach of choice. Note that an internal peer review or technical review often precedes an external peer review." *Id.* The Peer Review Handbook defines the external peer review as "a review by non-EPA experts with appropriate knowledge and skills who are independent from the development of the work product. External reviewers may come from other federal agencies, state and local government agencies, academia, industry, nongovernmental organizations or other outside organizations." *Id.* at 23. Importantly, the Handbook outlines with great specificity the extent that a work product undergoes a particular peer review mechanism. With respect to the best approach, the Handbook states:

> The approach best suited to a specific work product will depend on the nature of the topic and the intended use of the final product. Generally, the more novel or complex the science or technology, the greater the cost implications of the impending decision or public policy, and the more controversial the issue, the stronger the indication is for a more extensive and involved peer review and for an external peer review in particular. Certain work products may lend themselves clearly to extensive external peer review; generally, these will be products with large impacts. Other work products may not need a large-scale external peer review and may utilize a less involved, less resource-intensive review. [97]

In its Residual Risk Assessment (RRA) Report to Congress published in March 1999, EPA states the following as its rationale for developing the report:

> Section 112(f) of the Clean Air Act (CAA), as amended, directs EPA to prepare the Residual Risk Report to Congress on the methods to be used to assess the risk remaining (i.e., the residual risk) after control technology standards applicable to emission sources of hazardous air pollutants (HAPs) have been promulgated and applied. [98]

The Report goes on to outline and describe in detail the methodology for the development of residual risk assessments, including the importance of the external peer review process and the independent evaluation of the risk assessment methods and supporting data from the SAB. The Report to Congress took into account both the SAB review and the comments received during the comment period. The Report states: "For chronic non-cancer and cancer criteria, the preferred source of data is EPA's IRIS. This data[]base provides toxicity criteria that have undergone internal peer review, and, for recent assessments, external peer review, and have been approved Agency-wide." [99] The Report goes on to state: "For HAPs not having adequate toxicity information in IRIS, EPA will develop and follow a hierarchy of data sources, including various kinds of Agency health effects assessment documents, ATSDR toxicological profiles, and other

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[97] *Id.* at 54.
[98] EPA, *Residual Risk Report to Congress* EPA-453/R-99-001, at ES-1 (March 1999), https://www.epa.gov/sites/default/files/2013-08/documents/risk_rep.pdf (attached).
[99] EPA, *Science and Technology Policy Council Peer Review Handbook* 56–57 (4th ed. 2015).

sources."[100] Indeed, EPA, in the 2024 Sterilizers RRA cites IRIS values as the preferred program for toxicity values, in order of prioritization.[101] The cited 2010 SAB document makes clear that "[t]he preferred database for chronic dose- response data is and should be the IRIS database."[102] As it notes though, "some chemicals of interest do not have IRIS values, and values for other chemicals have not been reviewed recently."[103] Other sources of data may be considered if they have undergone "rigorous scientific peer review."[104]

There is no legitimate scientific basis to ignore or reconsider the 2016 IRIS value. If EPA wishes to undermine the IRIS value and create a new one, it must follow the agency's specific IRIS external peer-review process in order for it to be scientifically legitimate and thus rational to rely on. As explained, IRIS has many steps to assure scientific integrity and data quality, and is led and performed by scientists, not policymakers or rule writers. Changing the EtO IRIS value would require a rigorous peer review process that, for the reasons explained above, is properly done by ORD in compliance with the above IRIS process. Circumventing that process and just relying on public comment, as EPA attempts to do here, is inconsistent with EPA's practice, improper, and arbitrary and capricious.

Any reliance on the April 27, 2026 Fotouhi Memo would be unlawful and arbitrary and capricious. Memo from David Fotouhi to General Counsel, Subject: Future Development and Use of Risk Assessments (Apr. 27, 2026) ("Fotouhi IRIS Memo") (attached). Deputy Administrator David Fotouhi transmitted a memo to the EPA General Counsel regarding EPA risk assessments and the IRIS program, stating that "EPA is taking steps to address the concerns raised about the IRIS program" and directing program offices "that previously utilized IRIS assessments and IRIS program information as part of regulatory decision-making" to "review how that information was employed in their specific regulatory or programmatic actions and determine if any updates or changes are warranted." Fotouhi IRIS Memo at 4–5. That memo appears to contradict EPA's longstanding policy and practice under the Clean Air Act to consider IRIS values as the "the preferred source of toxicity information used by EPA."[105] That memo changes course not just for any given value, but attempts to call into question every IRIS value ever published, every action that has ever relied on any IRIS value, and the entire IRIS program. It makes this course change without any scientific peer review and without public notice and comment, based on what appear to be unnamed and unidentified stakeholders' cited "concerns" about IRIS values like the EtO value. The memo also appears to implement and rely on an Executive Order, labeled as the "Gold Standard Science" EO, that is not cited or relied on in this record, and that is an extra-statutory document that cannot govern above the Clean Air Act requirements here. The Fotouhi Memo demonstrates that EPA's attempt to ignore the IRIS value in this rulemaking is part of the agency's overall effort to overhaul and politicize science that has

[100] *Id.* at 57.
[101] 2024 RRA, EPA-HQ-OAR-2019-0178-1576, at 25–26.
[102] Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies – MACT I Petroleum Refining Sources and Portland Cement Manufacturing at 5 (May 7, 2010), EPA-HQ-OAR-2010-0682-0103 (attached).
[103] *Id*.
[104] *Id.*
[105] EPA, *Basic Information about the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process (Oct. 1, 2025) (attached).

followed basic integrity principles, and not about the EtO IRIS value or any lawful considerations under the Clean Air Act in this rulemaking. Any reliance on the Fotouhi Memo and the Executive Order it cites in this rulemaking would be unlawful and arbitrary and capricious not only because it would violate CAA's notice-and-comment and rulemaking requirements, *see infra* Section X.A, but also because the change in policy it reflects was issued without public notice-and comment, without reasoned decision-making, without the requisite "detailed justification" for changing course, and without following all applicable legal requirements. *Fox*, 556 U.S. at 515. The new assessment process it appears to outline and the memo itself lacks peer review or assurance that risk assessments would rely on the best available science.

D. EPA Admits That its Alleged Uncertainties With the EtO IRIS Value are Unsupported.

EPA proposes to rescind the section 112(f)(2) standards on the basis of "significant uncertainties regarding the magnitude of EtO's carcinogenic potency, particularly at low concentrations." 91 Fed. Reg. at 12714. EPA states that "new scientific evidence has continued to emerge" since *Hunstman*, but, critically, it does not explain what those studies conclude or why those conclusions are relevant here. *Id.* at n.55, 56. Instead, EPA fishes for both the facts and explanation it does not have:

> While it is not entirely clear how many new studies or methodological advancements have developed in recent years, given the sensitivity of EtO risk estimates at low concentrations to both model selection and the underlying cancer data, it is plausible that any new information could change the EPA's understanding of EtO's carcinogenic potency. Therefore, the EPA is proposing that the significant uncertainties in the 2016 EtO IRIS value are an additional reason to support reconsideration and repeal of the 2024 Final Rule,

Id. at 12714 (emphases added). EPA fails to support its asserted "significant uncertainties" with any new evidentiary support, and instead asks commenters to find support for the agency's speculation. In doing so, EPA's proposal belies the fact that it does not have sufficient evidence to ignore or not use the 2016 EtO IRIS value to assess cancer risks, much less to repeal the 112(f) health protections based on such evidence.

Seeking to find support for its speculation, EPA requests "relevant data, studies, and analyses to support any claims made about the adequacy or inadequacy of the 2016 EtO IRIS value and any alternative values the commenter believes would be more appropriate and consistent with the statutory framework," including information relevant to: "analyzing the relationship between occupational human exposure to EtO and the development of cancer not yet considered by the Agency" (Question 3); "any new or updated information relevant to dose response model selection such as consideration of statistical analyses, visual model fit, or biological plausibility" (Question 4); and "any new or updated studies on human exposure to EtO, including information on occupational, smoking, background, or endogenous exposures not yet considered by the Agency" (Question 5). *Id.* at 12714–15.

But EPA may not lawfully propose to rescind a rule based on alleged uncertainty without evidence. Agencies may not act "based on speculation." *Delaware Dep't of Nat. Res. & Env't Control*, 785 F.3d at 11 (D.C. Cir. 2015) (citation omitted). At most, it may put forth a request for information. But EPA's attempt to propose to rescind a rule and paper over it later with evidence EPA hopes to find violates principles of reasoned decisionmaking. It is not reasoned decisionmaking to repeal a supported, health-protective rule based on the plausibility that something it might find might change something.

As explained in Section II.H, any reliance on the new information received in public comment would also violate the Clean Air Act by depriving the public of the right to review and comment on this proposal in view of whatever hypothetical information EPA might find. *See* 42 U.S.C. § 7607(d)(7)(B).

E. EPA Cannot Lawfully or Rationally Rely on TCEQ's Scientifically and Procedurally Flawed Factor.

Notably, EPA does not propose to use the TCEQ value, and it would have no basis for doing so. EPA has already rationally rejected Texas's scientifically and procedurally flawed value, which estimated a cancer risk about 3,000 times lower than EPA's model, in the administrative process [106] and before the D.C. Circuit. *See Huntsman*, 114 F.4th 727. The D.C. Circuit upheld EPA's rejection of the TCEQ EtO factor and use of the 2016 EtO IRIS value. *See id.* at 740–41. TCEQ's factor has also been rejected by an independent committee of the National Academies of Sciences, Engineering, and Medicine (NASEM), which also urged TCEQ to conduct a systematic review following best practices established by ORD for IRIS assessments. [107] Any reliance on the TCEQ factor would be unlawful, arbitrary, capricious, and inconsistent with EPA's longstanding policies on peer review.

In support of these comments, we attach and incorporate by reference the Comments submitted by Earthjustice et al., EPA-HQ-OAR-2018-0746-0083 (Feb. 18, 2020), in support of EPA's proposal to reject TCEQ's scientifically flawed EtO factor, and to reaffirm EPA's 2016 EtO IRIS value as the best available science. [108]

It would be unlawful and arbitrary and capricious for EPA to rely on TCEQ's EtO factor due to its fundamental flaws, including but not limited to the those discussed below. Moreover, TCEQ's Development Support Document (DSD) shows that TCEQ's EtO factor relies heavily on industry-funded articles and the "analyses" of an industry-funded consultant, and did not undergo an adequate or rigorous peer review.

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[106] TCEQ, Petition for Reconsideration, EPA-HQ-OAR-2018-0746-0260, at 9 (Oct. 12, 2020) [hereinafter "TCEQ Recon Petition"] (attached); Reconsideration of the 2024 MON Rule, 87 Fed. Reg. at 77985–95.
[107] National Academies of Sciences, Engineering, and Medicine, Review of Texas Commission on Environmental Quality's Ethylene Oxide Development Support Document, National Academies Press (June 6, 2025) https://www.ncbi.nlm.nih.gov/books/NBK616245/ [hereinafter "NASEM Review"] (attached).
[108] Comment submitted by Earthjustice et al., EPA-HQ-OAR-2018-0746-0083_attachment_1 (Feb. 18, 2020) (attached).

1. TCEQ's value is based on an incorrect model (Cox model). TCEQ's modeling approach is, in effect, a threshold approach, which ignores the risk from exposure at what TCEQ considers "endogenous" levels.[109] Such a threshold approach is inappropriate to measure the risk from carcinogens, particularly those with a known mutagenic mode of action, which have no safe threshold.[110] TCEQ's factor relies on an inappropriate modeling approach that EPA and the SAB already carefully considered, evaluated, and rejected. *See* 87 Fed. Reg. at 6472. The D.C. Circuit upheld EPA's rejection of TCEQ's use of the Cox model. *Huntsman*, 114 F.4th at 741.

TCEQ claimed that the damage to DNA from ethylene oxide exposure can be "detoxif[ied]" by DNA repair enzymes.[111] However, TCEQ did not adequately support or explain this claim—and ignores that inhaling ethylene oxide would add to any "endogenous" ethylene oxide. In August 2021, EPA's Office of Research and Development (ORD) responded to a similar argument raised in the American Chemistry Council Request for Correction of EPA's National Air Toxics Assessment. The ORD memo makes clear that EPA accounted for the potential for endogenous exposures to ethylene oxide by ensuring that the IRIS risk estimate represented *increased risk* "above any potential existing risks from endogenous ambient background levels of EtO exposure."[112] Indeed, any endogenous production of a carcinogen would warrant a more-protective cancer risk factor, not a less-protective factor.

In its review of the TCEQ value, NASEM also describes multiple failings of TCEQ's interpretation of the statistical fit criteria. NASEM rejected the use of this log-linear model for unit factor derivation. Specifically, NASEM concluded that "[f]or lymphoid cancers, categorical dose-response analyses indicate a nonlinear association" and that "TCEQ did not adequately consider flexible, nonlinear models (e.g. splines) when evaluating potential dose-response models to estimate the URF."[113] NASEM also notes that "TCEQ did not prioritize selecting a model that best fits the lowest end of the exposure-response function," which is critical given that the unit risk factor is used for assessment of environmental EtO exposures which occur at these lower doses.[114] Because of these issues, NASEM did not support TCEQ's model selection but rather noted that "the two-piece spline model may better reflect the supralinear dose-response shape at the lowest end of the exposure distribution."[115]

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[109] *See* TCEQ, Proposed DSD at 10 (attached); TCEQ, Final DSD (May 15, 2020) at 10, 36 (attached).
[110] S. Rep. No. 101-228 at 171, 1990 U.S.C.C.A.N. at 3560 (amending the provision, 42 U.S.C. § 7412, that requires regulation of ethylene oxide as a hazardous air pollutant); S. Rep. No. 101-228, at 175, 1990 U.S.C.C.A.N. at 3560; *NRDC v. EPA*, 824 F.2d 1146, 1147 (D.C. Cir. 1987) (en banc) ("Current scientific knowledge does not permit a finding that there is a completely safe level of human exposure to carcinogenic agents.").
[111] *See* TCEQ Final DSD at 36.
[112] ORD Review of Comments at 6 ("The potential for endogenous exposures to EtO and the IRIS Assessment's handling of such exposures was discussed in public comment and SAB peer review of the assessment. It is important to recognize that the IRIS risk estimate for EtO represents the increased cancer risk due to exposure to EtO emissions – above any potential existing risks from endogenous or ambient background levels of EtO exposure.").
[113] NASEM Review at 36.
[114] *Id.*
[115] *Id.* at 37.

The D.C. Circuit held that EPA adequately explained why it rejected that model: TCEQ's model did not fit the data, and EPA's chosen model did. Specifically, TCEQ's model was "inconsistent with the data and with the pattern of all the other model results indicating a plateauing response with a relatively steeper slope in the lower exposure range of the NIOSH data, a pattern the SAB specifically recognized." *Huntsman*, 114 F.4th at 740 (citations omitted). Thus, the model's inflexible shape "prevented it from usefully representing the NIOSH study data. *Id.* Its "'adjusted' figure thus does not demonstrate that its model is consistent with the other models and data. Accordingly, it does not undermine EPA's reasons for rejecting the TCEQ model." *Id.* at 741.The Court also held that "EPA reasonably developed and selected its chosen spline model and adequately explained its reasons for doing so." *Id.* at 740.

2. TCEQ improperly ignored breast cancer risk. As EPA correctly highlighted in its rejection of TCEQ's factor, TCEQ's factor improperly excludes breast cancer risk for women. *See* Reconsideration of MON NESHAP, 87 Fed. Reg. 6466, 6472 (Feb. 4, 2022). EPA's cancer risk value is "based on strong epidemiological evidence supplemented by other lines of evidence" on lymphoid and breast cancers.[116] EPA has "relatively high" confidence in its value as an estimate of the upper bound on risk from lifetime exposure, with "particularly high" confidence for its breast cancer component.[117]

TCEQ rejects breast cancer by arguing that the epidemiological evidence is weak and by pointing to two industry-funded meta-analyses, Marsh et al. (2019) and Vincent et al. (2019).[118] Neither study justifies exclusion of breast cancer.

Notably, Vincent (2019) relied solely on epidemiological and toxicological studies already characterized by EPA in its 2016 IRIS assessment. The study methodology—which is described as a synthesis or literature review—makes clear that it failed to identify any new relevant human and/or animal studies that the IRIS assessment had not already considered. The study appears to restate arguments raised by the American Chemistry Council and addressed by EPA in the Appendix to the 2016 IRIS Assessment and response to comments, stating: "Although the epidemiological database for breast cancer is more limited (i.e., few studies with sufficient numbers of female breast cancer cases) than that for lymphohematopoietic cancers, the EPA determined that the available evidence is sufficient to consider breast cancer a potential hazard from EtO exposure."[119] The Vincent article is also particularly questionable because it failed to find evidence of breast cancer or of lympho-hematopoietic cancer. Final TCEQ DSD at 13.

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[116] 2016 IRIS Assessment, EPA-HQ-OAR-2019-0178-0477, at 1-4.
[117] *Id.*
[118] Final TCEQ DSD at 13; *see* Marsh (2019) at 19 ("Earlier work on this commentary was performed under a consulting agreement between GM and the American Chemistry Council (ACC). Later work including the meta-analysis and preparation of this manuscript was performed under a consulting agreement between Cardno ChemRisk and the ACC."); Vincent (2019) at 15 ("The author(s) disclosed receipt of the following financial support for the research and/or authorship of this article: The study was supported by Vantage Specialty Chemicals, Inc.").
[119] 2016 IRIS Appendices, app. K at K-2 to K-3 ("Comment: The evidence for breast cancer is too weak. (ACC, EOSA) EPA Response: Although the epidemiological database for breast cancer is more limited (i.e., few studies with sufficient numbers of female breast cancer cases) than that for lymphohematopoietic cancers, the EPA determined that the available evidence is sufficient to consider

Similarly, EPA already considered all of the studies included in the Marsh et al. (2019) analyses, except one unpublished study from 1990. A member of the American Chemistry Council's Ethylene Oxide Panel provided the data from that still-unpublished study. [120] NASEM agreed that reliance on Marsh et al. (2019) and Vincent et al. (2019) "does not reflect best practices for evaluation of a prior review for quality and rigor using established tools ... as have been implemented in National Academies' reports." [121]

Further, TCEQ's petition for reconsideration misrepresented the recent Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profile for ethylene oxide. [122] The ATSDR toxicological profile characterizes the available data on ethylene oxide and its associated health effects. Throughout the report, ATSDR summarizes ethylene oxide's carcinogenic effects, including breast cancer. TCEQ mischaracterized the ATSDR report by inferring that it provides "good visual representation of how the weight of scientific evidence does not support that [ethylene oxide] causes breast cancer," when in fact, the referenced table shows only the concluding risk estimates and confidence intervals without critical discussion of individual study design and results. [123] TCEQ incorrectly concluded that the table itself provides sufficient evidence that the data does not support breast cancer as an endpoint.

Finally, the TCEQ petition cites an additional study published by Jain (2020) to justify its argument against the inclusion of breast cancer in EPA's development of the ethylene oxide unit risk estimate. [124] The petition states that "[t]he author found no association between measured blood EtO and breast cancer in women." [125] However, the study was not designed to adequately assess breast cancer as an endpoint in the analysis. The study analyzed blood levels of ethylene oxide using National Health and Nutrition Examination Survey (NHANES) data, and in its analysis, pooled data across different age groups, including of women ages 20 years on who self-reported a diagnosis of breast cancer. [126] While the study did not show statistical significance

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breast cancer a potential hazard from ethylene oxide exposure. In addition, the epidemiological database is strengthened by the follow-up study (Mikoczy et al., 2011) of the Swedish cohort of sterilizer workers first reported on by Hagmar et al. (Hagmar et al., 1995; Hagmar et al., 1991) (see Section J.2.2 of app. J), and the epidemiological evidence is supported by the finding of mammary gland carcinomas in female mice exposed to ethylene oxide by inhalation (NTP, 1987) and by mechanistic data (see Section 3.4.1.3). The 2007 SAB panel did not object to the derivation of unit risk estimates based on the available breast cancer evidence.").

[120] Marsh (2019) at 19 ("The authors thank Dr. Jane Teta for providing data from the unpublished Divine (1990) study and for her helpful comments on the draft manuscript."); *see* ACC/Exponent PowerPoint at 10, 46 (attached).

[121] NASEM Review at 22.

[122] ATSDR, Toxicological Profile for Ethylene Oxide (Aug. 2022), https://www.atsdr.cdc.gov/toxprofiles/tp137.pdf (attached).

[123] TCEQ Recon Petition, EPA-HQ-OAR-2018-0746-0260, at 9.

[124] Ram B. Jain, *Associations Between Observed Concentrations of Ethylene Oxide in Whole Blood and Smoking, Exposure to Environmental Tobacco Smoke, and Cancers Including Breast Cancer: Data for US Children, Adolescents, and Adults*, 27 Env't Sci. & Pollution Rsch. 20912 (2020), https://doi.org/10.1007/s11356-020-08564-z.

[125] TCEQ Recon Petition, EPA-HQ-OAR-2018-0746-0260, at 9.

[126] Jain et al. (2020) at 20913.

with respect to the association between ethylene oxide and having ever been diagnosed with cancer, the analysis did show a positive slope, meaning that cancer diagnoses increased as ethylene oxide levels in the blood went up. Additionally, there are several flaws with the methodology that may explain why ethylene oxide's association with breast cancer was not significant, including that the data did not assess occupational exposure or other potential sources of ethylene oxide (aside from smoking history), and it did not stratify across age groups over 20 years. Importantly, the ATSDR toxicological profile for ethylene oxide includes a table depicting similar data derived from the NHANES database and stratifies its findings of blood ethylene oxide levels among smokers and nonsmokers across individuals aged 18 to 49 and 50 years on.[127] Presenting the data with stratification across relevant age groupings allows for a greater understanding of observed blood ethylene oxide levels and potential associations with cancer outcomes.

Ultimately, NASEM concluded that "the committee is not confident in the conclusions resulting from TCEQ's hazard assessment" and identified several flaws in TCEQ's analysis.[128] Primarily, the committee found that TCEQ "inappropriately excluded human evidence lacking dose-response data that could have contributed to the hazard assessment for breast cancer."[129] NASEM supported EPA's inclusion of breast cancer risk, stating that "analyses of breast cancer incidence in the NIOSH studies of sterilizer workers showed significant exposure-response effects" and that these findings were further supported by breast cancer mortality analyses, as described thoroughly in its section on "Epidemiological Evidence for Breast Cancer" in the report.[130]

3. TCEQ's "reality check" on EPA's model failed. TCEQ argued that EPA's chosen model was inaccurate compared to real-world data, as calculated in TCEQ's "reality check"—a statistical analysis that ran EPA's model against real-world data to gauge the accuracy of the model's predictive power. TCEQ's reality check compared the number of lymphoid cancer deaths predicted by EPA's model with the number of lymphoid cancer deaths that actually occurred in the NIOSH study data, and it concluded that EPA's model significantly overpredicted the number of lymphoid cancer deaths from EtO exposure. In *Huntsman*, the D.C. Circuit held that EPA had adequately explained "why the TCEQ reality check erred and thus did not call the accuracy of EPA's model into question." 114 F.4th at 740. Specifically, EPA explained that the TCEQ reality check misused EPA's model because it did not appropriately account for the "healthy worker effect," accounting for only 15 to 16%, which was materially smaller than the effect indicated by the relevant data (22 to 28%). *Id.* NASEM's review also includes a thorough explanation of multiple aspects of the healthy worker effect, including a section on "TCEQ's Misconceptions about HWE."[131]

4. TCEQ's factor improperly relied on studies showing no link between EtO and lymphoid cancer in tobacco smokers. The D.C. Circuit upheld EPA's rejection of studies of cancer incidence in tobacco smokers. *Huntsman*, 114 F.4th at 741. First, EPA explained that

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[127] *See,* ATSDR, Toxicological Profile for Ethylene Oxide at 121 tbl. 5-10.
[128] NASEM Review at 5.
[129] *Id.* at 7.
[130] *Id.* at 23.
[131] *Id.* at 26–27.

the studies lack a quantitative analysis of the relationship between lymphoid cancer and EtO. "The studies did not account for the interactions between the multiple carcinogens in cigarette smoke, and thus faced the issue of what EPA terms on appeal 'confounding exposures.'" *Id.* And "even if the studies had been limited to the relationship" between EtO and lymphoid cancer, they lacked a sufficient quantitative analysis of that relationship showing how the studies' observed lymphoid-cancer rates compared with the rate of non-smokers. *Id.* Second, EPA explained that the studies use an unvalidated method—a hemoglobin biomarker—as a proxy to measure EtO exposure. As EPA explained, that method "was not validated to assess the low environmental exposures that EPA was examining (in contrast to high occupational exposures), and the biomarker is a less accurate proxy regardless because smoking causes other changes that could affect it." *Id.*

5. TCEQ's factor improperly relied on speculative data on endogenous and background levels of EtO. The D.C. Circuit upheld EPA's rejection of studies about endogenous and background levels of ethylene oxide. *Huntsman*, 114 F.4th at 742. EPA rejected the studies first because they provided little quantitative data, were highly speculative, and offered findings of only a "exploratory and qualitive nature." *Id*. Second, "EPA acknowledged that if … there were reliable and high measurements of endogenous and background levels, that would make it more difficult to measure risks from marginal additional exposures. But EPA explained that it is not possible to identify background levels of ethylene oxide with confidence because of how difficult it is to reliably monitor and measure such low levels. EPA also explained how the NIOSH study mitigated these general concerns." *Id.* at 742 (citations omitted).

6. TCEQ's peer review was inadequate. It would also be arbitrary and irrational for EPA to use this factor because it is not a federal or California value and has not "undergone adequate and rigorous scientific review."[132] EPA policy directs prioritization of federal values, then California EPA OEHHA values.[133] If a federal or California value is not available, or if there are "gaps" to fill—neither of which is the case here—EPA may look to "other sources" that "have undergone adequate and rigorous scientific review."[134] EPA has never used a TCEQ value and has already concluded that the TCEQ EtO factor is significantly flawed.

TCEQ has not demonstrated that its letter peer review—or its toxicology process generally—meets EPA's standards. For example, the IRIS independent external peer review is "conducted in an open forum and the public is invited to attend the[] peer review meetings as observers."[135] At that meeting, the IRIS peer review Panel Chair is directed "not to engage the [EPA representative] in the discussion (except for limited clarification) or provide any opportunity for EPA, or anyone else present at the meeting, to bias the panelists' discussion."[136] By contrast, the TCEQ letter peer review panel held a private "teleconference" which was not open to the public; afterward, "the experts were given the opportunity to revise their written

[132] 87 Fed. Reg. at 6471 (citing SAB review of EPA health reference value prioritization).
[133] *Id.*
[134] *Id.* (citing EPA Risk and Technology Review Methodologies).
[135] NCEA Policy and Procedures for Conducting IRIS Peer Reviews (effective July 30, 2009), at 5, https://www.epa.gov/sites/default/files/2014-05/documents/policy_iris_peer_reviews.pdf.
[136] *Id.* at 13.

responses to the charge questions."[137] The IRIS peer review process took a year,[138] while the TCEQ "peer review" took less than three months.[139] And TCEQ made no changes to its value or methodology as a result of the "peer review."[140]

7. TCEQ's factor heavily relies on industry-funded research and the work of an industry-funded consultant. The TCEQ cancer risk factor fails based on the science, but even if that were not the case, the DSD's significant reliance on research funded by the very industry seeking to avoid further emissions reductions further undermines the integrity of the factor. It would be arbitrary and irrational for EPA to use this factor.

In developing its evaluation, Texas met with Petitioner American Chemistry Council. The ACC presented a slide deck to the agency recommending that TCEQ: (1) "[u]se the estimate from Valdez-Flores et al. (2010) instead of from the U.S. EPA IRIS (2016),"[141] (2) ignore breast cancer,[142] and (3) incorporate a "data update" identified as "Bender et al."[143] Before meeting with the American Chemistry Council, Texas had rejected the 2010 Valdez-Flores study because it failed to capture risk for all but the highest exposure groups. TCEQ, Ethylene Oxide (March 6, 2017). Afterwards, Texas not only selected the 2010 Valdez-Flores study as its key study, but went further, contracting with Valdez-Flores himself.[144] Texas even cited "personal communication" with Valdez-Flores as factual support in its evaluation.[145] Notably, Valdez-Flores published work funded by the American Chemistry Council just one month before Texas's draft evaluation was posted online. Texas relied on other industry-funded work, including a 2017 study by Kirman and Hays.[146] This study wrongly suggests that normal endogenous levels of

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[137] University of Cincinnati, Dep't of Environmental and Public Health Sciences, Risk Science Center, Letter Peer Review of TCEQ DSD, at 60 (Apr. 30, 2020), https://www.tceq.texas.gov/downloads/toxicology/peer-review/eto.pdf.

[138] EPA, IRIS, Ethylene Oxide – Background, History, and Other Supporting Documents, https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=329730 (EPA submitted for peer review on Aug. 2014; SAB issued final report on Aug. 2015).

[139] Revised TCEQ DSD (Jan. 31, 2020) (attached); University of Cincinnati, Letter Peer Review of TCEQ DSD at 7 ("The revised DSD ... [is] under review in this peer review.").

[140] *Compare* Revised DSD at 5 ("ADAF-adjusted URF of 4.1E-06 per ppb (2.3E-06 per $\mu g/m^3$)"), *with* TCEQ, Final DSD at 2 ("ADAF-adjusted URF of 4.1E-06 per ppb (2.3E-06 per $\mu g/m^3$)").

[141] ACC/Exponent Powerpoint at 1 (attached).

[142] *Id.* at 46.

[143] *Id.* at 59.

[144] TCEQ DSD at 29 ("key study"); *id.* at 30, 51, 87 (contracting with Valdez-Flores). Valdez-Flores has a long history of work for the American Chemistry Council and other ethylene oxide industry groups. *See* Comments submitted by Earthjustice et al., EPA-HQ-OAR-2018-0746-0083 (Feb. 18, 2020).

[145] TCEQ DSD at 34, 87.

[146] Kirman & Hays, *Derivation of Endogenous Equivalent Values to Support Risk Assessment and Risk Management Decisions for an Endogenous Carcinogen: Ethylene Oxide*, 91 Regulatory Toxicology and Pharmacology 165 (Dec. 2017) ("The analysis presented here was funded by the Ethylene Oxide Panel of the American Chemistry Council (contract 5478)."); *see also* Marsh (2019) at 19 ("Earlier work on this commentary was performed under a consulting agreement between GM and the American Chemistry Council (ACC). Later work including the meta- analysis and preparation of this manuscript was performed under a consulting agreement between Cardno ChemRisk and the ACC."); Vincent (2019) at 15 ("The study was supported by Vantage Specialty Chemicals, Inc.").

ethylene oxide are many times higher than the equivalent exposure of living near an ethylene oxide sterilizer.[147]

The National Academy of Sciences has warned that industry funding can create biases and affect the outcome of a study,[148] and thus recommends that "[f]unding sources should be considered" when EPA evaluates a study.[149] EPA policy likewise outlines the importance of "ensur[ing] impartiality" and "promot[ing] scientific integrity throughout the Agency."[150] EPA policy goes on to discuss the requirement for Agency leadership to base its scientific quality considerations on methods that are clear and appropriate and to ensure the "presentation of results and conclusions [are] impartial."[151] As the SAB has explained, industry funding of research can suggest a "conflict of interest" and can cause "funding bias" or "publication bias" and affect the outcome of a study.[152] For example, researchers have found that industry-sponsored studies "are more often favorable to the sponsor's product compared with studies with other sources of sponsorship,"[153] and have identified similar "[c]orporate manipulation of

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[147] EPA-HQ-OAR-2018-0746-0316/attachment_11 (figure citing Kirman & Hays (2017)); EPA-HQ-OAR-2018-0746-0316/attachment_12 (citing Kirman & Hays (2017) for "General Population Endogenous-Equivalent Exposure").

[148] National Academies, Peer Review of IRIS Draft Handbook at 25–26 (Nov. 2021); *id.* at 4 ("Funding bias refers to an association between study funding sources and financial ties of investigators with research outcomes that are favorable for the sponsors. Publication bias is the publication or non-publication of research results based on the nature and direction of the results."), https://www.nap.edu/catalog/26289/review-of-us-epas-ord-staff-handbook-fordeveloping-iris-assessments; *see also* Comments of Air Alliance Houston et al., EPA-HQ-OAR-2018-0746-0315, at 14 (March 24, 2022) (citing same).

[149] National Academies, Review of EPA's Integrated Risk Information System (IRIS) Process at 79 (2014); *id.* at 67 (discussing "the need to consider bias related to funding source that might arise from systematic influences on the design and conduct of a study and the extent to which the full results and analyses of the study are published"), https://nap.nationalacademies.org/catalog/18764/review-of-epas-integrated-risk-information-system-iris-process; *see also* Comments of Air Alliance Houston et al., EPA-HQ-OAR-2018-0746-0315, at 15 (March 24, 2022) (citing same).

[150] EPA, Scientific Integrity Policy at 5 (2012), https://www.epa.gov/scientific-integrity/epas-scientific-integrity-policy; *see also* Comments of Air Alliance Houston et al., EPA-HQ-OAR-2018-0746-0315, at 15 (March 24, 2022) (citing same).

[151] EPA, Scientific Integrity Policy at 7.

[152] National Academy of Sciences, Peer Review of IRIS Draft Handbook at 4, 25–26 ("Funding bias refers to an association between study funding sources and financial ties of investigators with research outcomes that are favorable for the sponsors. Publication bias is the publication or non-publication of research results based on the nature and direction of the results.").

[153] Lundh et al., *Industry sponsorship and research outcome*, Cochrane Database for Systematic Reviews, No. 2, Art. No. MR000033 (Feb. 2017) at 2 (finding "more favorable efficacy results and conclusions" for the industry in studies sponsored by the manufacturing company in analyses that "suggest the existence of an industry bias that cannot be explained by standard 'risk of bias' assessments"), https://www.cochranelibrary.com/cdsr/doi/10.1002/ 14651858.MR000033.pub3/full; Lisa Bero, A. Anglemyer, H. Vesterinen & D. Krauth, *The Relationship Between Study Sponsorship, Risks of Bias, and Research Outcomes in Atrazine Exposure Studies Conducted in Non-Human Animals: Systematic Review and Meta-Analysis*, 92–93 Env't Int'l 597, 599 (2015) ("Our findings support the inclusion of research sponsorship as a risk of bias criterion in tools used to assess risks of bias in animal studies for systematic

research" across various industries that may include "funding and publishing research that supports industry interests."[154]

TCEQ has failed to show that industry funding did not bias the studies on which it relies, or that its reliance on industry-funded studies and the work of an industry-funded consultant did not bias the risk factor itself.

8. Texas resisted transparency in its evaluation. After Texas posted its draft evaluation online, Sierra Club submitted a request for public information underlying Texas's evaluation.[155] Sierra Club's public information request sought information about industry influence on Texas's evaluation.[156] Among Sierra Club's concerns was the potential influence of Petitioner American Chemistry Council.[157] Texas refused to release over 6,000 pages of documents in response to Sierra Club's request.[158] Under state law, Texas first requested a decision from its Attorney General's Office. The Attorney General ruled that Texas must release the requested information. Rather than comply, Texas filed a suit against its Attorney General, in which Sierra Club intervened.[159] Both the district court and the appellate court ordered Texas to release the information.[160] Texas petitioned to the state Supreme Court, which granted the petition to review, but the information remains under a protective order.[161] Texas's continued refusal to promptly produce the requested information prejudices the public's ability to learn the extent of that influence.

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reviews."), https://pubmed.ncbi.nlm.nih.gov/26694022/; Mandrioli et al., *Correction: Relationship Between Research Outcomes and Risk of Bias, Study Sponsorship, and Author Financial Conflicts of Interest in Reviews of the Effects of Artificially Sweetened Beverages on Weight Outcomes: A Systematic Review of Reviews*, 15 PLOS ONE e0231208, at *2 (2020) ("Reviews performed by authors that had a financial conflict of interest with the food industry (disclosed in the article or not) were more likely to have favorable conclusions [] than reviews performed by authors without conflicts of interest…. Risk of bias was similar and high in most of the reviews."), https://pmc.ncbi.nlm.nih.gov/articles/PMC7064233/pdf/pone.0230469.pdf.

[154] J. White et al., *Corporate Manipulation of Research: Strategies Are Similar Across Five Industries*, 21 Stan. Law & Pol'y Rev. 105, 106 (2010) (analyzing case studies to evaluate strategies used to affect health risk research by the pharmaceutical, tobacco, lead, vinyl chloride, and silicosis-generating industries).

[155] Sierra Club, *Public Information Act Request to TCEQ* (July 1, 2019), attached as Ex. A to Plea in Intervention and Pet. for Writ of Mandamus, *TCEQ v. Paxton*, No. D-1-GN-19-006941 (353d Dist. Ct., Travis Cnty., Tex.), EPA-HQ-OAR-2018-0746-0154_attachment_14.

[156] Mot. for Summ. J. at 6, *TCEQ v. Paxton*, No. D-1-GN-19-006941 (53d Dist. Ct., Travis Cnty., Tex. Oct. 16, 2020).

[157] *Id.*

[158] Order, *TCEQ v. Paxton*, No. D-1-GN-19-006941 (53d Dist. Ct., Travis Cnty., Tex. May 5, 2021) (citing Bates Nos. 0001–6414).

[159] Petition, *TCEQ v. Paxton*, No. D-1-GN-19-006941 (53d Dist. Ct., Travis Cnty., Tex. Oct. 4, 2019); Plea in Intervention & Pet. for Writ of Mandamus of Sierra Club, *TCEQ v. Paxton*, No. D-1-GN-19-006941 (53d Dist. Ct., Travis Cnty., Tex. Dec. 18, 2019).

[160] Order, *TCEQ v. Paxton*, No. D-1-GN-19-006941 (53d Dist. Ct., Travis Cnty., Tex. May 5, 2021); Op., *TCEQ y v. Paxton*, No. 03-21-00256-CV (Tex. App.—Austin Nov. 22, 2022).

[161] *TCEQ v. Sierra Club*, No. 23-0244 (Tex.), Order (granting petition for review and maintaining protective order) (Dkt. 60).

F. EPA Cannot Indefinitely Abdicate Its Statutory Obligations due to Alleged Uncertainty.

EPA does not propose to adopt an alternative assessment of ethylene oxide risks from commercial sterilization facilities. Instead, the agency proposes to rescind the risk review with no replacement. "But the mere invocation of 'substantial uncertainty'" is not a sufficient basis to rescind the 112(f)(2) review or to indefinitely abdicate the agency's statutory obligation to provide an ample margin of safety. *Murray Energy Corp.*, 936 F.3d at 619 (quoting *State Farm*, 463 U.S. at 52). Although EPA should consider new scientific information, it cannot indefinitely delay its obligations under section 112(f)(2), and certainly not based on information it had at the time it promulgated the 2024 Rule. EPA cannot rescind these standards based on a mere possibility that the agency might change its mind in the future.

Key here, health-protective assumptions (also known as scientific "defaults") and uncertainties are always present in risk assessments where the goal is to attempt to predict and prevent future harm. According to EPA's own cancer risk guidelines, even "a high level of uncertainty does not imply that a risk assessment or a risk management action should be delayed," and "[a]ssessments should discuss the significant uncertainties encountered in the analysis."[162] Congress understood that there would likely be scientific limits and uncertainties that would make it difficult or impossible to assess the exact amount of additional cancer risk a person faced from a given industrial source category. Congress did not authorize EPA to indefinitely delay health protections due to uncertainties—quite the opposite, Congress directed EPA to issue section 112(f)(2) reviews within eight years of promulgating section 112(d) standards based on the best available science at the time so that scientific uncertainties did not lead to dangerous gaps in health protection. 42 U.S.C. § 7412(f)(2). Congress did not direct EPA to take the most basic, lowest level of action possible, but to assure standards provide "an ample margin of safety to protect public health." *Id.*

None of EPA's identified uncertainties justifies its proposal to rescind section 112(f)(2) standards. This is particularly true where EPA identifies no new uncertainties with the IRIS assessment, seeks to rely on two uncertainties it already acknowledged and put to rest, and does not propose replacing the IRIS value with any other particular value. This is unlike *Center for Biological Diversity v. EPA*, where the D.C. Circuit upheld EPA's determination that the available data was too uncertain to support setting a standard for acid rain precursors. 749 F.3d 1079 (D.C. Cir. 2014). In that rulemaking, EPA "explained in great detail", *id.* at 1088, why the scientific uncertainties were so "unusually profound" that the agency "could not form" a reasoned judgment as to a requisite level of protection, *id.* at 1090–91. The independent Clean Air Scientific Advisory Committee concurred with that assessment. *Id.* at 1086 n.11. Here, in contrast, EPA has identified no "unusually profound" uncertainties on which it "could not form" a reasoned judgment; rather, EPA identified two uncertainties that it already formed a reasoned judgment about in the 2016 IRIS assessment.

EPA is essentially attempting to repeal based on reconsideration alone, and section 307(d) does not allow that. *See Air Alliance v. EPA*, 906 F.3d 1049, 1067 (D.C. Cir. 2018) ("to say that no policy is better than the old policy solely because a new policy *might* be put into place in the

[162] 2005 Carcinogen Risk Assessment Guidelines at 3-29.

indefinite future is as silly as it sounds"). To the extent EPA reconsiders the section 112(f)(2) review, "[s]uch reconsideration shall not postpone the effectiveness of the rule," and a rule may not be stayed for more than three months. 42 U.S.C. § 7607(d)(7)(B).

G. EPA Arbitrarily Fails to Consider the Forgone Health Benefits of the Risk Standards.

EPA proposal, by its own estimate in the 2024 Rule, would subject more than 38 million people to increased cancer risk.[163] But in the Proposed Rule, EPA "fail[s] to consider an important aspect of the problem"—the forgone health and pollution benefits of the section 112(f)(2) standards it proposes to rescind. *State Farm*, 463 U.S. at 43. These are undoubtedly an "important aspect of the problem" because they are the core purpose of the section 112(f)(2) program, which Congress designed to address residual cancer and environmental risks. *Id.* The Clean Air Act is unequivocal: EPA must protect the health of "the individual most exposed" to hazardous air pollutant emissions. 42 U.S.C. § 7412(f)(2)(A). A proposed rescission that ignores the very purpose of the action cannot support reasoned decisionmaking. *See State v. U.S. Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1122 (N.D. Cal. 2017) ("Without considering both the costs and the benefits of" a deregulatory action, an agency "fail[s] to take [an] 'important aspect' of the problem into account….").

EPA makes no real attempt to address forgone health benefits resulting from the Proposed Rule. EPA merely acknowledges that "[n]on-monetized health disbenefits are expected under this proposed reconsideration from estimated increases of 7.8 tons of EtO annually relative to the 2024 Final Rule." 91 Fed. Reg. at 12734. It provides only a paltry "qualitative discussion of the health effects associated with EtO exposure," and only in the context of the regulatory impact analysis.[164] EPA states only that "[d]ue to methodological and data limitations, the EPA was not able to quantify and monetize the potential human health impacts of the changes in EtO emissions in this analysis." 2026 RIA at 10–11 (citations omitted). The "qualitative discussion" of health effects consists only of the following paragraph:

> The Department of Health and Human Services and the International Agency for Research on Cancer have classified EtO as a known human carcinogen. The EPA has concluded that EtO is carcinogenic to humans by the inhalation route of exposure. Evidence in humans indicates that exposure to EtO increases the risk of lymphoid cancer (including non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia) and, for females, breast cancer. Noncancer health endpoints affected by chronic exposure to EtO include irritation of the eyes, skin, nose, throat, and lungs, and damage to the brain and nervous system. There is also some evidence linking EtO exposure to

[163] 2024 RRA, EPA-HQ-OAR-2019-0178-1576, at 6.

[164] EPA, Memorandum: 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, EPA-HQ-OAR-2019-0178-1609, at 10 (March 11, 2026), [hereinafter "2026 RIA"].

> reproductive and developmental effects. EtO is a mutagen, meaning it acts directly on DNA and causes chromosome damage. Children may be particularly susceptible to the harmful effects of mutagenic substances.

Id.

This is an insufficient consideration of the forgone health benefits. Although the Proposed Rule acknowledges 7.8 additional tons per year of EtO emissions, it provides no assessment of where those emissions will occur, who will be exposed, or what the resulting health consequences will be. 2026 RIA at 4. The Proposed Rule does not conduct any new modeling or analysis of the health consequences of rescinding the risk-based standards or weakening the section 112(d)(6) standards.

EPA did not even attempt the rudimentary step of inverting the positive health benefit estimates from the 2024 Rule. That rulemaking contained extensive quantitative risk analyses that the agency could have drawn upon—or simply inverted—to estimate the harms of rescinding those protections. The 2024 Rule modeled cancer risk for each census block within 50 km of every commercial sterilization facility and found that, under baseline conditions (i.e., without the 2024 Rule's protections), the maximum individual lifetime cancer risk was 6,000-in-1 million based on actual emissions and 8,000-in-1 million based on allowable emissions. 2024 RRA, EPA-HQ-OAR-2019-0178-1576, at 6. It further found that approximately 8.5 million people were exposed to cancer risks greater than or equal to 1-in-1 million from facility emissions, and approximately 19,000 people were exposed to cancer risks exceeding 100-in-1 million—the threshold EPA itself considers unacceptable. *Id.* The 2024 Rule RIA estimated that the 2024 Rule would reduce cancer incidence from 0.9 excess cancer cases per year to 0.1–0.2 excess cancer cases per year—an 80 to 90 percent reduction—and would reduce the population exposed to unacceptable cancer risks above 100-in-1 million from 19,000 people to zero. *Id*.

The Proposed Rule would reverse those gains and fails to address them. The failure to address the forgone health benefits of EtO reductions is particularly egregious here, where EPA still acknowledges that EtO is carcinogenic and particularly harmful to children given its mutagenic mode action.

H. EPA Must Take Additional Comment on Any New Methodologies, Models, or Conclusions Relied on in the Final Rule Regarding the IRIS Value.

To the extent EPA receives any new information not in the record in response to its questions on the IRIS value (Questions 3–5)—such as new or updated information relevant to dose-response model selection, studies, factual data, methodology used to analyze that data, or quantitative assumptions or determinations not currently in the record—the agency may not rely on that information in the final rule without providing an additional opportunity for public comment through mandatory reconsideration of the rule.

The Clean Air Act requires EPA to provide the public with a meaningful opportunity to comment on all information it relies upon in a final rule. *See* 42 U.S.C. § 7607(d)(7)(B). EPA

must provide notice of its proposed rule that "shall be accompanied by a statement of its basis and purpose," including "the factual data on which the proposed rule is based; ... the methodology used in obtaining the data and in analyzing the data; and ... the major ... policy considerations underlying the proposed rule." *Id.* § 7607(d)(3). These notice requirements are designed "(1) to ensure that Agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of review." *Envt'l Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) (quoting *United Mine Workers of America v. Mine Safety & Health Admin*., 407 F.3d 1250, 1259 (D.C. Cir. 2005)).

If EPA does not provide the public with an opportunity to comment on important aspects of a final rule, it must reconsider that rule. Section 307(d)(7)(B) provides:

> If the person raising an objection [to a rule] can demonstrate to the Administrator that it was impracticable to raise such objection within such time or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule, the Administrator shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed.

42 U.S.C. § 7607(d)(7)(B) (emphasis added).

"[I]f the Final Rule deviates too sharply from the proposal, affected parties will be deprived of notice and opportunity to respond to the proposal." *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 547 (D.C. Cir. 1983). "[A]mbiguous comments and weak signals from the Agency g[i]ve petitioners no … opportunity to anticipate and criticize the rules or to offer alternatives. Under these circumstances, the … rules exceed the limits of a logical outgrowth." *United Mine Workers of America*, 407 F.3d at 1261 (citation omitted). Therefore, considering the purposes of notice, a final rule that is not the logical outgrowth of a proposed rule does not provide the public with meaningful notice under section 307(d)(3). *See Env't Integrity Project*, 425 F.3d at 996–97. Objections to aspects of a final rule that did not grow logically from the proposed rule are, necessarily, ones that were "impracticable to raise" or the grounds for which arose only after the public comment period. 42 U.S.C. § 7607(d)(7)(B). Even if EPA's conclusion were a logical outgrowth of the proposal, findings and analyses underlying the conclusion that were not disclosed in the proposal are the proper subject of mandatory reconsideration. *See Chesapeake Climate Action Network v. EPA*, 952 F.3d 310, 320–21(D.C. Cir. 2020). An objection is of central relevance if it "provides substantial support for the argument that the regulation should be revised." *Coal. for Responsible Regul. v. EPA*, 684 F.3d 102, 125 (D.C. Cir. 2012), *aff'd in part, rev'd in part on other grounds sub nom*. *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302 (2014) (citation omitted). An objection that "go[es] to the very legality" of a final rule satisfies this test, even if EPA could conceivably claim alternative support for its action. *Chesapeake Climate Action Network*, 952 F.3d at 322.

Commenters will have had no opportunity to comment on analyses submitted by other commenters, nor on the Agency's own analysis performed only after the comment period and made public only with a final rule. Mandatory reconsideration would provide the public with the required period for public comment to critique new modeling and analyses or reliance on a different risk value. Accordingly, EPA is required to provide notice of and an opportunity to comment on any new methodologies, models, or conclusions relied on in the final rule regarding EtO's health risk, including the 2016 EtO IRIS value.

III. The Proposed Rescission of Permanent Total Enclosure Violates the Clean Air Act and is Arbitrary and Capricious. (Response to Questions 11–13)

In the 2024 Rule, EPA set standards for previously unregulated fugitive emissions under section 112(d)(2), (3), and (5) as part of the section 112(d)(6) and section 112(f)(2) reviews. EPA grouped fugitive emissions into Group 1 room air emissions and Group 2 room air emissions.

For Group 1 room air emissions at major sources, EPA set beyond-the-floor MACT requirements under section 112(d)(2) and (3). 89 Fed. Reg. at 24111. For Group 2 room air emissions at major sources, EPA set requirements at the MACT floor level under section 112(d)(2) and (3). *Id.* at 24112. EPA also promulgated GACT standards under section 112(d)(5) and risk-based standards under section 112(f)(2) for Group 1 and Group 2 room air emissions at area sources, which required most area sources to meet a numerical control standard. *Id*. at 24093–94. For all sources subject to a numerical standard for Group 1 and 2 room air emissions, EPA required PTE in accordance with EPA Method 204 as part of the standard. *Id.*

Now, EPA proposes to rescind all PTE requirements while retaining the numerical emission limits promulgated in the 2024 Rule. 91 Fed. Reg. at 12718. EPA's stated justifications for proposed rescission of PTE requirements for standards promulgated under section 112(d) are that: (1) states are "better positioned to determine whether PTE is required for any given sterilization facility"; and, in the alternative, (2) EPA did not account for the impacts of facilities shutting down due to inability to meet PTE requirements; and (3) PTE is not necessary to assure compliance with additional standards mandated by *Louisiana Envt'l Action Network v. EPA*, 955 F.3d 1088 (D.C. Cir. 2020) ("*LEAN*"). 91 Fed. Reg. at 12718.

EPA's proposal is unlawful and arbitrary and capricious. *See* 42 U.S.C. § 7607(d)(9)(A); 5 U.S.C. § 706(2). This section explains that (A) PTE requirements are inextricable from the numerical emissions standards. Because PTE is part of the room air emission limits that EPA promulgated under section 112(d) and 112(f), EPA cannot lawfully remove the PTE requirements because they are necessary to meet the requirements of section 112(d) and 112(f). This section further explains that: (B) the proposal violates section 112(d)(6) and *LEAN*, which require EPA to regulate previously unregulated emissions sources of HAPs; (C) EPA's other justifications regarding PTE enacted pursuant to section 112(d) are unlawful and arbitrary; and (D) the proposed rescission of PTE enacted pursuant to section 112(f)(2) is unlawful and arbitrary.

A. The PTE Requirements Are Inextricable From the Numerical Emissions Standards.

EPA's proposal incorrectly attempts to treat the PTE requirements as separate from numerical control requirements and outside of the statutory standards in sections 112(d)(2), (3), and (5). But EPA's MACT methodology and its own statements demonstrate that the PTE requirements are inextricably part of the numerical control requirements. That is, the PTE requirements are part of the section 112(d) and 112(f) standards EPA promulgated for Group 1 and 2 room air emissions in the 2024 Rule, and they are inextricable from the numerical emission limits EPA proposes to retain.

EPA's MACT floor calculation for Group 1 and 2 room air emissions incorporated PTE. EPA relied on performance tests conducted by Sterilization Services of Georgia, which had implemented PTE at the time of those performance tests. *See* MACT Floor and Beyond the Floor Analysis for Ethylene Oxide Commercial Sterilization – Chamber Exhaust Vents and Room Air Emission Sources – Promulgation, EPA-HQ-OAR-2019-0178-1551, at 15–16 ("[T]he existing source MACT floor is based on 1 facility (Fac ID 65).") [hereinafter "2024 MACT Analysis"]; *id.*, app. A at 15 (identifying Fac ID 65 as Sterilization Services of Georgia). In fact, the performance tests EPA relied on for its MACT analysis were conducted on the same day that the Georgia Environmental Protection Division also found that "[t]he building qualifies as a Permanent Total Enclosure (PTE) according to the requirements of EPA Method 204."[165] EPA did not—and could not—establish numerical emission limits without incorporating PTE into its calculations. *See generally*, *Nat'l Ass'n of Clean Water Agencies v. EPA*, 734 F.3d 1115, 1138–39 (D.C. Cir. 2013) (reasonability of EPA's MACT determination depended on whether EPA established that factors besides the control efficiency demonstrated by the control technology had a negligible effect on emissions). *See also*, Sahu Expert Report, Attachment A, at 5 ("EPA's data on pollution controls assumes a 100% capture rate.").

EPA's own statements confirm that the numerical standards promulgated in the 2024 Rule incorporate PTE as a necessary part of the emission limit. EPA stated in the 2024 Rule: "The emission standards for room air emissions that we evaluated assume 100 percent capture of EtO emissions." 89 Fed. Reg. at 24114 (citation omitted). EPA concluded that "[i]n order to meet the emission standards, it is necessary to ensure that all emissions are captured and routed to a control system.… Therefore, EPA Method 204 is appropriate to apply to this source category in order to ensure complete capture of room air emissions." *Id.*; *see id.* at 24104 ("In order to ensure complete capture of EtO emissions and, in turn, compliance with the proposed standards, [EPA] proposed to require each facility to operate areas with room air emissions subject to an emission standard in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51."). EPA also stated in the 2023 Proposed Rule that the proposed MACT and other numerical room air emission standards "are based on complete capture" of room air emissions. 88 Fed. Reg. at 22819. EPA made clear that "[f]or existing and new sources, the MACT floor

[165] EPD Test Review (SSG Permanent Total Enclosure), *Sterilization Services of Georgia Tests, Monitoring Reports and Engineering Studies*, Georgia EPD, downloadable at https://epd.georgia.gov/sterilization-services-georgia-tests-monitoring-reports-and-engineering-studies (Feb. 25, 2021) (attached).

will consist of capturing the room air emissions and routing to an add-on APCD." 2024 MACT Analysis, EPA-HQ-OAR-2019-0178-1551, at 15.

B. EPA's Proposed Rescission of the PTE Requirements Violates Clean Air Act Section 112(d)(6) as Interpreted in *LEAN*, Which Requires EPA to Regulate Previously Unregulated Emissions Sources, and Sections 112(d)(1), (2), (3), and (5).

(Response to Question 12)

i. *LEAN* requires EPA to regulate all emissions sources of a regulated HAP in a source category by setting missing section 112(d)(2), (3), and (5) standards in section 112(d)(6) reviews.

EPA proposes to rescind the PTE requirements issued under section 112(d) on the basis that it has no obligation to regulate uncontrolled emissions sources if the agency is already regulating that same pollutant from other emissions sources in the source category, notwithstanding *LEAN*, 91 Fed. Reg. at 12718. EPA's proposed interpretation of its duties under section 112(d)(6) and *LEAN* are incorrect. Section 112(d)(6) requires EPA to regulate all previously unregulated emissions sources of a regulated HAP because that is "necessary" to achieve the maximum achievable reduction in emissions, as required under section 112(d)(1)–(3). 42 U.S.C. § 7412(d)(6). That is the "best reading" of the Act, for it is the only interpretation consistent with the Act's text, structure, and purpose. *Loper Bright*, 603 U.S. at 400 ("[C]ourts use every tool at their disposal to determine the best reading of the statute."). Additionally, the "reasoning underlying" the D.C. Circuit's holding in *LEAN* is binding, correct, and requires EPA to regulate all emissions sources of a regulated HAP in a source category. *Bucklew v. Precythe*, 587 U.S. 119, 136 (2019); *see LEAN*, 955 F.3d at 1096. For this source category, PTE requirements are necessary to ensure maximum achievable reductions in emissions. Thus, EPA's proposed rescission of PTE is unlawful under section 112(d)(6), *LEAN*, and sections 112(d)(1), (2), (3), and (5).

The plain text of section 112 requires EPA to regulate all emissions sources of a regulated HAP within a source category. Specifically, emissions standards "shall require the maximum degree of reduction in emissions of the [HAP] subject to this section … that the Administrator … determines is achievable … through application of measures, processes, methods, systems or techniques." 42 U.S.C. § 7412(d)(2) (emphasis added). These are known as "MACT" standards. MACT standards require comprehensive measures to achieve maximum emissions reduction, including, but not limited to, those which:

> (A) reduce the volume of, or eliminate emissions of, such pollutants through process changes, substitution of materials or other modifications,
> (B) enclose systems or processes to eliminate emissions,
> (C) collect, capture or treat such pollutants when released from a process, stack, storage or fugitive emissions point,
> (D) are design, equipment, work practice, or operational standards (including requirements for operator training or certification) as provided in subsection (h), or

(E) are a combination of the above.

Id. Section 112(d)(2)(C) makes clear that Congress wanted regulation process-by-process, stack-by-stack, and fugitive-emissions-point-by-point.

Section 112(d)(6) requires EPA to "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." *Id.* § 7412(d)(6). An "emission standard" is "a requirement … which limits the quantity, rate, or concentration of emissions of air pollutants on a continuous basis, including any requirement relating to the operation or maintenance of a source to assure continuous emission reduction, and any design, equipment, work practice or operational standard promulgated under this chapter." *Id.* § 7602(k). The "emission standards" that section 112 directs EPA to promulgate—and that section 112(d)(6) requires EPA to review and revise—are emissions standards for source categories. *See id*. § 7412(c)(2), (d)(1); *LEAN*, 955 F.3d at 1096.

When conducting a section 112(d)(6) review of these standards, EPA must revise them "as necessary" to bring them into compliance with the Clean Air Act, including section 112(d)(2)'s requirement to assure the maximum achievable degree of emission reduction. 42 U.S.C. § 7412(d)(2). The maximum degree of achievable reduction necessarily requires EPA to set standards reducing emissions for *all* emissions sources of a HAP in the relevant source category. *See Nat'l Lime Ass'n*, 233 F.3d at 633 (holding that no-control standards violate section 112(d)). As a matter of logic, EPA cannot achieve the "maximum degree of reduction in emissions" of a HAP if it regulates anything less than all sources emitting that HAP. 42 U.S.C. § 7412(d)(2). Any other reading defies the plain text of section 112.

The "reasoning underlying" the D.C. Circuit's holding in *LEAN* is binding, correct, and requires EPA to regulate all emissions sources of a regulated HAP in a source category in setting standards under section 112(d). *Bucklew*, 587 U.S. at 136. In *LEAN*, the D.C. Circuit held that EPA must regulate previously unregulated HAP emissions when conducting a section 112(d)(6) review. *LEAN*, 955 F.3d at 1096. The court explained that emissions standards under section 112(d)(6) "are not constrained by past, potentially flawed and underinclusive agency action, as EPA now suggests." *Id.* at 1097. Rather, the plain text of section 112(d)(6) gives EPA no discretion on "whether or not to bring underinclusive standards into compliance with section 112(d)(2)–(3) when conducting its periodic section 112(d)(6) review." *Id.* at 1096. It is a "mandate to address the adequacy of each emission standard on the books against the statutory demand of section 112(d)(2) for an 'emission standard' for each source category—one with the requisite degree of control of all of the air toxics the source emits." *Id.* at 1097. That "requisite degree of control" is the "maximum degree of reduction in emissions that is deemed achievable," 42 U.S.C. § 7412(d)(3)—explicitly including "pollutants when released from a process, stack, storage or fugitive emissions point," *id.* § 7412(d)(2)(C).

The "maximum degree of reduction" necessarily includes all emissions sources, the same way it necessarily includes all HAPs. "The obligatory periodic review and revision of 'emission standards' thus must ensure that each source category's standard imposes appropriate limits—not just on whatever subset of toxics the existing standard addressed, but on all the toxics the source

category emits." *LEAN*, 955 F.3d at 1097. Applying that same reasoning here, EPA must regulate all emissions sources of a regulated HAP.

Additionally, "in calling for 'emission standards for each category or subcategory of major sources of hazardous air pollutants listed for regulation,' section 112(d) defines air pollution 'emission standards' as source-specific, not toxic-specific." *Id.* at 1096–97 (quoting 42 U.S.C. § 7412(d)(1)). "[T]he 'standards' to which section 112(d)(6) refers—the 'emission standards promulgated under this subsection'—are statutorily defined as comprehensive controls for each source category that must include limits on each hazardous air pollutant the category emits." *Id.* at 1096 (citing 42 U.S.C. § 7412(d)(1)–(3), (6)). "Accordingly, 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." *Id.* at 1097 (emphasis added). That necessarily includes all emissions sources, not just one or some.

Consistent with the plain text of the statute and the D.C. Circuit's holding and reasoning in *LEAN*, the structure of section 112 confirms that Congress intended EPA's periodic review and revision of its emissions standards to encompass setting limits on all emissions sources of a regulated HAP. EPA agrees that the Clean Air Act requires it to regulate emissions of specific HAPs; allowing it to regulate only some emissions sources would not be consistent with that requirement. Section 112(d)(6) is section 112's only technology-based mechanism for ensuring that EPA regulates previously unregulated pollutants and emissions sources. As explained below, denying section 112(d)(6) this function eviscerates the purpose of section 112, which was enacted to ensure that the emissions of all listed hazardous air pollutants be reduced to the "maximum" degree that is "achievable." 42 U.S.C. § 7412(d)(2).

This is also the only reading of the statute that is consistent with the purpose of section 112 and specifically section 112(d). EPA's interpretation—allowing it to regulate just one emission point of a HAP—would eviscerate the purpose of the Clean Air Act and the 1990 amendments. In enacting the 1990 amendments to the Act, Congress intended to limit EPA's discretion on which emissions sources and HAPs to regulate. "In 1990, Congress, concerned about the slow pace of EPA's regulation of HAPs, altered section 112 by eliminating much of EPA's discretion in the process." *New Jersey*, 517 F.3d at 578. [166] The amendments curtailed EPA's discretion regarding which HAPs to regulate: Congress itself enacted an "Initial list" of more than 100 hazardous air pollutants and set forth detailed requirements for adding new pollutants to the list. 42 U.S.C. § 7412(b)(1)–(3); *see New Jersey*, 517 F.3d at 578. The amendments also curtailed EPA's discretion regarding which sources to regulate. 42 U.S.C. § 7412(c)(2), (d)(1). Congress also constrained EPA's discretion regarding the stringency of the standards EPA sets, requiring the "maximum degree of reduction" that is "achievable," considering cost and other factors, *id.* § 7412(d)(1)–(2), and setting requirements for the floor, *id.* § 7412(d)(3). [167]

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[166] *See also Nat'l Lime Ass'n*, 233 F.3d at 633–34; *Mossville Envt'l Action Now v. EPA*, 370 F.3d 1232, 1242 (D.C. Cir. 2004); *Sierra Club v. EPA*, 479 F.3d 875, 878, 883–84 (D.C. Cir. 2007); *NRDC v. EPA*, 489 F.3d 1364, 1371 (D.C. Cir. 2007); *U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 623 (D.C. Cir. 2016).
[167] *See also Nat'l Lime Ass'n*, 233F.3d at 629; *Cement Kiln Recycling Coal.*, 255 F.3d 861–62 (D.C. Cir. 2001); *Sierra Club*, 479 F.3d at 878; *New Jersey*, 517 F.3d at 578.

EPA's reading in the Proposed Rule undermines the core mandates of section 112, over which EPA has no discretion. The agency's reading would "allow but not require the Agency to address previously uncontrolled air toxics during a scheduled section 112(d)(6) review," which "implausibly leaves no statutory prompt for the completion of statutorily deficient controls." *LEAN*, 955 F.3d at 1099. It would allow the agency to satisfy its statutory duties by regulating one single emissions source of a HAP, potentially allowing the majority of HAP emissions to go uncontrolled. This would lead to absurd results. For example, the agency could theoretically satisfy its duties by limiting emissions from the vacuum pump only (attributable to about 0.1% of EtO used) and leave sterilization chamber vents (attributable to at least 93.36% of EtO used) unregulated. Congress clearly did not intend this result, and EPA's interpretation cannot be the best reading. *See*, *e.g.*, *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998) ("In deciding whether a result is absurd, we consider not only whether that result is contrary to common sense, but also whether it is inconsistent with the clear intentions of the statute's drafters—that is, whether the result is absurd when considered in the particular statutory context.").

Finally, the legislative history of section 112 reflects Congress's intent for MACT to be determined for each source of emissions:

> There may be pollutants which because they are emitted from more than one point in a facility or because they are particularly difficult to control require the application of more than one control technology at the same site. For instance, adequate control of dioxin emissions from municipal waste combustion units is best achieved through a combination of good combustion practices and the installation of acid gas scrubbers. In another case, a particular VOC may be released from both a stack and from non-point sources in the facility. In the latter case, MACT will be determined for each type of emissions point and not for the facility as a whole.

S. Rep. No. 101-228, at 168 (1989), reprinted in 5 *A Legislative History of the Clean Air Act Amendments of 1990* 8338, 8508 (1993).

ii. EPA arbitrarily fails to explain its change in position on section 112(d)(6) and *LEAN*.

EPA bases its proposed rescission of PTE, in the alternative, on its new interpretation of section 112(d)(6) and *LEAN*. EPA acknowledges its past practice and change in position as follows:

> In certain actions since that decision [in *LEAN*], however, the EPA has sometimes suggested that this holding includes not only previously unregulated pollutants, but also additional emission points within an already regulated source (*e.g.*, an additional point or fugitive) that emit pollutants already captured by the NESHAP. We now propose to clarify that when conducting a CAA section

> 112(d)(6) review, the EPA is not obligated under the interpretation adopted in *LEAN* to prescribe particular standards for emission points with respect to pollutants already regulated under the NESHAP.

89 Fed. Reg. at 12718; *see, e.g.*, EPA Mot. at 2, *Blue Ridge Envt'l Defense League v. Regan*, No. 16-364 (D.C. Cir. Apr. 13, 2021) (moving to extend deadlines for five rulemakings "to set all necessary emission limits for HAP emissions as part of its final rules as required by LEAN"). But EPA may not only announce its change in position; it must also give "good reasons for the new policy." *Fox*, 556 U.S. at 515. EPA fails to do so here: It provides no explanation or legal support for its new interpretation of section 112(d)(6) or *LEAN*. EPA does not explain how section 112(d)(6) or *LEAN* do not require it to regulate all emissions sources of a regulated HAP, or how leaving emissions sources uncontrolled is even arguably consistent with section 112's purpose. Nor could it. As explained above, the plain text, structure, and purpose of section 112(d), specifically 112(d)(6), in addition to the D.C. Circuit's legally binding reasoning in *LEAN*, confirm that EPA is required to regulate previously unregulated emissions. In failing to provide any explanation for its change in position, EPA's action is arbitrary, in violation of the Act. *See* 42 U.S.C. § 7607(d)(9)(A); 5 U.S.C. § 706(2).

iii. Rescinding the PTE requirements would violate CAA sections 112(d)(2), (3), and (5) and would be arbitrary and capricious.

EPA's Proposed Rule makes no findings that the "maximum degree of reduction in emissions" achievable no longer requires PTE, *id.* § 7412(d)(2), that PTE is not part of the "emission control that is achieved in practice by the best controlled similar source," *id.* § 7412(d)(3), or that PTE is no longer a "generally available control technolog[y] … to reduce emissions," *id.* § 7412(d)(5). Record evidence, in fact, points to the contrary. Rescinding the PTE requirements as proposed would therefore violate sections 112(d)(2), 112(d)(3), and 112(d)(5) and be arbitrary and capricious.

In the 2024 Rule, EPA set MACT standards for existing and new Group 1 and Group 2 room air emissions at major sources, consisting of a numerical emission reduction percentage and PTE. 89 Fed. Reg. at 24105; *see also* 2024 MACT Analysis, EPA-HQ-OAR-2019-0178-1551, at 15 ("For existing and new sources, the MACT floor will consist of capturing the room air emissions and routing to an add-on APCD.").

EPA set section 112(d) standards for Group 2 room air emissions at major sources at the MACT floor level. 89 Fed. Reg. at 24112. EPA may not consider costs when setting the MACT floor or use cost to justify setting standards below the MACT floor. *See Nat'l Lime Ass'n*, 233 F.3d at 629. In the Proposed Rule, EPA raises costs and cost-effectiveness of implementing PTE as one basis for supporting the proposed rescissions of PTE for all room air emission standards. 91 Fed. Reg. at 12718. Because the MACT standard for Group 2 room air emissions at major sources is already set at the MACT floor—the minimum control standard allowed under the Act—it is unlawful and would violate section 112(d)(2) and 112(d)(3) for EPA to weaken this standard on the basis of costs. This would also be arbitrary and capricious because EPA is "rel[ying] on factors which Congress has not intended it to consider." *State Farm*, 463 U.S. at 43.

EPA has also failed to demonstrate that the remaining Group 1 and 2 room air emission standards for major sources would satisfy the "maximum degree of reduction in emissions" achievable standard without the PTE requirement. 42 U.S.C. § 7412(d)(2)–(3). In the 2024 Rule, EPA promulgated a beyond-the-floor standard for Group 1 emissions at major sources of a numerical requirement of 97% control together with PTE. 89 Fed. Reg. at 24111. EPA thus determined that this standard constituted the "maximum degree of reduction in emissions" achievable, "taking into consideration the cost of achieving such emission reductions." 42 U.S.C. § 7412(d)(2). EPA's proposal fails to provide a rational explanation for how the 97% numerical limit, without PTE, constitutes the "maximum degree of reduction" achievable under section 112(d)(2).

With respect to GACT requirements for Group 1 and 2 emissions at area sources, EPA has failed to demonstrate how its proposal to rescind the PTE requirements would meet the standard in section 112(d)(5) to "reduce emissions of hazardous air pollutants." *Id.* § 7412(d)(5). For Group 1 and 2 emissions at area sources, EPA promulgated GACT requirements including PTE requirements where a numerical control requirement applied. 89 Fed. Reg. at 24112–14. In setting standards under section 112(d)(5), EPA must "determine that the standard would 'reduce emissions of hazardous air pollutants.'" *U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 608 (D.C. Cir. 2016) (quoting 42 U.S.C. § 7412(d)(5)). EPA's proposal fails to meet this standard because more emissions will escape to the atmosphere uncontrolled if facilities are not required to enclose their operations using PTE, and EPA fails to establish otherwise. Even if EPA has discretion to choose between GACT standards, it must still meet the minimum statutory standard of "reduc[ing] emissions of hazardous air pollutants." 42 U.S.C. § 7412(d)(5). *See Sea-Land Serv.*,137 F.3d at 646 ("An agency action, however permissible as an exercise of discretion, cannot be sustained 'where it is based … on an erroneous view of the law.'").

Moreover, EPA has arbitrarily failed to explain its departure from its previous findings that the standards it promulgated under sections 112(d)(2), (3), and (5) are cost-effective. For each of the standards promulgated, EPA determined that the numerical reduction standard—which includes PTE—is cost effective and generally available. *See* 89 Fed. Reg. at 24111.

iv. EPA's proposal unlawfully and arbitrarily allows facilities to demonstrate compliance while emitting EtO in excess of emission limits.

By definition, uncaptured emissions are uncontrolled emissions. Without PTE, EPA estimates that 0.64% of EtO used at a facility escapes into the atmosphere as fugitives. EPA, Technical Support Document, EPA-HQ-OAR-2019-0178-0469, at 11 [hereinafter "2023 TSD"]. Facilities can demonstrate compliance with emission limits by calculating the percentage EtO controlled from inlet and outlet EtO concentrations,[168] or, if EPA's proposal is finalized, by measuring operating parameters based on operating parameter limits ("OPLs") established

[168] *See* 40 C.F.R. § 63.364(f) (facilities using CEMS to demonstrate compliance must measure outlet concentrations using CEMS and "must also conduct monitoring for each inlet to the control system," with the exception of SCV-only emission streams for which facilities can determine the mass of EtO being emitted prior to controls by calculating the mass of EtO sent to controls from the SCV); 40 C.F.R. § 63.363(f).

during the most recent performance test. But uncaptured room air emissions will not be reflected by inlet concentration measurements or during performance tests, so emission control calculations will overstate the rate at which the facility is actually controlling EtO. Facilities would be able to purportedly demonstrate compliance even if their actual emissions of EtO exceed emission limits—potentially in significant amounts. EPA's proposal would introduce a giant loophole into the room air emission limits, practically eliminating any way to verify actual continuous compliance with the numerical emission standards.

This would contravene the Act's mandate for regulations to require the "maximum degree of reduction in emissions," 42 U.S.C. § 7412(d)(2),(3), and would be arbitrary and capricious, *see Animal Legal Def. Fund v. Perdue*, 872 F.3d 602, 620 (D.C. Cir. 2017) (agency must "act[] rationally and engage[] in reasoned decisionmaking" when determining what information it can rely on to demonstrate compliance, especially when the agency "has concrete evidence that" the regulated entity "is routinely … out of compliance").

This compliance loophole is especially problematic where facilities choose to demonstrate compliance by monitoring combined emission streams after streams are combined, thereby foregoing the requirement to monitor room air emissions on their own for the purposes of demonstrating compliance with the applicable numerical control requirement. [169]

The 2024 Rule allows facilities that combine emission streams to demonstrate compliance by determining the mass of EtO entering the control device after the point of combination and applying a mass rate emission limit calculated using the most stringent emission reduction standard applicable to the component streams. [170] Facilities using this configuration may demonstrate compliance by meeting a mass rate emission limit calculated based on the mass of EtO at the ACPD inlet. As explained above, EtO mass at the inlet will not represent the true mass of EtO emissions that must be controlled because some EtO will escape the facility uncontrolled if there is not 100% capture. If a facility combines room air emissions with other emission streams that are subject to more stringent numerical emission limits, then the facility could potentially demonstrate compliance even if only some or even no room air emissions are controlled.

To illustrate, consider an existing area source facility using 30 tpy of EtO per year and combining emission streams from the CEV and Group 1 room air emissions. It would be subject to a 99% control efficiency for CEVs and an 80% control efficiency for Group 1 room air emissions. Suppose the mass EtO from the CEV at the inlet is 1 lb and the mass EtO from Group 1 room air emissions at the inlet is 0.1 lb under full capture conditions, meaning the combined mass at the inlet is 1.1 lb if PTE is implemented. The 99% control efficiency would apply, resulting in an emission limit of 0.011 lb.

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[169] See 40 C.F.R. § 63.362(i)(2) (where facilities elect to monitor before emission streams are combined, they must calculate the 30-operating day rolling sum of inlet mass to the control system for each component stream).

[170] 89 Fed. Reg. at 24136 (explaining two options for demonstrating compliance with combined emission streams; *id.* at 24101 (summarizing changes in compliance demonstration requirements for combined emission streams).

By contrast, imagine the same scenario but only half of Group 1 room air emissions is captured (0.05 lb) and the rest is emitted as uncontrolled fugitives. This would result in a combined inlet mass of 1.05 lb, and under a 99% control efficiency, a mass emission limit of 0.0105 lb. The facility could demonstrate compliance with the 0.0105 lb limit, but have actual emissions of 0.0605 lb EtO—5.5x higher than the emission limit when accounting for the 0.05 lb of EtO emitted without capture. If no Group 1 RAE is captured, the inlet mass would be 1 lb, resulting in an emission limit of 0.01 lb. The facility could demonstrate compliance by meeting the 0.01 lb limit even though its actual emissions, accounting for 0.1 lb of uncontrolled fugitives, would be 0.11 lb—11x higher than the emission limit that the facility is purportedly demonstrating compliance with.

EPA's proposal would plainly fail to require the maximum degree of emissions reductions achievable as required under section 112(d)(2), and would be "so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43.

Facilities must demonstrate continuous compliance, and the numerical emission limit inherently requires control of all emissions from that source, not just those that are captured. EPA's proposal would render the numerical room air emission requirements meaningless by allowing an unknown and potentially significant amount of Group 1 and 2 room air emissions to escape facilities uncontrolled. EtO that leaks from facilities in the absence of PTE are completely uncontrolled emissions—a 0% destruction removal efficiency that plainly violates the numerical room air emission limits.

EPA's proposal is neither "reasonable" nor "reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021) ("*Prometheus Radio*"). EPA bears an "affirmative burden" of "examining a key assumption" when "promulgating and explaining a non-arbitrary, non-capricious rule." *Hisp. Affs. Project v. Acosta*, 901 F.3d 378, 389 (D.C. Cir. 2018) (quotations and alterations omitted). By irrationally and illogically assuming that facilities can and will still meet numerical emission limits without implementing PTE in accordance with Method 204, EPA has failed to carry that burden.

Further, EPA fails to acknowledge or explain its change in position regarding the need for PTE to comply with the numerical room air emission limits. *See*, *e.g.*, 89 Fed. Reg. at 24134 ("In order to ensure that emissions are not leaving through uncontrolled spaces, it is critical to demonstrate continuous compliance with EPA Method 204."); *id.* at 24099 ("To demonstrate compliance with the emission limits, we are finalizing capture requirements."); *see also*, *e.g.*, *id.* at 24104 ("In order to ensure complete capture of EtO emissions and, in turn, compliance with the proposed standards, we proposed to require each facility to operate areas with room air emissions subject to an emission standard in accordance with the PTE requirements of EPA Method 204.…").

But in rescinding the PTE requirements, EPA is silent on whether it still believes the room air emission limits are dependent on 100% capture of EtO emissions or whether 100% capture of EtO emissions can be achieved with alternatives to Method 204. Its proposed action implies that the agency believes compliance with the RAE limits to be possible without PTE in accordance with Method 204, which is "inconsistent with an earlier position" and constitutes a

change in policy that must be acknowledged and explained. *FDA v. Wages & White Lion Investments*, 604 U.S. 542, 570 (2025) (citation omitted). EPA's proposal arbitrarily and capriciously fails to "display awareness that it is changing position" and fails to "offer good reasons for the new policy." *Id.*; *see Fox*, 556 U.S. at 515 ("An agency may not … depart from a prior policy sub silentio.").

v. EPA's proposal arbitrarily fails to account for the overwhelming record evidence of significant fugitive emissions emitted by the source category.

EPA's proposal "entirely fail[s] to consider an important aspect of the problem": the significant amount of fugitive emissions emitted by this source category and their impact on public health. *State Farm*, 463 U.S. at 43. Without PTE, fugitive EtO emissions escape from facilities in significant quantities, including at quantities that harm public health. EPA estimates that 0.64% of EtO used at facilities becomes room air emissions. 2023 TSD at 11. The information reported by facilities in response to EPA's ICR shows that actual EtO use across facilities is approximately 6763 tpy. EPA, app. B – NESHAP – Modeling File proposal.xlsx, EPA-HQ-OAR-2019-0178-0482, Attachment 1 (Sheet "Fac", Column F). Accordingly, prior to the 2024 Rule, the commercial sterilizer source category may have been emitting over 43 tons per year of EtO solely in fugitive emissions. *See also id.* at Sheet "Emis", sum of Column Q (filtered for Group 1 and Group 2 under Column Y) (indicating approximately 13 tpy of actual Group 1 and Group 2 emissions). Even in the supporting materials for this proposal, EPA estimates actual room air emissions to be 3.3 tpy prior to the 2024 Rule. Cost Impacts and Emission Reductions for the Ethylene Oxide Commercial Sterilization Facilities Source Category — Reconsideration, Proposal Review for Ethylene Oxide Commercial Sterilization Source Category, EPA-HQ-OAR-2019-0178-1608 Attachment 1 ("NESHAP Impacts Risk Reconsideration Docket," sheet "Em_Red_compare" cells C6:C7).

These fugitive emissions contribute to ambient EtO concentrations at levels that harm public health. An ambient air monitoring study focused on the Midwest sterilizer facility in Laredo, TX found that downwind concentrations of ambient EtO, sampled from October to November 2025, were 3.00 to 8.17 $\mu g/m^3$ higher than upwind concentrations. Aecom, Ethylene Oxide Monitoring in Laredo, Texas at 22 tbl. 3-7 (Feb. 16, 2026) (attached). EPA has previously estimated that the ambient EtO concentration associated with a 100-in-1 million cancer risk for a lifetime of continuous exposure is 0.02 $\mu g/m^3$.[171]

There is no "rational connection" between the record evidence that facilities emit significant amounts of uncontrolled room air emissions and EPA's proposal to stop requiring facilities to capture those emissions. *State Farm*, 463 U.S. at 43 (citation omitted).

[171] *See* EPA, Ethylene Oxide Emissions: Frequent Questions, https://19january2021snapshot.epa.gov/il/ethylene-oxide-emissions-frequent-questions_.html (archived Jan. 19, 2021) (attached).

C. EPA's Other Reasons for Rescinding PTE Requirements are Unlawful and Arbitrary and Capricious.

EPA's stated justifications for its proposal to rescind PTE requirements for standards promulgated under section 112(d) (in addition to its incorrect interpretation of section 112(d)(6) and *LEAN*) are that: (1) states are "better positioned to determine whether PTE is required for any given sterilization facility"; and, in the alternative, (2) EPA did not account for the impacts of facilities shutting down due to inability to meet PTE requirements. For the reasons below, these justifications do not pass the test for reasoned decisionmaking. *See* 42 U.S.C. § 7607(d)(9); 5 U.S.C. § 706(2).

i. EPA's conclusion that states are in a better position to determine whether PTE is appropriate for any individual facility contravenes the Act and is not a lawful basis for rescinding the PTE requirements.

EPA's primary rationale for rescinding the PTE requirements is that "whether PTE would be necessary to assure compliance with an emission standard could depend on a facility's design and configuration," and "EPA has historically left such case-by-case reviews of facility design to the states to decide as part of their permitting process." 91 Fed. Reg. at 12718.

The text of section 112 vests standard-setting authority exclusively in EPA; EPA may not punt the regulatory duty Congress gave it under section 112 to the states. States may receive delegated authority only to implement and enforce standards that EPA has already established. Congress opted for federal standards for HAP-emitters, whereas in section 110 it gave states significantly more latitude in determining how to regulate sources. Rescinding a specific control on the ground that states are better situated to determine on a facility-by-facility basis whether it should be required contradicts section 112, is an unauthorized subdelegation of authority, and is an arbitrary and capricious change in position.

The plain text of section 112 vests standard-setting authority to EPA only not the States: "The Administrator shall promulgate regulations establishing emission standards for each category or subcategory of major sources and area sources of hazardous air pollutants listed for regulation pursuant to subsection (c)…." 42 U.S.C. § 7412(d)(1) (emphasis added). The word "shall" creates a non-discretionary duty. Nothing in section 112 authorizes EPA to rescind a specific control on the ground that States are better positioned to make facility-level determinations.

The states' role in section 112 is carefully circumscribed. Under section 112(*l*)(1), states may receive delegated authority only "to implement and enforce emissions standards," and any such delegation "shall not include authority to set standards less stringent than those promulgated by the Administrator." *Id.* § 7412(l)(1). This forecloses the reading that Congress intended states to fill in the substantive content of NESHAP standards by deciding whether individual controls are appropriate—exactly what EPA's proposed rescission would allow them to do. Section 112(j)'s backstop provision reinforces this reading. Under section 112(j), if EPA fails to promulgate a national MACT standard on time, the permitting authority (EPA or the state agency) are required to establish case-by-case MACT standards in individual permits. *See id.* §

7412(j)(5). State-level, facility-specific determinations, therefore, are the exception, a backstop Congress created to deal with EPA inaction. They are not a substitute Congress expected EPA voluntarily to create through rescissions.

EPA cannot voluntarily re-create the pre-1990 patchwork of state-by-state flexibility that Congress expressly rejected: As discussed above, Congress enacted the current section 112 framework precisely because the pre-1990 approach, which gave EPA broader discretion and resulted in case-by-case risk assessments, had produced exceptionally poor results. *See* 1990 U.S.C.C.A.N. 3385, 3552 ("To rectify this insufficiency and to further integrate control technology requirements under various part of the Act, the 1984 bill amended the BACT review under the PSD program…. Although the 1984 bill was not ultimately enacted and this legislation does not make extensive modifications to the PSD program, some of the conceptual work done for the 1984 bill is carried over to this new subsection establishing technology-based standards for major sources of noncriteria air pollutants."). EPA's proposed rationale here—that states should determine whether a specific control is appropriate on a facility-by-facility basis—reintroduces the same case-by-case approach that Congress rejected. "EPA may not construe [a] statute in a way that completely nullifies textually applicable provisions meant to limit its discretion." *Whitman v. American Trucking Associations*, 531 U.S. 457, 485 (2001).

Similarly, section 112 prescribes specific criteria for EPA to consider when setting standards, including criteria like achievability, cost, non-air quality health and environmental impacts, and energy requirements. *See* 42 U.S.C. § 7412(d), (f). Nothing in section 112 suggests that an appropriate consideration when setting or rescinding standards is depending on states' preferences.

Transferring EPA's exclusive authority to set these standards to the States is an unlawful subdelegation of authority. "[W]hile federal agency officials may subdelegate their decision-making authority to subordinates absent evidence of contrary congressional intent, they may not subdelegate to outside entities—private or sovereign—absent affirmative evidence of authority to do so." *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 566 (D.C. Cir. 2004). "The fact that the subdelegation in this case is to state commissions rather than private organizations does not alter the analysis." *Id.* Section 112 contains no clear statement allowing EPA to delegate this authority to state entities. To the contrary, the only provision addressing the states' role in section 112 is section is 112(*l*), which limit States to "to implement and enforce emissions standards" and explicitly prohibits States from setting "authority to set standards less stringent than those promulgated by the Administrator." 42 U.S.C. § 7412(*l*)(1). And EPA's own regulations implementing section 112(*l*) define "state" as "delegated authority to implement" NESHAP standards. 40 C.F.R. § 63.2.

ii. EPA's conclusion that states are in a better position to determine whether PTE is appropriate is an arbitrary and capricious basis for rescinding the PTE requirements.

EPA's contention that States are in a better position to determine whether PTE is appropriate is unsupported and does not provide a rational basis to support rescission of the PTE requirements. EPA's primary justification for its proposal to rescind PTE under section 112(d) is

that "whether PTE would be necessary to assure compliance with an emission standard could depend on a facility's design and configuration," and states are "better positioned to determine whether PTE is required for any given sterilization facility." 91 Fed. Reg. at 12718. These are merely "sweeping and arbitrary inferences" that cannot support reasoned decision-making. *Trans Union Corp. v. FTC*, 81 F.3d 228, 235 (D.C. Cir. 1996).

EPA points to two observations that "suggest" that the necessity of PTE "could depend on a facility's design and configuration:" "[S]ome state permits require PTE while others do not," and "configuration and design of sterilization facilities vary widely." *Id.* EPA fails to explain how these observations support a finding that whether PTE is necessary "could depend on a facility's design and configuration." *Id.*

EPA does not identify which state permits it is basing its conclusion on, thereby denying commenters the opportunity to fully evaluate the agency's reasoning, in violation of section 307(d) notice requirements, and section 307(h)'s requirements for meaningful public participation. 42 U.S.C. § 7607(d), (h). Regardless, EPA fails to address the fact that state permits without PTE requirements likely predate the 2024 Rule, which required PTE and numerical room air emission limits for the first time at the federal level. Those states had no legal impetus to require PTE or require facilities to control fugitive emissions, and it cannot be inferred from the lack of a PTE requirement in some state permits predating the 2024 Rule that those states made a judgment that PTE is not necessary to assure compliance with room air emission standards.

EPA also arbitrarily does not explain how its observation that "configuration and design of sterilization facilities vary widely" would "suggest" that this variation is relevant to or determinative of whether PTE is necessary to assure compliance with numeric room air emission limits. The leaps in EPA's reasoning are easily demonstrated by analogy: By EPA's logic, the fact that only some state permits require PTE, together with the fact that the number of employees at sterilization facilities varies widely, suggests that the need for PTE to ensure compliance with emission limits depends on the number of employees at a facility.

In addition to its logical gaps, EPA's proposal lacks factual support. EPA's proposed rescission must be supported by more than conjecture that these observations "suggest" that the need for PTE "could" vary between facilities. EPA "may not tolerate needless uncertainties in its central assumptions when the evidence fairly allows investigation and solution of those uncertainties." *NRDC v. Herrington*, 768 F.2d 1355, 1391 (D.C. Cir. 1985). Here, EPA relies on its "review of state permits" to justify its speculation that the need for PTE could vary based on facility design and configuration—if EPA maintains that these permits support its proposal, they should also enable EPA to investigate and make a definitive finding as to whether its conclusion is supported in fact.

One central premise of EPA's proposal is that there are circumstances where PTE is not necessary to assure compliance with numerical emission limits. But as explained above, this premise defies logic, and EPA provides no explanation or example of any such circumstance where states could assure that facilities achieve compliance with numerical emission limits without PTE.

Without any such explanation, EPA has failed to acknowledge or explain its change in position from the agency's previous findings. *See Fox*, 556 U.S. at 515. In 2024, EPA said it "strongly disagree[s] with the commenters that EPA Method 204 is not appropriate to apply to this source category," noting that Method 204 is "agnostic to the industry it is applied" to and "has been applied widely to any industrial processes that need[] to control VOC emissions, including several existing commercial sterilizers" that are already in compliance with Method 204. 89 Fed. Reg. at 24114 (emphasis added). EPA stated that Method 204 is its "established protocol … for ensuring complete capture of room air emissions" that has been applied "in numerous new source performance standards, NESHAPs, and federally enforceable State and local programs (e.g., Title V permits, State implementation plans)." *Id.*

These statements convey EPA's prior position that PTE is necessary in *all* facilities in the source category with RAE emission limits. EPA "must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored." *Lone Mountain Processing, Inc. v. Sc'y of Lab.,* 709 F.3d 1161, 1164 (D.C. Cir. 2013).

Additionally, EPA has not identified any alternatives to PTE that could assure compliance with RAE emission limits, and it previously concluded that there are no voluntary control standards that are acceptable alternatives to Method 204.

Finally, EPA's explanation is not "reasonable and reasonably explained," *Prometheus Radio*, 592 U.S. at 423, because it fails to acknowledge that the lack of a Title V permit requirement for commercial sterilizers means that some states will not engage in permitting to require compliance with the NESHAP at all. EPA cannot rationally rely on states to conduct evaluations of whether PTE should be implemented at a facility.

iii. EPA's claim that it did not account for the impacts of facilities shutting down is unexplained and countered by the record evidence. (Response to Question 11)

EPA provides that one basis for rescinding the PTE requirements is that the agency "did not account for the impacts of facilities shutting down due to [] variation" of the facility's design and configuration. 91 Fed. Reg. at 12718. EPA does not explain what it means by a facility shutting down due to its design and configuration, nor does it specify what "impacts" it is referring to our how they would justify rescission of the PTE requirements.

The only explanation EPA provides for its alternative rationale is: "If the facility is unable to establish PTE and meet the other requirements, then the facility would be required to shut down thus significantly raising the costs and making it not cost-effective to establish PTE." *Id.* This circular reasoning is more confusing than clarifying; it is a basic feature of the Clean Air Act that a facility unable to meet the relevant standards must cease operating. 42 U.S.C. § 7412(i)(3)(A) ("After the effective date of any emissions standard, limitation or regulation promulgated under this section and applicable to a source, no person may operate such source in violation of such standard, limitation or regulation…."); indeed, it is a basic feature of laws that they must be complied with. And EPA does not explain how shutting down would raise the costs

of compliance. Even if the ratio of costs to revenue for one particular facility would increase if that facility stops generating revenue, that does not mean coming into compliance in order to reopen the facility would not be cost-effective.[172] EPA has failed to provide a "satisfactory explanation." *State Farm*, 463 U.S. at 43.

Critically, EPA's proposal does not make any new findings about the cost or cost-effectiveness of implementing PTE, so to the extent that EPA contends that cost considerations justify its proposal, that contention is also not reasonably explained or supported by factual findings in the record.

To the extent that EPA is alleging that the agency previously failed to consider the cost impact or technological feasibility of the PTE requirements, this argument is plainly belied by the record. In the last rulemaking, EPA found that all Group 1 and 2 emission standards, which incorporate PTE requirements, were cost-effective. 89 Fed. Reg. at 24111–14. EPA specifically accounted for the costs of retrofitting facilities, noting that "commercial sterilization facilities tend to be simple buildings (in some cases, re-purposed warehouses) with a relatively small footprint, which helps the retrofitting process." *Id.* at 24114. EPA estimated that there were only 28 facilities that would have costs associated with the new PTE requirements and that total capital investment would be $77,500,000 with total annual costs of $8,280,000. *Id.* at 24094 tbl. 2; *see also id.* at 24138 ("We expect that 28 facilities still need to meet the PTE requirements of EPA Method 204."). For new facilities, EPA found that "a few companies have constructed, or are in the process of constructing, new facilities with state-of-the-art design and control installations to ensure full capture and control of EtO emissions." *Id.* at 24138. EPA concluded, "These early actions by industry demonstrate the feasibility of implementing the requirements in this final rule." *Id.* at 24139. EPA even recognized in its 2019 ANPRM that commercial sterilization facilities have either implemented or were planning to implement PTE to control fugitive emissions at that time. 84 Fed. Reg. at 67894–95. *See also* Sahu Expert Report, Attachment A, at 5 ("Several sterilizers claim to have implemented PTE requirements, demonstrating that … they are cost-effective and feasible.").

EPA's suggestion that some facilities might shut down due to the costs of compliance with the PTE requirement is unsupported and "runs counter to the evidence." *State Farm*, 463 U.S. at 43. Facilities have successfully implemented PTE without significant shutdowns. For instance, Sterigenics facilities in Ontario, CA, Vernon, CA, Atlanta, GA and Salt Lake City, UT have implemented PTE or are currently in the process of doing so.[173] Sterilization Services of

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[172] Most sterilizer facilities are owned by large companies, many of which own several sterilizer facilities and have other resources to fund compliance. 2024 RIA, EPA-HQ-OAR-2019-0178-1557, at 5-5 tbl. 5-3.

[173] Sterigenics of Ontario, CA received a permit to construct a PTE on July 19, 2024. *Sterigenics Emissions Investigation in Ontario*, SCAQMD, https://perma.cc/T8J6-87FE (attached); Sterigenics of Vernon, CA received a permit to construct a PTE on Jan. 27, 2023 and has since notified SCAQMD that its PTE has been constructed. *Sterigenics Emissions Investigation in Vernon*, SCAQMD, https://perma.cc/Z98G-ATM9 (attached); Sterigenics of Atlanta, GA had a third party test team test its PTE on March 24, 2020, which indicated that the system was working as designed. Letter from Karen Hays to Rob Hosack (March 24, 2020), https://epd.georgia.gov/sterigenics-us-llc ("EPD Letter re: Negative Pressure System Testing") (attached); Sterigenics of Salt Lake City submitted a notice of intent

Georgia confirmed a working PTE system in 2021.[174] Medline Industries in Waukegan, IL verified its PTE in March 2020.[175] For further discussion of facilities that have demonstrated compliance, see Section VI.

EPA arbitrarily fails to examine the available evidence on PTE installation and only mentions that the "feasibility of PTE has been raised by stakeholders over time" without specifying any arguments or supporting evidence brought forth by these stakeholders or EPA's evaluation of their merits. 91 Fed. Reg. at 12718. EPA has substantial evidence that PTE is viable, and EPA must provide substantial evidence to counter that, *see City of Naples Airport Authority v. FAA*, 409 F.3d 431, 436 (D.C. Cir. 2005). EPA presents no such evidence. Its unsupported assertion does not reflect reasoned decision-making, and EPA "abdicates its role as a rational decision-maker if it does not exercise its own judgment, and instead cedes near-total deference to private parties' estimates." *Texas Off. of Public Util. Couns. v. FCC*, 265 F.3d 313, 328 (5th Cir. 2001).

D. EPA's Proposed Rescission of Section 112(f)(2) PTE Standards Would Violate the Act and be Arbitrary and Capricious.

Additionally, as explained in Section I and II of these comments, EPA's rescission of standards promulgated under section 112(f)(2)(A), including standards for Group 1 and 2 room air emissions, would violate the Clean Air Act and be arbitrary and capricious. *See Land Serv., Inc.*, 137 F.3d at 646 ("An agency action, however permissible as an exercise of discretion, cannot be sustained 'where it is based … on an erroneous view of the law.'" (internal citation omitted)).

In the 2024 Rule, EPA promulgated emission standards for Group 1 and 2 room air emissions at larger area sources under section 112(f)(2)(A). EPA now proposes to rescind the standards issued under section 112(f)(2) based on an erroneous view of that provision. Rescinding those requirements would violate section 112(f)(2) because, as EPA concluded in the 2024 Rule, PTE is necessary to provide the requisite "ample margin of safety." 42 U.S.C. § 7412(f)(2); 89 Fed. Reg. at 24100; *see id.* at 24119. Group 2 room air emissions in particular are one of the primary drivers of the overall 6,000-in-1 million MIR that EPA calculated. *See* 89 Fed. Reg. at 24116 ("At proposal the maximum lifetime individual cancer risk posed by the 97 modeled facilities, based on whole facility emissions, was 6,000-in-1 million, with EtO emissions from SCVs and Group 2 room air emissions … driving the risk."); *id.* at 24120 ("Group 2 room air emissions [at facilities where EtO usage is above 4 tpy] contribute to unacceptable risks from existing area sources in this source category" even after application of section 112(d) controls); *id.* at 24121 (Group 1 room air emissions contribute to unacceptable

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to install PTE in September 2022, which was issued on Apr. 30, 2024. Approval Order DAQE-AN104350031-24 (attached).

[174] EPD Test Review (SSG Permanent Total Enclosure), *Sterilization Services of Georgia Tests, Monitoring Reports and Engineering Studies*, Georgia EPD, https://epd.georgia.gov/sterilization-services-georgia-tests-monitoring-reports-and-engineering-studies (attached).

[175] Letter from Steve Flaherty to Jasper Titus, Subject: PTE Verification (March 23, 2020), https://epa.illinois.gov/content/dam/soi/en/web/epa/topics/community-relations/sites/ethylene-oxide/documents/pte-report-200323.pdf (attached).

risk levels at four facilities). Because these standards are necessary to provide "an ample margin of safety," rescinding them would violate section 112(f)(2) of the Clean Air Act *See supra* Section I.

By failing to consider the health risk that fugitive emissions standards and PTE address, EPA's proposal arbitrarily "entirely fail[s] to consider an important aspect of the problem"—the central purpose of section 112(f)(2), which is to protect public health. *State Farm*, 463 U.S. at 43. Said another way, rescission would "run counter to the evidence" on the necessity of capturing fugitive emissions to provide an ample margin of safety. *Id.*
The record shows that without PTE, fugitive EtO emissions escape from facilities in significant quantities. EPA has previously concluded that the "the high risk [from the source category] is being driven by fugitive emissions. Fugitive emissions of EtO, which are currently unregulated, often disperse laterally and in relatively high amounts." EPA, Ethylene Oxide Commercial Sterilizers: Clean Air Act National Emission Standards for Hazardous Air Pollutants (NESHAP), Risk Assessment Results and Plans for Outreach, Presentation for State, Local, and Tribal Air Agencies (May 5, 2022) at 16 (attached); 89 Fed. Reg. at 24116 (Group 2 room air emissions are one of the primary drivers of the overall 6,000-in-1 million maximum individual risk EPA calculated). In addition to cancer risk, EPA found that risks for non-cancer neurological effects were driven in part from post-aeration and pre-aeration handling of sterilized material as well as hazardous chemical dispensing. 2024 RRA, EPA-HQ-OAR-2019-0178-1576, at 6. There is no "rational connection" between the record evidence that facilities emit significant amounts of uncontrolled room air emissions, harming public health, and EPA's proposal to stop requiring facilities to capture those emissions. *State Farm*, 463 U.S. at 43.

E. EPA Must Implement Additional Requirements to Ensure Compliance with PTE Requirements.

As explained above, total capture of EtO emissions is necessary to meet Clean Air Act requirements and is inextricable from numerical emission limits. To ensure that PTE is being properly maintained and effectuating total capture, EPA must not allow spatial or temporal averaging between pressure differential measurements, must require facilities to maintain sufficient negative pressure, must require assurance from facilities that their control devices are able to treat all captured fugitive emissions, and must require fenceline monitoring to verify full capture of EtO fugitive emissions. Commenters incorporate the arguments on these issues as described in Sahu Expert Report, Attachment A, at 5–7.

IV. EPA Unlawfully and Arbitrarily Proposes to Weaken the Section 112(d)(6) Technology Review. (Response to Questions 7 and 8)

In the 2024 Rule, EPA required a control efficiency of 99.9% at new aeration room vents ("ARVs") at facilities using at least 10 tpy of EtO because it "would achieve greater emission reductions than [99.6%], and … would be more cost-effective." 88 Fed. Reg. at 22841; *see* 89 Fed. Reg. 24125. EPA conducted cost-effectiveness calculations based on a model plant for new ARVs reflecting the average number of ARVs, EtO use, and operating hours as an existing facility, resulting in cost-effectiveness values of $2.2 million per ton at a 99.9% EtO reduction and $2.6 million per ton of reductions at a 99.6% EtO reduction. 88 Fed. Reg. at 22841 tbl. 31.

EPA concluded that 99.9% was achievable: The 99.9% emissions reduction was demonstrated in 50% of available performance tests. *Id.*

Now, EPA proposes to amend the standard for new ARVs at facilities using at least 10 tpy of EtO from 99.9% to 99.6% reduction on the basis that the 99.6% requirement is more cost-effective than the 99.9% option, contrary to what EPA had concluded in the 2024 Rule. Specifically, EPA contends that the agency's last rulemaking "did not consider that, under the 99.6 percent reduction option, which would result in the same standards for both new and existing ARVs, a new ARV could share and make use of ductwork, control devices, and other existing infrastructure for the ARVs already in place at the facility," and that, therefore, capital and annual costs for the 99.6% control option for new ARVs "would be much lower than the estimate in the 2024 Final Rule." 91 Fed. Reg. at 12716. In other words, EPA argues that the 2024 Rule overestimated the costs of requiring 99.6% reductions for new ARVs since it did not consider such costs of adding new ARVs at existing facilities, so at existing facilities, 99.6% would be more cost effective than 99.9% reductions. EPA also contends that because existing ARVs are subject to a 99.6% requirement, applying this lower standard to new ARVs also "has the benefit of allowing facilities to share infrastructure, streamline facility operations, and reduce costs" and "would also reduce the amount of auxiliary fuel burned in combustion-type control devices." *Id.* These considerations are not tied to the relevant statutory provisions, which instruct EPA to consider "developments in practices, processes, and control technologies," 42 U.S.C. § 7412(d)(6), and to set standards that achieve "the maximum degree of reduction in emissions of the hazardous air pollutants" that is "achievable," *id*. § 7412(d)(2).

Notably, EPA provides no cost calculation to support its conclusion that the 99.6% option "would be much lower than the estimate in the 2024 Final Rule." 91 Fed. Reg. at 12716. EPA does not rebut its conclusion that 99.9% is achievable. It does not argue that 99.6% is the maximum achievable control, and it does not address its prior findings that 99.9% would achieve over 51% more emissions reductions from new ARVs than the 99.6% option (0.053 tpy compared to 0.035 tpy of reductions). 88 Fed. Reg. at 22841 tbl. 31. The Proposed Rule does not address emissions reductions at all. Instead, EPA argues that it can rescind the maximum achievable technology to require a cheaper, less effective control, regardless of emissions reductions. EPA's proposal is unlawful and arbitrary because its contention that it may use alleged cost-effectiveness to avoid requiring achievable reductions is contrary to the Act. EPA has "relied on factors which Congress has not intended it to consider." *State Farm*, 463 U.S. at 43.

A. EPA May Not Use Alleged Cost-Effectiveness to Avoid Requiring Achievable Reductions.

Rescinding a requirement to use the maximum achievable control technology in order to allow cheaper, less effective controls violates the Clean Air Act's plain text mandate for EPA to "require the maximum degree of reduction in emissions" that EPA "determines is achievable." 42 U.S.C. § 7412(d)(2). EPA has no authority to set emission limits that are less stringent than that standard while conducting a review under section 112(d)(6) on the basis that the less stringent standard is less costly than what EPA had previously thought. Section 112(d)(6) does not excuse

EPA from requiring the maximum achievable control technology where such a revision is not as "cost-effective."

Section 112(d)(6) directs that: "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." *Id.* § 7412(d)(6) (emphasis added). This language obligates EPA to revise its section 112 standards as necessary to meet "the statutory demand of section 112(d)(2)," *LEAN*, 955 F.3d at 1097. Section 112(d)(2) standards "shall require the maximum degree of reduction in emissions of the [HAPs] subject to this section … that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable." 42 U.S.C. § 7412(d)(2) (emphasis added). *See West Virginia v. EPA*, 597 U.S. 697, 708 (2022) ("EPA must directly require all covered sources to reduce their emissions to a certain level. And it chooses that level by determining the 'maximum degree of reduction' it considers 'achievable' in practice by using the best existing technologies and methods." (emphasis added)). Thus, here, EPA must make any revisions necessary to ensure that its standards continue to secure "the maximum degree of reduction" of hazardous air pollutants that is "achievable" "taking into consideration" cost and including consideration of "a prohibition on such emissions, where achievable" for sources in the category. 42 U.S.C. § 7412(d)(2); *see LEAN*, 955 F.3d at 1090 (citing *Nat'l Lime Ass'n*, 233 F.3d at 634).

Section 112(d)(6) does not excuse EPA from revising section 112(d)(6) standards to where such a revision is not as "cost-effective" or cost reductive as another option. EPA's metric of "cost-effectiveness" to try to justify less stringent standards is inconsistent with the Act and with EPA's responsibility to protect public health. Courts have deferred to EPA's consideration of cost under section 112(d)(6) in certain instances, though it is not clearly a required or allowable factor for EPA to consider, as it does not appear anywhere in the provision. Under that precedent, the only lawful way to consider cost is to revise the standards "as necessary" to ensure compliance the "maximum achievable" test in section 112(d)(2) (which includes the explicit consideration of "cost"). Considering "cost" is plainly not equivalent to injecting a balancing test that EPA has created out of whole cloth, known as the "cost-effectiveness" approach. Under this approach, EPA's proposal turns the cost factor into a cost per ton of emissions reductions test. Under this analysis, EPA does not assess whether facilities can pay the cost of additional emission reduction, but asks only what the cost per ton of that reduction is, at a given point in time for the remaining sources (that have not yet achieved that level of control), and considers whether EPA regards that cost as reasonable, based on its current policy preferences. EPA has not attempted to explain how this approach is lawful or consistent with section 112(d)(6).

The D.C. Circuit has considered and ruled on what it means to set a standard that requires the level of reduction that is "achievable" "taking into account the cost of achieving such reduction." *Essex Chem. v. Ruckelshaus*, 486 F.2d 427, 433–34 (D.C. Cir. 1973) (quoting 42 U.S.C. § 1857c-6(a)(1) (1970)). "An achievable standard is one which is within the realm of the adequately demonstrated system's efficiency and which, while not at a level that is purely theoretical or experimental, need not necessarily be routinely achieved within the industry prior to its adoption." *Id.*; *see also Nat'l Lime Ass'n v. EPA*, 627 F.2d 416, 431 n. 46 (D.C. Cir. 1980)

(same). EPA has applied this familiar standard repeatedly over many years and must meet that test here.

EPA correctly applied that standard in 2024 when it concluded that the 99.9% reduction is the maximum achievable degree of reduction in emissions. 89 Fed. Reg. at 24128. The 99.9% standard achieves EtO emission reductions that are 51% greater than the 99.6% standard EPA now proposes. 88 Fed. Reg. at 22841 tbl. 31. And prior to the 2024 Rule, 50% of existing sources were already meeting a 99.9% control standard. 89 Fed. Reg. at 24128; 91 Fed. Reg. 12715–16; *see id.* at 12732 ("[N]ew ARVs (as defined in the 2024 Final Rule) that already started up are currently operating under the more stringent 99.9 percent reduction standard in the 2024 Final Rule.").

EPA does not contest that the 99.9% reduction would obviously reduce emissions more than the 99.6% reduction, nor does it contest that the 99.9% reduction is achievable. EPA does not contend or establish that the lower standard constitutes the maximum degree of reductions achievable. Nor could it, given that the existing standard achieves 51% more emission reductions than EPA's proposal and is already being achieved by 50% of existing facilities. Instead, the agency argues that it can rescind the maximum achievable control in order to reduce costs, reduce the amount of auxiliary fuel burned in combustion-type control devices, and to streamline facility operations. 91 Fed. Reg. at 12716. This fails to demonstrate that the 99.6% standard meets the mandate of sections 112(d)(6) and 112(d)(2). The fact that the weaker standard proposed would allow new ARVs at existing facilities to "share and make use of ductwork, control devices, and other existing infrastructure," *id.*, is not a factor EPA can lawfully rely on to revise standards under section 112(d)(6), *see Nat'l Lime Ass'n*, 627 F.2d at 431, n.46 ("capital costs of new technology" are less "intimately intertwined with 'achievability'" than other types of costs).

EPA attempts to evade the plain text of the Act and construct an atextual off-ramp, contending that EPA may rescind or weaken achievable requirements if EPA deems them cheaper or not as cost-effective. EPA's attempt to read "cost-effectiveness" as the statutory standard has no grounding in the text or context of section 112(d)(6) or 112(d)(2). EPA's reading cannot be understood as the best reading of the statute. *See Loper Bright*, 603 U.S. at 400.

By proposing to change the MACT standard based only on the ratio of cost to emissions reduction, EPA unlawfully fails to set standards requiring the "maximum ... emission reduction" that is "achievable." Instead, it looks only at how costly each additional ton of reduction is, unmoored from section 112(d)(6) and 112(d)(2). EPA has not attempted to explain how this approach is lawful or consistent with section 112(d)(6) or 112(d)(2).

The unlawfulness of EPA's interpretation is also evidenced by section 112(d)(2)'s mandate for EPA to require "a prohibition on such emissions, where achievable." 42 U.S.C. § 7412(d)(2). Even if the last of emissions reductions achievable by a facility is more costly than earlier reductions, Congress intended for EPA to require as much emissions reductions as possible, including eliminating emissions if achievable. This makes clear that Congress did not intend EPA to promulgate weaker standards than what is determined to be "achievable" just because the weaker standards cost less to implement per unit of pollution controlled.

EPA's cost-effectiveness approach is also contrary to the structure of section 112, which requires EPA to review technology-based standards on a regular basis "taking into account developments in practices, processes, and control technologies." 42 U.S.C. § 7412(d)(6) (emphasis added). The objective of section 112(d)(6) is to ensure that "EPA maintains source standards compliant with the law and on pace with emerging developments that create opportunities to do even better." *LEAN*, 955 F.3d at 1093 (citing 42 U.S.C. § 7412(d)(1)–(3) (emphasis added)). But EPA's approach eviscerates the upward-trending design of section 112(d)(6) and turns the statutory standard into a cost per ton of emissions reductions test that disfavors further reductions over time. It is generally likely that as the standards achieve emission reductions over time, it will become more expensive per ton of emissions remaining. EPA must apply the straightforward statutory test in section 112(d)(2) to assure revisions "as necessary" to comply with the Act, including by taking into account developments. Otherwise, technology reviews under section 112(d)(6) could potentially stall any further reductions over time or even backslide from the initial section 112(d)(2)–(3) standard-setting purely on the basis of cost, which is contrary to the Act.

Under EPA's approach, the *more* achievable reductions that some facilities have demonstrated over time, the *less* cost-effective EPA is likely to find those reductions to be for the rest of the source category. This approach not only contradicts the plain text of section 112(d)(6), but it also produces an absurd result contrary to the Act's purpose.

To the extent that EPA is allowed to consider cost effectiveness in determining what is "achievable" under section 112(d)(2) and in reviewing and revising standards under section 112(d)(6), those considerations must be rationally explained and "subordinate to" the Act's "overriding goal" of air quality. *Husqvarna AB v. EPA*, 254 F.3d 195, 200 (D.C. Cir. 2001). In *Husqvarna AB v. EPA*, the D.C. Circuit interpreted similar language in CAA section 213(a)(3), which requires the "greatest degree of emission reduction achievable … giving appropriate consideration to the cost of applying such technology." *Id.* The court upheld EPA's cost consideration only because it was a "secondary factor[]," explaining that "[t]he overriding goal of the section is air quality and the other listed considerations, while significant, are subordinate to that goal." *Id.*

Similarly, in *American Petroleum Institute v. EPA*, the D.C. Circuit analyzed CAA section 211(k)(1), which requires EPA to "require the greatest reduction in emissions of [VOCs and air toxics] … achievable …, taking into consideration the cost of achieving such emission reductions, any nonair-quality and other air-quality related health and environmental impacts." 52 F.3d 1113, 1115 (D.C. Cir. 1995) (quoting 42 U.S.C. § 7545(k)(1)). The court held that EPA exceeded its authority when it promulgated a fuel standard requiring a fuel composition in furtherance of "nonair-quality" impacts rather than the reduction of VOCs and air toxics. The court wrote:

> The overriding goal is air quality, and the other listed considerations are subordinate to that goal. Once EPA has taken the factors into consideration in the context of attaining the greatest reduction in VOCs and toxics emissions achievable, the statute does not

> authorize it to use these factors as a basis for imposing any additional restrictions … even if the additional restrictions would yield some benefit among the factors to be taken into consideration.

Id. at 1120. Here, cost considerations are "subordinate" to the section's overriding goal of "pollution prevention," and EPA cannot rely on cost as a basis for weakening ARV standards that it has deemed "achievable" even if such regulatory changes would yield some cost benefit. 42 U.S.C. § 7401(c). EPA's proposal unlawfully relies on subordinate considerations of cost and energy requirements to justify rescinding the current standard, contravening the Act. And EPA fails to "display awareness that it is changing position" and fails to "show … good reasons" for its new finding that the 99.9% standard is not cost effective, contrary to its previous position. *Fox*, 556 U.S. at 515 (emphasis omitted). *See* 89 Fed. Reg. at 24127 ("[T]he highest cost-effectiveness number that we found was $19,420,188/ton. We did not receive adverse comment on our finding that this is cost-effective.").

Finally, EPA's interpretation of its authority under section 112(d)(6) and the standard under 112(d)(2) cannot be the best reading because it would render the distinction between new and existing sources surplusage. Congress recognized that new sources are generally able to meet more stringent emission standards than existing sources. *See* 42 U.S.C. § 7412(d)(3) (emission standards for new sources cannot be less stringent than the emission control achieved in practice by the best controlled similar source); *id.* § 7412(a)(4) (defining "new source"). EPA's approach here cannot be squared with section 112(d)(3) because it would set a ceiling on emission standards for new sources at the level of emission standards for existing sources, since it relies on the purported cost benefits of imposing the "same standards for both new and existing ARVs." 91 Fed. Reg. at 12716. But if this were a legitimate application of the Act, EPA could—in fact, *must*, given the mandatory nature of section 112(d)(2)—limit standards for any new source to the corresponding standard for existing sources so long as the new source could theoretically cut costs by sharing infrastructure with an existing source at the same facility. EPA cannot adopt a reading that "de facto erases" a statutory distinction. *U.S. Telecom Ass'n. v. FBI*, 276 F.3d 620, 626 (D.C. Cir. 2002).

B. EPA Arbitrarily Considers the Wrong Factors in Proposing to Weaken Standards for New ARVs.

EPA's proposal is arbitrary and capricious for its failure to consider the appropriate factors and for its failure to supply a "reasoned analysis for the change" in ARV standards. *State Farm*, 463 U.S. at 30.

EPA's obligation under section 112(d)(2), to require the "maximum degree of reduction in emissions" achievable, constrains the agency's authority to voluntarily weaken established technology-based standards. 42 U.S.C. § 7412(d)(2). EPA must justify its proposal with new evidence showing that the 99.9% level is no longer the maximum degree of emissions reductions achievable, and with evidence that the 99.6% proposed standard is the maximum degree of emissions reductions achievable. EPA has done neither, instead justifying its proposal on the basis that it will reduce costs, will reduce the amount of auxiliary fuel burned in combustion-type control devices, and will streamline facility operations. 91 Fed. Reg. at 12716.

As explained in the previous section, EPA improperly prioritizes cost considerations over the statutory mandate to set standards at the maximum degree of reductions achievable. EPA's proposal thus "entirely fail[s] to consider an important aspect of the problem"—what the best technology available and maximum emissions reductions achievable for the source category. *State Farm*, 463 U.S. at 43; *see also West Virginia*, 597 U.S. at 708 (EPA must set standards "by determining the 'maximum degree of reduction' it considers 'achievable' in practice by using the best existing technologies and methods.") (quoting 42 U.S.C. § 7412(d)(3)). Requiring the maximum achievable emissions reductions is a "statutorily mandated factor, [which] by definition, is an important aspect of any issue before an administrative agency, as it is for Congress in the first instance to define the appropriate scope of an agency's mission." *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1216 (D.C. Cir. 2004). An agency's failure to engage with a statutory requirement, standing alone, is "sufficient to establish an arbitrary-and-capricious decision requiring vacatur of the rule." *Id.*

EPA also "relied on factors which Congress has not intended it to consider," *State Farm*, 463 U.S. at 43, when it justified its proposal on the grounds that it "has the benefit of allowing facilities to share infrastructure, streamline facility operations, and reduce costs," 91 Fed. Reg. at 12716. As explained above, the extent to which EPA can consider costs is limited to whether those costs render a certain standard "achievable," and any cost consideration must be secondary to the section's primary goal of reducing HAP emissions. EPA here has made no findings that the cost of the existing requirement renders it unachievable, nor has it "offered an explanation for its decision that runs counter to the evidence before the agency," which firmly establishes that 99.9% emissions reductions are achievable. *State Farm*, 463 U.S. at 43; *see, e.g.*, 89 Fed. Reg. at 24128 ("We disagree with the commenters' position that [the 99.9% standard is] not achievable," noting that 50% of existing sources are already meeting the 99.9% level, and "performance test data from ARVs … are both plentiful and representative of actual operating conditions.").

EPA's rationales reflect its failure to consider the statutory factor of maximum emissions reductions achievable. EPA contends that the prior rulemaking overestimated costs of requiring new ARVs at facilities using more than 10 tpy of EtO to meet the 99.6% standard, because EPA previously failed to consider that new ARVs installed at existing facilities will incur lower costs. But, even setting aside the contrary to law and arbitrary nature of EPA's rationale, EPA's rationale is internally inconsistent and unsupported and cannot sustain its proposal.

EPA provides no analysis identifying or comparing the costs of new ARVs at existing facilities meeting either the 99.6% or 99.9% standard, and it simply concludes that estimated costs from the 99.6% option considered "would be much lower than the estimate in the 2024 Final Rule." 91 Fed. Reg. at 12716. EPA implies that controlling emissions from new ARVs at existing facilities will be less costly than controlling emissions from new ARVs at new facilities, but EPA provides no cost calculation to support this implication. Nor could it. *See* Sahu Expert Report, Attachment A, at 11 (explaining why EPA "cannot make the generalization that costs will be much lower to add new ARVs at existing facilities" or even that "new ARVs at existing facilities will be sharing ductwork, control devices, or other infrastructure.").

To the extent that EPA's approach is legitimate , which it is not, it requires showing that the 99.6% standard is more cost effective than the 99.9% standard for new ARVs at existing facilities, not that the cost is less than what EPA estimated in 2024. Any cost savings from new ARVs sharing infrastructure and control devices with existing ARVs is applicable to both control options. And EPA cannot simply ignore the costs it calculated with respect to new ARVs at new facilities. 88 Fed. Reg. at 22841 tbl. 31. EPA bears the "affirmative burden" of "examining a key assumption" when "promulgating and explaining a non-arbitrary, non-capricious rule," and it has failed to carry that burden. *Hisp. Affs. Project*, 901 F.3d at 389 (quotations and alterations omitted).

Moreover, EPA relies heavily on the premise that requiring the same control efficiency for existing and new ARVs will enable cost savings via sharing of "ductwork, control devices, and other existing infrastructure." 91 Fed. Reg. at 12716. But EPA fails to consider the fact that EPA's current standard does not preclude new ARVs from sharing the same ductwork, control devices, and other existing infrastructure while achieving the current standard, since facilities can demonstrate compliance using combined emission streams. EPA also arbitrarily fails to consider the alternative of requiring both new and existing ARVs to meet the 99.9% standard, which would be reasonable in light of EPA's finding that 50% of ARVs are already meeting this heightened standard. Thus, EPA's reasons for weakening the standard also support retaining the existing standard or increasing the standard for existing ARVs, and EPA has failed to consider these "technological alternative[s] within the ambit of the [agency's] existing standard." *State Farm*, 462 U.S. at 51. EPA has also failed to "articulate a … rational connection between the facts found and the choice made." *Id.* at 43.

C. Setting Standards To Manufacturer Guaranteed Emissions Levels Would Be Unlawful and Arbitrary. (Response to Question 8)

EPA requests comment on whether, given its proposal to rescind the continuous emission monitoring system ("CEMS") requirement, "there is still a concern that would necessitate considering setting ARV standards based on manufacturer guaranteed levels." 91 Fed. Reg. at 12716. Setting ARV standards at manufacturer guarantee levels would be contrary to the Act and arbitrary.

When conducting a section 112(d)(6) review, EPA must revise standards "as necessary," 42 U.S.C. § 7412(d)(6), to bring them into compliance with the Clean Air Act, including section 112(d)(3)'s requirement to assure the "maximum degree of reduction in emissions that is deemed achievable," *id.* § 7412(d)(3). Section 112(d)(3) requires EPA to set the MACT floor for existing sources at the "average emission limitation achieved by the best performing 12 percent of the existing sources (for which the Administrator has emissions information)." *Id.* § 7412(d)(3)(A). For smaller source categories, the MACT floor must be set at the "average emission limitation achieved by the best performing 5 sources (for which the Administrator has or could reasonably obtain emissions information)." *Id.* § 7412(d)(3)(B). EPA must determine what has been "achieved" by the best existing sources as indicated by "emissions information," making clear that MACT levels must be based on empirical control levels that have been demonstrated in reality. Similarly, for new sources, EPA must set the MACT floor at the degree of reduction in

emissions "achieved in practice by the best controlled similar source," making clear the standards must be based on empirical evidence. *Id.* § 7412(d)(3).

Adopting manufacturer guarantees as emission limits would plainly not be based on the emission limits sources have achieved and would be contrary to the Act. It would also be arbitrary and capricious for EPA to consider a factor Congress did not intend it to consider. *See State Farm*, 463 U.S. at 43.

As explained above, EPA provides no evidence to undermine the conclusion that 99.9% is not the maximum emissions reductions achievable for new ARVs. Indeed, EPA accounted for manufacturer guarantees in setting emission standards under the 2024 Rule. 89 Fed. Reg. at 24104. Manufacturer guarantees alone inherently cannot represent the "maximum" degree of reductions achievable because they are biased toward lower control efficiencies; they serve as a floor above which the control device is guaranteed to perform. EPA provides no support for the premise that a manufacturer guarantee represents the maximum degree of reductions achievable, nor could it.

Moreover, EPA must set the standards based on what it has "determined" to be achievable—it cannot outsource that determination to control equipment manufacturers. 42 U.S.C. § 7412(d)(3). Outsourcing this determination would be both contrary to Congress's directive in section 112(d) and arbitrary. "An agency abdicates its role as a rational decision-maker if it does not exercise its own judgment, and instead cedes near-total deference to private parties' estimates." *Texas Off. Of Pub. Util. Couns.*, 265 F.3d at 328.

Finally, EPA must require the "maximum degree of reduction in emissions" achievable using "developments" in a variety of measures and methods, including process changes, substitution of material**s**, enclosure of systems, and work practice and operational standards. 42 U.S.C. §§ 7412(d)(2), (6). Congress required EPA to take a comprehensive approach in determining what constitutes the maximum emissions achievable—not only the destruction removal efficiency of a control device, and certainly not only the manufacturer guarantee on such a control device. Congress also required EPA to take a comprehensive approach in assessing and requiring "developments" in technologies under section 112(d)(6). If EPA based the MACT standard only on the manufacturer guarantee of a certain destruction or removal efficiency, then it would be unlawfully ignoring the other methods and measures Congress required it to consider when setting MACT standards under section 112(d)(2).

Setting standards at the manufacturer guarantee level is also arbitrary for several other reasons.

First, EPA fails to explain its change in course regarding how it sets efficiency levels. Historically, including in the Proposed Rule, EPA has set efficiency levels based on its own testing. In the 2024 Rule, EPA rejected a commenter's suggestion to set ARV standards at manufacturer guaranteed levels for two reasons: First, "there is no need to rely on manufacturer guaranteed emission levels because there are available performance test data for ARVs that are representative of actual operating conditions…. [P]erformance test data are representative of actual operating conditions." 89 Fed. Reg. at 24128. Second, "performance test data for ARVs

are plentiful…. [T]here are 47 facilities where EtO use is at least 10 tpy, 41 of which have ARVs. Of these 41 facilities, 32 (78 percent) have performance test data." *Id.* Thus, "[b]ecause the performance test data from ARVs at these facilities are both plentiful and representative of actual operating conditions, there is no need to rely on a manufacturer guaranteed emission reduction level in this instance." *Id.* If EPA were to change its policy or reasoning from this previous position on manufacturer guaranteed levels and its practice on how it sets efficiency levels, it must "supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored." *Lone Mountain Processing v. Sec'y of Labor*, 709 F.3d 1161, 1164 (D.C. Cir. 2013). EPA fails to do so here.

Second, EPA fails to explain why industry concerns about CEMS would support setting ARV standards at manufacturer guaranteed levels. EPA states that industry comments during the last rulemaking regarding the use of manufacturer guarantees for ARVs "were focused on the requirement to use CEMS for demonstrating compliance." 91 Fed. Reg. at 12716. But EPA does not identify which comments it was specifically referring to, or otherwise explain the relationship between CEMS, a compliance verification method, and the stringency of the emission control limits themselves. EPA must "articulate … a rational connection between the facts found and the choice made," *State Farm*, 463 U.S. at 43, and its action must be "reasonable and reasonably explained," *Prometheus Radio*, 592 U.S. at 423. EPA's proposal fails to explain why requiring or implementing CEMS would justify setting standards at manufacturer guarantee levels.

Third, EPA does not support or explain its assertion that it "is significantly concerned about setting standards more stringent than manufacturer certification." 91 Fed. Reg. at 12716. EPA cannot simply point to concerns raised by regulated entities and assume their validity without demonstrating a reasonable analysis of the merits and the record evidence. EPA's "significant[] concern[]" is contradicted by the agency's own admission that it "does not have data on the manufacturer's guaranteed levels for reducing ARV emissions." *Id.* Without information that manufacturer guarantees are less than EPA's emission limits—which are based on emission reductions demonstrated in practice—EPA fails to explain why it would need to even consider setting standards based on manufacturer guaranteed levels. *See Fox*, 55 U.S. at 515–16 (When an agency's "new policy rests upon factual findings that contradict those which underlay its prior policy," it must provide a detailed explanation for its change.).

Fourth, commercial sterilization facilities use multiple methods of destruction for EtO control, and EPA provides no explanation for how it would determine which manufacturer guarantee would apply. *See* 2023 TSD at 86–91. And EPA does not explain how it would use manufacturer guarantee levels to set only ARV limits, when facilities can demonstrate compliance using combined emission streams that must meet the most stringent limit among the component streams.

Finally, if EPA bases any conclusions in the final rule on information it receives during the public comment process on manufacturer guaranteed levels, it must allow the public an additional opportunity to comment on that new information. *See infra* Section X.

D. EPA Must Consider Additional Developments Under Section 112(d)(6).

By proposing changes to PTE and ARV standards that were promulgated under 112(d)(6) authority, EPA has reopened its technology review under (d)(6) and has an obligation to consider available information to determine whether the technological developments evident from the reported facility emissions and permitting records demonstrate that revised standards are necessary. *See, e.g.*, *Public Emps. For Envt'l Responsibility v. EPA*, 77 F.4th 899, 914 (D.C. Cir. 2023) (reopener when agency explicitly asks for public feedback) (citing *Appalachian Power Co. v. EPA*, 251 F.3d 1026 (2001)). In the 2024 112(d)(6) review, EPA identified and analyzed only emissions reductions as "developments." TSD at 37–38. EPA must consider and require fenceline monitoring, CEMS, PTE, and alternatives to EtO as "developments" under section 112(d)(6). Failure to consider these developments would be unlawful under section 112(d)(6) and arbitrary because it would be contrary to EPA's existing regulatory framework for identifying and analyzing developments. *See Encino Motorcars v. Navarro*, 579 U.S. 211, 222 (2016).

EPA uses a two-step regulatory framework for conducting technology reviews. Because EPA recommitted to its use here, it remains "on the books." *Fox*, 556 U.S. at 515. First, EPA "identif[ies]" developments. 88 Fed. Reg. at 22799. Fenceline monitoring, CEMS, and PTE all meet EPA's longstanding definition of "developments." Specifically, they are "work practice[s] or operational procedure[s] that [were] not identified or considered during development of the original MACT and GACT standards." *Id.* at 22800. EPA has identified and required fenceline monitoring, CEMS, and PTE as developments under section 112(d)(6) in many rulemakings, including specifically for controlling fugitive emissions. *See, e.g.*, Petroleum Refinery Rule, 80 Fed. Reg. 75178, 75182, 75191–194 (Dec. 1, 2015) (requiring fenceline monitoring); HON Rule, 89 Fed. Reg. 42932, 42949 (May 16, 2024) (requiring fenceline monitoring); MATS Rule, 89 Fed. Reg. 38508, 38521 (May 7, 2024) (requiring CEMS); Secondary Lead Rule, 77 Fed. Reg. 556, 564 (Jan. 5, 2012) (requiring CEMS and PTE). EPA's failure to do so here is arbitrary and unlawful.

Second, EPA "analyze[s] [the development's] technical feasibility, estimated costs, energy implications, and non-air environmental impacts …. [and] the emission reductions." 88 Fed. Reg. at 22799–800. EPA already analyzed many of these factors for CEMS and PTE in the 2024 section 112(f)(2) review. *See, e.g.*, TSD at 43–44, 96–98 (estimating costs and emission reductions for CEMS and PTE). The apparent proliferation of these technologies at commercial sterilization facilities is evidence that these developments are technically feasible. As detailed above, a majority of commercial sterilization facilities are already capable of meeting—or even exceeding—the 2024 (f)(2) standards at their SCVs, ARVs, and CEVs with the practices and technologies they already have. *See* 89 Fed. Reg. at 24138. And since that information was collected for the 2024 Rule, even more facilities have installed technologies and made upgrades that will allow them to meet the (f)(2) standards. Additionally, as explained above, many facilities already deploy fenceline monitoring, CEMS, and PTE, including those subject to SCAQMD Rule 1405. *See* 89 Fed. Reg. at 24138. And since that information was collected for the 2024 Rule, even more facilities have installed vent controls, PTE, CEMS, and fenceline monitoring. This information is already in EPA's possession or is readily obtainable from public records, such as the permits discussed in Section VI.B, without a significant delay or resource

burden on the agency. Thus, EPA must require these developments under section 112(d)(6). Failure to do so is unlawful and arbitrary.

As for alternatives to EtO, EPA's failure to consider feasible, less harmful, and federally approved alternatives to EtO is arbitrary and capricious. While EtO has been the medical device industry's preferred sterilization method for decades, there are safer, recognized alternatives that offer similarly effective sterilization with significantly fewer health risks.[176] EPA is aware of these alternatives but failed to adequately analyze them. TSD at 92.

For example, in January 2024, FDA recognized vaporized hydrogen peroxide as an Established Category A sterilization process for medical devices, meaning it has a "long history of safe and effective use as demonstrated through multiple sources of information such as ample literature, clearances of 510(k)s or approvals of premarket approval (PMA) applications, and satisfactory QS inspections."[177] FDA announced that this recognition advances the agency's approach to reducing the use of EtO where possible. Vaporized hydrogen peroxide is effective on materials and devices that cannot tolerate high temperatures and humidity and has been shown to be effective on over 95% of medical devices and materials tested.[178]

Importantly, in the last two decades, new, low-temperature modalities have been developed to accommodate instruments made of synthetic materials or that contain electrical components. These effective, low-temperature modalities include sterilization via chlorine dioxide, which was approved by the FDA for contract sterilization of medical devices in 2021, and vaporized hydrogen peroxide, which the FDA recognized as a "Category A" established method of sterilization for medical devices in 2024.[179] The alternative which appears to be most desirable from a health perspective is hydrogen peroxide, which is converted to a plasma and can be employed as a sterilant on all materials excluding cellulose, linens, and liquids. Rutala et al. at 118. Hydrogen peroxide gas plasma sterilization is safe for the environment and leaves no toxic residuals (water and oxygen) with a short cycle time. *Id.* For sterilizing materials made entirely of metal and glass, steam has been—and continues to be—an effective, harmless method. *Id.*

Sterilization can be done safely without causing carcinogenic emissions, and it is critical that we move towards safer alternatives, including those that the FDA has already approved for

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[176] *See*, *e.g.*, *Comparison of Alternative Sterilization Chemicals to Ethylene Oxide (EtO)*, Ass'n of Surgical Technologists (May 2025), https://www.ast.org/ceonline/articles/500/500.pdf.
[177] *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile Guidance for Industry and Food and Drug Administration Staff* 3, U.S. FDA (Jan. 2024), https://www.fda.gov/media/74445/download.
[178] *See* William Rutala et al., U.S. CDC, *Guideline for Disinfection and Sterilization in Healthcare Facilities* 65 (last updated June 2024), https://www.cdc.gov/infection-control/media/pdfs/guideline-disinfection-h.pdf; *FDA Facilitates Broader Adoption of Vaporized Hydrogen Peroxide for Medical Device Sterilization*, U.S. FDA (Jan. 8, 2024), https://www.fda.gov/news-events/press-announcements/fda-facilitates-broader-adoption-vaporized-hydrogen-peroxide-medical-device-sterilization.
[179] *See Comparison of Alternative Sterilization Chemicals to Ethylene Oxide (EtO)*, Ass'n of Surgical Technologists (May 2025), https://www.ast.org/ceonline/articles/500/500.pdf.

industry use. EPA's failure to identify and analyze these ample, viable, safe, established, industry- and government-approved alternatives is arbitrary and capricious.

In the alternative, even if EPA's incorrect interpretation of section 112(d)(6) were correct—that the provision allows EPA to consider health risks—it would be arbitrary for the agency not to consider additional developments in the (d)(6) review, in light of the high health risks this source category presents. *See* MATS Repeal Rule, 91 Fed. Reg. at 9090. Many commercial sterilizers present a greatly elevated cancer risk: EPA identified at least 23 facilities that present elevated cancer risk above 100-in-1 million and concluded that the 112(f)(2) standards were necessary to provide an ample margin of safety for millions of people. 2024 RRA at 6. Under EPA's (incorrect) reading of section 112(d)(6), in which health risks is relevant, the agency must consider the costs of its action—here, in lives and health sacrificed to cancer—and consider lawful alternatives that avoid those costs by retaining the stringency of the 2024 standards under its (d)(6) authority. That is, even under EPA's (incorrect) reading of section 112(d)(6), EPA should conclude that technological developments—illustrated by the many facilities that are already capable of complying with more stringent standards—make it "necessary" to revise standards (or retain the 2024 standards revised under (f)(2)).

V. EPA Must Maintain the Requirement to Demonstrate Compliance Through the Use of Continuous Emission Monitoring Systems. (Response to Questions 9, 10, 17)

Prior to 2024, EPA required facilities to demonstrate compliance through an initial performance test and continuous parametric monitoring, with additional work practice standards for catalytic oxidizers. 88 Fed. Reg. at 22843. Also prior to 2024, the NESHAP allowed facilities to use CEMS to measure EtO from the exhaust of catalytic or thermal oxidation controls for the purpose of parametric monitoring of those control options. *Id.* at 22846. In the 2024 Rule, EPA finalized a requirement for facilities using more than 100 lb/year of EtO to demonstrate compliance using EtO CEMS. 89 Fed. Reg. at 24101. This requirement applies to all facilities EPA identified during the last rulemaking. *See* 2023 TSD at App. A (listing facilities and EtO usage). Under the 2024 Rule, facilities using less than 100 lb/year of EtO may demonstrate compliance using CEMS or by conducting parametric monitoring together with performance testing. 89 Fed. Reg. at 24101.

Now, EPA proposes to withdraw the EtO CEMS compliance demonstration requirement and allow facilities to choose between demonstrating compliance using EtO CEMS or parametric monitoring with performance testing. Facilities should not have the option of using either parametric monitoring and performance testing or CEMS to demonstrate initial and continuous compliance with the Commercial Sterilization Facilities NESHAP. Parametric monitoring provides significantly less assurance that emissions are accurately measured. For the reasons below, EPA's proposal is unlawful under the Clean Air Act and arbitrary and capricious.

A. EPA's Justification for Repealing CEMS is Unlawful, Arbitrary, and Fails to Support EPA's Proposal.

Although EPA has "broad discretion in selecting a monitoring regime that ensures compliance," it must "reasonably articulate the basis for its decision." *U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 655 (D.C. Cir. 2016) (cleaned up). EPA fails to carry that burden. Its sole justification for proposing to repeal the EtO CEMS requirement is that it "was based on the results of an unauthorized second residual risk assessment and risk-based standards-setting for this source category." 91 Fed. Reg. at 12716. That justification is unlawful, incorrect, and arbitrary for several reasons, and it fails to meet the Clean Air Act's requirement for reasoned decisionmaking.

EPA's position that the 2024 residual risk review was unlawful is legally incorrect and thus cannot support its proposed rescission of the EtO CEMS requirement. "An agency decision cannot be sustained … where it is based not on the agency's own judgment but on an erroneous view of the law." *Prill*, 755 F.2d at 947. *See supra* Sections I and II.

Second, EPA's characterization of the CEMS requirement as being "derived from" and based on the second residual risk review is inaccurate. 91 Fed. Reg. at 12716. The fact that the lowest-risk facilities were exempt from the CEMS requirement does not mean that the decision to exempt them was based on the second residual risk review. The 2024 Rule required all facilities using more than 100 lbs/year to use CEMS to "demonstrate[] compliance" under section 114 with all emission standards applicable to those facilities, not just standards derived from the second residual risk review. 89 Fed. Reg. at 24132.

And EPA's mischaracterization of the EtO CEMS requirement as being based on the second residual risk review ignores the non-risk reason EPA provided in 2024 for exempting the smallest facilities from implementing EtO CEMS, which is that these, small facilities "tend to have relatively simple control systems," so there is less concern about the complexities and inefficiencies associated with parametric monitoring for multiple control devices. *Id.*

Further, EPA's rationale that CEMS must be repealed for its association with the second residual risk review does not explain why EPA is also proposing to repeal the EtO CEMS requirement as it applies to demonstrating compliance with section 112(d) standards.

Finally, even assuming arguendo that the CEMS exception for the smallest facilities was derived from EPA's second residual risk review, this supports an argument that EPA must require EtO CEMS for *all* facilities, regardless of risk. Such a requirement would be agnostic to risk and unconnected to a risk review that EPA contends was unlawful. EPA makes no indication that it considered this alternative that flows from its rationale, which is better supported by the record evidence on the advantages of CEMS than EPA's proposal to completely rescind the CEMS requirement.

B. EPA Fails to Explain its Reversal From its Previous Findings on the Inadequacy of Parametric Monitoring and the Need for CEMS.

EPA's proposal to rescind CEMS and allow parametric monitoring represents a change in position on the weaknesses of parametric monitoring and the superiority of CEMS as a method of assuring compliance. *See Fox*, 556 U.S. at 515 ("An agency may not … depart from a prior policy sub silentio or simply disregard rules that are still on the books."); *Encino Motorcars*, 579 U.S. at 222 ("an unexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change from agency practice" (citations omitted)). EPA must provide a "more detailed justification" when "its new policy rests upon factual findings that contradict those which underlay its prior policy." *Fox*, 556 U.S. at 515. Here, EPA's "new policy" is "contradict[ed]" by its previous findings that parametric monitoring is insufficient to assure compliance and the superiority and feasibility of CEMS. *Id.* By failing to address the inadequacies of parametric monitoring, EPA "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43.

As EPA explained in the 2024 Rule and before the D.C. Circuit, CEMS provides several key advantages over EPA's proposed alternative of parametric monitoring. EPA Br. at 67–75, *Cal. Cmtys. Against Toxics v. EPA*, Nos. 24-1178/1180 (consolidated) (D.C. Cir. Feb. 24, 2025), Doc. #2102382. EPA required CEMS over parametric monitoring in the 2024 Rule because it reflects EtO emissions more accurately, simplifies monitoring systems, leads to faster detection of excess emissions, facilitates compliance demonstration, and is technologically and economically feasible. 89 Fed. Reg. at 24132. The Proposed Rule acknowledges none of this.

EPA's own guidance states that CEMS is the most accurate emissions estimation method available.[180] Even before EPA finalized the CEMS requirement for most facilities, EPA maintained that the "preferred approach for determining compliance with the [proposed NESHAP amendments] relies on use of continuous emission rate monitoring systems (CERMS), continuous emission monitoring systems (CEMS), and use of permanent total enclosures (PTEs) to aggregate separate exhaust flows and then send them to one series of control devices." EPA, *Memorandum: Approaches for Determining Compliance with Proposed Subpart O, Ethylene Oxide (EtO) Emission Standards for Sterilization Facilities*, EPA-HQ-OAR-2019-0178-0476 at 1 (March 20, 2023). Unlike parametric monitoring, CEMS can detect very small fluctuations in EtO and minimum detection levels down to the low ppt range, meaning that CEMS can be used to verify that facilities are complying with permitted emission rates and to capture short-term spikes in EtO emissions, particularly during start-up, shutdown, or malfunction events. *See* Comments of Environmental and Community Groups on 2023 Proposed Rule, EPA-HQ-OAR-2019-0178-0634, at 19; 89 Fed. Reg. at 24132; 2023 TSD at 43–44.

On the other hand, "parametric monitoring, as it exists now, or with EPA's suggested changes, does not provide an accurate indication of actual control efficiencies of the control devices." Sahu Expert Report, Attachment A, at 8. The surrogates that parametric monitors measure do not accurately indicate actual control efficiencies. *See id.* at 7–9 (explaining why

[180] EPA, *Best Practices for Estimating Emissions Using Emissions Factors for Clean Air Act Permitting* (Nov. 2021), https://www.epa.gov/system/files/documents/2022-02/emissions-factors-best-practices_0.pdf (attached).

temperature, tank levels, glycol levels, and L/G levels are insufficient parameters and easily manipulated).

Additionally, EPA fails to acknowledge that performance testing for parametric monitoring does not determine if standards are met at all times or even at certain times because performance tests are not conducted under representative operating conditions. "It is no secret that operators take extra steps (such as conducting maintenance or 'tuning' equipment or even replacing components such as catalysts, etc.) prior to testing in order to obtain the highest testing efficiency." Sahu Expert Report, Attachment A, at 9. In contrast, EtO CEMS allows facilities to continuously monitor emissions, which they can then average over a 30-day period to show compliance with the standards, and to ensure that emission reductions are happening continuously at more than just one moment in time.

Because CEMS is continuous and directly measures emissions, unlike parametric monitoring, it can also help facility operators and employees more rapidly address inefficient or ineffective pollution control equipment and subsequently reduce public and worker exposure to hazardous levels of EtO.

EPA's proposal also ignores the fact that CEMS is "the only way to ensure continuous compliance" at facilities that are not conducive to parametric monitoring, such as those that rely on gas-solid reactors (i.e., dry bed scrubbers) to control emissions. 88 Fed. Reg. 22845. EPA explained in the 2023 proposal that these controls are "commonly used at commercial sterilization facilities" but the operating parameters previously used to assure compliance, including pressure drop and temperature across the dry bed packing, "are not viable parameters to monitor as indicators of EtO removal because neither indicate that the reaction is occurring on the media bed nor the remaining activity of the dry bed media." *Id.* EPA proposed to require EtO CEMS for all facilities that use gas-solid reactors even before it finalized the rule requiring CEMS for all facilities using more than 100 lb/year of EtO. *Id.* EPA completely ignores these facts in the proposal.

EPA also fails to acknowledge that CEMS is a simpler monitoring system than parametric monitoring, which must be applied separately to each pollution control device and "can lead to multiple, simultaneous parameter collection and processing, increasing system complexity and increasing the time necessary for diagnosis and correction of control device or process problems." 89 Fed. Reg. at 24132.

EPA does not address its finding in the 2024 Rule that CEMS is technologically feasible and "readily available." 89 Fed. Reg. at 24132. Several states and localities have successfully implemented EtO CEMS requirements through rules or permits. [181] EPA itself has supported the inclusion of CEMS in state permits. In comments on the draft permit for the Becton Dickinson facility proposed in Tucson, Arizona, the EPA Region 9 Office stated, "[g]iven the proposed facility's location near workers and residences, we strongly encourage the [county] to require

[181] *See*, *e.g.*, So. Coast Air Qual. Mgmt. Dist., Rule 1405 (amended Dec. 1, 2023); Illinois Public Act 101-002, , Georgia Environmental Protection Division Rule 391-3-1-.02(a)(b)(29), Permit No. 7389-067-0093-S-06-0 for Sterigenics (Atlanta, GA) (issued Jan. 6, 2022), condition 5.6; Permit No. 0544-AR-12 for Baxter (Mountain Home, AR) (issued Mar. 9, 2015) at 21.

CEMS in any final Class II air permit for the facility as the compliance demonstration method."[182]

EPA does not address its finding in the 2024 Rule that CEMS is economically feasible. 89 Fed. Reg. at 24132. EPA estimated that the total capital investment for the source category associated with monitoring and testing would be $48.1 million, with total annual costs of $19.4 million (inclusive of performance testing costs). 89 Fed. Reg. at 24094 tbl. 2; *see* 2024 Rule EPA Response to Comments at 279 ("EPA disagrees with the commenter' [sic] suggestions that the monitoring and reporting requirements are burdensome."). These costs are extremely modest compared to the annual revenues of parent companies in the source category. *See* 2024 Rule RIA, EPA-HQ-OAR-2019-0178-1557, at tbl. 5-3. EPA in 2023 estimated the capital cost for an EtO CEMS instrument to be $75,000, and noted that CEMS with a multi-port manifold can enable measurement in multiple areas with one measurement. 2023 TSD at 44. Facilities can also reduce costs by demonstrating compliance using combined emission streams, which requires fewer CEMS instruments. To be sure, EPA has no duty to demonstrate that the benefits of CEMS outweigh the costs. *See Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1039 (D.C. Cir. 2012) (a statutory obligation to consider economic consequences "does not mean that the regulation's benefits must outweigh its costs").

Instead of addressing any of these fatal flaws in parametric monitoring, EPA points to and mischaracterizes its statement in the 2024 Rule preamble that "in the majority of instances, parametric monitoring is used to good effect as an ongoing means of ensuring that the control devices continue to get necessary emission reductions." 91 Fed. Reg. at 12716 (quoting 89 Fed. Reg. at 24101). But EPA arbitrarily ignores the sentence that immediately follows: "[G]iven the nature of EtO, in which small amounts can have large risk impacts, parametric monitoring alone will not be sensitive enough to detect very small fluctuations in EtO concentration." 89 Fed. Reg. at 24101.

EPA's proposal arbitrarily fails to address the weaknesses of parametric monitoring and benefits of CEMS, which is "an important aspect of the problem," *see State Farm*, 463 U.S. at 43. EPA's proposal is also arbitrary for failing to provide a "more detailed justification" for EPA's reversal on its previous findings that CEMS is superior to parametric monitoring for measuring EtO emissions and ensuring compliance. *See Fox*, 556 U.S. at 515.

C. EPA Should Require Equidistant Measurement Points in CEMS.

Regarding question 17, modifying EPA 40 C.F.R. § 63.363(b)(1) to indicate that CEMS measurement points do not need to be equidistant "would allow measurements to be dominated by one measurement, reducing accuracy." Sahu Expert Report, Attachment A, at 10. EPA does

[182] Pima Cnty. Dep't Env't Qual., *Response to Public Comments: Air Quality Permit for Becton, Dickinson, and Company*, 3 (May 11, 2022), https://content.civicplus.com/api/assets/1e7cb039-07c0-4383-a0ef-581dc52a48c2?cache=1800 (attached). The Pima County Department of Environmental Quality ultimately included CEMS in the permit. *Id.* at 4. The facility has since switched from EtO sterilization to electron beam sterilization. Memo from Jan Lesher to Pima County Board of Supervisors, Re: Becton, Dickinson and Company Air Quality Permit Update (Mar. 22, 2023).

not support this proposed change with any rationale and fails to acknowledge the impact it would have on accuracy, making this proposal arbitrary and capricious.

D. EPA's Proposed Operating Parameter Limit Provisions Are Unlawful and Arbitrary and Capricious.

In addition to proposing to allow a surrogate-based compliance demonstration through parametric monitoring, EPA proposes problematic standards on recalculating operating parameter limits ("OPLs"). EPA proposes to rewrite Section 63.363(a) as follows: "If you have a deviation from the established OPL and corrective actions do not confirm the established OPL, a performance test must occur to establish a new OPL within 150 days." EPA, *Memorandum: Redline/Strikeout for proposed changes to the Commercial Sterilization Facilities 2024 Final Rule*, EPA-HQ-OAR-2019-0178-1614 at 70 (March 10, 2026) ("Redline Memo"). EPA also proposes: "The OPL must be calculated after every performance test and monitoring parameters reset. These OPL and monitoring parameters must be updated and included in the quarterly compliance reports according to § 63.366(b) and (c)." *Id.* at 75.

To the extent that EPA's proposal requires facilities to recalculate OPLs every quarter, EPA's proposal could create an unlawful, structural loophole in compliance. The core theory of parametric monitoring assumes OPLs represent the operating conditions necessary to achieve demonstrated emission control performance. Thus, exceeding the OPL must be a violation of the standard. To commenters knowledge, no other NESHAP mandates that OPLs be automatically recalculated and reset quarterly. Rather, in other NESHAPs, OPLs are typically established during initial performance testing and apply continuously unless a deviation occurs that triggers corrective action; OPLs may be reset under limited circumstances only. *See, e.g.*, Industrial Boilers NESHAP, 40 C.F.R. § 63.7540; Portland Cement NESHAP, *id.* § 63.1350. Thus, OPLs function as regulatory boundary derived from the best performers and are fixed in place, subject to strict conditions for recalculating. EPA must ensure that when facilities calculate and recalculate OPLs, they accurately reflect emission reductions requirements. Without that, required quarterly recalculations of OPLs creates a structural loophole to compliance. Recalculations could allow facilities to realign OPLs with their actual or desired operation, rather than with emissions standards; allowing facilities to move the goalposts cannot "provide a reasonable assurance of compliance with emissions standards." *NRDC v. EPA*, 194 F.3d 130, 136 (D.C. Circ. 1999).

Additionally, EPA must require facilities to comply with emissions standards during the 150-day period for recalculation of a new OPL; otherwise, this period functions as an unlawful temporary exemption from compliance. Emission standards must be complied with continuously. *See* 42 U.S.C. § 7602(k); *Sierra Club*, 551 F.3d at 1027–28; *U.S. Sugar Corp.*, 830 F.3d at 607–08. The proposal does not make clear how compliance with the underlying standard is enforceable during that time. Additionally, the 150-day window is substantially longer than comparable provisions in other NESHAPs, which typically require performance testing within 30–45 days of a deviation. *See, e.g.*, Boilers NESHAP, 40 C.F.R. § 63.7540(a)(18)(ii)(C) (requiring compliance test to verify or re-establish CPMS within 30 days of deviation); CISWI Rules, *id.* § 60.2145 (30 days for test and 45 days for OPL); Gold Mine Ore NESHAP, *id.* at § 63.11647 (40 days for test and OPL). EPA fails to "examine the relevant data and articulate a

satisfactory explanation for its action"—specifically why allowing facilities 150 days to recalculate OPLs is necessary, or how the agency would determine compliance during the 150-day period, given that its own prior practice across multiple source categories has converged on 30 days as the appropriate window. *State Farm*, 463 U.S. at 43.

E. The Liquid to Gas Ratio is an Inaccurate Parameter. (Response to Question 10)

EPA proposes using a liquid-to-gas ratio as a parameter, but this is "an insufficient parameter and easily abused." Sahu Expert Report, Attachment A, at 8. Specifically:

> L/G ratio is an insufficient parameter and easily abused. EPA in its current proposal has suggested that glycol levels and tank levels be eliminated and that a new parameter the liquid to gas ratio (L/G) be tracked instead. While this may be a conceptually better idea, it too is insufficient because the L/G ratio does not ensure that the liquid composition (i.e., its total glycol content) is proper for EtO removal. For example, for the same L/G ratio, a fresh liquid with little to no glycol in it will provide much better control efficiency than a recirculated liquid, with higher glycol content (and therefore more chemical back-pressure). Just requiring L/G as a parameter without regard to the glycol content is therefore insufficient. In fact it will lead to abuse. Nothing prevents an operator from doing a compliance test with fresh liquid and thereby establishing the "compliant" L/G ratio parameter – which will not ensure that this same L/G ratio with high glycol levels is adequate at all times, including as the liquid's glycol content deteriorates.

Id. If EPA persists in allowing the use of surrogates, it must address technical deficiencies explained in the attached expert report. *See* Sahu Report, Attachment A, at 7–9. Otherwise, using the L/G ratio as a parameter does not "provide a reasonable assurance of compliance with emissions standards." *NRDC*, 194 F.3d at 136.

F. EPA's Proposal Arbitrarily Fails to Consider Alternatives it Declined to Make in 2024 Based on the CEMS or PTE Requirements, Including Fenceline Monitoring.

In the 2024 Rule, EPA declined several policy options on the basis that the agency was finalizing CEMS and PTE requirements. For example, it walked back its proposal to require a 24-hour test period for facilities using more than 10 tpy EtO partly on the basis that it was finalizing the CEMS requirement. 89 Fed. Reg. 24133. EPA also walked back its proposal for facilities to obtain Title V permits partly on the basis that the 2024 Rule "will ensure transparency around the emissions from these facilities by requiring that EtO CEMS data be reported on a quarterly basis, and this data will be made available to the public." *Id.* at 24136.

In 2023, EPA's proposed rule did not require fenceline monitoring on the basis that PTE in accordance with Method 204 "would effectively and continuously ensure [] previously

uncontrolled [room air] emissions are captured and routed to exhaust points that are then subject to removal or emission rate standards." 89 Fed. Reg. at 24131.[183] EPA finalized its decision to not require fenceline monitoring for the source category after concluding that PTE in accordance with Method 204 "has been demonstrated to be feasible for commercial sterilization facilities," and that PTE in combination with the CEMS requirement obviate the need for fenceline monitoring. *Id.* at 24132. EPA noted that "room air releases at commercial sterilization facilities are typically at ground-level and consist of uncontrolled building emissions through doorways, loading points, and ventilation exhausts, all of which can be captured while inside the building and routed through a vent to a control device." *Id.* at 24131. And EPA explained in its 2023 proposal that fenceline monitoring would not "identify a compliance issue that has not already been detected through the continuous monitoring requirements." 88 Fed. Reg. at 22848.

Although EPA is not required to consider every conceivable alternative, it "is required to consider responsible alternatives to its chosen policy and to give a reasoned explanation for its rejection of such alternatives" so long as they are "significant and viable." *Am. Radio Relay League v. FCC*, 524 F.3d 227, 242 (D.C. Cir. 2008) (cleaned up). Now that EPA is proposing to rescind the PTE and CEMS requirements, EPA's proposal is arbitrary for failing to consider the "responsible alternative" of fenceline monitoring to support verification of continuous compliance. Given that EPA in 2024 justified its decision to not require fenceline monitoring by relying on its promulgation of PTE and CEMS requirements, fenceline monitoring undoubtedly constitutes a "technological alternative within the ambit of the [agency's] existing standard." *See State Farm*, 463 U.S. at 51. Fenceline monitoring is "significant," as evidenced by EPA's solicitation of comment during the 2023 rulemaking. It is also "viable" as evidenced by EPA's own conduct of fenceline or ambient air monitoring around sterilizer facilities,[184] EPA's actions to require or propose fenceline monitoring it for other source categories,[185] and numerous ambient air monitoring studies of commercial sterilizers' EtO emissions conducted by other public and private entities.[186] EPA's failure to consider fenceline or ambient air monitoring is arbitrary and capricious.

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[183] *See also* 88 Fed. Reg. at 22847 ("Moreover, the proposed PTE design criteria, proposed room air emission standards, and associated parametric monitoring discussed in section III.B.8 will effectively and continuously ensure these previously uncontrolled emissions are captured and routed to exhaust points that are subject to removal or emission rate standards.").

[184] *See*, *e.g.*, EPA Region 2, Sampling the Air for Ethylene Oxide Near the Steri-Tech, Inc. Facility in Salinas, PR (Jan. 25, 2023) (attached); EPA Region 6, EPA's Work in Laredo (May 2024) (attached).

[185] *See* 89 Fed. Reg. 42832 (New Source Performance Standards and NESHAP amendments for chemical manufacturing facilities requiring fenceline monitoring, including for EtO).

[186] Aecom, Ethylene Oxide Monitoring in Laredo, Texas (Feb. 16, 2026) (attached); South Coast AQMD, Parter Emissions Investigation in Carson, https://www.aqmd.gov/home/news-events/community-investigations/parter (last visited May 14, 2026) (screenprint attached); South Coast AQMD, Sterigenics Emissions Investigation in Vernon, https://www.aqmd.gov/home/news-events/community-investigations/sterigenics (last visited May 14, 2026) (screenprint attached); Sterigenics Emissions Investigation in Ontario, https://www.aqmd.gov/home/news-events/community-investigations/sterigenics-ontario (last visited May 14, 2026) (screenprint attached).

G. EPA Should Clarify That all Monitoring Data Will be Made Public.

The 2024 Rule requires facilities to submit key compliance documents to the Compliance and Emissions Data Reporting Interface ("CEDRI"), including initial compliance reports, performance test results, and quarterly CEMS data. 40 C.F.R. § 63.366. The 2024 Rule clarifies that "[t]he EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed CBI." *Id.* § 63.366(b), (c).

The Proposed Rule eliminates this language without even acknowledging it does so in the preamble. *See* Redline Memo at 99–100 (proposed amendments to 40 C.F.R. § 63.366(b) providing for public availability of monitoring plans, initial compliance reports, emissions data, hours of operation, monthly EtO use, applicability of combined emission stream limits, and deviations from standards); *id.* at 103 (proposed amendments to 40 C.F.R. § 63.366(c), providing for public availability of quarterly compliance reports, including emissions data, hours of operation, monthly EtO use, information on monitoring system performance, and deviation information). The Proposed Rule docket includes the March 12, 2026, memorandum on electronic reporting requirements, which clarifies that "[a]ll information submitted through CEDRI is made available to the public without further notice to the certifier and cannot later be claimed to be CBI," but the preamble and proposed regulations do not mention this memorandum. *Memorandum: Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules*, EPA-HQ-OAR-2019-0178-1616, at 4 (March 12, 2026).

To be clear, the absence of this language from a NESHAP does not exempt CEDRI submissions from section 114(c)'s requirements. EPA is legally required to make these compliance records public. 42 U.S.C. § 7414(a), (c); *see also* 40 C.F.R. § 2.301. Section 114(c) provides that "any records, reports or information obtained under subsection (a) shall be available to the public," subject only to a narrow trade secret exception that applies to records, reports, or information "other than emission data." 42 U.S.C. § 7414(c). Section 114(c) thus contains an absolute prohibition on CBI claims for "emission data." *Id.* Congress's use of the parenthetical "(other than emission data)" is unambiguous: emissions data submitted to EPA under section 114(a), including data obtained through NESHAP reporting requirements, is categorically excluded from confidential treatment. There is no discretion afforded to the agency to shield such data from public view.

EPA acknowledges that electronic reporting "further assists in the protection of public health and the environment, and ultimately results in less burden on regulated facilities." *Memorandum: Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules*, EPA-HQ-OAR-2019-0178-1616, at 6 (March12, 2026). EPA also acknowledged that "[e]lectronic storage of reports make data more accessible for review, analysis and sharing. Electronic reporting also eliminates paper-based, manual processes; thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors and providing data quickly and accurately to affected facilities, air agencies, EPA, and the public." *Id*

There is no rational reason to rescind this language, particularly given that the absence of this language from a NESHAP would not exempt CEDRI submissions from section 114(c)'s requirements. The language enhances transparency and clarity, and it is EPA's standard practice to include such language in NESHAPs. EPA should include the language in the regulation and ensure that all information posted on CEDRI is publicly accessible.

VI. EPA's Reconsideration of the Rule Based on Alleged Capacity Constraints is Unlawful and Arbitrary and Capricious. (Response to Question 21)

A. EPA Fails to Explain Its Change in Position on Supply Chain Impacts and Presents No Evidence to Support Its New Conclusion.

EPA fails to sufficiently explain its change in position on the impact of the 2024 112(f)(2) standards on commercial sterilization supply chain capacity. In the 2024 Rule, EPA concluded that "[g]iven that key industry players are already planning for compliance, and in light of the significant changes made between the proposal and this final rule, the EPA does not anticipate that the implementation of these standards will have any adverse impacts on the medical supply chain." 89 Fed. Reg. at 24092. EPA determined that the "group of facilities that have already installed or are installing required controls includes many facilities that the FDA has identified as critical to the medical device supply chain." 2024 RIA, EPA-HQ-OAR-2019-0178-1557, at 1-17. Despite the installation of required controls, "The completed and ongoing upgrades at these facilities have not thus far resulted in industry capacity issues to EPA's knowledge." *Id.*

EPA found that compliance related upgrades would take "approximately one year, meaning that not all facilities would potentially need to slow their operations while upgrading at the same time." *Id.* at 1-18. EPA noted that upgrades are likely to be staggered across the compliance period, *id.*, which would further mitigate any potential supply chain issues. Further, EPA acknowledged FDA's outreach to manufacturers deemed at risk for shortages, which indicate that "all the firms' shortage mitigation plans involved either switching the EtO sterilization site to a different location or distributing other unaffected devices to replace the ones affected by the shortage." *Id.* at 2-9.

Now, EPA proposes to weaken the 2024 Rule on the premise that it "would help ensure a secure medical supply chain as it would decrease the probability of commercial sterilizers shuttering." 91 Fed. Reg. at 12734. But EPA arbitrarily does not provide any supporting evidence of capacity constraints in achieving the 2024 Rule or otherwise explain how its assessment of the facts has changed to justify its change in position. "[A]n agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance." *State Farm*, 463 U.S. at 42. And when an agency's "new policy rests upon factual findings that contradict those which underlay its prior policy," it must provide a detailed explanation for its change. *Fox*, 556 U.S. at 515. EPA's proposal to reverse its recent, well-supported conclusions in the 2024 Final Rule on the basis of alleged capacity constraints does not meet these standards and is arbitrary and capricious.

B. EPA's Proposal Runs Contrary to the Evidence That the 2024 Rule Would Not Lead to Facility Shutdowns or Supply Chain Issues.

The agency ignores significant evidence that facilities can meet and are meeting the 2024 Rule standards without disrupting medical supply chains—evidence that directly contravenes its speculation that the 2024 Rule standard pose medical device supply chain risks. The record for the 2024 Rule, compliance information submitted by facilities themselves, and stack testing reports each demonstrate that a significant portion of the source category is already complying with the 2024 Rule. Where EPA's proposed rescissions rely on speculative supply chain concerns, EPA's proposal relies on an explanation that "runs counter to the evidence." *State Farm*, 463 U.S. at 43; *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018) (An agency cannot "ignore evidence that undercuts its judgment" or "minimize such evidence without adequate explanation.").

i. EPA found that a significant part of the source category was already meeting the 2024 EtO Rule standards at the time of the 2024 Rule.

According to EPA's own analysis in the 2024 Rule preamble, "[o]f the 88 existing facilities [in the source category], seven appear to have already met the emission standards and do not need to install additional emission controls." 89 Fed. Reg. at 24138. EPA acknowledged in the RIA for the 2024 Rule that "several facilities affected by this rule have already installed or started installing the required controls to reduce emissions, including some facilities that were identified as critical to the medical device supply chain.… The completed and ongoing upgrades at these facilities are of a similar scale to those required by the rule and have not thus far resulted in industry capacity issues to EPA's knowledge." 2024 RIA, EPA-HQ-OAR-2019-0178-1557, at 2-9.

EPA concluded that many facilities appeared to already be in compliance with one or more of the 2024 Rule standards at the time that rule was finalized. 89 Fed. Reg. at 24138 tbl. 22. EPA found that 66 of 88 facilities—75% of the source category—appeared to already be in compliance with the 2024 standards for sterilization chamber vents. *Id.* Of the 55 facilities with aeration room vents, EPA found that almost half appeared to already be in compliance with the 2024 aeration room vent standards. *Id.*; *see also id.* at 24128 (75% of ARVs are meeting 99.6% emissions reductions, and 50% are meeting 99.9% emissions reductions). Of the 40 facilities with chamber exhaust vents, EPA found that half appeared to already be in compliance with 2024 chamber exhaust vent standards. 89 Fed. Reg. at 24138 tbl. 22. Almost a third of facilities with Group 1 room air emissions and over half of facilities with Group 2 room air emissions appeared to already be in compliance. *Id.*

TABLE 22—APPARENT COMPLIANCE STATUS WITH FINAL RULE AND COMPLIANCE TIMEFRAMES

Emission source	Facility EtO use	Number of facilities with this affected source	Number of facilities appearing to achieve final standard [1]	Compliance timeframe
SCV	At least 30 tpy	38	19	Two years.
	At least 10 but less than 30 tpy.	9	9	Two years.
	At least 1 but less than 10 tpy.	18	16	Two years.
	Less than 1 tpy	23	22	Three years.
ARV	At least 30 tpy	36	12	Two years.
	At least 10 but less than 30 tpy.	5	5	Three years.
	At least 1 but less than 10 tpy.	10	7	Three years.
	Less than 1 tpy	4	2	Three years.
CEVs at major source facilities	N/A	0	N/A	Three years.
CEVs at area source facilities	At least 60 tpy	25	12	Two years.
	Less than 60 tpy	15	8	Three years.
Group 1 room air emissions at major sources	N/A	0	N/A	Three years.
Group 1 room air emissions at area sources	At least 40 tpy	36	16	Two years.
	Less than 40 tpy	38	7	Three years.
Group 2 room air emissions at major sources	N/A	1	0	Three years.
Group 2 room air emissions at area sources	At least 20 tpy	44	17	Two years.
	At least 4 but less than 20 tpy.	13	1	Two years.
	Less than 4 tpy	27	27	Three years.

EPA's findings are confirmed by information submitted by facilities' own submissions in response to EPA's 2019 and 2021 information collection requests. At least 24 facilities submitted emissions data showing emissions rates that would comply with one or more of the standards established in the 2024 Rule. *See Compliant Facilities ICR Analysis,* attached.

For example, the Sterigenics facility located on Gifford Avenue in Vernon, CA reported annual air emissions data indicating that it was achieving 99.9998% emission reduction from its SCV from at least 2015-2019, and was achieving 99.7653-99.9365% emission reduction from its CEV over the same period. [187] Under the 2024 Rule, the Sterigenics Vernon facility is subject to a 99.99% emission reduction standard for SCVs and a 99.9% standard for CEVs.

Similarly, the Sterigenics facility in Santa Teresa, NM reported annual air emissions data from 2015-2019 showing that it was achieving 99.97-99.99% removal efficiency at its aeration room vent and chamber exhaust vent—indicating that both of these point sources already complied with the 2024 Rule. [188]

At least one facility even reported meeting standards at each emissions point. The Cook Incorporated facility in Ellettsville, IN, reported data in response to an EPA information request that indicated that, in 2020, it was already achieving 99.99% emission reduction at its SCVs,

[187] Response to 2021 Section 114 ICR from Sterigenics US LLC, EPA-HQ-OAR-2019-0178-0212_attachment_13, "Annual emissions calcs (1 of 1)".
[188] Response to 2019 Section 114 ICR from Sterigenics US LLC Santa Teresa, EPA-HQ-OAR-2019-0178-0194_attachment_5, "Annual emissions calcs (1 of 1)".

99.90% emission reduction at its ARVs, and 99.94-99.9963% emission reduction at its CEVs.[189] These destruction removal efficiencies are also sufficient to comply with the 2024 Rule.

Stack testing for several other facilities shows that the facilities were sufficiently complying with the tightened 2024 standards. For example, in 2020, the Sterigenics facility in Atlanta, Georgia tested its entire system and achieved a 99.9987% control efficiency, which would be compliant with every applicable standard finalized in the 2024 Rule. [190] For its SCV, Sterigenics uses two scrubbers in series—a Ceilcote scrubber and an Advanced Air Technologies scrubber with dry bed adsorbers.[191] In 2005, 2014, 2016, and 2020, the Ceilcote scrubber alone tested at or above 99.99% emissions reduction;[192] in 2022, the entire SCV control system tested at 99.998% emissions reduction.[193] For its ARV and CEV, Sterigenics uses the same Advanced Air Technologies scrubber with dry bed adsorbers that it uses for its SCV.[194] In 2022, this scrubber tested at or above 99.90% emissions reduction for the ARV[195] and CEV.[196] For groups 1 and 2 room air emissions, Sterigenics uses an indoor air dry bed adsorber control system.[197] In 2022, this system tested at 98.24% emissions reduction.[198] Sterigenics passed a permanent total enclosure test in 2020 [199] and installed CEMS, which passed its most recent relative accuracy test audit in 2025.[200]

And as of 2023, Sterilization Services of Georgia reported compliance with SCV, CEV, group 1 air emissions, permanent total enclosure, and CEMS standards. In 2020, 2021, 2022, and

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[189] Response to 2021 Section 114 ICR from Cook Inc. Ellettsville North Facility, EPA-HQ-OAR-2019-0178-0263_attachment_8, "Annual Emissions Calcs (1 of 5)".
[190] CleanAir Engineering, Report on Ethylene Oxide Testing: Atlanta Facility Process Control System & Indoor Air Control System, at 15 (July 27, 2020), https://perma.cc/UJU5-XKQ7 (attached).
[191] Ga. Env't Prot. Div., Air Quality Permit, Sterigenics U.S. LLC, No. 7389-067-0093-S-06-0 (Jan. 6, 2022), https://permitsearch.gaepd.org/permit.aspx?id=PDF-OP-27153 (attached).
[192] Kremer Env't Servs., Table 1, Exhaust Phase Ethylene Oxide Control Efficiency of a Ceilcote Emission Control Sys. Operated by Sterigenics EO, Inc. (June 24, 2005), https://perma.cc/HW9T-KVSQ (attached); Memo to Sean Taylor, from Anna Gray, regarding Source Test Report Review, at 3 (Feb 17, 2015), https://perma.cc/WU7Z-K5DN (attached); Memo to Michael Odom, from Anna Gray, regarding Source Test Report Review (July 18, 2016), https://perma.cc/84QS-HBYN (attached); Memo to Stephen Damaske, from Danial McCain, regarding Source Test Report Review, at 2 (June 25, 2020), https://perma.cc/9Y83-YGRW (attached).
[193] Memo to William Fleming, from Marie Miller, regarding Source Test Report Review (Nov. 8, 2022) at 2, https://perma.cc/WNJ9-7BTX (attached).
[194] Ga. Env't Prot. Div., Air Quality Permit, Sterigenics U.S. LLC, No. 7389-067-0093-S-06-0, at 1 (Jan. 6, 2022), https://perma.cc/EX3C-VTZ8 (attached).
[195] Memo to William Fleming, from Marie Miller, regarding Source Test Report Review (Nov. 8, 2022), https://perma.cc/WNJ9-7BTX (control efficiency of ARV was 99.96%, at 6) (attached).
[196] Memo to William Fleming, from Marie Miller, regarding Source Test Report Review (June 30, 2022), https://perma.cc/4647-M244 (attached).
[197] Ga. Env't Prot. Div., Air Quality Permit, Sterigenics U.S. LLC, No. 7389-067-0093-S-06-0, at 1.
[198] Memo to William Fleming, from Marie Miller, regarding Source Test Report Review (July 1, 2022), https://perma.cc/4JGY-E57G (attached).
[199] Memo to Stephen Damaske, from Joshua Pittman, regarding Source Test Report Review (March 24, 2020), https://perma.cc/6TZK-8P6P (attached).
[200] Memo to William Fleming, from Joanna Pecko, regarding Source Test Report Review (March 2, 2025), https://perma.cc/6AVH-HURD (attached).

2023, this facility's scrubber, which controls emissions from its SCVs, tested at or above 99.99% emissions reduction for all three chambers.[201] For its CEV, Sterilization Services of Georgia uses an Advanced Air Technologies scrubber with four dry beds.[202] In 2021 and 2023, this scrubber tested at or above 99.90% emissions reduction.[203] For group 1 air emissions, Sterilization Services of Georgia installed an Advanced Air Technologies scrubber with four dry beds.[204] In 2022 and 2023, this scrubber tested at or above 98.0% emissions reduction.[205] Also in 2023, this facility demonstrated controls of Group 2 room air emissions to 94.6%.[206] Sterilization Services of Georgia passed a permanent total enclosure test in 2021 and 2022,[207] and it installed a CEMS, which passed its most recent relative accuracy test audit in 2024.[208]

The record for the 2024 Rule, information submitted by facilities themselves, and stack testing all demonstrate that a significant proportion of commercial sterilizers is already complying with the 2024 standards that the Administration now seeks to roll back. EPA's proposal arbitrarily and capriciously relies on purely speculative supply chain concerns unsupported by "substantial evidence on the record considered as a whole," *State Farm*, 463 U.S. at 44, and in fact "run[] counter to the evidence before the agency," *id.* at 43.

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[201] Memo to Stephen Damaske, from Ray Shen, regarding Source Test Report Review (May 13, 2020), https://perma.cc/U2RJ-FD6U (attached); Memo to Stephen Damaske, from Joshua Pittman, regarding Source Test Report Review (Feb. 23, 2021), https://perma.cc/9AR2-3S3A (attached); Memo to Sean Taylor, from Ray Shen, regarding Source Test Report Review (Chamber 1) (March 22, 2022), https://perma.cc/CY4B-USRK (attached); Memo to Sean Taylor, from Ray Shen, regarding Source Test Report Review (Chamber 2) (March 22, 2022), https://perma.cc/7E4U-5DRG (attached); Memo to William Fleming, from Joanna Pecko, regarding Source Test Report Review (Chamber 2) (March 15, 2023), https://perma.cc/3YH5-B328 (attached); Memo to William Fleming, from Joanna Pecko, regarding Source Test Report Review (Chamber 3) (March 15, 2023), https://perma.cc/ZTT3-THRW; Memo to William Fleming, from Ray Shen, regarding Source Test Report Review (Chamber 2, 3), at 5-6 (Jan. 31, 2024), https://perma.cc/5U85-7LVV (attached).

[202] Ga. Env't Prot. Div., Air Quality Permit, Sterilization Services of Georgia, No. 3841-121-0010-S-04-0, at 1.

[203] Memo to Stephen Damaske, from Ray Shen, regarding Source Test Report Review (Mar 11, 2020), https://perma.cc/GF5Q-AKUT (attached); Memo to Stephen Damaske, from Joshua Pittman, regarding Source Test Report Review (Feb. 24, 2021), https://perma.cc/K38X-NRSQ (attached); Memo to William Fleming, from Joanna Pecko, regarding Source Test Report Review (March 16, 2023), https://perma.cc/BN9T-DSU6 (attached); Memo to William Fleming, from Ray Shen, regarding Source Test Report Review (Backvent), at 4 (Jan. 31, 2024), https://perma.cc/5U85-7LVV (attached).

[204] Ga. Env't Prot. Div., Air Quality Permit, Sterilization Services of Georgia, No. 3841-121-0010-S-04-0, at 1.

[205] Memo to Sean Taylor, from Ray Shen, regarding Source Test Report Review (Apr. 22, 2022), https://perma.cc/6DBB-HFS9 (attached); Memo to William Fleming, from Ray Shen, regarding Source Test Report Review (Fugitive Emissions 1) at 2 (Jan. 31, 2024), https://perma.cc/5U85-7LVV (attached).

[206] Memo to William Fleming, from Ray Shen, regarding Source Test Report Review (Fugitive Emissions 1) at 1 (Jan. 31, 2024), https://perma.cc/5U85-7LVV (attached).

[207] Memo to Stephen Damaske, from Joshua Pittman, regarding Source Test Report Review (Apr. 27, 2021), https://perma.cc/MHF5-L2MK (attached); Memo to Sean Taylor, from Ray Shen, regarding Source Test Report Review (Apr. 21, 2022), https://perma.cc/7V8P-NDGE (attached).

[208] Memo to William Fleming, from Daniel McCain, regarding Source Test Report Review (Jan. 28, 2025), https://perma.cc/N56R-83H2 (attached).

ii. New information since the 2024 Rule demonstrates that commercial sterilization facilities can comply with the 2024 Rule.

Developments since EPA's last information collection in support of the 2024 Rule also demonstrate that commercial sterilization facilities can upgrade pollution control equipment and install PTE and CEMS to comply with the more stringent standards EPA proposes to rescind without causing facility shutdowns or supply chain disruptions.

For example, South Coast Air Quality Management District (SCAQMD) Rule 1405 (as amended Dec. 1, 2023) (attached) is more comprehensive and stringent than the 2024 Rule, and the latest compliance deadlines for Rule 1405 came to pass on January 1, 2026 without any evidence of medical supply chain disruptions due to sterilization delays.[209] *See* Section VI.C. Rule 1405 requires sterilizers using more than 1 tpy of EtO to achieve control efficiencies of 99.99% for all control systems, to implement CEMS, PTE, and fenceline monitoring, and to curtail EtO use if fenceline monitoring shows EtO emissions exceeding certain thresholds. 1405(d)(1)-(3), (d)(8), and (q)(1). Post-aeration storage facilities and certain warehouses must also comply with the rule. 1405(b).

The Sterigenics facilities in Vernon, California (located at Gifford Avenue and E. 50th Street) received permits to construct PTE in January 2023,[210] and by 2025 Sterigenics had notified the South Coast Air Quality Management District (SCAQMD) that the PTEs for both buildings had been constructed.[211] In 2019, the Sterigenics facility located on Gifford Avenue in Vernon, CA had already reported achieving a 99.9998% emission reduction at its sterilization chamber vent between 2015-2019.[212] Since then, those facilities also received permits to modify additional pollution control systems to meet a control efficiency of 99.99% or greater emission reduction, most recently in 2025.[213]

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[209] *See* FDA, *Medical Device Shortages List*, https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/medical-device-shortages-list (last updated March 13, 2026); *see* attachments to this comment: "FDA Medical Device Shortages List_03-13-2026," "FDA Medical Device Discontinuance List_03-13-26," "FDA Medical Device Shortage and Discontinuation Lists 2020-2024."

[210] SCAQMD, Permit to Construct for equipment located at 4900 S. Gifford Ave, Los Angeles, CA 90058 (Fac. ID 126197), Application No. 637897, granted Jan. 27, 2023 (attached); SCAQMD, Permit to Construct for equipment located at 4801-63 E 50th St., Los Angeles, CA 90058 (Fac. ID 126191), Application No. 637894, granted Jan. 27, 2023 (attached).

[211] *See* SCAQMD, *Sterigenics Emissions Investigation in Vernon*, https://perma.cc/Z98G-ATM9 (attached).

[212] Response to 2021 Section 114 ICR from Sterigenics US LLC, EPA-HQ-OAR-2019-0178-0212_attachment_13 (Apr. 13, 2023).

[213] *E.g.*, SCAQMD, Permit to Construct for equipment at 4801-63 E 50th St, Los Angeles, CA 90058 (Fac. ID 126191), App. No. 658713, granted May 21, 2025 (attached); SCAQMD, Permit to Construct for equipment at 4900 S Gifford Ave, Los Angeles, CA 90058 (Fac. ID 126197), App. No. 658712, granted May 21, 2025 (attached).

Likewise, the Sterigenics facility in Ontario, California, received permits to construct PTE on July 19, 2024.[214] Those permits also covered the construction of air pollution control systems that would meet a control efficiency of 99.99% or greater.[215]

Further, EPA acknowledges that two new facilities have begun operation since promulgation of the 2024 Rule but does not account for this fact in its unsupported contentions of supply chain concerns. 91 Fed. Reg. at 12708. These facilities demonstrate that it is feasible for facilities to comply with the 2024 Rule. New facilities enlarging the supply chain are also an "important aspect" of evaluating whether there is truly any risk of supply chain impacts, and EPA did not address this. *See State Farm*, 463 U.S. at 43.

These developments further establish that the control efficiency, PTE, and CEMS requirements EPA proposes to rescind or weaken are technically feasible and achievable by commercial sterilization facilities without supply chain impacts. EPA must confront these facts—and collect information about the current state of developments at regulated facilities—rather than relying on sweeping, unsupported assumptions about the impacts of the 2024 Rule on commercial sterilizers. *See*, *e.g.*, *State Farm*, 463 U.S. at 44 (agency action must be "supported by 'substantial evidence on the record considered as a whole'" (citation omitted)); *Friends of Back Bay v. U.S. Army Corps. of Engineers*, 681 F.3d 581, 588 (4th Cir. 2012) ("A material misapprehension of the baseline conditions existing in advance of an agency action can lay the groundwork for an arbitrary and capricious decision.").

EPA cannot weaken the sterilizer NESHAP without accounting for these and other changes in facility controls. EPA must consider the evidence of facilities' compliance with the 2024 standards in its assessment of the ability of the industry to install more effective pollution controls without impacting supplies of sterilized medical equipment, and in its assessment of the avoided compliance costs of the Proposed Rule, which will be lower than the mere inverse of the estimated compliance costs of the 2024 Rule because of these changes, *see* Section XII. Failing to seek or incorporate information on these topics would amount to ignoring an "an important aspect of the problem" and be arbitrary and capricious. *State Farm*, 463 U.S. at 43.

C. Facility Shutdowns Have Not Caused Supply Chain Impacts.

EPA presents no evidence that the 2024 Rule has or could cause supply chain concerns and ignores evidence to the contrary. Justifying any rollback of the 2024 Rule on the speculative premise of supply chain concerns would be arbitrary and capricious.

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[214] SCAQMD, Permit to Construct for equipment at 687 Wanamaker Ave, Ontario, CA 91761 (Fac. ID 126060), App. No. 647992, granted July 19, 2024 (attached); SCAQMD, Permit to Construct for equipment at 687 Wanamaker Ave, Ontario, CA 91761 (Fac. ID 126060), App. No. 647990, granted July 19, 2024 (attached); *see* SCAQMD, *Sterigenics Emissions Investigation in Ontario*, https://perma.cc/T8J6-87FE (attached).

[215] SCAQMD, Permit to Construct for equipment at 687 Wanamaker Ave, Ontario, CA 91761 (Fac. ID 126060), App. No. 647992, granted July 19, 2024 (attached); SCAQMD, Permit to Construct for equipment at 687 Wanamaker Ave, Ontario, CA 91761 (Fac. ID 126060), App. No. 647990, granted July 19, 2024 (attached).

As far as Commenters are aware, manufacturers have not reported impacts on medical supply chains attributable to promulgation of this rule. For some medical devices sterilized with EtO, manufacturers are required to report manufacturing discontinuations or interruptions to the FDA if there may be a meaningful disruption of the supply of that device in the U.S. 21 U.S.C. § 356j(a). To date, medical device manufacturers have never reported any such medical device shortages due to delays in or disruptions to sterilization.[216] EPA's predictive judgments about the economic effects of a rule "must be based on some logic and evidence, not sheer speculation." *Sorenson Communications v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014). EPA has failed to do so here and has thus failed to "articulate a satisfactory explanation for its action." *State Farm*, 463 U.S. at 43.

The record here does not include any findings or evidence of supply chain issues, shortages, or disruptions caused by the 2024 Rule, let alone "substantial evidence" as required by the APA. *State Farm*, 463 U.S. at 44.

Importantly, even documented shutdowns of sterilizer facilities have not resulted in reported supply chain disruption. For example, Becton-Dickinson shut down all sterilization operations at its Covington, Georgia facility from October 30, 2019, to November 7, 2019, pursuant to a consent decree that also required extended aeration periods and reduced product lots to lower fugitive emissions.[217] Until the Georgia Environmental Protection Division issued a final permit for the Covington facility, Becton-Dickinson was not permitted to increase EtO usage at its nearby facility in Madison to offset the process changes at the Covington facility.[218] The company "represent[ed] that the proposed process changes will not impact the FDA validated process and will not require FDA or other regulatory approval."[219] The consent decree imposed these process and throughput limitations until installation of fugitive emissions control systems.[220]

Sterigenics likewise ceased all sterilization operations at its Atlanta, Georgia facility in order to comply with control requirements in a consent decree from August 26, 2019, to March 26, 2020.[221] Operations resumed only in response to the unprecedented COVID-19 pandemic,[222] underscoring the absence of supply chain issues even with a facility closure.

Moreover, some of the commercial sterilization facilities regulated under this Rule—including facilities that present elevated cancer risks—do not sterilize medical equipment at all,

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[216] *See* FDA, *Medical Device Shortages List*, https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/medical-device-shortages-list (last updated March 13, 2026); *see* attachments to this comment: "FDA Medical Device Shortages List_03-13-2026," "FDA Medical Device Discontinuance List_03-13-26," "FDA Medical Device Shortage and Discontinuation Lists 2020-2024."
[217] Consent Order, *Dunn v. Becton, Dickinson & Co.*, No. SUCV201900219 (Oct. 28, 2019) (attached), at Att. A ¶ 1, 4.
[218] *Id.* at Att. A ¶ 15.
[219] *Id.* at Att. A ¶ 6.
[220] *Id.* at Att. A ¶ 11.
[221] Georgia Department of Natural Resources, Environmental Protection Division, Consent Order, *Re: Sterigenics U.S. LLC*, Order No. EPD-AQC-6980 (attached).
[222] EPA, Ethylene Oxide: Technical Reviews and Outreach to Potentially Affected Communities Status Report – Sterigenics Cobb County, Smyrna, Georgia (Jan. 2021) (attached).

and thus would have no effect on the supply chain of sterilized medical equipment. These facilities include two Elite Spice facilities in Maryland, and the Cosmed facility in Linden, New Jersey—which EPA estimated presents lifetime cancer risk as high as 2,000-in-1 million prior to the 2024 Rule.[223] EPA has not explained why facilities that have no connection to the medical device supply chain cannot implement the more stringent standards adopted in 2024.

D. EPA's Failure to Consider Alternative Methods of Sterilization is Arbitrary and Capricious.

In concluding that more stringent standards would detrimentally impact the availability of sterilized equipment, EPA also fails to consider the availability of alternative methods of sterilization. There are several established, FDA-approved methods of sterilization, including but not limited to dry heat, moist heat, and hydrogen peroxide, that EPA must account for in setting any standard for EtO and in any analysis of the impacts of an EtO standard on medical device supply chains. Specifically, the existence of viable alternatives may mitigate any supply chain impacts, and failing to consider this "relevant and significant aspect of a problem" renders EPA's proposal arbitrary and capricious. *See Am. Farm Bureau Fed. v. EPA*, 559 F.3d 512, 520 (D.C. Cir. 2009). EPA must address the possibility of requiring alternative sterilization modes as a regulatory alternative to rescinding or weakening the 2024 Rule. *See Am. Radio Relay League*, 524 F.3d at 242 ("An agency is required 'to consider responsible alternatives to its chosen policy and to give a reasoned explanation for its rejection of such alternatives.'" (cleaned up)).

There are safer, recognized alternatives that offer similarly effective sterilization with significantly fewer health risks.[224] For example, in January 2024, FDA recognized vaporized hydrogen peroxide as an Established Category A sterilization process for medical devices, meaning it has a "long history of safe and effective use as demonstrated through multiple sources of information such as ample literature, clearances of 510(k)s or approvals of premarket approval (PMA) applications, and satisfactory QS inspections.[225] FDA announced that this recognition advances the agency's approach to reducing the use of EtO where possible. Vaporized hydrogen peroxide is effective on materials and devices that cannot tolerate high temperatures and humidity, and has been shown to be effective on over 95% of medical devices and materials tested.[226]

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[223] *Linden, New Jersey* (*ETO Sterilization-Plant #2)*, EPA, https://perma.cc/EPY9-MEQS.
[224] *See*, *e.g.*, Ass'n of Surgical Technologists*, Comparison of Alternative Sterilization Chemicals to Ethylene Oxide (EtO)* (May 2025), https://www.ast.org/ceonline/articles/500/500.pdf (attached).
[225] FDA, *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile Guidance for Industry and Food and Drug Administration Staff* at 3-4 (Jan. 8, 2024) (attached).
[226] William Rutala et al., U.S. CDC, Guideline for Disinfection and Sterilization in Healthcare Facilities at 65 (last updated June 2024), https://www.cdc.gov/infection-control/media/pdfs/guideline-disinfection-h.pdf (attached); *see also FDA Facilitates Broader Adoption of Vaporized Hydrogen Peroxide for Medical Device Sterilization*, U.S. FDA (Jan. 8, 2024), https://www.fda.gov/news-events/press-announcements/fda-facilitates-broader-adoption-vaporized-hydrogen-peroxide-medical-device-sterilization.

In the last two decades, other low-temperature modalities have been developed to accommodate instruments made of synthetic materials or that contain electrical components. These effective, low-temperature modalities include sterilization via chlorine dioxide, which was approved by the FDA for contract sterilization of medical devices in 2021, and vaporized hydrogen peroxide, which the FDA recognized as a "Category A" established method of sterilization for medical devices in 2024.[227]

The alternative which appears to be most desirable from a health perspective is hydrogen peroxide, which is converted to a plasma and can be employed as a sterilant on all materials excluding cellulose, linens, and liquids.[228] Hydrogen peroxide gas plasma sterilization is safe for the environment and leaves no toxic residuals (water and oxygen) with a short cycle time. *Id.* For sterilizing materials made entirely of metal and glass, steam has been—and continues to be—an effective, harmless method. *Id.*

Sterilization can be done safely without causing carcinogenic emissions, and it is critical that we move towards safer alternatives, including those that the FDA has already approved for industry use. EPA's failure to account for these ample, viable, safe, established, industry- and government-approved alternatives in the Proposed Rule is arbitrary and capricious.

VII. EPA's Proposed Definition for "Operating Day" is Arbitrary and Capricious.

Currently, "operating day" is defined as "any day that a facility is engaged in a sterilization operation." 40 CFR 63.361. "Sterilization operation" is defined as "any time when EtO is removed from the sterilization chamber through the SCV or the chamber exhaust vent, when EtO is removed from the aeration room through the aeration room vent, when EtO is stored within the building, when EtO is dispensed from a container to a chamber, when material is moved from sterilization to aeration, or when materials are handled post-aeration." *Id.*

EPA is proposing to amend the definition for "operating day" to "any day that an affected source is engaged in a sterilization operation." 91 Fed. Reg. at 12726 (emphasis added). EPA's rationale, based on the statements of one company, is that the current definition inadvertently "implies that if any affected source at a facility is engaged in a sterilization operation then all affected sources are engaged in a sterilization operation, regardless of whether or not they are actually in use." *Id.* Thus, in a situation where one or more regulated sources in a facility are not actually operating, but other regulated sources in the facility are, the facility may be required to demonstrate compliance for the non-operating sources because the current definition of "operating day" applies to any day that the "facility" is engaged in a sterilization operation.

EPA's proposed definition change must have a "satisfactory explanation" and must consider an "important aspect[s] of the problem," *State Farm*, 463 U.S. at 43—here, the need for facilities to demonstrate continuous compliance with all applicable standards.

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[227] *See* Ass'n of Surgical Technologists*, Comparison of Alternative Sterilization Chemicals to Ethylene Oxide (EtO)* at 212 (May 2025), https://www.ast.org/ceonline/articles/500/500.pdf (attached).
[228] William Rutala et al., U.S. CDC, Guideline for Disinfection and Sterilization in Healthcare Facilities at 118 (last updated June 2024), https://www.cdc.gov/infection-control/media/pdfs/guideline-disinfection-h.pdf (attached).

First, under EPA's proposed definition, sources that are purportedly not operating during a particular day will have no requirement to demonstrate that they are in fact not operating that day. If the modified definition allows facilities to determine for themselves on any given day that a particular emission point is not operating, without a corresponding verification mechanism, the monitoring regime may not "provide a reasonable assurance of compliance with emissions standards." *NRDC v. EPA*, 194 F.3d at 136. If EPA finalizes its proposal to change the definition of "operating day," it must, at the very least, require facilities claiming non-operating days for any particular source to document and report that information in their quarterly compliance reports.

Second, 40 CFR 63.364(i) requires facilities to "monitor and record on a daily basis the daily and 30-operating day EtO usage." If EPA finalizes its proposal, EPA must clarify that facilities must track EtO usage as required under 40 CFR 63.364(i) for each day where any affected source in the facility is producing EtO emissions.

Third, EPA must amend the definition of "sterilization operation" to include any time when material contains EtO levels above FDA-allowed residual amounts. *See* Sahu Expert Report, Attachment A, at 11-12.

Without making these changes or clarifications, EPA's proposal to change the definition of "operating day" would be arbitrary and capricious if finalized.

VIII. EPA Must Retain a Compliance Deadline of April 5, 2027.

EPA seeks comment on its proposal to retain a compliance deadline of April 5, 2027 for section 112(d) standards for existing and new sources. 91 Fed. Reg. at 12732. Commenters support retaining the April 5, 2027 compliance deadline. Extending the compliance deadline beyond that date would violate section 112(i)(3)'s compliance deadline requirements, 42 U.S.C. § 7412(i)(3), and be arbitrary and capricious, *id.* § 7607(d)(9)(A), 5 U.S.C. § 706(2)(A).

A. EPA Has No Legal Authority to Extend the Deadline for the Source Category Beyond April 5, 2027.

The Clean Air Act provides EPA with no authority to extend the compliance deadlines for 112(d) standards beyond April 5, 2027. For existing sources, section 112 requires compliance with 112(d) standards "as expeditiously as practicable, but in no event later than 3 years after the effective date of such standard." *Id.* § 7412(i)(3) (emphasis added). EPA promulgated these 112(d) standards on April 5, 2024 and allotted the maximum statutory time of three years to comply. *See* 89 Fed. Reg. at 24090, 24102. Nothing in section 112(d) allows EPA to extend these deadlines. For new sources, Clean Air Act section 112(i) mandates that "no person may construct" a new source "unless the Administrator ... determines that such source … will comply with the [112(d), (f) or (h)] standard, regulation or limitation." 42 U.S.C. § 7412(i)(1). New sources therefore may not construct or operate without compliance, and no extension is permissible.

To the extent EPA's proposal suggests that the 2025 Presidential Exemption would allow some facilities until April 5, 2029 to comply with the Proposed Rule, such an extension would be unlawful and arbitrary and capricious. EPA has no authority to issue these exemptions, which Congress exclusively authorized the President, not EPA, to issue. 42 U.S.C. § 7412(i)(4). The President's authority to grant exemptions under section 112(i)(4) does not confer on EPA any authority to extend compliance dates. EPA is bound by section 112(i)(3), which makes no exception for presidential exemptions and does not make such exemptions a relevant factor for EPA to consider.

B. Extending the Compliance Deadlines Would Run Contrary to Evidence in the Record and be Unsupported.

EPA concludes that "sources can still meet the current compliance deadlines with the removal of the section 112(f)(2) standards" because many sterilizers are already meeting the standards. 91 Fed. Reg. at 12732. Extending the compliance deadline beyond April 4, 2027 for any source would "run[] counter to the evidence" that sterilizers can comply by this deadline. *State Farm*, 463 U.S. at 43.

EPA concluded that new and existing sources subject to section 112(f)(2) standards under the 2024 Rule could comply with section 112(d) standards by April 5, 2027 because "compliance with section 112(f)(2) standards would also mean compliance with section 112(d) standards," and they were required to comply with the 112(f)(2) standards by April 6, 2026. 91 Fed. Reg. at 12,732. Additionally, the Proposed Rule is only weakening the section 112(d) standards, and sterilizers are already meeting these weakened standards. Specifically, EPA is proposing to change standards for new ARVs at facilities where EtO usage is at least 10 tpy from 99.9 percent reduction to 99.6 percent reduction. "Because new ARVs … that already started up are currently operating under the more stringent 99.9 percent reduction standard in the 2024 Final Rule, they are already meeting the less stringent proposed standard of 99.6 percent reduction." *Id.* Thus, "EPA does not foresee problems with new ARVs (as defined by the 2024 Final Rule) at facilities where EtO usage is at least 10 tpy complying with the proposed revised standard by the current deadlines in the 2024 Final Rule (*i.e.,* upon startup or by April 5, 2024, whichever is later)." *Id.* Sterilizers would "return to the compliance demonstration practice currently used by industry." *Id.* As for proposed amendments to parametric monitoring and performance test approach, EPA concluded that "these changes do not represent a substantial change in methods and should not present a substantial burden to industry. As such, the EPA does not anticipate these changes to need more time than provided by the compliance deadline already in place." *Id.*

IX. Exemptions Issued Under Section 112(i)(4) Cast Further Doubt on EPA's Proposal.

The President issued a proclamation under section 112(i)(4) purporting to exempt several sterilizers from the 2024 Rule for an additional two years. 90 Fed. Reg. 34747 (July 23, 2025) ("Exemption Proclamation"); *see* 42 U.S.C. § 7412(i)(4). In this proposal, EPA fails to account for the Exemption Proclamation and fails to address or resolve apparent conflicts between the Proclamation and the Proposed Rule. As EPA "fail[s] to consider an important aspect of the problem"—the Exemption Proclamation and how it undermines EPA's proposal—the agency cannot finalize the Proposed Rule. *State Farm*, 463 U.S. at 43.

To be sure, some Commenters here are pursuing legal challenges to the Exemption Proclamation. But assuming, arguendo, that the Proclamation were validly issued, it undermines EPA's proposal. Although EPA premises its repeal of certain standards on its new view that the industry compliance costs identified in the 2024 Rule are too high, are underestimated, or are no longer outweighed by the benefits, the Exemption Proclamation exempts about half of all regulated facilities from compliance with those standards until April 2028 or 2029. EPA's review of the 2024 cost data failed entirely to recognize that, by virtue of the Exemption Proclamation, many covered facilities will be exempted from compliance with the 2024 standards until 2029 rather than having to comply beginning now, under the terms of the 2024 Rule as finalized. EPA's proposal does not address whether and how a delay in implementation of that magnitude and for that many facilities—which, at a minimum, extends the lead time for installation of controls and monitoring systems—will affect expected costs of compliance with the 2024 Rule. Purported compliance costs cannot be a basis for the Agency's proposal here—at least not without full consideration of how those costs have been altered by the Exemption Proclamation. By failing to account for the actual circumstances on the ground, EPA's analysis is per se arbitrary and capricious. 42 U.S.C. § 7607(d)(9); 5 U.S.C. § 706(2). It "fails to consider an important aspect of the problem," *State Farm*, 463 U.S. at 43, and fails to "give reasoned consideration to the issues before [it] and reach a result which rationally flows from this consideration," *Motor Equipment Mfrs. Assoc. v. EPA*, 627 F.2d 1095, 1106 (D.C. Cir. 1979). EPA cannot finalize a rule based on this proposal without conducting the missing analysis.

Indeed, as explained below, the docket underlying EPA's proposal does not include the requests solicited from and submitted by covered facilities for exemptions under section 112(i)(4). The docketing of those requests is required if EPA considered the requests when formulating this proposal. *See* 42 U.S.C. § 7607(d)(2), (3), & (6)(C). Their absence suggests that EPA did not consider a significant body of relevant data concerning the supposed unavailability of the technologies in the 2024 Rule—even though such industry submissions were plainly germane to the reconsideration of the 2024 Rule. While Commenters dispute any suggestion that the technologies in question are not available or feasible, not least because they are already installed at many facilities, EPA "fails to consider an important aspect of the problem" if it failed to consider industry data concerning technology availability that is indisputably in the Agency's possession. *State Farm*, 463 U.S. at 43; *see* 42 U.S.C. § 7607(d)(9); *see* 5 U.S.C. § 706(2).

The Exemption Proclamation also frustrates the public's ability to rely on the faithful execution of the Clean Air Act's process and participation provisions. With the broad grant of exemptions from the 2024 Rule—itself undertaken without any public process or satisfactory explanation whatsoever—the public cannot have confidence that participation in this rulemaking is not a futile and performative exercise. The President's abuse of the section 112(i)(4) exemption authority—and the breadth of the resulting Proclamations—have placed a significant thumb on the scale here and deprive the public of confidence that EPA will faithfully consider, with the requisite "open-minded attitude," public input on this proposal. *Nat'l Tour Brokers Ass'n*, 491 F.2d at 902. This fundamentally suppresses public engagement in the process and frustrates the public procedures guaranteed by statute. While the unlawful

exemptions from the 2024 Rule remain in place, this rulemaking cannot provide due process consistent with the requirements of the Clean Air Act and the Administrative Procedure Act.

X. EPA's Rulemaking Violates Notice-and-Comment Requirements.

A. EPA's Rulemaking Docket Omitted Key Information and Relevant Documents.

EPA omitted key information and relevant documents from the docket for this rulemaking in violation of the Clean Air Act. The CAA requires EPA to publish a notice of proposed rulemaking accompanied by a "statement of its basis and purpose" that "shall include a summary of—

> (A) the factual data on which the proposed rule is based;
> (B) the methodology used in obtaining the data and in analyzing the data; and
> (C) the major legal interpretations and policy considerations underlying the proposed rule."

42 U.S.C. § 7607(d)(3). Further, "All data, information, and documents referred to in this paragraph on which the proposed rule relies shall be included in the docket on the date of publication of the proposed rule." *Id.* § 7607(d)(3)(C). These protections are also required to assure meaningful judicial review. *See id.* § 7607(d)(7)(A). The Act further provides that "the Administrator in promulgating any regulation under this chapter, shall ensure a reasonable period for public participation of at least 30 days." *Id.* § 7607(h).

EPA's proposal has failed to satisfy these requirements: EPA has failed to include information on the agency's actions or plans to weaken or eliminate the IRIS program, how these actions or plans relate to this rulemaking, and documents or information relating to the 2025 Presidential Exemption.

EPA did not add the Fotouhi IRIS Memo to this docket, nor did it otherwise acknowledge or explain whether agency-wide directives to reevaluate the use of IRIS assessments played any role in the development of the Proposed Rule. In fact, the memo is currently not available on EPA's website. It has been made publicly available only through press.[229] The ramifications of the Fotouhi IRIS Memo are not clear, but it explicitly mentions the EtO IRIS value in the context of this rulemaking. Fotouhi IRIS Memo at 3. To the extent EPA relies or intends to rely on the Fotouhi IRIS Memo in this rulemaking, finalizing this proposal without a complete "statement of its basis and purpose," followed by further opportunity for comment, would violate the Clean Air Act. 42 U.S.C. § 7607(d)(3).

Documents and information relating to the 2025 Presidential Exemption are also missing from the docket—this omission is particularly problematic given EPA's own linking of the two actions. *See, e.g.*, 91 Fed. Reg. at 12709. Information from regulated industry about the availability of technology, the impact of the 2024 Rule on national security interests, and the ability of sources to meet compliance deadlines are all relevant to EPA's decision to withdraw or maintain the 2024 Rule. The public needs access to these documents to provide

[229] *See* https://insideepa.com/sites/insideepa.com/files/documents/2026/may/epa2026_0752.pdf.

informed comments on the proposal. While EPA has placed the proclamation itself in the regulatory docket, there are numerous other documents related to the proclamation (and to this rulemaking) that EPA has not placed in the docket—including the requests from sources for exemptions and the information submitted as part of those requests. All of the information submitted by regulated industry and EPA's responses should be placed in the docket for this rulemaking. EPA's failure to do so is a violation of the Clean Air Act. *See* 42 U.S.C. § 7607(d)(3).

Finalizing the Proposed Rule would also be arbitrary and capricious under the APA; EPA's action must be "reasonable and reasonably explained," *Prometheus Radio Project*, 592 U.S. at 423, and EPA must "disclose the basis" for its action, *Burlington Truck Lines v. United States*, 371 U.S. 156, 167–68 (1962). EPA has not done so here.

B. EPA Cannot Use This Rulemaking Process to Bind Other EtO- or IRIS-Related Rulemakings.

EPA states that if its position on the 2016 EtO IRIS value is finalized in this rulemaking, "EPA would evaluate as necessary and appropriate in future regulatory actions other EtO risk values, ranges, or additional means to assess risk when relevant to the statutory scheme." 91 Fed. Reg. at 12714. EPA does not identify to which other EtO risk values or future regulatory actions it refers. This presents multiple notice-and-comment issues.

First, EPA provides inadequate notice to commenters in the current rulemaking whose participation is effectively limited to a proceeding that is ostensibly about withdrawal but whose record will be used for broader purposes. Adequate notice "must come—if at all—from the agency," not from the creative interpretations of commenters. *Ctr. for Biological Diversity v. U.S. Fish & Wildlife Serv.*, 698 F. Supp. 3d 39, 62 n.10 (D.D.C. 2023).

Second, EPA cannot lock in its position on the 2016 EtO IRIS value or its use of IRIS assessments writ large in this rulemaking and inoculate those positions from challenge in future rules. *See Sierra Club v. EPA*, 705 F.3d 458, 467 (D.C. Cir. 2013). Using this withdrawal docket to lock in a scientific determination for future use would deny meaningful notice-and-comment rights in the very proceedings where those determinations will be dispositive—that is, in "future regulatory actions" that will be bound by scientific determinations made here without a docket framed around those future regulatory contexts. 91 Fed. Reg. at 12714. A comment period is inadequate where the key determination has already been made before the comment period opens. *See, e.g.*, *Nat'l Tour Brokers Ass'n v. United States*, 591 F.2d 896, 902 (D.C. Cir. 1978) ("We doubt that persons would bother to submit their views or that the Secretary would seriously consider their suggestions after the regulations are a Fait accompli." (quotations omitted)).

The D.C. Circuit and district courts have concluded that this type of cross-proceeding scientific determination requires its own notice-and-comment process. An agency may not use one proceeding to effectively resolve issues that properly belong to a separate rulemaking. For example, in *CropLife Am. v. EPA*, the D.C. Circuit vacated an EPA directive that purported to change the agency's established regulatory approach to scientific data—its reliance on human studies—without going through notice-and-comment rulemaking because the directive was

binding in nature. 329 F.3d 876 (D.C. Cir. 2003). Here, EPA's express admission that it would apply its position made in this rulemaking on the IRIS EtO value and other risk values to future regulatory actions functions similarly: The agency announces an intention to make a binding methodological change to how EPA assesses EtO risk and potentially the IRIS program across future proceedings, without those future proceedings having their own appropriately framed notice period. That is unlawful and arbitrary and capricious. 42 U.S.C. § 7607(d)(9); 5 U.S.C. § 706(2).

XI. EPA Must Fully Consider and Justify Harm to Reliance Interests. (Response to Question 1)

EPA fails to address the relevant and serious reliance interests that are at stake in repealing the 2024 Rule. The burden is on EPA to provide a reasoned explanation for its change in position, and here EPA has largely and impermissibly shifted that burden to stakeholders by summarily stating "we do not believe that the standards or supporting interpretations adopted in the 2024 Final Rule have generated significant and cognizable reliance interests" and seeking comment on "whether the 2024 Final Rule and underlying interpretations have generated such reliance interests."[230] In changing policy, EPA must "assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 33 (2020). Failing to follow these steps, as EPA has done here, is arbitrary and capricious under the APA. *Id.*

A. EPA Must Fully Consider and Justify Harms to Reliance Interests in the 2024 Rule.

EPA has an obligation to consider the public's reliance interests in the 2024 Rule before weakening or rescinding the policy. *Id.* at 30–33. This is so even though the agency claims that the 2024 Rule was unlawful in certain respects. Furthermore, polling suggests that many individuals know of and support current levels of environmental protections: A 2024 survey found that more than one-third of respondents view EPA as doing just the right amount to protect the public from air pollution and other environmental threats.[231]

EPA must consider the reliance interests of the communities located near commercial sterilization facilities who currently benefit from the reductions that have occurred so far and who adjusted their expectations and community planning activities in reliance on these reductions. The 2024 Rule found that baseline cancer risks would be reduced to 100-in-1 million from 6,000-in-1 million—significant reductions in cancer incidence. 89 Fed. Reg. at 24122–23. EPA also found that the 2024 Rule would reduce health risks to children in particular, who are disproportionately impacted by ethylene oxide. *Id.* at 24149. By EPA's own estimation, the standards proposed to be eliminated would have reduced cancer incidence from 8 cases every year to 1 case every 5 years; and eliminating those standards would subject at least 85,000 more people to a cancer risk greater than EPA's "acceptable" cancer risk benchmark of 100-in-1-

[230] 91 Fed. Reg. at 12705.
[231] Env't Prot. Network, *2024 Voter Priorities* (Nov. 2024), https://www.environmentalprotectionnetwork.org/wp-content/uploads/2024/11/2024-Post-Election-Poll-EPN-Questions-Deck.pdf (attached).

million and at least 38 million people to a greater than 1-in-1-million cancer risk.[232] The individuals who will not develop cancer or cancer risk because of these reductions—including the children EPA identified as disproportionately at risk—have concrete reliance interests in the 2024 Rule that EPA must account for.

For example, in Richmond, Virginia, approximately 109,000 people and nearly 100 schools and childcare centers are located within five miles of the Sterilization Services of Virginia facility.[233] Emissions from that facility contribute to a maximum excess cancer risk of 1,000 additional cases per one million people.[234] Although the facility was exempted by Presidential Proclamation, Richmond individuals and other entities have adjusted their expectations and planning activities in reliance on protections the 2024 Rule will eventually afford.

EPA must also consider the reliance interests of individuals and entities who have adjusted their expectations and planning activities in reliance on information that compliance with the 2024 Rule would provide. The 2024 Rule requires continuous emissions monitoring and quarterly reporting for most commercial sterilization facilities, available to the public under Clean Air Act section 114(c). 89 Fed. Reg. at 24101. Thus, the 2024 Rule provides communities with transparent access to emissions data from nearby facilities which empowers residents, public interest groups (including signatories to these comments), and academics to hold companies accountable, advocate for pollution reductions, and identify opportunities to protect public health. For example, environmental and community groups and their members, including many Commenters, plan to use such information to raise public awareness of air pollution and to further their advocacy, education, and outreach efforts to reduce air pollution and protect public health. Rolling back the 2024 Rule's monitoring and reporting requirements would deprive these entities of information they have expressly planned to use and force them to expend additional time and resources on community air monitoring, independent sampling, Freedom of Information Act requests, and technical analysis to fill the information gap. *See supra* Section V.G.

EPA hinges its assertion that the 2024 Rule has not generated significant reliance interests in part on the claim that "the standards have not yet gone fully into effect." 91 Fed. Reg. at 12705. While it is true that some standards have compliance dates of April 5, 2027 and some facilities have been purportedly exempted from compliance for two years by a Presidential Proclamation, which is currently being challenged in court, numerous standards required compliance no later than April 5, 2024 or no later than April 6, 2026, dates that have already passed. 89 Fed. Reg. at 24101–02. Even though some of the compliance deadlines of the 2024 Rule have yet to pass, EPA must acknowledge that the public has come to rely on the current state of lowered emissions that much of the sector is already achieving—from the compliance

[232] 2024 RRA, EPA-HQ-OAR-2019-0178-1576, at 6 (demonstrating that the 2024 Rule would have reduced the number of people facing greater than 100-in-1-million risk from 260,000 to 0 based on allowable emissions).
[233] *Ethylene Oxide in Virginia*, Union of Concerned Scientists (Feb. 7, 2023), https://www.ucs.org/resources/virginia.
[234] *Id.*

dates that have passed and from facilities that are already complying with parts of the 2024 Rule.[235]

The public is currently benefiting from the fact that much of the sector can and has achieved lower emissions of ethylene oxide. The 2024 Rule protects those reliance interests by requiring lower emissions rates to protect the public from sudden increases in emissions. But the Proposed Rule ignores those reliance interests and offers to allow commercial sterilization facilities demonstrably achieving rates below the 2024 Rule's requirements the freedom to increase those emissions at any point. Without acknowledging and grappling with the public's reliance on existing environmental protections—reliance grounded in concrete community health stakes, ongoing organization planning, and emissions improvements already underway, the Proposed Rule is arbitrary. *Regents*, 591 U.S. at 30–33.

B. EPA Must Fully Consider and Justify Harms to Reliance Interests in the Underlying Interpretations.

The 2024 Rule adopted the interpretation that Clean Air Act section 112(f)(2) allows EPA to conduct additional discretionary residual risk reviews beyond the initial eight-year review. 89 Fed. Reg. at 24094. The Proposed Rule reverses that interpretation, asserting that section 112(f)(2) is a one-time authority. 91 Fed. Reg. at 12712–13. EPA has an obligation to consider the reliance interests in the 2024 Rule's interpretation before changing course. *Regents*, 591 U.S. at 30–33. This is so regardless of whether the agency argues that the 2024 Rule's interpretation is inconsistent with the best reading of the statute. *See Smiley v. Citibank*, 517 U.S. 735, 742 (1996) ("[C]hange that does not take account of legitimate reliance on prior interpretation may be 'arbitrary, capricious [or] an abuse of discretion.'" (internal citations omitted)); *cf. Regents*, 591 U.S. at 30–33 (rejecting the dissent's argument that "reliance interests are irrelevant when assessing whether to rescind an action that the agency lacked statutory authority to take," *id.* at 60 (Thomas, J., concurring in part and dissenting in part)).

The 2024 Rule generated significant reliance interests with respect to its underlying statutory interpretation of section112(f)(2). EPA itself acknowledged that this interpretation was applied to two other source categories—the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins—and proposed for a third. 91 Fed. Reg. at 12705 n.10. The interpretive position adopted in 2024 was thus the operative legal framework governing EPA's approach to residual risk reviews across multiple major industrial source categories, affecting a broad and diverse set of regulated facilities, environmental and public health stakeholders, and affected communities simultaneously.

The Proposed Rule's reversal has concrete and significant consequences for state and local agencies who have structured air toxics programs or deferred state-level action expecting ongoing federal reviews based on the 2024 Rule's interpretations. Communities and environmental and public health organizations have forgone or declined to pursue alternative avenues for protection in reliance on the availability of additional federal residual risk reviews

[235] EPA noted in the 2024 Rule that several facilities had already implemented one or more controls needed for compliance and that "key industry players" were already planning for compliance. 89 Fed. Reg. at 24092.

under the 2024 Rule's interpretation. Without considering and addressing these significant reliance interests, the Proposed Rule is arbitrary. *See Regents*, 591 U.S. at 30–33.

XII. The Regulatory Impact Analysis Is Flawed.

EPA's Regulatory Impact Analysis for the Proposed Rule ("2026 RIA") is deficient. EPA has produced an analytically incomplete and biased RIA that focuses narrowly on compliance cost savings to industry while ignoring or dismissing the profound public health harms that will result from rolling back protective air pollution standards. The RIA for this Proposed Rule is a sixteen-page memorandum—a fraction of the comprehensive, 100-page RIA that accompanied the 2024 Rule—that fails to adequately address or weigh the health benefits that would be forfeited by rescinding the 2024 Rule's risk-based standards. 2024 RIA, EPA-HQ-OAR-2019-0178-1557, at 10. As discussed in Section II.G, EPA's failure to consider the forgone health benefits of the 2024 standards make the Proposed Rule arbitrary and capricious.

Below, we discuss additional problems with the RIA's cost-benefit analysis. Importantly, cost-benefit analysis is not a lawful consideration in standard-setting under Clean Air Act section 112(d) or (f)(2), so any EPA reliance on the RIA's cost-benefit analysis to rationalize its unlawful and arbitrary weakening of those standards is unlawful and arbitrary. Assuming arguendo that such reliance were not categorically unlawful, any such EPA reliance is arbitrary because of the serious flaws in the RIA described below.

A. EPA's RIA Rests on a Distorted and Unreliable Baseline.

EPA's RIA is fundamentally flawed because the agency has failed to establish an accurate and updated baseline against which to measure the impacts of the Proposed Rule. The RIA states that "[f]rom the perspective of this proposed reconsideration action, the standards analyzed in the 2024 Final Rule RIA are considered in the baseline, and this proposed action is the 'policy case.'" 2026 RIA at 2. The RIA then assumes that all capital costs of the 2024 Rule would be incurred starting in 2026 and projects $630 million in cost savings from rescinding those requirements over a twenty-year analytical timeframe. *Id.* at 4. But this assumption ignores the fact that many facilities have already invested in the controls required by the 2024 Rule. As EPA itself acknowledged in the 2024 Rule RIA, "many facilities have already installed or started installing one or more of the controls required to comply with the revised standards," including "many facilities that the FDA has identified as critical to the medical device supply chain," and that "[t]he completed and ongoing upgrades at these facilities have not thus far resulted in industry capacity issues." 2024 RIA, EPA-HQ-OAR-2019-0178-1557, at 1-17. To the extent that facilities have already incurred capital expenditures to comply with the 2024 Rule, those resources are expended and cannot be "saved" by rescinding the 2024 Rule. EPA's failure to account for already-incurred compliance investments means this RIA systematically overstates the cost savings of the Proposed Rule—potentially by a substantial margin. This is especially true given that the 2024 Rule was finalized nearly two years before this Proposed Rule and facilities had strong incentives to begin compliance upgrades promptly to meet compliance deadlines of April 6, 2026, and April 5, 2027. 89 Fed. Reg. at 24192–95.

Moreover, EPA cannot reasonably rely on an outdated regulatory and market baseline when significant policy and factual developments have occurred since the prior rule was finalized. *See* Comments of Public Health and Environmental Organizations on EPA's Proposed Repeal of Amendments to the MATS Rule ("MATS Comments"), EPA-HQ-OAR-2018-0794-7609, at 48–51 (Aug. 11, 2025) (attached). Since the 2024 Rule was finalized, the regulatory and factual landscape has shifted materially. Executive Order 14192, "Unleashing Prosperity Through Deregulation," established a new federal deregulatory mandate, and the Proposed Rule itself states that it is "consistent with" and "expected to be" a deregulatory action under that Order. 91 Fed. Reg. at 12735. Presidential Proclamation 10959 (July 17, 2025), "Regulatory Relief for Certain Stationary Sources to Promote American Security With Respect to Sterile Medical Equipment," exempted 34 units—representing 38 percent of uniquely affected facilities—from compliance with the 2024 Rule for two years, fundamentally altering the compliance timeline and cost assumptions that underpin the RIA's baseline. 90 Fed. Reg. 34747 (July 23, 2025). The composition of the regulated sector has also changed: Since the 2024 Rule, two new facilities have opened and one facility has decommissioned its use of EtO, yet the RIA does not reassess the health impacts of rescission in light of these changes. 91 Fed. Reg. at 12708.

EPA's failure to update the baseline to reflect these developments—including federal deregulatory policies, presidential exemptions, and changes in the sterilization industry—means that the RIA's cost-benefit analysis is fundamentally unreliable. Specifically, the distorted baseline inflates the projected cost savings of rescission (by assuming compliance costs that have already been incurred will be "saved") while simultaneously obscuring the health benefits that would be forfeited—benefits that EPA is required to consider under section 112(f)(2), as discussed elsewhere in these comments. EPA cannot finalize a proposal that rests on a baseline the agency itself concedes is inaccurate. By not incorporating these developments, EPA's analysis distorts the true costs and benefits of the Proposed Rule.

B. EPA Arbitrarily Uses an Outdated 3% Discount Rate in Computing the Costs and Benefits of the Proposed Rule.

EPA's use of a 3% discount rate to project the costs and benefits of the Proposed Rule is contrary to the best current economic data and methods. The RIA presents its cost savings using discount rates of 3% and 7% from the 2003 version of OMB Circular A-4 (attached). 2026 RIA at 4, 12–13. The best current economic data and scholarship support using an annual discount rate of 2%, as reflected in OMB's 2023 update to Circular A-4.

Since 2003, experts have repeatedly observed that economics and current financial data no longer support the use of a 3% discount rate. In 2017, the Council of Economic Advisers explained that "real interest rates around the world have come down since" the 2003 Circular A-4, and that recent evidence supports lowering the consumption-based discount rate to at most 2%.[236] The 2023 revised Circular A-4 incorporated economic scholarship and data from the past

[236] Council of Econ. Advisers, *Discounting for Public Policy: Theory and Recent Evidence on Merits of Updating the Discount Rate* 1 (2017), https://obamawhitehouse.archives.gov/sites/default/files/page/files/201701_cea_discounting_issue_brief.pdf.

twenty years to derive a default annual discount rate of 2%, a revision that underwent expert peer review, with reviewers expressing widespread support for lowering both the 3% consumption-based rate and the 7% capital-based rate to around 2%.[237]

If EPA reverts to discount rates of 3% and 7% from the 2003 version of Circular A-4, it would be applying outdated economic data and would systematically distort the costs and benefits of the Proposed Rule. *See* MATS Comments at 52. For example, in the context of the 2024 MATS Rule, EPA found that the updated standards would yield $300 million in air-quality-related health benefits when calculated with a 2% discount rate, but only $260 million when calculated using a 3% discount rate. *Id.* EPA's use of the outdated discount rates is arbitrary and capricious.

C. EPA Arbitrarily Fails to Consider the Proposed Rule's Forgone Reductions of EtO.

EPA's RIA acknowledges that the Proposed Rule will forgo emissions reductions of 7.8 tons per year of EtO that were estimated to result from the 2024 Rule. 2026 RIA at 4. Yet EPA did not quantify or monetize the health impacts associated with these emissions changes. *Id.* at 10. The agency states only that "[d]ue to methodological and data limitations, the EPA was not able to quantify and monetize the potential human health impacts of the changes in EtO emissions in this analysis" and provides a bare "qualitative discussion" of health effects that consists only of the following paragraph:

> The Department of Health and Human Services and the International Agency for Research on Cancer have classified EtO as a known human carcinogen. The EPA has concluded that EtO is carcinogenic to humans by the inhalation route of exposure. Evidence in humans indicates that exposure to EtO increases the risk of lymphoid cancer (including non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia) and, for females, breast cancer. Noncancer health endpoints affected by chronic exposure to EtO include irritation of the eyes, skin, nose, throat, and lungs, and damage to the brain and nervous system. There is also some evidence linking EtO exposure to reproductive and developmental effects. EtO is a mutagen, meaning it acts directly on DNA and causes chromosome damage. Children may be particularly susceptible to the harmful effects of mutagenic substances.

Id. at 10–11 (citations omitted).

EPA's claim that it lacks the methodology or data to quantify health impacts is belied by the agency's own 2024 Rule RIA, which contained extensive quantitative risk analyses—including analyses of health risks remaining after application of only 112(d) standards—that the agency could have drawn upon to estimate the harms of rescinding protections from the 2024

[237] *See, e.g.*, Peter H. Howard et al., *U.S. Benefit-Cost Analysis Requires Revision*, 380 Science 803 (2023), https://pubmed.ncbi.nlm.nih.gov/37228186/.

Rule. The 2024 Rule RIA modeled cancer risk for each census block within 50 km of every commercial sterilization facility and found that, under baseline conditions (*i.e.*, without the 2024 Rule's protections), the maximum individual lifetime cancer risk was 6,000-in-1 million based on actual emissions and 8,000-in-1 million based on allowable emissions. 2024 RRA, EPA-HQ-OAR-2019-0178-1576, at 6. After application of the 112(f) standards in the 2024 Rule, maximum individual risk from the source category would be reduced to100-in-1 million. *Id.* But after application of only 112(d) standards, maximum individual lifetime cancer risk would still be 5,000-in-1 million based on actual emissions and 6,000-in-1 million based on allowable emissions. *Id.*

EPA further found that under baseline conditions, approximately 8.5 million people were exposed to cancer risks greater than or equal to 1-in-1 million from facility emissions, and approximately 19,000 people were exposed to cancer risks exceeding 100-in-1 million—the threshold EPA itself considers unacceptable. *Id.* With the 2024 Rule's section 112(f) standards, the population exposed to unacceptable cancer risks above 100-in-1 million from 19,000 people to zero. *Id*. But after application of only 112(d) standards, 4.2 million people would still be exposed to cancer risks greater than or equal to 1-in-1 million, and 3,900 people would still be exposed to cancer risks greater than 100-in-1 million. *Id.*

EPA found that with the 112(f) standards, cancer incidence would be reduced to 0.1 cases per year, or 1 case every 10 years. *Id.* But after application of only 112(d) standards, cancer incidence would remain at 0.4 cases a year caused by actual emissions, or 1 case every 2.5 years—a four-fold increase. *Id.*

The Proposed Rule would reverse the gains achieved by the section 112(f) standards. The Proposed Rule would likely cause even more harm due to greater fugitive emissions where facilities do not install PTE, inaccurate compliance demonstrations where facilities do not use EtO CEMS, and weaker standards for new ARVs. Yet EPA's current RIA contains none of this quantitative analysis and makes no attempt to estimate how many additional cancer cases or health impacts and related costs will result from rescinding the risk-based standards.

EPA's approach is contrary to well-established principles of rational agency decisionmaking. Uncertainty is not a sufficient reason to refuse to monetize health effects in regulatory decisionmaking. *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198–1203 (9th Cir. 2008). Even where there is some uncertainty in the proper valuation of health damages, "the value of [emissions] reduction is certainly not zero." *Id.* at 1200. Federal courts have repeatedly recognized that rational agency analysis requires making predictive judgments under uncertain conditions because "[r]egulators by nature work under conditions of serious uncertainty" and "are often called upon to confront difficult administrative problems armed with imperfect data." *Pub. Citizen*,374 F.3d at 1221. The "proper response" to uncertainty is "for the [agency] to do the best it can with the data it has," not to willfully ignore available information. *Mont. Wilderness Ass'n v. McAllister*, 666 F.3d 549, 559 (9th Cir. 2011).

EPA's own Guidelines for Preparing Economic Analyses recognize that "[u]ncertainty is inherent in" regulatory analysis, and that "[t]reatment of uncertainty is an essential component of

analysis" to "present useful conclusions to inform policy decisions."[238] OMB's Circular A-4 likewise directs that "[a]n effect of a regulation should not be excluded from a regulatory analysis simply because its estimation is highly uncertain" because "even for highly uncertain effects, it is often possible to use available evidence to produce estimates of those effects for inclusion in a regulatory analysis that are more accurate than assuming uncertain effects do not occur or have no benefits or costs." Circular A-4 at 67 (attached).

The failure to quantify and monetize the health benefits of EtO reductions is particularly egregious here, where the health effects of EtO are well-documented. As EPA itself acknowledges, the Department of Health and Human Services and the International Agency for Research on Cancer have classified EtO as a known human carcinogen. 2026 RIA at 10. EPA has concluded that EtO is carcinogenic to humans by the inhalation route of exposure, with evidence indicating that exposure to EtO increases the risk of lymphoid cancer and, for females, breast cancer. *Id.* EtO is a mutagen, meaning it acts directly on DNA and causes chromosome damage, and children may be particularly susceptible to the harmful effects of mutagenic substances. *Id.* at 10–11. By treating these well-established health effects as mere "non-monetized disbenefits," EPA has effectively excluded them from the cost-benefit analysis, rendering the analysis one-sided and arbitrary. *Id.* at 14.

The RIA's barebones "qualitative discussion" (at 10–11) of the benefits of EtO reductions and the RIA's purported analysis (at 14) of those qualitative benefits do not fill the gap. EPA generically recites the human health harms from EtO, but arbitrarily nowhere explains how it weighs those qualitative benefits against the costs it chose to monetize. EPA's proposal is also arbitrary for failing to address the quantified health benefits it found in the 2024 residual risk assessment. *Fox*, 556 U.S. at 515.

D. EPA's Consideration of Health Benefits of the 2024 Rule Is Fatally Flawed.

EPA has arbitrarily minimized the health benefits of the pollution reductions the 2024 Rule would achieve. The Proposed Rule's treatment of health benefits is utterly deficient. EPA did not even attempt the rudimentary step of inverting the positive health benefit estimates from the 2024 Rule. *See* 2024 RIA, EPA-HQ-OAR-2019-0178-1557, at 4-4. Instead, it merely acknowledges that "[n]on-monetized health disbenefits are expected under this proposed reconsideration from estimated increases of 7.8 tons of EtO annually relative to the 2024 Final Rule," 91 Fed. Reg. at 12734, and provides only "a qualitative discussion of the health effects associated with EtO exposure," 2026 RIA at 10.

This approach fails to meet the basic requirements of reasoned decisionmaking. The 2024 Rule RIA was a comprehensive 100-page document detailing the financial, public health, emissions, and environmental justice impacts of the standards. The 2024 Rule RIA included a detailed cancer risk analysis estimating maximum individual risk, population exposure at multiple risk thresholds, and cancer incidence under both baseline and post-control scenarios for all 88 modeled facilities. 2024 RIA, EPA-HQ-OAR-2019-0178-1557, at 4-3 to 4-5. It also

[238] EPA, *Guidelines for Preparing Economic Analyses* 5-29 (3d ed. 2024) (attached), https://www.epa.gov/system/files/documents/2024-12/guidelines-for-preparing-economic-analyses_final_508-compliant_compressed.pdf.

included a comprehensive environmental justice analysis evaluating the demographics of populations within 10 km of facilities at each risk tier, finding that 17.3 million people live within 10 km of commercial sterilization facilities, and that African Americans and people living below the poverty level were disproportionately represented near the highest-risk facilities. *Id.* at 4-8 to 4-14. In contrast, EPA's RIA for the Proposed Rule does not conduct any new modeling or analysis of the health consequences of rescinding the risk-based standards—it contains no risk assessment, no population exposure analysis, and no environmental justice analysis whatsoever. EPA has effectively placed its thumb on the scale by estimating cost savings to industry—$630 million at a 3% discount rate—while refusing to quantify or meaningfully weigh the health costs to communities. 2026 RIA at 4. The asymmetry is stark: The 2026 RIA devotes fourteen of its sixteen pages to detailing industry cost savings across multiple tables, while dismissing the health consequences of 7.8 additional tons per year of a known human carcinogen in a one-paragraph qualitative summary reproduced above. 2026 RIA at 10–11.

OMB's Circular A-4 has recognized that when all of the benefits of a regulation are not quantified or monetized, "the policy that most enhances social welfare will not necessarily be the one with the largest quantified and monetized net-benefit estimate." OMB, Circular A-4 at 44. EPA's decision to present only monetized cost savings of the Proposed Rule while minimizing profound health harms as unquantifiable "disbenefits" is misleading and "fail[s] to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. The only reasonable conclusion from the RIA as constructed is that EPA listed categories of non-monetized lost benefits but did not actually assign them any weight in its overall analysis of the costs and benefits of the Proposed Rule.

E. EPA Fails to Address the Number of People Who Live Near Commercial Sterilization Facilities or Who Will Be Exposed to Additional Cancer Risk Due to the Proposed Rule.

Perhaps the most striking deficiency in the RIA is EPA's complete failure to analyze or even acknowledge the number of people who will be exposed to additional cancer risk as a result of the Proposed Rule. As the Coalition documented in its 2023 comments on the 2023 Proposed Rule, more than 13 million people nationwide live within five miles of a commercial sterilization facility, and more than 10,000 schools and childcare centers are within those same areas.[239]

The communities surrounding these facilities face cancer risks from air toxics that are nearly three times the national average—approximately 60 additional cancer cases per one million people, compared to the national average of 20.[240] EtO emissions contribute to roughly one-third of the total cancer risk in the census tracts where these facilities are located, representing a significant portion of cancer risk among 138 air toxics included in EPA's AirToxScreen.[241] These are not abstract figures. Fifteen facilities are located in census tracts with

[239] Comments of Environmental and Community Groups on the 2023 Proposed Rule, EPA-HQ-OAR-2019-0178-0634, App. B at 2 (citing Union of Concerned Scientists, Invisible Threat, Inequitable Impact: Communities Impacted by Cancer-Causing Ethylene Oxide Pollution (Feb. 2023)).
[240] *Id.*
[241] *Id.*

a total air toxics cancer risk of at least 100 per one million—EPA's own threshold for acceptable risk.[242]

Yet EPA's RIA for the Proposed Rule contains no analysis whatsoever of how many people currently live near commercial sterilization facilities, how many will be exposed to increased EtO emissions as a result of rescinding the risk-based standards, or how cancer risks for these communities will change. The RIA acknowledges that the Proposed Rule will result in 7.8 additional tons per year of EtO emissions but provides no assessment of where those emissions will occur, who will be exposed, or what the resulting health consequences will be. 2026 RIA at 4. This stands in stark contrast to the 2024 Rule RIA, which found that 115 million people live within 50 km of the 88 modeled commercial sterilization facilities, that 8.5 million of those people faced cancer risks of 1-in-1 million or greater from facility emissions under the baseline, and that 19,000 people faced cancer risks exceeding the 100-in-1 million threshold EPA considers unacceptable. 2024 Rule RIA, EPA-HQ-OAR-2019-0178-1557, at 1-14. The 2024 Rule RIA further demonstrated that the 2024 Rule would reduce the number of people exposed to unacceptable risks above 100-in-1 million from 19,000 to zero and would cut total cancer incidence by 80 to 90 percent. *Id.* at 1-14, 4-4 to 4-5. Yet the Proposed Rule's RIA makes no effort to estimate how many of these individuals will once again face elevated cancer risk, or how many additional cancer cases will result, once the risk-based standards are rescinded.

EPA's 2024 residual risk assessment found a cancer risk of 6000-in-1 million from actual emissions, or 8000-in-1 million for allowed emissions—or 60 to 80 times EPA's own 100-in-one-million benchmark. 2024 RRA, EPA-HQ-OAR-2019-0178-1576, at 6. EPA additionally found that breathing pollution from these sources is causing approximately eight additional cases of cancer every year, with this pollution and risk falling disproportionately on communities of color and low-income communities. *Id.*; 2024 RIA, EPA-HQ-OAR-2019-0178-1557, at 4-10 tbl. 4-4. By rescinding the risk-based standards that were designed to address these unacceptable risks, the Proposed Rule will leave millions of people exposed to elevated cancer risk—and EPA has not even attempted to quantify the magnitude of harm.

EPA's failure to conduct an environmental justice analysis as part of the Proposed Rule's RIA further underscores the inadequacy of the agency's approach. The 2024 Rule RIA included a detailed environmental justice analysis that found stark racial disparities in proximity to commercial sterilization facilities. 2024 Rule RIA, EPA-HQ-OAR-2019-0178-1557, at 4-6 to 4-15. As some Commenters discussed in prior comments, a 2023 analysis by Union of Concerned Scientists found that for nearly 60 percent of commercial sterilization facilities, the proportion of people of color within five miles was greater than the average proportion of people of color in the counties in which the facilities are located.[243] The 2024 Rule RIA's own risk-based demographic analysis found that, under baseline conditions, African Americans constituted 43 percent of the population living within 10 km of facilities with cancer risks at or above 50-in-1 million—more than three times the nationwide African American population share of 12 percent—and that 25 percent of the population facing cancer risks above 100-in-1 million lived below the poverty level, compared to 13 percent nationwide. 2024 RIA, EPA-HQ-OAR-2019-

[242] *Id.*

[243] Comments of Environmental and Community Groups on 2023 Proposed Rule, EPA-HQ-OAR-2019-0178-0634, at 9.

0178-1557, at 4-10 tbl. 4-4. The 2024 Rule RIA further demonstrated that implementing the risk-based standards would reduce the population exposed to cancer risks above 100-in-1 million to zero and dramatically reduce disproportionate impacts on African Americans at the 50-in-1 million risk tier. *Id.* at 4-13 to 4-14. By rescinding those very standards without conducting any environmental justice analysis, EPA ignores the reality that the Proposed Rule will restore the baseline conditions of disproportionate harm that the 2024 Rule was specifically designed to remedy. Research suggests that failing to address the historic disparities in addressing ethylene oxide risks and harms may further exacerbate exposure disparities in overburdened communities.[244]

The Proposed Rule's RIA is arbitrary and capricious because EPA "fail[s] to consider an important aspect of the problem"—namely, the health and welfare of the millions of people who live near commercial sterilization facilities and who will bear the consequences of increased EtO emissions. *State Farm*, 463 U.S. at 43. The Clean Air Act is unequivocal: EPA must protect the health of "the individual most exposed" to hazardous air pollutant emissions. 42 U.S.C. § 7412(f)(2)(A). An RIA that ignores the very people the statute is designed to protect cannot support reasoned decisionmaking.

XIII. EPA Must Require Title V Permits.

In the 2024 Rule, EPA arbitrarily exempted commercial sterilization facilities from Title V requirements. 89 Fed. Reg. at 22851; *see* Petrs.' Op. Br. at 12–22, *Cal. Communities Against Toxics v. EPA* (D.C. Cir. No. 24-1179), Doc. No. 2102450. EPA's continued exemption of commercial sterilization facilities from Title V requirements is even more arbitrary and capricious in light of EPA's proposed rescissions in this rulemaking.

Congress created the Title V permitting program "so that the public might 'better determine the requirements to which [a] source is subject, and whether the source is meeting those requirements.'" *U.S. Sugar Corp.*, 830 F.3d at 597 (quoting S. Rep. No. 101-228, at 347 (1989)). Title V permits must set forth information including "monitoring, compliance certification, and reporting requirements to assure compliance" with emission limits. 42 U.S.C. § 7661c(c). EPA may exempt some or all of an area source category from Title V only if it "finds that compliance with such requirements is impracticable, infeasible, or unnecessarily burdensome." *Id.* § 7661a(a).

In deciding whether to exempt area sources from Title V permitting, EPA employs a four-factor balancing test: "(1) Whether title V would result in significant improvements to the compliance requirements …; (2) whether title V permitting would impose significant burdens on the area source category …; (3) whether the costs of title V permitting for area sources would be justified taking into consideration any potential gains in compliance likely to occur for such sources; and (4) whether adequate oversight by state and local permitting authorities could achieve high compliance with the NESHAP." 88 Fed. Reg. at 22850. EPA must also consider

[244] *See* A. Wood & M. Howarth, *How Federal and State Regulatory Systems Perpetuate Environmental Injustice in the United States: Industrial Ethylene Oxide Emissions as Case Study*, 16 Envtl. Just. 297 (2023); J. C. Gross et al., *Evaluating the Justice and Risk Dimensions of Ethylene Oxide Governance in the U.S.*, 75 Envtl. Just. 730 (2025).

whether the exemption is consistent with the Clean Air Act's legislative history, which "suggests that EPA should not grant exemptions where doing so would adversely affect public health, welfare, or the environment." *Id.*

As explained in Section V of these comments, EPA's proposal to rescind the CEMS requirement would significantly reduce the accuracy of compliance demonstrations because parametric monitoring does not accurately reflect emission control rates. *See* Sahu Expert Report, Attachment A, at 7–10. Title V permit requirements ensure sufficient monitoring requirements to verify compliance with emission limits. *See* 42 U.S.C. § 7661c(c). And the record shows that the costs of obtaining a Title V permit is modest: 391 labor hours and $67,211 in total costs for the first year of compliance, and 43 labor hours and $6,287 in total costs for the second and third years of compliance. 88 Fed. Reg. at 22851 (also noting that the labor hours estimate is likely an overestimate).

In light of EPA's proposed rescissions of significant portions of the 2024 Rule, including the section 112(f) requirements and the CEMS and PTE requirements, the Title V exemption factors weigh even more heavily toward requiring commercial sterilization facilities—over half of which use EtO in quantities that would normally qualify them as major sources—to obtain Title V permits. *See* 89 Fed. Reg. at 24093 n.10. Title V permits would result in improvements to compliance and would not impose significant burdens on the source category; the costs would be justified by compliance gains, and oversight from state and local agencies is not adequate to achieve high compliance because it cannot make up for the inherent inadequacies of allowing unreliable compliance assurance using parametric monitoring under the standards. Thus, EPA must require commercial sterilization facilities to have Title V permits.

XIV. EPA Arbitrarily Fails to Disclose the Extent to Which the Proposal is Based on The Directives of Executive Orders 14192 and 14303, Which Cannot Justify It.

EPA's proposed repeal of the 2024 Rule runs contrary to the requirements governing administrative decisionmaking in its passing references to EO 14192, "Unleashing Prosperity Through Deregulation," 90 Fed. Reg. 9065 (Feb. 6, 2025). EPA fails to provide reasoned explanations of its reliance on and consideration of the EO's directives in this rulemaking. Further, some directives in EO 14192 contradict the Clean Air Act's statutory requirements, making the lack of reasoned discussion of the EPA's reliance on them particularly problematic. The EPA cannot rely on this EO to justify its proposal because the Clean Air Act's requirements cannot be overridden by ideological concerns regarding overregulation. Additionally, assuming that EPA followed EO 14303, "Restoring Gold Standard Science," Exec. Order No. 14303, 90 Fed. Reg. 22601 (May 29, 2025), it must explain how the EO influenced its review of the data and analyses underlying the 2024 Rule and how its consideration of EO14303 is in accord with the CAA's statutory requirements. The standards set forth in the EO cannot be used to bypass existing procedures in the statute or dictate an ideological outcome.

A. EPA Cannot Rely on Executive Order 14192, "Unleashing Prosperity Through Deregulation," Because CAA Requirements Cannot be Overridden by Ideological Concerns Regarding Overregulation.

Executive Order 14192 is concerned with a purported "ever-expanding morass of complicated Federal regulation impos[ing] massive costs on the lives of millions of Americans, creat[ing] a substantial restraint on our economic growth and ability to build and innovate, and hamper[ing] our global competitiveness." Exec. Order No. 14192, 90 Fed. Reg. at 9065. Because of this, it requires "an executive department or agency" to "identify at least 10 existing regulations to be repealed" when it "proposes for notice and comment or otherwise promulgates a new regulation." *Id.* The goal of the EO is for the "total incremental cost of all regulations … [to] be significantly less than zero." *Id.*

The extent of EPA's discussion of this EO in the proposed repeal of the 2024 Rule is: "This action is expected to be an Executive Order 14192 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in EPA's analysis of the potential costs and benefits associated with this action." 91 Fed. Reg. at 12735.

EPA's discussion of its reliance on this EO does not meet the requirements of the Clean Air Act. EPA fails to explain how the EO's directives are weighed against the substantive requirements of the CAA or are in accordance with the law. As a result, the influence of the EO on the proposed repeal is unclear to the interested public, obscuring what should be a transparent process. EPA must explain how it relied on or carried out the mandates of the EO in drafting the proposed rule. EPA must also provide an explanation of any other EOs it might have relied on but not cited.

To the extent EPA relied on the EO's directives, it must withdraw the proposal because these directives are contrary to the Clean Air Act, and executive orders cannot supersede statutory authority. EPA cannot use executive branch policies to overcome statutory requirements. *Cf. Chamber of Com. v. Reich*, 74 F.3d 1322, 1332 (D.C. Cir. 1996). To start, nothing in the CAA allows for the rescission of standards because the Executive Branch believes there are too many regulations. CAA emissions standards cannot be revoked or revised based on an arbitrary "ten for every one" policy. The EPA also fails to note what new regulation it promulgated that required it to review ten other regulations or if this action was done in accordance with the EO policy.

Next, while EPA must consider the "cost of achieving" the "maximum degree of reduction in emissions," the CAA does not permit consideration of overarching regulatory cost across the portfolio of EPA's regulations.[245] This would be contrary to the purpose of the CAA, 42 U.S.C. § 7401, and the plain text of section 112 that enumerates specific factors for EPA to consider, and does not anticipate or allow for such arbitrary consideration of cumulative regulatory costs. *See* 42 U.S.C. § 7412(d)(6). Moreover, there is no place for acontextual concern about how "complicated" a regulation may be under the CAA without corresponding consideration of the benefits achieved, including benefits to public and environmental health. In sum, if EPA relied on this EO for the proposed repeal, it must withdraw its proposal.

[245] *See* 42 U.S.C. § 7412(d)(2) ("Emissions standards promulgated under this subsection…shall require the maximum degree of reduction in emissions…that the Administrator, taking into consideration the cost of achieving *such emission reduction* … determines is achievable.") (emphasis added).

B. EPA's Apparent Reliance on Executive Order 14303, "Restoring Gold Standard Science," is Improper.

EO 14303, "Restoring Gold Standard Science," sets forth standards for agency scientific analysis. Exec. Order No. 14303, 90 Fed. Reg. 22601 (May 29, 2025). This EO is not cited or referred to by the EPA in the Proposed Rule. Due to its binding nature, however, we assume EPA implemented its directives in issuing this proposal. If the EPA requested a waiver pursuant to section 8 of the EO, then it must disclose this request and include the waiver on the docket for public review. If the EPA did not request a waiver and was therefore mandated to follow the EO's directives, it must explain how it implemented those directives.

Therefore, assuming the EPA followed this EO, it must explain how the EO influenced its review of the data and analyses underlying the 2024 Rule and how it re-evaluated those data. Specifically, it must explain how it is in accord with statutory requirements. The CAA already has robust standards and systems to ensure that reviews and emission limits are set based on the latest, peer-reviewed science.[246] For decades, the CAA has set its own "gold standard science," with expert oversight, peer-review processes, and robust research. *See* 42 U.S.C. § 7403. The standards set forth in the EO cannot be used to bypass existing procedures in the statute or dictate an ideological outcome. Also, if the EPA is following this EO, it is unclear how it can meet its "gold standard" requirements when it is laying off most of its research and science staff.[247] In sum, if the EPA used the EO to justify any changes to the 2024 Rule, it is not in accordance with the law.

Accordingly, the EOs that EPA bases this action on contradict the CAA in multiple ways. EPA improperly obscures this from the public by failing to discuss the role these EOs played in this proposal. Relying on the directives of EOs that contravene the plain text of the CAA is improper and not in accordance with the law. As such, EPA must withdraw this proposed repeal.

XV. EPA Must Withdraw the Proposal Because Its Basis is Pretextual.

This Administration has made several public statements and announcements in the lead up to this proposal that—in addition to the contents of the proposal itself—suggest that EPA's proffered justification for the Proposed Rule is pretextual and does not communicate the Administration's actual basis for this action. First, for all the reasons already explained, EPA's justifications for the Proposed Rule are arbitrary, capricious, and fails to draw logical conclusions from the record before the agency. Taken against President Trump's clearly stated agenda to deregulate no matter the consequences[248] and EPA Deputy Administrator Fotouhi's

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[246] *The Clean Air Act: Solving Air Pollution Problems with Science and Technology*, U.S. EPA (Feb. 17, 2026), https://www.epa.gov/clean-air-act-overview/clean-air-act-solving-air-pollution-problems-science-and-technology.

[247] Matthew Daly, *EPA Eliminates Research and Development Office, Begins Layoffs*, AP News (July 19, 2025), https://apnews.com/article/epa-zeldin-trump-reorganization-science-research-acf0ad3a649f940e138b2a917169405f.

[248] EPA, Press Release, *EPA Launches Biggest Deregulatory Action in the U.S. History* (March 12, 2025), https://www.epa.gov/newsreleases/epa-launches-biggest-deregulatory-action-us-history.

direction to dismantle the IRIS program[249], the strong implication is that the decision to repeal the standards preceded the invention of the justifications for their repeal that EPA provides in the proposal. Because EPA fails to "offer genuine justifications for [the] important decisions" proposed, and rather provides only "contrived" reasoning, the Proposed Rule cannot be finalized. *Dep't of Com. v. New York*, 588 U.S. 752, 785 (2019).

On March 12, 2025, a mere 52 days after President Trump's inauguration, EPA Administrator Lee Zeldin announced that "the agency will undertake 31 historic actions in the greatest and most consequential day of deregulation in U.S. history, to advance President Trump's Day One executive orders and Power the Great American Comeback."[250] While every administration will have its own agenda and policy priorities that it will seek to implement, a policy priority to "deregulate" for the sake of deregulation—with no consideration of the benefits of a regulation, statutory purposes and requirements, or public health and welfare needs—cannot sustain action under the Clean Air Act. And the Administration has otherwise failed to lawfully justify this proposal. The speed with which this proposal was issued and the fact that no new analysis or fact-finding supports it undermines the credibility of EPA's assertion that it is necessary for the supply chain. The more accurate conclusion under these circumstances is that the proposal is based purely on the deregulatory policy priorities of the Administration.

EPA does not appear to have considered any alternatives to this proposal, which further suggests that EPA was not earnestly addressing problems with cost effectiveness and achievability of the standard as it claims, but fully and solely focused on repealing the 2024 Rule. As we explain above, there are options other than a full repeal of the 2024 Rule that could reduce costs and technological requirements but that are still more stringent than the 2006 standards.

For the reasons explained above, none of President Trump's executive orders and the policies they enshrine, which arbitrarily favor deregulation with no holistic consideration of the benefits of regulatory action or the purposes of the Clean Air Act, provide a proper basis for rescinding the 2024 Rule. The Agency has not properly explained or justified the Proposed Rule, and purely pretextual reasoning cannot support agency rulemaking. Therefore EPA must withdraw the Proposal.

CONCLUSION

EPA should withdraw the Proposed Rule.

[249] *See* Fotouhi IRIS Memo (Apr. 27, 2026) (attached).
[250] EPA, Press Release, *EPA Launches Biggest Deregulatory Action in the U.S. History* (March 12, 2025), https://www.epa.gov/newsreleases/epa-launches-biggest-deregulatory-action-us-history.

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MASTER INDEX

Environmental and Public Health Organizations' Sterilizers Rollback Comment Attachments

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

Attachment A: Ron Sahu Expert Report

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