

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CALIFORNIA COMMUNITIES AGAINST
TOXICS
P.O. Box 845
Rosamond, CA 93560

CLEAN POWER LAKE COUNTY
347 Douglas Ave.
Waukegan, IL 60085

RIO GRANDE INTERNATIONAL STUDY
CENTER
1 West End Washing St., Bldg. P-11
Laredo, TX 78040

SIERRA CLUB
2101 Webster St., Suite 1300
Oakland, CA 94612

UNION OF CONCERNED SCIENTISTS
Two Brattle Square
Cambridge, MA 02138,

Plaintiffs,

v.

MICHAEL S. REGAN, in his official capacity
as Administrator, United States Environmental
Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460,

Defendant.

Civil Action No. 1:22-cv-3724

**COMPLAINT FOR
DECLARATORY AND
INJUNCTIVE RELIEF**

INTRODUCTION

1. This is a suit to compel the Administrator of the U.S. Environmental Protection Agency (“EPA”) to take actions required by the Clean Air Act (“Act”) to protect the public from ethylene oxide emitted from commercial sterilizer facilities. *See* 42 U.S.C. §§ 7401-7671. Under the Clean Air Act, EPA is required limit air emissions of cancer-causing pollutants, like ethylene

oxide, by promulgating National Emission Standards for Hazardous Air Pollutants (“NESHAP” or “air toxics standards”). *Id.* § 7412(d). Furthermore, EPA must “review, and revise as necessary” these standards “no less often than every 8 years.” *Id.* § 7412(d)(6).

2. EPA first issued air toxics standards for commercial sterilizers in 1994. *National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations*, 59 Fed. Reg. 62,585 (Dec. 6, 1994). Despite EPA’s duty to review and revise the section 112(d) standards no less often than every 8 years, EPA did not issue another rule until 2006. *Ethylene Oxide Emissions Standards for Sterilization Facilities*, 67 Fed. Reg. 17,712 (April 7, 2006).

3. More than 16 years have passed since EPA last reviewed and revised its emission standards for commercial sterilizers.

4. For the past 8 years, EPA has been in ongoing violation of the Clean Air Act. 42 U.S.C. § 7412(d)(6).

5. EPA’s failure to review and revise the air toxics standards for commercial sterilizers has caused and is continuing to cause harm to Plaintiffs’ members who live, work, and recreate near commercial sterilizers. EPA’s violation of the Act has left emission standards in place for more than 8 years without review or revision, exposing Plaintiffs’ members to hazardous air pollution from insufficiently regulated commercial sterilizers.

6. To remedy EPA’s failure to comply with its statutory obligation, Plaintiffs seek declaratory and injunctive relief compelling EPA to review and, as necessary, revise the air toxic standards for the commercial sterilizer source category as expeditiously as possible.

JURISDICTION AND VENUE

7. This action arises under the Clean Air Act, 42 U.S.C. § 7412(d)(6).

8. This Court has jurisdiction pursuant to 42 U.S.C. § 7604(a) and 28 U.S.C. §§ 1331 and 1361.

9. This Court may grant the relief Plaintiffs request pursuant to 42 U.S.C. § 7604(a)(2) and 28 U.S.C. §§ 2201(a), 2202, and 1361. Plaintiffs have a right to bring this action pursuant to the Clean Air Act, 42 U.S.C. § 7604(a)(2); 28 U.S.C. § 1361.

10. Plaintiffs provided the Administrator with written notice of this action on September 20, 2022, as required by the Clean Air Act, 42 U.S.C. § 7604(b)(2), and 40 C.F.R. Part 54. As sixty days have passed since these submissions, Plaintiffs have satisfied the notice requirements in 42 U.S.C. § 7604(b)(2).

11. Venue is proper in this Court under 28 U.S.C. § 1391(e) because the Defendant, EPA Administrator Michael S. Regan, resides in this district.

PARTIES

12. Plaintiff California Communities Against Toxics (“CCAT”) is a nonprofit organization headquartered in Rosamond, California. CCAT is an environmental justice network of member groups that advocates for environmental justice and protection from toxic air pollution in the State of California and nationally. Through public education, advocacy, and community organizing, CCAT aims to reduce individuals’ exposure to pollution, to expand knowledge about the effects of toxic chemicals on human health and the environment, and to protect the most vulnerable people from harm.

13. Plaintiff Clean Power Lake County (“CPLC”) is a nonprofit organization headquartered in Highland Park, Illinois. CPLC is a community-driven coalition committed to

local action to secure environmental, economic, and racial justice. CPLC's mission is to ensure clean air, clean water, and healthy soil for every Lake County community member and to achieve the self-determination of those disproportionately impacted by environmental pollution.

14. Plaintiff Rio Grande International Study Center ("RGISC," pronounced "risk"), is a chartered nonprofit organization headquartered in Laredo, Texas, and founded in January 1994. RGISC is a frontline environmental advocacy group dedicated to using science, data, people power, and creative actions to preserve and protect the Rio Grande-Rio Bravo watershed, local ecosystems, and its people. RGISC pushes for a positive vision of our South Texas border region via research, public awareness campaigns, grassroots building, signature community events, and advocacy for local ordinances and policy making.

15. Plaintiff Sierra Club is a nonprofit corporation with its headquarters located in Oakland, California. Sierra Club is a national membership organization dedicated to the protection of public health and the environment, including clean air, with chapters in Arizona, California, Colorado, Georgia, Maryland, Michigan, Missouri, Ohio, Pennsylvania, Texas, Utah, Wisconsin, and other states, and with more than 800,000 members who reside in all 50 states, the District of Columbia, and U.S. territories.

16. Plaintiff The Union of Concerned Scientists ("UCS") is a national nonprofit organization founded in 1969 by scientists at the Massachusetts Institute of Technology. UCS's headquarters are located in Cambridge, Massachusetts, with offices in Washington, DC; Oakland, California; and Chicago, Illinois. UCS's mission is to achieve a healthier planet and a safer world by fostering independent, science-based solutions that improve people's lives. UCS has more than 500,000 members and supporters across the United States, along with 24,000

members of its Science Network, a group of scientists and technical experts across the country who are working to ensure science informs decisions that affect health, safety, and environment.

17. Defendant Michael Regan is the Administrator of the EPA. In that role he is charged with the duty to uphold the Clean Air Act and to implement the required regulatory actions by the relevant statutory deadlines. 42 U.S.C. § 7601.

FACTUAL BACKGROUND: ETHYLENE OXIDE

18. Ethylene oxide is a flammable, colorless, gas. Since the 1940s, ethylene oxide's mutagenetic, or DNA-damaging, properties have been well known to scientists.¹ Because of this quality, ethylene oxide gas is used as one of many methods to sterilize medical equipment.

19. Ethylene oxide is also incredibly toxic to humans. In 2016, EPA's Integrated Risk Information System ("IRIS") program completed a long-awaited evaluation of the inhalation carcinogenicity of ethylene oxide. The evaluation found that based on the weight of the evidence, ethylene oxide is "'carcinogenic to humans' by the inhalation route of exposure."² Based on this conclusion, EPA determined that ethylene oxide is 60 times more toxic than previously understood, with a greater risk posed to children, whose cells divide more frequently than adults.³

¹ EPA, IRIS, Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide, Executive Summary at 5-6 (Dec. 2016), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/1025_summary.pdf.

² *Id.* at 2.

³ EPA established a cancer risk factor for ethylene oxide of 3.0×10^{-3} per $\mu\text{g}/\text{m}^3$ for adult exposure, or 5.0×10^{-3} per $\mu\text{g}/\text{m}^3$ over a lifetime, accounting for increased vulnerability from early-life exposure. *Id.* at 5-6; *see* EPA, Frequent Questions about Ethylene Oxide (EtO), <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/frequent-questions-about-ethylene-oxide-eto>.

20. In 2018, EPA’s air office applied the new IRIS risk value to the 2014 National Emissions Inventory to better understand the risks posed by ethylene oxide to communities. This study—known as the 2014 National Air Toxics Assessment—found that ethylene oxide contributed to a cancer risk equal to or greater than 100-in-one million, EPA’s benchmark for “unacceptable risk,” in 58 census tracts across the United States. These “high risk” areas include census tracts where commercial sterilizers are located and where Plaintiffs’ members live, work, and recreate.

21. Despite this information, EPA has failed to update its air toxics emission standards for commercial sterilizers as the Clean Air Act requires. In 2019, EPA’s own National Environmental Justice Advisory Council—in response to public input from members of communities affected by ethylene oxide emissions—urged EPA to prioritize the regulation of ethylene oxide air emissions and to meaningfully involve affected communities in the regulatory process.

22. In 2021, EPA’s Office of the Inspector General (“OIG”) urged 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.”⁴ The OIG’s report noted that “[i]n the absence of updated reviews for the applicable source categories, the Agency cannot provide assurance that its current NESHAPs are protective” of public health.⁵

⁴ 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 (May 6, 2021), https://www.epa.gov/sites/default/files/2021-05/documents/epaoig_20210506-21-p-0129.pdf.

⁵ *Id.* at 21.

STATUTORY AND REGULATORY BACKGROUND

23. 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)(1). One “primary goal” of the statute is “pollution prevention.” *Id.* § 7401(c).

24. As part of its duty to implement the Clean Air Act, Congress tasked EPA with regulating emissions from a list of hazardous air pollutants, including ethylene oxide. 42 U.S.C. § 7412. To effectuate that goal, Congress first tasked EPA with creating a list of “all categories and subcategories” of all sources of air pollutants from Congress’s initial list of hazardous air pollutants. 42 U.S.C. § 7412(c)(1). Based on this list of categories, Congress tasked EPA with establishing emission standards that require “the maximum degree of reduction in emissions of the hazardous air pollutants” for new and existing sources that is “achievable.” 42 U.S.C. § 7412(c)(2), (d)(2).

25. But EPA’s duty to protect the public health from hazardous air pollutants does not end after it sets an initial set of emission standards. The Clean Air Act directs EPA to “review, and revise as necessary (taking into account developments in practices, processes, and control technologies), emission standards [for each source category] ... every 8 years.” 42 U.S.C. § 7412(d)(6). In this rulemaking, EPA must make all revisions “necessary” to bring standards into full compliance with the Clean Air Act, including: (1) setting limits on uncontrolled hazardous air pollutant emissions, *see Louisiana Env’tl. Action Network (LEAN) v. EPA*, 955 F.3d 1088, 1096 (D.C. Cir. 2020); and (2) removing illegal exemptions and loopholes for emissions during startup, shutdown, and malfunction periods. *See, e.g., Sierra Club v. EPA*, 551 F.3d 1019, 1028 (D.C. Cir. 2008); *NRDC v. EPA*, 749 F.3d 1055, 1062-64 (D.C. Cir. 2014). Thus, every 8 years,

the Administrator must review emissions standards and promulgate either a revision of the standards or a determination that no revision is “necessary.” 42 U.S.C. § 7412(d)(6)

ALLEGATIONS: EPA’S FAILURE TO TIMELY REVIEW (AND REVISE AS NECESSARY) THE COMMERCIAL STERILIZER RULE

26. Here, EPA promulgated its first set of emission standards for commercial sterilizers in 1994. 59 Fed. Reg. 62,585. Among other requirements, this rule set emission limits for three sections of a commercial sterilization facility: sterilization chamber vents, aeration room vents, and chamber exhaust vents. But in 2001, the agency amended the rule to remove the emission limits for chamber exhaust vents. *Ethylene Oxide Emissions Standards for Sterilization Facilities*, 66 Fed. Reg. 55,577 (Nov. 2, 2001).

27. Since promulgating its first NESHAP for sterilizers in 1994, EPA has not strengthened the emission standards for commercial sterilization facilities.

28. In 2006, EPA completed a risk and technology review of the commercial sterilizer NESHAP and decided “not to revise the Ethylene Oxide Emission Standards for Sterilization Facilities, originally promulgated on December 6, 1994.” 67 Fed. Reg. 17,712.

29. EPA was legally required to complete a new review rulemaking pursuant to section 112(d)(6) no later than April 7, 2014.

30. EPA failed to complete a new review rulemaking by April 7, 2014.

31. An additional review rulemaking, taking into account technological changes since 2014, was due on April 7, 2022.

32. EPA failed to complete this additional review rulemaking by April 7, 2022.

33. Despite issuing an advance notice of proposed rulemaking in 2019, 84 Fed. Reg. 67,889 (Dec. 12, 2019), EPA has yet to issue a proposed or final rule or other final action to fulfill its legal obligation. EPA is in breach of its legal duty to complete a new review rulemaking under the Clean Air Act.

PLAINTIFFS' INJURIES

34. EPA's failure to review, and if necessary, revise commercial sterilizer emission standards, as section 112(d)(6) requires, is harming and will continue to harm Plaintiffs and their members.

35. Commercial sterilizers emit ethylene oxide, which is a highly carcinogenic chemical that also causes damage to the brain and nervous systems.

36. Many of these emissions are fugitive, emitted during the process of sterilizing a product, or after the sterilization process when a product "off-gases" ethylene oxide.

37. EPA currently allows commercial sterilizers to emit fugitive ethylene oxide emissions without implementing pollution controls.

38. Plaintiffs' members live, work, recreate, and engage in a variety of other activities near commercial sterilizers. Plaintiffs' members have no choice but to breathe ethylene oxide emitted by commercial sterilizers.

39. Plaintiffs' members are concerned about the presence of ethylene oxide in the communities where they live, work, recreate, and engage in other activities. As a result of these reasonable concerns about harms stemming from increased exposure to ethylene oxide, Plaintiffs' members' enjoyment of the activities which they previously enjoyed has been significantly diminished. Plaintiffs' members' recreational and aesthetic interests are harmed.

40. The Administrator's failure to take the action for commercial sterilizers required by section 112(d)(6) deprives Plaintiffs' members of the rulemaking and cleaner air that would result from such action. EPA's inaction prolongs and increases Plaintiffs' members' exposure to higher levels of ethylene oxide that harms Plaintiffs' members' health, recreational, and aesthetic interests, as described above. Performing the overdue rulemaking and assuring emissions reductions as required under section 112(d)(6) would avoid and reduce these exposures, and the resulting health, recreational, aesthetic, and other harms suffered by Plaintiffs' members.

41. In its overdue rulemaking, EPA would also have to "tak[e] into account developments in practices, processes, and control technologies," 42 U.S.C. § 7412(d)(6), such as fenceline monitoring and corrective action for fugitive air emissions of ethylene oxide, as well as other developments in pollution controls.

42. EPA would also have to comply with the D.C. Circuit's decision in *LEAN* to set limits on any uncontrolled emissions, like fugitive emissions. 955 F.3d at 1099-100.

43. The Administrator's failure to take the action for commercial sterilizers required by section 112(d)(6) also deprives Plaintiffs and their members of the opportunity to present written comments, data, documentary information, views, and arguments to EPA and have them considered by the agency and responded to as part of the overdue section 112(d)(6) rulemaking. The Administrator's failure to conduct the overdue rulemaking has thus denied Plaintiffs and their members the opportunity to seek greater health protections and emissions reductions and to have EPA consider and respond to such comments in taking the final action required by section 112(d)(6). This deprivation of the opportunity to present comments and arguments and have them considered and addressed by EPA impairs Plaintiffs' and their members' ability to serve and protect their interests and fulfill their organizational missions.

44. The Administrator's failure to take the action for commercial sterilizers required by section 112(d)(6) also deprives Plaintiffs and their members of information, including determinations from the Administrator pursuant to section 112(d)(6) and underlying evidence related to such determinations. Such information includes: the emission limitations existing sources have achieved; the current pollution control methods, practices, and technologies that could be or are being used to achieve emission reductions; the emissions that remain under the existing standards; and other information EPA would consider and make public during the overdue rulemaking that is relevant to the review and need for stronger emission standards. Plaintiffs and their members are entitled to information by law. *See, e.g.*, 42 U.S.C. § 7607(d)(3)-(6) (describing documents that must be made "open to public inspection" as part of section 112 rulemakings).

45. Plaintiffs need this information to advance their organizational purposes, including educating their members and constituents, and working to assure stronger health and environmental protections. Plaintiffs' members need this information to better understand the operations of and dangers posed by commercial sterilizer facilities near their homes, to take self-protective measures to minimize their exposure to ethylene oxide emitted by commercial sterilizers, and to work for stronger health and environmental protections.

46. A court order requiring EPA to promptly review, and if necessary, revise the regulations for commercial sterilizers complained of here, as the law requires, would redress Plaintiffs' and Plaintiffs' members' injuries.

CLAIM FOR RELIEF

47. The allegations of all foregoing paragraphs are incorporated as if set forth fully here.

Violation of Section 112(d)(6) of the Clean Air Act

48. The Administrator's failure to review and revise as necessary the Ethylene Oxide Emissions Standards for Sterilization Facilities category in 40 C.F.R. Part 63, Subpart O, as required by section 112(d)(6) of the Act constitutes a "failure of the Administrator to perform ... [an] act or duty ... which is not discretionary" within the meaning of section 304(a)(2) of the Clean Air Act, 42 U.S.C. § 7604(a)(2).

49. Each day the Administrator fails to take these legally required actions, Defendant commits new, additional, and ongoing violations of the Clean Air Act.

PRAYER FOR RELIEF

Plaintiffs respectfully request that the Court:

(1) Declare that EPA's failure to timely review the National Emission Standards for Hazardous Air Pollutants for commercial sterilizers, 40 C.F.R. Part 63, Subpart O, and either revise those standards as necessary or issue a final determination that such revisions are not necessary, as required by section 112(d)(6) of the Clean Air Act, constitutes a "failure of the Administrator to perform any act or duty under this chapter which is not discretionary with the Administrator" within the meaning of section 304(a)(2) of the Clean Air Act, 42 U.S.C. § 7604(a)(2).

(2) Order the Defendant Administrator to review the National Emission Standards for Hazardous Air Pollutants for commercial sterilizers, 40 C.F.R. Part 63, Subpart O, and either to revise them as necessary or to issue a determination that revision is not necessary, in accordance

with section 112(d)(6) of the Clean Air Act and pursuant to an expeditious deadline set by this Court;

- (3) Retain jurisdiction to ensure compliance with the Court's decree;
- (4) Award Plaintiffs the costs of this action, including attorneys' fees; and,
- (5) Grant such other relief as the Court deems just and proper.

DATED: December 14, 2022

Respectfully Submitted,

/s/ Marvin C. Brown IV

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