



September 20, 2022

Michael S. Regan, Administrator
United States Environmental Protection Agency
Office of the Administrator: Mail Code 1101A
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460
regan.michael@epa.gov

VIA CERTIFIED MAIL, RETURN RECEIPT REQUESTED

RE: Sixty-day notice of intent to file a citizen suit under Section 304 of the Clean Air Act for failure to review, and revise as necessary, the National Emission Standards for Sterilization Facilities, 40 C.F.R. Part 63 Subpart O.

Dear Administrator Regan:

This is a notice of “a failure of the Administrator to perform any act or duty under this chapter which is not discretionary with the Administrator” under section 304 of the Clean Air Act (“the Act”). 42 U.S.C. § 7604(a)(2). Pursuant to 42 U.S.C. § 7604(b)(2) and 40 C.F.R. Part 54, the following organizations give notice of their intent to commence a civil action against you in your official capacity as Administrator of EPA for failing to perform certain nondiscretionary duties under the Clean Air Act:

California Communities Against Toxics P.O. Box 845 Rosamond, CA 93560	Clean Power Lake County 347 Douglas Ave Waukegan, Illinois 60085
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Rio Grande International Study Center 1 West End Washington St. Bldg. P-11 Laredo, TX 78040	Sierra Club 2101 Webster St., Ste. 1300 Oakland, CA 94612
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Union of Concerned Scientists
Two Brattle Square
Cambridge, MA 02138

As further specified below, we intend to sue to compel you to review, and as necessary revise, the emissions standards for commercial sterilizers under section 112(d)(6) of the Clean Air Act.

EPA is eight years overdue in reviewing and revising, as necessary, the emission standards for Sterilization Facilities.

Section 112(d)(6) of the Clean Air Act requires EPA to “review, and revise as necessary (taking into account developments in practices, processes, and control technologies), emission

standards promulgated under [section 112] no less often than every 8 years.” *Id.* § 7412(d)(6).

Ethylene oxide, a flammable, colorless, gas is highly toxic to humans and EPA has long recognized its threat to public health. In 1994, EPA promulgated its first set of emission standards for sterilization facilities. *National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations*, 59 Fed. Reg. 62,585 (Dec. 6, 1994). Among other requirements, this rule set emission limits for three sections of a sterilization facility: sterilization chamber vents, aeration room vents, and chamber exhaust vents. But in 2001, the agency amended the rule to remove the emission requirements for chamber exhaust vents. *Ethylene Oxide Emissions Standards for Sterilization Facilities*, 66 Fed. Reg. 55,577 (Nov. 2, 2001).

Since promulgating its first NESHAP for sterilizers in 1994, EPA has not strengthened the emission standards for sterilization facilities. In 2006, EPA completed a risk and technology review (RTR) of the sterilizer NESHAP and decided to “not revise the Ethylene Oxide Emissions Standards for Sterilization Facilities, originally promulgated on December 6, 1994.” *Ethylene Oxide Emissions Standards for Sterilization Facilities*, 67 Fed. Reg. 17,712 (April 7, 2006).

Under the Clean Air Act, EPA is required to review its technology standards for the NESHAP, no less than every 8 years and “revise as necessary (taking into account developments in practices, processes, and control technologies).” 42 U.S.C. § 7412 (d)(6). EPA was legally required to complete a new review rulemaking pursuant to section 112(d)(6) no later than April 7, 2014. An additional review rulemaking, taking into account technological changes since 2014, was due on April 7, 2022. Despite issuing an advance notice of proposed rulemaking in 2019, 84 Fed. Reg. 67,889, 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.

EPA’s failure to timely review and revise the NESHAP for Sterilization Facilities puts hundreds of frontline communities at risk.

Over the past decade, EPA’s understanding of the risk posed by ethylene oxide has dramatically changed. 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 since the 1940s, the DNA-damaging effects of ethylene oxide, or its mutagenicity, has been well known, an effect that makes the chemical an effective sterilizer. But newer studies also showed that this mutagenic effect increased cancer risks in humans and other mammals, especially lymphoma and breast cancer. Due to the weight of this evidence, IRIS concluded that ethylene oxide is ““carcinogenic to humans’ by the inhalation route of exposure.”¹ 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.² Other authoritative scientific agencies, including the National Toxicology Program,

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 EPA established a cancer risk factor for EtO 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.

International Agency for Research on Cancer, and the Occupational Safety and Health Administration, have also concluded that ethylene oxide is carcinogenic to humans.³

In 2018, EPA released the 2014 National Air Toxics Assessment (NATA), which revealed a severe public health risk posed by commercial sterilizers.⁴ This data showed that across the U.S. were individuals living near commercial sterilizers that emitted dangerously high levels of ethylene oxide—emission levels that resulted in a cancer-risk rate far above EPA’s unacceptable risk benchmark of 100-in-1 million.⁵

Following the release of the 2014 NATA data, many communities began to learn of the danger posed by their local sterilization facility. Despite the urgency that the data should have prompted, EPA has been slow to act. In one area, Willowbrook, Illinois, EPA moved quickly to perform ambient air monitoring and to inform the community of the risks posed by their local sterilization facility.⁶ But for many other communities, EPA failed to even inform residents of the threat posed by ethylene oxide. 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.⁷ By 2020, when EPA still hadn’t informed many communities of the threat posed by ethylene oxide-emitting facilities, EPA’s inspector general issued a management alert to EPA that “prompt action” was needed “to inform residents who live near facilities with significant ethylene oxide emissions about their elevated

Id.; see also, EPA, Frequent Questions about Ethylene Oxide (EtO), <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/frequent-questions-about-ethylene-oxide-eto>.

³ National Toxicology Program, Report on Carcinogens, Fourteenth Addition, Ethylene Oxide (Nov. 3, 2016), <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/ethyleneoxide.pdf>; International Agency for Research on Cancer, IARC Monographs 100F Ethylene Oxide (2012), <https://monographs.iarc.fr/wp-content/uploads/2018/06/mono100F-28.pdf>; Occupational Safety and Health Administration, OSHA Fact Sheet Ethylene Oxide (2002), <https://www.osha.gov/sites/default/files/publications/ethylene-oxide-factsheet.pdf>.

⁴ 2014 National Air Toxics Assessment, <https://www.epa.gov/national-air-toxics-assessment/2014-nata-assessment-results>. EPA’s latest air toxics risk information in the form of AirToxScreen, based on 2018 and released in 2022, similarly shows that despite four years of warning, many of the same sterilizer facilities continue to pose a serious threat to public health, <https://www.epa.gov/AirToxScreen/2018-airtoxscreen-assessment-results>.

⁵ EPA, U.S. EPA’s National Air Toxics Assessment (NATA) and Ethylene Oxide (Aug. 2019), https://www.epa.gov/sites/default/files/2019-08/documents/nata_overview_-_kelly_rimer.pdf. EPA set the 100-in-1 million benchmark in 1989 and it is outdated and far too high. EPA should revise and reduce this benchmark to recognize lower levels of cancer risk from a source category are unacceptable in light of children’s vulnerability to cancer risk, environmental justice concerns, multiple source impacts, and the availability of current monitoring and pollution controls.

⁶ EPA, Sterigenics Willowbrook Facility – Updates, <https://www.epa.gov/il/sterigenics-willowbrook-facility-updates>; Sharon Lerner, *A Tale of Two Toxic Cities*, *The Intercept* (Feb. 24, 2019), <https://theintercept.com/2019/02/24/epa-response-air-pollution-crisis-toxic-racial-divide/>.

⁷ NEJAC Letter to EPA (May 3, 2019), https://www.epa.gov/sites/default/files/2019-08/documents/nejac-letter-ethylene_oxide-may-3-2019-final.pdf.

estimated cancer risks so they can manage their health risks.”⁸ For some communities, like Laredo, TX, EPA waited an additional two years to inform residents of their health risks, four years after it first learned of the problem.

In 2021, the OIG again urged EPA to take action; this time, urging the agency to fulfill its overdue duty to complete new rulemaking that would protect “people in some areas of the country” from “unacceptable health risks from ...ethylene oxide emissions.”⁹ 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.¹⁰ And furthermore, EPA was failing to meet its statutory deadlines for conducting technology reviews, including the sterilizer review. The OIG specifically noted that “[t]he [Clean Air Act] does not provide any exceptions for this requirement.”¹¹

EPA’s failure to act means that there remains a myriad of emission sources at sterilizer facilities that continue to threaten the public’s health without regulation. For example, in Georgia, communities living near a sterilizer facility learned in 2019 that a warehouse storing sterilized products had a significant amount of ethylene oxide emissions. As a result, the state issued a notice of violation to the facility for failing to operate without a permit.¹² But in the years since, EPA has failed to issue an updated rule to control fugitive emissions, like those at warehouses. And in addition to fugitive emissions, EPA’s current rule fails to set emission limits for chamber exhaust vents, storage vessels, or to assure compliance with emission standards during startup, shutdown, or malfunction periods.¹³

⁸ EPA OIG, Management Alert - Prompt Action Needed to Inform Residents Living Near Ethylene Oxide-Emitting Facilities About Health Concerns and Actions to Address Those Concerns, Report No. 20-N-0128, At A Glance (Mar. 31, 2020), https://www.epa.gov/sites/default/files/2020-03/documents/_epaog_20200331-20-n-0128_glance.pdf.

⁹ 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/_epaog_20210506-21-p-0129.pdf.

¹⁰ *Id.* at 21.

¹¹ *Id.* at 24.

¹² For example, Georgia Environmental Protection Division has entered into a consent order with BD Covington for operating a warehouse containing insufficiently aerated EtO-sterilized materials and releasing a substantial amount of EtO emissions without an air permit. 2nd Amendment to BD Covington/Madison Consent Order (Mar. 25, 2020), <https://epd.georgia.gov/bd-covington-orders-notices-and-response-letters>; see also, GA EPD, Statement from Georgia EPD Regarding BD Notice of Violation (Dec. 20, 2019), <https://epd.georgia.gov/press-releases/2019-12-20/statement-georgia-epd-regarding-bd-notice-violation>; GA EPD, BD Covington Orders, Notices and Response Letters, <https://epd.georgia.gov/bd-covington-orders-notices-and-response-letters>.

¹³ *Louisiana Env’t Action Network (LEAN) v. EPA*, 955 F.3d 1088, 1096 (D.C. Cir. 2020) (requiring “necessary” revisions to bring rule into compliance with the Act’s definition of an adequate “emission standard” in section 112(d)(1)-(3)); *Sierra Club v. EPA*, 551 F.3d 1019, 1028 (D.C. Cir. 2008) (finding EPA’s exemption for startup, shutdown, or malfunction periods (SSM) to be unlawful with section 112’s requirement for “continuous” emission standards).

Each day that passes worsens the impact of EPA’s continuing Clean Air Act violations as community members suffer the consequences of exposure to high levels of toxic air pollution from sterilizers. Recently, EPA acknowledged that as a result of data collected in a recent information collection request (ICR), there continue to be at least 23 facilities whose emissions contribute to unacceptably high “lifetime [cancer] risk level[.]”¹⁴ Some of these facilities were identified two-years ago by EPA’s inspector general as a “high-priority” facility for EPA intervention and have continued to pose a threat to public health in the absence of EPA action. And this list does not even include sterilizer facilities in Southern California, where state officials have discovered elevated cancer risks from fenceline monitoring.¹⁵ Given this development, EPA should require immediate fenceline monitoring at all sterilizer facilities across the U.S.¹⁶

Under the Clean Air Act, EPA has a duty to protect public health and prevent air pollution. Section 112(d)(2) directs EPA to “require the maximum degree of reduction in emissions” of hazardous air pollutants, like ethylene oxide, from sterilizer facilities that is “achievable.” 42 U.S.C. § 7412(d)(2). Under section 112(d)(6), EPA is required to assure compliance with the Act, including this provision, and to promulgate all “necessary” revisions to the standards “taking into account developments in practices, processes, and control technologies”. Among other things, this includes setting emission limits on *all* HAP emissions from a source category.¹⁷ It includes removing illegal loopholes and assuring compliance with the Act.¹⁸ In the overdue rulemaking, the undersigned parties seek stronger emission standards that will prevent and reduce ethylene oxide emissions to the maximum degree achievable, with prompt compliance deadlines that will finally protect public health, increase the likelihood of prompt compliance, and speed up enforcement in the future if non-compliance occurs. The new rule should include compliance mechanisms and pollution control measures that are “developments” under section 112(d)(6), such as fenceline monitoring with corrective action to protect public health, frequent and transparent public reporting, automatic liability admissions, automatic corrective action, and automatic penalty requirements.¹⁹

¹⁴ EPA New Release, *EPA Launches Community Engagement Efforts on New Ethylene Oxide Risk Information* (Aug. 3, 2022), <https://www.epa.gov/newsreleases/epa-launches-community-engagement-efforts-new-ethylene-oxide-risk-information>.

¹⁵ Tony Briscoe, *Medical sterilizing facilities face growing scrutiny due to toxic gas concerns*, LA Times (Aug. 9, 2022) (The article notes that “notices of violation were issued [to multiple sterilization facilities] after testing revealed that concentrations of EtO were many times higher than the state’s ‘significant’ cancer risk threshold for people who work near these sites”), <https://www.latimes.com/environment/story/2022-08-09/medical-sterilizing-facilities-face-growing-scrutiny>.

¹⁶ EPA, List of commercial sterilization facilities, <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-commercial-sterilization-facilities>.

¹⁷ *LEAN*, 955 F.3d at 1096; see also, *Nat’l Lime Ass’n v. EPA*, 233 F.3d 625, 642 (D.C. Cir. 2000).

¹⁸ *Sierra Club*, 551 F.3d at 1028.

¹⁹ See, e.g., Cynthia Giles, *Next Generation Compliance: Environmental Regulation for the Modern Era Part I: Rules with Compliance Built In* (Jan. 27, 2020), <http://eelp.law.harvard.edu/wp-content/uploads/Cynthia-Giles-Part-1-FINAL.pdf>.

60-Day Notice.

This letter, pursuant to section 304 of the Clean Air Act, provides notice of California Communities Against Toxics, Clean Power Lake County, Rio Grande International Study Center, Sierra Club, and Union of Concerned Scientists intention to commence a civil action to enforce EPA's nondiscretionary duties described in this letter to compel EPA to perform the above duties at any time beginning sixty days from the postmark of this letter which is September 20, 2022. See 42 U.S.C. § 7604(b)(2); 40 C.F.R. § 54.2(d). This means that these groups may file suit on or after November 19, 2022, to compel EPA to fulfill these critical nondiscretionary duties and may seek a court order for EPA to comply with the Clean Air Act as expeditiously as possible.

Contact Information. We are acting as attorneys for the above-listed organization in this matter. We welcome the opportunity to meet with EPA to discuss promptly resolving this matter. Please contact us at your earliest convenience regarding this matter and address any communications to the email addresses and telephone number listed below.

Sincerely,



Marvin C. Brown IV,
Associate Attorney
Emma Cheuse,
Senior Attorney
Earthjustice
1001 G St. NW, Suite 1000
Washington, DC 20001
T: 202.794.5355
F: 202.667.2356
mcbrown@earthjustice.org
echeuse@earthjustice.org

*Counsel for California Communities Against
Toxics, Clean Power Lake County, Rio Grande
International Study Center, Sierra Club, Union
of Concerned Scientists*