

EPA ORGANIZATION

Internal deliberative pre-decisional - FOR USE BY 2024 PRESIDENT-ELECT TRANSITION TEAM MEMBERS ONLY

ISSUE SUMMARY:

Steri-Tech Inc. (STI) owns and operates a commercial sterilizing facility in Salinas, PR (Facility) that uses ethylene oxide (EtO) in its process. The Facility operates under an operation permit issued by the Puerto Rico Department of Natural and Environmental Resources under the Puerto Rico Regulations for the Control of Atmospheric Pollution (PR RCAP), and is subject to the Clean Air Act (CAA) and its implementing regulations under 40 C.F.R. Part 63, Subpart O, § 63.360, et seq. (NESHAP Subpart O). Since EPA Region 2 began its investigation of Steri-Tech in 2018, the Facility has been out of compliance with applicable regulations and its permit. Given the toxicity of EtO, STI's violations of emission standards pose a significant increased health risk to the community adjacent to the Facility. EPA is working with the Department of Justice (DOJ) to ensure STI complies with applicable standards by, among other things, installing new pollution controls at the Facility to reduce EtO emissions, and seeking early compliance with the new EtO regulations to address uncontrolled emissions at the company's warehouses. .

KEY POINTS:

Region 2 has initiated enforcement against STI to bring the Facility into compliance. In October 2023, Region 2 issued an administrative compliance order (Order) to STI requiring that it discontinue use of a thermal oxidizer that did not demonstrate compliance with emission standards, and test and exclusively operate its catalytic recuperative oxidizer (CRO) for pollution control. STI completed the required performance test for the CRO in January 2024 and the test results showed noncompliance with the applicable standards in its permit and NESHAP Subpart O. STI appealed the Order; that appeal is still pending as of October 2024. In May 2024, Region 2 referred the STI matter to DOJ for civil litigation. Since then, Region 2, DOJ, and STI have been working on an agreement for compliance.

In September 2024, STI conducted a retest of the CRO; the final test report for this test is due by mid-November 2024. Preliminary results indicate that the Facility met the NESHAP Subpart O standard but was not able to show compliance with its permit limits. STI proposed installing a new EtO control system and is working with its engineering consultants on the design of plant modifications and the new emissions control unit, which has additional capacity to meet the new amendments to the NESHAP Subpart O standards, which were promulgated in April 2024. The amendments include more stringent emission limits for sources of EtO at sterilization facilities, such as requiring 99.99% reduction from sterilization chambers, installation of continuous emission monitoring systems (CEMS), and the collection and control of previously unregulated "room air" EtO emissions from the off-gassing of sterilized product. The compliance date for meeting the new standards is April 6, 2026.

ONGOING/UPCOMING REVIEWS FOR FY2025:

Region 2's effort to bring the Facility into compliance will include a review of STI's engineering design plans for constructing a new, more efficient EtO pollution control system. The engineering plans must cover the design and installation of new controls equipped with CEMS, and the capture and control of room air emissions in compliance with the new EtO standards.

KEY EXTERNAL STAKEHOLDERS:

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| <input type="checkbox"/> Congress | <input checked="" type="checkbox"/> Industry | <input checked="" type="checkbox"/> States | <input type="checkbox"/> Tribes | <input checked="" type="checkbox"/> Media | <input checked="" type="checkbox"/> Other Federal Agency |
| <input checked="" type="checkbox"/> NGO | <input checked="" type="checkbox"/> Local Governments | <input checked="" type="checkbox"/> Public | | | |

MOVING FORWARD:

Region 2 will continue to work with DOJ and STI, holding frequent settlement conferences to try to finalize a settlement agreement with STI; and will continue to work with DOJ to defend the Order EPA issued to the Facility. Additionally, Region 2 will continue regular oversight of the Facility to assure compliance with the applicable standards and address the current health risks posed to the public by the Facility.