

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 2**

In the Matter of:

Steri-Tech, Inc.  
Salinas, Puerto Rico

Respondent

In a proceeding under Section 113(a)(1)  
of the Clean Air Act, 42 U.S.C. § 7413(a)(1)

**NOTICE OF VIOLATION**  
CAA-02-2024-1305

**SUMMARY**

The United States Environmental Protection Agency (“EPA”) Region 2 Director of the Caribbean Environmental Protection Division (“CEPD Director”) issues this Notice of Violation (“NOV”), under Section 113(a)(1) of the Clean Air Act (“CAA” or “the Act”), 42 U.S.C. § 7413(a)(1), to Steri-Tech, Inc. (“STI” or “Respondent”), the owner and operator of a commercial ethylene oxide sterilization facility located at Road 701 Km. 0.7 (the “Facility”), in the municipality of Salinas, Puerto Rico. EPA alleges that Respondent violated requirements of the Puerto Rico Regulations for the Control of Atmospheric Pollution (“RCAP”) that EPA has approved into the Puerto Rico State Implementation Plan (“SIP”).

**STATUTORY, REGULATORY AND PERMITTING BACKGROUND**

1. Section 302(e) of the Act, 42 U.S.C. § 7602(e), provides that the term “person” includes an individual, corporation, partnership, association, State, municipality, political subdivision of a State, and any agency, department, or instrumentality of the United States and any officer, agent, or employee thereof.
2. Section 113(a)(1) of the Act, 42 U.S.C. § 7413(a)(1), provides, in relevant part, that whenever the EPA Administrator finds, on the basis of any information available to the Administrator, that any person has violated or is in violation of any requirement or

prohibition of a SIP, the Administrator shall notify the person and the state in which the SIP applies of such finding. Section 113(a)(1) of the Act further provides that 30 days after providing such notice, the Administrator may issue an order requiring such person to comply with the requirements or prohibitions of such plan or permit; issue an administrative penalty order in accordance with Section 113(d) of the Act, 42 U.S.C. § 7413(d); or bring a civil action in accordance with Section 113(b) of the Act, 42 U.S.C. § 7413(b).

3. The CEPD Director is authorized by the EPA Administrator through the EPA Region 2 Regional Administrator to make findings of violations, issue notices thereof, and gather information, pursuant to Sections 113 and 114 of the Act. *See* EPA Delegation of Authority 7-6-A; EPA Region 2 Delegation of Authority 7-6-A; EPA Delegation of Authority 7-8; EPA Region 2 Delegation of Authority 7-8.

*Puerto Rico State Implementation Plan*

4. Section 109 of the CAA, 42 U.S.C. § 7409, directs the EPA Administrator to promulgate regulations establishing national ambient air quality standards (“NAAQS”) for each air pollutant for which air quality criteria have been issued pursuant to Section 108 of the Act, 42 U.S.C. § 7408.
5. Section 110(a)(1) of the CAA, 42 U.S.C. § 7409, requires each state to adopt and submit to EPA for approval a plan that provides for the implementation, maintenance, and enforcement of each of the NAAQS. Such plans, once approved by EPA, are known as State Implementation Plans, or SIPs, and are federally enforceable by the EPA.

Commonwealth of Puerto Rico Regulations for the Control of Atmospheric Pollution

6. Pursuant to the Puerto Rico Environmental Public Policy Act Law No. 9 of June 18, 1970,<sup>1</sup> the Puerto Rico Environmental Quality Board (“EQB”) developed the Puerto Rico Regulations for the Control of Atmospheric Pollution (“RCAP”).
7. By virtue of Law 122 of December 18, 2017, EQB’s functions, services, programs and/or powers were transferred to the Puerto Rico Department of Natural and Environmental Resources (“DNER”).<sup>2</sup>
8. On January 22, 1997, EPA approved the RCAP, as submitted to EPA on September 29, 1995, as part of the federally approved SIP for the Commonwealth of Puerto Rico. 62 Fed. Reg. 3211. At all times relevant to this NOV, the federally approved SIP for the Commonwealth of Puerto Rico has included the applicable RCAP provisions cited below.
9. RCAP Rule 203(A) (Permit to construct a source or modification) establishes that no person shall construct or modify a source without a permit from DNER.
10. RCAP Rule 203(B) (Standards for granting a permit to construct) establishes that a permit to construct or modify a source shall be granted only if the applicant demonstrates, among other things, that, to the satisfaction of DNER, the source shall be able to comply with all applicable rules and regulations; and that air pollutant emissions from the source will be limited in accordance with applicable rules and regulations.
11. RCAP Rule 203(C) (Application for a permit to construct) establishes that each application for a permit to construct or modify a source shall include, among other things,

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<sup>1</sup> Repealed and superseded by Act No. 416 of September 22, 2004.

<sup>2</sup> Any actions taken by the EQB prior to December 18, 2017, will be referenced as actions taken by the DNER.

detailed plans and specifications of the emissions and of any air pollution control equipment or measures proposed to be installed and constructed to achieve compliance with applicable rules and regulations; a layout plan of the source (projected and existing), indicating all air pollutant discharge, ventilation, exhaust and release points; and detailed plans and specifications of the source including: location, height of the emissions points, fuel used, process details, concentration and duration of emissions.

12. RCAP Rule 204(A)(1) (Permit to operate a source; Permit required) establishes that no person shall operate or cause the operation of a source or air pollution control equipment without a permit to operate or a temporary permit to operate from DNER.
13. RCAP Rule 204(A)(3) establishes that no person shall operate or cause the operation of an existing source without an operation permit or without the required application of renewal provided that the operation conditions previously approved by DNER are the same or are unchanged.
14. RCAP Rule 401(B) provides that no person shall cause or permit the emission of any air pollutant in violation of “applicable rules and regulations.”
15. RCAP Rule 102 defines “Air Pollutant” as, among other things, fumes, mist, vapors, gases, physical or chemical substances, or any combination thereof, but not including uncombined water vapor.
16. RCAP Rule 102 defines “Air Pollution Control Equipment” as any process equipment, device, and all appurtenances thereto, used for eliminating, reducing, or controlling the emission of any air pollutant.
17. RCAP Rule 102 defines “Applicable Rules and Regulations” as all rules and regulations promulgated under the Environmental Public Policy Act (Law No. 9, June 18, 1970, as

amended) and the “Clean Air Act” for the control of atmospheric pollution, including, among other things, all requirements established by the RCAP or any other applicable laws or regulations of the Commonwealth of Puerto Rico.

18. RCAP Rule 102 defines “Owner or Operator” as any person who owns, leases, operates, controls or supervises a source or facility.
19. RCAP Rule 102 defines “Person” as any person, natural or juridical, or group of persons, private or public, including agencies, government bodies, municipalities and public or quasi-public corporations.
20. RCAP Rule 102 defines “Source” as any structure, building, facility or installation (or combination thereof), which is located on one or more contiguous or adjacent properties under common ownership or operation, which emits or may emit any air pollutants.

#### **FINDINGS OF FACT**

The following findings of fact are based on a review of Facility records, information provided to EPA by STI, and inspections of the Facility performed by EPA:

21. Respondent owns and/or operates the Facility which has been in operation since 1986.
22. EPA Region 2 has been investigating Respondent’s Facility pursuant to its authority under Section 114 of the Act, 42 U.S.C. § 7414 (“EPA Investigation”). The EPA Investigation has included, in part: a) numerous site visits and inspections of the Facility during calendar year 2022, through the present; b) written and verbal information requests made to STI regarding the Facility and its operations; and c) a review of Respondent’s records, data, and other information as provided to EPA in response to such information requests.

23. Respondent operates sources of EtO air emissions, including four sterilization chambers and four post-sterilization aeration rooms. According to STI's annual EtO consumption logs from 2016-2022, the Facility uses on average approximately 35-40 tons per year of EtO for sterilization operations. Respondent operates air pollution control equipment for eliminating, reducing, and controlling EtO emissions from the Facility.
24. On April 28, 2021, the DNER issued STI a renewal minor source operating permit, PFE-RG-63-0715-0810-I-II-III-O (the "April 2021 Operation Permit"), under RCAP Rule 204. The April 2021 Operation Permit had an effective date of April 28, 2021, and an expiration date of April 28, 2026.
25. On November 8, 2021, the DNER issued STI a modification to the April 2021 Operation Permit, using the same permit number PFE-RG-63-0715-0810-I-II-III-O. This modification removed two boilers as alternative control devices for the Facility aeration rooms. With this modified permit, a thermal oxidizer was the only authorized air pollution control equipment for controlling EtO emissions from the Facility sterilization chambers and aeration rooms. The April 2021 Operation Permit, and the November 8, 2021, modified permit, included applicable requirements in the "Ethylene Oxide Emissions Standards for Sterilization Facilities," which are codified at 40 C.F.R. Part 63, Subpart O ("NESHAP Subpart O") with respect to the thermal oxidizer and the Facility.
26. On July 8, 2021, Respondent submitted to DNER an application requesting a modification to the Facility construction permit under RCAP Rule 203, seeking authorization to construct a new aeration room #4 and to install a catalytic recuperative

oxidizer (“CRO”) as the new air pollution control equipment for controlling EtO from the Facility sterilization chambers and aeration rooms.

27. On July 26, 2022, DNER issued to Respondent the construction permit authorizing the construction of aeration room #4 and the installation of the CRO as the air pollution control equipment for controlling EtO from the Facility sterilization chambers and aeration rooms.
28. On August 29, 2022, Respondent submitted an application to DNER to modify its operation permit PFE-RG-63-0715-0810-I-II-III-O, seeking authorization to operate the CRO as the air pollution control equipment for controlling EtO emissions from the Facility sterilization chambers and aeration rooms.
29. On October 6, 2022, DNER issued a modified operation permit, using the same permit number PFE-RG-63-0715-0810-I-II-III-O (the “October 2022 Operation Permit”), which authorizes STI to operate the CRO as the emission control device for the Facility. The October 2022 Operation Permit supersedes all previous versions of the operation permit, and it expires on April 28, 2026.
30. The October 2022 Operation Permit includes applicable NESHAP Subpart O requirements with respect to the CRO and the Facility.
31. Section II of the October 2022 Operation Permit authorizes Respondent to operate the Facility sterilization chambers and aeration rooms, and requires operation of the CRO as the only permitted air pollution control equipment for controlling EtO emissions from the sterilization chambers and aeration rooms.

32. Section II of the October 2022 Operation Permit does not authorize continued use of the thermal oxidizer as air pollution control equipment for any source of EtO emissions at the Facility.
33. Section IV.3 and IV.4 of the October 2022 Operation Permit provides that emissions from the sterilization chambers and the aeration rooms, respectively, must be routed to the CRO.
34. Section IV.7 of the October 2022 Operation Permit requires Respondent to conduct a performance test for the CRO to demonstrate that it complies with a minimum removal efficiency of 99.9% for the EtO emissions from the Facility sterilization chambers and the aeration rooms.
35. Since the issuance of the October 2022 Operation Permit, Respondent made several attempts to operate the CRO. On three different occasions, on October 28, 2022, January 19, 2023, and March 13, 2023, the CRO experienced operational issues that caused loud “blowback” incidents. During these incidents, the lower explosive limit (“LEL”), of the EtO exhaust gases routed from the sterilization chamber to the CRO exceeded the value established through the CRO programming, which triggered an automatic shutdown of the CRO.
36. These unsuccessful attempts to operate the CRO resulted in Respondent continuing to operate the thermal oxidizer as the air pollution control equipment for EtO emissions from the Facility sterilization chambers and aeration rooms during active sterilization cycles.
37. Respondent made numerous attempts to address the CRO startup incidents, including a series of projects intended to automate the CRO for continuous operation; specifically,

the installation of an additional LEL meter, a valve for regulating fresh dilution air introduced to the exhaust stream routed to the CRO, and variable frequency drives and programmable logic controllers for each sterilization chamber vacuum pump. In addition, Respondent installed computer screens at the sterilization operator control room where the operators can visually observe and monitor the operation of the CRO, and monitor critical parameters such as the LEL values and EtO exhaust flow rates from the sterilization chambers.

38. On May 22, 2023, Respondent informed EPA that a contractor had begun work on conducting a series of simulations in which each sterilization chamber would be operated under numerous scenarios to determine the CRO's capability to react and adjust to variable EtO exhaust flow rates and concentrations so that the CRO may be operated in continuous compliance with the applicable standards and requirements.
39. On June 15, 2023, Respondent informed EPA that the contractor completed the CRO simulations and started a series of test runs under different operational scenarios. However, these runs triggered the need for additional corrective actions including replacing LEL sensors and completing further automation programming and fine tuning of the CRO systems to optimize the CRO's performance. During this time Respondent continued to run sterilization cycles using the unpermitted thermal oxidizer as the air pollution control equipment for EtO emissions from the sterilization chambers and aeration rooms.
40. On August 22, 2023, Respondent submitted for EPA's review a performance test protocol for conducting a performance test for the CRO. The performance test will establish the

CRO's operational parameters for demonstrating compliance with the October 6, 2022 Operation Permit and with NESHAP Subpart O.

41. On September 12, 2023, Respondent informed EPA that the performance test is scheduled for the week of November 6, 2023, with the test runs at the CRO scheduled to be conducted on November 8 and 9, 2023.
42. Information provided to EPA by Respondent on September 27, 2023, indicates that the CRO has been in continuous operation at the Facility since September 4, 2023, except during brief power outages during which the CRO automatically shut down and the active sterilization cycle was automatically suspended, as programmed, until power was restored and the CRO became operational again.
43. Prior to September 4, 2023, Respondent was using the thermal oxidizer as the primary air pollution control equipment for controlling EtO emissions from the sterilization chambers and aeration rooms during active sterilization cycles at the Facility. On September 27, 2023, Respondent confirmed that the thermal oxidizer has been placed out of service and has not been operated since September 4, 2023.
44. On September 29, 2023, EPA issued a letter to Respondent approving the August 22, 2023 performance test protocol for the CRO.

#### **CONCLUSIONS OF LAW**

Based on the Findings of Facts set forth above, EPA reaches the following conclusions of law:

45. Respondent is a "person" within the meaning of Section 302(e) of the Act, and RCAP Rule 102.

46. Respondent is the owner and operator of the Facility within the meaning of RCAP Rule 102.
47. The Facility is subject to the applicable requirements in the October 6, 2022 Operation Permit, PFE-RG-63-0715-0810-I-II-III-O, issued under RCAP Rule 204, which is approved by EPA into the Puerto Rico SIP and is therefore federally enforceable.
48. The conditions in the October 2022 Operation Permit are “Applicable Rules and Regulations” within the meaning of RCAP Rule 102 and Rule 401(B).
49. From October 6, 2022, through on or around September 4, 2023, Respondent continued to operate the thermal oxidizer at the Facility without an operation permit that authorizes this air pollution control equipment, in violation of RCAP Rule 204(A)(1) and (A)(3), and Section II of the October 6, 2022 Operation Permit.
50. From October 6, 2022, through on or around September 4, 2023, Respondent failed to operate the CRO as the permitted and required air pollution control equipment for controlling EtO emissions from the Facility sterilization chambers and aeration rooms in accordance with the October 2022 Operation Permit, in violation of RCAP Rule 401(B), and Sections II and IV of the October 2022 Operation Permit.

### **ENFORCEMENT**

Section 113(a)(1) and (3) of the CAA, provide that the Administrator may bring a civil action whenever, on the basis of any information available to the Administrator, the Administrator finds that any person has violated or is in violation of any requirement rule or permit issued under the provisions of Section 113 of the CAA. Administrator shall notify the person and the State in which the plan applies of such a finding. At any time after the expiration

of thirty (30) days following the date this Notice of Violation is issued, the Administrator may, without regard to the period of violation (subject to section 2462 of title 28):

- a. issue an order requiring such person to comply with the requirements or prohibitions of a SIP or permit;
- b. issue and administrative penalty order in accordance with CAA Section 113(d); or
- c. bring a civil action in accordance with CAA Section 113(b) for civil penalties and/or injunctive relief.

The amount of civil penalties that may be recovered for violations such as those discussed above of the CAA and its implementing regulations is set by statute at not more than \$25,000 per day for each violation, but has been adjusted over time as required by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. § 2461 note; Pub. L. 101-410), as amended by the Debt Collection Improvement Act of 1996, and most recently, by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (28 U.S.C. § 2461 note; Pub. L. 114-74, Section 701). For civil penalties for violations that occurred after November 2, 2015, and are assessed on or after January 6, 2023, this daily penalty maximum is adjusted to \$117,468 for judicial actions, and \$55,808 for administrative actions. *See* 40 C.F.R. Part 19, Table 1.

Furthermore, for any person who knowingly violates any requirements or prohibition of an applicable SIP and permit for more than 30 days after the date of the issuance of an NOV, Section 113(c) of the Act provides for criminal penalties or imprisonment, or both. In addition, under Section 306 of the Act, the regulations promulgated thereunder (40 C.F.R. Part 15), and Executive Order 11,738, facilities to be utilized in federal contracts, grants and loans must be in full compliance with the Act and all regulations promulgated pursuant thereto. Violation of the

Act may result in the subject facility or other facilities owned or operated by Respondent, being declared ineligible for participation in any federal contract, grant, or loan program.

### **PENALTY ASSESSMENT CRITERIA**

Section 113(e)(1) of the Act provides that if a penalty is assessed pursuant to Section 113 of the Act, EPA or the court, as appropriate, shall, in determining the amount of the penalty to be assessed, take into consideration the size of the business, the economic impact of the penalty on the business, the violator's full compliance history and good faith efforts to comply, the duration of the violation as established by any credible evidence (including evidence other than the applicable test method), payment by the violator of penalties previously assessed for the same violation, the economic benefit of non-compliance, the seriousness of the violation, and other factors as justice may require.

Section 113(e)(2) of the Act allows EPA or the court, as appropriate, to assess a penalty for each day of violation. In accordance with Section 113(e)(2) of the Act, EPA will consider a violation to continue for the date the violation began until the date Respondent establishes that has achieved continuous compliance. If Respondent proves that there was an intermittent day of compliance or that the violation was not continuous in nature, EPA will reduce the penalty accordingly.

### **OPPORTUNITY FOR A CONFERENCE**

Respondent may request a conference with EPA concerning the violations alleged in this NOV. This conference will enable Respondent with an opportunity to advise the Agency of any further information the EPA should consider with respect to the alleged violations and to present evidence bearing on the finding of violations, on the nature of the violations, and on any efforts it may have taken or proposes to take to achieve compliance. Respondent has the right to be

represented by counsel. A request for a conference must be made within 10 days of receipt of this NOV. A request for a conference or other inquiries concerning the NOV should be made via electronic mail or in writing to:

Nancy Rodríguez, Chief  
Multimedia Permits and Compliance Branch  
Caribbean Environmental Protection Division  
U.S. Environmental Protection Agency - Region 2  
City View Plaza II – Suite 7000  
#48 Road. 165 Km. 1.2  
Guaynabo, Puerto Rico 00968-8073  
Attn: Alex Rivera, Enforcement Officer  
rivera.alex@epa.gov

If you are represented by counsel, your counsel may contact:

Evelyn Rivera-Ocasio  
Office of Regional Counsel  
Caribbean Environmental Protection Division  
U.S. Environmental Protection Agency - Region 2  
City View Plaza II – Suite 7000  
#48 Road. 165 Km. 1.2  
Guaynabo, Puerto Rico 00968-8073  
rivera-ocasio.evelyn@epa.gov

By offering the opportunity for a conference or participating in one, EPA does not waive or limit its right to any remedy available under the CAA. Also, notwithstanding this NOV and the opportunity for conference, Respondent must comply with all applicable requirements of the CAA.

For the United States Environmental Protection Agency, Region 2:

**CARMEN**  
**GUERRERO PEREZ**

Digitally signed by CARMEN  
GUERRERO PEREZ  
Date: 2023.10.23 11:35:46  
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Carmen R. Guerrero, Director  
Caribbean Environmental Protection Division  
U.S. Environmental Protection Agency - Region 2

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