

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

Received Electronically
January 17, 2024
United States Court of Appeals
For the First Circuit

STERI-TECH, INC.

PETITIONERS

v.

UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY,
REGION 2, CARIBBEAN
ENVIRONMENTAL PROTECTION
DIVISION

RESPONDENT

Docket No. _____

PETITION FOR REVIEW

Petitioner, Steri-Tech, Inc. (“STI” or “Petitioner”) hereby petitions the Court, pursuant to Section 307(b)(1) of the Clean Air Act (“CAA”) 42 U.S.C. §7607(b)(1) and Rule 15(a) of the Federal Rules of Appellate Procedure (“FARP”), for review of Administrative Compliance Order CAA-02-2024-1001 (“Order”), issued by the United States Environmental Protection Agency (“EPA”), Region 2, Director of the Caribbean Environmental Protection Division (“CEPD”) pursuant to Section 113(a) of the CAA. A copy of the Order, issued on October 23, 2023, is attached as Exhibit A.

In the Order, EPA sets forth certain Findings of Fact and Conclusions of Law, including that Petitioner had allegedly violated certain regulations promulgated under the CAA in connection with certain activities at STI’s commercial ethylene oxide (“EtO”) sterilization facility (“Facility”) located in the municipality of Salinas, Puerto Rico. Petitioner seeks judicial review of the Order because certain

EPA's Findings of Fact are erroneous, and EPA's Conclusions of Law are unsupported by substantial evidence. As a result, EPA's issuance of the Order was arbitrary and capricious, and an abuse of discretion. On November 7, 2023, Petitioner and EPA's CEPD held a conference where STI raised its concerns regarding certain findings of fact and conclusions of law as alleged in the Order, and requested the agency reconsider those findings and conclusions. The agency did not reconsider.

STI seeks review of the Order, more specifically, of the Findings of Fact included in paragraphs 48, and of the Conclusions of Law included in paragraphs 63, 64, 65 and 66. As can be concluded from Findings of Fact 38, 39, 42, 43, 44, 45, 46 and 47, STI did in fact comply with all requirements to complete a performance stack test of the thermal oxidizer ("TO") at its Facility, as per a protocol that was duly approved by the EPA. STI completed the performance test as per the approved protocol, rendered a report with the results thereof and addressed EPA's questions and concerns in two report addendums. See Exhibit B. Instead of advising STI of the alleged deficiencies and giving STI and its contractor the opportunity to address or respond to these, almost five months after submittal of the last addendum, EPA rejected STI's test report on April 7, 2022. See Exhibit C. Moreover, instead of advising STI that it could complete or continue with a revised performance test, or review, discuss, address and correct the alleged deficiencies, EPA insisted without substantial evidence that would support such a determination, that STI permanently cease operation of the TO and disconnect the same, once the catalytic recuperative oxidizer ("CRO") was permitted. See Exhibit C. Respectfully, STI asserts that EPA's finding, and disconnection included in the Order is arbitrary, capricious and an abuse of its discretion, and thus, subject to judicial review.

STI respectfully alleges herein that the EPA erroneously concluded that STI is in violation of 40 C.F.R. §§ 63.362(c), 63.363(a)(1), and 63.363(b)(3), and Section 112 of the CAA. The agency erred in concluding that STI failed to demonstrate that the TO operated in compliance with the EtO emissions destruction efficiency of 99% at a lower minimum baseline temperature and did not

provide STI opportunity to continue performance testing. EPA also erred in its conclusion that STI failed to demonstrate that the CRO installed by STI operates in compliance with the applicable 99% destruction efficiency standard for sterilization chambers and aeration room emissions. These Conclusions of Law are intimately related.

The EPA's allegations regarding the findings of fact and conclusions of law were addressed by STI in its reply to Notice of Violation CAA-02-2021-1303, issued on June 29, 2021. See Exhibit D. It is a fact that STI completed a performance test that showed that the TO at its Facility was and has been operated in compliance applicable standards. Notwithstanding, the agency has ordered its permanent disconnection.

Hence, STI respectfully requests judicial review of EPA's Order and that it be allowed to continue with the performance test of the TO to continue the operation of the TO as a back up to the CRO or in conjunction therewith. Any order to the contrary is not supported by substantial evidence and therefore reviewable by this Honorable Court.

Jurisdiction and venue are proper in this Court under 42 U.S.C. §7607(b)(1) because the Order is a locally applicable final action of the EPA and is not nationally applicable. The petition for review is timely filed within sixty (60) days of the Effective Date of the Order, which became effective on November 17, 2023, ten (10) days after Petitioner held the conference with EPA's CEPD pursuant to Paragraph 77 of the Order.

Dated January 17, 2024

Respectfully submitted,

STERI-TECH, INC.

/s/ Rafael A. Toro Ramirez

Rafael A. Toro-Ramírez

rtoro@toro-arsuaga.com

Bar No. 27304

TORO & ARSUAGA, LLC

P.O. Box 11064, San Juan, P.R. 00922-1064

Tel 787.299-1100, Fax 787.793.1146

CERTIFICATE OF SERVICE

I, Rafael A. Toro Ramírez, attorney for Steri-Tech, Inc., hereby CERTIFY that on this day I served by electronic mail and by personal delivery true and exact copy of the Petition for Review filed in the United States Court of Appeals for the First Circuit, for review of Administrative Compliance Order CAA-02-2024-1001, issued by the United States Environmental Protection Agency (“EPA”), Region 2, Director of the Caribbean Environmental Protection Division (“CEPD”) to Ms. Evelyn Rivera-Ocasio, Esq. rivera-ocasio.evelyn@epa.gov and Mr. Héctor L. Vélez, Esq. velez.hector@epa.gov , both attorneys for the EPA’s CEPD. The copy includes the Exhibits to the Petition.

In San Juan, Puerto Rico, this 17th day of January 2024.

/s/ Rafael A. Toro Ramirez
Rafael A. Toro-Ramírez
rtoro@toro-arsuaga.com
Bar No. 27304

TORO & ARSUAGA, PSC
P.O. Box 11064
San Juan, P.R. 00922-1064
Tel 787.299-1100
Fax 787.793.1146