

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1**

Received by
EPA Region 1
Hearing Clerk

In the matter of)
)
)
Professional Contract Sterilization, Inc.)
40 Myles Standish Boulevard)
Taunton, Massachusetts 02780)
Respondent)
)
Proceeding under Section 113 of)
the Clean Air Act)
_____)

Docket No: CAA-01-2022-0059

**CONSENT AGREEMENT
AND FINAL ORDER**

CONSENT AGREEMENT

On June 28, 2022, the United States Environmental Protection Agency, Region 1 (“EPA” or “Complainant”), filed a complaint (“Complaint”) alleging that Professional Contract Sterilization, Inc. (“Respondent”) violated the Clean Air Act (“CAA”), 42 U.S.C. § 7401 et seq., and federal regulations promulgated thereunder. As further explained herein, the complaint alleged that Respondent failed to timely respond to an information request and a testing requirement that EPA issued to assess the company’s compliance with an emission standard for ethylene oxide, a hazardous air pollutant.

Complainant and Respondent (together, the “Parties”) agree that settlement of this matter is in the public interest and that entry of this Consent Agreement and Final Order (“CAFO”) without further litigation is the most appropriate means of resolving this matter. Pursuant to 40 C.F.R. § 22.13(b) of EPA’s Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits

("Consolidated Rules"), set out at 40 C.F.R. Part 22, Complainant and Respondent agree to simultaneously commence and settle this action by the issuance of this CAFO.

Therefore, before any hearing, and without adjudication of any issue of fact or law, the Parties agree to comply with the terms of this CAFO as follows:

I. STATUTORY AND REGULATORY AUTHORITY

1. Section 113(d) of the CAA, 42 U.S.C. § 7413(d), authorizes the EPA Administrator to issue an order assessing civil administrative penalties against any person that has violated or is violating any requirement or prohibition of subchapters I, III, IV-A, V or VI of the Act, or any requirement or prohibition of any rule, order, waiver, permit or plan promulgated pursuant to any of those subchapters.

2. Section 114 of the Clean Air Act, 42 U.S.C. § 7414(a), among other things, authorizes EPA to require testing and reporting of information reasonably necessary for determining the compliance status of any person that owns or operates any emission source. The failure to timely provide information EPA requested under 42 U.S.C. § 7414(a) is a violation of CAA.

3. Section 302(e) of the CAA, 42 U.S.C. § 7602(e), provides that whenever the term "person" is used in the Act, the term 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.

4. Section 112(a) of the CAA, 42 U.S.C. § 7412(a), defines the term "owner or operator" as meaning any person who owns, leases, operates, controls, or supervises a stationary source.

5. Section 112(a) of the CAA also defines an "area source" of emissions as "any stationary source of hazardous air pollutants that is not a major source" with "major source"

meaning any “stationary source or group of stationary sources that emits or has the potential to emit 10 tons per year or more” of any hazardous air pollutant (“HAP”). 42 U.S.C. § 7412(a)(1)-(2). Pursuant to CAA Section 112(a)(6) and (b), 42 U.S.C. § 7412(a)(6) and (b), ethylene oxide is one such HAP.

6. Section 112(a) of the CAA further defines a “stationary source” as any building, structure, facility, or installation which emits or may emit any air pollutant. 42 U.S.C. § 7411(a)(3).

7. Section 112(c)(1), (d), and (e) of the CAA authorize EPA to promulgate regulations to establish emission standards for HAPs. Pursuant to such authority, EPA promulgated the Ethylene Oxide Emissions Standards for Sterilization Facilities, found at 40 C.F.R. Part 63, Subpart O at §§ 63.360-63.368.

8. Sections 113(a)(3) and (d) of the CAA, 42 U.S.C. § 7413(a)(3) and (d) provide for the assessment of civil penalties for the violations alleged in the Complaint. Statutory maximum penalties are adjusted for inflation, as provided in 40 C.F.R. Part 19. Where violations occurred after November 2, 2015, and a penalty is assessed on or after January 12, 2022, but before January 6, 2023, an administrative civil penalty may not exceed \$51,796 per day of violation. This amount has since increased to \$55,808. Pursuant to Section 113(d)(1) of the CAA and 40 C.F.R. § 19.4, table 1, as of January 6, 2023, EPA’s authority to seek administrative penalties currently is limited to a total penalty of \$446,456, unless the Administrator of the EPA and the Attorney General jointly determine that a matter involving a larger penalty amount is appropriate for administrative penalty assessment. The penalty sought in this matter does not exceed \$446,456.

II. STIPULATED FACTS

9. Respondent is a corporation organized under the laws of the State of Massachusetts and, therefore, is a “person” as defined by Section 302(e) of the CAA, 42 U.S.C. § 7602(e).

10. Respondent operates a commercial ethylene oxide sterilization facility subject to 40 C.F.R. Part 63 Subpart O located at 40 Myles Standish Boulevard, Taunton, Massachusetts (“Facility”).

11. Respondent's Facility is an area source of HAP emissions within the meaning of Section 112(a)(1)-(3) of the CAA, 42 U.S.C. § 7412(a)(1)-(3).

12. Accordingly, Respondent operates an emission source to which the requirements of CAA Section 114(a), 42 U.S.C. § 7414(a), apply.

III. GENERAL ALLEGATIONS

13. On September 13, 2021, EPA’s Headquarters office issued a CAA Section 114 Information Collection Request letter (“Information Request”) to Respondent requiring it to submit its response no later than November 19, 2021.

14. On July 5, 2022, Respondent submitted its response to the September 13, 2021, Information Request.

15. EPA inspected Respondent’s Facility on March 23, and April 7, 2022.

16. On April 7, 2022, EPA issued a CAA Section 114 Testing Requirement to Respondent, directing Respondent to conduct the performance testing required by 40 C.F.R. Part 63 Subpart O and to submit a performance test plan (“Test Plan”) to EPA no later than May 7, 2022.

17. On June 7, 2022, Respondent submitted its Test Plan in response to EPA’s April 7, 2022, Testing Requirement.

IV. VIOLATIONS

Count 1: Failure to Timely Respond to CAA Section 114 Information Request

18. Respondent's Facility is an area source of HAP emissions subject to requirements of Section 114(a) of the CAA, 42 U.S.C. § 7414(a), and 40 C.F.R. Part 63 Subpart O.

19. Respondent was required to submit its response to EPA's Information Request on or before November 19, 2021.

20. After EPA filed the Complaint in this action dated June 28, 2022, Respondent submitted its response to EPA's Information Request on July 5, 2022.

21. Accordingly, PCS failed to timely respond to EPA's September 13, 2021, Information Request.

22. Respondent's failure to timely respond violated Section 114(a) of the Clean Air Act, 42 U.S.C. § 7414(a).

Count 2: Failure to Timely Comply with CAA Section 114 Testing Requirement

23. Respondent's Facility is an area source of HAP emissions subject to requirements of Section 114(a) of the CAA, 42 U.S.C. § 7414(a), and 40 C.F.R. Part 63 Subpart O.

24. Respondent was required to submit a Test Plan in response to EPA's Testing Requirement on or before May 7, 2022. See 42 U.S.C. § 7414(a); 40 C.F.R. § 63.362.

25. After EPA filed the Complaint in this action dated June 28, 2022, Respondent submitted its performance test plan to EPA's Information Collection Request on July 5, 2022.

26. Accordingly, PCS failed to submit a Test Plan to EPA by May 7, 2022, as required by EPA's April 7, 2022, Testing Requirement.

27. Respondent's failure to timely submit a performance test plan violated Section 114(a) of the Clean Air Act, 42 U.S.C. § 7414(a).

V. TERMS OF SETTLEMENT

28. Respondent certifies that it has corrected the violations alleged in Counts 1 and 2. Further, Respondent certifies that it is currently in compliance with 40 C.F.R. Part 63, Subpart O (ethylene oxide emissions standards for sterilization facilities) and 40 C.F.R. Part 63, Subpart A (general provisions that apply to all the national emissions standards in 40 C.F.R. Part 63).

29. Respondent admits, for the purposes of this proceeding, that Complainant has jurisdiction over the subject matter alleged in this CAFO and that this CAFO states claims upon which relief may be granted against Respondent. Respondent waives any defenses it might have as to jurisdiction and venue.

30. Respondent waives its right to a judicial or administrative hearing on any issue of law or fact set forth in this CAFO and waives its right to appeal the Final Order.

31. Respondent consents to the terms and issuance of this CAFO and agrees to the payment of the civil penalty set forth herein. The provisions of this CAFO shall be binding on Respondent and Respondent's officers, directors, agents, employees, successors, and assigns.

32. Pursuant to the relevant factors for penalties issued pursuant to Section 113(e) of CAA, 42 U.S.C. § 7413(e), and taking into account any such matters as justice may require, Complainant has determined that it is fair and proper that Respondent pay a total civil penalty in the amount of \$15,000 due to its limited financial ability to pay a higher penalty to resolve the violations alleged in Section IV of this CAFO.

33. Respondent agrees to:

- i. Pay the civil penalty of \$15,000 within 30 calendar days of the effective date of this agreement (*i.e.*, the day the CAFO is filed with the Regional Hearing Clerk);

- ii. Pay the penalty using any appropriate method provided on the website <https://www.epa.gov/financial/makepayment>, identifying the payment with “*In the Matter of Professional Contract Sterilization, Inc.*, Docket No. CAA-01-2022-0059;” and
- iii. Within 24 hours of payment of the penalty, send proof of payment by email to the addresses below. “Proof of payment” means, as applicable, a copy of the check, confirmation of credit card or debit card payment, confirmation of wire or automated clearinghouse transfer, and any other information required to demonstrate that payment has been made according to EPA requirements, in the amount due, and identified with “Docket No. CAA-01-2022-0059”. The email addresses are as follows:

Wanda Santiago
Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 1
santiago.wanda@epa.gov
and
R1_Hearing_Clerk_Filings@epa.gov

and

Jaegun Lee
Enforcement Counsel
U.S. Environmental Protection Agency, Region 1
Lcc.Jaegun@epa.gov

34. Pursuant to 31 U.S.C. § 3717, EPA is entitled to assess interest and penalties on debts owed to the United States and a charge to cover the cost of processing and handling a delinquent claim. In the event that Respondent does not fully pay the civil penalty required by Paragraphs 32 and 33 of this CAFO when due, the unpaid penalty shall be payable with accrued interest from the original due date to the date of payment, with the interest calculated at the rate established in accordance with 31 C.F.R. § 901.9(b)(2). A charge will be assessed to cover the

costs of debt collection, including processing and handling costs and attorneys' fees. In addition, a penalty charge of six percent per year, compounded annually, will be assessed on any portion of the debt which remains delinquent more than ninety (90) days after payment is due, with the charge accruing from the date of delinquency in accordance with 31 C.F.R. § 901.9(d). In any such collection action, the validity, amount, and appropriateness of the penalty shall not be subject to review.

35. The civil penalty under this CAFO and any interest, nonpayment penalties, and other charges paid pursuant to any penalty collection action arising from this CAFO shall represent penalties assessed by EPA within the meaning of 26 U.S.C. § 162(f) and shall not be deductible for purposes of federal, state, or local taxes. Accordingly, Respondent agrees to treat all payments made pursuant to this CAFO as penalties within the meaning of 26 C.F.R. § 1.162-21, and further agrees not to use these payments in any way as, or in furtherance of, a tax deduction under federal, state, or local law.

36. This CAFO constitutes a settlement by EPA of all claims for civil penalties pursuant to Section 113(d)(5) of the CAA, 42 U.S.C. § 7413(d)(5), for the violations specifically alleged in Section IV of this CAFO. Compliance with this CAFO shall not be a defense to any actions subsequently commenced pursuant to federal laws and regulations administered by EPA, and it is the responsibility of Respondent to comply with such laws and regulations. This CAFO in no way relieves Respondent or its employees of any criminal liability. Nothing in this CAFO shall be construed to limit the authority of the United States to undertake any action against Respondent in response to conditions which may present an imminent and substantial endangerment to the public.

37. Nothing in this CAFO shall be construed as prohibiting, altering, or in any way limiting the ability of EPA to seek any other remedies or sanctions if Respondent is in violation

of this CAFO or continues to be in violation of the statutes and regulations upon which the allegations in this CAFO are based, or if Respondent violates any other applicable provision of federal, state, or local law.

38. Each of the undersigned representatives of the Parties certifies that he or she is fully authorized by the party responsible to enter into the terms and conditions of this CAFO and to execute and legally bind that Party to it.

39. Complainant and Respondent, by entering into this CAFO, each give their respective consent to accept digital signatures hereupon. Respondent further consents to accept electronic service of the full executed CAFO, by electronic mail, to the following address: [tfranklin@rubinrudman.com]. Respondent understands that this e-mail address may be made public when the CAFO and Certificate of Service are filed and uploaded to a searchable database. Complainant has provided Respondent with a copy of the EPA Region 1 Regional Judicial Officer's Authorization of EPA Region 1 Part 22 Electronic Filing System for Electronic Filing and Service of Documents Standing Order, dated June 19, 2020. Electronic signatures shall comply with and be maintained in accordance with that Order.

40. Each Party shall bear its own costs and attorneys' fees in this proceeding and specifically waives any right to recover such costs pursuant to the Equal Access to Justice Act, 5 U.S.C. § 504, or other applicable laws.

41. The terms, conditions, and compliance requirements of this CAFO may not be modified or amended except upon the written agreement of the Parties and approval of the Regional Judicial Officer.

42. In accordance with 40 C.F.R. § 22.31(b), the effective date of this CAFO is the date on which this CAFO is filed, either in person or electronically via email, with the Regional Hearing Clerk.

FOR RESPONDENT:

Mary Cranston President 1/26/24
Date
Gary Cranston
President
Professional Contract Sterilization, Inc.

In the Matter of Professional Contract Sterilization, Inc., Docket No. CAA-01-2022-0059
Consent Agreement and Final Order

FOR COMPLAINANT:

Carol Tucker, Acting Director
Enforcement and Compliance Assurance Division
EPA Region 1

Date

FINAL ORDER

Pursuant to 40 C.F.R. §§ 22.18(b) and (c) of the Consolidated Rules, the foregoing Consent Agreement resolving this matter is incorporated by reference into this Final Order and is hereby ratified. Respondent Professional Contract Sterilization, Inc. is ordered to pay the civil penalty amount specified in the Consent Agreement in the manner indicated therein. The terms of the Consent Agreement shall become effective on the date that the CAFO is filed, either in person or electronically via email, with the Regional Hearing Clerk.

LeAnn Jensen
Regional Judicial Officer
EPA Region 1

Date