

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 1**

**RECEIVED**

JUN 28 2022

EPA ORC (MS)  
Office of Regional Hearing Clerk

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In the Matter of: ) )  
 ) )  
Professional Contract Sterilization, Inc. ) )  
40 Myles Standish Boulevard ) )  
 ) )  
Taunton, MA 02780 ) )  
 ) )  
Proceeding under Section 113 ) )  
of the Clean Air Act ) )  
\_\_\_\_\_)

Docket No. CAA-01-2022-0059

**COMPLAINT**

**I. Preliminary Statement**

1. This is a proceeding to assess administrative civil penalties under Section 113(a) of the Clean Air Act, 42 U.S.C. § 7413(a).
2. Complainant is the Director of the Enforcement and Compliance Assurance Division, Region 1, U.S. Environmental Protection Agency (“Complainant”).
3. Respondent is Professional Contract Sterilization, Inc. (“PCS” or “Respondent”).
4. PCS is a “person” as defined in section 302(e) of the CAA, 42 U.S.C. § 7602(e).
5. PCS operates a commercial ethylene oxide sterilization facility at 40 Miles Standish Boulevard, Taunton, Massachusetts (“Facility”).

**II. Jurisdiction**

6. This action is brought under section 113(a) of the CAA, 42 U.S.C. § 7413(a), in accordance with the United States Environmental Protection Agency’s (“EPA”) “Consolidated

Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits,” 40 C.F.R. Part 22 (“Consolidated Rules”).

7. The EPA may assess administrative civil penalties for violations of Section 114(a) of the CAA, 42 U.S.C. § 7414(a).

### **III. Governing Law**

8. Section 114 of the Clean Air Act, 42 U.S.C. § 7414(a), among other things, authorizes EPA to require the provision of information reasonably necessary for determining the compliance status of any person, that owns or operates any emission source.

9. The failure to provide information EPA requested under Section 114 of the Clean Air Act, 42 U.S.C. § 7414(a), is a violation of the Clean Air Act.

10. Where violations occurred after November 2, 2015, and a penalty is assessed on or after January 12, 2022, an administrative civil penalty may not exceed \$414,364 against each violator, 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. CAA § 205(c)(1), 42 U.S.C. § 7524(c)(1); 40 C.F.R. § 19.4, table 1. The penalty sought in this matter does not exceed \$414,364.

### **IV. General Allegations**

11. PCS operates a commercial sterilization facility that is subject to Subpart O and uses more than ten tons or more of ethylene oxide (“EtO”) in sterilization or fumigation operations. Therefore, PCS is subject to the emissions standards found at 40 CFR § 63.362.

12. PCS is considered an area source of hazardous air pollutant (“HAP”) emissions. See 40 CFR §§ 63.2 and 63.6585(c).

13. On March 24, 1998, PCS submitted an initial notification to EPA as required by 40 CFR § 63.360 and 63.9(b)(2).
14. On September 13, 2021, EPA issued an Information Collection Request letter to PCS.
15. EPA inspected the Facility on March 23, and April 7, 2022.
16. On April 7, 2022, EPA issued a Testing Requirement to PCS, directing the facility to conduct the performance testing required by Subpart O and to submit a performance test plan, also known as a test protocol, to EPA no later than May 7, 2022.
17. On April 25, 2022, EPA and PCS held a conference call to discuss the Testing Requirement. At that time PCS did not indicate it would not be able to supply the performance test plan by the due date.
18. On May 17, 2022, PCS provided EPA, by email, a proposal made by LCH Consulting Associates Inc. to develop a performance test plan.
19. On May 18, 2022, EPA explained, by email, that the proposal provided was not a performance test plan and reiterated that the actual performance test plan was overdue.
20. On May 20, 2022, PCS emailed EPA to say a performance test plan would be provided the following week.
21. On June 7, 2022, via email, PCS submitted a Test Plan. EPA has reviewed this Plan and determined that it is deficient. The Plan lacks much of the information that must be included for the test to be successful. On June 13, 2022, EPA provided PCS with detailed comments on the Plan.

## **V. FINDINGS**

### **Count 1 – Failure to Respond to Section 114 Information Request**

22. PCS failed to respond to EPA's September 13, 2021, Information Collection Request letter.

23. Accordingly, PCS violated Section 114 of the Clean Air Act, 42 U.S.C. § 7414(a).

**Count 2 – Failure to Comply with Section 114 Testing Requirement**

24. PCS failed to submit a performance test plan to EPA by May 7, 2022, as required by EPA's April 7, 2022, Testing Requirement.

25. Accordingly, PCS has violated Section 114 of the Clean Air Act, 42 U.S.C. § 7414(a).

**VI. Relief Sought: Civil Penalty**

26. Consistent with the Clean Air Act Stationary Source Civil Penalty Policy - October 25, 1991, Complainant seeks an administrative penalty of **\$126,781** against Respondent for the violations of the Clean Air Act identified in Count 1 and Count 2, above.

27. In determining the amount of the penalty to be assessed under Section 113 of the CAA, EPA must take into consideration the size of the violator's 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 violations, payment by the violator of penalties previously assessed for the same violations, the economic benefit of the violations, the seriousness of the violations, and such other factors as justice may require. See CAA Section 113(e), 42 U.S.C. § 7413(e).

28. In proposing a penalty for the violations set forth in this Complaint, Complainant has taken into account the particular facts and circumstances of this case, the statutory penalty factors listed in CAA Section 113(e), and EPA's *Clean Air Act Stationary Source Penalty Policy* ("Penalty Policy"), dated October 25, 1991, a copy of which is attached to this Complaint. The

Penalty Policy assigns penalty components reflecting the seriousness or the gravity of the violations and the size of the violator's business. The Penalty Policy also provides for a penalty component to recover the estimated economic benefit Respondent derived from the violations. Adjustments to a proposed penalty are considered in light of the violator's degree of willfulness or negligence in committing the violations, its degree of cooperation with the EPA, any good faith efforts to comply, and any pertinent compliance history or previous penalty payments for the same violation.

29. In this case, due to the lack of responsiveness of the Respondent, EPA has made an upward adjustment to the penalty.

30. The penalty to be assessed may be considered in light of any evidence presented by Respondent that the proposed penalty would impair Respondent's ability to continue in business. To support such a claim, Respondent must provide Complainant with adequate financial documentation.

#### **VII. Opportunity to Request a Hearing and File an Answer**

31. In accordance with Section 113 of the CAA and 40 C.F.R. § 22.14, Respondent has the right to request a formal hearing to contest any material fact alleged in this Complaint, or to contest the appropriateness of the proposed penalty. **To request a hearing, Respondent must file a written Answer within thirty (30) days of Respondent's receipt of this Complaint.**

Respondent shall send the Answer to the Regional Hearing Clerk at the following address:

Regional Hearing Clerk  
U.S. Environmental Protection Agency, Region 1  
5 Post Office Square – Suite 100 (Mail Code ORA18-1)  
Boston, Massachusetts 02109-3912

32. Respondent shall serve copies of the Answer and any subsequent pleadings that Respondent files in this action to the following address:

Michael Wagner, Senior Enforcement Counsel  
U.S. Environmental Protection Agency, Region 1  
5 Post Office Square – Suite 100 (Mail Code 04-3)  
Boston, Massachusetts 02109-3912  
Wagner.michael@epa.gov  
617-918-1735

33. Any such hearing would be conducted in accordance with the Consolidated Rules of Practice, 40 C.F.R. Part 22 (copy attached). See 40 C.F.R. § 22.15 for the required contents of the Answer.

34. Respondent has a continuing obligation to comply with the CAA, with the terms and conditions of any applicable permits, the Administrative Order, and with any other order issued under Section 113 of the CAA, 42 U.S.C. § 7413.

#### **VIII. DEFAULT ORDER**

35. Respondent may be found to be in default pursuant to 40 C.F.R. § 22.17 if the Respondent fails to file a timely Answer to the Complaint. For the purposes of this action only, default by Respondent would constitute an admission of all facts alleged in the Complaint and a waiver of Respondent's right to contest such factual allegations. Any penalty assessed in the default order would be due and payable by Respondent without further proceedings after the default order becomes final under 40 C.F.R. § 22.27(c).

#### **IX. SETTLEMENT CONFERENCE**

36. Respondent may confer informally with EPA concerning the alleged violations. Such a conference provides Respondent with an opportunity to provide whatever additional information may be relevant to the disposition of this matter. Any settlement would be made final by the

issuance of a written Consent Agreement and Final Order by the Regional Judicial Officer of EPA Region I.

37. Please note that a request for an informal settlement conference does not extend the period for filing a written Answer. To explore the possibility of settlement in this matter, Respondent should contact Michael Wagner, Senior Counsel, at (617) 918-1735. Pursuant to 40 C.F.R. § 22.5(c)(4), Michael Wagner is authorized to receive service on behalf of EPA at the address listed above in Paragraph 48. Pursuant to 40 C.F.R. § 22.5(b)(2), EPA consents to service by email at wagner.michael@epa.gov.

**KAREN  
MCGUIRE**

Digitally signed by  
KAREN MCGUIRE  
Date: 2022.06.28  
10:56:07 -04'00'

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Karen McGuire, Director  
Enforcement and Compliance Assurance Division  
U.S. Environmental Protection Agency, Region 1  
5 Post Office Square, Suite 100  
Boston, MA 02109-3912

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Date

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Docket No. CAA-01-2022-0059

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Administrative Complaint and Notice of Opportunity to Request a Hearing has been sent to the following persons on the date noted below:

Original and one copy,  
hand-delivered:

Ms. Wanda Rivera  
Regional Hearing Clerk  
U.S. EPA, Region I (ORA18-1)  
5 Post Office Square, Suite 100  
Boston, MA 02109-3912

Copy, by Certified Mail,  
Return Receipt Requested, with  
copy of 40 C.F.R. Part 22:

Gary Cranston, President  
Professional Contact Sterilization, Inc.  
40 Myles Standish Boulevard  
Taunton, MA 02780



Robert A. Fasanella, Esq.  
Rubin and Rudman LLP  
53 State Street  
Boston, MA 02109

Dated: 6/28/2022

A handwritten signature in black ink, appearing to read "Michael Wagner", written over a horizontal line.

Michael Wagner  
Enforcement Counsel  
U.S. Environmental Protection Agency, Region 1  
5 Post Office Square, Suite 100  
Boston, MA 02109-3912  
Tel (617) 918-1735