

UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
REGION IX



In the matter of:	)	U.S. EPA Docket No.
	)	
	)	RCRA-09-2023-0037
Polypeptide Labs, Inc.	)	
365 Maple Avenue	)	CONSENT AGREEMENT AND
Torrance, CA 90503	)	FINAL ORDER PURSUANT TO
	)	40 C.F.R. SECTIONS 22.13 AND
	)	22.18
<u>Respondent.</u>	)	

**CONSENT AGREEMENT**

**A. PRELIMINARY STATEMENT**

1. This is a civil administrative enforcement action instituted pursuant to Section 3008(a)(1) of the Resource Conservation and Recovery Act (“RCRA”), as amended, 42 U.S.C. § 6928(a)(1), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits, as codified at 40 Code of Federal Regulations (C.F.R.) Part 22 (“Consolidated Rules”).
2. Complainant is the United States Environmental Protection Agency, Region IX (“EPA”).
3. Respondent is Polypeptide Labs, Inc., headquartered at 365 Maple Avenue Torrance, California, 90503 (“Respondent” or “Polypeptide”).
4. This Consent Agreement and Final Order (“CA/FO”), pursuant to 40 C.F.R. §§ 22.13 and 22.18, simultaneously commences and concludes this proceeding, wherein EPA alleges that Respondent violated Section 3008 of RCRA, 42 U.S.C. § 6928, and state regulations adopted pursuant to the State of California’s (“State’s”) authorized hazardous waste management program under RCRA.
5. The Parties agree that settling this action without the filing of a complaint or the adjudication of any issue of fact or law is in their respective interests and in the public interest.

**B. STATUTORY AND REGULATORY FRAMEWORK**

6. Subtitle C of RCRA requires the EPA Administrator to promulgate regulations establishing a hazardous waste management program. Section 3006 of RCRA, 42 U.S.C. § 6926, provides, *inter alia*, that authorized state hazardous waste management programs are carried out under Subtitle C of RCRA. Therefore, a violation of any requirement of

law under an authorized state hazardous waste program is a violation of a requirement of Subtitle C of RCRA.

7. The State received authorization to administer the hazardous waste management program in lieu of the federal program pursuant to Section 3006 of RCRA, 42 U.S.C. § 6926, and 40 C.F.R. Part 271, on or about August 1, 1992. This authorization was updated on September 26, 2001 (*see* 66 FR 49118, September 26, 2001), on October 7, 2011 (*see* 76 FR 62303, October 7, 2011), and again on January 14, 2020 (*see* 85 FR 2038, as corrected [*see* 86 FR 29207, June 1, 2021]). The authorized hazardous waste program is established pursuant to the Hazardous Waste Control Law, Chapter 6.5 of Division 20 of the California Health and Safety Code, and the regulations promulgated thereunder at Title 22, Division 4.5 of the California Code of Regulations, 22 C.C.R. §§ 66001 *et seq.* The State is authorized for all the hazardous waste management regulations referenced in this CA/FO.<sup>1</sup>
8. A violation of the State's authorized hazardous waste program, found at Health & Safety Code § 251000 *et seq.*, constitutes a violation of Subtitle C of RCRA and, therefore, a person who violates the State's authorized hazardous waste program is subject to the powers vested in the EPA Administrator by Section 3008 of RCRA, 42 U.S.C. § 6928.

**C. EPA'S GENERAL ALLEGATIONS**

9. Respondent owns and operates the facility located at 365 Maple Avenue Torrance, California 90503 (the "Facility"), with an EPA identification number of CAR000030080. Respondent is a custom manufacturer of polypeptides for academic institutions, small to medium-sized biotech companies, and large pharmaceutical companies. Respondent is a large quantity generator of "hazardous wastes" as defined in California Health & Safety Code § 25117, and 22 C.C.R. §§ 66260.10 and 66261.3 [*see also* 40 C.F.R. §§ 260.10 and 261.3].
10. On March 30, 2021, and October 15, 2021, respectively, EPA performed a compliance evaluation inspection ("CEI") of the Facility pursuant to Subtitle C of RCRA. Based upon the information gathered during this inspection and subsequent investigation, EPA determined that Respondent violated California Health & Safety Code § 251000, *et seq.* and the regulations adopted pursuant thereto, as approved and authorized by the United States.
11. Section 3008 of RCRA, 42 U.S.C. § 6928, authorizes the EPA Administrator to issue orders assessing a civil penalty and/or requiring compliance immediately or within a specified time for violation of any requirement of Subtitle C of RCRA, 42 U.S.C. § 6921, *et seq.*, and state regulations adopted pursuant thereto.

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1. All citations to the "C.C.R." refer to Division 4.5 of Title 22 of the current California Code of Regulations. EPA is enforcing California hazardous waste management program requirements as approved and authorized by the United States. As a convenience, corresponding Federal citations are provided in brackets.

12. The Administrator has delegated enforcement authority under Section 3008 of RCRA, 42 U.S.C. § 6928, to the EPA Regional Administrators, with delegation 8-9-A, last revised February 4, 2016. The Regional Administrator, EPA Region IX, in turn, redelegate that authority to the Director of the Enforcement Division (now the Enforcement and Compliance Assurance Division), Region IX, with delegation R9-1200 TN 111, dated January 22, 2016.
13. Respondent is a “person” as defined in 22 C.C.R. § 66260.10 [*see also* 40 C.F.R. § 260.10].
14. Respondent is the “owner” of a facility as defined in 22 C.C.R. § 66260.10 [*see also* 40 C.F.R. § 260.10].
15. Respondent is the “operator” of a facility as defined in 22 C.C.R. § 66260.10 [*see also* 40 C.F.R. § 260.10].
16. Respondent is a “generator” of hazardous waste as defined in 22 C.C.R. § 66260.10 [*see also* 40 C.F.R. § 260.10].
17. Respondent is or has been engaged in “treatment,” “storage,” or “disposal” of “hazardous waste” as defined in 22 C.C.R. §§ 66260.10 and 66261.3 [*see also* 40 C.F.R. §§ 260.10 and 261.3].
18. At the Facility, Respondent generates and accumulates, or has generated and accumulated, “hazardous waste,” as defined in California Health & Safety Code § 25117, and 22 C.C.R. §§ 66260.10 and 66261.2 [*see also* RCRA § 1004(5), and 40 C.F.R. §§ 260.10 and 261.2]. These hazardous wastes include but are not limited to the following hazardous waste codes: D001, D002, F002, and F006.

**D. EPA’S ALLEGED VIOLATIONS**

**COUNT I**

**(Failure to Comply with Air Emission Standards for Equipment Leaks)**

19. Paragraphs 1 through 18 above are incorporated herein by this reference as if they were set forth here in their entirety.
  20. 22 C.C.R. § 66262.34 [*see also* 40 C.F.R. § 262.17(a)(1)(i)] allows generators of hazardous waste to accumulate such waste on-site for up to 90 days without a permit or grant of interim status provided that, among other things, the waste is accumulated in containers or tanks and the generator complies with the air emissions standards for equipment leaks found at 22 C.C.R. § 66265.1060 *et seq.* [*see also* 40 C.F.R. § 265.1060 *et seq.*]
  21. Title 22, Division 4.5, Chapter 15, Article 28 (Air Emission Standards for Equipment Leaks) of the California Code of Regulations (“Article 28”), 22 C.C.R. §§ 66265.1050-
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1065 [*see also* 40 C.F.R. §§ 265.1050-1065] requires a large quantity generator of RCRA hazardous wastes to control air emissions from equipment leaks, by, *inter alia*, determining the percent-by-weight total organics in the hazardous waste stream at the equipment, tagging all equipment subject to Article 28, conducting leak detection monitoring, and development and implementation of recordkeeping requirements for regulated equipment.

22. Respondent generates volatile organic wastes, which are piped and stored in two 2,200-gallon tanks and a 5,000-gallon tank. The volatile organic wastes have a concentration greater than 500 parts per million by weight. Therefore, Respondent is subject to the Air Emission Standards for Equipment Leaks.
23. During the inspection, EPA observed that Respondent was not implementing the air emissions standards for equipment leaks, including: determinations of whether the waste exceeds 10% parts per million by weight, determining which equipment contains or contacts organic waste meeting or exceeding 10% parts per million by weight, tagging of equipment required to be included in the leak detection and repair program, monitoring of regulated equipment, and development and implementation of recordkeeping requirements for regulated equipment.
24. Therefore, EPA alleges that Respondent failed to comply with the requirements for air emission standards for equipment leaks, in violation of 22 C.C.R. §§ 66262.34(a)(1)(i); 66265.1050(a); 66265.1050(c); 66265.1057; 66265.1063(d); 66265.1064(b)(1) [*see also* 40 C.F.R. §§ 262.17(a)(1)(i); 265.1050(a); 265.1050(c); 265.1057; 265.1063(d); 265.1064(b)(1)].

## **COUNT II**

### **(Failure to Comply with Air Emission Control Standards for Tanks)**

25. Paragraphs 1 through 18 above are incorporated herein by this reference as if they were set forth here in their entirety.
26. 22 C.C.R. § 66262.34 [*see also* 40 C.F.R. § 262.17(a)(1)(i)] allows generator's of hazardous waste to accumulate such waste on-site for up to 90 days without a permit or grant of interim status provided that, among other things, the waste is accumulated in containers, tanks or surface impoundments and the generator complies with the air emissions standards found at 22 C.C.R. § 66265.1080 *et seq.* [*see also* 40 C.F.R. § 265.1080 *et seq.*].
27. Title 22, Division 4.5, Chapter 14, Article 28.5 (Air Emission Standards for Tanks, Surface Impoundments, and Containers) of the California Code of Regulations ("Article 28.5"), 22 C.C.R. §§ 66265.1080-1090 [*see also* 40 C.F.R. §§ 265.1080-1090] applies to owners and operators of facilities that treat, store, or dispose of RCRA hazardous waste in, among other things, tank systems used to transfer, store, or treat hazardous waste. Owners and operators are required to control air emissions from tanks, by, *inter alia*, determining whether the waste exceeds 500 parts per million by weight, determining the

maximum organic vapor pressure for a hazardous waste to be managed in the tank before the first time the waste is placed in the tank, monitoring of regulated tanks, and development and implementation of recordkeeping requirements for regulated tanks.

28. Respondent generates volatile organic wastes, which are piped and stored in two 2,200-gallon tanks and a 5,000-gallon tank. The volatile organic wastes have a concentration greater than 500 parts per million by weight. Therefore, Respondent is subject to the Air Emission Standards for Tanks.
29. During the inspection, EPA observed that Respondent was not implementing the air emissions standards for tanks, including: determining whether the waste meets or exceeds 500 parts per million by weight, determination of the maximum organic vapor pressure of the waste in the tanks, and development and implementation of a written plan and schedule to perform required inspections and monitoring.
30. Therefore, EPA alleges that Respondent failed to comply with the requirements for air emissions standards for tanks, in violation of 22 C.C.R. §§ 66265.1084(c)(1); 66265.1084(c)(4)(B) and (D); 66265.1088(b); 66265.1089(b) [*see also* 40 C.F.R. §§ 265.1084(c)(1); 265.1084(c)(4)(ii); 265.1088(b); and (iv); 265.1089(b)].

#### **E. CIVIL PENALTY**

31. Complainant proposes that Respondent be assessed, and Respondent agrees to pay FIFTY-SEVEN THOUSAND FOUR HUNDRED SEVENTY-TWO DOLLARS (\$57,472) as the civil penalty for the violations alleged herein.
32. The proposed penalty was calculated in accordance with the “June 2003 RCRA Civil Penalty Policy,” as amended by the 2020 Amendment to the EPA’s Resource Conservation and Recovery Act (RCRA) Civil Penalty Policy to Address Generator Storage Violation Cases, issued on May 1, 2020, and was adjusted for inflation by the Federal Civil Penalties Inflation Adjustment Act, as amended, and the Civil Monetary Penalty Inflation Adjustment Rule, 40 C.F.R. Part 19.

#### **F. ADMISSIONS AND WAIVERS OF RIGHTS**

33. In accordance with 40 C.F.R. § 22.18(b)(2) and for the purpose of this proceeding, Respondent: (i) admits that EPA has jurisdiction over the subject matter of this CA/FO and over Respondent; (ii) neither admits nor denies the specific factual allegations contained in this CA/FO; (iii) consents to any and all conditions specified in this CA/FO and to the assessment of the civil administrative penalty under Section E of this CA/FO; (iv) waives any right to contest the allegations contained in Sections C and D of the CA/FO; and (v) waives the right to appeal the proposed final order attached to this Consent Agreement and made part of this CA/FO.

#### **G. PARTIES BOUND**



34. This CA/FO shall apply to and be binding upon Respondent and its agents, successors and assigns, until the civil penalty required under Section E and H has been paid in accordance with Section H, and any stipulated penalties have been resolved. At such time as those matters are concluded, this CA/FO shall terminate and constitute full settlement of civil penalty liability of the violations alleged herein.
35. No change in ownership or corporate, partnership or legal status relating to the Facility will in any way alter Respondent's obligations and responsibilities under this CA/FO.
36. The undersigned representative of Respondent hereby certifies that he is fully authorized by Respondent to enter into this CA/FO, to execute and legally bind Respondent to it.

#### **H. PAYMENT OF CIVIL PENALTY**

37. Respondent consents to the assessment of and agrees to pay a civil penalty of FIFTY-SEVEN THOUSAND FOUR HUNDRED SEVENTY-TWO DOLLARS (\$57,472) in full settlement of the federal civil penalty claims set forth in this CA/FO.
38. Respondent shall submit payment within thirty (30) calendar days of the "Effective Date" of this CA/FO, as that term is defined in Section N.
39. All payments shall indicate the name of the Facility, EPA identification number of the Facility (CAR 000 030 080), the Respondent's name and address, and the EPA docket number of this action. Payment shall be made by certified or cashier's checks payable to "Treasurer of the United States." Information on how to make a payment to EPA can accessed here: <https://www.epa.gov/financial/makepayment>.

A copy of each check, or notification that the payment has been made by one of the other methods listed above, including proof of the date payment was made, shall be sent with a transmittal letter, indicating Respondent's name, the case title, and docket number, to both:

Regional Hearing Clerk (ORC-1)  
Office of Regional Counsel  
U.S. Environmental Protection Agency - Region IX  
R9HearingClerk@epa.gov

And

Daniel Fernandez (ENF-2-2)  
Enforcement and Compliance Assurance Division  
U.S. Environmental Protection Agency - Region IX  
Fernandez.Daniel@epa.gov

40. Each payment must be received by the due date set forth in this CA/FO to avoid additional charges. If payment is not received by the due date, interest will accrue from the Effective Date of this CA/FO at the current rate published by the United States
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Treasury as described at 40 C.F.R. § 13.11. In addition, a 6% per annum penalty assessed monthly will further apply on any principal amount not paid within ninety (90) calendar days of its due date. Respondent further will be liable for stipulated penalties as set forth below for any payment not received by its due date.

41. The penalties specified in this CA/FO shall represent civil penalties assessed by EPA and shall not be deducted by Respondent or any other person or entity for federal, state, or local taxation purposes.

**I. DELAY IN PERFORMANCE/STIPULATED PENALTIES**

42. In the event that Respondent fails to meet any requirement set forth in this CA/FO, Respondent shall pay stipulated penalties up to FIVE HUNDRED DOLLARS (\$500.00) per day for the first to fifteenth day of delay, up to ONE THOUSAND DOLLARS (\$1,000.00) per day for the sixteenth to thirtieth day of delay, and up to THREE THOUSAND DOLLARS (\$3,000.00) per day for each day of delay thereafter.
43. All penalties and interest owed to EPA under this Section shall be due within thirty (30) days of receipt of a notification of noncompliance. Such notification shall describe the noncompliance and shall indicate the amount of penalties due. Interest at the current rate published by the United States Treasury, as described at 40 C.F.R. § 13.11, shall begin to accrue on the unpaid balance at the end of the thirty-day period.
44. All penalties and interest shall be remitted in the same manner described in Section H.
45. The payment of stipulated penalties shall not alter in any way Respondent's obligation to complete the performance required hereunder.
46. Notwithstanding any other provision of this Section, EPA may, in its unreviewable discretion, waive any portion of stipulated penalties that have accrued pursuant to this CA/FO.
47. The stipulated penalties set forth in this Section do not preclude EPA from pursuing any other remedies or sanctions that may be available to EPA because of Respondent's failure to comply with any of the requirements of this CA/FO.
48. The payment of stipulated penalties specified in the Section shall not be deducted by Respondent or any other person or entity for federal, state or local taxation purposes.

**J. CERTIFICATION OF COMPLIANCE**

49. In executing this CA/FO, Respondent certifies under penalty of law to EPA that it has fully complied with Section 3008 of RCRA, 42 U.S.C. § 6901, and its implementing regulations that formed the basis for the violations alleged in Section D, above.
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50. This certification of compliance is based upon true, accurate, and complete information, which the signatory can verify personally or regarding which the signatory has required of the person or persons directly responsible for gathering the information.

**K. RESERVATION OF RIGHTS**

51. EPA hereby reserves all of its statutory and regulatory powers, authorities, rights and remedies, both legal and equitable, including the right to require that Respondent perform tasks in addition to those required by this CA/FO. EPA further reserves all of its statutory and regulatory powers, authorities, rights and remedies, both legal and equitable, which may pertain to Respondent's failure to comply with any of the requirements of this CA/FO, including without limitation, the assessment of penalties under Section 3008 of RCRA, 42 U.S.C. § 6928. This CA/FO shall not be construed as a covenant not to sue, release, waiver or limitation of any rights, remedies, powers or authorities, civil or criminal, which EPA has under RCRA, or any other statutory, regulatory or common law enforcement authority of the United States.
52. Compliance by Respondent with the terms of this CA/FO shall not relieve Respondent of its obligations to comply with RCRA or any other applicable local, State or federal laws and regulations.
53. The entry of this CA/FO and Respondent's consent to comply shall not limit or otherwise preclude EPA from taking additional enforcement actions should EPA determine that such actions are warranted except as they relate to Respondent's liability for federal civil penalties for the alleged violations as set forth in Section D of this CA/FO.
54. This CA/FO is not intended to be nor shall it be construed as a permit. This CA/FO does not relieve Respondent of any obligation to obtain and comply with any local, State or federal permits.

**L. OTHER CLAIMS**

55. Nothing in this CA/FO shall constitute or be construed as a release from any other claim, cause of action or demand in law or equity by or against any person, firm, partnership, entity or corporation for any liability it may have arising out of or relating in any way to the generation, storage, treatment, handling, transportation, release, or disposal of any hazardous constituents, hazardous substances, hazardous wastes, pollutants, or contaminants found at, taken to, or taken from the Facility.

**M. MISCELLANEOUS**

56. This CA/FO may be amended or modified only by written agreement executed by both EPA and Respondent.
57. The headings in this CA/FO are for convenience of reference only and shall not affect interpretation of this CA/FO.
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58. Each party to this action shall bear its own costs and attorneys' fees.
59. Respondent consents to entry of this CA/FO without further notice.
60. By signing this CAFO, Respondent acknowledges that this CAFO will be available to the public and agrees that this CAFO does not contain any confidential business information or personally identifiable information.

**N. EFFECTIVE DATE**


61. In accordance with 40 C.F.R. §§ 22.18(b)(3) and 22.31(b), this CA/FO shall be effective on the date that the Final Order contained in this CA/FO, signed by the Regional Judicial Officer, is filed with the Regional Hearing Clerk.

IT IS SO AGREED.

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FOR RESPONDENT POLYPEPTIDE LABS, INC.:

May 23, 2023  
Date

  
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Timothy F. Culbreth  
President – US Operations  
Polypeptide Labs, Inc.

FOR COMPLAINANT, U.S. ENVIRONMENTAL PROTECTION AGENCY,  
REGION 9:

**JOEL  
JONES**

Digitally signed by JOEL  
JONES  
Date: 2023.07.06  
10:42:59 -0700'

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for/Amy C. Miller-Bowen, Director  
Enforcement and Compliance Assurance Division  
U.S. Environmental Protection Agency, Region IX





