

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 1**

IN THE MATTER OF	)	
	)	
TEI Biosciences, Inc.	)	Docket No: EPCRA-01-2021-0080
7 Elkins Street	)	
Boston, Massachusetts 02127,	)	
Respondent.	)	<b>CONSENT AGREEMENT AND FINAL ORDER</b>
	)	
Proceeding under Section 325(c) of the	)	
Emergency Planning and Community	)	
Right-to-Know Act, 42 U.S.C. § 11045(c)	)	
	)	

**CONSENT AGREEMENT**

The United States Environmental Protection Agency (“EPA”), Region 1 (“Complainant”), alleges that TEI Biosciences, Inc. (“Respondent”) violated the Emergency Planning and Community Right-to-Know Act (“EPCRA”), 42 U.S.C. §§ 11001- 11050, and the federal regulations promulgated thereunder.

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. Pursuant to Sections 313 and 328 of EPCRA, 42 U.S.C. §§ 11023 and 11048, EPA promulgated Toxic Chemical Release Reporting: Community Right-to-Know regulations at 40 C.F.R. Part 372.

2. Section 313(a) of EPCRA, 42 U.S.C. § 11023(a), requires owners or operators of a facility subject to the requirements of Section 313(b) of EPCRA to submit annually, no later than July 1 of each year, a Toxic Chemical Release Inventory Reporting Form, EPA Form 9350-1 (hereinafter, “Form R”), for each toxic chemical listed under 40 C.F.R. § 372.65 that was manufactured, processed, or otherwise used during the preceding calendar year in quantities exceeding the toxic chemical thresholds established under Section 313(f) of EPCRA, 42 U.S.C. § 11023(f), and 40 C.F.R. §§ 372.25 and 372.28. If an owner or operator determines that the alternative reporting threshold specified in 40 C.F.R. § 372.27 applies, the owner or operator may instead submit an alternative threshold certification statement that contains the information required under 40 C.F.R. § 372.95 (“Form A”). Each Form R or Form A (hereinafter, referred to together as “TRI Forms”) must be submitted to EPA and a designated state authority.

3. Section 313(b) of EPCRA, 42 U.S.C. § 11023(b), and 40 C.F.R. §§ 372.22 and 372.30 provide that owners or operators of facilities that have 10 or more full-time employees; that are in a Standard Industrial Classification (“SIC”) code or North American Industry Classification System (“NAICS”) code set forth in 40 C.F.R. § 372.23; and that manufactured, processed, or otherwise used a toxic chemical listed under 40 C.F.R. § 372.65 in a quantity exceeding the established threshold during a calendar year, must submit TRI Forms to EPA and the state authority for each of these substances for that year.

4. Section 325(c)(1) of EPCRA, 42 U.S.C. § 11045(c)(1), the Federal Civil Penalties Inflation Adjustment Act of 1990 as amended through 2016 (“FCPIAA”), and the FCPIAA’s implementing regulations as promulgated and updated by EPA at 40 C.F.R. Part 19 (most recently at 85 Fed. Reg. 83818, 83821 (Dec. 23, 2020)), together authorize the assessment of civil administrative penalties of up to \$59,017 for each violation of Section 313 of EPCRA that occurs after November 2, 2015. Pursuant to Section 325(c)(3) of EPCRA, 42 U.S.C. § 11045(c)(3), each day that an EPCRA Section 313 violation continues constitutes a separate violation.

## **II. GENERAL ALLEGATIONS**

5. Respondent is a corporation organized under the laws of the State of Delaware.

6. Respondent operates a biomedical manufacturing facility located at 7 Elkins St., Boston, MA 02127 (the “Facility”), at which Respondent processes cow hides into collagen matrix sheets for use in the medical field. The Facility uses chloroform to chemically treat the cow hides in its de-fleshing operation.

7. Respondent is a “person” as defined by 42 U.S.C. § 11049(7).

8. Respondent operates a “facility,” as defined by 42 U.S.C. § 11049(4) and 40 C.F.R. § 372.3.

9. The Facility has 10 or more “full-time employees,” as defined by 40 C.F.R. § 372.3.

10. The Facility is classified in a NAICS code set forth in 40 C.F.R. § 372.23.

11. The requirements of 42 U.S.C. § 11023 apply to the Facility.

### III. VIOLATIONS

#### **Count 1: Failure to Timely Submit TRI Form For Chloroform for Calendar Year 2017**

12. During the calendar year 2017, Respondent otherwise used chloroform, a toxic chemical listed under 40 C.F.R. § 372.65(a), at the Facility in quantities greater than the 10,000-pound threshold amount established for EPCRA TRI reporting by 40 C.F.R. § 372.25(b).

13. Respondent was therefore required to submit to EPA a TRI Form for chloroform for calendar year 2017 on or before July 1, 2018. *See* Section 313(a) of EPCRA and 40 C.F.R. §§ 372.30 (a) and (d).

14. Respondent submitted a TRI Form for chloroform for calendar year 2017 on December 23, 2019.

15. Respondent failed to submit a TRI Form for chloroform for calendar year 2017 to EPA on or before July 1, 2018.

16. Respondent's failure to timely submit a TRI Form for chloroform violated Section 313 of EPCRA and 40 C.F.R. Part 372.

#### **Count 2: Failure to Timely Submit TRI Form For Chloroform for Calendar Year 2018**

17. During the calendar year 2018, Respondent otherwise used chloroform, a toxic chemical listed under 40 C.F.R. § 372.65(a), at the Facility in quantities greater than the 10,000-pound threshold amount established for EPCRA TRI reporting by 40 C.F.R. § 372.25(b).

18. Respondent was therefore required to submit to EPA a TRI Form for chloroform for calendar year 2018 on or before July 1, 2019. *See* Section 313(a) of EPCRA and 40 C.F.R. §§ 372.30 (a) and (d).

19. Respondent submitted a TRI Form for chloroform for calendar year 2018 on December 23, 2019.

20. Respondent failed to submit a TRI Form for chloroform for calendar year 2018 to EPA on or before July 1, 2019.

21. Respondent's failure to timely submit a TRI Form for chloroform violated Section 313 of EPCRA and 40 C.F.R. Part 372.

#### **IV. TERMS OF SETTLEMENT**

22. Respondent certifies that it has corrected the alleged violations cited in this CAFO and will operate its Facility in compliance with Section 313 of EPCRA, 42 U.S.C. § 11023, and the regulations promulgated thereunder at 40 C.F.R. Part 372.

23. 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.

24. 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.

25. Without admitting or denying the facts and violations alleged in Section III of this CAFO, 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.

26. Pursuant to the relevant factors for penalties issued pursuant to Section 325(c)(1) of EPCRA, 42 U.S.C. § 11045(c)(1), 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 \$34,895 to resolve the violations alleged in Section III of this CAFO.

27. Respondent agrees to:

- i. Pay the civil penalty of \$34,895 within 30 calendar days of the Effective Date of this agreement (*i.e.*, the day it is filed with the Regional Hearing Clerk);
- ii. Pay the EPA Penalty using any method, or combination of methods, provided on the website <http://www2.epa.gov/financial/additional-instructions-making-payments-epa>, identifying each and every payment with “Docket No. EPCRA-01-2021-0080”; and
- iii. Within 24 hours of payment of EPA Penalty, send proof of payment by mail and 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. EPCRA-01-2021-0080”).

Wanda Santiago  
Regional Hearing Clerk  
U.S. Environmental Protection Agency, Region 1  
5 Post Office Square, Suite 100  
Mail Code 4-6  
Boston, MA 02109-3912  
[santiago.wanda@epa.gov](mailto:santiago.wanda@epa.gov)  
and  
[R1\\_Hearing\\_Clerk\\_Filings@epa.gov](mailto:R1_Hearing_Clerk_Filings@epa.gov)

and

Kristen Scherb  
Attorney-Advisor  
U.S. Environmental Protection Agency, Region 1  
5 Post Office Square, Suite 100  
Mail Code 4-6  
Boston, MA 02109-3912  
[scherb.kristen@epa.gov](mailto:scherb.kristen@epa.gov)

28. 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 26 and 27 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.

29. 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. § 1.16221, 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.

30. This CAFO constitutes a settlement by EPA of all claims for civil penalties pursuant to Section 325(c) of EPCRA for the violations specifically alleged in Section III 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.

31. 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.

32. 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.

33. 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: [jami.segota@integralife.com](mailto:jami.segota@integralife.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.

34. 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.

35. 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.

36. 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.

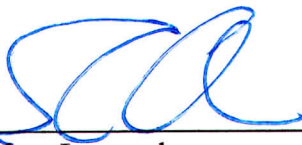
For COMPLAINANT:

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James Chow, Deputy Director *for* Karen McGuire, Director  
Enforcement and Compliance Assurance Division  
EPA Region 1

*Dated by electronic signature*

For RESPONDENT TEI BIOSCIENCES, INC.:



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Stephen Leonard  
Corporate Vice President  
Integra LifeSciences

Date: 29 AUG 2021

**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 TEI Biosciences, 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.

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LeAnn Jensen  
Regional Judicial Officer  
EPA Region 1

*Dated by electronic signature*