



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

FEB 24 2015

REPLY TO THE ATTENTION OF:

SC-5J

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dale Rosene, Director
HSE & Risk Management
CSL Behring L.L.C.
1201 N. Kinzie Avenue
Bradley, Illinois 60915

Re: CSL Behring L.L.C., Bradley, Illinois, Consent Agreement and Final Order
Docket No. CAA-05-2015-0021

Dear Mr. Rosene:

Please find enclosed a final, signed and filed version of the Consent Agreement and Final Order (CAFO) in resolution of the above case. The U. S. Environmental Protection Agency has filed the other original CAFO with the Regional Hearing Clerk on February 24, 2015. Please note that pursuant to Paragraph 50 of the CAFO, CSL Behring L.L.C. must pay a \$62,780 civil penalty within 30 days after the effective date of this CAFO.

Please feel free to contact Silvia Palomo at (312) 353-2172 if you have any questions regarding the enclosed documents. Please direct any legal questions to Catherine Garypie, Associate Regional Counsel at (312) 886-5825. Thank you for your assistance in resolving this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Bob H. Hans".

Michael E. Hans, Chief
Chemical Emergency
Preparedness and Prevention Section

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

IN THE MATTER OF:

) Docket No. CAA-05-2015-0021

)

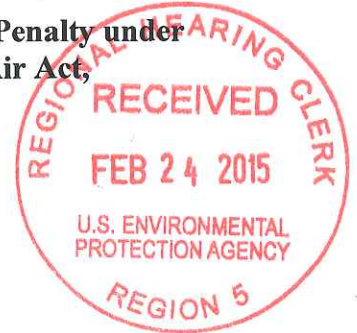
CSL Behring L.L.C.
1201 N Kinzie Avenue
Bradley, Illinois 60915

)

) Proceeding to Assess a Civil Penalty under
) Section 113(d) of the Clean Air Act,
) 42 U.S.C. § 7413(d)

Respondent.

)



Consent Agreement and Final Order

Preliminary Statement

1. This is an administrative action commenced and concluded under Section 113(d) of the Clean Air Act (the "Act"), 42 U.S.C. § 7413(d), and Sections 22.1(a)(2), 22.13(b), and 22.18(b)(2) and (3) of the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits*, as codified at 40 C.F.R. Part 22, for alleged violations of Section 112(r) of the Act, 42 U.S.C. § 7412(r), and the implementing regulations.

2. Complainant is the Director of the Superfund Division, United States Environmental Protection Agency ("EPA"), Region 5, Chicago, Illinois.

3. The Respondent is CSL Behring L.L.C., a company doing business in the State of Illinois.

4. Where the parties agree to settle one or more causes of action before the filing of a complaint, the administrative action may be simultaneously commenced and concluded by the issuance of a consent agreement and final order ("CAFO"). 40 C.F.R. § 22.13(b).

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 interest and in the public interest.

6. In order to resolve this matter without litigation, Respondent consents to entry of this CAFO and the assessment of the specified civil penalty, and agrees to comply with the terms of the CAFO.

Jurisdiction and Waiver of Right to Hearing

7. Respondent admits the jurisdictional allegations in this CAFO and neither admits nor denies the factual allegations in the CAFO.

8. Respondent waives its right to request a hearing as provided at 40 C.F.R. § 22.15(c), any right to contest the allegations in this CAFO, and its right to appeal this CAFO.

Statutory and Regulatory Background

9. In accordance with Section 112(r) of the Act, on June 20, 1996, EPA promulgated regulations to prevent accidental releases of regulated substances and minimize the consequences of those releases that do occur. 42 U.S.C. § 7412(r). These regulations, known as the Risk Management Program regulations, are codified at 40 C.F.R. Part 68.

10. The Risk Management Program regulations apply to all stationary sources with processes that contain more than a threshold quantity of a regulated substance.

11. A “stationary source” is any building, structure, facility, or installation which emits or may emit any air pollutant. 40 U.S.C. § 7411(a)(3).

12. A “process” is any activity involving a regulated substance, including any use, storage, manufacturing, handling or on-site movement of such a substance. *See* 40 C.F.R. § 68.3.

13. The List of Regulated Toxic Substances and Threshold Quantities for Accidental Release Prevention is codified at 40 C.F.R. § 68.130. Anhydrous ammonia is a “regulated

substance,” as that term is defined in Section 112(r)(3) of the Act and 40 C.F.R. § 68.3. *See* 40 C.F.R. § 68.130, Table 1.

14. The “threshold quantity” (as that term is defined in 40 C.F.R. § 68.3) for anhydrous ammonia is 10,000 pounds in a process. *See* 40 C.F.R. § 68.130, Table 1.

15. The Risk Management Program regulations require that the owner or operator of a facility subject to the regulations develop and implement a program for preventing accidental releases to the air and minimizing the consequences of releases that do occur. *See* 40 C.F.R. § 68.12.

16. The owner or operator shall submit a single Risk Management Plan (“RMP”) that includes the information required by 40 C.F.R. §§ 68.155 through 68.185 and 40 C.F.R. § 68.150(a).

17. A facility’s RMP must be submitted no later than: June 21, 1999; three years after the date on which the regulated substance is first listed under 40 C.F.R. § 68.130; or the date on which a regulated substance is first present in more than a threshold quantity in a process, whichever is later. *See* 40 C.F.R. §§ 68.10(a) and 68.150.

18. The processes subject to these requirements are divided into three tiers of eligibility: Programs 1, 2, and 3. *See* 40 C.F.R. §§ 68.10 and 68.150.

19. Program 3 applies to all processes which do not meet the requirements of 40 C.F.R. § 68.10(b) and are subject to the OSHA Process Safety Management (“PSM”) standard set forth at 29 C.F.R. § 1910.119. *See* 40 C.F.R. § 68.10(d).

20. The owner or operator of a stationary source with a process subject to Program 3 requirements shall implement the prevention requirements of 40 C.F.R. §§ 68.65 through 68.87.

21. The Administrator of EPA (the Administrator) may assess a civil penalty of up to \$32,500 per day of violation, up to a total of \$270,000 for violations that occurred after March 15, 2004 through January 12, 2009; and may assess a civil penalty of up to \$37,500 per day of violation up to \$295,000 for violations that occurred after January 12, 2009, pursuant to Section 113(d)(1) of the Act, 42 U.S.C. § 7413(d)(1), and 40 C.F.R. Part 19.

22. Section 113(d)(1) limits the Administrator's authority to matters where the first alleged date of violation occurred no more than 12 months prior to initiation of the administrative action, except where the Administrator and Attorney General of the United States jointly determine that a matter involving a longer period of violation is appropriate for an administrative penalty action.

23. The Administrator and the Attorney General of the United States, each through their respective delegates, have determined jointly that an administrative penalty action is appropriate for the period of violations alleged in this complaint.

Factual Allegations and Alleged Violations

24. The Respondent is an Illinois company with a plant located at 1201 N. Kinzie Avenue (Illinois Route 50 and Armour Road), Bradley, Illinois 60915 ("the Facility").

25. At the Facility, the Respondent is engaged in the business of manufacturing biotherapies derived from human plasma.

26. The Respondent is a "person," as that term is defined at Section 302(e) of the Act, 42 U.S.C. § 7602(e).

27. The Facility is a "stationary source" as that term is defined at 40 C.F.R. § 68.3.

28. For purposes of the requirements at 40 C.F.R. Part 68, the Respondent is the "owner or operator" of the Facility as that term is defined at Section 112(a)(9) of the Act.

29. The Respondent operates a two stage refrigeration system which utilizes anhydrous ammonia as a refrigerant.

30. The Respondent uses and stores up to 130,000 lbs. of anhydrous ammonia in the refrigeration system.

31. The Respondent reported in its RMP that the refrigeration system is a "process," as that term is defined at 40 C.F.R. § 68.3.

32. The Facility is subject to the "Program 3" eligibility requirements because the process: (a) does not meet the requirements of 40 C.F.R. § 68.10(b), because the distance to a toxic or flammable endpoint for a worst-case release assessment conducted under Subpart B and 40 C.F.R. § 68.25 is greater than the distance to any public receptor; and (b) is subject to the OSHA process safety management standard set forth at 29 C.F.R. § 1910.119 and 40 C.F.R. § 68.10(d) because the process involves anhydrous ammonia above its threshold quantity.

33. On May 3, 1999, the Respondent had present at the Facility an amount of anhydrous ammonia greater than the threshold quantity listed in 40 C.F.R. § 68.130, as determined in accordance with the threshold determination requirements of 40 C.F.R. § 68.115.

34. Because the Respondent had present at the Facility an amount of anhydrous ammonia greater than the threshold quantity listed in 40 C.F.R. § 68.130, it was required to submit an RMP no later than June 21, 1999. 40 C.F.R. §§ 68.10(a), 68.150.

35. On June 18, 1999, Respondent's predecessor Aventis Behring L.L.C. submitted an RMP. Subsequent updates and revisions were submitted on October 4, 2000, October 27, 2000, November 23, 2004 and May 17, 2010.

36. On August 11, 2009, a representative from EPA inspected the Facility under the authority of Section 114(a) of the Act, 42 U.S.C. § 7414(a). The purpose of the inspection was to determine whether the Respondent was complying at the Facility with Section 112(r) of the Act and the regulations at 40 C.F.R. Part 68.

37. On December 12, 2011, EPA requested information from Respondent via electronic mail. Respondent responded on February 13, 2012. The purpose of the information request was to determine whether the Respondent was complying with Section 112(r) of the Act and the regulations implementing Section 112(r) at 40 C.F.R. Part 68 at the Facility.

38. On March 8, 2012, EPA requested additional information from Respondent via electronic mail. Respondent responded on March 9, 2012. The purpose of the information request was to determine whether the Respondent was complying with Section 112(r) of the Act and the regulations implementing Section 112(r) at 40 C.F.R. Part 68 at the Facility.

39. Based on the inspection conducted by EPA and information gathered by EPA after the inspection, the Facility failed to comply with the Risk Management Program regulations at 40 C.F.R. Part 68 for Program 3 requirements as set forth below in Paragraphs 38 through 41.

40. When responsibility for individual requirements of 40 C.F.R. Part 68 was assigned to persons other than the person with overall responsibility for the development, implementation and integration of the risk management program elements, Respondent was required to document the names or positions of those people and the relevant lines of authority. 40 C.F.R. § 68.15(c). Respondent failed to document the names or positions of those people and the relevant lines of authority, violating 40 C.F.R. § 68.15(c) on August 11, 2009.

41. Respondent was required to review operating procedures as often as necessary to assure that they reflect current operating practice (including changes that result from changes in

process chemicals, technology, and equipment, and changes to stationary sources) and certify annually that these operating procedures are current and accurate. 40 C.F.R. § 68.69(c).

42. Respondent failed to review operating procedures and certify annually that these operating procedures were current and accurate, violating 40 C.F.R. § 68.69(c) on August 11, 2009 through September 26, 2014.

43. Respondent was required to provide refresher training at least every three years, and more often if necessary, to each employee involved in operating a process to assure that the employee understands and adheres to the current operating procedures of the process. 40 C.F.R. § 68.71(b).

44. Respondent failed to provide refresher training at least every three years to each employee involved in operating a process to assure that the employee understands and adheres to the current operating procedures of the process, violating 40 C.F.R. § 68.71(b) on August 11, 2009 through February 21, 2012.

45. Respondent was required to conduct inspection and testing following recognized and generally accepted good engineering practices. 40 C.F.R. § 68.73(d)(1) and (2). The frequency of inspections and tests of process equipment was required to be consistent with applicable manufacturers' recommendations and good engineering practices, and more frequently if determined to be necessary by prior operating experience. 40 C.F.R. § 68.73(d)(3). Also, Respondent was required to document each inspection and test that has been performed on process equipment (identifying the date of the inspection or test, the name of the person who performed the inspection or test, the serial number or other identifier of the equipment on which the inspection or test was performed, a description of the inspection or test performed, and the results of the inspection or test). 40 C.F.R. § 68.73(d)(4).

46. Respondent failed to replace or test 194 pressure relief valves every 5 years of service per manufacturer's recommendations and the International Institute of Ammonia Refrigeration (IIAR) Bulletin Number 109, Section 4.9 on August 11, 2012.

47. Respondent failed to conduct a 5-year independent thorough inspection of the ammonia refrigeration system as recommended by IIAR Bulletin Number 109, Section 5.3 on August 11, 2009.

48. Respondent failed to inspect all the piping in the refrigeration system per IIAR Bulletin Number 109, Section 4.7 on August 11, 2009 through June 21, 2012.

Civil Penalty

49. Complainant has determined that an appropriate civil penalty to settle this action is \$62,780. In determining the penalty amount, Complainant has considered the factors specified in Section 113(e) of the Act, 42 U.S.C. § 7413(e), the facts and circumstances of this case, and other factors such as the cooperation of Respondent throughout the entire compliance monitoring, case development, and settlement process. Complainant has also considered EPA's Combined Enforcement Policy for Clean Air Act Sections 112(r)(1), 112(r)(7), and 40 C.F.R. Part 68 (June 2012).

50. Within 30 days after the effective date of this CAFO, Respondent must pay a \$62,780 civil penalty by Automatic Clearinghouse ("ACH") electronic funds transfer ("EFT"), payable to "Treasurer, United States of America," and sent to:

US Treasury REX Cashlink ACH Receiver
ABA: 051036706
Account Number: 310006, Environmental Protection Agency
CTX Format Transaction Code 22 – checking

51. In the comment area of the electronic funds transfer, state Respondent's name and the docket number of this CAFO.

52. A transmittal letter stating Respondent's name, complete address and the case docket number must accompany the payment. Respondent must send a copy of the ACH/EFT transfer record and transmittal letter to:

US EPA Region 5
Office of the Regional Hearing Clerk
Attention: La Dawn Whitehead
77 W. Jackson Blvd.
Mailcode: E-19J
Chicago, IL 60604-3590

Silvia Palomo (SC-5J)
Chemical Emergency Preparedness and Prevention Section
Superfund Division
U.S. Environmental Protection Agency, Region 5
77 West Jackson Boulevard
Chicago, IL 60604

Catherine Garypie, Associate Regional Counsel
Office of Regional Counsel
U.S. Environmental Protection Agency, Region 5
77 West Jackson Boulevard (C-14J)
Chicago, IL 60604

53. This civil penalty is not deductible for federal tax purposes.

54. If Respondent does not pay timely the civil penalty, EPA may bring an action to collect any unpaid portion of the penalty with interest, handling charges, nonpayment penalties and the United States' enforcement expenses for the collection action under Section 113(d)(5) of the Act, 42 U.S.C. § 7413(d)(5). The validity, amount, and appropriateness of the civil penalty are not reviewable in a collection action.

55. Pursuant to 31 C.F.R. § 901.9, Respondent must pay the following on any amount overdue under this CAFO. Interest will accrue on any overdue amount from the date payment

was due at a rate established by the Secretary of the Treasury. Respondent must pay a \$15 handling charge each month that any portion of the penalty is more than 30 days past due. In addition, Respondent must pay a quarterly nonpayment penalty each quarter during which the assessed penalty is overdue according to Section 113(d)(5) of the Act, 42 U.S.C. § 7413(d)(5). This nonpayment penalty will be 10 percent of the aggregate amount of the outstanding penalties and nonpayment penalties accrued from the beginning of the quarter.

General Provisions

56. This CAFO resolves only Respondent's liability for federal civil penalties for the violations alleged in this CAFO.

57. The effect of the settlement described in paragraph 56, above, is conditioned upon the accuracy of Respondent's representations to EPA, as memorialized in Respondent's email dated February 13, 2012, email dated March 9, 2012, letter dated April 30, 2014, letter dated July 31, 2014, letter dated July 25, 2014, email dated September 12, 2014, email dated October 2, 2014, and email dated October 29, 2014.

58. The CAFO does not affect the right of EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violation of law.

59. This CAFO does not affect Respondent's responsibility to comply with the Act and other applicable federal, state, and local laws and regulations. Except as provided in Paragraph 49, above, compliance with this CAFO will not be a defense to any actions subsequently commenced pursuant to federal laws administered by Complainant.

60. Respondent certifies that it is complying fully with Section 112(r) of the Act and 40 C.F.R. Part 68.

61. This CAFO constitutes an “enforcement response” as that term is used in EPA’s Combined Enforcement Policy for Clean Air Act Sections 112(r)(1), 112(r)(7), and 40 C.F.R. Part 68 (June 2012) to determine Respondent’s “history of violations.”

62. The terms of this CAFO bind Respondent, its successors, and assigns.

63. Each person signing this consent agreement certifies that he or she has the authority to sign for the party whom he or she represents and to bind that party to its terms.

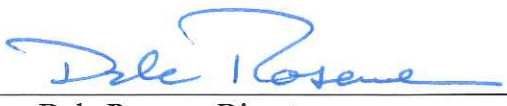
64. Each party agrees to bear its own costs and attorneys’ fees in this action.

65. This CAFO constitutes the entire agreement between the parties.


66. The effective date of this CAFO is the date when this CAFO is filed with the Regional Hearing Clerk’s office.

In the Matter of: CSL Behring L.L.C.
Docket No. _____

CSL Behring L.L.C., Respondent:

Date: Feb. 6, 2015 By: 
Dale Rosene, Director
HSE & Risk Management
CSL Behring L.L.C.

United States Environmental Protection Agency, Complainant


Date: 2-12-15 By: 
Richard Karl, Director
Superfund Division

In the Matter of: CSL Behring L.L.C.
Docket No. CAA-05-2015-0021

Final Order

This Consent Agreement and Final Order, as agreed to by the parties, shall become effective immediately upon filing with the Regional Hearing Clerk. This Final Order concludes this proceeding pursuant to 40 C.F.R. §§ 22.18 and 22.31. IT IS SO ORDERED.

2-17-2015
Date



Susan Hedman
Regional Administrator
U.S. Environmental Protection Agency

In the matter of: CSL Behring L.L.C.
Docket Number: CAA-05-2015-0021

CERTIFICATE OF SERVICE

I certify that I served a true and correct copy of the foregoing **Consent Agreement and Final Order**, which was filed on February 24, 2015, this day in the following manner to the addressees:

Copy by certified mail
return-receipt requested:

Dale Rosene, Director
HSE & Risk Management
CSL Behring L.L.C.
1201 N. Kinzie Avenue
Bradley, Illinois 60915


Copy by e-mail to
Attorney for Complainant:

Catherine Garypie
garypie.catherine@epa.gov

Copy by e-mail to
Regional Judicial Officer:

Ann Coyle
coyle.ann@epa.gov

Dated: February 24, 2015



LaDawn Whitehead
Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 5