



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

May 3, 2021

**VIA ELECTRONIC MAIL**  
**DELIVERY RECEIPT REQUESTED**

Jose Gonzalez  
Senior Vice President and General Manager  
CSL Behring LLC  
1201 N. Kinzie Ave.  
Bradley, Illinois 60915  
Email: jose.gonzalez@cslbehring.com

Re: **CSL Behring, LLC, Bradley Illinois**  
Consent Agreement and Final Order  
Docket No. CAA-05-2021-0018

Dear Mr. Gonzalez,

Enclosed please find a fully executed Consent Agreement and Final Order (CAFO) in resolution of the above case. U.S. EPA has filed the original CAFO with the Regional Hearing Clerk on May 3, 2021. Please note CSL Behring's obligation to pay a civil penalty in the amount of \$527,144 in the manner prescribed in paragraphs 32-37 and please reference your check with the docket number.

Please feel free to contact Monika Chrzaszcz at chrzaszcz.monika@epa.gov if you have any questions regarding the enclosed documents. Please direct any legal questions to William Wagner, Associate Regional Counsel, at wagner.william@epa.gov. Thank you for your assistance in resolving this matter.

Sincerely yours,

*Michael E. Hans 4-6-21*  
X  
Michael E. Hans 4-6-21  
Chief, CEPPS

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

Enclosure

cc. William Wagner, ORC  
Monika Chrzaszcz, CEPPS

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 5**

<b>In the Matter of:</b>	)	<b>Docket No. CAA-05-2021-0018</b>
	)	
<b>CSL Behring LLC Bradley, Illinois</b>	)	<b>Proceeding to Assess a Civil Penalty Under</b>
	)	<b>Section 113(d) of the Clean Air Act, 42</b>
<b>Respondent.</b>	)	<b>U.S.C. § 7413(d)</b>
	)	
	)	

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**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 Section 22.1(a)(2), 22.13(b), and 22.18(b)(2)-(3) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (Consolidated Rules) as codified at 40 C.F.R. § 22.1(a)(2), 22.13(b), and 22.18(b)(2)-(3), for alleged violations of Section 112(r) of the Act, 42 U.S.C. § 7412(r) and the implementing regulations at 40 C.F.R. Part 68.

2. The Complainant is, by lawful delegation, the Director of the Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency (EPA), Region 5.

3. Respondent is CSL Behring LLC (“CSL” or “Respondent”), a corporation 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 commenced and concluded simultaneously by the issuance of a consent agreement and final order (CAFO). *See* 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. Respondent consents to the terms of this CAFO, including the assessment of the civil penalty specified below.

**Jurisdiction and Waiver of Right to Hearing**

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

8. Respondent waives any and all remedies, claims for relief, and otherwise available rights to judicial or administrative review that Respondent may have with respect to any issue of fact or law set forth in this CAFO, including any right of review under Section 113(d)(4) of the Act, 42 U.S.C. § 7413(d)(4), and under 40 C.F.R. § 22.15(c), its right to seek federal judicial review of the CAFO pursuant to Chapter 7 of the Administrative Procedure Act, 5 U.S.C. §§ 701-06, any right to contest the allegations in this CAFO, and its right to appeal this CAFO. Respondent also consents to the issuance of this CAFO without further adjudication.

9. Under Section 113(d)(1) of the Act, 42 U.S.C. § 7413(d)(1), the Administrator of EPA (Administrator) may issue an administrative order against any person assessing a civil administrative penalty whenever, on the basis of any available information, the Administrator finds that such person has violated Section 112(r) of the Act and 40 C.F.R. Part 68. The Administrator may assess a civil penalty of up to \$47,357 per day for each violation, with a maximum of \$378,852, for violations that occurred after November 2, 2015, where penalties were assessed on or after February 6, 2019 but before January 13, 2020, and \$48,192 per day for each violation, with a maximum of \$385,535, for violations that occurred after November 2,

2015, where penalties are assessed on or after January 13, 2020. 42 U.S.C. § 7413(d)(1) and 40 C.F.R. Part 19.

10. The Administrator may assess a penalty greater than the administrative penalty cap where the Administrator and the Attorney General of the United States jointly determine that a matter involving a larger penalty is appropriate for an administrative penalty action.

42 U.S.C. § 7413(d)(1) and 40 C.F.R. Part 19.

11. The Administrator and the Attorney General of the United States, each through their respective delegates, have determined jointly that this matter, involving a penalty greater than \$385,535, is appropriate for an administrative penalty action.

12. Section 113(d)(1) of the Act, 42 U.S.C. § 7413(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 the Attorney General of the United States jointly determine that a matter involving a longer period of violation is appropriate for an administrative penalty action.

13. 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 CAFO.

#### **Statutory and Regulatory Background**

14. In accordance with Section 112(r) of the Act, 42 U.S.C. § 7412(r), EPA promulgated the "Accidental Release Prevention Requirements: Risk Management Programs Under Clean Air Act Section 112(r)(7)," 61 Fed. Reg. 31,668 (June 20, 1996), to prevent accidental releases of regulated substances and to minimize the consequences of those releases

that do occur. *See also* 84 Fed. Reg. 69,834 (Dec. 19, 2019). These regulations were codified at 40 C.F.R. Part 68 (Chemical Accident Prevention Provisions) and are commonly known as the “Risk Management Program regulations.”

15. The Risk Management Program regulations apply to all stationary sources with processes that contain more than a threshold quantity of a regulated substance. *See* 40 C.F.R. § 68.10(a). The List of Regulated Toxic Substances and Threshold Quantities for Accidental Release Prevention is codified at 40 C.F.R. § 68.130.

16. The Risk Management Program regulations define a “stationary source” as “any buildings, structures, equipment, installations, or substance emitting stationary activities which belong to the same industrial group, which are located on one or more contiguous properties, which are under the control of the same person (or persons under common control), and from which an accidental release may occur.” *See* 40 C.F.R. § 68.3.

17. The Risk Management Program regulations define a “process” as “any activity involving a regulated substance including any use, storage, manufacturing, handling, or on-site movement of such substances, or combination of these activities.” *See id.*

18. Ammonia is a “regulated substance” as that term is defined in Section 112(r)(2) of the Act and 40 C.F.R. § 68.3. *See* 40 C.F.R. § 68.130, Table 1.

19. The “threshold quantity” (as that term is defined in 40 C.F.R. § 68.3) for ammonia is 10,000 pounds. This threshold quantity is present at a stationary source if the total quantity of ammonia contained in a process exceeds 10,000 pounds. *See* 40 C.F.R. §§ 68.115(a) and 68.130, Table 1.

20. Each process in which a regulated substance is present in more than a threshold

quantity (a “covered process”) is subject to one of three risk management programs. *See* 40 C.F.R. § 68.10(g)-(i). Section 68.10(i) of the Risk Management Program regulations provides that a covered process is subject to Program 3 requirements if the process does not meet the requirements of 40 C.F.R. § 68.10(g) and if either of the following conditions is met: the process is in NAICS codes 32211, 32411, 32511, 325188, 325192, 325199, 325211, or 32532; or the process is subject to the U.S. Occupational Safety and Health Administration (OSHA) process safety management standard, 29 C.F.R. § 1910.119.

21. In addition to meeting the requirement to submit a risk management plan (RMP) under 40 C.F.R. § 68.12(a), the Program 3 requirements include developing and implementing a management system as provided in 40 C.F.R. § 68.15; conducting a hazard assessment as provided in 40 C.F.R. §§ 68.20 through 68.42; implementing the prevention requirements of 40 C.F.R. §§ 68.65 through 68.87; developing and implementing an emergency response program as provided in 40 C.F.R. §§ 68.90 to 68.96; and submitting as part of the RMP the data on prevention program elements for Program 3 processes as provided in 40 C.F.R. § 68.175. *See* 40 C.F.R. § 68.12(d).

#### **Factual Allegations and Alleged Violations**

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

23. Respondent owns and operates a facility at 1201 N. Kinzie Ave., Bradley, Illinois 60915 (the “facility”). Respondent is thus the “owner or operator” of the facility for purposes of 40 C.F.R. Part 68. *See* 42 U.S.C. § 7412(a)(9) (definition of “owner or operator”).

24. The facility consists of buildings, structures, equipment, installations, or

substance emitting stationary activities which belong to the same industrial group, which are located on one or more contiguous properties, which are under the control of the same person (or persons under common control), and from which an accidental release may occur. The facility is thus a “stationary source” under 40 C.F.R. § 68.3.

25. Respondent stores and uses ammonia, a “regulated substance” under Section 112(r)(3) of the Act and 40 C.F.R. § 68.3, at the facility in parts of the storage and refrigeration process. Respondent’s activities involving a regulated substance thus constitute a “process” under 40 C.F.R. § 68.3.

26. Respondent’s storage and refrigeration process described in paragraph 25 contains more than the threshold quantity (10,000 pounds) of ammonia. *See* 40 C.F.R. § 68.130, Table 1.

27. The Risk Management Program regulations apply to Respondent’s facility as a stationary source with a process that contains more than a threshold quantity of a regulated substance. *See* 40 C.F.R. § 68.10(a).

28. Respondent’s storage and refrigeration process does not meet the eligibility requirements for Program 1 under 40 C.F.R. § 68.10(g) and is subject to the OSHA process safety management standard since the process involves ammonia above the threshold quantity in 29 C.F.R. § 1910.119, App. A. Therefore, Respondent’s storage and refrigeration process is subject to Program 3 pursuant to 40 C.F.R. § 68.10(i), and must meet the requirements of Program 3 set forth at 40 C.F.R. § 68.12(a) and (d).

29. On June 19, 2018 and July 24, 2018, representatives from EPA conducted an inspection at 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 Risk Management Program regulations.

30. Based on the inspection conducted by EPA, EPA alleges that Respondent failed to comply with the Risk Management Program regulations at the facility for Program 3 requirements as set forth below:

#### Hazard Assessment

- a. CSL failed to use the most recent Census data or other updated information to estimate the population potentially affected, as required under 40 C.F.R. § 68.30(c).
- b. CSL failed to review and update the offsite consequence analyses at least once every five years, as required under 40 C.F.R. § 68.36(a).
- c. CSL failed to maintain records on the offsite consequence analyses that includes for the worst-case release scenario, a description of the vessel or pipeline and substance selected as worst case, assumptions and parameters used, and the rationale for the selection, and any anticipated effects of controls and mitigation on the release quantity and rate, as required under 40 C.F.R. § 68.39(a).
- d. CSL failed to maintain records on the offsite consequence analyses that include for the alternative release scenarios, a description of the scenarios identified, assumptions and parameters used, the rationale for the selection of specific scenarios, and the effects of controls and mitigation on the release quantity and rate, as required under 40 C.F.R. § 68.39(b).
- e. CSL failed to maintain records on the offsite consequence analyses that includes the data used to estimate population and environmental receptors potentially affected, as required under 40 C.F.R. § 68.39(e).

#### Process Safety Information

- f. CSL failed to compile written process safety information including information pertaining to the equipment in the process, specifically electrical classification, as required under 40 C.F.R. § 68.65(d)(1)(iii).
- g. CSL failed to compile written process safety information including information pertaining to the equipment in the process, specifically relief system design and design basis, as required under 40 C.F.R. § 68.65(d)(1)(iv).



- h. CSL failed to compile written process safety information including information pertaining to the equipment in the process, specifically ventilation system design, as required under 40 C.F.R. § 68.65(d)(1)(v).
- i. CSL failed to document that equipment complies with recognized and generally accepted good engineering practices, as required under 40 C.F.R. § 68.65(d)(2).

#### Process Hazard Analysis

- j. CSL failed to perform a process hazard analysis that addressed the hazards of the process, identification of previous incidents which had a likely potential for catastrophic consequences, engineering and administrative controls applicable to the hazards and their interrelationships, consequences of failure of engineering and administrative controls, stationary source siting, human factors, and a qualitative evaluation of a range of the possible safety and health effects of failure of controls, as required under 40 C.F.R. § 68.67(c).
- k. CSL failed to establish a system to promptly address the team's findings and recommendations; assure that the recommendations are resolved in a timely manner and that the resolution is documented; document what actions are to be taken; complete actions as soon as possible; develop a written schedule of when these actions are to be completed; communicate the actions to operating, maintenance, and other employees whose work assignments are in the process and who may be affected by the recommendations or actions, as required under 40 C.F.R. § 68.67(e).

#### Operating Procedures

- l. CSL failed to develop written operating procedures that provide clear instructions for safely conducting activities involved in each covered process consistent with the process safety information and that address emergency shutdown including the conditions under which emergency shutdown is required and the assignment of shutdown responsibility to qualified operators to ensure that emergency shutdown is executed in a safe and timely manner, as required under 40 C.F.R. § 68.69(a)(1)(iv).
- m. CSL failed to develop written operating procedures that provide clear instructions for safely conducting activities involved in each covered process consistent with the process safety information and that address emergency operations, as required under 40 C.F.R. § 68.69(a)(1)(v).

## Mechanical Integrity

- n. CSL failed to implement written procedures to maintain the ongoing integrity of process equipment, as required under 40 C.F.R. § 68.73(b).
- o. CSL failed to perform inspections and tests on process equipment at a frequency consistent with applicable manufacturers' recommendations and good engineering practices, and more frequently if determined to be necessary by prior operating experience, as required under 40 C.F.R. § 68.73(d)(3).
- p. CSL failed to correct deficiencies in equipment that are outside acceptable limits before further use or in a safe and timely manner when necessary means are taken to assure safe operations, as required under 40 C.F.R. § 68.73(e).

## Management of Change

- q. CSL failed to implement written procedures to manage changes to process chemicals, technology, equipment, and procedures, as required under 40 C.F.R. § 68.75(a).
- r. CSL failed to assure that the procedures addressed the time period necessary for the changes, as required by 40 C.F.R. § 68.75(b)(4).

## Compliance Audit

- s. CSL failed to promptly determine and document an appropriate response to each of the findings of the compliance audit and document that deficiencies have been corrected, as required under 40 C.F.R. § 68.79(d).

## Hot Work

- t. CSL failed to issue a hot work permit that identified the object on which hot work is to be performed, as required by 40 C.F.R. § 68.85(b).

## Emergency Response

- u. CSL failed to develop and implement an emergency response program that included an emergency response plan with procedures on the use of emergency response equipment and for its inspection, testing and maintenance, as required under 40 C.F.R. § 68.95(a)(2).

## Risk Management Plan

- v. CSL failed to revise and update the RMP within six months of a change that

requires a revised PHA or hazard review, as required under 40 C.F.R. § 68.190(b)(5).

31. Section 112(r)(7)(E) of the Act, 42 U.S.C. § 7412(r)(7)(E), provides that after the effective date of any regulation or requirement imposed under Section 112(r) of the Act, it shall be unlawful for any person to operate any stationary source subject to such regulation or requirement in violation of such regulation or requirement.

#### **Civil Penalty**

32. Complainant has determined that an appropriate civil penalty to settle this action is \$527,144. 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 cooperation and expeditious return to compliance. Complainant has also considered U.S. 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).

33. Within 30 days after the effective date of this CAFO, Respondent must pay the \$527,144 civil penalty by sending a cashier's or certified check, payable to the "Treasurer, United States of America," to:

U.S. Environmental Protection Agency  
Fines and Penalties  
Cincinnati Finance Center  
P.O. Box 979077  
St. Louis, Missouri 63197-9000

The check must note the following: the case title ("In the Matter of CSL Behring LLC") and the docket number of this CAFO.

34. A transmittal letter stating Respondent's name, complete address, and the docket number of this CAFO must accompany the payment in paragraph 32. Respondent must send a

copy of the check and transmittal letter to:

Regional Hearing Clerk (E-19J)  
U.S. EPA, Region 5  
77 West Jackson Boulevard  
Chicago, Illinois 60604

Monika Chrzaszcz (SE-5J)  
Environmental Engineer  
U.S. EPA, Region 5  
77 West Jackson Boulevard  
Chicago, Illinois 60604  
Chrzaszcz.monika@epa.gov

William Wagner (C-14J)  
Office of Regional Counsel  
U.S. EPA, Region 5  
77 West Jackson Boulevard  
Chicago, Illinois 60604  
Wagner.william@epa.gov

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

36. If Respondent does not timely pay the civil penalty, EPA shall request the Attorney General to bring a civil action in the appropriate district court to recover the amount assessed (plus interest at rates established pursuant to 26 U.S.C. § 6621(a)(2) from the effective date of the CAFO), as well as the United States enforcement expenses, including but not limited to attorneys fees and costs incurred by the United States for collection proceedings. Respondent acknowledges that, in such an action, the validity, amount, and appropriateness of the civil penalty shall not be subject to review.

37. 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 amount overdue from the date the 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). Such nonpayment penalty shall be 10 percent of the aggregate amount of such person's outstanding penalties and nonpayment penalties accrued as of the beginning of such quarter. *Id.*

### **General Provisions**

38. Pursuant to 40 C.F.R. § 22.5(b)(2), the Parties consent to service of this CAFO by email at the following email addresses: wagner.william@epa.gov (for Complainant) and jose.gonzalez@cslbehring.com (for Respondent). *See* 40 C.F.R. § 22.5-6. The parties waive their right to service by the methods specified in 40 C.F.R. § 22.6.

39. Respondent's full compliance with this CAFO shall only resolve Respondent's liability for federal civil penalties for the violations alleged in the CAFO.

40. This CAFO does not affect the rights of EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law.

41. This CAFO does not affect Respondent's responsibility to comply with the Act, the Risk Program Management regulations, and any other applicable federal, state, and local laws and regulations.

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

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

44. Each person signing this CAFO 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.

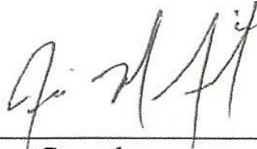
45. Each party agrees to bear its own costs and attorney's fees in this action.

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

47. The effective date of this CAFO is the date on which it is filed with the Regional Hearing Clerk.

**In the Matter of CSL Behring LLC**  
**Docket No. CAA-05-2021-0018**

3/25/2021  
Date

  
\_\_\_\_\_  
Jose Gonzalez  
Senior Vice President and General Manager  
CSL Behring LLC

**United States Environmental Protection Agency, Complainant**

\_\_\_\_\_  
Date

**MICHAEL HARRIS**   
\_\_\_\_\_  
Michael D. Harris,  
Director  
Enforcement and Compliance Assurance Division

Digitally signed by  
MICHAEL HARRIS  
Date: 2021.04.23  
11:31:45 -05'00'

**In the Matter of CSL Behring LLC**  
**Docket No. CAA-05-2021-0018**

**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.

\_\_\_\_\_  
Date

**ANN COYLE** Digitally signed by ANN  
COYLE  
Date: 2021.04.28  
12:24:51 -05'00'  
\_\_\_\_\_  
Ann L. Coyle  
Regional Judicial Officer  
United States Environmental Protection Agency  
Region 5



Consent Agreement and Final Order  
In the matter of: CSL Behring LLC  
Docket Number:

**CERTIFICATE OF SERVICE**

I certify that I served a true and correct copy of the foregoing **Consent Agreement and Final Order**, docket number \_\_\_\_\_ which was filed on \_\_\_\_\_ in the following manner to the following addresses:

Copy by E-mail to  
Respondent:

Jose Gonzalez  
Email: [jose.gonzalez@cslbehring.com](mailto:jose.gonzalez@cslbehring.com)

Copy by E-mail to  
RMP Contact:

Monika Chrzaszcz  
Chrzaszcz.monika@epa.gov

Copy by E-mail to  
Attorney for Complainant:

William Wagner  
Wagner.william@epa.gov

Copy by e-mail to  
Regional Judicial Officer:

Ann Coyle  
[coyle.ann@epa.gov](mailto:coyle.ann@epa.gov)

Dated: \_\_\_\_\_

LADAWN WHITEHEAD Digitally signed by LADAWN WHITEHEAD  
Date: 2021.05.03 10:55:10 -05'00'

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