

**BEFORE THE UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
REGION III**

In the Matter of: :  
:  
Sanofi Pasteur, Inc. :  
:  
Respondent, :  
:  
Sanofi Pasteur, Inc. :  
1 Discovery Drive :  
Swiftwater, PA 18730, :  
:  
Facility. :  
:  
:

EPA Docket No. RCRA-03-2014-0235

Proceeding under Section 3008(a)  
of the Resource Conservation and  
Recovery Act, as amended, 42 U.S.C.  
Section 6928(a)

REGIONAL HEARING OFFICE  
 EPA REGION III, PHILADELPHIA, PA  
 2014 SEP 30 AM 7:47

RECEIVED

**I. PRELIMINARY STATEMENT**

1. This Consent Agreement is entered into by the Director, Land and Chemicals Division, U.S. Environmental Protection Agency, Region III (“EPA”, “Agency” or “Complainant”) and Sanofi Pasteur, Inc. (“Respondent”) pursuant to Sections 3008(a) and (g) of the Solid Waste Disposal Act, commonly known as the Resource Conservation and Recovery Act of 1976, as amended by *inter alia*, the Hazardous and Solid Waste Amendments of 1984 (collectively referred to hereinafter as “RCRA”), 42 U.S.C. §§ 6928(a) and (g), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, and the Revocation/Termination or Suspension of Permits (“Consolidated Rules of Practice”), 40 C.F.R. Part 22, including, specifically, 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3).
2. This Consent Agreement (“CA”) and the accompanying Final Order (“FO”) address alleged violations by Respondent of RCRA and the federally authorized Pennsylvania Hazardous Waste Management Regulations (“PaHWMR”), codified at 25 Pa. Code Chapters 260a – 266a, 266b, and 268a – 270a. Effective January 30, 1986, the PaHWMR was authorized by the EPA pursuant to Section 3006(b) of RCRA, 42 U.S.C. § 6926(b), and 40 C.F.R. Part 271, Subpart A and thereby became requirements of RCRA Subtitle C and enforceable by EPA pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a). See *51 Fed.Reg. 1791* (January 15, 1986), *65 Fed. Reg. 57734* (September 26, 2000), *69 Fed. Reg. 2674* (January 20, 2004) and *74 Fed. Reg. 19453* (April 29, 2009). The PaHWMR incorporate, with certain exceptions, specific provisions of Title 40 of the 1999 Code of

Federal Regulations by reference. See 25 Pa. Code § 260a.3(e).

3. Pursuant to Section 22.13(b) of the Consolidated Rules of Practice, 40 C.F.R. § 22.13(b), this CA and the attached FO (hereinafter jointly referred to as this “CAFO”) simultaneously commence and conclude an administrative proceeding against Respondent, brought under Sections 3008(a) and (g) of RCRA, 42 U.S.C. §§ 6928(a) and (g), to resolve alleged violations of RCRA at Respondent’s facility at 1 Discovery Drive, Swiftwater, Pennsylvania, 18730.
4. For purposes of this proceeding only, Respondent admits the jurisdictional allegations set forth in this CAFO.
5. For purposes of this proceeding, Respondent neither admits nor denies the specific factual allegations and conclusions of law set forth in this CA, except as provided in Paragraph 4, above.
6. For the purposes of this proceeding only, Respondent agrees not to contest EPA’s jurisdiction with respect to the execution and issuance of this CAFO, or the enforcement of the CAFO.
7. For purposes of this proceeding only, Respondent hereby expressly waives its right to contest the allegations set forth in this CA and any right to appeal the accompanying FO.
8. Respondent consents to the issuance of this CAFO and agrees to comply with its terms.
9. Each party shall bear its own costs and attorney’s fees in connection with this proceeding.

Notice of Action to the Commonwealth of Pennsylvania

10. EPA has given the Commonwealth of Pennsylvania, through the Pennsylvania Department of Environmental Protection (“PaDEP”), prior notice of the initiation of this action in accordance with Section 3008(a)(2) of RCRA, 42 U.S.C. § 6928(a)(2).

II. FINDINGS OF FACT AND CONCLUSIONS OF LAW

In accordance with 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3), Complainant alleges the following findings of fact and conclusions of law:

11. Respondent is, and was at the time of the violations alleged herein, a corporation of the State of Delaware, and is a “person” as defined in Section 1004(15) of RCRA, 42 U.S.C. § 6903(15), and as defined in 25 Pa. Code § 260a.10.

12. Respondent is, and has been at all times relevant to this Consent Agreement, the “owner” and “operator” of a “facility”, described below, as the term “facility” is defined in 25 Pa. Code § 260a.10 and the terms “owner” and “operator” are defined in 40 C.F.R. § 260.10 as incorporated by reference in 25 Pa. Code § 260a.1.
13. The facility referred to in Paragraph 12, above, including all of its associated equipment and structures (hereinafter the “Facility”), is a manufacturing facility located at 1 Discovery Place, Swiftwater, Pennsylvania, 18730.
14. Respondent generates more than 1,000 kilograms of hazardous waste per month. Respondent is assigned EPA ID No. PAD086723285.
15. Respondent is and, at all times relevant to this CAFO, has been a “generator” of, and has engaged in the “storage” in “containers” and “tanks” at the Facility of materials described below that are “solid wastes” and “hazardous wastes”, as those terms are defined in 40 C.F.R. § 260.10 as incorporated by reference by 25 Pa. Code § 260a.1, which with the exception, of “storage” which is defined in 25 Pa. Code § 260a.10.
16. On September 20-22, 2011 and February 20, 2013, representatives of EPA and the PaDEP conducted RCRA Compliance Evaluation Inspections (“RCRA CEI”) at the Facility.
17. On September 20-22, 2011 and February 20, 2013, “hazardous wastes” generated by Respondent, identified below in paragraphs 18 – 21, were in “storage” in containers and tanks at the Facility.
18. Respondent generates waste mixture of ethanol and phenol at the Facility. Waste mixed ethanol and phenol is a hazardous waste (D001) within the meaning of 25 Pa. Code § 261a.1, which incorporates by reference 40 C.F.R. § 261.21, because it exhibits the characteristic for ignitability.
19. Respondent generates high pH buffer waste at the Facility. High pH buffer waste is a hazardous waste (D002) within the meaning of 25 Pa. Code § 261a.1, which incorporates by reference 40 C.F.R. § 261.22, because it exhibits the characteristic for corrosivity.
20. Respondent generates a waste mixture of acetonitrile, triethylamine, and hydrogen chloride (“ACE/TEA/HCL”) at the Facility. Waste ACE/TEA/HCL is a hazardous waste (D002) within the meaning of 25 Pa. Code § 261a.1, which incorporates by reference 40 C.F.R. § 261.22, because it exhibits the characteristic for corrosivity.
21. Respondent generates waste aerosol cans at the Facility. Waste aerosol cans are hazardous waste (D001) within the meaning of 25 Pa. Code § 261a.1, which incorporates by reference 40 C.F.R. § 261.21, because it exhibits the characteristic for ignitability.

COUNT I

(Operating Without Qualifying for a Permit Exemption or Obtaining Interim Status or a Permit)

22. The preceding paragraphs are incorporated by reference.
23. 25 Pa. Code § 270a.1, which incorporates by reference 40 C.F.R. § 270.1(b), and Section 3005(a) and (e) of RCRA, 42 U.S.C. § 6925(a) and (e), provide, in pertinent part, that a person may not own or operate a facility for the treatment, storage or disposal of hazardous waste unless such person has first obtained a permit for such facility or has qualified for interim status for the facility.
24. 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(3) provides, in pertinent part, that a generator may accumulate hazardous waste in containers on-site for 90 days or less without a permit or having interim status provided that, among other things, while being accumulated on-site, the generator labels each container is clearly marked with the words “Hazardous Waste.”
25. 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(c)(1) provides, in pertinent part, that a generator may accumulate up to 55 gallons of hazardous waste or one quart of acutely hazardous waste listed in 40 C.F.R. § 261.31 or 40 C.F.R. § 261.33(e) in containers at or near the point of generation where wastes initially accumulate which is under the control of the operator of the process generating the waste without a permit or having interim status provided that, among other things, the generator complies with the requirements of 40 C.F.R. § 262.34(c)(1)(ii). 40 C.F.R. § 262.34(c)(1)(ii) requires each container be labeled with the words “Hazardous Waste” or with other words that identify the contents of the container.
26. At the time of the September 20 – 22, 2011 RCRA CEI, Respondent had not labeled a five gallon carboy used to accumulate waste high pH buffer with the words “Hazardous Waste” as required by 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(3).
27. At the time of the September 20 – 22, 2011 RCRA CEI, Respondent had not labeled a five gallon carboy used as a satellite accumulation container for waste high pH buffer with the words “Hazardous Waste” or with other words that identify the contents of the container as required by 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(c)(1)(ii).

28. 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(1)(i) provides, in pertinent part, that a generator may accumulate hazardous waste in containers on-site for 90 days or less without a permit or having interim status provided that, among other things, while being accumulated on-site, the generator complies with the requirements of 40 C.F.R. § 265.173(a). 40 C.F.R. § 265.173(a) requires each container holding hazardous waste be closed during storage, except when necessary to add or remove waste.
29. 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(c)(1)(i) provides, in pertinent part, that a generator may accumulate up to 55 gallons of hazardous waste or one quart of acutely hazardous waste listed in 40 C.F.R. § 261.31 or 40 C.F.R. § 261.33(e) in containers at or near the point of generation where wastes initially accumulate which is under the control of the operator of the process generating the waste without a permit or having interim status provided that, among other things, the generator complies with the requirements of 40 C.F.R. § 265.173(a). 40 C.F.R. § 265.173(a) requires each container holding hazardous waste be closed during storage, except when necessary to add or remove waste.
30. At the time of the September 20 – 22, 2011 inspection, Respondent did not keep a container holding waste ACE/TEA/HCL closed during storage except when necessary to add or remove waste as required by 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(1)(i), which in turn references 40 C.F.R. § 265.173(a).
31. At the time of the September 20 – 22, 2011 inspection, Respondent did not keep a satellite container holding waste ACE/TEA/HCL closed during storage except when necessary to add or remove waste as required by 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(c)(1)(i), which in turn references 40 C.F.R. § 265.173(a).
32. 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(c)(1) provides, in pertinent part, that a generator may accumulate up to 55 gallons of hazardous waste or one quart of acutely hazardous waste listed in 40 C.F.R. § 261.31 or 40 C.F.R. § 261.33(e) in containers at or near the point of generation where wastes initially accumulate which is under the control of the operator of the process generating the waste without a permit or having interim status provided that, among other things, the generator complies with the requirements of 40 C.F.R. § 262.34(c)(1).
33. At the time of the September 20 – 22, 2011 RCRA CEI, Respondent accumulated waste aerosol cans in a 30 gallon container located in Room 162 of the Facility, which was not at or near the point of generation where the waste aerosol wastes were generated, as required by 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(c)(1).

34. 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(1)(i) provides, in pertinent part, that a generator may accumulate hazardous waste in containers on-site for 90 days or less without a permit or having interim status provided that, among other things, while being stored on-site, the generator complies with the applicable requirements of 40 C.F.R. Part 265, Subpart BB. 40 C.F.R. Part 265, Subpart BB at § 265.1057, provides that owners and operators of facilities which treat, store or dispose of hazardous waste must monitor monthly each valve that contains or contacts hazardous wastes with organic concentrations of at least 10 percent by weight and that is managed in a unit listed in 40 C.F.R. § 265.1050(b)(1) – (3).
35. From at least July 1, 2009 until July 1, 2014, Respondent did not monitor each month three valves identified as HV099, XV6004, and HV015, which were subject to the requirements of 40 C.F.R. § 265.1057 as required by 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(1)(i), which in turn references 40 C.F.R. § 265.1057.
36. 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(1)(i) provides, in pertinent part, that a generator may accumulate hazardous waste in containers on-site for 90 days or less without a permit or having interim status provided that, among other things, while being stored on-site, the generator complies with the applicable requirements of 40 C.F.R. Part 265, Subpart BB. 40 C.F.R. Part 265, Subpart BB at § 265.1056(a)(1), provides that owners and operators of facilities which treat, store or dispose of hazardous waste must equip each open-ended valve or line that contains or contacts hazardous wastes with organic concentrations of at least 10 percent by weight and that is managed in a unit listed in 40 C.F.R. § 265.1050(b)(1) – (3) with a cap, blind flange, or a second valve.
37. From at least July 1, 2009 until July 1, 2014, Respondent did not equip one open-ended valve that contains or contacts hazardous wastes with organic concentrations of at least 10 percent by weight and that is managed in a unit listed in 40 C.F.R. § 265.1050(b)(1) – (3) with a cap, blind flange, or a second valve as required by 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(1)(i), which in turn references 40 C.F.R. § 265.1056(a)(1).
38. 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(1)(i) provides, in pertinent part, that a generator may accumulate hazardous waste in containers on-site for 90 days or less without a permit or having interim status provided that, among other things, while being stored on-site, the generator complies with the applicable requirements of 40 C.F.R. Part 265, Subpart BB. 40 C.F.R. Part 265, Subpart BB at § 265.1063(d), provides that owners and operators of facilities which treat, store or dispose of hazardous waste must determine, for each piece of equipment, whether the equipment contains or contacts a hazardous waste with organic concentrations of at least 10 percent by weight.

39. From at least July 1, 2009 until May 28, 2014, Respondent did not determine, for valves identified as HV099, XV6004, and HV015, whether such equipment contains or contacts a hazardous waste with organic concentrations of at least 10 percent by weight as required by 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(1)(i), which in turn references 40 C.F.R. § 265.1063(d).
40. Respondent failed to qualify for the “less than 90-day” generator accumulation exemption of 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a), by failing to satisfy the conditions for such exemptions as set forth in 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a), referred to in Paragraphs 24, 28, 34, 36 and 38, above as described in Paragraphs 26, 30, 35, 37 and 39, above.
41. Respondent failed to qualify for the generator satellite accumulation exemption of 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(c), by failing to satisfy the conditions for such exemptions as set forth in 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(c), referred to in Paragraphs 25, 29, and 32, above, as described in Paragraphs 27, 31 and 33, above.
42. By failing to meet the criteria for an exemption from permitting or interim status under 40 C.F.R. § 262.34(a) and/or (c), the Facility became a hazardous waste treatment, storage or disposal “facility”, as that term is defined by 25 Pa. Code § 260a.10.
43. Respondent does not have, and never had, a permit or interim status pursuant to 25 Pa. Code § 270a.1, which incorporates by reference 40 C.F.R. § 270.1(b), or Section 3005(a) of RCRA, 42 U.S.C. § 6925(a), for the storage of hazardous waste at the Facility.
44. Respondent was required by 25 Pa. Code § 270a.1, which incorporates by reference 40 C.F.R. § 270.1(b), and Section 3005(a) of RCRA, 42 U.S.C. § 6925(a), to obtain a permit for its hazardous waste storage activities described in this count.
45. Respondent violated 25 Pa. Code § 270a.1, which incorporates by reference 40 C.F.R. § 270.1(b), and Section 3005(a) of RCRA, 42 U.S.C. § 6925(a), by operating a hazardous waste storage facility without a permit or interim status or valid exemption.

COUNT II  
(Subpart BB Monitoring Requirements)

46. The preceding paragraphs are incorporated by reference.

47. 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.1057, requires owners and operators of facilities which treat, store or dispose of hazardous waste to monitor monthly, using the method set forth in 40 C.F.R. § 264.1063(b), each valve in gas/vapor or light liquid service at the Facility that contains or contacts hazardous wastes with organic concentrations of at least 10 percent by weight and that is managed in a unit listed in 40 C.F.R. § 264.1050(b)(1) – (3).
48. From at least July 1, 2009 until July 1, 2014, Respondent did not monitor, using the method set forth in 40 C.F.R. § 264.1063(b), three valves in gas/vapor or light liquid service identified as HV099, XV6004, and HV015 at the Facility that contain or contact hazardous wastes with organic concentrations of at least 10 percent by weight and that are managed in a unit listed in 40 C.F.R. § 264.1050(b)(1) – (3) as required by 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.1057.
49. Respondent violated 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.1057 by failing to monitor monthly, using the method set forth in 40 C.F.R. § 264.1063(b), three valves in gas/vapor or light liquid service at the Facility that contain or contact hazardous wastes with organic concentrations of at least 10 percent by weight and that are managed in a unit listed in 40 C.F.R. § 264.1050(b)(1) – (3).

### COUNT III

#### (Standards for Opened-Ended Valves or Lines)

50. The preceding paragraphs are incorporated by reference.
51. 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.1056(a)(1), requires owners and operators of facilities which treat, store or dispose of hazardous waste to equip each open-ended valve or line that contains or contacts hazardous wastes with organic concentrations of at least 10 percent by weight and that is managed in a unit listed in 40 C.F.R. § 264.1050(b)(1) – (3) with a cap, blind flange, or a second valve.
52. From at least July 1, 2009 until July 1, 2014, Respondent did not equip valve HV099, an open-ended valve at the Facility that contains or contacts hazardous wastes with organic concentrations of at least 10 percent by weight and that is managed in a unit listed in 40 C.F.R. § 264.1050(b)(1) – (3), with a cap, blind flange, or a second valve as required by 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.1056(a)(1).
53. Respondent violated 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.1056(a)(1), by failing to equip valve HV099, an open-ended valve at the Facility that contains or contacts hazardous wastes with organic concentrations of at least 10 percent by weight and that is managed in a unit listed in 40 C.F.R. § 264.1050(b)(1) – (3), with a cap, blind flange, or a second valve as required by 25 Pa. Code § 264a.10, which incorporates by reference 40 C.F.R. § 264.1056(a)(1).

COUNT IV  
(Subpart BB Equipment Determinations)

54. The preceding paragraphs are incorporated by reference.
55. 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.1063(d), requires owners and operators of facilities which treat, store or dispose of hazardous waste to determine, using a method set forth in 40 C.F.R. § 264.1063(d)(1) – (3), for each piece of equipment, whether the equipment contains or contacts a hazardous waste with organic concentrations of at least 10 percent by weight.
56. From at least July 1, 2009 until July 1, 2014, Respondent did not determine, using a method set forth in 40 C.F.R. § 264.1063(d)(1) – (3), for three valves at the Facility, whether such valves contain or contact a hazardous waste with organic concentrations of at least 10 percent by weight as required by 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.1063(d).
57. Respondent violated 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.1063(d), by failing to determine, using a method set forth in 40 C.F.R. § 264.1063(d)(1) – (3), for three valves at the Facility, whether such valves contain or contact a hazardous waste with organic concentrations of at least 10 percent by weight as required by 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.1063(d).

COUNT V  
(Manifests)

58. The preceding paragraphs are incorporated by reference.
59. 25 Pa. Code § 262a.1, which incorporates by reference 40 C.F.R. § 262.42(a)(2), requires that a generator of greater than 1000 kilograms of hazardous waste in a calendar month who does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within forty-five days of the date the waste was accepted by the initial transporter, must submit an Exception Report conforming to the requirements of 40 C.F.R. § 262.42(a)(2)(i) and (ii) to the EPA Regional Administrator for the Region in which the generator is located.
60. At the time of the September 20 – 22, 2011 RCRA CEI, over forty-five days had passed from the time the initial transporter accepted the waste shipped under hazardous waste manifest #005022476JJK, dated June 6, 2011, until Respondent received a copy of the manifest with the handwritten signature of the owner or operator of the designated facility.

61. At the time of the September 20 – 22, 2011 RCRA CEI, Respondent had not submitted an Exception Report conforming to the requirements of 40 C.F.R. § 262.42(a)(2)(i) and (ii) to the EPA Regional Administrator for EPA Region III for waste shipped under hazardous waste manifest #005022476JJK, dated June 6, 2011 as required by 25 Pa. Code § 262a.1, which incorporates by reference 40 C.F.R. § 262.42(a)(2).
62. Respondent violated 25 Pa. Code § 262a.1, which incorporates by reference 40 C.F.R. § 262.42(a)(2), by failing to submit an Exception Report conforming to the requirements of 40 C.F.R. § 262.42(a)(2)(i) and (ii) to the EPA Regional Administrator for EPA Region III for the hazardous waste shipped under hazardous waste manifest #005022476JJK dated June 6, 2011.

COUNT VI  
(Contingency Plan)

63. The preceding paragraphs are incorporated by reference.
64. Pursuant to 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.53(b), Respondent is required to submit a copy of the Facility's contingency plan and all revisions of the plan to all local police departments, fire departments, hospitals, and State and local emergency response teams that may be called upon to provide emergency services.
65. At the time of the September 20-22, 2011 and February 20, 2013 EPA RCRA CEIs, Respondent had not submitted a copy of the Facility's contingency plan and all revisions of the plan to the Office of Water Protection for the Pennsylvania Department of Environmental Protection and the Monroe County Office of Emergency Services as required by 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.53(b).
66. Respondent violated 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.53(b) by failing submit a copy of the Facility's contingency plan and all revisions of the pan to all local police departments, fire departments, hospitals, and State and local emergency response teams that may be called upon to provide emergency services.

COUNT VII  
(Container Management)

67. The preceding paragraphs are incorporated by reference.

68. 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.173(a), requires owners and operators that treat, store or dispose of hazardous waste to keep hazardous waste containers closed during storage, except when it is necessary to add or remove waste.
69. At the time of the September 20 – 22, 2011 RCRA CEI, Respondent did not keep closed a two gallon hazardous waste container holding waste ACE/TEA/HCL except when necessary to add or remove waste, as required by 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.173(a).
70. Respondent violated 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.173(a), by failing to keep a two gallon hazardous waste container of waste ACE/TEA/HCL closed except when necessary to add or remove waste.

### **III. CIVIL PENALTIES**

71. Respondent agrees to pay a civil penalty in the amount of **\$77,643** in settlement of the alleged violations set forth in this CAFO, which Respondent agrees to pay in accordance with the terms set forth below. Such civil penalty amount shall become due and payable immediately upon Respondent's receipt of a true and correct copy of the executed and filed CAFO. In order to avoid the assessment of interest, administrative costs, and late payment penalties in connection with such civil penalty as described in this CAFO, Respondent must pay the civil penalty no later than thirty (30) calendar days after the date on which a copy of the executed and filed CAFO is mailed or hand-delivered to Respondent.
72. Having determined that this Consent Agreement is in accordance with law and that the civil penalty amount was determined after consideration of the statutory factors set forth in Section 3008(a) of RCRA, 42 U.S.C. § 6928(a) which include the seriousness of the violation and any good faith efforts to comply with the applicable requirements, EPA hereby agrees and acknowledges that payment of the civil penalty shall be in full and final satisfaction of all civil claims for penalties which Complainant may have under Section 3008(a) of RCRA for the violations alleged in this CAFO.
73. The Parties find and represent that the aforesaid settlement amount is reasonable and is based upon Complainant's consideration of a number of factors, including the penalty criteria set forth in Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), which include the seriousness of the violation and any good faith efforts to comply with the applicable requirements. These factors were applied to the particular facts and circumstances of this case with specific reference to EPA's October, 1990 RCRA Civil Penalty Policy, as revised in June, 2003 ("RCRA Penalty Policy"), which reflects the statutory penalty criteria and factors set forth at Sections 3008(a)(3) and (g) of RCRA, 42 U.S.C. §§ 6982(a)(3) and (g), the *Adjustment of Civil Monetary Penalties for Inflation*, pursuant

to 40 C.F.R. Part 19, and the November 16, 2009 Memorandum by EPA Office of Civil Enforcement, Waste and Chemical Enforcement Division Director Rosemarie A. Kelly, entitled *Adjusted Penalty Matrices based on the 2008 Civil Monetary Penalty Inflation Adjustment Rule*.

74. Respondent shall remit the full penalty pursuant to paragraphs 71, above, and/or any administrative fees and late payment penalties, by cashier's check, certified check or electronic wire transfer, in the following manner:
- A. All payments by Respondent shall reference Respondent's name and address, and the Docket Number of this action, *i.e.*, RCRA-03-2014-0235
  - B. All checks shall be made payable to "United States Treasury";
  - C. All payments made by check and sent by regular mail shall be addressed to:

U.S. Environmental Protection Agency  
Cincinnati Finance Center  
P.O. Box 979077  
St. Louis, MO 63197-9000  
Contact: Craig Steffen 513-487-2091

- D. All payments made by check and sent by overnight delivery service shall be addressed for delivery to:

U.S. Environmental Protection Agency  
Government Lockbox 979077  
1005 Convention Plaza  
Mail Station SL-MO-C2-GL  
St. Louis, MO 63101  
Contact: 314-418-1818

- E. All payments made by electronic wire transfer shall be directed to:

Federal Reserve Bank of New York  
ABA = 021030004  
Account No. = 68010727  
SWIFT address = FRNYUS33  
33 Liberty Street  
New York, NY 10045

Field Tag 4200 of the Fedwire message should read:  
"D 68010727 Environmental Protection Agency"

- F. All electronic payments made through the Automated Clearinghouse (ACH), also known as Remittance Express (REX), shall be directed to:

US Treasury REX / Cashlink ACH Receiver  
ABA = 051036706  
Account No.: 310006, Environmental Protection Agency  
CTX Format Transaction Code 22 - Checking  
Physical location of U.S. Treasury facility:

Physical Location of U.S. Treasury facility:  
5700 Rivertech Court  
Riverdale, MD 20737  
Contact: John Schmid 202-874-7026 or REX, 1-866-234-5681

- G. On-Line Payment Option: [WWW.PAY.GOV/PAYGOV](http://WWW.PAY.GOV/PAYGOV)

Enter sfo 1.1 in the search field. Open and complete the form.

- H. Point Of Contact regarding payment questions (i.e. how to make payment via wire, ACH, check, pay.gov):  
Craig Steffen, 513-487-2091, [steffen.craig@epa.gov](mailto:steffen.craig@epa.gov)

Additional payment guidance is available at:  
<http://www2.epa.gov/financial/makepayment>.

75. At the time of payment, Respondent shall send a notice of such payment, including a copy of any check or electronic transfer, as appropriate, to:

Lydia Guy  
Regional Hearing Clerk  
U.S. Environmental Protection Agency  
Region III (Mail Code 3RC00)  
1650 Arch Street  
Philadelphia, PA 19103-2029

and

Joyce A. Howell  
Senior Assistant Regional Counsel  
U.S. Environmental Protection Agency  
Region III (Mail Code 3RC30)  
1650 Arch Street  
Philadelphia, PA 19103-2029

76. Respondent agrees not to deduct for civil taxation purposes the civil penalty specified in this Consent Agreement and the attached Final Order.
77. Pursuant to 31 U.S.C. § 3717 and 40 C.F.R. § 13.11, EPA is entitled to assess interest and late payment penalties on outstanding debts owed to the United States and a charge to cover the costs of processing and handling a delinquent claim, as more fully described below. Accordingly, Respondent's failure to make timely payment as specified in this CAFO shall result in the assessment of late payment charges including interest, penalties, and/or administrative costs of handling delinquent debts.
78. Interest on the civil penalty assessed in this CAFO will begin to accrue on the date that a copy of the executed and filed CAFO is mailed or hand-delivered to Respondent. However, EPA will not seek to recover interest on any amount of the civil penalty that is paid within thirty (30) calendar days after the date on which such interest begins to accrue. Interest will be assessed at the rate of the United States Treasury tax and loan rate in accordance with 40 C.F.R. § 13.11(a).
79. The costs of the Agency's administrative handling of overdue debts will be charged and assessed monthly throughout the period the debt is overdue. 40 C.F.R. § 13.11(b). Pursuant to Appendix 2 of EPA's *Resources Management Directives - Cash Management*, Chapter 9, EPA will assess a \$15.00 administrative handling charge for administrative costs on unpaid penalties for the first thirty (30) day period after the payment is due and an additional \$15.00 for each subsequent thirty (30) days the penalty remains unpaid. A penalty charge of six percent per year will be assessed monthly on any portion of the civil penalty which remains delinquent more than ninety (90) calendar days. 40 C.F.R. § 13.11(c). Should assessment of the penalty charge on the debt be required, it shall accrue from the first day payment is delinquent. 31 C.F.R. § 901.9(d).

#### **IV. EFFECT OF SETTLEMENT**

80. Payment of the penalty specified in Paragraph 71 above, shall constitute full and final satisfaction of all civil claims for penalties which Complainant has under RCRA Sections 3008(a) and (g), for the specific violations alleged in Counts I through VII, above. Compliance with this CAFO shall not be a defense to any action commenced at any time for any other violation of the federal laws and regulations administered by EPA.

## **V. RESERVATION OF RIGHTS**

81. This CAFO resolves only EPA's claims for civil penalties for the specific violations alleged in the CAFO. EPA reserves the right to commence action against any person, including Respondent, in response to any condition which EPA determines may present an imminent and substantial endangerment to the public health, public welfare, or the environment. In addition, this settlement is subject to all limitations on the scope of resolution and to the reservation of rights set forth in Section 22.18(c) of the Consolidated Rules of Practice. Further, EPA reserves any rights and remedies available to it under RCRA, the regulations promulgated thereunder, and any other federal laws or regulations for which EPA has jurisdiction, to enforce the provisions of this CAFO, following its filing with the Regional Hearing Clerk. Respondent reserves all available rights and defenses it may have to defend itself in any such action.

## **VI. OTHER APPLICABLE LAWS**

82. Nothing in this CAFO shall relieve Respondent of any duties otherwise imposed upon it by applicable federal, state, or local law and/or regulation.

## **VII. CERTIFICATION OF COMPLIANCE**

83. As to all relevant provisions of RCRA Subtitle C, 42 U.S.C. §§ 6901 *et seq.*, and the Commonwealth of Pennsylvania's federally authorized hazardous waste management program allegedly violated as set forth in at 25 Pa Code §§ 260a.1 *et seq.*, Respondent certifies to EPA that, upon investigation, to the best of Respondent's knowledge and belief, Respondent is currently in compliance with all such relevant provisions and regulations.

## **VIII. PARTIES BOUND**

84. This Consent Agreement and the accompanying Final Order shall apply to and be binding upon the EPA, the Respondent, Respondent's officers and directors (in their official capacity) and Respondent's successors and assigns. By his or her signature below, the person signing this Consent Agreement on behalf of Respondent acknowledges that he or she is fully authorized to enter into this Consent Agreement and to bind the Respondent to the terms and conditions of this Consent Agreement and the accompanying Final Order.

## **IX. EFFECTIVE DATE**

85. The effective date of this CAFO is the date on which it is filed with the Regional Hearing Clerk after signature by the Regional Judicial Officer or Regional Administrator.

For Respondent, Sanofi Pasteur, Inc.:

Date: 9/15/14

By: 

Name: Ron DiCola  
Title: Senior Director  
Health Safety and Environment

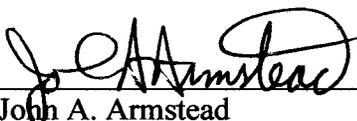
For Complainant, United States Environmental Protection Agency, Region III:

Date: 9/23/2014

By:   
Joyce A. Howell  
Senior Assistant Regional Counsel

After reviewing the foregoing Consent Agreement and other pertinent information, the Director, Land and Chemicals Division, EPA Region III, recommends that the Regional Administrator or the Regional Judicial Officer issue the Final Order attached hereto.

9.24.14  
Date

By:   
John A. Armstead  
Director  
Land and Chemicals Division

**BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION III  
1650 Arch Street  
Philadelphia, PA 19103-2029**

In the Matter of:	:	
	:	
Sanofi Pasteur, Inc.	:	
	:	
Respondent,	:	
	:	EPA Docket No. RCRA-03-2014-0235
Sanofi Pasteur, Inc.	:	
1 Discovery Drive	:	
Swiftwater, PA 18730	:	
	:	Proceeding under Section 3008(a)
	:	of the Resource Conservation and
	:	Recovery Act, as amended, 42 U.S.C.
	:	Section 6928(a)
Facility.	:	

**FINAL ORDER**

Complainant, the Director of the Land and Chemicals Division, U.S. Environmental Protection Agency - Region III, and Respondent, Sanofi Pasteur, Inc., have executed a document entitled "Consent Agreement" which I ratify as a Consent Agreement in accordance with the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits ("Consolidated Rules of Practice"), 40 C.F.R. Part 22 (with specific reference to 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3)). The terms of the foregoing Consent Agreement are incorporated herein by reference.

NOW, THEREFORE, pursuant to Section 3008(a) of the Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. § 6928(a), and based upon the representations of the parties set forth in the Consent Agreement that the civil penalty amount agreed to by the parties in settlement of the above-captioned matter is based upon a consideration of the factors set forth in RCRA Section 3008(a)(3), 42 U.S.C. § 6928(a)(3), IT IS HEREBY ORDERED THAT Respondent shall pay a civil penalty in the amount of **\$77,643.00**, as specified in the Consent Agreement, and comply with the terms and conditions of the Consent Agreement.

The effective date of this Final Order and the accompanying Consent Agreement is the date on which the Final Order is filed with the Regional Hearing Clerk of U.S. EPA, Region III.

Date: 9-25-14

By:   
Heather Gray  
Regional Judicial Officer

BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION III  
1650 Arch Street  
Philadelphia, PA 19103-2029

In the Matter of:

Sanofi Pasteur, Inc.

Respondent,

Sanofi Pasteur, Inc.  
1 Discovery Drive  
Swiftwater, PA 18730

Facility.

EPA Docket No. RCRA-03-0014-025

Proceeding under Section 3008  
of the Resource Conservation  
Recovery Act, as amended; 42 U.S.C.  
Section 6928(a)

2014 SEP 30 AM 7:47  
REGIONAL HEARING CLERK  
EPA REGION III PHILADELPHIA, PA

RECEIVED

**CERTIFICATE OF SERVICE**

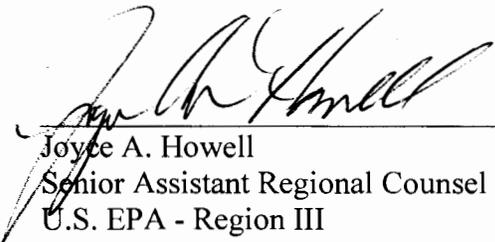
I certify that I sent a copy of the Consent Agreement and Final Order to the addressee listed below. The original and one copy of the Complaint were hand-delivered to the Regional Hearing Clerk, U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA 19103-2029.

Via UPS, next day delivery:

Christopher R. Nestor  
K&L Gates LLP  
17 North Second Street  
18th Floor  
Harrisburg, PA 17101-1507

Dated:

9/30/2014

  
Joyce A. Howell  
Senior Assistant Regional Counsel  
U.S. EPA - Region III