



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1650 Arch Street
Philadelphia, Pennsylvania 19103-2029

In the Matter of:)
)
Merck Sharp & Dohme Corporation)
2778 South East Side Highway)
Elkton, Virginia)
22827,)
)
Respondent.)
)
Merck Sharp & Dohme Corporation)
2778 South East Side Highway)
Elkton, Virginia)
22827,)
)
Facility.)
)

EPA Docket Nos.: EPCRA-03-2012-0164

Proceedings Pursuant to Sections 304, 312,
and 325 of the Emergency Planning and
Community Right-to-Know Act, 42 U.S.C.
§§ 11004, 11021, 11045.

REGIONAL HEARING CLERK
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CONSENT AGREEMENT

STATUTORY AUTHORITY

This Consent Agreement is proposed and entered into under the authority vested in the Administrator of EPA by Section 325 of the Emergency Planning and Community Right-to-Know Act of 1986 (“EPCRA”), 42 U.S.C. § 11045, delegated to the Regional Administrator by EPA Delegation No. 22-3-A, and redelegated to Complainant by EPA Region III Delegation No. 22-3-A. This Consent Agreement is also proposed and entered into under the authority provided by 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 (“Part 22”). The parties agree to the commencement and conclusion of this cause of action by issuance of this Consent Agreement and Final Order (referred to collectively herein as “CA/FO”) as prescribed by the Consolidated Rules of Practice pursuant to 40 C.F.R. § 22.13(b), and having consented to the entry of this CA/FO, agree to comply with the terms of this CA/FO.

PRELIMINARY STATEMENT

1. The implementing regulations for the hazardous chemical reporting requirements of Section 312 of EPCRA, 42 U.S.C. § 11022, are codified at 40 C.F.R. Part 370. On November 3, 2008, EPA issued a final rule, 73 Fed. Reg. 65451 (Nov. 3, 2008), *inter alia*, to make these regulations easier to read by presenting them in a plain language format. The amendments resulted in a re-numbering of 40 C.F.R. Part 370, which became effective on December 3, 2008. This CA/FO references the newly effective numbering, but includes the pre-2008 numbering in parentheses since those regulations were in effect at the time of certain of the violations alleged herein.

FINDINGS OF FACT

2. Section 302(a) of EPCRA, 42 U.S.C. § 11002(a), requires the Administrator of EPA to publish a list of Extremely Hazardous Substances (“EHSs”) and to promulgate regulations establishing that quantity of any EHS the release of which shall be required to be reported under Section 304(a) through (c) of EPCRA, 42 U.S.C. § 11004(a) through (c), (“Reportable Quantity” or “RQ”). The list of EHSs and their respective RQs is codified at 40 C.F.R. Part 355, Appendices A and B.

3. Respondent Merck Sharp & Dohme Corporation (“Merck” or “Respondent”) is a corporation established under the laws of the State of New Jersey, with its principal place of business located at 1 Merck Drive in Whitehouse Station, New Jersey.

4. As a corporation, Respondent is a “person” as defined by Section 329(7) of EPCRA, 42 U.S.C. § 11049(7), and 40 C.F.R. §§ 355.61 and 370.66 (370.2).

5. Beginning in or about 1941, and at all times relevant to this CA/FO, Respondent has been the owner and operator of, within the meaning of Section 304 of EPCRA, 42 U.S.C. § 11004, of the manufacturing facility located at 2778 South East Side Highway in Elkton, Virginia (“Merck Facility”).

6. The Merck Facility is a “facility” as defined by Section 304 of EPCRA, 42 U.S.C. § 11004, and 40 C.F.R. §§ 355.61 and 370.66 (370.2).

7. On or about July 20, 2010, EPA conducted an inspection of the Merck Facility to determine the facility’s compliance with Section 103 of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended, 42 U.S.C. § 9603, and Sections 302-312 of EPCRA, 42 U.S.C. §§ 11002-11022.

8. At all times relevant to this CA/FO, the Merck Facility was a facility at which a hazardous chemical was produced, used or stored.

**FINDINGS OF FACT RELATED TO THE
VIOLATION OF SECTION 304(c) OF EPCRA – SERC**

9. The findings of fact and conclusions of law contained in paragraphs 1 through 8 of this CA/FO are incorporated by reference herein as though fully set forth at length.

10. Section 304(a) and (b) of EPCRA, 42 U.S.C. § 11004(a) and (b), as implemented by 40 C.F.R. Part 355, Subpart C, requires, in relevant part, the owner or operator of a facility at which hazardous chemicals are produced, used, or stored to notify the State Emergency Response Commission (“SERC”) and the local Emergency Planning Committee (“LEPC”) immediately following a release of a hazardous substance or an EHS in a quantity equal to or exceeding the RQ for the hazardous substance or EHS.

11. Section 304(c) of EPCRA, 42 U.S.C. § 11004(c), as implemented by 40 C.F.R. Part 355, Subpart C, requires, in relevant part, that when there has been a release of a hazardous substance or an EHS requiring notification under Section 304(a) of EPCRA, 42 U.S.C. § 11004(a), the owner or operator of the facility from which the release occurred must provide a written follow-up report regarding the release to the SERC and the LEPC as soon as practicable.

12. Beginning on or about July 12, 2009, at or about 8:43 p.m., an estimated 400 pounds of ammonia, Chemical Abstracts Service (“CAS”) No. 7664-41-7, were released from the Merck Facility (the “Release”).

13. Ammonia is an EHS as defined under Section 302(a) of EPCRA, 42 U.S.C. § 11002(a), and 40 C.F.R. § 355.61, with an RQ of 100 pounds, as listed in 40 C.F.R. Part 355, Appendices A and B.

14. The SERC for the Merck Facility for the purpose of emergency release notification is, and has been at all times relevant to this CA/FO, the Virginia Emergency Response Counsel, c/o Virginia Department of Environmental Quality, 629 East Main Street, in Richmond, Virginia.

15. The Release constitutes a release of an EHS in a quantity equal to or exceeding its RQ, requiring immediate notification of the SERC and LEPC pursuant to Section 304(a) and (b) of EPCRA, 42 U.S.C. § 11004(a) and (b), and 40 C.F.R. Part 355, Subpart C (40 C.F.R. § 355.40), and, consequently, requiring submission of written follow-up reports to the SERC and LEPC pursuant to Section 304(c) of EPCRA, 42 U.S.C. § 11004(c), and 40 C.F.R. Part 355, Subpart C.

16. Respondent did not provide a written follow-up report regarding the Release to the SERC until September 18, 2009, more than two months after the Release occurred.

17. Respondent failed to provide a written follow-up report regarding the Release to the SERC as soon as practicable following the Release, as required by Section 304(c) of EPCRA, 42 U.S.C. § 11004(c), and 40 C.F.R. Part 355, Subpart C.

**CONCLUSION OF LAW RELATED TO THE
VIOLATION OF SECTION 304(c) OF EPCRA – SERC**

18. Respondent's failure to provide a written follow-up report regarding the Release to the SERC as soon as practicable following the Release is a violation of Section 304(c) of EPCRA, 42 U.S.C. § 11004(c), and is, therefore, subject to the assessment of penalties under Section 325 of EPCRA, 42 U.S.C. § 11045.

**FINDINGS OF FACT RELATED TO THE
VIOLATION OF SECTION 304(c) OF EPCRA – LEPC**

19. The findings of fact and conclusions of law contained in paragraphs 1 through 18 of this CA/FO are incorporated by reference herein as though fully set forth at length.

20. The LEPC for the Merck Facility is, and has been at all times relevant to this CA/FO, the Harrisonburg/Rockingham Joint Local Emergency Planning Committee, located at 800 S. Main Street in Harrisonburg, Virginia.

21. Respondent did not provide a written follow-up report regarding the Release to the LEPC until September 18, 2009, more than two months after the Release occurred.

22. Respondent failed to provide a written follow-up report regarding the Release to the LEPC as soon as practicable following the Release, as required by Section 304(c) of EPCRA, 42 U.S.C. § 11004(c), and 40 C.F.R. Part 355, Subpart C.

**CONCLUSION OF LAW RELATED TO THE
VIOLATION OF SECTION 304(c) OF EPCRA – LEPC**

23. Respondent's failure to provide a written follow-up report regarding the Release to the LEPC as soon as practicable following the Release is a violation of Section 304(c) of EPCRA, 42 U.S.C. § 11004(c), and is, therefore, subject to the assessment of penalties under Section 325 of EPCRA, 42 U.S.C. § 11045.

**FINDINGS OF FACT RELATED TO THE
VIOLATION OF SECTION 312 OF EPCRA – CALENDAR YEAR 2010**

24. The findings of fact and conclusions of law contained in paragraphs 1 through 23 of this CA/FO are incorporated by reference herein as though fully set forth at length.

25. Section 312 of EPCRA, 42 U.S.C. § 11022, as implemented by 40 C.F.R. Part 370 (40 C.F.R. § 370.25), requires the owner or operator of a facility required to prepare or have available a MSDS for a hazardous chemical in accordance with the OSHA Hazard Communication Standard, 29 U.S.C. §§ 651 *et seq.*, and 29 C.F.R. § 1910.1200, and at which facility a hazardous chemical (including, but not limited to, a hazardous chemical which also

qualifies as an EHS) is present at any one time during a calendar year in a quantity equal to or greater than its applicable threshold level or threshold planning quantity (“TPQ”) established by 40 C.F.R. § 370.10 (40 C.F.R. § 370.20), to submit on or before March 1, 1988, and by March 1st of each year thereafter, a completed Emergency and Hazardous Chemical Inventory Form identifying the hazardous chemical and providing the information described in Section 312(d)(1) of EPCRA, 42 U.S.C. § 11022(d)(1), to the appropriate SERC, LEPC, and local fire department with jurisdiction over the facility.

26. Respondent is engaged in a business where chemicals are either used, distributed, or are produced for use or distribution.

27. Respondent is an “employer” as that term is defined at 29 U.S.C. § 1910.1200(c).

28. Respondent is required to have MSDSs at the Merck Facility for each hazardous chemical it uses, pursuant to 29 C.F.R. § 1910.1200(g).

29. Respondent is the owner or operator of a facility that is required to prepare or have available an MSDS for hazardous chemicals under the OSHA Hazard Communication Standard, 29 U.S.C. §§ 651 *et seq.*, and 29 C.F.R. § 1910.1200.

30. Ethylenediamine, CAS No. 107-15-3; isopropyl alcohol, CAS No. 67-63-0; magnesium sulfate heptahydrate, CAS No. 10034-99-8; thiophenol, CAS No. 108-98-5; and 5,6-dihydro-(S)-4-hydroxy-(S)-6-methyl-4H-thieno(2,3-b)thiopyran-7,7-dioxide, CAS No. 147086-81-5; are “hazardous chemicals” as defined by Section 311(e) of EPCRA, 42 U.S.C. § 11021(e), and 40 C.F.R. § 370.66 (40 C.F.R. § 370.2). Ethylenediamine and thiophenol are also EHSs as defined in Section 329(3) of EPCRA, 42 U.S.C. § 11049(3), and 40 C.F.R. § 370.66 (40 C.F.R. § 370.2), and as listed in 40 C.F.R. Part 355, Appendices A and B.

31. Pursuant to 40 C.F.R. § 370.10 (40 C.F.R. § 370.20), the threshold levels for the hazardous chemicals referenced in Paragraph 30 above are as follows:

Hazardous Chemical	Threshold Level
ethylenediamine	500 pounds
isopropyl alcohol	10,000 pounds
magnesium sulfate heptahydrate	10,000 pounds
thiophenol	500 pounds
5,6-dihydro-(S)-4-hydroxy-(S)-6-methyl-4H-thieno(2,3-b)thiopyran-7,7-dioxide	10,000 pounds

32. During calendar year 2010, Respondent had present at the Merck Facility 3,303 pounds of ethylenediamine and 535 pounds of thiophenol.

33. At any one time during calendar year 2010, Respondent had present at the Merck Facility hazardous chemicals in quantities exceeding their respective threshold levels.

34. By March 1, 2011, Respondent was required to submit to the SERC, LEPC, and local fire department, an Emergency and Hazardous Chemical Inventory Form identifying ethylenediamine and thiophenol as present at the Merck Facility during calendar year 2010 in quantities equal to or greater than their respective threshold quantities, and providing the information required by Section 312(d) of EPCRA, 42 U.S.C. § 11022(d), about the hazardous chemicals.

35. The LEPC accepts submissions of Emergency and Hazardous Chemical Inventory Forms on behalf of both itself and the local fire department.

36. Respondent submitted an Emergency and Hazardous Chemical Inventory Form for calendar year 2010 to the SERC and LEPC/local fire department, as required by Section 312 of EPCRA, 42 U.S.C. § 11022, on March 1, 2011.

37. Respondent's Emergency and Hazardous Chemical Inventory Form submitted to the SERC and LEPC/local fire department for calendar year 2010 did not identify two (2) hazardous chemicals, namely ethylenediamine and thiophenol, as present at the Merck Facility in quantities equal to or greater than their respective threshold levels, and failed to provide the required information concerning the hazardous chemicals.

38. On or about November 28, 2011, Respondent informed EPA that it had failed to submit to the SERC, LEPC, and local fire department, an Emergency and Hazardous Chemical Inventory Form identifying ethylenediamine and thiophenol as present at the Merck Facility during calendar year 2010 in quantities equal to or greater than their respective threshold quantities, and providing the information required by Section 312(d) of EPCRA, 42 U.S.C. § 11022(d), about the hazardous chemicals.

39. Respondent failed to submit to the SERC and LEPC/local fire department, by March 1, 2011, a complete and accurate Emergency and Hazardous Chemical Inventory Form identifying two (2) hazardous chemicals, namely ethylenediamine and thiophenol, as present at the Merck Facility in quantities equal to or greater than their respective threshold levels at any one time during calendar year 2010, and providing the required information concerning the hazardous chemicals.

**CONCLUSION OF LAW RELATED TO THE
VIOLATION OF SECTION 312 OF EPCRA – CALENDAR YEAR 2010**

40. Respondent's failure to submit to the SERC and LEPC/local fire department, by March 1, 2011, a complete and accurate Emergency and Hazardous Chemical Inventory Form identifying two (2) hazardous chemicals, namely ethylenediamine and thiophenol, as present at the Merck Facility in quantities equal to or greater than their respective threshold levels at any one time during calendar year 2010, and providing the required information concerning those chemicals, constitutes a violation of Section 312 of EPCRA, 42 U.S.C. § 11022, is, therefore, subject to the assessment of penalties under Section 325 of EPCRA, 42 U.S.C. § 11045.

**FINDINGS OF FACT RELATED TO THE
VIOLATION OF SECTION 312 OF EPCRA – CALENDAR YEAR 2009**

41. The findings of fact and conclusions of law contained in paragraphs 1 through 40 of this CA/FO are incorporated by reference herein as though fully set forth at length.

42. During calendar year 2009, Respondent had present at the Merck Facility 9,329 pounds of ethylenediamine; 10,576 pounds of magnesium sulfate heptahydrate; and 733 pounds of thiophenol.

43. At any one time during calendar year 2009, Respondent had present at the Merck Facility hazardous chemicals in quantities exceeding their respective threshold levels.

44. By March 1, 2010, Respondent was required to submit to the SERC, LEPC, and local fire department, an Emergency and Hazardous Chemical Inventory Form identifying ethylenediamine, magnesium sulfate heptahydrate, and thiophenol as present at the Merck Facility during calendar year 2009 in quantities equal to or greater than their respective threshold quantities, and providing the information required by Section 312(d) of EPCRA, 42 U.S.C. § 11022(d), about the hazardous chemicals.

45. Respondent submitted an Emergency and Hazardous Chemical Inventory Form for calendar year 2009 to the SERC and LEPC/local fire department, as required by Section 312 of EPCRA, 42 U.S.C. § 11022, on February 26, 2010.

46. Respondent's Emergency and Hazardous Chemical Inventory Form submitted to the SERC and LEPC/local fire department for calendar year 2009 did not identify three (3) hazardous chemicals, namely ethylenediamine, magnesium sulfate heptahydrate, and thiophenol, as present at the Merck Facility in quantities equal to or greater than their respective threshold levels, and failed to provide the required information concerning the hazardous chemicals.

47. Respondent failed to submit to the SERC and LEPC/local fire department, by March 1, 2011, a complete and accurate Emergency and Hazardous Chemical Inventory Form identifying three (3) hazardous chemicals, namely ethylenediamine, magnesium sulfate heptahydrate, and thiophenol, as present at the Merck Facility in quantities equal to or greater

than their respective threshold levels at any one time during calendar year 2009, and providing the required information concerning the hazardous chemicals.

**CONCLUSION OF LAW RELATED TO THE
VIOLATION OF SECTION 312 OF EPCRA – CALENDAR YEAR 2009**

48. Respondent's failure to submit to the SERC and LEPC/local fire department, by March 1, 2010, a complete and accurate Emergency and Hazardous Chemical Inventory Form identifying three (3) hazardous chemicals, namely ethylenediamine, magnesium sulfate heptahydrate, and thiophenol, as present at the Merck Facility in quantities equal to or greater than their respective threshold levels at any one time during calendar year 2009, and providing the required information concerning those chemicals, constitutes a violation of Section 312 of EPCRA, 42 U.S.C. § 11022, is, therefore, subject to the assessment of penalties under Section 325 of EPCRA, 42 U.S.C. § 11045.

**FINDINGS OF FACT RELATED TO THE
VIOLATION OF SECTION 312 OF EPCRA – CALENDAR YEAR 2008**

49. The findings of fact and conclusions of law contained in paragraphs 1 through 48 of this CA/FO are incorporated by reference herein as though fully set forth at length.

50. During calendar year 2008, Respondent had present at the Merck Facility 8,694 pounds of ethylenediamine; 50,337 pounds of isopropyl alcohol; 511 pounds of thiophenol; and 22,656 pounds of 5,6-dihydro-(S)-4-hydroxy-(S)-6-methyl-4H-thieno(2,3-b)thiopyran-7,7-dioxide.

51. At any one time during calendar year 2008, Respondent had present at the Merck Facility hazardous chemicals in quantities exceeding their respective threshold levels.

52. By March 1, 2009, Respondent was required to submit to the SERC, LEPC, and local fire department, an Emergency and Hazardous Chemical Inventory Form identifying ethylenediamine, isopropyl alcohol, thiophenol, and 5,6-dihydro-(S)-4-hydroxy-(S)-6-methyl-4H-thieno(2,3-b)thiopyran-7,7-dioxide as present at the Merck Facility during calendar year 2008 in quantities equal to or greater than their respective threshold quantities, and providing the information required by Section 312(d) of EPCRA, 42 U.S.C. § 11022(d), about the hazardous chemicals.

53. Respondent submitted an Emergency and Hazardous Chemical Inventory Form for calendar year 2008 to the SERC and LEPC/local fire department, as required by Section 312 of EPCRA, 42 U.S.C. § 11022, on February 26, 2009.

54. Respondent's Emergency and Hazardous Chemical Inventory Form submitted to the SERC and LEPC/local fire department for calendar year 2008 did not identify four (4) hazardous chemicals, namely ethylenediamine, isopropyl alcohol, thiophenol, and 5,6-dihydro-(S)-4-hydroxy-(S)-6-methyl-4H-thieno(2,3-b)thiopyran-7,7-dioxide, as present at the Merck

Facility in quantities equal to or greater than their respective threshold levels, and failed to provide the required information concerning the hazardous chemicals.

55. Respondent failed to submit to the SERC and LEPC/local fire department, by March 1, 2009, a complete and accurate Emergency and Hazardous Chemical Inventory Form identifying four (4) hazardous chemicals, namely ethylenediamine, isopropyl alcohol, thiophenol, and 5,6-dihydro-(S)-4-hydroxy-(S)-6-methyl-4H-thieno(2,3-b)thiopyran-7,7-dioxide, as present at the Merck Facility in quantities equal to or greater than their respective threshold levels at any one time during calendar year 2008, and providing the required information concerning the hazardous chemicals.

**CONCLUSION OF LAW RELATED TO THE
VIOLATION OF SECTION 312 OF EPCRA – CALENDAR YEAR 2008**

56. Respondent's failure to submit to the SERC and LEPC/local fire department, by March 1, 2009, a complete and accurate Emergency and Hazardous Chemical Inventory Form identifying four (4) hazardous chemicals, namely ethylenediamine, isopropyl alcohol, thiophenol, and 5,6-dihydro-(S)-4-hydroxy-(S)-6-methyl-4H-thieno(2,3-b)thiopyran-7,7-dioxide, as present at the Merck Facility in quantities equal to or greater than their respective threshold levels at any one time during calendar year 2008, and providing the required information concerning those chemicals, constitutes a violation of Section 312 of EPCRA, 42 U.S.C. § 11022, is, therefore, subject to the assessment of penalties under Section 325 of EPCRA, 42 U.S.C. § 11045.

**FINDINGS OF FACT RELATED TO THE
VIOLATION OF SECTION 312 OF EPCRA – CALENDAR YEAR 2007**

57. The findings of fact and conclusions of law contained in paragraphs 1 through 56 of this CA/FO are incorporated by reference herein as though fully set forth at length.

58. During calendar year 2007, Respondent had present at the Merck Facility 3,298 pounds of ethylenediamine.

59. At any one time during calendar year 2007, Respondent had present at the Merck Facility hazardous chemicals in quantities exceeding their respective threshold levels.

60. By March 1, 2008, Respondent was required to submit to the SERC, LEPC, and local fire department, an Emergency and Hazardous Chemical Inventory Form identifying ethylenediamine as present at the Merck Facility during calendar year 2007 in quantities equal to or greater than its threshold quantity, and providing the information required by Section 312(d) of EPCRA, 42 U.S.C. § 11022(d), about ethylenediamine.

61. Respondent submitted an Emergency and Hazardous Chemical Inventory Form for calendar year 2007 to the SERC and LEPC/local fire department, as required by Section 312 of EPCRA, 42 U.S.C. § 11022, on February 21, 2008.

62. Respondent's Emergency and Hazardous Chemical Inventory Form submitted to the SERC and LEPC/local fire department for calendar year 2007 did not identify ethylenediamine as present at the Merck Facility in quantities equal to or greater than its threshold level, and failed to provide the required information concerning ethylenediamine.

63. Respondent failed to submit to the SERC and LEPC/local fire department, by March 1, 2008, a complete and accurate Emergency and Hazardous Chemical Inventory Form identifying ethylenediamine as present at the Merck Facility in quantities equal to or greater than its threshold levels at any one time during calendar year 2007, and providing the required information concerning ethylenediamine.

**CONCLUSION OF LAW RELATED TO THE
VIOLATION OF SECTION 312 OF EPCRA – CALENDAR YEAR 2007**

64. Respondent's failure to submit to the SERC and LEPC/local fire department, by March 1, 2008, a complete and accurate Emergency and Hazardous Chemical Inventory Form identifying ethylenediamine as present at the Merck Facility in quantities equal to or greater than its threshold level at any one time during calendar year 2007, and providing the required information concerning ethylenediamine, constitutes a violation of Section 312 of EPCRA, 42 U.S.C. § 11022, is, therefore, subject to the assessment of penalties under Section 325 of EPCRA, 42 U.S.C. § 11045.

CIVIL PENALTY

65. In full and final settlement and resolution of all allegations referenced in the foregoing Findings of Fact and Conclusions of Law, and in full satisfaction of all civil penalty claims pursuant thereto, for the purpose of this proceeding, the Respondent consents to the assessment of a civil penalty for the violations of Sections 304(c) and 312 of EPCRA, 42 U.S.C. §§ 11004(c), 11022, set forth above, in the amount of **\$12,374.37** ("civil penalty").

SUPPLEMENTAL ENVIRONMENTAL PROJECT

66. Respondent agrees to undertake the following Supplemental Environmental Project ("SEP"), which the parties agree is intended to secure environmental or public health benefits, and EPA finds is consistent with applicable EPA policy and guidelines, specifically EPA's Supplemental Environmental Projects Policy, effective May 1, 1998.

67. Respondent agrees to purchase two special service passenger vehicles ("SSPVs"), which Respondent will donate to the Elkton Volunteer Fire Company and the McGaheysville Volunteer Fire Company, respectively, to use when responding to hazardous materials incidents (the "SEP"). The vehicles will replace old vehicles, each of which has exceeded 150,000 miles, and will be equipped with computers that will provide access to pre-emergency software, emergency response guides, and technical resources. The SEP is described further in

Respondent's Supplemental Environmental Project Proposal ("SEP Proposal"), attached hereto as Attachment A and incorporated herein by reference.

68. Respondent's total expenditure for the SEP shall not be less than \$57,241.75, in accordance with the specifications set forth in the SEP Proposal. The SEP has been valued at \$56,900.00, pursuant to EPA's Project Model. Respondent shall include documentation of the expenditures made in connection with the SEP as part of the SEP Completion Report described in Paragraph 72 below.

69. Respondent hereby certifies that it is not a party to any open federal financial assistance transaction that is funding or could be used to fund the same activity as the SEP. Respondent further certifies that, to the best of its knowledge and belief after reasonable inquiry, there is no such open federal financial transaction that is funding or could be used to fund the same activity as the SEP, nor has the same activity been described in an unsuccessful federal financial assistance transaction proposal submitted to EPA within two years of the date of this CA/FO (unless the project was barred from funding as statutorily ineligible). For the purposes of this certification, the term "open federal financial assistance transaction" refers to a grant, cooperative agreement, loan, federally-guaranteed loan guarantee, or other mechanism for providing federal financial assistance, the performance period of which has not yet expired.

70. Respondent hereby further certifies that, as of the date of this CA/FO, Respondent is not required to perform or develop the SEP by any federal, state, or local law or regulations and that it has not received, and is not presently negotiating to receive, credit in any other enforcement action for the SEP.

71. Respondent shall complete the SEP within 90 days of the effective date of this CA/FO. Respondent shall notify EPA, c/o Allison F. Gardner at the address noted in Paragraph 72, below, when such implementation is complete. EPA may grant Respondent an extension of time to fulfill its SEP obligations if EPA determines, in its sole and unreviewable discretion, that, through no fault of Respondent, Respondent is unable to complete the SEP obligations within the time frame required by this paragraph. Request for any extension must be made in writing within 48 hours of any event, the occurrence of which renders the Respondent unable to complete the SEP within the required time frame ("force majeure event"), and prior to the expiration of the allowed SEP completion deadline. Any requests should be directed to Allison F. Gardner at the address noted in Paragraph 72, below.

72. SEP Completion Report

a. Respondent shall submit a SEP Completion Report to EPA, c/o Allison F. Gardner (3RC42), 1650 Arch Street, Philadelphia, Pennsylvania 19103, within fourteen (14) days of completing the SEP as set forth in Paragraph 71. The SEP Completion Report shall contain the following information:

- (i) A detailed description of the SEP as implemented;

- (ii) A description of any problems encountered and the solution thereto;
- (iii) Itemized costs; and
- (iv) A certification that the SEP has been implemented in accordance with this CA/FO.

b. Respondent shall, by its officers, sign the report required by this Paragraph 72 and certify under penalty of law that the information contained therein is true, accurate, and not misleading, by including and signing the following statement:

I certify under penalty of law that I have examined and am familiar with the information submitted in this document and all attachments and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment.

c. Respondent agrees that failure to submit the report required by this Paragraph 72 shall be deemed a violation of this CA/FO and, in such an event, Respondent will be liable for stipulated penalties pursuant to Paragraph 74 below.

d. In itemizing its costs in the SEP Completion Report, Respondent shall clearly identify and provide acceptable documentation for all eligible SEP costs. Where the report includes costs not eligible for SEP credit, those costs must be clearly identified as such. For purposes of this Paragraph 72, "acceptable documentation" includes invoices, purchase orders, or other documentation that specifically identifies and itemizes the individual costs of the goods and/or services for which payment is being made. Canceled drafts do not constitute acceptable documentation unless such drafts specifically identify and itemize the individual costs of the goods and/or services for which payment is being made.

73. EPA Acceptance of SEP Completion Report

a. Upon receipt of the SEP Completion Report, EPA may exercise one of the following options:

(i) notify the Respondent in writing that the SEP Completion Report is deficient, provide an explanation of the deficiencies, and grant Respondent an additional thirty (30) days to correct those deficiencies;

(ii) notify the Respondent in writing that EPA has concluded that the project has been satisfactorily completed; or

(iii) notify the Respondent in writing that EPA has concluded that the project has not been satisfactorily completed, and seek stipulated penalties in accordance with Paragraph 74 herein.

b. If EPA elects to exercise option (i) above, EPA shall permit Respondent the opportunity to object in writing to the notification of deficiency within ten (10) days of receipt of such notification. EPA and Respondent shall have an additional thirty (30) days from the receipt by EPA of the notification of objection to reach agreement on changes necessary to the SEP Completion Report. If agreement cannot be reached within this thirty (30) day period, EPA shall provide to the Respondent a written statement of its decision on the adequacy of the completion of the SEP, which shall be final and binding upon Respondent. Respondent agrees to comply with any requirements imposed by EPA as a result of any failure to comply with the terms of this CA/FO. In the event the SEP is not completed as contemplated herein, as determined by EPA, stipulated penalties shall be due and payable by Respondent to EPA in accordance with Paragraphs 74 and 76 herein.

74. Stipulated Penalties

a. In the event that Respondent spends less than 90 percent of the estimated costs of the SEP as set forth in Paragraph 68 and Attachment A, Respondent shall pay a stipulated penalty to EPA in the amount of \$6,828.00.

b. In the event that Respondent fails to fully implement the SEP by the completion date set forth in Paragraph 71 above, and as otherwise required by this CA/FO, Respondent shall pay a stipulated penalty to EPA in the amount of \$49,497.50 (the "SEP Credit Amount").

c. If the SEP is not completed in accordance with Paragraphs 67 through 71, but the EPA determines that the Respondent: (1) made good faith and timely efforts to complete the project; and (2) certifies, with supporting documentation, that at least 90 percent of the amount of money which was required to be spent was expended on the SEP, Respondent shall not be liable for any stipulated penalty.

d. In the event that Respondent fails to submit the SEP Completion Report required by Paragraph 72 above, Respondent shall pay a stipulated penalty in the amount of \$250.00 for each day after the report was originally due until the report is submitted.

e. The determinations of whether the SEP has been satisfactorily implemented and whether the Respondent has made a good faith, timely effort to implement the SEP shall be in the sole discretion of EPA.

f. Respondent shall pay stipulated penalties in accordance with the provisions of Paragraphs 76 and 77 below, not more than fifteen (15) days after receipt of written demand by EPA for such penalties. Interest and late charges shall be paid as set forth in Paragraphs 79 through 82 below.

75. Nothing in this agreement shall be construed as prohibiting, altering, or in any way limiting the ability of EPA to seek any other remedies or sanctions available by virtue of Respondent's violation of this agreement or of the statutes and regulations upon which this agreement is based, or for Respondent's violation of any applicable provision of law.

PAYMENT TERMS

76. In order to avoid the assessment of interest, administrative costs, and late payment penalties in connection with the civil penalties described in this CA/FO, Respondent shall pay the civil penalty of \$12,374.37, no later than thirty (30) days after the effective date of the Final Order (the "final due date") by cashier's check, certified check, or electronic wire transfer. Payment of the civil penalty shall be made in the following manner:

- a. All payments by Respondent shall reference Respondent's name and address, and the Docket Numbers of this action;
- b. All checks for the civil penalty shall be made payable to **United States Treasury**;
- c. All payments for the civil penalty made by check and sent by regular mail shall be addressed to:

U.S. EPA
Fines and Penalties
Cincinnati Finance Center
P.O. Box 979077
St. Louis, MO 63197-9000

- d. All payments for the civil penalty made by check and sent by overnight delivery service shall be addressed for delivery to:

U.S. EPA
Fines and Penalties
U.S. Bank
1005 Convention Plaza
Mail Station SL-MO-C2GL
St. Louis, MO 63101

- e. All payments made by check in any currency drawn on banks with no USA branches shall be addressed for delivery to:

Cincinnati Finance
US EPA, MS-NWD
26 W. M.L. King Drive
Cincinnati, OH 45268-0001

- f. 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

- g. 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:
5700 Rivertech Court
Riverdale, MD 20737
Contact: Jesse White 301-887-6548 or REX, 1-866-234-5681

- h. On-Line Payment Option:

WWW.PAY.GOV/PAYGOV

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

- i. Additional payment guidance is available at:

http://www.epa.gov/ocfo/finservices/make_a_payment.htm

77. The Respondent shall submit proof of the penalty payment, noting the title and docket numbers of this case, to the following persons:

Lydia Guy (3RC00)
Regional Hearing Clerk
U.S. EPA, Region III
1650 Arch Street
Philadelphia, PA 19103-2029

and

Allison F. Gardner (3RC42)
Senior Assistant Regional Counsel
U.S. EPA Region III
1650 Arch Street
Philadelphia, PA 19103-2029

78. The civil penalty stated herein is based upon Complainant's consideration of a number of factors, including, but not limited to, the penalty criteria set forth in Section 325 of EPCRA, 42 U.S.C. § 11045, and are consistent with 40 C.F.R. Part 19, and EPA's *Enforcement Response Policy for Sections 304, 311 and 312 of the Emergency Planning and Community Right-to-Know Act and Section 103 of the Comprehensive Environmental Response, Compensation and Liability Act*, dated September 30, 1999.

79. 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 by the final due date or to comply with the conditions in this CA/FO shall result in the assessment of late payment charges, including interest, penalties, and/or administrative costs of handling delinquent debts.

80. Interest on the civil penalty assessed in this CA/FO will begin to accrue on the date that a copy of this CA/FO is mailed or hand-delivered to Respondent. However, EPA will waive 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).

81. The costs of the Agency's administrative handling of overdue debts will be charged and assessed monthly throughout the period the debt is overdue in accordance with 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 final due date and an additional \$15.00 for each subsequent thirty (30) day period the penalty remains unpaid.

82. A penalty charge of six (6) percent per year will be assessed monthly on any portion of the civil penalty which remains delinquent more than ninety (90) calendar days in accordance with 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, in accordance with 31 C.F.R. § 901.9(d).

83. Failure by the Respondent to pay the \$12,374.37 civil penalty assessed by the Final Order in full by the final due date may subject Respondent to a civil action to collect the assessed penalty, plus interest, pursuant to Section 325 of EPCRA, 42 U.S.C. § 11045. In any such collection action, the validity, amount and appropriateness of the penalty shall not be subject to review.

GENERAL PROVISIONS

84. For the purpose of this proceeding, Respondent admits to the jurisdictional allegations set forth above.

85. Respondent agrees not to contest EPA's jurisdiction with respect to the execution or enforcement of this CA/FO.

86. For the purpose of this proceeding, and with the exception of Paragraph 84, above, Respondent neither admits nor denies factual allegations or conclusions of law set forth in this Consent Agreement, but expressly waives its rights to contest said allegations.

87. For the purpose of this proceeding, Respondent expressly waives its right to a hearing and to appeal the Final Order under Section 325 of EPCRA, 42 U.S.C. § 11045.

88. The provisions of this CA/FO shall be binding upon Respondent, its officers, directors, agents, servants, employees, and successors or assigns. By his or her signature below, the person signing this Consent Agreement on behalf of the Respondent is acknowledging that he or she is fully authorized by the party represented to execute this Consent Agreement and to legally bind Respondent to the terms and conditions of the Consent Agreement and accompanying Final Order.

89. This CA/FO resolves only those civil claims which are alleged herein. Nothing herein shall be construed to limit the authority of the Complainant to undertake action against any person, including the Respondent in response to any condition which Complainant determines may present an imminent and substantial endangerment to the public health, public welfare or the environment. Nothing in this CA/FO shall be construed to limit the United States' authority to pursue criminal sanctions.

90. Each party to this action shall bear its own costs and attorney's fees.

FOR MERCK SHARP & DOHME CORPORATION:


SIGNATURE

08/27/2012
DATE

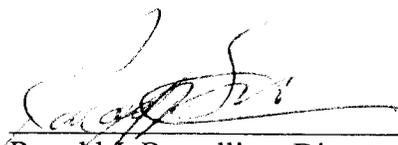
Name: Raul E. Diaz

Title: AVP, Plant Manager, Elkton Facility

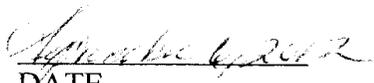
In re: Merck Sharp & Dohme Corporation

EPCRA-03-2012-0164

FOR THE U.S. ENVIRONMENTAL PROTECTION AGENCY



Ronald J. Borsellino, Director
Hazardous Site Cleanup Division



DATE



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1650 Arch Street
Philadelphia, Pennsylvania 19103-2029

In the Matter of:

Merck Sharp & Dohme Corporation
2778 South East Side Highway
Elkton, Virginia
22827,

Respondent.

Merck Sharp & Dohme Corporation
2778 South East Side Highway
Elkton, Virginia
22827,

Facility.

EPA Docket Nos.: EPCRA-03-2012-0164

Proceedings Pursuant to Sections 304, 312,
and 325 of the Emergency Planning and
Community Right-to-Know Act, 42 U.S.C.
§§ 11004, 11021, 11045.

FINAL ORDER

Pursuant to Section 325 of the Emergency Planning and Community Right-to-Know Act (“EPCRA”), 42 U.S.C. § 11045, and in accordance with 40 C.F.R. Part 22, and based on the representations in the Consent Agreement, having determined that the penalty agreed to in the Consent Agreement is based on a consideration of the factors set forth in Section 325 of EPCRA, 42 U.S.C. § 11045, the foregoing Consent Agreement is hereby approved and incorporated by reference into this Final Order. The Respondent is ordered to comply with the terms of the referenced Consent Agreement.

Effective Date

This Final Order shall become effective upon the date of its filing with the Regional Hearing Clerk.

Renée Sarajian
Regional Judicial Officer
EPA, Region III

9/13/12
DATE



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1650 Arch Street
Philadelphia, Pennsylvania 19103-2029

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Merck Sharp & Dohme Corporation
2778 South East Side Highway
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EPA Docket Nos.: EPCRA-03-2012-0164

Proceedings Pursuant to Sections 304, 312,
and 325 of the Emergency Planning and
Community Right-to-Know Act, 42 U.S.C.
§§ 11004, 11021, 11045.

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on the date provided below, I hand-delivered and filed the original of the signed Consent Agreement and Final Order with the Regional Hearing Clerk, U.S. EPA, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103-2029, and that true and correct copies of the Consent Agreement and Final Order were sent by first class mail to:

Steven E. Tarnowski, Esq.
Merck & Company, Inc.
One Merck Drive
Whitehouse Station, New Jersey 08889

9/18/12
DATE

Allison F. Gardner (3RC42)
Senior Assistant Regional Counsel
Counsel for Complainant
(215) 814-2631