



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION I – New England  
5 Post Office Square - Suite 100 (OES 04-3)  
Boston, Massachusetts 02109-3912

OFFICE OF  
ENVIRONMENTAL STEWARDSHIP

HUGH W. MARTINEZ  
SENIOR ENFORCEMENT COUNSEL  
(direct: 617-918-1867)

**BY HAND**

July 30, 2013

Wanda I. Santiago, Regional Hearing Clerk  
EPA Region 1 – New England  
5 Post Office Square, Suite 100 (ORA 18-1)  
Boston, MA 02109-3912

Re: *In Re: EMD Millipore Corporation, Docket No. FIFRA-01-2013-0017;*  
*Approved Consent Agreement and Final Order*

Dear Ms. Santiago:

Please find enclosed for filing the original and one copy of a Consent Agreement and Final Order (CAFO) resolving the above-referenced pre-filing enforcement case. Also enclosed is the original and one copy of a Certificate of Service documenting that, on this date, a copy of the CAFO and this cover letter were sent to James A. Thompson, Jr., Counsel for Respondent.

Thank you for your assistance in this matter.

Sincerely,

A handwritten signature in blue ink, appearing to read "Hugh W. Martinez".

Hugh W. Martinez, Senior Enforcement Counsel  
U.S. EPA Region 1

Enclosure

cc: James A. Thompson, Jr., Counsel for EMD Millipore

U. S. ENVIRONMENTAL PROTECTION AGENCY  
REGION 1 (NEW ENGLAND)

\_\_\_\_\_  
In the Matter of: )

EMD Millipore Corporation )  
290 Concord Road )  
Billerica, MA 01821 )

Respondent. )

Proceedings under Section 14(a) )  
of the Federal Insecticide, Fungicide, )  
and Rodenticide Act, as amended, )  
7 U.S.C. Section 136l(a). )  
\_\_\_\_\_ )

Docket No. FIFRA-01-2013-0017

**CONSENT AGREEMENT  
and  
FINAL ORDER**

**I. INTRODUCTION**

1. The United States Environmental Protection Agency-Region 1 (“EPA”), as Complainant, and EMD Millipore Corporation as Respondent (hereinafter “EMD” or “Respondent”), enter into this Consent Agreement and Final Order (“CAFO”) by mutual consent. The CAFO informs Respondent of EPA’s intention to assess a penalty against EMD for alleged violations of Section 12 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (“FIFRA”), 7 U.S.C. § 136j, and implementing regulations at 40 C.F.R. Parts 150 – 180 and at 19 C.F.R. §§ 12.110 – 12.117 (collectively, “FIFRA Regulations”). The CAFO also informs Respondent of its right to request a hearing.

2. This CAFO simultaneously commences and concludes the cause of action described herein, pursuant to 40 C.F.R. §§ 22.13(b) and 22.18(b), and Section 14(a) of FIFRA, 7 U.S.C. § 136l(a). Complainant and Respondent (collectively, the “Parties”) agree that settlement of this matter is in the public interest and that entry of this CAFO without litigation is the most appropriate means of resolving this matter.

3. Therefore, before any hearing or the taking of any testimony, without adjudication of any issue of fact or law herein, the Parties agree to comply with the terms of this CAFO.

## II. PRELIMINARY STATEMENT

4. EMD is a business incorporated under the laws of the Commonwealth of Massachusetts with its principal place of business located at 290 Concord Road in Billerica, MA (the “Billerica Establishment”).

5. Millipore Corporation (“Millipore”) of 290 Concord Road in Billerica, MA was acquired by Merck KGaA, Darmstadt, Germany (“MDG”) in July 2010. Effective on December 31, 2011, EMD Chemicals Inc., the preexisting U.S. subsidiary of MDG, was merged with and into Millipore, which combined company operates as the headquarters company of MDG’s Life Sciences Division. The name of the company was changed from “Millipore Corporation” to “EMD Millipore Corporation,” effective on January 1, 2012.

6. On December 21, 2010, EPA Region 1 filed a Consent Agreement and Final Order (the “2010 CAFO”) resolving administrative civil penalty claims alleged in a Complaint filed by Region 1 in September 2010, under Section 14(a) of FIFRA, against Millipore Corporation. Among other things, the 2010 CAFO required Millipore to pay a civil penalty in settlement of the violations alleged by EPA which, under the terms of the agreement, were neither admitted nor denied by Millipore. *See In the Matter of Millipore Corporation*, Docket No. FIFRA-01-2010-0077.

7. Respondent *distributes or sells*<sup>1</sup> a variety of products, including products

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<sup>1</sup> Words that appear in italics upon first use indicate terms that are defined in Section 2 of FIFRA, 7 U.S.C.

defined as “*devices*” under Section 2(h) of FIFRA, 7 U.S.C. § 136(h), primarily used in the research, development, and production of biotechnology and pharmaceutical drug therapies.

8. The types of products or “families” of products (i.e. groups of different product models of the same functional or design type) that are marketed by EMD include devices which range from desktop-sized cartridges to room-sized machinery and are customized to meet buyer specifications for the removal, retention, and filtration of bacteria, viruses, and other microorganisms. Such devices are for laboratory use in research, clinical diagnostics, and manufacturing, and not marketed for use by the general public.

9. Section 2(h) of FIFRA, 7 U.S.C. § 136(h), defines the term “device” as “any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any *pest* or any other form of plant or animal life (other than man and other bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.” [italics added]

10. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines the term “pest” to mean, in pertinent part, “any insect, rodent, nematode, fungus, weed” or “any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organisms” declared by EPA to be a pest under Section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1).

11. Respondent operates FIFRA device-producing *establishments* in Molsheim, France (the “Molsheim Establishment”) and Jaffrey, New Hampshire (the

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§ 136, and/or the FIFRA Regulations. Such terms are relevant to the EPA findings specified in this CAFO and, unless otherwise indicated, are intended to be used as so defined.

“Jaffrey Establishment”).

12. Respondent operates additional establishments at locations in the United States (including Bedford, Burlington, and Danvers, Massachusetts) and abroad (including Carrigtwohill, Ireland). EMD currently uses each of these establishments for product component manufacturing and/or storage/warehousing.

13. EMD is a *person* as defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s) and is also a *producer* as defined by Section 2(w) of FIFRA, 7 U.S.C. § 136(w), and 40 C.F.R. § 167.3.

14. EPA regulations at 40 C.F.R. Part 152, Subpart Z enumerate the provisions of FIFRA and FIFRA regulations that are applicable to devices. *See* 40 C.F.R. § 152.500.

Such applicable provisions include, among others, the following:

- a. *Labeling* requirements under Section 2(q)(1) of FIFRA, 7 U.S.C. §136(q)(1), and 40 C.F.R. Part 156;
- b. Establishment registration and reporting requirements under FIFRA Section 7, 7 U.S.C. § 136e, and 40 C.F.R. Part 167;
- c. Requirements relating to books and records and establishment inspections under Sections 8 and 9 of FIFRA, 7 U.S.C. §§ 136f and 136g, and 40 C.F.R. Part 169;
- d. Importation requirements under FIFRA Section 17, 7 U.S.C. § 136o; and,
- e. Requirements relating to FIFRA violations, enforcement, and penalties under Sections 12, 13, and 14 of FIFRA, 7 U.S.C. §§ 136j, 136k, and 136l. *See also* 41 Fed. Reg. 51065 (November 19, 1976).

15. Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N), provides that it is unlawful for any person who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by FIFRA. Such reports include, but are not limited to, NOAs submitted to EPA for each shipment of pesticides or devices that are imported into the United States under Section 17 of FIFRA, 7 U.S.C. § 136o, and 19

C.F.R. § 12.112(a).

16. The FIFRA requirement to submit NOAs prior to importing a pesticide or device into the United States protects against unreasonable risks to human health or the *environment* by providing EPA with vital information about pesticides and devices before their arrival into the United States for distribution or sale. NOAs provide information — including active ingredients, quantities, countries of origin, identity of producing establishments, carriers, and ports of entry— that enables EPA to make informed decisions about whether importation will pose unreasonable adverse risks to public health or the environment and, also, provide critical contact information in the event of an emergency related to the movement of potentially harmful pesticides or devices.

17. Section 12(a)(1)(F) of FIFRA, 7 U.S.C. § 136j(a)(1)(F), provides that it is unlawful for any person in any *State* to distribute or sell to any person any device which is *misbranded*.

18. The FIFRA prohibition against the distribution or sale of misbranded pesticides and devices is important because it helps ensure that end users and members of the public have the most accurate, up-to-date, and compliant information available about pesticides and devices in the marketplace and about the establishments in which they are *produced*.

19. Section 12(a)(2)(L) of FIFRA, 7 U.S.C. § 136(a)(2)(L), provides that it is unlawful for any *producer* to violate any provision of FIFRA Section 7, 7 U.S.C. § 136e, including the requirement to produce pesticides or devices subject to FIFRA only in an establishment which has been registered with EPA as a producing establishment as well as the requirement to submit reports to EPA concerning annual production and sales of

pesticides and devices.

20. The FIFRA requirement to register establishments at which pesticides or devices are produced is important because it helps maintain the integrity of the federal pesticide program EPA implements, a primary purpose of which is to ensure that no pesticide or device is produced, imported, distributed, sold, or used in a manner that may pose an unreasonable risk to human health or the environment. The requirements to properly register pesticide- and pesticide device-producing establishments and for registered establishments to report production and sales information help EPA carry out compliance, risk assessment, and risk reduction functions important for *protecting human health and the environment* because without proper establishment registrations, EPA cannot determine where and in what manner pesticides and devices are being produced, sold, and distributed.

21. Section 14(a) of FIFRA, 7 U.S.C. § 136l(a), authorizes the assessment of civil penalties of up to \$5,000 against any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor for each violation of FIFRA and the FIFRA Regulations. Under the Debt Collection Improvement Act of 1996 (“DCIA”), 31 U.S.C. § 3701 note, and EPA’s Civil Monetary Penalty Inflation Adjustment Rule (“Penalty Inflation Rule”) at 40 C.F.R. Part 19, this amount was increased to \$6,500 for violations occurring after March 15, 2004 and \$7,500 for violations occurring after January 12, 2009.

22. Under Section 7(a) of FIFRA, 7 U.S.C. § 136e(a), and 40 C.F.R. § 167.20, on or about January 18, 1978, EPA registered the Molsheim Establishment as a pesticide- and pesticide device-producing establishment, subsequently identified as “EPA Est. No.

41237-FRA-001.”

23. Under Section 7(a) of FIFRA and 40 C.F.R. § 167.20, on or about January 18, 1978, EPA registered the Jaffrey Establishment as a pesticide device-producing establishment, subsequently identified as “EPA Est. No. 41237-NH-001.” The EPA establishment registration for the Jaffrey Establishment lapsed on or about December 6, 1996 and was not reregistered by EPA until on or about May 10, 2012.

24. Between December 6, 1996, when the Jaffrey Establishment registration lapsed, and May 10, 2012, when EMD sought and obtained reregistration for the Jaffrey Establishment, Respondent produced numerous FIFRA-regulated devices at that location without it being registered with EPA as a pesticide device-producing establishment under Section 7(a).

25. Under FIFRA Section 7(a) and 40 C.F.R. § 167.20, on or about May 10, 2012, Respondent sought and obtained EPA establishment registrations for each of the previously unregistered establishments in Massachusetts and Ireland referenced in Paragraph 12, above, each identified by the establishment registration number assigned thereto, as follows:

- a. Bedford, MA – “EPA Est. No. 41237-MA-002;”
- b. Burlington, MA – “EPA Est. No. 41237-MA-004;”
- c. Danvers, MA – “EPA Est. No. 41237-MA-003;” and,
- d. Carrigtwohill, Ireland – “EPA Est. No. 41237-IRL-001.”

### **III. EPA FINDINGS**

26. Upon information and belief, EMD is the corporate successor to Millipore.

27. On April 6, 2012, EMD voluntarily submitted a self-disclosure and request for penalty mitigation (the “Self-Disclosure”) under EPA’s “Audit Policy,” entitled



*Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations* (December 22, 1995, rev'd. April 11, 2000). The Self-Disclosure cited an unspecified number of potential FIFRA violations pertaining to numerous EMD devices and the production of those devices at the Molsheim Establishment and at the Jaffrey Establishment.

28. On May 3, 2012, after analyzing the Self-Disclosure, EPA Region 1 issued a Notice of Determination letter (the "EPA Determination") to EMD which described EPA's conclusion that EMD did not qualify for penalty mitigation under the Audit Policy since the Self-Disclosure failed to satisfy all of the criteria required for penalty reduction.

29. Based on the Self-Disclosure, Respondent's subsequent written communications to EPA, meetings between Respondent and personnel from the Antimicrobial Division of the EPA Headquarters Office of Pesticide Programs in Washington, D.C., as well as further investigation by EPA, the potential FIFRA noncompliance outlined in the Self-Disclosure and at issue in this CAFO include the following, as further detailed below: (a) failure to file reports of device imports with EPA (i.e., NOAs) in violation of Sections 12(a)(2)(N) and 17(c); (b) distribution or sale of misbranded devices (i.e., no valid EPA establishment number on the *label* or labeling) in violation of Sections 12(a)(1)(F) and 2(q)(1)(D); (c) producing devices in an unregistered establishment in violation of Sections 12(a)(2)(L) and 7(a); and, (d) incomplete reporting of device production and sales under FIFRA Section 7 in violation of Sections 12(a)(2)(L) and 7(c)(1).

30. Upon information and belief, the violations at issue in the Self-Disclosure and this CAFO involved devices within the following types or “families” of products collectively, the “EMD Devices”) identified by the product names and intended uses indicated:

	<u>Product Family/Device</u>	<u>Intended Use</u>
1	Aerex	Gas sterilization filter
2	Aervent	Gas sterilization filter
3	AFS	Water purification
4	AFSPak	Water purification
5	Bevigard	Bioburden reduction in beverage production
6	Biopak	Water purification
7	Brewpore	Microbiological stabilization in beer production
8	ChomaSorb	Trace impurity (virus) removal
9	Clarigard	Bioburden reduction
10	Direct-Q	Water purification
11	Durapore	Sterilizing quality filtration and bioburden reduction
12	Elix	Water purification
13	Lifegard	Prefiltration of viscous biological fluids
14	MILLI-Q	Water purification
15	Millidisk	Sterile filtration
16	Milligard	Low protein binding prefiltration and purification
17	Millipak	Sterilizing filtration
18	Millipore Express	Low protein binding sterile filtration
19	Opticap	Sterile filtration
20	Optiscale	Sterile filtration
21	Optiseal	Sterile filtration
22	Polygard	Sterilizing applications
23	Polysep	Bioburden reduction
24	RiOs	Water purification
25	RiOS-DI	Water purification
26	Simplicity	Water purification
27	Stericap	Sterilizing filtration
28	SteriPak	Sterilizing filtration
29	Steritop	Sterilizing filtration
30	Sterivex	Sterilizing filtration
31	Super-Q	Water purification
32	Synergy	Water purification
33	Viresolve	Virus removal
34	Vitipore	Microorganism removal

31. At all times relevant to the violations alleged in Section IV of this CAFO, below, Respondent produced, imported into the United States, distributed, sold, offered for sale, shipped, and/or delivered for shipment one or more of the EMD Devices listed in Paragraph 30 of this CAFO, each of which is a “device” as defined by FIFRA.

#### IV. ALLEGATIONS OF VIOLATION

##### Count 1 – Failing to File Reports of Device Imports (Notices of Arrival)

32. Upon information and belief, on numerous occasions between January 1, 2008 and the effective date of this CAFO,<sup>2</sup> Respondent imported into the United States for distribution or sale one or more of the EMD Devices listed in Paragraph 30 of this CAFO without filing a report (i.e., NOA) with EPA, as required by Section 17 of FIFRA and 19 C.F.R. § 12.112(a).

33. Accordingly, on numerous occasions between January 1, 2008 and the effective date of this CAFO, Respondent violated Section 12(a)(2)(N) of FIFRA and the regulations at 19 C.F.R. §§ 12.110 – 12.117, each of which is a violation for which penalties may be assessed pursuant to Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1).

##### Count 2 – Distributing or Selling Misbranded Devices

34. Upon information and belief, on numerous occasions between January 1, 2008 and the effective date of this CAFO, Respondent distributed or sold, or imported into the United States for distribution or sale, one or more of the EMD Devices listed in Paragraph 30 of this CAFO when the labels for the EMD Devices did not bear a valid establishment registration number assigned under FIFRA Section 7 to the establishment

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<sup>2</sup> The term “effective date” refers to the date that EPA files the final CAFO, signed by the Parties and the Regional Judicial Officer, with the Regional Hearing Clerk.

in which the device(s) was produced, as required under Section 7(a) of FIFRA, 7 U.S.C. § 136e(a), and 40 C.F.R. § 156.10(f). *See also* Section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D).

35. Accordingly, on numerous occasions between January 1, 2008 and the effective date of this CAFO, Respondent violated FIFRA Section 12(a)(1)(F) and 40 C.F.R. § 156.10(f), each of which is a violation for which penalties may be assessed pursuant to Section 14(a)(1) of FIFRA.

**Count 3 – Producing Devices in an Unregistered Establishment (Jaffrey, NH)**

36. Upon information and belief, on numerous occasions between January 1, 2008 and May 10, 2012, Respondent produced one or more of the EMD Devices listed in Paragraph 30 of this CAFO in the Jaffrey Establishment.

37. Accordingly, by producing devices in the Jaffrey Establishment at a time when the Jaffrey Establishment was not registered as a producing establishment under Section 7(a) of FIFRA, Respondent violated FIFRA Section 12(a)(2)(L) and the regulations at 40 C.F.R. Part 167, Subpart E on numerous occasions, each of which is a violation for which penalties may be assessed pursuant to Section 14(a)(1) of FIFRA.

**Count 4 – Failing to File Complete Production Reports (Molsheim, France)**

38. Upon information and belief, during each of the calendar years 2008, 2009, 2010, 2011, and 2012, the Molsheim Establishment was registered with EPA as a producing establishment under Section 7(b) of FIFRA, 7 U.S.C. § 136e(b), and 40 C.F.R. Part 167.

39. Upon information and belief, during each of the calendar years 2008, 2009, 2010, 2011, and 2012, Respondent produced one or more of the EMD Devices

listed in Paragraph 30 of this CAFO in the Molsheim Establishment without reporting such production in the reports required by Section 7(c)(1) of FIFRA and 40 C.F.R. Part 167, Subpart E, for each such calendar year (2008 – 2012), due on March 1<sup>st</sup> of 2009, 2010, 2011, 2012, and 2013, respectively.

40. Accordingly, by failing to submit a complete production report by March 1<sup>st</sup> following each calendar year 2008, 2009, 2010, 2011, and 2012, Respondent violated Section 7(c)(1) of FIFRA and 40 C.F.R. Part 167, Subpart E on at least five (5) occasions, each of which is unlawful under FIFRA Section 12(a)(2)(L) and a violation for which penalties may be assessed pursuant to Section 14(a)(1) of FIFRA.

#### V. TERMS OF SETTLEMENT

41. Respondent stipulates that EPA has jurisdiction over the subject matter alleged in this CAFO. For the purposes of this proceeding, Respondent waives any defenses it might have as to jurisdiction and venue and, without admitting or denying the Preliminary Statement, EPA Findings, or Allegations of Violation herein, consents to the terms of this CAFO.

42. Respondent acknowledges that it has been informed of its right to request a hearing and hereby waives its right to request a judicial or administrative hearing on any issue of law or fact set forth in this CAFO. Respondent also waives its right to appeal the Final Order accompanying the Consent Agreement.

43. By signing this CAFO, Respondent certifies that, to the best of its information and belief, it is presently operating in compliance with FIFRA and the FIFRA Regulations promulgated thereunder, that it has fully addressed the violations alleged by EPA herein, and that the information it has provided to EPA during the course

of the EPA investigation of this matter is true and accurate.

44. In light of the above, and taking into account the factors enumerated in Section 14(a) of FIFRA, the December 2009 FIFRA Enforcement Response Policy and the May 2010 Enforcement Response Policy for FIFRA Section 7(c) Establishment Reporting Requirements, both issued by the Waste and Chemical Enforcement Division of the EPA Headquarters Office of Enforcement and Compliance Assurance in Washington, D.C., the DCIA and Penalty Inflation Rule, and other factors as justice may require, EPA has determined that it is fair and appropriate that Respondent pay a civil penalty in the amount of two million six hundred eighty-one thousand five hundred dollars (\$2,681,500) in settlement of the violations alleged herein.

45. Respondent shall pay the penalty of \$2,681,500 within thirty (30) days of the effective date of this CAFO.

46. Respondent shall make the payment due under this CAFO by submitting a bank or certified check, to the order of the "Treasurer, United States of America," in the appropriate amount to:

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

Alternatively, Respondent may make payment by electronic funds transfer via:

Federal Reserve Bank of New York  
ABA = 021030004  
Account = 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“

Respondent shall simultaneously submit a copy of the penalty payment check or confirmation of electronic wire transfer to:

Regional Hearing Clerk  
U.S. Environmental Protection Agency  
Region 1 (Mail Code: ORA18-1)  
5 Post Office Square, Suite 100  
Boston, MA 02109-3912

and

Hugh W. Martinez, Senior Enforcement Counsel  
U.S. EPA, Region 1  
5 Post Office Square  
Suite 100 (OES 04-3)  
Boston, MA 02109-3912

Respondent shall include the case name and docket number (*In the Matter of EMD Millipore Corporation*, FIFRA-01-2013-0017) on the face of the check or wire transfer confirmation.

47. If Respondent fails to pay the civil penalty, it will be subject to an action to compel payment, plus interest, enforcement expenses and a nonpayment penalty. Pursuant to 31 U.S.C. § 3717, EPA is entitled to assess interest and penalties on debts owed to the United States, as well as a charge to cover the cost of processing and handling a delinquent claim. Interest will therefore begin to accrue on the civil penalty (or any portion thereof) on the date it is due under this CAFO if such penalty (or portion

thereof) is not paid in full by such due date. Interest will be assessed at the rate of the United States Treasury tax and loan rate in accordance with 31 C.F.R. § 901.9(b)(2). In addition, a penalty charge of six percent (6%) per year and an amount to cover the costs of collection will be assessed on any portion of the debt that remains delinquent more than ninety (90) days after payment is due. Should assessment of the penalty charge on the debt be required, it will be assessed as of the first day payment is due, under 31 C.F.R. § 901.9(d). In any action to compel payment of civil penalties owed under this CAFO, the validity, amount, and appropriateness of the penalty shall not be subject to review.

48. The civil penalty due and any interest, non-payment penalties, or charges that arise pursuant to this CAFO shall represent penalties assessed by EPA and shall not be deductible for the purposes of Federal taxes. Accordingly, Respondent agrees to treat all payments made pursuant to this CAFO as penalties within the meaning of Internal Revenue Service regulations, including 26 C.F.R. § 1.162-21, and further agrees not to use these payments in any way as, or in furtherance of, a tax deduction under Federal, State or local law.

49. This CAFO constitutes a settlement and release by EPA of all claims for civil penalties pursuant to Section 14(a) of FIFRA arising out of the facts set forth in the Self-Disclosure and the violations alleged in Section IV of this CAFO.

50. This CAFO in no way relieves Respondent of any criminal liability, and EPA reserves all its other criminal and civil enforcement authorities, including the authority to seek injunctive relief and the authority to take any action to address imminent hazards. Compliance with this CAFO shall not be a defense to any action subsequently




commenced pursuant to Federal laws and regulations administered by EPA, and it is the responsibility of Respondent to comply with said laws and regulations.

51. Each of the Parties shall bear its own costs and attorneys' fees in the action resolved by this CAFO, and Respondent specifically waives any right to seek attorneys' fees under the Equal Access to Justice Act, 5 U.S.C. § 504.

52. The terms and conditions of this CAFO may not be modified or amended except upon the written agreement of both parties, and approval of the Regional Judicial Officer.

53. The undersigned representative(s) of Respondent certifies that he or she is fully authorized to enter into the terms and conditions of this CAFO and to execute and legally bind Respondent to it.

For Respondent, EMD Millipore Corporation:

  
\_\_\_\_\_  
(Signature)  
Robert Yates, President  
EMD Millipore Corporation  
290 Concord Road  
Billerica, MA 01821

6/20/13  
(Date)

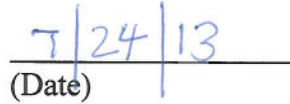
**MM**  
**Legal**  
*[Handwritten initials]*

For U.S. EPA - Region 1:

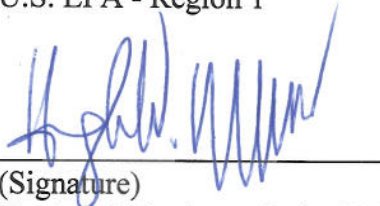


(Signature)

Joanna B. Jerison, Legal Enforcement Manager  
Office of Environmental Stewardship  
U.S. EPA - Region 1

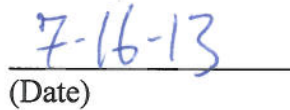


(Date)



(Signature)

Hugh W. Martinez, Senior Enforcement Counsel  
Regulatory Legal Office  
Office of Environmental Stewardship  
U.S. EPA - Region 1



(Date)

**VI. FINAL ORDER**

The foregoing Consent Agreement is hereby approved and incorporated by reference into this Final Order. The Respondent, EMD, is hereby ordered to comply with the terms of the above Consent Agreement, effective on the date it is filed with the Regional Hearing Clerk.

7/25/13  
(Date)

  
\_\_\_\_\_  
LeAnn W. Jensen, Acting Regional Judicial Officer  
U.S. EPA – Region 1

**CERTIFICATE OF SERVICE**

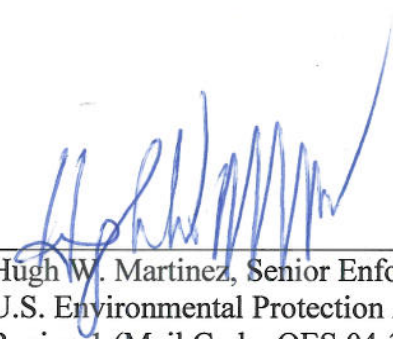
I hereby certify that this Certificate of Service and the foregoing Consent Agreement and Final Order and cover letter to the Regional Hearing Clerk were delivered in the following manner to the addressees listed below:

Originals and One Copy by Hand Delivery to: Wanda I. Santiago  
Regional Hearing Clerk  
Environmental Protection Agency  
5 Post Office Square, Suite 100 (ORA 18-1)  
Boston, MA 02109-3912

One Copy by Certified Mail – Return Receipt Requested to: James A. Thompson, Jr., Esquire  
Pepper Hamilton LLP  
Hamilton Square  
600 Fourteenth Street, N.W.  
Washington, D.C. 20005-2004

Date : 7-30-13

Signed: \_\_\_\_\_

  
Hugh W. Martinez, Senior Enforcement Counsel  
U.S. Environmental Protection Agency  
Region 1 (Mail Code: OES 04-3)  
5 Post Office Square, Suite 100  
Boston, MA 02109-3912  
Phone (617) 918-1867  
Fax (617) 918-0867  
[martinez.hugh@epa.gov](mailto:martinez.hugh@epa.gov)