

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION I – New England 5 Post Office Square - Suite 100

Boston, Massachusetts 02109-3912

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Office of Regional Hearing Clerk

BY HAND

September 30, 2010

Wanda I. Santiago, Regional Hearing Clerk U.S. Environment Protection Agency, Region I 5 Post Office Square, Suite 100 (ORA18-1) Boston, MA 02109-3912

Re: In the Matter of Millipore Corporation., Docket No. FIFRA-01-2010-0077

Dear Ms. Santiago:

Enclosed for filing in the above-referenced matter are the original and one copy of a Complaint and Notice of Opportunity for Hearing.

Thank you for your assistance in this matter.

Sincerely,

Kevin P. Pechulis Enforcement Counsel

Enclosures

cc: David P. Hutchinson, President, Millipore Corporation

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 1

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In the Matter of:)
Millipore Corporation 290 Concord Road Billerica, MA 01821) Office of Regional Hearing Clerk) Docket No. FIFRA-01-2010-0077
Respondent.)
) COMPLAINT and NOTICE OF
Proceedings under Section) OPPORTUNITY FOR HEARING
14(a) of the Federal	
Insecticide, Fungicide, and	
Rodenticide Act, as amended	
7 U.S.C. Section 136l(a).	()

COMPLAINT

This Complaint and Notice of Opportunity for Hearing (the "Complaint") is being issued under Section 14(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), as amended, 7 U.S.C. §136*l*(a)(1), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits, 40 C.F.R. Part 22 ("Part 22" or the "Consolidated Rules"). This Complaint alleges that the Respondent, Millipore Corporation ("Millipore" or the "Respondent"), has violated Sections 12(a)(1)(A) and 12(a)(2)(N) of FIFRA, 7 U.S.C. §§ 136j(a)(1)(A) and 136j(a)(2)(N), and the regulations promulgated pursuant to FIFRA at 40 C.F.R. Part 152 *et seq.* and 19 C.F.R. §§12.110 – 12.117. This Complaint provides written notice of the United States Environmental Protection Agency's ("EPA") proposal to assess administrative penalties for the violations alleged herein. This Complaint also provides notice of Respondent's opportunity to request a hearing on the

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 1

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7 U.S.C. Section 136l(a).	
7 0.5.C. Section 1501(a).)

COMPLAINT

This Complaint and Notice of Opportunity for Hearing (the "Complaint") is being issued under Section 14(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), as amended, 7 U.S.C. §136/(a)(1), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits, 40 C.F.R. Part 22 ("Part 22" or the "Consolidated Rules"). This Complaint alleges that the Respondent, Millipore Corporation ("Millipore" or the "Respondent"), has violated Sections 12(a)(1)(A) and 12(a)(2)(N) of FIFRA, 7 U.S.C. §§ 136j(a)(1)(A) and 136j(a)(2)(N), and the regulations promulgated pursuant to FIFRA at 40 C.F.R. Part 152 et seq. and 19 C.F.R. §§12.110 – 12.117. This Complaint provides written notice of the United States Environmental Protection Agency's ("EPA") proposal to assess administrative penalties for the violations alleged herein. This Complaint also provides notice of Respondent's opportunity to request a hearing on the

proposed penalty. The Complainant is, by lawful delegation, the Legal Enforcement Manager in the Office of Environmental Stewardship, EPA Region 1.

GENERAL ALLEGATIONS

- 1. The Respondent is Millipore, a company that produces, imports into the United States, distributes and sells water purification devices, among other things. Respondent also produced, imported, distributed and sold chlorine tablets used for sanitation purposes in conjunction with its water purification devices. Respondent is a business incorporated under the laws of the Commonwealth of Massachusetts, doing business at all relevant times in Massachusetts. Respondent's principal place of business is located at 290 Concord Road, Billerica, Massachusetts 01821.
- 2. Respondent is a "person" as defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s), and is subject to FIFRA and the regulations promulgated thereunder.
- 3. Respondent operates a facility that is located in France at the following address: Zone Industrielle, Molsheim, France 67120 (the "Millipore S.A. Facility"). The Millipore S.A. Facility has been registered by EPA under Section 7 of FIFRA, 7 U.S.C. §136e, as a pesticide-producing establishment since January 18, 1978, and was assigned the EPA establishment number ("EPA Est. No.") 041237-FRA-001.
- 4. Section 2(dd) of FIFRA, 7 U.S.C. § 136(dd), defines the term "establishment" as "any place where a pesticide or device or active ingredient used in producing a pesticide is produced, or held, for distribution or sale." Accordingly, Respondent's Millipore S.A. Facility is an "establishment" under Section 2(dd) of FIFRA.

- 5. At all times relevant to the violations alleged in this Compliant, Respondent produced and imported into the United States, distributed, sold, offered for sale, shipped, and/or delivered for shipment a product known as "Millipore Chlorine Tablets," which contained chlorine, as sodium dichloroisocyanurate, dehydrate (CAS No. 51580-86-0) in a concentration of greater than 50% by weight, as the active ingredient to sanitize filters or cartridges used in water purification devices that are imported, distributed and/or sold by Respondent.
- 6. At all times relevant to the violations alleged in this Complaint, the labels used for the Millipore Chlorine Tablets contained, *inter alia*, the following text: "[s]ee the system user manual for specific instructions on how to sanitize your system."
- 7. 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).
- 8. Section 2(u)(1) of FIFRA, 7 U.S.C § 136(u)(1), defines the term "pesticide" to mean, in pertinent part, "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest."
- 9. The Millipore Chlorine Tablets contain chlorine, as sodium dichloroisocyanurate, dehydrate (CAS No. 51580-86-0) in a concentration of greater than 50% by weight, that is intended for preventing, destroying, repelling or mitigating a pest; therefore, each Millipore Chlorine Tablet is a "pesticide" as defined by Section 2(u)(1) of FIFRA, 7 U.S.C. § 136(u)(1).
 - 10. At all times relevant to the violations alleged in this Compliant, Respondent

produced, imported into the United States, distributed, sold, offered for sale, shipped and delivered for shipment at least ten types of water purification devices known by the following product names: AFS, DIRECT-Q, ELIX, MILLI-DI, RiOs (formerly named MILLI-RO), SIMPLICITY, SUPER Q, SYNERGY, WPM (Millipore) and MILLI-Q (hereinafter, collectively referred to as the "Millipore Water Purification Devices"). According to the user manuals for the Millipore Water Purification Devices and other publically available information, including the Millipore Internet webpage, the Millipore Water Purification Devices are intended to be used to purify water in laboratory or other commercial settings.

- 11. 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."
- 12. The Millipore Water Purification Devices are instruments that are intended for trapping, destroying, or mitigating pests contained in the water that they are used to purify; therefore, the Millipore Water Purification Devices are each a "device" as defined by Section 2(h) of FIFRA, 7 U.S.C. §136(h).
- 13. On or about October 1, 2008, Respondent's U.S. Customs Broker, FedEx Trade
 Networks, contacted EPA regarding Millipore Chlorine Tablets that were being denied entry into
 the United States by the U.S. Customs and Border Protection ("U.S. CBP") at the Air France
 Cargo Warehouse, 152 Harbor Side Drive, East Boston, MA at the Logan International Airport

(the "Logan International Air France Cargo Warehouse") due to a lack of approval from the EPA Administrator through a Notice of Arrival of Pesticides and Devices Form, EPA Form 3540-1 ("NOA").

- 14. On or about October 9, 2008, a duly-authorized EPA inspector (the "EPA Inspector") conducted a FIFRA inspection at the Logan International Air France Cargo Warehouse pursuant to Sections 8 and 9 of FIFRA, 7 U.S.C. §§ 136f and 136g, to investigate the suspected import and distribution or sale of the unregistered Millipore Chlorine Tablets by Respondent (the "October 2008 Inspection").
- 15. During the October 2008 Inspection, the EPA Inspector collected documentary samples (e.g., photographs or photocopies) of boxes containing the Millipore Chlorine Tablets and documented the import into the United States, and the intended distribution or sale of, the Millipore Chlorine Tablets.
- 16. On information and belief, at all times relevant to the violations alleged in this Complaint, Respondent never registered the Millipore Chlorine Tablets as a pesticide with EPA as required by Section 3 of FIFRA, 7 U.S.C. § 136a.
- 17. The unregistered Millipore Chlorine Tablets documented during the October 2008 Inspection were returned to France upon EPA's request pursuant to Section 17(c) of FIFRA, 7 U.S.C. § 1360(c).
- 18. In response to a request by the EPA Inspector, on or about October 10, 2008, the EPA Inspector received copies, via electronic mail, of a portion Respondent's import records for the Millipore Chlorine Tablets from Respondent's U.S. Customs Broker, Fed Ex Trade

Networks, with a copy provided to Respondent via electronic mail.

- In response to a request by the EPA Inspector, on or about June 28, 2010, Respondent, through its U.S. Customs Broker, Fed Ex Trade Networks, provided the EPA Inspector with a revised version of a portion Respondent's import records for the Millipore Chlorine Tablets (the "Chlorine Tablet Import Records"). The Respondent's Chlorine Tablet Import Records document Respondent's import of the Millipore Chlorine Tablets into the United States from on or about March 15, 2004 through September 29, 2008, inclusive. Respondent's Chlorine Tablet Import Records identify, among other things, the "entry number" (i.e., shipment number), "entry date," "part number," "country of origin," and "broker file number" for each shipment of Millipore Chlorine Tablets imported into the United States for distribution or sale by Respondent.
- 20. On December 17, 2008, the EPA Inspector conducted a FIFRA inspection at the Logan International Air France Cargo Warehouse pursuant to Sections 8 and 9 of FIFRA, 7 U.S.C. §§ 136f and 136g, to investigate the suspected import of pesticide devices into the United States by Respondent (the "December 2008 Inspection").
- 21. During the December 2008 Inspection, the EPA Inspector documented the import into the United States of the Millipore Water Purification Devices and examined the labels used for the Millipore Water Purification Devices.
- 22. In response to a request by the EPA Inspector, on or about March 4, 2009,
 Respondent provided the EPA Inspector with Respondent's import records for a two-year period
 for the Millipore Water Purification Devices (the "Device Import Records"). Respondent's

Device Import Records include a two-year import history for all products that Respondent identified as pesticide devices and imported into the United States. Respondent's Device Import Records document Respondent's import of the Millipore Water Purification Devices into the United States from on or about February 1, 2007 through February 1, 2009, inclusive. For each shipment of devices Respondent imported into the United States for distribution or sale, Respondent's Device Import Records identify, among other things, the "entry number" (i.e., shipment number), "entry date," "part number," and "part quantity."

- 23. Section 12(a)(1)(A) of FIFRA states, in pertinent part, that it "shall be unlawful for any person in any State to distribute or sell to any person any pesticide that is not registered" with EPA under Section 3 of FIFRA, 7 U.S.C. § 136a. The FIFRA regulations at 40 C.F.R. Part 152 set forth procedures, requirements, and criteria concerning the registration of pesticides under Section 3 of FIFRA.
- 24. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines "to distribute or sell" as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver."
- 25. At all times relevant to the violations alleged in this Complaint, by producing, distributing, selling, offering for sale, shipping, and/or delivering for shipment the pesticide known as Millipore Chlorine Tablets, Respondent engaged in actions that fall within the scope of the term "to distribute or sell" as defined in Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg).
 - 26. Based upon the EPA Inspector's review of Respondent's Chlorine Tablet Import

Records, the October 2008 Inspection, and further investigation by EPA, at time periods relevant to the violations alleged in this Complaint, Respondent distributed or sold the unregistered Millipore Chlorine Tablets on at least 344 separate occasions from September 30, 2005 to September 29, 2008 in violation of Sections 12(a)(1)(A) and 3 of FIFRA, 7 U.S.C. §§ 136j(a)(1)(A) and 136a.

- 27. Pursuant to Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N), it is unlawful for "for any person ... who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by this subchapter."
- 28. At all times relevant to the violations alleged in this Complaint, by producing, importing, distributing, selling, offering for sale, shipping, and/or delivering for shipment the Millipore Chlorine Tablets and the Millipore Water Purification Devices, Respondent engaged in actions that fall within the scope of the term "to distribute or sell" as defined in Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg). Accordingly, Respondent is a distributor for purposes of Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N).
- 29. The import of pesticides and devices into the United States is governed by Sections 17(c) and (e) of FIFRA, 7 U.S.C. §§ 136o(c) and 136o(e), and the regulations promulgated thereunder by the Secretary of the Treasury in consultation with the Administrator of the EPA.
- 30. FIFRA Section 17(c), 7 U.S.C. § 1360(c), requires the Secretary of the Treasury to notify the EPA Administrator of the arrival of pesticides and devices in the United States.
 - 31. FIFRA Section 17(e), 7 U.S.C. § 136o(e), requires the Secretary of the Treasury,

 Page 8 of 18

in consultation with the Administrator, to prescribe regulations for the enforcement of FIFRA Section 17(c), 7 U.S.C. § 1360(c).

- 32. Pursuant to FIFRA Section 17(e), 7 U.S.C. § 136o(e), the Secretary of the Treasury, acting through the United States Custom Service, prescribed regulations for the enforcement of Section 17(c) of FIFRA at 19 C.F.R. §§ 12.110 12.117 (the "Pesticide /Device Import Regulations").
- 33. The Pesticide/Device Import Regulations at 19 C.F.R. § 12.112(a) state, in pertinent part, that "an importer desiring to import pesticides or devices into the United States shall submit to the Administrator a Notice of Arrival of Pesticides and Devices (Environmental Protection Agency Form 3540-1), hereinafter referred to as a Notice of Arrival, prior to the arrival of the shipment in the United States."
- 34. Through the NOA, the importer reports vital information to EPA regarding the pesticides or devices such as the major active ingredients, quantity, country of origin, producing establishment number, carrier, port of entry, and points of contact. This information allows EPA to make informed decisions, before pesticides and devices arrive in the United States, as to whether such importation will pose unreasonable adverse risks to public health and the environment. The NOA also provides contact information in the event of an emergency related to the movement of potentially toxic pesticide materials.
- 35. An NOA constitutes a report under Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N), that must be filed with the EPA Administrator prior to the arrival of each shipment of pesticides or devices in the United States.

- 36. During the October 2008 Inspection, the EPA Inspector documented the import of the unregistered Millipore Chlorine Tablets into the United States by Respondent.
- 37. On information and belief, at all times relevant to the violations alleged in this Complaint, Respondent failed to file the required NOAs for the Millipore Chlorine Tablets that Respondent imported into the United States.
- 38. Based upon the EPA Inspector's review of Respondent's Chlorine Tablet Import Records, the October 2008 Inspection, and further investigation by EPA, at time periods prior to September 29, 2008 and relevant to the violations alleged in this Complaint, Respondent imported shipments of the unregistered Millipore Chlorine Tablets into the United States for distribution or sale without filing the required NOA with EPA on at least 344 separate occasions from September 30, 2005 to September 29, 2008.
- 39. During the December 2008 Inspection, the EPA Inspector documented the import of the Millipore Water Purification Devices into the United States by Respondent.
- 40. On information and belief, at all times relevant to the violations alleged in this Complaint and at least prior to October 31, 2008, Respondent failed to file the required NOAs for the Millipore Water Purification Devices that Respondent imported into the United States.
- 41. Based upon the EPA Inspector's review of Respondent's Device Import Records, the December 2008 Inspection, and further investigation by EPA, at time periods prior to October 31, 2008 and relevant to the violations alleged in this Complaint, Respondent imported shipments of the Millipore Water Purification Devices into the United States for distribution or sale without filing the required NOA on at least 1,173 separate occasions from February 1, 2007

to October 31, 2008.

COUNT 1 - Sale or Distribution of Unregistered Pesticide

- 42. Paragraphs 1 through 41 are realleged and incorporated by reference.
- 43. Based upon the October 2008 Inspection, a review of Respondent's Chlorine Tablet Import Records, and further investigation by EPA, the EPA Inspector documented that Respondent imported for distribution or sale the Millipore Chlorine Tablets.
- 44. At the time of the October 2008 Inspection, Respondent had not registered the Millipore Chlorine Tablets as a pesticide with EPA, as required under Section 3 of FIFRA, 7 U.S.C. § 136a.
- 45. Based upon the October 2008 Inspection, a review of Respondent's Chlorine

 Tablet Import Records, and further investigation by EPA, EPA determined that Respondent imported for distribution or sale the unregistered Millipore Chlorine Tablets on at least 344 separate occasions when Respondent caused such Millipore Chlorine Tablets to enter the United States and into the stream of commerce.
- 46. Accordingly, on at least 344 separate occasions Respondent violated Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), and the regulations promulgated pursuant to FIFRA at 40 C.F.R. Part 152 *et seq.*, each of which is a violation for which penalties may be assessed pursuant to Section 14(a)(1) of FIFRA, 7 U.S.C. § 136*l*(a)(1).

COUNT 2 - Failure to File Report of Pesticide Import

- 47. Paragraphs 1 through 46 are realleged and incorporated by reference.
- 48. Based upon the October 2008 Inspection, a review of Respondent's Chlorine

Tablet Import Records, and further investigation by EPA, the EPA Inspector documented that Respondent imported for distribution or sale the Millipore Chlorine Tablets.

- 49. Based upon the October 2008 Inspection, a review of Respondent's Chlorine Tablet Import Records, and further investigation by EPA, EPA determined that between September 30, 2005 and at least September 29, 2008, Respondent failed to file reports (i.e., NOAs) with EPA for the import of the Millipore Chlorine Tablets as required by Section 17 of FIFRA, 7 U.S.C. § 1360, and 19 C.F.R. § 12.112(a), on at least 344 separate occasions.
- 50. Accordingly, on at least 344 separate occasions Respondent violated Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N), and the regulations promulgated pursuant to FIFRA 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. § 136*l*(a)(1).

COUNT 3 - Failure to File Reports for Device Imports

- 51. Paragraphs 1 through 50 are realleged and incorporated by reference.
- 52. Based upon the December 2008 Inspection, a review of Respondent's Device Import Records, and further investigation by EPA, EPA determined that Respondent imported for distribution or sale the Millipore Water Purification Devices.
- 53. Based upon the December 2008 Inspection, a review of Respondent's Device Import Records, and further investigation by EPA, EPA determined that between February 1, 2007 and at least October 31, 2008, Respondent failed to file reports (i.e., NOAs) with EPA for the import of the Millipore Water Purification Devices, as required by Section 17 of FIFRA, 7 U.S.C. § 1360, and 19 C.F.R. § 12.112(a), on at least 1,173 separate occasions.

54. Accordingly, on at least 1,173 separate occasions Respondent violated Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N), and the regulations promulgated pursuant to FIFRA 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).

PROPOSED CIVIL PENALTY

- 55. Section 14(a) of FIFRA, 7 U.S.C. § 136l(a), authorizes EPA to assess a civil penalty of up to \$5,000 for each violation of FIFRA and the regulations promulgated pursuant thereto. Pursuant the Debt Collection Improvement Act of 1996 ("DCIA"), Pub. L. No. 104-134, 110 Stat. 1321 (1996), and EPA's Civil Monetary Penalty Inflation Adjustment Rule, promulgated thereunder and codified at 40 C.F.R. Part 19, this amount was increased to \$6,500 for violations occurring after March 15, 2004, and to \$7,500 for violations occurring after January 12, 2009. *See* 69 Fed. Reg. 7121 (February 13, 2004) and 73 Fed. Reg. 75340 (December 11, 2008).
- 56. Based on the forgoing findings of violations of FIFRA, EPA seeks to assess a civil penalty of up to \$6,500 per violation for each of the violations alleged in Counts 1-3 above. The assessment of a penalty is warranted because the Millipore Chlorine Tablets were sold or distributed without first being registered as a pesticide under FIFRA Section 3, 7 U.S.C. § 136a, and the Millipore Chlorine Tablets and Millipore Water Purification Devices were imported into the United States without Respondent filing the required reports (i.e., NOAs) with EPA. The FIFRA Section 3 registration requirement serves the fundamental purpose of ensuring that no pesticide or device is distributed, sold, or used in a manner that may pose an unreasonable risk to

human health or the environment. The requirement to submit reports (i.e., NOAs) to EPA prior to the importation into the United States of a pesticide or device also protects against unreasonable risk to human health or the environment by providing EPA with vital information regarding the pesticides or devices before they arrive in the United States for distribution or sale. In order to effectively regulate the importation of pesticides and devices, it is essential to know when the pesticides or devices arrive in the United States such that the appropriate officials may act promptly to prevent any adverse exposure, as necessary.

- 57. In determining the amount of the penalty to be assessed under Section 14(a) of FIFRA, 7 U.S.C. § 136*l*(a), EPA will take into account the statutory factors listed in Section 14(a)(4) of FIFRA, 7 U.S.C. § 136*l*(a)(4), which include the appropriateness of the penalty to the size of the business of the person charged, the effect of the penalty on the person's ability to continue in business, and the gravity of the violation. EPA will also take into account the "FIFRA Enforcement Response Policy" issued by the Waste and Chemical Enforcement Division, Office of Civil Enforcement, Office of Enforcement and Compliance Assurance, dated December 2009 (the "Penalty Policy"), a copy of which is enclosed with this Complaint.
- 58. Prior to any hearing on this case, EPA will file a document specifying a proposed penalty for Respondent's FIFRA violations and explaining how the proposed penalty was calculated, as required by the Consolidated Rules (enclosed).
- 59. Neither assessment nor payment of any administrative penalty shall affect Respondent's continuing obligation to comply with FIFRA and its implementing regulations.

NOTICE OF OPPORTUNITY TO REQUEST A HEARING

60. As provided in Section 14(a)(3) of FIFRA, 7 U.S.C. § 136l(a)(3), and in accordance with 5 U.S.C. § 554 and 40 C.F.R. § 22.14, Respondent has the right to request a formal hearing to contest any material fact set forth in this Complaint or to contest the appropriateness of the proposed penalty. To avoid being found in default and having a penalty assessed without further proceedings, Respondent must file a written Answer within thirty (30) days of receipt of this Complaint. The Answer should (1) clearly and directly admit, deny, or explain each of the factual allegations contained in the Complaint, (2) briefly state all facts and circumstances, if any, which constitute grounds for a defense, and (3) specifically request an administrative hearing (if desired). The denial of any material fact or raising any affirmative defense(s) shall be construed as a request for a hearing. Failure to deny any of the factual allegations in this Complaint will constitute an admission of the undenied allegations. The original and one copy of the Answer, as well as a copy of all other documents that Respondent files in this action, must be sent to:

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

61. Respondent should also send a copy of the Answer, as well as a copy of all other documents that Respondent files in this action to Kevin P. Pechulis, the attorney assigned to represent EPA and designated to receive service on behalf of Complainant in this matter at:

Kevin P. Pechulis

Page 15 of 18

In the Matter of Millipore Corporation, Docket No. FIFRA-01-2010-0077 Complaint and Notice of Opportunity for Hearing

Enforcement Counsel
U.S. Environmental Protection Agency
Office of Environmental Stewardship (OES04-3)
5 Post Office Square, Suite 100
Boston, MA 02109-3912
(617) 918-1612
(617) 918-0612 fax

- 62. The hearing that will be held upon Respondent's request will be conducted in accordance with the Administrative Procedure Act (5 U.S.C. §§ 551 et seq.) and the Consolidated Rules.
- 63. If Respondent fails to file a written Answer within thirty (30) days of the service of this Complaint, pursuant to 40 C.F.R § 22.17(a) Respondent may be found in default, which constitutes an admission of all the facts alleged in this Complaint and a waiver of the right to a hearing, and the above-referenced penalties may be assessed without further proceedings.

INFORMAL SETTLEMENT CONFERENCE

- 64. Whether or not Respondent requests a hearing, Respondent may confer informally with EPA to discuss the facts of this case, or the proposed penalties, and/or the possibility of settlement. EPA has the authority to modify the amount of the proposed penalty, where appropriate, to reflect any settlement reached with Respondent in an informal conference. The terms of such an agreement would be embodied in a Consent Agreement and Final Order. A Consent Agreement and Final Order, signed by Complainant and Respondent, would be binding as to all terms and conditions specified therein.
- 65. A request for an informal settlement conference does not extend any deadline in this proceeding, including the thirty (30) day period for the submission of a written Answer to

<u>In the Matter of Millipore Corporation,</u> Docket No. FIFRA-01-2010-0077 Complaint and Notice of Opportunity for Hearing

this Complaint.

66. If Respondent has any questions concerning the settlement process, or wishes to arrange for an informal conference, Respondent should contact Kevin P. Pechulis at (617) 918-

1612.

For Joanna B. Jerison, Legal Enforcement Manager

Office of Environmental Stewardship

Date: 9/27/10

In the Matter of Millipore Corporation, Docket No. FIFRA-01-2010-0077 Complaint and Notice of Opportunity for Hearing

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Complaint and Notice of Opportunity for Hearing was delivered in the following manner to the addresses listed below:

Original and One Copy by

Hand Delivery to:

Wanda I. Santiago

Regional Hearing Clerk

Environmental Protection Agency

5 Post Office Square, Suite 100 (DRA 18-1)

Boston, MA 02109-3912

One Copy by Certified Mail

David P. Hutchinson, President

Return Receipt Requested to:

Millipore Corporation

290 Concord Road

Billerica, Massachusetts 01821

Date

Signed:

Kevin P. Pechulis

Enforcement Counsel

Office of Environmental Stewardship (OES04-3)

U.S. Environmental Protection Agency

5 Post Office Square, Suite 100

Boston, MA 02109-3912