



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 2

290 BROADWAY

NEW YORK, NEW YORK 10007-1866

U.S. ENVIRONMENTAL PROTECTION AGENCY-REG.II

2013 AUG 19 P 3:22

REGIONAL HEARING CLERK

AUG 16 2013

United States First Class Mail

Alberto Ramos, Esq.
Alberto Ramos Law Offices
PO Box 750
Mercedita, Puerto Rico 00715-9750

Re: In the Matter of Sartorius Stedim Filters, Inc.
Docket No.: RCRA-02-2013-7102

Dear Mr. Ramos:

Enclosed is a fully executed Consent Agreement and Final Order (CA/FO) under Section 3008 of the Resource Conservation and Recovery Act as amended, 42 U.S.C. § 6928, resolving the above referenced action.

Please do not hesitate to contact me if you have any questions. Thank you for your cooperation in this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Amy R. Chester".

Amy R. Chester
Assistant Regional Counsel
212 637-3213

Enclosure

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2**

In The Matter of: Sartorius Stedim Filters, Inc. Respondent Proceeding Under Section 3008 of the Solid Waste Disposal Act, as amended.	CONSENT AGREEMENT AND FINAL ORDER Docket No.: RCRA-02-2013-7102 U.S. ENVIRONMENTAL PROTECTION AGENCY-REGION 2 2013 AUG 19 P 3:22 REGIONAL HEARINGS CLERK
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PRELIMINARY STATEMENT

This civil administrative proceeding was instituted pursuant to Section 3008 of the Solid Waste Disposal Act, as amended by various laws including the Resource Conservation and Recovery Act, and the Hazardous and Solid Waste Amendments of 1984, 42 United States Code (U.S.C.) §§ 6901-6991 (together hereafter the “Act” or “RCRA”).

The Complainant in this proceeding, Dore LaPosta, the Director of the Division of Enforcement and Compliance Assistance, Region 2 EPA, has been duly delegated the authority to institute and carry forward this proceeding.

The Respondent is Sartorius Stedim Filters, Inc. (“Respondent”). Respondent owns and operates a manufacturing plant located in Yauco, Puerto Rico.

Under Section 3006(b) of the Act, 42 U.S.C. § 6926(b), the Administrator of EPA may, if certain criteria are met, authorize a state to operate a “hazardous waste program” (within the meaning of Section 3006 of the Act, 42 U.S.C. § 6926) in lieu of the federal hazardous waste program. The Commonwealth of Puerto Rico (“Puerto Rico” or “the Commonwealth”) is a “State” within the meaning of this provision. Puerto Rico has not received authorization to operate a hazardous waste program pursuant to this provision. As a result, federal hazardous waste regulations remain in effect.

The Complainant issued a Complaint, Compliance Order and Notice of Opportunity for Hearing (the “Complaint”) to Respondent on or about March 29, 2013. The Complaint alleged that Respondent failed to comply with RCRA and hazardous waste regulations at its facility in Puerto Rico. Complainant and Respondent conducted settlement negotiations which led to this agreement. During these negotiations, Respondent also provided evidence which persuaded Complainant not to further prosecute Count 4 of the Complaint.

Complainant and Respondent agree, by entering into this Consent Agreement and Final Order (“CA/FO”), that settlement of this matter upon the terms set forth in this CA/FO is an appropriate means of resolving this case without further litigation.

EPA'S FINDINGS OF FACT AND CONCLUSIONS OF LAW

RESPONDENT

1. The Respondent is Sartorius Stedim Filters, Inc.
2. Respondent owns and operates a manufacturing plant located in Yauco, Puerto Rico. The plant produces cellulose acetate filters.
3. Respondent is a "person" as that term is defined in Section 1004(15) of the Act, 42 U.S.C. § 6903(15), and 40 C.F.R. § 260.10.
4. The Yauco, Puerto Rico location where Respondent conducts its manufacturing business constitutes a "facility" as that term is defined in 40 C.F.R. § 260.10 (hereinafter "facility").
5. Respondent is and has been the "owner" and "operator" of the facility as those terms are defined in 40 C.F.R. § 260.10.
6. On or about April 21, 1986, Respondent submitted a Section 3010 Notification of Regulated Waste Activity to EPA informing EPA of its hazardous waste activities at its facility. In response, EPA assigned Respondent with EPA Identification Number PRD049532807.
7. Respondent never submitted a Part A or a Part B Permit Application to EPA for its facility and never received "interim status" or a hazardous waste permit to treat, store or dispose of hazardous waste at its facility.
8. Respondent is and has been a "generator" of "hazardous waste" at its facility as those terms are defined in 40 C.F.R. § 260.10. The requirements for generators are set forth in 40 C.F.R. Part 262.
9. Respondent has generated, and continues to generate, at least 1000 kilograms ("kg") of hazardous waste in a calendar month at its facility. (Generators that generate 1000 kg or more in a month are commonly referred to as large quantity generators ("LQGs")).
10. Respondent has been holding, and continues to hold, hazardous waste generated at its facility in a hazardous waste container storage area and/or hazardous waste tank(s) for a temporary period of time, constituting "storage" as that term is defined in 40 C.F.R. 260.10. Respondent stores hazardous waste on site for a period of 90 days or less.
11. Pursuant to 40 C.F.R. § 262.34, LQGs may accumulate hazardous waste on site without interim status or a permit for 90 days or less provided that they comply with, among other things, the applicable requirements set forth in 40 C.F.R Part 265, Subparts BB and CC. Having failed to comply with certain requirements set forth in Subparts BB and CC as

described herein, Respondent became subject to the requirements set forth in 40 C.F.R. Part 264. See 40 C.F.R. § 264.1(b).

40 C.F.R. Part 264, Subpart BB

12. Subpart BB of 40 C.F.R. Parts 264 sets forth air emission standards for “equipment,” as that term is defined in 40 C.F.R. § 264.1031, that contains or contacts hazardous waste with organic concentrations of at least 10 percent by weight (hereafter referred to as “organic hazardous waste”). These requirements are set forth at 40 C.F.R. §§ 264.1050-1065.
13. Since at least April 2009, Respondent has conveyed, and continues to convey, organic hazardous waste through pipes and equipment, including pumps and valves, to an above ground storage tank(s) at its facility.
14. Pursuant to 40 C.F.R. § 264.1050(f), equipment that contains or contacts organic hazardous waste for less than 300 hours per calendar year is excluded from certain specified Subpart BB requirements provided that equipment is identified in the facility’s operating log as required by 40 C.F.R. § 264.1064(g)(6).
15. During the period of time between at least April 17, 2009 and April 17, 2012, Respondent’s operating log did not identify any equipment at its facility as being subject to Subpart BB and did not identify whether any equipment subject to Subpart BB came into contact with or contained organic hazardous waste for less than 300 hours.

Failure to Maintain Required Records for Equipment Subject to Subpart BB

16. 40 C.F.R. § 264.1064 sets forth the recordkeeping requirements for owners and operators subject to Subpart BB.
17. 40 C.F.R. § 264.1064(b)(1) requires owners and operators of equipment to which Subpart BB applies to record, among other things, the following information in the operating log: i) equipment identification numbers and hazardous waste management unit identification; ii) approximate locations of equipment within the facility; iii) the type of equipment (*i.e.*, valve or pump); and iv) the percentage by weight total organics in the waste stream at the equipment.
18. 40 C.F.R. § 264.1064(g) further requires owners and operators with equipment subject to the requirements set forth in 40 C.F.R. §§ 264.1052-1060 to record in the operating record, among other things, all equipment that comes into contact with organic hazardous waste for less than 300 hours.
19. During the period of time between at least April 17, 2009 and April 17, 2012, Respondent’s operating log did not contain any information regarding equipment at its facility subject to Subpart BB in violation of 40 C.F.R. § 264.1064.

Failure to Conduct Monitoring of Pumps in Light Liquid Service

20. Pursuant to 40 C.F.R. § 264.1052(a)(1) each pump in light liquid service shall be monitored monthly to detect leaks by methods specified in 40 C.F.R. §264.1063(b).
21. Pursuant to 40 C.F.R. § 264.1063(b)(1), monitoring shall comply with Reference Method 21 in 40 C.F.R. Part 60.
22. During the period of time between at least April 17, 2009 and April 17, 2012, Respondent had five pumps in “light liquid service,” as that term is defined in 40 C.F.R. § 264.1031, at its facility.
23. During the period of time between at least April 17, 2009 and April 17, 2012, Respondent failed to conduct monthly leak detection monitoring pursuant to Reference Method 21 on the five pumps in light liquid service at its facility in violation of 40 C.F.R. § 264.1052(a)(1).

Failure to Conduct Monitoring of Valves in Light Liquid Service

24. Pursuant to 40 C.F.R. § 264.1057(a), each valve in light liquid service shall be monitored monthly to detect leaks by the methods specified in 40 C.F.R. § 264.1063(b).
25. Pursuant to 40 C.F.R. § 264.1063(b)(1), monitoring shall comply with Reference Method 21.
26. During the period of time between at least April 17, 2009 and April 17, 2012, Respondent had 27 valves in “light liquid service,” as that term is defined in 40 C.F.R. § 264.1030, at its facility.
27. During the period of time between at least April 17, 2009 and April 17, 2012, Respondent failed to perform monthly leak detection monitoring pursuant to Reference Method 21 on 27 valves at its facility in violation of 40 C.F.R. § 264.1057(a).

CONSENT AGREEMENT

Pursuant to Section 3008 of RCRA and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and Revocation or Suspension of Permits, 40 C.F.R. § 22.18, it is hereby agreed by and between the parties and Respondent knowingly and voluntarily agrees as follows:

1. Commencing upon the effective date of this Consent Agreement and Final Order (CA/FO) and continuing thereafter, Respondent shall:
 - a) Comply with all applicable provisions of 40 C.F.R. Part 264 Subparts BB and CC, including a) maintaining requisite records pursuant to 40 C.F.R. § 264.1064; and b) monitoring pumps and valves in light liquid service

pursuant to 40 C.F.R. § 264.1052(a)(1) and 40 C.F.R. § 264.1057(a), respectively; or

- b) To the extent Respondent is a large quantity generator accumulating waste pursuant to 40 C.F.R. § 262.34, comply with all applicable provisions of 40 C.F.R Part 265, Subparts BB and CC, including a) maintaining requisite records pursuant to 40 C.F.R. § 265.1064; and b) monitoring pumps and valves in light liquid service pursuant to 40 C.F.R. § 265.1052(a)(1) and 40 C.F.R. § 265.1057(a).
2. Within thirty (30) days of the effective date of this Consent Agreement and Final Order, Respondent shall send a Compliance Report to EPA detailing its present compliance with the requirements set forth in Paragraph 1.a or 1.b. of this Consent Agreement. This Compliance Report shall include all appropriate documentation and evidence. If appropriate, Respondent may reference documentation previously submitted to EPA. The Compliance Report should be sent to:

Mr. John Wilk
Compliance Officer
RCRA Compliance Branch
Division of Enforcement and Compliance Assistance
U.S. Environmental Protection Agency - Region 2
290 Broadway, 21st Floor
New York, NY 10007-1866

3. For the purpose of this proceeding, Respondent admits the jurisdictional allegations of the Complaint and neither admits nor denies specific factual allegations contained in Counts 1 to 3 of the Complaint.
4. Respondent shall pay a civil penalty to EPA in the total amount of fifty-eight thousand (\$58,000). Such payment shall be made by cashier's or certified checks or by Electronic Fund Transfers ("EFT"). If the payments are made by checks, then the checks shall be made payable to the "Treasurer, United States of America," and shall be mailed to:

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

Each check shall be identified with a notation thereon: **In the Matter of Sartorius Stedim Filters, Inc.** and shall bear thereon the Docket Number: **RCRA-02-2013-7102**. If Respondent chooses to make the payment by EFT, then Respondent shall provide the following information to its remitter bank:

- 1) Amount of Payment

- 2) SWIFT address: FRNYUS33, 33 Liberty Street, New York, NY 10045.
- 3) Account Code for Federal Reserve Bank of New York receiving payment: 68010727.
- 4) Federal Reserve Bank of New York ABA routing number: 021030004.
- 5) Field Tag 4200 of the Fedwire message should read: "D68010727 Environmental Protection Agency."
- 6) Name of Respondent: **Sartorius Stedim Filters, Inc.**
- 7) Case Number: **RCRA-02-2013-7102.**

Whether the payments are made by checks or by EFT, the Respondent shall promptly thereafter furnish reasonable proof that such payments have been made to:

Amy Chester
Assistant Regional Counsel
U.S. Environmental Protection Agency-Region 2
290 Broadway, 16th Floor
New York, New York 10007-1866

and

Karen Maples
Regional Hearing Clerk
U.S. Environmental Protection Agency- Region 2
290 Broadway, 16th Floor
New York, New York 10007-1866

Payment must be received on or before forty-five (45) calendar days after the date of signature of the Final Order, which is located at the end of this CA/FO. The date by which payment must be received shall hereinafter be referred to as the "Due Date."

- a. Failure to pay the civil penalty in full according to the above provisions may result in referral of this matter to the United States Department of Justice or the United States Department of the Treasury for collection.
- b. Further, if the payment is not received on or before the Due Date, interest will be assessed at the annual rate established by the Secretary of the Treasury pursuant to the Debt Collection Act, 31 U.S.C. § 3717, on the overdue amount from the due date through the date of payment. In addition, a late payment handling charge of fifteen dollars (\$15.00) will be assessed for each thirty (30) day period (or any portion thereof) following the due date in which the balance remains unpaid. A six percent (6%) per annum penalty will also be applied on any principal amount not paid within ninety (90) days of the Due Date.
- c. The civil penalty constitutes a penalty within the meaning of 26 U.S.C. § 162(f). Respondent has read the Consent Agreement, understands its terms, finds it to be reasonable and consents to its terms. Respondent consents to the issuance of the

accompanying Final Order. Respondent agrees that all the terms of the settlement are set forth herein.

5. This CA/FO is being voluntarily and knowingly entered into by the parties to resolve (upon full payment of the civil penalty herein) the civil and administrative claims alleged in the Complaint in this matter. Nothing herein shall be read to preclude EPA or the United States, however, from pursuing appropriate injunctive or other equitable relief or criminal sanctions for any violations of law.
6. This CA/FO and any provision herein shall not be construed as an admission of liability in any criminal or civil action or other administrative proceeding, except in an action, suit or proceeding to enforce this CA/FO or any of its terms and conditions.
7. Respondent waives its right to request a hearing on the Complaint, this Consent Agreement, or the Final Order included herein, including any right to contest any allegations or EPA's Findings of Fact or Conclusions of Law contained within this document.
8. Respondent waives any right it may have pursuant to 40 C.F.R. § 22.8 to be present during discussions with or to be served with and to reply to any memorandum or communication addressed to the Regional Administrator, the Deputy Regional Administrator or Regional Judicial Officer where the purpose of such discussion, memorandum, or communication is to discuss a proposed settlement of this matter or to recommend that such official accept this Consent Agreement and issue the attached Final Order.
9. This CA/FO does not waive, extinguish, or otherwise affect Respondent's obligation to comply with all applicable provisions of the Act and the regulations implementing it, nor shall it be construed as the issuance of a permit or a ruling on, or determination of, any issues related to any federal, state or local law, regulation or permit.
10. Each party shall bear its own costs and fees in this matter.
11. The representative of Respondent signing this Consent Agreement certifies that he or she is duly and fully authorized to enter into and ratify this Consent Agreement and all the terms and conditions set forth in this Consent Agreement. The provisions of this Consent Agreement shall be binding upon Respondent and its officials including authorized representatives and successors or assigns.
12. Respondent consents to service upon Respondent by a copy of this CA/FO by an EPA employee other than the Regional Hearing Clerk.
13. The effective date of this CA/FO shall be the date of filing with the Regional Hearing Clerk, U.S. EPA, Region 2, New York, New York.

RESPONDENT:

Sartorius Stedim Filters, Inc. BY:



NAME: Marcos A. Lopez Acevedo

TITLE: Director Operations FT

DATE: 07/29/2013


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In the Matter of Sartorius Stedim Filters, Inc.
Docket No.: RCRA-02-2013-7102

COMPLAINANT:

United States Environmental Protection
Agency – Region 2

BY:

A handwritten signature in black ink, appearing to read "Dore LaPosta", written over a horizontal line. The signature is stylized and extends to the right of the line.

NAME:

Dore LaPosta

TITLE:

Director, Division of
Enforcement & Compliance
Assistance

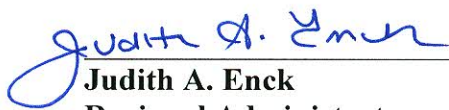
DATE:

August 15, 2013

In the Matter of Sartorius Stedim Filters, Inc.
Docket No.: RCRA-02-2013-7102

FINAL ORDER

The Regional Administrator of the U.S. Environmental Protection Agency, Region 2, ratifies the foregoing Consent Agreement. The Agreement entered into by the parties is hereby approved, incorporated herein, and issued as an Order pursuant to Section 3008 of the Act and 40 C.F.R. § 22.18(b)(3). The effective date of this Order shall be the date of filing with the Regional Hearing Clerk, U.S. EPA, Region 2, New York, New York 10007.



Judith A. Enck
Regional Administrator
EPA-Region 2

DATE: 8.15.13

CERTIFICATE OF SERVICE

I hereby certify that on the AUG 16 2013 I caused a copy of the Consent Agreement and Final Order entered in In the Matter of: Sartorius Stedim Filters, Inc., Docket No.: RCRA-02-2013-7102 to be sent to the following persons in the manner indicated:

By United States First Class Mail:

Alberto L. Ramos, Esq.
Alberto L. Ramos Law Offices
PO Box 750
Mercedita, Puerto Rico 00715-9750

Honorable Susan L. Biro
Chief Administrative Law Judge
Office of Administrative Law Judges
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Mail Code 1900R
Washington, DC 20460

By Hand Delivery:

Karen Maples
Regional Hearing Clerk
U.S. EPA – Region 2
290 Broadway, 16th Floor
New York, New York 10007

Date: AUG 16 2013


Mildred Baez