



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 2  
290 BROADWAY  
NEW YORK, NY 10007-1866

SEP 27 2011

CERTIFIED MAIL/RETURN RECEIPT

Mark A. Stevens, Esq.,  
Langsam, Stevens & Silver LLP.  
1616 Walnut Street  
Suite 1700  
Philadelphia, PA 19103-5319

U.S. ENVIRONMENTAL  
PROTECTION AGENCY-REG.11  
2011 SEP 27 A 11:50  
REGIONAL HEARING  
CLERK

Re: Roche Molecular Systems Inc.  
Docket No. RCRA-02-2011-7106

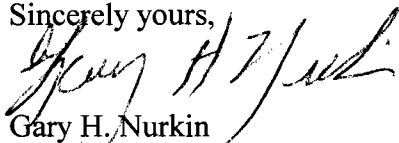
Dear Mr. Stevens:

Enclosed is a copy of the Consent Agreement and Final Order (“CA/FO”) in the above referenced proceeding signed by the Regional Administrator of the U.S. Environmental Protection Agency.

Please note that payment is due within forty-five (45) days of signature of the Final Order by the Regional Administrator. Please arrange for payment of this penalty according to the instructions given in that Order.

If you have any questions, please contact me at 212-637-3195.

Sincerely yours,

  
Gary H. Nurkin  
Assistant Regional Counsel

cc: Michael Hastry, NJDEP

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Region 2

U.S. ENVIRONMENTAL  
PROTECTION AGENCY-REG. II  
2011 SEP 27 A 11: 50  
REGIONAL HEARING  
CLERK

In The Matter of:

**Roche Molecular Systems, Inc.**

Respondent.

Proceeding under Section 3008 of the Solid  
Waste Disposal Act, as amended.

CONSENT AGREEMENT  
AND  
FINAL ORDER

Docket Number: RCRA-02-2011-7106

**PRELIMINARY STATEMENT**

This is a civil administrative proceeding 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 U.S.C. §§ 6901, *et seq.* (referred to collectively as “RCRA” or the “Act”).

Section 3008 of RCRA, 42 U.S.C. § 6928, authorizes the Administrator to enforce violations of the Act and the regulations promulgated or authorized pursuant to it. Complainant in these proceedings, the Director of the Division of Enforcement and Compliance Assistance (“DECA”), the United States Environmental Protection Agency (“EPA”) Region 2, issued a “Complaint and Notice of Opportunity for Hearing” on June 30, 2011 to Respondent Roche Molecular Systems Inc., (“Roche”), which owns and operates a facility at 1080 U.S. Route 202 South, Branchburg, NJ 08876-3733 (“Branchburg facility”). The Complaint alleges that Respondent violated requirements of RCRA and regulations concerning the management of organic hazardous waste at its Branchburg facility. EPA and Respondent agree that none of the allegations assert that actual harm to human health or the environment ever occurred.

EPA and Respondent have subsequently engaged in settlement discussions with respect to the violations alleged in the aforementioned Complaint. Respondent, in these discussions, has denied the allegations and objected to the method used by EPA to calculate its proposed penalty. Nevertheless, both EPA and Respondent have agreed that entering into this Consent Agreement/Final Order (“CA/FO”) is an appropriate means of resolving the alleged noncompliance with RCRA requirements that EPA believes existed at the Branchburg facility without further litigation or other administrative action.

This CA/FO is being issued pursuant to, and under the authority of, 40 C.F.R. § 22.18(b). No adjudicated findings of fact or conclusions of law have been made. Respondent neither admits nor denies EPA's Findings of Fact and Conclusions of Law set forth below.

### **FINDINGS OF FACT AND CONCLUSIONS OF LAW**

1. The Respondent is Roche.
2. Respondent is a corporation.
3. Respondent is a "person" as that term is defined in ' 1004(15) of the Act, 42 U.S.C. ' 6903(15) and 40 C.F.R. ' 260.10(1993) (N.J.A.C. 7:26G-4.1(a)).
4. At all times relevant hereto, Respondent has owned and operated a facility located at 1080 U.S. Route 202 South, Branchburg, NJ 08876-3733.
5. Respondent produces Polymerase Chain Reaction ("PCR") kits for the research, diagnostic and blood screening markets.
6. Organic hazardous waste (primarily spent solvent from the Respondent's High Performance Liquid Chromatography ("HPLC") and DNA synthesizers) is generated during the manufacture of PCR kits. This organic hazardous waste is transported to a solvent waste surge tank. When the level in the surge tank reaches about 30%, the HPLC/synthesizer hazardous waste is automatically pumped to a larger solvent waste storage tank where it is stored before being transported off-site for disposal as hazardous waste.
7. Respondent has been and remains the "owner" and has been and remains the "operator" of the Branchburg facility as those terms are defined in 40 C.F.R. § 260.10 (1993) (N.J.A.C. 7:26G-4.1(a)).
8. The waste generated at the Branchburg facility and stored in the tank system described above is classified as hazardous waste as defined within 40 C.F.R. 261 Subpart C (1993)(N.J.A.C. 7:26G-5.1(a)).
9. The organic hazardous waste, stored in both storage tanks, has a volatile organic concentration of more than 500 parts per million ("ppm").
10. Respondent has been a "generator" of "hazardous waste," as those terms are defined in 40 C.F.R.' 260.10(1993)(N.J.A.C. 7:26G-4.1(a)), at its Branchburg facility.
11. For at least three years prior to EPA's March 2010 inspection, Respondent generated, and continues to generate, at least 1,000 kilograms ("kg") of hazardous waste per calendar month at its Branchburg facility.

12. On or about March 3, 2010, duly designated representatives of EPA, pursuant to Section 3007 of the Act, 42 U.S.C. § 6927, conducted a Compliance Evaluation Inspection (“March Inspection”) of the Branchburg facility.
13. On or about March 15, 2010, Respondent submitted to EPA Requested Information from the March 3, 2010 Inspection.
14. On or about July 26, 2010, EPA issued to Respondent a combined Notice of Violation (“NOV”) and Request for Information (“IRL”).
15. The NOV, which was issued pursuant to Section 3008 of the Act, 42 U.S.C. ' 6928, informed Respondent that EPA had identified a number of potential violations of both the air emission requirements for equipment leaks found at 40 C.F.R. Part 265 Subpart BB(1993)(N.J.A.C. 7:26G-9.1(a)) and the air emission standards for tanks, surface impoundments and containers found at 40 C.F.R. Part 265 Subpart CC(1998)(N.J.A.C. 7:26G-9.1(a)) and requested Respondent to provide a description and documentation of the actions Respondent had taken to correct the violations identified by EPA in that NOV.
16. The IRL, which was issued pursuant to Section 3007 of RCRA, 42 U.S.C. ' 6927, sought, in part, information and documentation relating to the air emission activities regulated under 40 C.F.R. Part 265 Subpart BB (1993)(N.J.A.C. 7:26G-9.1(a)) and 40 C.F.R. Part 265 Subpart CC (1998)(N.J.A.C. 7:26G-9.1(a)) and required submittal of certain documentation relating to those air emission activities at the Branchburg facility including, but not limited to: equipment subject to the air emission requirements; monitoring of valves and pumps; listing of equipment that was in contact with organic hazardous waste; the maximum organic vapor pressure determination for hazardous waste stored in tanks at the Branchburg facility; and other documentation relating to air emissions that would assist EPA in evaluating Respondent’s compliance with RCRA at its Branchburg facility.
17. On or about October 27, 2010, Respondent submitted its response to the combined NOV and IRL (“October Response”).
18. Based upon the Inspection and Respondent’s responses to the joint NOV/IRL, EPA issued a Complaint to Respondent on June 30, 2011, alleging that Respondent failed to: (1) conduct required monitoring of the pumps used to transport organic waste, (2) conduct required monitoring of valves in light liquid service, (3) conduct annual inspections of the fixed roof and the closure devices associated with the solvent waste surge tank and the larger solvent waste storage tank, and (4) determine the maximum organic vapor pressure for the organic hazardous waste stored in both tanks.
19. Respondent has informed EPA that: (a) by February 2010, it had been monitoring its pumps and valves in accordance with 40 C.F.R. Part 265 Subpart BB(1993) (N.J.A.C. 7:26G-9.1(a)), and (b) in 2010 it began conducting annual inspections of the fixed roof

and the closure devices associated with the solvent waste surge tank and the larger solvent waste storage tank in accordance with Subpart CC(1998)(N.J.A.C. 7:26G-9.1(a)).

20. Respondent has also informed EPA that in the future it intends to be a “generator” of hazardous waste and will not store hazardous waste at the Branchburg facility except for short term accumulation of hazardous waste in accordance with rules for such accumulation by generators.

### **CONSENT AGREEMENT**

Based upon the foregoing, and pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928, and 40 C.F.R. § 22.18 of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation or Suspension of Permits, 40 C.F.R. Part 22, it is hereby agreed by and between Complainant and Respondent and voluntarily and knowingly accepted by Respondent, that Respondent for purposes of this Consent Agreement: (a) admits that EPA has jurisdiction over this matter as stated in the Preliminary Statement of the CA/FO; (b) neither admits nor denies the Findings of Fact and Conclusions of Law stated above; (c) consents to the assessment of the civil penalty as set forth below; (d) consents to the issuance of the Final Order incorporating this Consent Agreement; and (e) waives its right to contest or appeal that Final Order.

It is further hereby agreed by and between Complainant and Respondent, and voluntarily and knowingly accepted by Respondent, that Respondent shall comply with the following terms and conditions:

1. Commencing on the Effective Date of the Final Order, as defined in Paragraph 12 below Respondent, to the extent it has not already done so, shall immediately correct the violations alleged in the Complaint issued in this matter and briefly summarized in Paragraph “18”, *supra*, of the Findings of Fact and Conclusions of Law. Respondent shall hereinafter maintain compliance at its Branchburg facility with all applicable organic air emission requirements set forth at 40 C.F.R. Section 265 Subparts BB(1993)(N.J.A.C. 7:26G-9.1(a)) and CC(1998)(N.J.A.C. 7:26G-9.1(a)), and 40 C.F.R. §265.31(1993)(N.J.A.C. 7:26G-9.1(a)) or in later versions of those regulations.
2. Respondent hereby certifies, at the time of its signature to this document, that, to the best of its knowledge and belief, it is in compliance with all of the applicable hazardous waste regulatory requirements with respect to management of hazardous waste (including organic hazardous waste) at its Branchburg facility.
3. This CA/FO is not intended, and shall not be construed, to waive, extinguish or otherwise affect Respondent’s obligation to comply with all applicable federal, state and local laws and regulations governing the generation, handling, treatment, storage, transport and disposal of hazardous waste.

4. Nothing in this document is intended nor shall be construed, to waive, prejudice or otherwise affect the right of EPA, or the United States, from pursuing any appropriate remedy, sanction or penalty prescribed by law against Respondent for having made any material misrepresentations or for Respondent having provided materially false information in any document submitted to EPA.
5. Respondent shall pay a civil penalty to EPA in the total amount of **NINETY THOUSAND DOLLARS (\$90,000)**. Such payment shall be made by cashier's or certified check or by Electronic Fund Transfer (EFT). If the payment is made by check, then the check 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

The check shall be identified with a notation thereon listing the following: *IN THE MATTER OF ROCHE MOLECULAR SYSTEMS, INC.* and shall bear thereon the Docket Number *RCRA-02-2011-7106*. Payment of the penalty must be *received* at the above address on or before forty-five (45) calendar days after the Effective Date of this CA/FO (the "Due Date").

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 "D 68010727 Environmental Protection Agency."
- 6) Name of Respondent: Roche Molecular Systems Inc.
- 7) Case Number: RCRA-02-2011-7106.

Such EFT must be received on or before forty-five (45) calendar days after the Effective Date of this CA/FO.

Whether the payment is made by check or by EFT, Respondent shall promptly thereafter furnish reasonable proof that such payment has been made, to both:

Gary H. Nurkin, Esq.  
Assistant Regional Counsel  
Environmental Protection Agency, Region 2  
290 Broadway, Room 1623  
New York, New York 10007-1866

and

Karen Maples, Regional Hearing Clerk  
Environmental Protection Agency, Region 2  
290 Broadway, 16<sup>th</sup> floor  
New York, New York 10007-1866

- a. Failure to pay the amount in full within the time period set forth above 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. Furthermore, if payment is not made on or before the date specified in this document, interest for said payment shall be assessed at the annual rate established by the Secretary of the Treasury pursuant to 31 U.S.C. § 3717, on the overdue amount from the date said payment was to have been made through the date said payment has been received. In addition, a late payment handling charge of \$15.00 will be assessed for each thirty (30) calendar day period or any portion thereof, following the date the payment was to have been made, in which payment of the amount remains in arrears. In addition, a 6% per annum penalty will be applied to any principal amount that has not been received by the EPA within ninety (90) calendar days of the date for which the payment was required hereto to have been made.
  - c. The civil penalties provided for herein are penalties within the meaning of Title 26, Section 162(f) of the United States Code, 26 U.S.C. § 162(f), and are not deductible expenditures for purposes of federal or state taxes.
6. This Consent Agreement is being voluntarily entered into by the parties in full and final settlement of all civil liabilities that attach or might have attached under the Act to Respondent as a result of the violations alleged in the Complaint bearing Docket Number RCRA-02-2011-7106. 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 violation of law.
  7. The provisions of this Consent Agreement shall be binding upon both Complainant and Respondent along with their authorized representatives and successors or assigns.

8. Respondent waives its right to request or to seek any Hearing on the terms and conditions set forth in the Consent Agreement and its accompanying Final Order and/or the Findings of Fact/Conclusions of Law, above.
9. Respondent waives any rights 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 the 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.
10. The undersigned signatory for Respondent certifies that he/she is duly and fully authorized to enter into this Consent Agreement and all the terms and conditions set forth in this Consent Agreement.
11. Respondent consents to the service of this Consent Agreement and Final Order by an EPA employee other than the Regional Hearing Clerk.
12. The Effective Date of this Consent Agreement and Final Order shall be the date that it is filed with the Regional Hearing Clerk, U.S. EPA Region 2, New York, New York. Complainant's counsel will endeavour to provide notice to Respondent's counsel of the filing of the Consent Agreement and Final Order with the Regional Hearing Clerk on or close to the date of such filing.
13. Each party hereto agrees to bear its own costs and fees in this matter.

RESPONDENT: **ROCHE MOLECULAR SYSTEMS INC.**

BY:                     *CDa*                      
 Authorized Signature  
 NAME:                     CHAD DAUE                      
                     (PLEASE PRINT)  
 TITLE:                     *V.P. of Global Operations*                      
 DATE:                     *9/19/2011*                    

Apprv'd As To Form  
 LAW DEPT.  
 By                     *PSA*



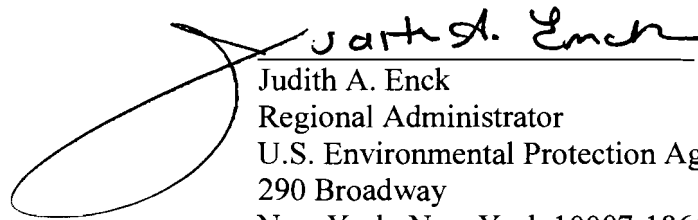
U.S. Environmental Protection Agency - Region 2  
290 Broadway  
New York, NY 10007  
DATE: 9/21/2011

**In the Matter of Roche Molecular Systems, Inc.**  
**Docket No. RCRA-02-2011-7106**

**FINAL ORDER**

The Regional Administrator of EPA, Region 2 concurs in the foregoing Consent Agreement in the case of In the Matter of Roche Molecular Systems, Inc., bearing Docket No. RCRA-02-2011-7106. Said Consent Agreement, having been duly accepted and entered into by the parties, is hereby ratified, incorporated into and issued as this Final Order, which shall become effective when filed with the Regional Hearing Clerk of EPA, Region 2. 40 C.F.R. § 22.31(b). This Final Order is being entered pursuant to the authority of 40 C.F.R. § 22.18(b)(3) and shall constitute an order issued under authority of Section 3008(a) of RCRA, 42 U.S.C. § 6928(a).

DATED: 9/22/11  
New York, New York

  
\_\_\_\_\_  
Judith A. Enck  
Regional Administrator  
U.S. Environmental Protection Agency-Region 2  
290 Broadway  
New York, New York 10007-1866

**In the Matter of Roche Molecular Systems, Inc.**  
**Docket No. RCRA-02-2011-7106**

**CERTIFICATE OF SERVICE**

I certify that I have this day caused to be sent the foregoing fully executed CONSENT AGREEMENT and FINAL ORDER, bearing the above-referenced docket number, in the following manner to the respective addressees below:

Original and One Copy  
By Hand:

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

Copy by Certified Mail,  
Return Receipt Requested:

Mark A. Stevens, Esq.  
Langsam, Stevens & Silver LLP  
1616 Walnut Street Suite 1700  
Philadelphia, PA 19103-5319  
Attorneys for Respondent, Roche  
Molecular Systems, Inc.

*Mildred N. Bag*

Dated: SEP 27 2011,  
New York, New York