



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

JUN 30 2011

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Article # 7005 3110 0000 5926 4652 &  
Article # 7005 3110 0000 5926 4669

Daniel O'Day, President  
Roche Molecular Systems Inc.  
4300 Hacienda Dr.  
Pleasanton, CA 94588

Robert Towney, Branch Manager  
Roche Molecular Systems, Inc.  
1080 U.S. Route 202 South  
Branchburg, NJ 08876-3733

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

Dear Messrs. O'Day and Towney:

Enclosed is the Complaint, Compliance Order and Opportunity for Hearing in the above-referenced proceeding. The Complaint alleges violations of the Solid Waste Disposal Act, as amended, 42 U.S.C. §§ 6901 *et seq.*

You have the right to a formal hearing to contest any of the allegations in the Complaint and/or to contest the penalty proposed in the Complaint. If you wish to contest the allegations and/or the penalty proposed in the Complaint, you must file an Answer within **thirty (30)** days of your receipt of the enclosed Complaint with the Regional Hearing Clerk of the Environmental Protection Agency ("EPA"), Region 2, at the following address:

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

U.S. ENVIRONMENTAL  
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2011 JUL -5 A 11:40  
REGIONAL HEARING  
CLERK

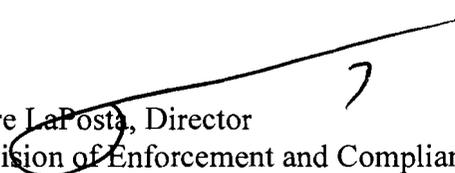
If you do not file an Answer within thirty (30) days of receipt of this Complaint and have not obtained a formal extension for filing an Answer from the Regional Judicial Officer of Region 2, a default order may be entered against you and the entire proposed penalty may be assessed. Whether or not you request a formal hearing, you may request an informal conference with EPA to discuss any issue relating to the alleged violations and the amount of the proposed penalty. EPA encourages all parties against whom it files a Complaint to pursue the possibility of settlement and to have an informal conference with EPA. However, a request for an informal conference **does not** substitute for a written Answer, affect what you may choose to say in an Answer, or extend the thirty (30) days by which you must file an Answer requesting a hearing.

You will find enclosed a copy of the "Consolidated Rules of Practice," which govern this proceeding. (A brief discussion of some of these rules appears in the later part of the Complaint.) For your general information and use, I also enclose both an "Information Sheet for U.S. EPA Small Business Resources" and a "Notice of SEC Registrants' Duty to Disclose Environmental Legal Proceedings" which may apply to you depending on the size of the proposed penalty and the nature of your company.

EPA encourages the use of Supplemental Environmental Projects, where appropriate, as part of any settlement. I am enclosing a brochure on "EPA's Supplemental Environmental Projects Policy." Please note that these are only available as part of a negotiated settlement and are not available if this case has to be resolved by a formal adjudication.

If you have any questions or wish to schedule an informal conference, please contact the attorney whose name is listed in the Complaint.

Sincerely yours,

 7  
Dore LaPosta, Director  
Division of Enforcement and Compliance Assistance

Enclosures

cc: Karen Maples, Regional Hearing Clerk (without enclosures)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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290 BROADWAY  
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Daniel O'Day, President  
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4300 Hacienda Dr.  
Pleasanton, CA 94588

Robert Towney, Branch Manager  
Roche Molecular Systems, Inc.  
1080 U.S. Route 202 South  
Branchburg, NJ 08876-3733

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

Dear Messrs. O'Day and Towney:

Enclosed is the Complaint, Compliance Order and Opportunity for Hearing in the above-referenced proceeding. The Complaint alleges violations of the Solid Waste Disposal Act, as amended, 42 U.S.C. §§ 6901 *et seq.*

You have the right to a formal hearing to contest any of the allegations in the Complaint and/or to contest the penalty proposed in the Complaint. If you wish to contest the allegations and/or the penalty proposed in the Complaint, you must file an Answer within **thirty (30)** days of your receipt of the enclosed Complaint with the Regional Hearing Clerk of the Environmental Protection Agency ("EPA"), Region 2, at the following address:

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

U.S. ENVIRONMENTAL  
PROTECTION AGENCY  
2011 JUL -5 A 11:41  
REGIONAL HEARING  
CLERK

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If you have any questions or wish to schedule an informal conference, please contact the attorney whose name is listed in the Complaint.

Sincerely yours,

  
Dore LaPosta, Director  
Division of Enforcement and Compliance Assistance

Enclosures

cc: Karen Maples, Regional Hearing Clerk (without enclosures)

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**Region 2**

In The Matter of:

Roche Molecular Systems, Inc.

Respondent,

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

**COMPLAINT, COMPLIANCE ORDER**  
**AND NOTICE OF OPPORTUNITY**  
**FOR HEARING**

Docket No. RCRA-02-2011-7106

U.S. ENVIRONMENTAL  
PROTECTION AGENCY  
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REGIONAL HEARING  
CENTER

**I. COMPLAINT**

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 ("HSWA"), 42 U.S.C. §§ 6901 et seq. (referred to collectively as the "Act" or "RCRA"). The United States Environmental Protection Agency ("EPA") has promulgated regulations governing the handling and management of hazardous waste at 40 C.F.R. Parts 260 - 273 and 279.

This COMPLAINT, COMPLIANCE ORDER AND NOTICE OF OPPORTUNITY FOR HEARING ("Complaint") serves notice of the United States Environmental Protection Agency's ("EPA") preliminary determination that Roche Molecular Systems, Inc. ("Roche" or "Respondent") has violated provisions of RCRA and the federally authorized New Jersey regulations concerning the management of hazardous waste at its Branchburg, New Jersey facility.

Pursuant to Section 3006(b) of the Act, 42 U.S.C. § 6926(b), the State of New Jersey was authorized by EPA to conduct a hazardous waste program (the "authorized State Program"). 64 Fed. Reg. 41823 (August 2, 1999). There were later changes in the scope of the authorized State Program as a result of EPA's authorization of New Jersey's regulations incorporating by reference changes to the federal program promulgated by EPA between July 2, 1993 and July 31, 1998. 67 Fed. Reg. 76995 (December 16, 2002). These changes became effective February 14, 2003. Prior to February 14, 2003, the authorized State Program incorporated by reference, with some minor modifications, the federal program at 40 Code of Federal Regulations (C.F.R.) Parts 124, 260-266, 268 and 270, as set forth in the 1993 edition. As of February 14, 2003, the authorized State Program, with some minor modifications, essentially incorporates by reference the regulations in the 1998 edition of the same Parts of Title 40 of the C.F.R. New Jersey's authorized regulations comprising the original State Program, authorized in 1999, can be found in the New Jersey Register. See 28 N.J.R. 4606 (October 21, 1996). The regulations authorized

in 2002 can be found at 31 N.J.R. 166 (January 19, 1999). New Jersey is not authorized for any HSWA regulations adopted by EPA after July 31, 1998. EPA is authorized to enforce the provisions of the authorized State program and retains primary responsibility for requirements promulgated pursuant to HSWA since July 31, 1998.

The Complainant in this proceeding, the Director of the Division of Enforcement and Compliance Assistance, EPA- Region 2, has been duly delegated the authority to institute this action. Complainant hereby alleges:

**Jurisdiction**

1. This Tribunal has jurisdiction over the subject matter of this action pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), and 40 C.F.R. § 22.1(a)(4).
2. In accordance with Section 3008(a)(2) of RCRA, 42 U.S.C. § 6928(a)(2), EPA has given the State of New Jersey prior notice of this action.

**Respondent's Background**

3. The Respondent is Roche Molecular Systems, Inc.
4. Respondent is a registered Delaware corporation whose principal office is located at 4300 Hacienda Drive, Pleasanton, CA 94588.
5. Respondent is a wholly owned subsidiary of Roche Holdings Inc (“Roche Holdings”), situated at 340 Kingsland St., Nutley, New Jersey.
6. Roche Holdings is a registered Delaware corporation.
7. Respondent owns and operates a manufacturing facility situated at 1080 U.S. Route 202 South, Branchburg, NJ 08876-3733.
8. Respondent produces Polymerase Chain Reaction (“PCR”) kits for the research, diagnostic and blood screening markets.
9. 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 250 gallon solvent waste surge tank in a subterranean vault by a direct-piping system. When the level in the 250 gallon solvent waste surge tank reaches about 30% (~75 gallons), the HPLC/synthesizer hazardous waste is automatically pumped to a 3,000 gallon above-ground solvent waste storage tank where it is stored before being transported off-site for disposal.

10. 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)).
11. The Branchburg operation is a “facility” as that term is defined in 40 C.F.R. § 260.10(1993)(N.J.A.C. 7:26G-4.1(a)).
12. Respondent is the “owner” and “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)).
13. Respondent was not in existence prior to November 19, 1980.
14. Respondent is a “new hazardous waste management facility” or “new facility” as that phrase is defined in 40 C.F.R. § 260.10(1993)(N.J.A.C. 7:26G-4.1(c)(4)(i)).

#### **Notification of Hazardous Waste Generation**

15. On or about April 13, 1992, Roche Diagnostics, Roche’s corporate predecessor, submitted a Notification of Regulated Waste Activity to EPA which stated it was a large quantity generator of hazardous waste.
16. In response to the Notification described in paragraph “15”, above, EPA provided Roche Diagnostics with the EPA Identification Number NJD986630630.
17. On or about March 13, 2002, Roche Diagnostics submitted a second Notification of Regulated Waste Activity to EPA informing EPA that Roche Diagnostics had changed its name and was now being referred to as Roche.

#### **Respondent’s Generation of Hazardous Waste**

18. The Branchburg facility produces PCR kits for the research, diagnostic and blood screening markets.
19. The hazardous wastes generated at the Branchburg facility in the manufacture of PCR kits have included, without limitation, characteristic wastes (“D wastes”), wastes from nonspecific sources (“F wastes”), and discarded commercial chemical products including manufacturing chemical intermediates (“U wastes” and “P wastes”) as defined within 40 C.F.R. § 261 Subpart C (1993)(N.J.A.C. 7:26G-5.1(a)).
20. The organic hazardous waste generated during the manufacture of PCR kits (“F waste” and “D waste”) is stored in a subterranean 250 gallon solvent waste surge tank and a 3,000 gallon above-ground solvent waste storage tank before being transported off-site for hazardous waste disposal.

21. The organic hazardous waste, stored in both the subterranean 250 gallon solvent waste surge tank and the 3,000 gallon above-ground solvent waste storage tank, has a volatile organic concentration of more than 500 parts per million (“ppm”).
22. The organic hazardous waste, entering and exiting these tanks that came in contact with equipment subject to subpart BB, had an organic concentration of more than 10% by weight.
23. At all times mentioned below in this Complaint and subsequent thereto, Respondent has been, at its Branchburg facility, 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)).
24. At least for 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.
25. As of March 2010, and for at least three years prior to February 2010, Respondent had been storing organic hazardous waste, for up to 90 days, in its subterranean 250 gallon solvent waste surge tank and 3,000 gallon above-ground solvent waste storage tank before that hazardous waste was transported off-site, accompanied by a Uniform Hazardous Waste Manifest, for treatment storage and disposal.
26. Pursuant to 40 C.F.R. § 262.34(a)(1)(ii) and 40 C.F.R. § 265.202, to be exempt from the permitting requirements, a generator (as that term is defined in 40 C.F.R. § 260.10(1993)(N.J.A.C. 7:26G-4.1(a))) of at least 1,000 kgs of hazardous waste [as that term is defined in 40 C.F.R. § 260.10(1993)(N.J.A.C. 7:26G-4.1(a))] per calendar month must, *inter alia*, manage all hazardous waste placed in tanks in accordance with the applicable requirements of 40 C.F.R. Part 265 Subpart J(1993)(N.J.A.C.7:26G-9.1(a)), and 40 C.F.R. §§ 265.1030 - 265.1090(1993 and 1998)(N.J.A.C. 7:26G-9.1(a)).

#### **New Jersey Department of Environmental Protection (“DEP”) Activities**

27. On or about January 13 and 14, 2010, a duly designated representative of the DEP conducted a compliance evaluation (“January 2010 Inspection”) of Respondent’s facility to determine its compliance with the Solid Waste Management Act (N.J.S.A. 13:E-1 *et. seq.*) and the regulations promulgated pursuant thereto (N.J.A.C. 7:26G-1 *et. seq.*)
28. At the time of the January 2010 Inspection, Respondent had not monitored any of its equipment pursuant to the monitoring requirements of 40 C.F.R. Part 265 Subpart BB (1993)(N.J.A.C. 7:26G-9.1(a)).

29. At the time of the January 2010 Inspection, the Respondent had not identified each piece of equipment subject to 40 C.F.R. Part 265 Subpart BB requirements in its operating log pursuant to 40 C.F.R. § 265.1064(g)(1998)(N.J.A.C. 7:26G-9.1(a)).

### **EPA Investigative Activities**

30. On or about March 3, 2010, duly designated representatives of EPA conducted a Focused Compliance Inspection (“March 2010 Inspection”) of Respondent’s facility pursuant to Section 3007 of the Act, 42 U.S.C. § 6927.
31. At the time of the March 2010 Inspection, there were approximately forty valves and two pumps associated with the tank system.
32. At the time of the March 2010 Inspection, the Respondent had not identified each piece of equipment subject to 40 C.F.R. Part 265 Subpart BB requirements in its operating log pursuant to 40 C.F.R. § 265.1064(g)(1998)(N.J.A.C. 7:26G-9.1(a)).
33. At the time of the March 2010 Inspection, Respondent had just begun monitoring its pumps and valves pursuant to the monitoring requirements of 40 C.F.R. Part 265 Subpart BB (1993)(N.J.A.C. 7:26G-9.1(a)).
34. At the time of the March 2010 Inspection, the Respondent had not conducted annual inspections of its subterranean 250 gallon solvent waste surge tank and its 3,000 gallon above-ground solvent waste storage tank storing organic hazardous waste with a volatile organic concentration at or above 500 ppm.

### **NOV/ Information Request and Response**

35. On or about July 26, 2010, EPA issued to Respondent a combined Notice of Violation (“NOV”) and Request for Information (“IRL”). The NOV, which was issued pursuant to Section 3008 of the Act, 42 U.S.C. § 6928, informed the Respondent that prior to February 2010, 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 Roche had taken to correct the violations identified by EPA in that NOV.
36. 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 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 storage stored in tanks at the facility; and other documentation relating to air emissions that would assist the EPA in evaluating Respondent's compliance with RCRA at its Branchburg facility.

37. On or about October 27, 2010, the Respondent submitted its response to the combined NOV and IRL ("October 2010 Response").
38. In its October 2010 Response, Respondent identified each pump and valve that contains or contacts hazardous waste with an organic concentration of at least 10% by weight.
39. In its October 2010 Response, Respondent identified the two pumps and five valves subject to Subpart BB requirements that were used for less than 300 hours per calendar year.
40. In its October 2010 Response, Respondent stated "there were 36 valves that were not exempt from Subpart BB."
41. In its October 2010 Response, Respondent stated "the [Leak Detection and Repair ("LDAR")] monitoring [of the valves] in accordance with Method 21 standards was not initiated until February 2010. One round of monthly monitoring was completed prior to the EPA inspection in March 2010."
42. In its October 2010 Response, Respondent stated that it does not have any pumps that are subject to Subpart BB because "each pump comes in contact with solvent less than 300 hours per year."
43. In its October 2010 Response, Respondent provided copies of tank inspection forms that were first utilized in October 2010 for the subterranean 250 gallon solvent waste surge tank and the 3,000 gallon above-ground solvent waste storage tank that included observations for closure devices such as conservation vents, pressure vents, and valves.

**Applicability of the Air Emission Standards for Equipment Leaks (Subpart BB)**

44. Pursuant to 40 C.F.R. § 264.1050(f)(1998)(N.J.A.C. 7:26G-9.1(a)), equipment that contains or contacts hazardous waste with an organic concentration of at least 10% by weight for less than 300 hours per calendar year is excluded from the requirements of 40 C.F.R. § 264.1052(1998) (N.J.A.C. 7:26G-9.1(a)) through 40 C.F.R. § 264.1060(1998)(N.J.A.C. 7:26G-9.1(a)) of this subpart (i.e. Subpart BB) if it is identified as required in 40 C.F.R. § 264.1064(g)(6)(1998)(N.J.A.C. 7:26G-9.1(a)).
45. Prior to February 2010, Respondent had not identified and documented in an operating log at its facility areas or groups of equipment that contained or contacted hazardous waste with an organic concentration of at least 10 percent by weight for less than 300 hours per calendar year.
46. As a result of Respondent's use of equipment that contains or contacts hazardous waste with an organic concentration of at least 10% by weight and/or the failures and facts alleged in paragraphs "28" – "29", "32", and "45", above; Respondent in February 2010 was not eligible for an exemption to the Subpart BB requirements for the air emission standards for equipment leaks for any of the pumps and valves noted in paragraph "31" above.
47. Respondent, prior to February 2010, was not eligible for an exemption from the Subpart BB requirements for the air emission standards for equipment leaks for the approximately 40 valves and two pumps noted in paragraph "31", above.

**Count 1 - Failure to Conduct Required Monitoring of Pumps  
Subject to Subpart BB**

48. Complainant re-alleges each allegation contained in paragraphs "1" through "47," inclusive, as if fully set forth herein.
49. Pursuant to 40 C.F.R. § 264.1052(a)(1)(1993)(N.J.A.C. 7:26G-9.1(a)), each pump in light liquid service shall be monitored monthly to detect leaks by methods specified in 40 C.F.R. § 264.1063(b)(1993)(N.J.A.C. 7:26G-9.1(a)).
50. Pursuant to 40 C.F.R. § 264.1063(b)(1)(1993)(1)(N.J.A.C. 7:26G-9.1(a)), monitoring shall comply with Reference Method 21.
51. From at least February 2007 until February 2010, Respondent was required to conduct monthly monitoring of each pump in light liquid service at its Branchburg facility using Reference Method 21.

52. During the March 2010 Inspection, Respondent admitted that the monitoring of pumps did not begin until February 2010.
53. At and for at least three years prior to February 2010, facility personnel had not been monitoring on a monthly basis at its Branchburg facility the two pumps (in light liquid service using Reference Method 21.
54. Respondent's failure to monitor the two pumps in light liquid service at its Branchburg facility on a monthly basis using Reference Method 21 prior to February 2010 is a violation of 40 C.F.R. § 264.1052 (a)(1)(1993)(N.J.A.C. 7:26G-9.1(a).

**Count 2 - Failure to Conduct Required Monitoring of  
Valves Subject to Subpart BB**

55. Complainant re-alleges each allegation contained in paragraphs "1" through "47," inclusive, as if fully set forth herein.
56. Pursuant to 40 C.F.R. §264.1057(a)(1993)(N.J.A.C. 7:26G-9.1(a)), Respondent was required to perform monthly emissions monitoring of valves in light liquid service by methods specified in 40 C.F.R. § 264.1063(b)(1993)(N.J.A.C. 7:26G-9.1(a)).
57. Pursuant to 40 C.F.R. § 264.1063(b)(1)(1993)(N.J.A.C. 7:26G-9.1(a)), emissions monitoring shall comply with Reference Method 21.
58. In its October 2010 Response, Respondent stated "LDAR monitoring in accordance with Method 21 standards was not initiated until February 2010."
59. For at least three years prior to February 2010, Respondent was required to conduct monthly monitoring of each valve in light liquid service using Reference Method 21.
60. Respondent's failure to perform monthly emissions monitoring of valves in light liquid service at its Branchburg facility using Reference Method 21 prior to February 2010 is a violation of 40 C.F.R. § 264.1057(a)(1993)(N.J.A.C. 7:26G-9.1(a)).

**Count 3 - Failure to Conduct Annual Inspections of Tanks  
Subject to Subpart CC**

61. Complainant re-alleges each allegation contained in paragraphs "1" through "47," inclusive, as if fully set forth herein.
62. Respondent has been storing organic hazardous waste with a volatile organic

concentration of greater than 500 ppm in its subterranean 250 gallon solvent waste surge tank and its 3,000 gallon above-ground solvent waste storage tank since at least February 2007.

63. Pursuant to 40 C.F.R. § 264.1085(c)(4)(ii)(1998) (N.J.A.C. 7:26G-9.1(a)), the owner/operator of tanks storing organic hazardous waste with a volatile organic concentration of above 500 ppm must perform an annual inspection of the fixed roof and its closure devices to check for defects that could result in air pollutant emissions.
64. Respondent did not perform annual inspections of the fixed roof and the closure devices associated with the subterranean 250 gallon solvent waste surge tank and the 3,000 gallon above-ground solvent waste storage tank in 2007, 2008, and 2009.
65. In its October 2010 Response, Respondent provided an Annual Tank Inspection form which documents that an annual inspection of the fixed roof and closure devices associated with the subterranean 250 gallon solvent waste surge tank and the 3,000 gallon above-ground solvent waste storage tank was conducted on or about October 19, 2010.
66. The Respondent's failures to have performed annual inspections of the fixed roof and the closure devices associated with the subterranean 250 gallon solvent waste surge tank and the 3,000 gallon above ground solvent waste storage tanks are violations of 40 C.F.R. § 264.1084(c)(4)(ii)(1998)(N.J.A.C. 7:26G-9.1(a)).

**Count 4 - Failure to Determine the Maximum Organic Vapor Pressure as Required by Subpart CC**

67. Complainant re-alleges each allegation contained in paragraphs "1" through "47," inclusive, as if fully set forth herein.
68. Pursuant to 40 C.F.R. § 264.1084(c)(1)(1998)(N.J.A.C. 7:26G-9.1(a)), owners/operators of tanks shall determine the maximum organic vapor pressure of an organic hazardous waste (with a volatile organic concentration of above 500 ppm) to be managed in a tank using Tank Level 1 controls before the first time the hazardous waste is placed in the tank.
69. Prior to February 2010, the Respondent had been storing organic hazardous waste with a volatile organic concentration of greater than 500 ppm in its subterranean 250-gallon solvent waste surge tank and its 3,000 gallon above-ground solvent waste storage tank at its Branchburg facility.
70. At the March 2010 Inspection, Respondent did not have a copy of the maximum organic vapor pressure determination for both its subterranean 250 gallon solvent

waste surge tank and its 3,000 gallon above-ground solvent waste storage tank at the Branchburg facility in its operating record.

71. In its October 2010 Response, Respondent stated that its subterranean 250 gallon solvent waste surge tank and its 3,000 gallon above-ground solvent waste storage tank were subject to Level 1 emission control requirements and the maximum organic vapor pressure calculations were “provided in the Roche letter dated March 15, 2010. . . based on guidance provided by the inspectors.”
72. From at least March 15, 2007, until March 15, 2010, Respondent had failed to make a determination of the maximum organic vapor pressure of the hazardous waste stored in both its subterranean 250 gallon solvent waste surge tank and its 3,000 gallon above-ground solvent waste storage tank.
73. The Respondent’s failure to make a timely determination of the maximum organic vapor pressure for the organic hazardous waste stored in both its subterranean 250 gallon solvent waste surge tank and its 3,000 gallon above-ground solvent waste storage tank is a violation of 40 C.F.R. § 264.1084(c)(1)(1998)(N.J.A.C. 7:26G-9.1(a)).

## II. PROPOSED CIVIL PENALTY

The proposed civil penalty has been determined in accordance with Section 3008(a)(3) of the Act, 42 U.S.C. § 6928(a)(3). For purposes of determining the amount of any penalty assessed, Section 3008(a)(3) requires EPA to "take into account the seriousness of the violation and any good faith efforts to comply with applicable requirements." The Federal Civil Penalty Penalties Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, required EPA to adjust penalties for inflation on a periodic basis. The penalty amounts were amended for violations occurring on or after January 31, 1997. The maximum civil penalty under Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), for violations occurring between March 15, 2004 and January 12, 2009 is \$32,500 per day of violation. 40 C.F.R. Part 19. The maximum civil penalty under Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), for violations after January 12, 2009 is \$37,500 per day of violation. 40 C.F.R. Part 19.

To develop the proposed penalty in this complaint, the Complainant has taken into account the particular facts and circumstances of this case and used EPA's 2003 RCRA Civil Penalty Policy, a copy of which is available upon request or can be found on the Internet at the following address: <http://www.epa.gov/compliance/resources/policies/civil/rcra/rcpp2003-fnl.pdf>. The penalty amounts in the 2003 RCRA Civil Penalty Policy have been amended to reflect inflation adjustments. These adjustments were made pursuant to the following: the September 21, 2004 document entitled "Modifications to EPA Policies to Implement the civil Monetary Penalty Inflation Rule (pursuant to Debt Collection Improvement Act of 1996, effective October 1, 2004)"; the January 11, 2005 document entitled "Revised Penalty Matrices for the RCRA Civil Penalty Policy"; the December 29, 2008 document entitled "Amendments to the EPA Civil Penalty Policies to Implement the 2008 Monetary Penalty Inflation Adjustment Rule (effective January 12, 2009)"; and the November 16, 2009 document entitled "Adjustment Penalty Policy Matrices Based on the 2008 Civil Monetary Penalty Inflation Adjustment Rule" (with a further revision not relevant to this action on April 6, 2010). The RCRA Civil Penalty provides a rational, consistent, and equitable calculation methodology for applying the statutory penalty factors to particular cases.

The Complainant proposes, subject to receipt and evaluation of further relevant information from the Respondent, that the Respondent be assessed the civil penalty as set out below for the violations alleged in this Complaint. A penalty calculation worksheet and narrative explanation to support the penalty figure for each violation cited in this Complaint are included in Attachment I, below. Matrices employed in the determination of individual and multi-day penalties are included as Attachments II, below.

In view of the above-cited violations, and pursuant to the authority of Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), and the RCRA Civil Penalty Policy, including the seriousness of the violations, any good faith efforts by the Respondent to comply with applicable requirements, the Complainant herewith proposes the assessment of a civil penalty in the total amount of one hundred thirty thousand and seven hundred forty-four dollars as follows:

Counts	Citation	Violation	Penalty
One	40 C.F.R. § 264.1052(a)(1)(1993) (N.J.A.C. 7:26G-9.1(a))	Failure to Conduct Required Monitoring of Two Pumps Subject to Subpart BB	\$78,450
Two	40 C.F.R. § 264.1057(a)(1993) (N.J.A.C. 7:26G-9.1(a))	Failure to Conduct Required Monitoring of Approximately 40 Valves Subject to Subpart BB	
Three	40 C.F.R. § 264.1084(c)(4)(ii) (1998)(N.J.A.C. 7:26G-9.1(a))	Failure to Conduct Annual Inspections of Tanks Subject to Subpart CC in 2007, 2008, and 2009	\$40,994
Four	40 C.F.R. § 264.1084(c)(1)(1998) (N.J.A.C. 7:26G-9.1(a))	Failure to Determine Maximum Organic Vapor Pressure as Required by Subpart CC	\$11,300
		Total	\$130,744

### **III. COMPLIANCE ORDER**

To the extent it has not already done so, and if it wishes to be exempt from the permitting requirements pursuant to 40 C.F.R. § 262.34(a)(1)(ii) and 40 C.F.R. § 265.202, the Respondent shall immediately upon the effective date of this Order correct the violations alleged in the previous section and come into compliance and shall thereafter maintain such compliance at its Branchburg facility with all the applicable organic air emission requirements set forth at 40 C.F.R. Parts 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)) or in later versions of those regulations. If Respondent does not qualify for the exemption from the permitting requirements, it shall comply with the Part 264 regulations cited in counts 1 - 4.

This Compliance Order shall take effect with respect to the Respondent within 30 days of date of service of the Order, unless by that date the Respondent has requested a hearing pursuant to 40 C.F.R. Section 22.15. See 42 U.S.C. Section 6928(b) and 40 C.F.R. §§ 22.37(b) and 22.7(c).

Any responses, documentation, and evidence submitted in response to this Compliance Order should be sent, within thirty (30) calendar days of the effective date of this Compliance Order, to:

**Sam Kerns, Environmental Engineer  
Hazardous Waste Compliance Section  
RCRA Compliance Branch  
Division of Enforcement and Compliance Assistance  
U.S. Environmental Protection Agency - Region 2  
290 Broadway, 21<sup>st</sup> Floor  
New York, New York 10007-1866**

Compliance with the provisions of this Compliance Order does not waive, extinguish or otherwise affect Respondent's obligation to comply with all other applicable RCRA statutory or regulatory (federal and/or state) provisions, nor does such compliance release Respondent from liability for any violations at its facility. In addition, nothing herein waives, prejudices or otherwise affects EPA's right to enforce any applicable provision of law, and to seek and obtain any appropriate penalty or remedy under any such law, regarding Respondent's generation, handling and/or management of hazardous waste at its facility.

#### **IV. NOTICE OF LIABILITY FOR ADDITIONAL CIVIL PENALTIES**

Pursuant to the terms of Section 3008(c) of RCRA and the Debt Collection Improvement Act of 1996, a violator failing to take corrective action within the time specified in a compliance order once it has taken effect is liable for a civil penalty of up to \$37,500 for each day of continued noncompliance which occurs after January 12, 2009. Such continued noncompliance may also result in suspension or revocation of any permits issued to the violator whether issued by EPA or the State of New Jersey.

#### **V. PROCEDURES GOVERNING THIS ADMINISTRATIVE LITIGATION**

The rules of procedure governing this civil administrative litigation have been set forth in 64 *Fed. Reg.* 40138 (July 23, 1999), entitled, "CONSOLIDATED RULES OF PRACTICE GOVERNING THE ADMINISTRATIVE ASSESSMENTS OF CIVIL PENALTIES, ISSUANCE OF COMPLIANCE OR CORRECTIVE ACTION COMPLIANCE ORDERS, AND THE REVOCATION, TERMINATION OR SUSPENSION OF PERMITS," and which are codified at 40 C.F.R. Part 22. A copy of these rules accompanies this "Complaint, Compliance Order and Notice of Opportunity for Hearing."

##### **A. Answering The Complaint**

Where Respondent intends to contest any material fact upon which the Complaint is based, to contend that the proposed penalty and/or the Compliance Order is inappropriate or to contend that Respondent is entitled to judgment as a matter of law, Respondent must file with the Regional Hearing Clerk of EPA, Region 2, both an original and one copy of a written answer to the Complaint, and such Answer must be filed within 30 days after service of the Complaint. 40 C.F.R. §§ 22.15(a) and 22.7(c). The address of the Regional Hearing Clerk of EPA, Region 2, is:

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

Respondent shall also then serve one copy of the Answer to the Complaint upon Complainant and any other party to the action. 40 C.F.R. § 22.15(a).

Respondent's Answer to the Complaint must clearly and directly admit, deny, or explain each of the factual allegations that are contained in the Complaint and with regard to which Respondent has any knowledge. 40 C.F.R. § 22.15(b). Where Respondent lacks knowledge of a particular factual allegation and so states in its Answer, the allegation is deemed denied. 40 C.F.R. § 22.15(b).

The Answer shall also set forth: (1) the circumstances or arguments that are alleged to constitute the grounds of defense, (2) the facts that Respondent disputes (and thus intends to

place at issue in the proceeding) and (3) whether Respondent requests a hearing. 40 C.F.R. § 22.15(b).

Respondent's failure affirmatively to raise in the Answer facts that constitute or that might constitute the grounds of their defense may preclude Respondent, at a subsequent stage in this proceeding, from raising such facts and/or from having such facts admitted into evidence at a hearing.

## **B. Opportunity To Request A Hearing**

If requested by Respondent, a hearing upon the issues raised by the Complaint and Answer may be held. 40 C.F.R. § 22.15(c). If, however, Respondent does not request a hearing, the Presiding Officer (as defined in 40 C.F.R. § 22.3) may hold a hearing if the Answer raises issues appropriate for adjudication. 40 C.F.R. § 22.15(c). With regard to the Compliance Order in the Complaint, unless Respondent requests a hearing pursuant to 40 C.F.R. § 22.15 within thirty (30) days after the Compliance Order is served, the Compliance Order shall automatically become final. 40 C.F.R. § 22.37

Any hearing in this proceeding will be held at a location determined in accordance with 40 C.F.R. § 22.21(d). A hearing of this matter will be conducted in accordance with the provisions of the Administrative Procedure Act, 5 U.S.C. §§ 551-59, and the procedures set forth in Subpart D of 40 C.F.R. Part 22.

## **C. Failure To Answer**

If Respondent fails in its Answer to admit, deny, or explain any material factual allegation contained in the Complaint, such failure constitutes an admission of the allegation. 40 C.F.R. § 22.15(d). If Respondent fails to file a timely [*i.e.* in accordance with the 30-day period set forth in 40 C.F.R. § 22.15(a)] Answer to the Complaint, Respondent may be found in default upon motion. 40 C.F.R. § 22.17(a). Default by Respondent constitutes, for purposes of the pending proceeding only, an admission of all facts alleged in the Complaint and a waiver of Respondent's right to contest such factual allegations. 40 C.F.R. § 22.17(a). Following a default by Respondent for a failure to timely file an Answer to the Complaint, any order issued therefore shall be issued pursuant to 40 C.F.R. § 22.17(c).

Any penalty assessed in the default order shall become due and payable by Respondent without further proceedings 30 days after the default order becomes final pursuant to 40 C.F.R. § 22.27(c). 40 C.F.R. § 22.17(d). If necessary, EPA may then seek to enforce such final order of default against Respondent, and to collect the assessed penalty amount, in federal court. Any default order requiring compliance action shall be effective and enforceable against Respondent without further proceedings on the date the default order becomes final under 40 C.F.R. § 22.27(c). 40 C.F.R. § 22.17(d).

#### **D. Exhaustion Of Administrative Remedies**

Where Respondent fails to appeal an adverse initial decision to the Agency's Environmental Appeals Board ("EAB"; see 40 C.F.R. § 1.25(e)) pursuant to 40 C.F.R. § 22.30, and that initial decision thereby becomes a final order pursuant to the terms of 40 C.F.R. § 22.27(c), Respondent waives its right to judicial review. 40 C.F.R. § 22.27(d).

To appeal an initial decision to the EAB, Respondent must do so "[w]ithin thirty (30) days after the initial decision is served." 40 C.F.R. § 22.30(a). Pursuant to 40 C.F.R. § 22.7(c), where service is effected by mail, "five days shall be added to the time allowed by these rules for the filing of a responsive pleading or document." Note that the 45-day period provided for in 40 C.F.R. § 22.27(c) [discussing when an initial decision becomes a final order] does not pertain to or extend the time period prescribed in 40 C.F.R. § 22.30(a) for a party to file an appeal to the EAB of an adverse initial decision.

#### **VI. INFORMAL SETTLEMENT CONFERENCE**

Whether or not Respondent requests a formal hearing, EPA encourages settlement of this proceeding consistent with the provisions of the Act and its applicable regulations. 40 C.F.R. § 22.18(b). At an informal conference with a representative(s) of Complainant, Respondent may comment on the charges made in the Complaint, and Respondent may also provide whatever additional information that it believes is relevant to the disposition of this matter, including: (1) actions Respondent has taken to correct any or all of the violations herein alleged, (2) any information relevant to Complainant's calculation of the proposed penalty, (3) the effect the proposed penalty would have on Respondent's ability to continue in business and/or (4) any other special facts or circumstances Respondent wishes to raise.

Complainant has the authority to modify the amount of the proposed penalty, where appropriate, to reflect any settlement agreement reached with Respondent, to reflect any relevant information previously not known to Complainant, or to dismiss any or all of the charges, if Respondent can demonstrate that the relevant allegations are without merit and that no cause of action as herein alleged exists. Respondent is referred to 40 C.F.R. § 22.18.

Any request for an informal conference or any questions that Respondent may have regarding this Complaint should be directed to:

**Gary H. Nurkin, Esq.**  
**Assistant Regional Counsel**  
**Office of Regional Counsel**  
**U.S. Environmental Protection Agency, Region 2**  
**290 Broadway, Room 1623**  
**New York, New York 10007-1866**  
**212-637-3195**

The parties may engage in settlement discussions irrespective of whether Respondent has requested a hearing. 40 C.F.R. § 22.18(b)(1). Respondent's requesting a formal hearing does not prevent it from also requesting an informal settlement conference; the informal conference procedure may be pursued simultaneously with the formal adjudicatory hearing procedure. A request for an informal settlement conference constitutes neither an admission nor a denial of any of the matters alleged in the Complaint. Complainant does not deem a request for an informal settlement conference as a request for a hearing as specified in 40 C.F.R. § 22.15(c).

A request for an informal settlement conference does not affect Respondent's obligation to file a timely Answer to the Complaint pursuant to 40 C.F.R. § 22.15. No penalty reduction, however, will be made simply because an informal settlement conference is held.

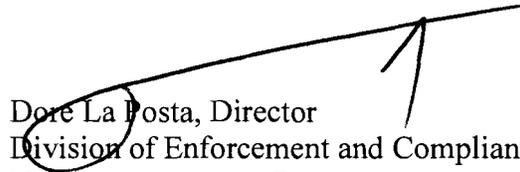
Any settlement that may be reached as a result of an informal settlement conference will be embodied in a written consent agreement. 40 C.F.R. § 22.18(b)(2). In accepting the consent agreement, Respondent waives its right to contest the allegations in the Complaint and waive its right to appeal the final order that is to accompany the consent agreement. 40 C.F.R. § 22.18(b)(2). To conclude the proceeding, a final order ratifying the parties' agreement to settle will be executed. 40 C.F.R. § 22.18(b)(3).

Respondent's entering into a settlement through the signing of such Consent Agreement and its complying with the terms and conditions set forth in the such Consent Agreement terminate this administrative litigation and the civil proceedings arising out of the allegations made in the complaint. Respondent's entering into a settlement does not extinguish, waive, satisfy or otherwise affect its obligation and responsibility to comply with all applicable statutory and regulatory requirements, and to maintain such compliance.

**VII. RESOLUTION OF THIS PROCEEDING WITHOUT HEARING OR CONFERENCE**

If, instead of filing an Answer, Respondent wishes not to contest the Compliance Order in the Complaint and wants to pay the total amount of the proposed penalty within thirty (30) days after receipt of the Complaint, Respondent should promptly contact the Assistant Regional Counsel identified on the previous page.

Complainant:

  
Dore La Posta, Director  
Division of Enforcement and Compliance Assistance  
U.S. Environmental Protection Agency, Region 2

Date JUNE 30, 2011

To: Robert Towney, Branch Manager  
Roche Molecular Systems, Inc.  
1080 U.S. Route 202 South  
Branchburg, NJ 08876-3733

Daniel O'Day, President  
Roche Molecular Systems Inc.  
4300 Hacienda Dr.  
Pleasanton, CA 94588

cc: Michael Hastry, Chief  
Hazardous Waste Compliance & Enforcement  
Mail Code 09-03  
PO Box 420  
Trenton, NJ 08625-0420

Franz B. Humer, President  
Roche Holdings Inc.  
340 Kingsland St.  
Nutley, NJ 07110

**In re: ROCHE MOLECULAR SYSTEMS, INC.**  
**Docket No. RCRA-02-2011-7106**

**CERTIFICATE OF SERVICE**

This is to certify that on the day of June 30, 2011, I caused to be mailed a true and correct copy of the foregoing "COMPLAINT, COMPLIANCE ORDER AND NOTICE OF OPPORTUNITY FOR HEARING," bearing Docket Number RCRA-02-2011-7106, together with Attachments I and II (collectively henceforth referred to as the "Complaint"), and with a copy of the "CONSOLIDATED RULES OF PRACTICE GOVERNING THE ADMINISTRATIVE ASSESSMENTS OF CIVIL PENALTIES, ISSUANCE OF COMPLIANCE OR CORRECTIVE ACTION COMPLIANCE ORDERS, AND THE REVOCATION, TERMINATION OR SUSPENSION OF PERMITS," 40 C.F.R. Part 22, by certified mail, return receipt requested, to: (a) Robert Towney, Branch Manager, Roche Molecular Systems, Inc., 1080 U.S. Route 202 South, Branchburg, NJ 08876-3733, and (b) Daniel O'Day, President, Roche Molecular Systems Inc., 4300 Hacienda Dr., Pleasanton, CA 94588. I hand carried the original and a copy of the Complaint to the Regional Hearing Clerk of the United States Environmental Protection Agency, Region 2, 290 Broadway, 16<sup>th</sup> floor, New York, New York 10007-1866.

Dated: June 30, 2011.  
New York, New York

Mildred N. Baez

ATTACHMENT I

PENALTY COMPUTATION WORKSHEET: COUNTS ONE AND TWO

**Company Name:** Roche Molecular Systems, Inc.

**EPA I.D. No.:** NJD986630630

**Address:** 1080 U.S. Route 202 South Branchburg, NJ 08876-3733

**Violations:** Count 1 - 40 C.F.R. § 264.1052(a)(1)(1993)(N.J.A.C. 7:26G-9.1(a)): Failure to Conduct Required Monitoring of Two Pumps Subject to Subpart BB  
Count 2 - 40 C.F.R. § 264.1057(a)(1993)(N.J.A.C. 7:26G-9.1(a)): Failure to Conduct Required Monitoring of Approximately 40 Valves Subject to Subpart BB

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1. Gravity based penalty from matrix .....	\$32,900
(a) Potential for Harm. ....	<u>Major</u>
(b) Extent of Deviation.....	<u>Major</u>
2. Select an amount from the appropriate multi-day matrix cell	
(March 2007 – December 2008).....	<u>\$1,290</u>
(January 2009 – January 2010).....	<u>\$1,420</u>
3. Multiply line 2 by number of months of violation minus 1 (for the pumps and valves associated with the hazardous waste storage tanks.) .....	<u>\$45,550</u>
4. Add line 1 and 3 .....	<u>\$78,450</u>
5. Percent decrease for good faith .....	<u>N/A</u>
6. Percent increase for willfulness/negligence .....	<u>N/A</u>
7. Percent increase for history of noncompliance.....	<u>N/A</u>
8. Total lines 5 through 7.....	<u>N/A</u>
9. Multiply line 4 by line 8 .....	<u>N/A</u>
10. Calculated economic benefit .....	<u>N/A</u>
11. Add lines 4, 9 and 10 for penalty amount to be inserted into the complaint.....	<u>\$78,450</u>

## NARRATIVE EXPLANATION TO SUPPORT PENALTY COMPUTATION

### 1. **Gravity Based Penalty**

**(a) Potential for Harm:** The “Potential for Harm” was “Major” because facility personnel had failed to monitor equipment subject to the 40 C.F.R. Part 264 Subpart BB requirements from at least March 2007 (if not earlier) through January 2010 which significantly increased the risks of not detecting releases of organic hazardous waste to the environment. In addition, by not complying with the Subpart BB regulations the facility also caused harm to the RCRA program, because these requirements are important to the prevention and control of organic air emissions. Major potential for harm was chosen because of the number of pieces of equipment involved.

**(b) Extent of Deviation:** The “Extent of Deviation” was determined to be “Major” because the facility personnel since at least March 2007 (if not earlier) had failed to comply with any of the Subpart BB requirements until February 2010. The midpoint of the cell range in the penalty matrix (\$32,915) was selected because a number of pieces of equipment (two pumps and five of the approximately 40 valves) would have been exempt from the monitoring requirements had an evaluation and appropriate documentation been included in the facility’s operating log.

**(c) Multi-day Penalties:** In our evaluation of the multi-day penalties, March 2007 was chosen as the starting date. The low point of the cell range in the penalty matrix was selected because if an evaluation had been done earlier some equipment (the two pumps and five valves, in particular) would have likely been exempt. However, the Agency is exercising its discretion and treating subsequent violations as a multi-day penalty. From March 2007 to December 2008, there would have been 22 monitoring events. From January 2009 to January 2010, there would have been 13 monitoring events. Penalty calculation is as follows:  $[(22 - 1) \times \$1,290] + [13 \times \$1,420] = \$27,090 + \$18,460 = \$45,550$ .

2. **Adjustment Factors** (Good faith, willfulness/negligence, history of compliance, ability to pay, environmental credits, and other unique factors must be justified, if applied):

**Good faith:** EPA at this time has made no adjustment for this factor in the penalty determination since EPA has no definite information concerning any mitigating factors; if EPA receives such information, it will then evaluate it and consider making an appropriate adjustment.

**Willfulness/Negligence:** Not applicable

**History of Compliance:** Not applicable

**Ability to Pay:** Not applicable

**Environmental Project:** Not applicable

**Other Unique Factors:** Not applicable

3. **Economic Benefit:** The economic benefit derived from the violations alleged in this Complaint was determined to be less than \$5,000. An economic benefit under this amount is deemed insignificant and is not included in the penalty assessment figure.

4. **Recalculation of Penalty Based on New Information:** N/A

**PENALTY COMPUTATION WORKSHEET: COUNT THREE**

**Company Name:** Roche Molecular Systems, Inc.

**Address:** 1080 U.S. Route 202 South Branchburg, NJ 08876-3733

**Violation:** Count 3 - 40 C.F.R. § 264.1084(c)(4)(ii)(1998)(N.J.A.C. 7:26G-9.1(a)):  
Failure to Conduct Annual Inspections of Tanks Subject to Subpart  
CC in 2007, 2008, and 2009

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1. Gravity based penalty from matrix .....	<u>\$32,900</u>
(a) Potential for Harm .....	<u>Major</u>
(b) Extent of Deviation.....	<u>Major</u>
2. Select an amount from the appropriate multi-day matrix cell .....	(for 2007-2008)..... <u>\$3,869</u>
.....	(for 2009)..... <u>\$4,225</u>
3. Multiply line 2 by number of inspections minus 1 .....	<u>\$8,094</u>
4. Add line 1 and 3.....	<u>\$40,994</u>
5. Percent increase/decrease for good faith .....	<u>N/A</u>
6. Percent increase for willfulness/negligence .....	<u>N/A</u>
7. Percent increase for history of noncompliance.....	<u>N/A</u>
8. Total lines 5 through 7.....	<u>N/A</u>
9. Multiply line 4 by line 8 .....	<u>N/A</u>
10. Calculated economic benefit .....	<u>N/A</u>
11. Add lines 4, 9 and 10 for penalty amount to be inserted into the complaint.....	<u>\$40,994</u>

## NARRATIVE EXPLANATION TO SUPPORT PENALTY COMPUTATION

### 1. Gravity Based Penalty

(a) **Potential for Harm:** The “Potential for Harm” was determined to be “Major.” The Respondent failed to inspect its two tanks which store organic hazardous waste on an annual basis for compliance with Subpart CC. This significantly increased the risks of not detecting releases of organic hazardous waste to the environment.

(b) **Extent of Deviation:** The “Extent of Deviation” was determined to be “Major” due to the fact that the Respondent did not conduct annual inspections in 2007, 2008, and 2009. The mid-point (\$32,915) of the matrix was used.

(c) **Multi-day Penalties:** The Respondent failed to conduct annual inspections of its tanks for 2007, 2008, and 2009. However, the Agency is exercising its discretion and treating subsequent violations as a multi-day penalty. The mid-points of the matrices were selected. For 2007 and 2008, the mid-point is \$3,869. For 2009, the mid-point is \$4,225. Penalty calculation is as follows:  $[(2 - 1) \times \$3,869] + [1 \times \$4,225] = \$8,094$ .

2. **Adjustment Factors** (Good faith, willfulness/negligence, history of compliance, ability to pay, environmental credits, and other unique factors must be justified, if applied):

**Good faith:** EPA at this time has made no adjustment for this factor in the penalty determination since EPA has no definite information concerning any mitigating factors; if EPA receives such information, it will then evaluate it and consider making an appropriate adjustment.

**Willfulness/Negligence:** Not applicable

**History of Compliance:** Not applicable

**Ability to Pay:** Not applicable

**Environmental Project:** Not applicable

**Other Unique Factors:** Not applicable

3. **Economic Benefit:** The economic benefit derived from the violations alleged in this Complaint was determined to be less than \$5,000. An economic benefit under this amount is deemed insignificant and is not included in the penalty assessment figure.

4. **Recalculation of Penalty Based on New Information:** N/A

**PENALTY COMPUTATION WORKSHEET: COUNT FOUR**

**Company Name:** Roche Molecular Systems, Inc.  
**Address:** 1080 U.S. Route 202 South Branchburg, NJ 08876-3733  
**Violation:** 40 C.F.R. § 264.1084(c)(1)(1998)(N.J.A.C. 7:26G-9.1(a))  
**Count 4 - Failure to Determine Maximum Organic Vapor Pressure as Required by Subpart CC**

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1. Gravity based penalty from matrix ..... \$11,300  
    (a) Potential for Harm ..... Moderate  
    (b) Extent of Deviation ..... Major
2. Select an amount from the appropriate multi-day matrix cell ..... N/A
3. Multiply line 2 by number of days of violation minus 1 [or other number, as appropriate (provide narrative explanation)] ..... N/A
4. Add line 1 and 3 ..... \$11,300
5. Percent increase/decrease for good faith ..... N/A
6. Percent increase for willfulness/negligence ..... N/A
7. Percent increase for history of noncompliance ..... N/A
8. Total lines 5 through 7 ..... N/A
9. Multiply line 4 by line 8 ..... N/A
10. Calculated economic benefit ..... N/A
11. Add lines 4, 9 and 10 for penalty amount to be inserted into the complaint ..... \$11,300

## NARRATIVE EXPLANATION TO SUPPORT PENALTY COMPUTATION

### 1. Gravity Based Penalty

(a) **Potential for Harm:** The “Potential for Harm” resulting from this violation was determined to be “Moderate.” Although the Respondent failed to determine the maximum organic vapor pressure of the organic hazardous waste stored in its hazardous waste storage tanks, this waste was shipped off-site on a regular basis, thereby reducing the potential for releases of hazardous waste. When the maximum organic vapor pressure *was* determined, it was within the acceptable range for Level 1 tanks with capacities of 250 and 3,000 gallons.

(b) **Extent of Deviation:** The “Extent of Deviation” was determined to be “Major” because facility personnel at the facility failed to determine and document the actual maximum vapor pressure of the contents of the tank.

The low point of the cell range in the penalty matrix (\$11,330) was selected because the facility had not exceeded the maximum allowable vapor pressure for the subterranean 250 gallon solvent waste surge tank and the 3,000-gallon above-ground solvent waste storage tank and there were no identified instances of any significant deterioration or corrosion.

2. **Adjustment factors** (Good faith, willfulness/negligence, history of compliance, ability to pay, environmental credits, and other unique factors must be justified, if applied):

**Good faith:** At this time, EPA has made no adjustment for this factor in the penalty determination since EPA has no definite information concerning any mitigating factors; if EPA receives such information, it will evaluate it and consider making an appropriate adjustment.

**Willfulness/Negligence:** Not applicable

**History of Compliance:** Not applicable

**Ability to Pay:** Not applicable

**Environmental Project:** Not applicable

**Other Unique Factors:** Not applicable

3. **Economic Benefit:** The economic benefit derived from the violations alleged in this Complaint was determined to be less than \$5,000. An economic benefit under this amount is deemed insignificant and is not included in the penalty assessment figure.

4. **Recalculation of Penalty Based on New Information:** N/A

**ATTACHMENT II-TABLE I**

**GRAVITY MATRIX**

**(For violations that occur after January 12, 2009)**

<b>EXTENT OF DEVIATION FROM REQUIREMENT</b>				
<b>P O T E N T I A L  F O R  H A R M</b>		<b>MAJOR</b>	<b>MODERATE</b>	<b>MINOR</b>
	<b>MAJOR</b>	<b>\$37,500 to \$28,330</b>	<b>\$28,329 to \$21,250</b>	<b>\$21,249 to \$15,580</b>
	<b>MODERATE</b>	<b>\$15,580 to \$11,330</b>	<b>\$11,329 to \$7,090</b>	<b>\$7089 to \$4,250</b>
	<b>MINOR</b>	<b>\$4,250 to \$2,130</b>	<b>\$2,129 to \$710</b>	<b>\$709 to \$150</b>

**ATTACHMENT II-TABLE II**

**MULTI-DAY MATRIX**

**(For violations that occur after January 12, 2009)**

<b>EXTENT OF DEVIATION FROM REQUIREMENT</b>				
<b>P O T E N T I A L  F O R  H A R M</b>		<b>MAJOR</b>	<b>MODERATE</b>	<b>MINOR</b>
	<b>MAJOR</b>	<b>\$7,090 to \$1,420</b>	<b>\$5,670 to \$1,070</b>	<b>\$4,250 to \$780</b>
	<b>MODERATE</b>	<b>\$3,120 to \$570</b>	<b>\$2,230 to \$360</b>	<b>\$1,420 to \$220</b>
	<b>MINOR</b>	<b>\$850 to \$150</b>	<b>\$430 to \$150</b>	<b>\$150</b>

**ATTACHMENT II-TABLE III**

**GRAVITY BASED MATRIX**

**(For violations that occurred between March 15, 2004 and January 12, 2009)**

		<b>EXTENT OF DEVIATION</b>		
<b>P O T E N T I A L  F O R  H A R M</b>		<b>MAJOR</b>	<b>MODERATE</b>	<b>MINOR</b>
	<b>MAJOR</b>	\$32,500 to 25,971	\$25,790 to 19,343	\$19,342 to 14,185
	<b>MODERATE</b>	\$14,184 to 10,316	\$10,315 to 6,448	\$6,447 to 3,869
	<b>MINOR</b>	\$3,868 to 1,934	\$1,933 to 645	\$644 to 129

**ATTACHMENT II-TABLE IV**

**MULTI-DAY MATRIX**

(For violations that occurred between March 15, 2004 and January 12, 2009)

		<b>EXTENT OF DEVIATION FROM REQUIREMENT</b>		
<b>P O T E N T I A L  F O R  H A R M</b>		<b>MAJOR</b>	<b>MODERATE</b>	<b>MINOR</b>
	<b>MAJOR</b>	\$6,448 to 1,290	\$5,158to \$967	\$3,869 to \$709
	<b>MODERATE</b>	\$2,837 to \$516	\$2,063to \$322	\$1,290 to \$193
	<b>MINOR</b>	\$774 to \$129	\$387to \$129	\$129