



COMMONWEALTH of VIRGINIA

DEPARTMENT OF ENVIRONMENTAL QUALITY
VALLEY REGIONAL OFFICE

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**STATE AIR POLLUTION CONTROL BOARD
ENFORCEMENT ACTION - ORDER BY CONSENT
ISSUED TO
MERCK SHARPE & DOHME CORP.
FOR
MERCK SHARPE & DOHME – STONEWALL PLANT
Registration No. 80524**

SECTION A: Purpose

This is a Consent Order issued under the authority of Va. Code §§ 10.1-1309 and -1316, between the State Air Pollution Control Board and Merck Sharp & Dohme Corp. – Stonewall Plant, for the purpose of resolving certain violations of the Virginia Air Pollution Control Law and the applicable permits and regulations.

SECTION B: Definitions

Unless the context clearly indicates otherwise, the following words and terms have the meaning assigned to them below:

1. "Board" means the State Air Pollution Control Board, a permanent citizens' board of the Commonwealth of Virginia, as described in Va. Code §§ 10.1-1184 and -1301.
2. "CFR" means the Code of Federal Regulations, as incorporated into the Regulations.
3. "Department" or "DEQ" means the Department of Environmental Quality, an agency of the Commonwealth of Virginia, as described in Va. Code § 10.1-1183.
4. "Director" means the Director of the Department of Environmental Quality, as described in Va. Code § 10.1-1185.

5. "Facility" means the Merck Sharp & Dohme Corp. – Stonewall Plant, located at 2778 So. East Side Highway in Rockingham County, Virginia which operates a pharmaceutical manufacturing facility.
6. "Notice of Violation" or "NOV" means a type of Notice of Alleged Violation under Va. Code § 10.1-1309.
7. "O&M" means operations and maintenance.
8. "Order" means this document, also known as a "Consent Order" or "Order by Consent," a type of Special Order under the Virginia Air Pollution Control Law.
9. "Permit" means the Title V permit to operate a stationary source of air pollution, which was issued under the Virginia Air Pollution Control Law and the Regulations to Merck & Co., Inc. (Stonewall Plant) on November 1, 2006.
10. "VRO" means the Valley Regional Office of DEQ, located in Harrisonburg, Virginia.
11. "Regulations" or "Regulations for the Control and Abatement of Air Pollution" mean 9 VAC 5 chapters 10 through 80.
12. "Merck" means Merck Sharp & Dohme Corp., a corporation authorized to do business in Virginia and its affiliates, partners, subsidiaries, and parents. Merck Sharp & Dohme Corp. is a "person" within the meaning of Va. Code § 10.1-1300
13. "Va. Code" means the Code of Virginia (1950), as amended.
14. "VAC" means the Virginia Administrative Code.
15. "Virginia Air Pollution Control Law" means Chapter 13 (§ 10.1-1300 *et seq.*) of Title 10.1 of the Va. Code.
16. "VEE" means a Visible Emissions Evaluation, as determined by EPA Method 9 (*see* 40 CFR 60, Appendix A).

SECTION C: Findings of Fact and Conclusions of Law

1. Merck owns and operates the Facility in Rockingham County, Virginia. The Facility is the subject of the Permit which allows for the manufacturing of various pharmaceutical intermediates and products.
2. On January 28 and 29, 2010, and February 1, 2010 DEQ staff conducted Partial Compliance Evaluations of a quarterly Hazardous Air Pollutant emission report ("HAP Report"), the Environmental Activities Update, and Visible Emissions Monitoring Letter submitted to DEQ by Merck for compliance with the requirements of the Virginia Air

Pollution Control Law, the Permit, and the Regulations. Based on the inspections and follow-up information, DEQ staff made the following observations:

- a. Fourth Quarter 2008 HAP Report indicates that modifications were made to the cyanide destruction system and that chloroform emissions were greater than 1 ton per year and combined HAP emissions increased by more than 2.5 tons per year. These amounts exceed the quantity used to define a significant modification in condition IV.E.4.(a) and (b) of Merck's Title V Permit. Merck did not provide DEQ with appropriate notification of the significant modification, as required by condition IV.E.4.(c) of the Permit.
 - b. On October 23, 2009, DEQ staff received correspondence from Merck confirming that while they knew that chloroform is a HAP that goes to their wastewater treatment, they do not measure it at the influent. Instead, they assume that it volatilizes into air and the quantity is estimated for reporting purposes.
 - c. On December 18, 2009, DEQ staff received notification from Merck that they had implemented an equipment or process change which resulted in an increased particulate matter (PM) emissions of greater than five tons per year for units listed in Attachment A of the Title V Permit. In October of 2008, Merck began using air pollution control equipment ID number TOU-2542/SCR2546 (Thermal Oxidizer) for the control of Chloroform emissions. This process change resulted in the increase of HCL emissions by greater than five tons per year. Merck did not provide DEQ with notification of the process change within 30 days of the event.
 - d. On December 18, 2009, DEQ staff received notification from Merck that they had implemented an equipment or process change on the Thermal Oxidizer (TOU-2542/SCR2546) during October of 2008 which resulted in HCL emissions and made this unit subject to Condition VI.B.2 monitoring. HCL emissions are considered particulate for the purposes of conducting visible emissions monitoring. Merck did not begin conducting visible emissions evaluations of the Thermal Oxidizer (TOU-2542/SCR2546) until September 2009.
3. Condition IV.E.4 of the Permit, states: "The permittee shall furnish notification to the Director, Valley Region, of significant modifications and significant new installations.
- a. Significant modifications for the purposes of this section are defined as changes to an existing process unit that result in an increase of the potential emissions of the process unit after consideration of existing controls of more than any of the significance levels listed in Condition IV.E.4.b.(1). Significant new installations for the purposes of this section are defined as new process units with potential emissions before controls that exceed either of the significance levels in Condition IV.E.4.b.(2). For purposes of this section, potential emissions means process unit point source emissions that would be generated by the process unit operating at its maximum capacity.
 - b. Significance levels for determining significant modifications and significant new installations:
 - (1) Significant modifications
 - a) An increase in emissions of any individual HAP greater than or equal to one ton/year;

- b) An increase in emissions of total HAPs greater than or equal to 2.5 tons/year;
 - c) Emissions of an individual HAP not previously emitted by the process unit greater than or equal to one ton/year.
 - (2) Significant new installations
 - a) Emissions of any individual HAP greater than or equal to one ton/year;
 - b) Emissions of total HAPs greater than or equal to 2.5 tons/year.
 - c. The notification shall be in writing and shall be submitted within 45 days of the commencement of operation. The notification shall include the following information:
 - (1) A description of the new or modified equipment, to include a schematic diagram showing the type and sequence of equipment installed or modified, equipment identification numbers, location of the new installation or modification on the plant site;
 - (2) Air pollution control equipment associated with the new installation or modification;
 - (3) The total emissions of each HAP emitted from each piece of new or modified equipment (before and after controls);
 - (4) Changes in emission factors for each HAP emitted (expressed as lbs HAP per production unit) resulting from the new installation or modification; and
 - (5) For modifications, a statement addressing the effect that the modification will have on the performance of existing air pollution control equipment. (9 VAC 5-80-110)"
4. Condition IV.C.9 of the Permit, states: "The permittee shall maintain records of all emission data and operating parameters necessary to demonstrate compliance with this permit... These records shall include, but are not limited to...Monthly and annual calculations of individual and total HAP emissions resulting from wastewater treatment. Calculations shall be based on TOXCHEM modeling utilizing measured data for influent flow, influent temperature, and monthly average values for influent HAP concentrations. Annual emissions shall be calculated monthly as specified in Condition IV.A.1. (9 VAC 5-80-110)"
5. Condition VI.E. of the Permit, states: "The permittee shall notify the Director, Valley Region, in writing within 30 days of equipment or process changes resulting in increased particulate matter (PM) emissions for units listed in Attachment A, if the resulting uncontrolled PM emissions level for such a unit is greater than five tons per year. Following the equipment or process change, such equipment shall be subject to the visible emissions monitoring requirements in Condition VI.B.2. If an emissions unit not listed in Attachment A undergoes equipment or process changes resulting in an adjusted uncontrolled PM emissions level below five tons per year, the permittee shall notify the Director, Valley Region in writing before ceasing the visible emissions monitoring required by Condition VI.B.2. At all times, an up-to-date version of Attachment A shall be maintained on site and available for inspection. (9 VAC 5-80-110)"

6. Condition VI.B.2 of the Permit, states: "The permittee shall conduct visible emission inspections on each process unit stack in accordance with the following procedures and frequencies:
 - a. At a minimum of once per month, the permittee shall determine the presence of visible emissions. If during the inspection, visible emissions are observed, a visible emission evaluation (VEE) shall be conducted in accordance with 40 CFR 60, Appendix A, EPA Method 9, unless timely corrective action is taken such that the stack resumes operation with no visible emissions. The VEE shall be conducted for a minimum of six minutes. If any of the observations exceed 20%, the VEE shall be conducted for a total of 60 minutes.
 - b. All visible emissions inspections shall be performed when the process unit is operating.
 - c. If visible emissions inspections conducted during 12 consecutive months show no visible emissions for a particular process unit stack, the permittee may reduce the monitoring frequency to once per quarter for that process unit stack. Anytime the quarterly visible emissions inspections show visible emissions, or when requested by DEQ, the monitoring frequency shall be increased to once per month for that stack.
 - d. For process units that do not operate year round, 12 non-consecutive monthly visible inspections shall be performed. If visible emissions inspections conducted during 12 non-consecutive months show no visible emissions for a particular process unit stack, the permittee may reduce the monitoring frequency to once per quarter for that process unit stack. Anytime the quarterly visible emissions inspections show visible emissions, or when requested by DEQ, the monitoring frequency shall be increased to once per month for that stack.
All observations, VEE results, and corrective actions taken shall be recorded.
(9 VAC 5-80-110)"
7. On April 28, 2010, based on the inspections and follow-up information, the Department issued Notice of Violation number AVRO7544 to Merck, for the violations described in paragraphs C.2. through C.6.
8. On May 10, 2010, Merck responded to the NOV requesting a meeting to discuss the violations.
9. On May 21, 2010, DEQ staff met with representatives of Merck to discuss the violations, including Merck's written response, potential remedies for resolution and returning to compliance. During this meeting, Merck did not contest any of the violations; however, they sought clarification of the one noted in paragraphs 2.b. and 4. Discussion focused on developing a plan to address DEQ's concerns over Merck's assumption that chloroform amounts measured during past research events were adequate representations of current chloroform emissions.
10. Based on the results of the January 28 and 29, 2010, and February 1, 2010 inspections, the May 21, 2010, meeting, and other submitted documentation, the Board concludes that

Merck has violated Conditions IV.E.4, IV.C.9, VI.E., and VI.B.2 of the Permit, as described in paragraphs C(2) through C(6), above.

11. On June 2, 2010, Merck submitted a proposal to conduct an Analysis of Wastewater Treatment Plant Influent Wastewater for Chloroform on July 5, 2010. On June 9, 2010, DEQ accepted this proposal as an adequate response to its concerns regarding chloroform emissions. The procedures proposed in the analysis comply with the requirements of Permit Condition IV.C.9. Additionally, to prevent future notification violations, Merck has added the applicable notification requirements to its Environmental Management System. The violation requiring the performance of VEEs on the Thermal Oxidizer (TOU-2542/SCR2546), was resolved in September 2009 as noted in paragraph C.2(d).

SECTION D: Agreement and Order

Accordingly, by virtue of the authority granted it in Va. Code §§ 10.1-1309 and -1316, the Board orders Merck, and Merck agrees to pay a civil charge of \$16,705.00 within 30 days of the effective date of the Order in settlement of the violations cited in this Order. Payment shall be made by check, certified check, money order or cashier's check payable to the "Treasurer of Virginia," and delivered to:

Receipts Control
Department of Environmental Quality
Post Office Box 1104
Richmond, Virginia 23218

Merck shall include its Federal Employer Identification Number (FEIN) with the civil charge payment and shall indicate that the payment is being made in accordance with the requirements of this Order for deposit into the Virginia Environmental Emergency Response Fund (VEERF).

SECTION E: Administrative Provisions

1. The Board may modify, rewrite, or amend this Order with the consent of Merck for good cause shown by Merck, or on its own motion pursuant to the Administrative Process Act, Va. Code § 2.2-4000 *et seq.*, after notice and opportunity to be heard.
2. This Order addresses and resolves only those violations specifically identified in Section C of this Order. This Order shall not preclude the Board or the Director from taking any action authorized by law, including but not limited to: (1) taking any action authorized by law regarding any additional, subsequent, or subsequently discovered violations; (2) seeking subsequent remediation of the facility; or (3) taking subsequent action to enforce the Order.
3. For purposes of this Order and subsequent actions with respect to this Order only, Merck admits to the jurisdictional allegations, and agrees not to contest, but neither admits nor denies, the findings of fact and conclusions of law in this Order.

4. Merck consents to venue in the Circuit Court of Frederick County for any civil action taken to enforce the terms of this Order.
5. Merck declares it has received fair and due process under the Administrative Process Act and the Virginia Air Pollution Control Law and it waives the right to any hearing or other administrative proceeding authorized or required by law or regulation, and to any judicial review of any issue of fact or law contained herein. Nothing herein shall be construed as a waiver of the right to any administrative proceeding for, or to judicial review of, any action taken by the Board to modify, rewrite, amend, or enforce this Order.
6. Failure by Merck to comply with any of the terms of this Order shall constitute a violation of an order of the Board. Nothing herein shall waive the initiation of appropriate enforcement actions or the issuance of additional orders as appropriate by the Board or the Director as a result of such violations. Nothing herein shall affect appropriate enforcement actions by any other federal, state, or local regulatory authority.
7. If any provision of this Order is found to be unenforceable for any reason, the remainder of the Order shall remain in full force and effect.
8. Merck shall be responsible for failure to comply with any of the terms and conditions of this Order unless compliance is made impossible by earthquake, flood, other acts of God, war, strike, or such other occurrence. Merck shall show that such circumstances were beyond its control and not due to a lack of good faith or diligence on its part. Merck shall notify the DEQ Regional Director verbally within 24 hours and in writing within three business days when circumstances are anticipated to occur, are occurring, or have occurred that may delay compliance or cause noncompliance with any requirement of the Order. Such notice shall set forth:
 - a. the reasons for the delay or noncompliance;
 - b. the projected duration of any such delay or noncompliance;
 - c. the measures taken and to be taken to prevent or minimize such delay or noncompliance; and
 - d. the timetable by which such measures will be implemented and the date full compliance will be achieved.

Failure to so notify the Regional Director verbally within 24 hours and in writing within three business days, of learning of any condition above, which the Merck intends to assert will result in the impossibility of compliance, shall constitute a waiver of any claim to inability to comply with a requirement of this Order.

9. This Order is binding on the parties hereto, their successors in interest, designees and assigns, jointly and severally.
10. This Order shall become effective upon execution by both the Director or his designee and Merck. Nevertheless, Merck agrees to be bound by any compliance date which precedes the effective date of this Order.

11. This Order shall continue in effect until:

- a. Merck petitions the Director or his designee to terminate the Order after it has completed all of the requirements of the Order and the Director or his designee approves the termination of the Order; or
- b. the Director or Board terminates the Order in his or its sole discretion upon 30 days' written notice to Merck.

Termination of this Order, or any obligation imposed in this Order, shall not operate to relieve Merck from its obligation to comply with any statute, regulation, permit condition, other order, certificate, certification, standard, or requirement otherwise applicable.

12. Any plans, reports, schedules or specifications attached hereto or submitted by Merck and approved by the Department pursuant to this Order are incorporated into this Order. Any non-compliance with such approved documents shall be considered a violation of this Order.
13. The undersigned representative of Merck certifies that he or she is a responsible official authorized to enter into the terms and conditions of this Order and to execute and legally bind Merck to this document. Any documents to be submitted pursuant to this Order shall also be submitted by a responsible official of Merck.
14. This Order constitutes the entire agreement and understanding of the parties concerning settlement of the violations identified in Section C of this Order, and there are no representations, warranties, covenants, terms or conditions agreed upon between the parties other than those expressed in this Order.

15. By its signature below, Merck voluntarily agrees to the issuance of this Order.

And it is so ORDERED this 21st day of July, 2010.



Amy Thatcher Owens, Regional Director
Department of Environmental Quality

Merck Sharp & Dohme Corp. voluntarily agrees to the issuance of this Order.

Date: 20 JULY 2010 By: [Signature], Vice President, Plant Manager
(Person) (Title)
Merck Sharp & Dohme Corp.

Commonwealth of Virginia
City/County of Rockingham

The foregoing document was signed and acknowledged before me this 20th day of July, 2010, by Craig Kennedy who is Vice President, Plant Manager of Merck Sharp & Dohme Corp., on behalf of the corporation.

[Signature]
Notary Public

7131432
Registration No.

My commission expires: 28-FEB-2011

Notary seal:

