



# COMMONWEALTH of VIRGINIA

## DEPARTMENT OF ENVIRONMENTAL QUALITY

VALLEY REGIONAL OFFICE

P.O. Box 3000, Harrisonburg, Virginia 22801

(540) 574-7800 Fax (540) 574-7878

Physical Address: 4411 Early Road, Harrisonburg, VA

[www.deq.virginia.gov](http://www.deq.virginia.gov)

Matthew J. Strickler  
Secretary of Natural Resources

David K. Paylor  
Director

Amy Thatcher Owens  
Regional Director

**STATE AIR POLLUTION CONTROL BOARD  
ENFORCEMENT ACTION - ORDER BY CONSENT  
ISSUED TO  
MERCK SHARP & DOHME CORP.  
FOR  
MERCK-ELKTON 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., regarding Merck-Elkton Plant, for the purpose of resolving certain violations of the Virginia Air Pollution Control Law, Regulations, and the applicable permit.

### **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. facility, located at 2778 South East Side Highway in Elkton, Virginia.
6. "Merck" means Merck Sharp & Dohme Corp., a corporation authorized to do business in Virginia, and its affiliates, partners, and subsidiaries. Merck is a "person" within the meaning of Va. Code § 10.1-1300.
7. "Notice of Violation" or "NOV" means a type of Notice of Alleged Violation under Va. Code § 10.1-1309.
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 a Title V permit to operate a pharmaceutical manufacturing facility, which was issued under the Virginia Air Pollution Control Law and the Regulations to Merck on November 1, 2006, and renewed on September 1, 2019.
10. "Regulations" or "Regulations for the Control and Abatement of Air Pollution" mean 9 VAC 5 chapters 10 through 80.
11. "Va. Code" means the Code of Virginia (1950), as amended.
12. "VAC" means the Virginia Administrative Code.
13. "Virginia Air Pollution Control Law" means Chapter 13 (§ 10.1-1300 *et seq.*) of Title 10.1 of the Va. Code.

#### **SECTION C: Findings of Fact and Conclusions of Law**

1. Merck owns and operates the Facility. Merck is subject to the Permit, which authorizes the operation of a Stationary Source of Air Pollution at the Facility.
2. On May 22, 2019, Merck initiated a stack test for Generator #1 at the Facility. The stack test was aborted prior to completion due to the Carbon Monoxide (CO) and oxides of Nitrogen (NOx) parameters being out of range. Generator #1 was immediately placed out of service, and the vendor was contracted to perform maintenance and tune up work on the generator. Once the tune up was completed, Merck rescheduled the stack test.
3. On May 30, 2019, Merck completed the stack test at the Facility, which resulted in passing results, where all three parameters from Generator #1 were below the

corresponding Permit emissions limits.

4. On July 19, 2019, Merck submitted a report to DEQ indicating that the May 22, 2019 stack test was aborted due to the CO and NOx parameters being out of range. NOx results from Run #1 were reported as 144.14 ppm and the CO results from Run #1 were reported as 292.32 ppm.
5. On August 29, 2019, DEQ issued NOV No. AVRO001292-001 to Merck for failure to complete the May 22, 2019, performance stack test. Merck immediately responded, and corrective action was complete at the time of the NOV issuance.
6. 40 CFR 60.4244(c-e) states: "You must conduct three separate test runs for each performance test required in this section, as specified in § 60.8(f). Each test run must be conducted within 10 percent of 100 percent peak (or the highest achievable) load and last at least 1 hour.... To determine compliance with the NOx mass per unit output emission limitation, convert the concentration of NOx in the engine exhaust using Equation 1 of this section.... To determine compliance with the CO mass per unit output emission limitation, convert the concentration of CO in the engine exhaust using Equation 2 of this section...."
7. 9 VAC 5-80-1200(E) states: "For sources subject to the provisions of 40 CFR Part 60, 61 or 63, the compliance determination and performance test requirements of subsections A, B and C of this section shall be met as specified in those parts of Title 40 of the Code of Federal Regulations."
8. Based on the results of the May 22, 2019 stack test and the documentation submitted by Merck on July 19, 2019, the Board concludes that Merck has violated 40 CFR 60.4244(c-e) and 9 VAC 5-80-1200(E) as described in paragraphs C(2) through C(7), above.
9. Merck has submitted documentation that verifies that the violations described in paragraph C(2) and C(4) have been corrected.

#### **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 \$20,925 by June 1, 2020, 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). If the Department has to refer collection of moneys due under this Order to the Department of Law, Merck shall be liable for attorneys' fees of 30% of the amount outstanding.

**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 the jurisdictional allegations, findings of fact, and conclusions of law contained herein.
4. Merck consents to venue in the Circuit Court of the City of Richmond 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 unforeseeable circumstances beyond its control and not due to a lack of good faith or diligence on its part. Merck shall demonstrate 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 parties intend 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 and any 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. the Director or his designee terminates the Order after Merck has completed all of the requirements of the Order;
  - b. 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
  - c. 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 25<sup>th</sup> day of March, 2020.



Amy T. Owens, Regional Director  
Department of Environmental Quality

----- (Remainder of Page Intentionally Blank) -----

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

Date: 25 Mar 2020 By: Jonathan Gast, 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 25 day of March, 2020, by Jonathan Gast who is Plant manager of Merck Sharp & Dohme Corp. on behalf of the corporation.

Destiny Miller  
Notary Public

7587337  
Registration No.

My commission expires: August 31, 2022

Notary seal:

