

IN THE SUPERIOR COURT OF NEWTON COUNTY
STATE OF GEORGIA

RICHARD E. DUNN, DIRECTOR,
ENVIRONMENTAL PROTECTION
DIVISION, GEORGIA DEPARTMENT OF
NATURAL RESOURCES,

Plaintiff,

v.

BECTON, DICKINSON and COMPANY,

Defendant.

CIVIL ACTION FILE NO.

SUCV2019002219

CONSENT ORDER

Plaintiff Richard E. Dunn, Director, Environmental Protection Division, Georgia Department of Natural Resources ("EPD") and Defendant Becton, Dickinson and Company ("BD") (collectively, the "Parties") file this Consent Order confirming their agreement as follows:

WHEREAS, EPD filed its Verified Complaint and Motion for Temporary Restraining Order against BD on October 21, 2019, seeking preliminary and permanent injunctive relief and a temporary closure of BD's medical device sterilization facility located in Covington, Georgia.

WHEREAS, on October 25, 2019, BD filed its Verified Answer and Brief in Opposition to EPD's Motion for Temporary Restraining Order. BD disputes EPD's allegations and disagrees that EPD is entitled to injunctive or any other relief.

WHEREAS, a hearing on EPD's Motion is scheduled for October 28, 2019.

WHEREAS, the Parties agree that voluntary settlement of the claims asserted in this action is in the best interest of the Parties and the public, and that entry of this Consent Order

FILED IN OPEN COURT

This 28th day of October, 2019

Rick D. Wynn CLERK
Newton County Superior Court,
Alcovy Circuit

without additional litigation between the Parties is the most appropriate means of resolving such claims.

THEREFORE, upon stipulation and full agreement of the parties, it is hereby ORDERED that:

1.

This Court has jurisdiction over EPD and BD and the subject matter of EPD's claims against BD for purposes of this Consent Order.

2.

This Consent Order constitutes a full and complete settlement of the claims alleged against BD in the Verified Complaint filed on October 21, 2019.

3.

In accordance with the conditions of this Consent Order, the Parties agree to and shall implement and complete the requirements and take other actions set forth in Attachment A, which is incorporated into and made part of this Consent Order. Any act required to be done under Attachment A shall be enforceable as an order of this Court.

4.

The Parties agree to perform all requirements within the time limits and schedules contained in Attachment A. In the event a party disputes any aspect of compliance with this Consent Order, that Party shall first, before bringing the dispute to this Court, attempt to resolve the dispute promptly in good faith between representatives of the Parties with authority to settle the dispute.

5.

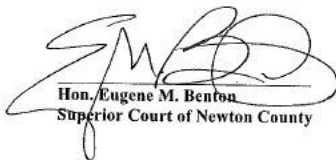
This Consent Order is a voluntary settlement of disputed facts and law. The Parties agree that nothing in this Consent Order shall be construed as an admission of fact or a conclusion of law on the part of either Party, and nothing in this Consent Order should be interpreted as acknowledgment of wrongdoing or other improper actions on behalf of either Party. Nothing in this Consent Order shall create any rights, obligations or responsibilities with respect to any third parties.

6.

This Consent Order may be modified only upon approval of the Court.

IT IS SO ORDERED.

This 28 day of October, 2019.

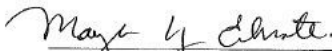


Hon. Eugene M. Benton
Superior Court of Newton County

IT IS SO STIPULATED, THROUGH COUNSEL OF RECORD.

DATED: October 28, 2019

STATE OF GEORGIA



Margate Kemperly Eckrote
Senior Assistant Attorney General
State Bar No. 238709


Christopher M. Carr
Attorney General
State Bar No. 112505
Isaac Byrd
Deputy Attorney General
State Bar No. 101150
Robin J. Leigh
State Bar No. 445845
Senior Assistant Attorney General

Georgia Department of Law
40 Capitol Square
Atlanta, Georgia 30334-1300
Tel: 404-656-7540
Attention: peckrote@law.ga.gov

**Counsel for Richard E. Dunn
Environmental Protection Division
Georgia Department of Natural Resources**

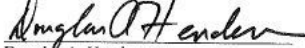
DATED: October 28, 2019

BALLARD, STEPHENSON & WATERS, LLP



Michael Waters
State Bar No. 740258
1117 Church Street
Covington, Georgia 30015
Phone: (770)-786-8123
Attention: mwaters@bswattorneys.com

KING & SPALDING LLP



Douglas A. Henderson

Georgia Bar No. 345537

Nicholas H. Howell

Georgia Bar No. 741064

KING & SPALDING LLP

1180 Peachtree Street, NE, Suite 1700

Atlanta, Georgia 30309

Phone: (404) 572-4600

Attention: dhenderson@kslaw.com

Counsel for Defendant

Becton, Dickinson and Company

Attachment A to Consent Order

1. BD will voluntarily cease all sterilization at BD Covington at 11:59 pm Eastern Standard Time on October 30, 2019, and shall be permitted to resume sterilization at BD Covington on November 7, 2019, at 12:00 am Eastern Standard Time.
2. All unpermitted releases of ethylene oxide at the BD Covington facility and the BD Madison facility, no matter the amount of the release, shall be reported to EPD immediately by email to the Air Protection Branch Stationary Source Compliance Program Manager. A follow-up report describing: (1) the release, (2) its causes, (3) the estimated amount of ethylene oxide released, and (4) the steps taken to contain it shall be emailed to the Air Protection Branch Stationary Source Compliance Program Manager within 48 hours of the initial notification.
3. By October 31, 2019, BD shall submit documentation that all technicians have been trained or retrained on the proper operation of all valves in the BD Covington facility, and that the facility has installed blanks on the outlets to all vacuum exhaust valves at the facility to prevent the flow of untreated ethylene oxide to the atmosphere.
4. When the BD Covington facility resumes operations on November 7, 2019, BD shall reduce fugitive emissions in Covington in accordance with this paragraph. BD will achieve this reduction by extending the aeration phases of the production process to no fewer than 24 hours per lot and reducing the number of product lots sterilized at Covington to an average of 600 product lots per month calculated on a rolling 90-day average as illustrated in paragraph 8. For purposes of this order, a "product lot" is eight pallets of product. BD shall reduce fugitive emissions of ethylene oxide to fewer than 30 pounds per month, based on a rolling 90-day average as illustrated in paragraph 8. All ethylene oxide from aeration will continue to be captured and controlled by the Regenerative Thermal Oxidizer (RTO).
5. The environmental benefit of the reduction in throughput and the extended aeration times will be to increase the total amount of ethylene oxide captured and destroyed by the RTO at the BD Covington facility and simultaneously reduce fugitive ethylene oxide emissions in accordance with paragraph 4.
6. BD represents that the proposed process changes will not impact the FDA validated process and will not require FDA or other regulatory approval.
7. BD will have a third-party confirm in writing that it has implemented this process and throughput change. The documentation of the changes in operating procedures and operator training shall be submitted to EPD in writing on or before November 12, 2019.
8. No later than Monday, October 28, 2019, BD will submit to EPD an illustration of BD's mass balance method used for calculating fugitive emissions, i.e., the amount of ethylene oxide used in the process less the amount of ethylene oxide captured and controlled by the RTO equals the calculated amount of ethylene oxide fugitive emissions. BD shall have a third-party engineer verify the correct application of this method, including documentation of the engineering calculations used to determine the

impact of BD's operational changes on fugitive ethylene oxide emissions at Covington. BD shall immediately implement these changes when sterilization operations resume on November 7, 2019 and shall submit monthly documentation to EPD confirming ethylene oxide fugitive emissions of no more than 30 pounds per month as measured on a 90-day rolling average. For illustration purposes, to calculate the average monthly fugitive emissions for the facility over any 90-day period, one would take the average total fugitive emissions from each of the prior three months, add them together and divide by three as follows: Month 1 = 28.5 pounds fugitive emissions, Month 2 = 32 pounds, and Month 3 = 29.5 pounds, which results in an average monthly amount of 30 pounds ($28.5 + 32 + 29.5 = 90$ divided by $3 = 30$). Similarly, for illustration purposes, to calculate the average number of product lots sterilized at Covington for purposes of calculating the throughput limitation of 600 lots per month referenced in paragraph 4 over any rolling 90-day period, one would take the total number of lots sterilized at Covington for each of the three previous months, add them together and divide that number by three to arrive at the average monthly number of lots sterilized at Covington ($598 + 602 + 600 = 600$).

9. EPD shall have the right to verify that the appropriate process changes have been implemented at the BD Covington facility and that BD is continuing to adhere to the changes through unannounced onsite inspections by EPD, USEPA, and EPD's contractors.
10. By December 15, 2019, BD shall provide estimates of the fugitive ethylene oxide emissions occurring at any offsite warehouse(s) located in Newton County using a method defined by a third-party engineering firm and approved by EPD, including documentation of the data and engineering calculations supporting those estimates.
11. The restrictions set forth in this agreement shall remain in place until a final air quality permit is issued by EPD (after any potential third party appeals) for the BD Covington facility, and the new air quality control equipment described in the new air quality permit amendment is placed into service.
12. BD agrees to provide documentation to EPD demonstrating that the emissions control equipment has been ordered, to notify EPD in writing when it has received the emissions control equipment, and to begin installation of the emissions control upgrades at the BD Covington facility within 30 days of receipt of equipment.
13. In accordance with an EPD-approved plan, BD shall conduct an initial demonstration of the fugitive emissions control system upgrades proposed in the permit application for the BD Covington facility no later than March 31, 2020. BD will use commercially reasonable efforts to accelerate this timeline, which is dependent upon receipt of the equipment from the suppliers.
14. BD shall institute a leak detection and repair program at both the BD Covington facility and the BD Madison facility to check all outside components (valves, flanges, fittings, etc.) for leaks with weekly monitoring of all components.

15. BD shall not increase ethylene oxide usage at the BD Madison facility greater than the average number of product lots processed at Madison during the months of July, August, and September 2019 until the final permit for the BD Covington facility is issued.
16. BD shall submit weekly reports of the daily number of lots sterilized, ethylene oxide usage, ethylene oxide destructed through the RTO, and sterilization cycle reports to demonstrate 24 hours of aeration time at the Covington and Madison facilities to EPD.
17. BD will submit its permit application for the proposed air quality control process at the BD Covington facility on or before October 31, 2019. The permit application shall include the installation of air pollution control equipment to capture fugitive emissions and route them to control device(s) with at least 99% control efficiency (fugitive emissions control system). The permit application package shall include air toxics modeling for ethylene oxide and any other air toxics emitted in the sterilization process.¹
18. BD will submit a complete permit application for the BD Madison facility on or before December 15, 2019. The permit application shall include the installation of air pollution control equipment to capture fugitive emissions and route them to control device(s) with at least 99% control efficiency (fugitive emissions control system). The permit application package shall include air toxics modeling for ethylene oxide and any other air toxics emitted in the sterilization process.²
19. BD shall complete installation and initial performance testing of the fugitive emissions control system and other related upgrades at the BD Madison facility no later than May 31, 2020. EPD will use reasonable efforts to issue the final permit for Madison no later than June 30, 2020. BD shall commence operation of the fugitive emissions control system at the BD Madison facility no later than June 30, 2020.
20. EPD will use reasonable efforts to issue a final permit for the BD Covington facility on or before April 30, 2020. BD shall commence operation of the emissions control system at the BD Covington facility no later than April 30, 2020. BD will use commercially reasonable efforts to accelerate these dates.

¹ Appendix A of EPD's Guideline for Ambient Impact Assessment of Toxics Air Pollutant Emissions

² Appendix A of EPD's Guideline for Ambient Impact Assessment of Toxics Air Pollutant Emissions