Message

From: AirAction [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FA78B989233840789 95E04A73D258D83-AIRACTION]
Sent: 4/2/2025 11:41:37 AM
To: Travis Anderton [travis_anderton@bd.com]
Subject: CORRECTION: Updated email address for CBI related to the Presidential Exemption

In the previous email, an incorrect email address was provided for the submission of electronic Confidential Business Information (CBI). The email address should be:

OAQPS_CBI@epa.gov

Thank you.

From: AirAction
Sent: Friday, March 28, 2025 10:27 AM
To: Travis Anderton <travis_anderton@bd.com>
Subject: RE: NESHAP: Ethylene Oxide Emissions Standards for Sterilization Facilities (89 FR 24090) (Sterilizer Rule); Becton Dickinson and Company facilities

Thank you for emailing the AirAction mailbox to request a Presidential Exemption under section 112(i)(4) of the Clean Air Act and for engaging with EPA in advancing President Trump's Executive Orders and Powering the Great American Comeback. We have received your email and will be in contact soon. If you have Confidential Business Information (CBI) that you'd like to submit, please submit it in electronic version to the CBI@epa.gov inbox or in hardcopy to:

USEPA, OAQPS
CORE CBI Office
4930 Old Page Road
Durham, NC 27703

From: Travis Anderton <travis_anderton@bd.com>
Sent: Thursday, March 27, 2025 4:39 PM
To: AirAction <AirAction@epa.gov>
Subject: NESHAP: Ethylene Oxide Emissions Standards for Sterilization Facilities (89 FR 24090) (Sterilizer Rule); Becton Dickinson and Company facilities

Dear Administrator Zeldin,

Consistent with EPA's request dated March 24, 2025, encouraging the regulated community to request a Presidential Exemption for compliance under section 112(i)(4) of the Clean Air Act (CAA) by March 31, 2025, Becton Dickinson and Company (BD) is requesting that the President issue a two-year exemption pursuant to his authority under CAA Section 112(i)(4) for all emission standards, monitoring requirements and any other applicable requirements in EPA's April 4, 2024 *National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review*, 89 FR 24090 (April 5, 2024) (Sterilizer Rule). BD requests this two-year compliance exemption for the following facilities which are regulated by the Sterilizer Rule and all sources therein:

Becton Dickinson and Company

BD Covington
8195 Industrial Boulevard
Covington, Georgia

Becton Dickinson and Company
BD Madison
1211 Mary Magnan Boulevard
Madison, Georgia

Becton Dickinson and Company
BD Medical
9450 South State Street
Sandy, Utah

Becton Dickinson and Company
BD Medical Pharmaceutical Systems
920 East 19th Street
Columbus, Nebraska

Becton Dickinson and Company
Edwards Lifesciences Technology Sàrl
Parque Industrial Carr. PR-402, Km. 1.4 N
Anasco, Puerto Rico

BD requests that the President issue a two-year exemption for compliance related to the new Sterilizer Rule. Specifically:

- For standards set or revised under CAA Section 112(f) and all corresponding requirements (including monitoring requirements), the exemption should apply as of April 6, 2026 (the compliance deadline for those standards);
- For standards set or revised under CAA Section 112(d) and all corresponding requirements (including monitoring requirements), the exemption should apply as of April 5, 2027 (the compliance deadlines for those standards).

An extension is requested to ensure that the technology used to comply with the standard is available, capable, and reliable:
Despite our best efforts, BD may not meet the April 6, 2026 compliance deadline. Although we started planning and design activities well in advance of the issuance of the new rule, the time necessary to execute very complex plant upgrades will likely exceed the compliance deadline(s). These upgrades require a methodical approach to engineering, procurement, and construction, including but not limited to; project planning, supplier qualification, facility and equipment design, procurement, permitting and approval by State and local authorities, construction of facilities, equipment installation, commissioning and validation, as well as training. Many of the systems and equipment necessary to meet the new rule are not off-the-shelf solutions. Each facility is unique, requiring highly customized solutions and will require careful integration and testing to ensure full compliance with various regulations and to avoid compromised safety of the operation, reliability of the plant and equipment, and to avoid disruption of supply.

It is questionable whether even the best control technologies can meet the requirements of the new rule under all operating conditions. For example, it is questionable whether or not certain emissions control devices can meet minimum DRE requirements under low inlet conditions such as would be expected during periods of low production, reduced operating capacity, plant shutdown/startup, and other atypical operating scenarios. It is also questionable whether current technology for the control of Group 1 and Group 2 emissions can meet the minimum DRE requirements under all operating conditions. Product type and volume sterilized at each facility vary widely and may be subject to swings in market demand among other external factors.

Additionally, the lead time of various materials and equipment required for the plant upgrades is variable. For example, the lead time of emissions control equipment is approximately 12-18 months and there is only a

limited number of vendors who can supply this equipment, and the lead time for high voltage transformers and electrical switch gear are currently 12 months or greater. In some cases additional utility requirements necessitate the involvement of the public utility company to increase local or regional capacity which may add additional complexity and time to project schedules.
Furthermore, BD anticipates additional financial burden and import/customs clearance complexity with the import of custom emissions control equipment specific to the Covington, Georgia and Madison, Georgia facility which add additional financial burden and lead time for delivery of such equipment due to current and pending tariffs.

An extension is in the national security interests of the United States for the following reasons:
BD supplies billions of sterile medical devices that enable healthcare providers to safely provide a variety of life saving therapies to patients in the US and around the world. Additionally, BD is a key supplier to the US Government.

Medical devices must be sterilized to prevent the spread of bacteria, viruses, and other pathogens, like methicillin-resistant Staphylococcus aureus ("MRSA"), HIV, and hepatitis B, that can lead to deadly infections. While BD sites deploy a variety of sterilization methods, approximately 50% of BD products currently can only be sterilized with EtO, including IV catheters, PICC catheters, surgical prep devices, surgical kits, Foley urinary catheter trays, glass syringes, chemotherapy ports, among many others. A more detailed summary of several of these products are outlined below.

BD produces sterile vascular access devices that allow healthcare providers to safely give medications, hydration and nutritional fluid therapies, and blood products to patients used both in the hospital as well as in outpatient areas of healthcare. Up to 90 % of hospitalized patients require IV therapy, and over 95% of the devices used are peripheral IV catheters ("PIVC"). This corresponds to over 1 billion peripheral IV insertions being performed worldwide, annually. BD supplies a significant portion of IV catheters to the US market.

BD produces drug delivery devices that improve a patient's quality of life, including ready-to-fill syringes that are used to deliver drugs and vaccines indicated to prevent invasive diseases, reduce the risks of life changing conditions like heart attacks and strokes, as well as treat chronic conditions such as Crohn's disease, arthritis and diabetes. A large majority of the injectable biotech drugs delivered subcutaneously or intramuscularly are delivered in BD's sterile Prefillable Syringes. Many of the top bio-pharma companies rely heavily on BD for these products.

BD also produces devices used to diagnose and treat patients with cancer (especially breast, liver and blood cancers), end-stage-renal disease, peripheral arterial disease, complex abdominal hernia and reconstruction, and hemostasis to prevent bleeding during advanced surgical procedures. Our products are used in the majority of patients undergoing surgery in these areas and those in intensive care/post-operative care units.

BD utilizes EtO sterilization because it is the only method of sterilization that can be used for these products. As EPA explains, "Commercial sterilization facilities play a vital role in maintaining an adequate supply of medical devices. According to the U.S. Food and Drug Administration (FDA), 'Literature shows that about fifty percent of all sterile medical devices in the U.S. are sterilized with ethylene oxide.'" 88 Fed. Reg. 22,793.

As voiced directly to EPA during the public comment period BD believes that the technical complexity of the new rules and the aggressive compliance deadline threaten supply continuity for critical medical products. BD respectfully requests extension to the compliance deadline to ensure upgrades are designed, constructed, and commissioned in accordance with all applicable regulatory requirements and industry standards while maintaining safe operations and avoiding unnecessary supply disruptions that would threaten or diminish the standard of care for patients.

BD appreciates EPA's attention to this important matter and request the exemption be granted as quickly as possible.

Respectfully,

Travis Anderton

BD

Travis Anderton
Vice President, Sterilization