

Ethylene oxide: Technical Reviews and Outreach to Potentially Affected Communities Status Report -- BD, Covington, Georgia

As EPA pursues its mission to protect public health and the environment, addressing ethylene oxide (EtO) remains a major priority for the Agency. EPA's National Air Toxics Assessment (NATA), released in August 2018, identified a number of areas (census tracts) with potentially elevated risk from continuous exposure, over 70 years, to EtO in the outdoor air. NATA estimated these risks based on EtO emissions from 2014, which were the most recently available at the time.

NATA is a screening-level analysis that is intended to identify pollutants or areas for closer examination. Because of this, additional work is needed to better understand emissions in areas that NATA identified as potentially having elevated risk. EPA has been supporting its state air agency partners as they conduct that work and identify opportunities for reducing EtO emissions from individual facilities, while the Agency reviews its national regulations for industrial facilities that emit EtO. Actual risks today may be higher or lower than NATA estimated due to several factors, including updated or more refined facility emissions information, or recent facility changes such as the installation of pollution controls.

The information below describes the technical analyses conducted for BD Covington commercial sterilization facility, as part of the follow-up work conducted since NATA was issued in August 2018. It also summarizes outreach to nearby communities about the NATA results. EPA is providing this information, in part, in response to the EPA Office of Inspector General's March 31, 2020, Management Alert which called on EPA to provide information to the 25 communities that NATA identified as potentially having the highest risk from EtO emissions.

Note: For commercial sterilizers, including BD Covington, EPA is compiling more current and complete emissions data to generate new risk estimates for ethylene oxide sterilizers across the country as part of its work to develop a proposed revision for the National Emissions Standards for Hazardous Air Pollutants for EtO sterilization facilities. EPA will share this information, which will include refined risk estimates at the census block level, with the public as part of its upcoming proposed rule.

Technical reviews conducted

Permit Reviews

- Permits issued by GA EPD can be found at <https://epd.georgia.gov/ethylene-oxide-information>.

Modeling

- In order to further evaluate potential risks indicated by EPA's NATA, GA EPD performed refined air dispersion modeling using EPA's recommended model, AERMOD.
- GA EPD performed the modeling using BD Covington emissions data to estimate EtO concentrations/risks in the area around the BD Covington facility (report dated June 7, 2019). The

results of the modeling are summarized in a memo found here: <https://epd.georgia.gov/bd-covington-tests-monitoring-reports-and-engineering-studies>.

- The results of the modeling showed risks above GA EPD's Acceptable Ambient Concentration (AAC) risk levels and helped inform GA EPD's decision to conduct ambient air monitoring and the installation of additional emissions controls at the facility.

Operations, Consent Orders, and Controls Installed

- BD Covington committed to make \$8 million in voluntary improvements in August 2019. On October 16, 2019, the Mayor of Covington sent a letter, requesting that the BD Covington facility cease until the additional controls were installed.
- On October 21, 2019, Georgia Attorney General Chris Carr, on behalf of the Governor and GA EPD, filed a temporary restraining order against BD.
- On October 28, 2019, BD entered into a Consent Order (Order) with GA EPD which was filed in Superior Court of Newton County, Georgia. Pursuant to the Order, BD agreed to cease certain activities, conduct additional testing, and implement process verification processes at its Covington and Madison, Georgia Facilities.
- BD Covington installed the controls between October 2019 and March 2020. In addition to the existing regenerative thermal oxidizer (sterilization vessel and aeration cells), the facility increased aeration time and installed new fugitive emission controls (dry bed scrubbers). The new dry bed scrubbers are designed to remove/control 99% of the EtO from the fugitive emissions.
- On January 15, 2020, the Order was first amended to include requirements that BD submit an indoor and outdoor monitoring plan, take air quality samples, undertake an engineering study and cease accepting Foley Catheter Procedural trays stored at a local distribution center.
- On March 25, 2020, pursuant to a joint motion to amend filed by BD and GA EPD, the Order was amended a second time to temporarily increase the number of monthly medical devices BD was allowed sterilize. Details of the Order and its amendments can be found at <https://epd.georgia.gov/bd-covington>.
- On April 30, 2020, BD commenced full time operation of the newly constructed emissions control system at the Covington facility; Successful testing was completed on all controls by June 19, 2020.
- Details of the existing controls can be found in the permits on GA EPD's website along with the results of any testing performed at <https://epd.georgia.gov/bd-covington>.
- EPA Region 4 staff will evaluate any new emissions data submitted by the state to the EPA's emissions inventory system on an ongoing basis.

Ambient Monitoring

- GA EPD is collecting ambient air monitoring samples in the vicinity of the BD Covington facility under a quality assurance project plan concurred on by EPA Region 4. Once validated, sample results are uploaded to GA EPD's website (<https://epd.georgia.gov/ethylene-oxide-information>).
- In September 2020, EPA announced that GA EPD was selected to receive a Community-Scale Ambient Air Toxics Monitoring Grant. With this funding (\$571,670), GA EPD plans to evaluate new technology for measuring ethylene oxide and to continue the evaluation of ambient ethylene oxide concentrations in three communities (including the area around BD/Covington), one rural area, and one urban background area to provide a larger dataset to encompass process changes of the identified facilities and the impact to the associated communities.
- Region 4 conducted a data review to evaluate variability in data collection, data uncertainty, and method uncertainty. Results of the review were shared with EPA Headquarters and GA EPD.

Inspections

GA EPD has inspected and performed various compliance monitoring activities regarding the facility since NATA was issued and has discussed those with EPA Region 4. Inspection reports, stack test reports and test report reviews are available on the GA EPD website at (<https://epd.georgia.gov/bd-covington>). In addition, compliance monitoring information summaries also are available through EPA's Enforcement and Compliance History Online database at <https://echo.epa.gov/>

Analytical Support

- Region 4 and GA EPD have regular calls to discuss issues such as sampling, data, questions on the analytical method, and studies conducted by other groups around the Atlanta area.
- EPA Region 4, in coordination with OAQPS, continues to provide technical assistance to GA EPD on questions and issues regarding sample collection, laboratory analysis, and data evaluation.
- As a QA/QC measure requested by GA EPD in December 2019, ERG analyzed a South Dekalb sample and sent the canister to EPA R4 for secondary analysis.

Outreach conducted

- Region 4 closely coordinates with GA EPD to provide information to the public and government officials on air emissions of EtO, particularly from several commercial sterilizers in the Atlanta area.
 - In collaboration with GA EPD and other government agencies, EPA held an open house and community meeting, on August 20, 2019, for communities around the Covington, Georgia, BD sterilizer facility. Over 350 people attended the meeting which provided an opportunity for EPA and EPD to relay information to and answer questions from the communities and the press about EtO emissions associated with the facility. In addition to the in-person, several hundred people viewed the meeting via live stream.
 - To facilitate the meeting, Region 4 worked with a professional facilitator and held several pre-meetings with community leaders to ascertain more of the on-the-ground concerns from the community.
 - Community members were provided the opportunity to submit questions prior to the community meeting in anticipation of responses being provided at the meeting.
 - Other participants in the meeting included key community leaders, ATSDR, the Georgia Department of Public Health and the Southeast Pediatric Environmental Health Specialty Unit.
 - Based on attendees at this meeting and questions emailed to regional staff, Region 4 developed a community list serve which is used to provide periodic updates on EPA actions.
 - Region 4 and GA EPD participated in a number of face-to-face meetings and calls to provide updates to elected officials, including members of the Congressional Ethylene Oxide Task Force, and community leaders to explain each agency's role, findings, next steps, etc.
 - Region 4 provides updates to stakeholder email lists, as they become available (e.g., posting of the Commercial Sterilizer Advance Notice of Proposed Rulemaking).
 - Region 4 provided updates to members of the congressional delegation and elected officials and responds to questions from members of the delegation and their constituents.
 - EPA Region 4 created a dedicated email box for the public to submit questions and concerns which can be accessed from the EPA Region 4 Ethylene Oxide webpage.
 - EPA Region 4 established a public facing webpage: <https://www.epa.gov/covington-eto> that includes the primary state and regional points of contact. The page also includes a Request for Information form that can be submitted by the public.

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