

Ethylene oxide: Technical Reviews and Outreach to Potentially Affected Communities

Status Report – B. Braun Medical Inc, Allentown, Pa.

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 B. Braun Medical Inc, (Braun). located in Allentown, Pa., 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 Braun, 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

The Pennsylvania Department of Environmental Protection (PADEP) has taken the lead for Braun. However, Region 3 has supported PADEP with the following:

- Provided 2014 NATA and EtO findings for the Mid-Atlantic Regional Air Management Association's (MARAMA) Air Toxics conference in August 2018.
- Presented 2014 NATA and EtO findings at R3 annual State Air Directors meeting in September 2018.
- Conducted an air enforcement inspection in October 2018.
- Shared remodeled risk results using 2017 emissions with PADEP on July 2019.

- Coordinated an EPA technical call on ambient EtO monitoring conducted by Office of Air Quality Planning and Standards (OAQPS) with the states of Pennsylvania, Delaware and West Virginia, (states with high risk facilities) in July 2019.
- Coordinated EPA webinar on technical methods used for EtO analysis for state and local agencies and contract laboratories in August 2019.

Actions to date:

- PADEP published its intent to approve a new control system for Braun in December 2019; a public hearing was offered; however, no request was received. PADEP approved the construction plan January 2020.
- Braun voluntarily installed a new Catalytic Oxidizer and Wet Scrubber Deoxx Unit with 99 percent control efficiency in July 2020.

Outreach conducted:

- PADEP has taken the lead for Braun and has not requested any R3 support as this time.