

## **Ethylene oxide: Technical Reviews and Outreach to Potentially Affected Communities**

### **Status Report -- Terumo BCT, Lakewood, Colorado**

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 Terumo BCT 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 Terumo BCT, 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:**

- August through October 2018- EPA R8 supported the Colorado Department of Health and Environment (CDPHE) on comprehensive EtO monitoring, which was conducted both before and after Terumo BCT installed additional controls to capture fugitive emissions of EtO. A link to the monitoring results is below.
- September 2018- CDPHE and EPA reviewed the state-issued permit and compliance reports of state-conducted inspections of Terumo BCT.
- September through November 2018- CDPHE monitored for background EtO levels around the Denver metropolitan area to determine baseline EtO to compare background EtO concentrations to ambient concentrations resulting from permitted emissions from Terumo BCT.

- November 2018- CDPHE used the monitoring results to develop a risk assessment (link below).
- October 2018- The local public health department for Lakewood, Jefferson County Public Health, and CDPHE queried the Colorado Central Cancer Registry for potential cancer incidence in the area NATA modeled as potentially being exposed to EtO. This data is included in CDPHE's Risk Assessment, and the results are summarized below.
- December 2018- EPA, CDPHE, Jefferson County Public Health, and Terumo BCT held a public meeting on December 11, 2018 to present the monitoring data, the risk assessment results, NATA modeling, and the EtO sterilization process.

### **Results of the reviews**

Review of the Colorado Central Cancer Registry determined that there is no statistically significant elevation of cancer incidence of those potentially exposed to EtO in the area surrounding the facility for the following cancers associated with EtO inhalation: Hodgkin's lymphoma, non-Hodgkin's lymphoma, multiple myeloma, lymphocytic leukemia, and breast cancer. This data is included in CDPHE's Risk Assessment.

- Terumo BCT voluntarily routed previously uncontrolled emissions through an existing acid scrubber, resulting in a 50-75% decrease in EtO emissions and an estimated 2 to 5 fold decrease in potential cancer risk.
- CDPHE and EPA reviewed the permit and compliance reports of Terumo BCT and found the facility has been complying with the permit limits.
- Pre- and post-control EtO monitoring results are available at the State of Colorado's EtO website: <https://www.colorado.gov/pacific/cdphe/ethylene-oxide>
- The CDPHE Risk Assessment (available at the [state's EtO website](#)) determined the following:
  - Additional emission controls installed by Terumo BCT in September 2018 resulted in a 2- to 5- fold reduction in cancer risk in the community.
  - Post-control installation, the range of cancer risk levels estimated for the area around Terumo BCT were similar to the range of background cancer risk levels from ethylene oxide measured outside of that area. Average cancer risk levels decreased to background levels within 2,000 feet west of the facility but remained slightly elevated as far as 5,000 feet to the east of the facility.

### Outreach conducted:

- EPA, CDPHE, Jefferson County Public Health, and Terumo BCT held a public meeting on December 11, 2018 to present the monitoring data, the risk assessment results, NATA modeling, and the EtO sterilization process.
- CDPHE and Jefferson County Public Health coordinated the meeting and presented monitoring results and risk assessment results. EPA presented the National Air Toxics Assessment results, and Terumo BCT presented about the sterilization process and why it is vital for sterilizing medical equipment.

- Community members in attendance were reassured that the facility had taken voluntary action to reduce emissions by 50-75% and that this partnership of health agencies had acted quickly and efficiently to determine the extent of the issue and work quickly to reduce emissions.
- Please see the CDPHE ethylene oxide page for a summary of the facility and links to the EtO monitoring results and risk assessment:  
<https://www.colorado.gov/pacific/cdphe/ethylene-oxide>