

Ethylene Oxide: Technical Reviews and Outreach to Potentially Affected Communities Status Report – Edwards Lifesciences Corp., Añasco, Puerto Rico

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 Edwards Lifesciences Corp. (the Facility) in Añasco, Puerto Rico, 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 Edwards Lifesciences Corp. (Facility) in Añasco, 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:

Emissions Inventory

- EPA Region 2 staff will evaluate any new emissions data submitted by the Commonwealth to the EPA's Emissions Inventory System on an ongoing basis. Emissions inventory information from 2019 shows that emissions were significantly lower than those used in the 2014 NATA.
- Region 2, the EPA Caribbean Environmental Protection Division (CEPD), the Puerto Rico Department of Environment and Natural Resource (PRDNER) and EPA's Office of Air Quality Planning & Standards (OAQPS) have been working with the Edwards facility to reduce emissions.

Human exposure modeling

- EPA and PRDNER used the latest EtO emissions data from the Facility to conduct exposure modeling using a human exposure model (HEM).
- In November 2019, PR DNER provided preliminary results of their EtO emissions modeling effort to EPA and the Facility.
- The Facility agreed to provide updated and more precise emission sources data and other scenarios contemplating changes in the Facility operations to reduce their emissions.
- In August 2020, PRDNER provided to EPA and the Facility additional preliminary results of the Facility EtO emissions modeling using HEM.
- EPA is compiling more current and complete emissions data to generate new risk estimates.

Weather Station

- After conversations with EPA and PRDNER about the EtO emissions dispersion and risk assessment modeling, the facility installed a weather station in August 2019. The intent was to collect on-site meteorological data for PRDNER to use as part of their emissions modeling efforts.
- The weather station started collecting meteorological data in August 2019.
- In September 2019, PRDNER's air emissions modeler and meteorologist visited the facility to evaluate the facility weather station capabilities and location.
- The Facility weather station was found adequate and with the necessary capabilities.
- In October 2020, the Facility provided EPA with a copy of the weather station data covering the period of August 2019 through October 2020.
- Preliminary risk modeling using the Facility's met data showed similar results to the previous runs that used the San Juan airport weather data.

Permit reviews (*Clean Air Act section 114, back vent*)

- In May 2020, the Facility requested permission from PRDNER to modify their construction and operation permit to convey the sterilization chambers back vent emissions to one of the Facility existing control devices.
- On September 17, 2020, PRDNER issued a modified construction permit and provided 20 days for public comments.
- On October 8, 2020, the Facility submitted a series of comments for PRDNER's consideration prior to finalizing the modified construction permit.

On-Site Inspection

- Air inspectors from CEPD and EPA National Enforcement Investigation Center (NEIC) conducted an inspection at Edwards Lifesciences in December 2019. The scope of the inspection was to determine Edwards Lifesciences compliance with 40 Code of Federal

Regulations (CFR) Part 63 Subpart O, to observe and evaluate site conditions and operation of control devices, and to conduct fugitive emission monitoring.

New modification to the Back Vent

- The Facility conveyed the sterilization chambers back vent emissions to the existing dry bed reactor, in an effort to quickly reduce EtO emissions.
- PRDNER is in the process of finalizing the facility construction and operating permits in order to determine whether the back-vent reconfiguration resulted in reduced emissions.

Response to CAA Section 114

- In October 2019 EPA Region 2 CEPD issued a Clean Air Act Section 114 request for information letter, requesting the Facility to conduct a new performance evaluation test to determine the facility emission control devices (wet-scrubber and dry bed reactor) EtO removal efficiencies.
- The Facility previously conducted a performance evaluation test in 2012.
- EPA also requested the Facility to submit a performance evaluation test protocol for review and approval, which the Facility submitted.
- EPA has reviewed and provided comments to the Facility performance evaluation test protocol, which has been subject to modifications as a result of EPA's review.
- Currently, EPA is waiting for the Facility to submit a modified performance evaluation test protocol proposing a new methodology.
- EPA and the Facility are also waiting for the back-vent emissions control project permit to be finalized by DNER. EPA will not approve the protocol until the back-vent emissions control project permit is issued. The test will be conducted at least 30 days after the back-vent emissions control project implementation start date.

Outreach conducted

Region 2, PRDNER and HQ had scheduled an in-person meeting for March 2020 in Añasco, however, the meeting had to be cancelled because of COVID-19. Region 2 is currently considering new approaches for sharing information with this community, including door-to-door flyers and website posting in areas where a webinar may not be the best option.

Material posted to Web

- <https://www.epa.gov/pr/edwards-lifesciences-anasco>

Meetings with local officials and the Facility

- CEPD held meetings with the Mayor of Añasco, and the facility in August 2018 and March 2020.

Preparation for public meeting

- Coordination between Region 2, PRDNER and EPA HQ for public outreach in the Añasco community in preparation for the March 2020 meeting that was later cancelled.