

## Ethylene Oxide: Technical Reviews and Outreach to Potentially Affected Communities

### Status Report - Second Quarter 2021 Update

April – June 2021

As EPA pursues its mission to protect public health and the environment, addressing ethylene oxide remains a major priority for the Agency. EPA's National Air Toxics Assessment (NATA), released in August 2018, identified a number of areas of the country where risks of cancer were potentially elevated because of ethylene oxide (EtO) emissions. NATA estimated risk based on emissions from 2014, which were the most recently available at the time.

Because NATA is a screening-level analysis, additional work is needed to better understand emissions in areas NATA identifies as potentially having elevated risk, and to identify opportunities for early reductions at individual facilities, while EPA reviews its regulations for industries. EPA is supporting its state air agency partners in that work.

In January 2021, EPA posted a status report describing the technical analysis and outreach work conducted for Edwards Lifesciences Corp. in Añasco, Puerto Rico. This document summarizes additional work conducted in the second quarter of 2021.

Note: EPA is compiling more current and complete emissions data to generate new risk estimates for the more than 100 EtO 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. These estimates will replace the NATA estimates and could include additional facilities. EPA will share this information with the public as part of its upcoming proposed rule.

#### Technical review updates:

##### **Emissions Inventory**

- EPA 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 2020 shows that emissions were lower than 2019.
- EPA, the EPA Caribbean Environmental Protection Division (CEPD), and the Puerto Rico Department of Environment and Natural Resource (PRDNER) have been working with the Edwards facility to reduce emissions.

##### **Permit reviews** (*section 114, back vent*)

- On June 24, 2021, PRDNER issued a modified operating permit to authorize the connection of sterilization chambers back vent emissions to the existing dry bed reactor.

##### **New modification to the Back Vent**

- PRDNER issued modifications of the facility construction and operating permits to allow the sterilization chambers back vent emissions to be conveyed to the existing dry bed reactor.

### **Edwards Lifesciences EtO emissions treatment reconfiguration project**

- On May 18, 2021, EPA representatives met with Edwards representatives about their proposal to reconfigure their EtO emissions treatment processes. According to the information provided, the project is expected to begin construction during the month of July. The project aims to increase the facility EtO emissions reduction efficiency to at least 99.99% of the emissions from the sterilization chambers, aeration rooms, warehouse building, and other areas such as the scrubbers and ethylene glycol tank areas. The project will also consolidate all emission sources (currently 3) into a single point of emission.
- EPA agreed on reviewing and approving a modified version of the performance test protocol that will now include the new EtO emissions treatment reconfiguration project. EPA will continue working along with OAQPS on this task.
- EPA will also keep PRDNER informed and involved in any conversations about the project to expedite the construction and operating permit application review process.
- On June 23, 2021, EPA representatives visited the Edwards facility for a facility walkthrough to further discuss the proposed EtO emissions treatment reconfiguration project and the facility operations.

### Outreach updates:

EPA hosted an open house and public availability session, on Wednesday, June 23, 2021, at the Luis Muñoz Marín High School in Añasco, PR. The event included an open table session with representatives from EPA, DNER, the Municipality of Añasco, and Edwards Lifesciences. The event was conducted in Spanish, and interpreters were available to translate questions posed to EPA technical staff. EPA and DNER presented details about EtO's emissions in the community, their potential health risks, and immediate actions been taken by the agencies and the facility, followed by a question and answer session.

The outreach activities conducted include:

- Presentations posted to Web
- Site visit at Edwards Lifesciences facility.
- Site visits at all Clean Air Act regulated facilities operating in the Añasco Industrial Park.
- Public Information Session and Open House
- Smaller meetings with community groups, mayor and local officials, representatives of other regulated facilities operating in the Añasco Industrial Park.