DRAFT
REGION 6 EXECUTIVE SUMMARY

TOPIC: Ethylene Oxide
DATE: August 8, 2019 CONTACTS: Ruben Casso 5-6763
PURPOSE/ACTION NEEDED: For Information DEADLINE DATE: None

BACKGROUND:
Ethylene oxide is a flammable, colorless gas used to make other chemicals that are used in making a range of products, including antifreeze, textiles, plastics, detergents and adhesives. Ethylene oxide also is used to sterilize equipment and plastic devices that cannot be sterilized by steam, such as medical equipment. Ethylene oxide in the air can come from different types of sources, including industries such as chemical manufacturers and sterilizers.

Based on the results of the 2014 National Air Toxics Assessment (NATA), released on August 22, 2018, EPA identified areas with elevated levels of risk associated with emissions of ethylene oxide from sterilizing and industrial facilities. NATA is the Agency's nationwide air toxics screening tool, designed to help EPA and state, local and tribal air agencies identify areas, pollutants or types of sources for further examination.

NATA estimates long-term risks – those that may occur from breathing air containing elevated levels of air toxics continuously for many decades. It does not estimate short-term (acute) or intermediate risks. However, based on an examination of available data, EPA does not expect ethylene oxide levels in the air in these areas to be high enough to cause immediate harm to health.

The 2014 NATA estimates that ethylene oxide significantly contributes to potential elevated cancer risks in some census tracts across the U.S. (less than 1 percent of the total number of tracts). These elevated risks are largely driven by an EPA risk value that was updated in late 2016.

EPA'S STRATEGY FOR ADDRESSING ETHYLENE OXIDE EMISSIONS:
EPA will work with industry, and state, local and tribal air agencies as it takes a two-pronged approach to address ethylene oxide emissions:

Reviewing Regulations

- EPA will review Clean Air Act regulations for facilities that emit ethylene oxide to ensure that they protect the public from significant risk. The Agency has begun its review of its air toxics emissions standards for miscellaneous organic chemical manufacturing (often referred to as the "MON"). As part of this review, the Agency will consider risks to health and the environment, along with advances in work practices, processes or emission controls that can further reduce air toxics emissions.

- EPA last updated this rule in 2006 and is under a court order to complete review of the rule by March 2020. A proposed rule is expected in summer 2019, with an opportunity for public comment.

- The Agency is taking a closer look at air toxics emissions standards for other industries that emit ethylene oxide to determine whether a review of those rules is needed. EPA started this closer look with its air toxics emissions standards for commercial sterilizers. EPA has begun a technology review of current rule under Clean Air Act. More than 100 major and area sources will be affected. The Agency is reviewing advancements in control technology and is considering other information, such as risks and costs. EPA anticipates publishing a proposed rule in summer 2019.

Gathering Emissions Information

- As part of its review of rules, EPA will gather additional information on industrial emissions of ethylene oxide, including where emissions occur, how those emissions can be controlled, and how current emission controls can be improved. The Agency also may seek information from emissions testing at facilities that emit ethylene oxide, focusing first on areas where NATA estimates elevated cancer risk. EPA is working with state air agencies to address areas identified with potential high public health risks.

- Existing ambient air monitoring methods are not sensitive enough to detect ethylene oxide at all levels in the outdoor air. EPA is working to develop new techniques for measuring ethylene oxide in outdoor air.

- EPA is working to improve emission inventory data for ethylene oxide (Toxic Release Inventory and National Emissions Inventory) and our understanding on which sources contribute to background levels.

- The information EPA obtains will help the Agency as it evaluates opportunities to reduce ethylene oxide emissions as part of its regulations review. It also will help EPA, our partner agencies and stakeholders determine whether more immediate emission reduction steps are necessary in any locations.

For more information

- For more information on ethylene oxide, and for updates on EPA's efforts to address risk from this chemical in the outdoor air, visit https://www.epa.gov/ethylene-oxide .

- To learn more about NATA, and to see the 2014 NATA results, visit https://www.epa.gov/national-air-toxics-assessment .

ENVIRONMENTAL/PUBLIC HEALTH VIEWPOINTS:

EPA is aware that on June 28, 2019, TCEQ announced a public comment period for their draft state Ethylene Oxide Effects Screening Level (ESL) Development Decision Document. EPA expects continued communication with TCEQ as they proceed with their state screening level development.

EPA has also received a Request for Correction under the Information Quality Act from the American Chemistry Council regarding the ethylene oxide information contained in the 2014 National Air Toxics Assessment as well as comments on EPA rulemakings that discuss ethylene oxide emissions and risks. EPA is currently evaluating these stakeholder concerns.

FOOD AND DRUG ADMINISTRATION (FDA) INNOVATION CHALLENGES: IDENTIFY STERILIZATION ALTERNATIVES AND REDUCE ETHYLENE OXIDE EMISSIONS

FDA announced two device sterilization challenges – one focused on identifying "new or alternative sterilization methods and technologies that are alternatives to those that use ethylene oxide," and one focusing on " reducing ethylene oxide emissions from the sterilization process." For more information see: https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices

RECOMMENDATIONS:

Ex. 5 Deliberative Process (DP)

DELIBERATIVE– DO NOT RELEASE
DRAFT SUPPLEMENTAL INFORMATION
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Texas

TCEQ is in the process of revising its state effects screening level (ESL) for ethylene oxide. TCEQ commented on the EPA IRIS value, and EPA proposed MACT rules which mention ethylene oxide. EPA, TCEQ, LDEQ, and ORD discussed the inhalation risk value for ethylene oxide on 5/28/19.

On 6/28/19 TCEQ released its ethylene oxide ESL draft decision document for a 45-day public notice. The EPA 2016 IRIS estimated 100-in-1 million risk level concentration is 0.011ppb (0.02 $\mu g/m^3$). The TCEQ set their draft ESL value at 7 ug/m^3 for a cancer risk level of 1 in 100, 000 (which corresponds to 70 ug/m3 at 100 in a million risk) is significantly higher than EPA's 0.02 ug/m^3 IRIS screening level. On 7/23/19: TCEQ granted comment period extension until 9/26/19 on their draft ESL document.

On 8/2/19: R6 receives a copy of a FOIA request sent to HQ from EarthJustice on behalf of the Sierra Club (Neil Carmen) requesting EPA information on TCEQ draft ethylene oxide ESL decision document. ORD has a briefing with Anne Idsal, Acting AA for OAR, the week of August 12th on ethylene oxide.

Louisiana

LDEQ has a state ambient air standard for ethylene oxide of 1.00 ug/m3 annual average. LDEQ has asked Region 6 to keep them apprised of relevant ethylene oxide risk screening levels/evaluations.

LDEQ is following the TCEQ draft ethylene oxide ESL development, the Request for Correction under the Information Quality Act from the American Chemistry Council regarding the ethylene oxide NATA results and comments on EPA rulemakings that discuss ethylene oxide emissions and risks. EPA is evaluating these stakeholder concerns and determining the best mechanism and timing for response.

Ex. 5 Deliberative Process (DP)