Message

From: Michael Honeycutt [Michael.Honeycutt@tceq.texas.gov]
Sent: 9/30/2019 1:39:21 PM
To: Casso, Ruben [Casso.Ruben@epa.gov]
Subject: RE: Is it time to crack down on ethylene oxide emissions? Chemical makers push back on possible tighter controls of carcinogen in the US

Thanks!

Mike

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From: Casso, Ruben <Casso.Ruben@epa.gov>
Sent: Monday, September 30, 2019 8:10 AM
To: Michael Honeycutt <Michael.Honeycutt@tceq.texas.gov>
Subject: Is it time to crack down on ethylene oxide emissions? Chemical makers push back on possible tighter controls of carcinogen in the US

https://cen.acs.org/environment/pollution/time-crack-down-ethylene-oxide/97/i38

Is it time to crack down on ethylene oxide emissions?

Chemical makers push back on possible tighter controls of carcinogen in the US

by Cheryl Hogue

SEPTEMBER 28, 2019 | APPEARED IN VOLUME 97, ISSUE 38

Ethylene oxide is a basic chemical building block for a slew of modern products, including plastics and medicines. This seven-atom molecule is the simplest epoxide. But not much is simple in the debate over how much of this flammable gas—which is carcinogenic when inhaled—is safe for the public to breathe.

The issue is coming to a head now because the US Environmental Protection Agency is under a court-imposed deadline to revise, by early next year, regulations on hazardous air pollution for plants that manufacture ethylene oxide.

On one side of this controversy are makers of ethylene oxide. They have found a partner in the Texas Commission on Environmental Quality (TCEQ) to support their assertion that the gas is a far less potent carcinogen than the EPA concluded in 2016. Texas is home to 5 of the nation's top 10 emitters of ethylene oxide, according to 2017 chemical release data, the most recent information available.

On the other side are environmentalists, community activists, and some federal and state lawmakers who are relying on the EPA's externally peer-reviewed scientific analysis of ethylene oxide's hazards. Regulation based on this analysis would likely require makers of the substance to ratchet down their emissions significantly.

Thai chemical maker Indorama Ventures is purchasing Huntsman's Port Neches, Texas, facility. In 2017, the plant was the largest emitter of ethylene oxide in the US.

Made from petroleum or natural gas, ethylene oxide is a key material in the manufacture of plastics, glycols, detergents, solvents, adhesives, and pharmaceuticals. It is also used as a pesticide to fumigate spices. In addition, commercial sterilization companies use ethylene oxide to render medical devices free of germs.

The chemical sector accounted for more than three-quarters of the 2017 nationwide emissions of ethylene oxide, as reported to the EPA under the community right-to-know law. That year, chemical and plastics manufacturers released 84 metric tons (t) of the chemical at 71 facilities, nearly half of which are in Texas or Louisiana.

Most ethylene oxide from chemical and plastics plants moves into the atmosphere through chimneys, stacks, or vents, says Neil Carman, clean air director at the Sierra Club's Lone Star Chapter. But a significant amount also leaks from pumps, valves, and other pressurized connections, adds Carman, a former air pollution inspector in Texas. Data reported to the EPA show that about 27%, or 23 t, of ethylene oxide released from these facilities in 2017 consisted of these fugitive emissions.

According to the American Chemistry Council (ACC), which lobbies on behalf of chemical manufacturers, 15 of the sites are ethylene oxide production facilities owned by nine companies. Ethylene oxide production involves more than 45,000 jobs and pours about $3.5 billion in direct value into the US economy, the ACC says.

At the same time, communities of color and low-income neighborhoods have disproportionately high levels of exposure to ethylene oxide from industrial facilities, the EPA's National Environmental Justice Advisory Council says in a May letter to the agency. The advisory group urged the agency to decrease emissions of the gas to protect public health.

The EPA is under a court order to decide by March 13, 2020, whether and how much to tighten existing emission limits for hazardous air pollutants, including ethylene oxide, from manufacturers of miscellaneous organic chemicals. Those standards were finalized in 2006.

The EPA's 2018 National Air Toxics Assessment also points to the need to address ethylene oxide emissions. Federal and state regulators use this risk-based assessment as a screening tool to identify areas, pollutants, or polluters for further scrutiny. The most recent results, made on the basis of emission data from 2014, indicated that lifetime cancer risk in some US census tracts was

significantly higher than the national average. Those tracts collectively are home to half a million people.

For ethylene oxide pollution specifically, the assessment says that the gas is "a potential concern" in several parts of the US. "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 agency says on a web page dedicated to the chemical.

But over time, people breathing in ethylene oxide pollution could develop health woes, the EPA warns.

"Long-term exposure to ethylene oxide can irritate the eyes, skin, nose, throat, and lungs, and harm the brain and nervous system," leading to problems including headaches, memory loss, and numbness, the EPA says separately from the assessment. "Studies show that breathing air containing elevated ethylene oxide levels over many years increases the risk of some types of cancers." These include white-blood-cell cancers such as non-Hodgkin's lymphoma, myeloma, and lymphocytic leukemia, as well as breast cancer, the agency says.

The National Air Toxics Assessment relied on an EPA hazard analysis for ethylene oxide done in 2016. In that analysis, the agency classified the chemical as a human carcinogen because of studies that found increased risk of white-blood-cell cancers in workers exposed to the chemical. That hazard analysis determined that there is a one-in-a-million chance of developing cancer from inhaling 0.1 parts per trillion (ppt) of ethylene oxide over a lifetime. How that 0.1 ppt value would translate into rules under the Clean Air Act is unclear because the EPA regulates hazardous air pollutants like ethylene oxide by requiring installation of the maximum emission controls available.

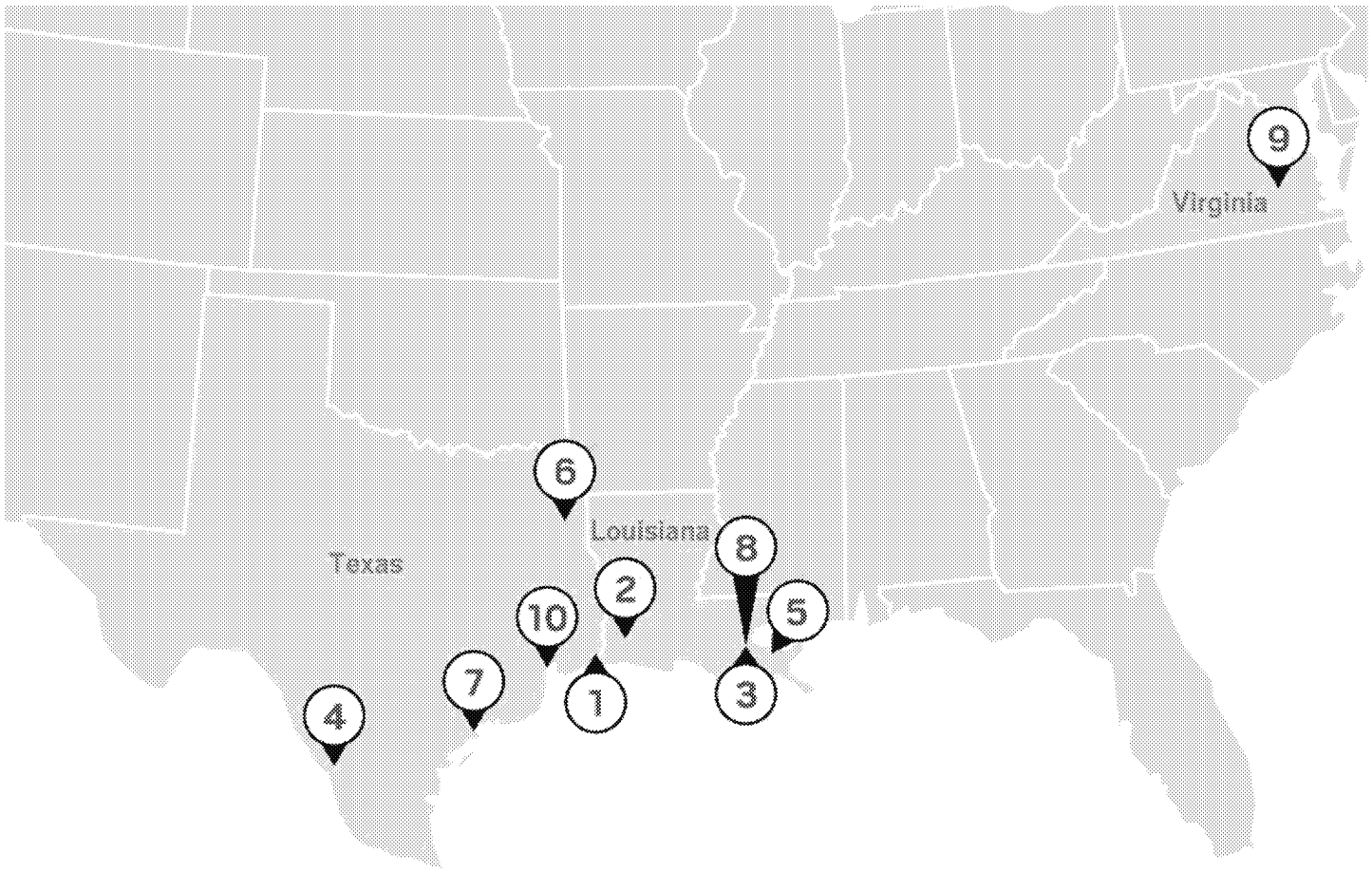
The ACC, the chemical manufacturers' group, is attacking the 0.1 ppt number, calling it "overly conservative . . . to the point of absurdity." In part, the ACC argues that estimates of historical exposures of workers to ethylene oxide were inaccurate. In a September 2018 letter to the EPA, the ACC asked the agency to withdraw the National Air Toxics Assessment's cancer-risk estimates for ethylene oxide and to revise them with "scientifically-supportable risk values." The EPA hasn't yet responded to the ACC's request.

Environmental advocates disagree with the ACC's position.

a well-supported conclusion on the potent cancer risk from this air pollutant after a multiyear process and independent peer review," says Emma Cheuse, an attorney for the nonprofit environmental law group Earthjustice. "EPA has no scientific reason to try to ignore the evidence of cancer risk from ethylene oxide."

Letting it out

Eight of the top 10 US emitters of ethylene oxide in 2017 were chemical manufacturing plants.



Ranking	Facility	Location	Ethylene oxide emitted (kg)
1	Huntsman Petrochemical[a]	Port Neches, TX	18,420
2	Sasol Chemicals	Westlake, LA	7,461
3	BASF	Geismar, LA	6,895
4	Midwest Sterilization	Laredo, TX	6,734
5	Union Carbide (owned by Dow)	Hahnville, LA	6,584
6	Eastman Chemical	Longview, TX	6,069
7	Union Carbide (owned by Dow)	Seadrift, TX	5,080
8	Shell Chemical	Geismar, LA	4,275
9	Sterilization Services of Virginia	Richmond, VA	3,515
10	Celanese	Pasadena, TX	2,870

Source: EPA Toxics Release Inventory. a Huntsman announced in August the sale of this plant to Indorama Ventures.

Environmental groups are particularly worried because Texas is embracing an alternative approach endorsed by the ACC that deems ethylene oxide less potent than the EPA does. The TCEQ used a different dose-response model than the EPA. It's a model that the ACC lobbied for the state agency to use, according to a presentation the chemical industry group gave to the TCEQ. Texas released the presentation slides in response to a public records request from the Lone Star Chapter of the Sierra Club, which shared them with C&EN.

The main difference between the EPA and the TCEQ calculations is that the state agency assumes that people in the worker study who had the lowest exposure to ethylene oxide represent the baseline exposure for the entire population, says Elena Craft, senior director of climate and health at the Environmental Defense Fund (EDF), an advocacy group. The EPA, on the other hand, assumes that some people are not exposed to the chemical, and those who are not exposed are the baseline for the risk calculation. On the basis of its analysis, the TCEQ in June proposed what it terms an "effects screening level" of 4 ppb—40,000 times as high as the EPA's number.

The Texas agency uses effects screening levels as it reviews applications for air pollution permits for new facilities. Screening levels aren't enforceable pollution limits and thus invoke no legal ramifications if a facility exceeds them, Craft explains.

In a statement, two TCEQ toxicologists describe the proposed 4 ppb level as "supported by robust science." One of those toxicologists is Michael Honeycutt, who chairs the EPA's Science Advisory Board and has long criticized the agency's hazard assessments of certain chemicals as being too stringent. The other, Sabine Lange, was appointed to the EPA's Clean Air Scientific Advisory Committee a year ago. Honeycutt and Lange have argued against the EPA's move to lower the national limit for ground-level ozone, saying it wouldn't measurably improve public health (*Int. J. Environ. Res. Public Health* 2018, DOI: 10.3390/ijerph15081586).

The Texas agency plans to revise its proposed assessment in response to public comments. The revised version will then undergo external peer review, a TCEQ spokesperson tells C&EN.

Adoption of the 4 ppb level by the TCEQ could pave the way in Texas for construction of new plants or expansion of existing facilities that make or use ethylene oxide, the Sierra Club's Carman says. It could also be used to challenge the EPA's hazard assessment methodology for the chemical, the EDF's Craft says.

ACC spokesperson Tom Flanagin says, "When finalized, TCEQ's risk value could serve as a needed alternative to EPA's flawed ethylene oxide risk value."

Whether a final TCEQ number could sway the Trump EPA, which is implementing regulatory rollbacks, isn't clear. At a recent congressional hearing, EPA administrator Andrew Wheeler said the agency is using the 2016 hazard analysis for its ethylene oxide regulatory efforts. Then he added, "We use all the available science."

The EPA is on the brink of releasing its updated regulations for hazardous air pollutants emitted by manufacturers of miscellaneous organic chemicals, including ethylene oxide. The White House Office of Management and Budget is reviewing the draft plan, the EPA said Sept. 13. The proposal is expected to be made public in the coming weeks or months. After the EPA receives public comments on the proposal, the agency will prepare a final rule, keeping an eye on the March deadline.

But the EPA's regulatory action on ethylene oxide emissions is not likely to end there. The agency says it is examining ethylene oxide emissions from other sectors, including polyether polyol production, synthetic organic chemical manufacturing, and sterilizers at hospitals. The agency will eventually decide whether industry-specific regulations on ethylene oxide emissions need to be revised.

For the Sierra Club's Carman, the bottom line is clear: "We don't need more ethylene oxide pollution. We need less."

STERILIZATION PLANTS USING ETHYLENE OXIDE FACE SCRUTINY

Ethylene oxide has garnered headlines in recent months in connection with US facilities that use the carcinogenic gas to sterilize medical devices. Regulators and the public are concerned that emissions of the chemical from some sterilization facilities pose health risks to people living near them.

Igniting these concerns was a recent assessment by the US Environmental Protection Agency showing that communities surrounding medical sterilization plants outside Chicago and Atlanta face a high cancer risk from ethylene oxide exposure.

Companies use ethylene oxide to kill germs on equipment and plastic devices that can't be sterilized with steam, according to the US Food and Drug Administration. Examples include wound dressings, stents, and catheters. Medical devices most likely to be sterilized with ethylene oxide are made from plastic, resin, metals, or glass. They may have multiple layers of packaging or hard-to-reach components, the FDA adds.

"For many medical devices, sterilization with ethylene oxide may be the only method that effectively sterilizes and does not damage the device during the sterilization process," the FDA says.

In July, the FDA unveiled two innovation challenges aimed at reducing emissions of the carcinogenic gas from the sterilization industry. One focuses on the development of new methods that don't rely on ethylene oxide to render medical devices free of pathogens. The second targets strategies or technologies to make emissions from ethylene oxide sterilization as close to zero as possible.

The current EPA regulation for sterilization facilities, issued in 1994, requires sterilization plants to use devices that reduce ethylene oxide in exhaust gases by 99%. It establishes a maximum allowable concentration of 5,300 ppm by volume of ethylene oxide in sterilization chambers before exhaust begins.

The EPA announced Sept. 13 that it will soon ask commercial sterilization companies to provide information on pollution-control devices, work practices, and costs of installing and operating emission-reduction technology. Eventually, the agency could propose a rule to clamp down on ethylene oxide releases from these facilities.

While the EPA gathers information, regulators in Illinois and Georgia are acting.

Illinois officials shut down Sterigenics sterilization operations in a Chicago suburb in February, citing concerns about the health risks from ethylene oxide emissions. The company's two facilities in Willowbrook, Illinois, remain closed. A court-approved consent order allows Sterigenics to reopen after it installs new pollution-control equipment. Meanwhile, an Illinois law enacted in June requires sterilization companies throughout the state to reduce their ethylene oxide releases.

In Georgia, Sterigenics struck a legal deal in August with the state to improve emission controls at a plant in Smyrna. The company announced in early September that it would suspend its operations at that facility until construction of pollution technology was complete.

In addition, Becton, Dickinson, and Company said in July that it is spending $8 million on new emission-reduction technologies for two sterilization plants also in metro Atlanta. The company said it is taking the action even though both plants "currently achieve greater than 99.95% destruction" of ethylene oxide in their emissions.