

October 10, 2019

ATTORNEY GENERAL RAOUL URGES EPA TO IMPLEMENT STRICTER ETHYLENE OXIDE EMISSION STANDARDS AND FIND ALTERNATIVES TO ETHYLENE OXIDE STERILIZATION

Chicago — Attorney General Kwame Raoul today led a coalition of 15 attorneys general in urging the U.S. Environmental Protection Agency (EPA) to promptly propose and finalize stricter standards for ethylene oxide (EtO) emissions and support research into alternatives to EtO sterilization. According to the EPA's own assessment, EtO is a carcinogen to humans by inhalation and among the most hazardous air pollutants.

[In a letter](#) sent to the EPA, Raoul and the coalition argue that the current EPA standard for EtO fails to adequately protect workers and communities and stricter emissions standards are necessary to protect residents nationwide from the harmful effects of EtO. Raoul and the coalition recognize that a critical step in reducing EtO emissions is to reduce the use of EtO, which is why the attorneys general are also calling on the EPA to work with the U.S. Food and Drug Administration (FDA) to support research into effective alternatives to EtO sterilization and end the over-reliance on the practice.

"Illinois has already acted to significantly reduce EtO emissions, but there is an urgent need for the EPA to adopt national restrictions to protect communities throughout the country," Raoul said. "All families, regardless of where they live, deserve to have confidence that their air is safe to breathe. The EPA has a responsibility to protect the health and safety of residents across the country by regulating hazardous air pollutants. I urge the EPA to live up to this responsibility and implement the standards needed to protect all residents from the risks posed by EtO emissions."

Commercial sterilization facilities are a major source of EtO emissions across the nation. Emissions from these facilities are subject to a National Emissions Standard for Hazardous Air Pollutants (NESHAP), which the EPA is required to review every eight years. The EPA last reviewed the NESHAP for commercial sterilizers in 2006 and failed to make any meaningful changes. In 2001, the EPA ended the requirement that facilities control emissions from the back vents of the chambers used to conduct EtO sterilization. As a result of this step backward, thousands of pounds of EtO escape out of these vents and into the ambient air annually, in addition to the tens of thousands of pounds of EtO the current NESHAP allows commercial sterilizers to release into communities annually.

Over 288,000 people live in areas across the country that the EPA identified to be at elevated risk of EtO exposure, and there are more than 100 commercial sterilization facilities subject to the nationwide EtO standard. These facilities are located in 36 states, including Illinois. Because the EPA has not updated the national standard to reflect current science, states have been required to step in and reevaluate the emissions standard for EtO, leading to a dramatic reduction in EtO emissions in those areas.

Attorney General Raoul has been an advocate for stricter limits on EtO emissions. Illinois recently passed the nation's strictest limits on ethylene oxide emissions from sterilization facilities. EtO-emitting sterilization facilities are prohibited from operating in Illinois unless the facility captures 100 percent of all EtO emissions generated by the facility. Additionally, these facilities must reduce EtO emissions to the atmosphere from each exhaust point by at least 99.9 percent, or to no more than 0.2 parts per million. The law also requires facilities to conduct annual emissions tests and submit results to the Illinois EPA. If a facility fails to meet the reduced emissions requirements, it must immediately cease operations. In 2018, the Attorney General's office filed a lawsuit against Sterigenics over toxic air pollution violations due to the release of EtO at its Willowbrook, Ill. plant. In September, Attorney General Raoul and DuPage County State's Attorney Robert Berlin obtained a court-enforced order that prevented Sterigenics from reopening unless and until it could

meet the stringent new standards. Earlier this month, Sterigenics announced that it will permanently close its Willowbrook plant.

Joining Raoul in the letter are the attorneys general of California, Connecticut, Delaware, the District of Columbia, Iowa, Maryland, Massachusetts, Minnesota, New Mexico, New York, North Carolina, Rhode Island, Vermont, Virginia, and Wisconsin.



OFFICE OF THE ATTORNEY GENERAL
STATE OF ILLINOIS

KWAME RAOUL
ATTORNEY GENERAL

October 10, 2019

The Honorable Andrew Wheeler
Administrator
U.S. Environmental Protection Agency
USEPA Headquarters
William Jefferson Clinton Building
1200 Pennsylvania Avenue N.W.
Mail Code: 1101A
Washington, D.C. 20460

Re: NESHAP for Ethylene Oxide Commercial Sterilizers

Dear Administrator Wheeler:

The undersigned Attorneys General of Illinois, California, Connecticut, Delaware, the District of Columbia, Iowa, Maryland, Massachusetts, Minnesota, New Mexico, New York, North Carolina, Rhode Island, Vermont, Virginia, and Wisconsin respectfully submit this letter urging the U.S. Environmental Protection Agency (EPA) to promptly propose and finalize stricter standards for ethylene oxide (EtO) emissions. As Attorneys General, we are charged in each of our respective States with enforcing laws to protect the health and safety of our residents. We are concerned that the current EPA standard for EtO fails to adequately protect workers and communities, and believe that stricter emissions standards for EtO are necessary to safeguard exposed populations nationwide from the harmful effects of this pollutant. We also believe that the use of EtO, particularly in the medical device sterilization industry, which is a major source of EtO emissions, must be reduced. That is why, in addition to calling for an appropriate stricter emissions standard for EtO, we are also calling on EPA to work with the U.S. Food and Drug Administration (FDA) to support research into effective alternatives to EtO sterilization.

Commercial sterilization facilities are a major source of EtO emissions across the nation. As you know, EtO emissions from these facilities are subject to a National Emissions Standard for Hazardous Air Pollutants (NESHAP), and Section 112(d)(6) of the federal Clean Air Act requires that the EPA review the sufficiency of NESHAPs every eight years. The EPA last

reviewed the NESHAP for commercial sterilizers in 2006, retaining the original standard from 1994. Unfortunately, the only change that EPA has made to the original NESHAP was a step in the wrong direction. In 2001, EPA ended the requirement that facilities control emissions from the back vents of the chambers used to conduct EtO sterilization. As a result of this step backward, thousands of pounds of EtO escape out of these vents and into the ambient air annually. Even without accounting for these back vent emissions, the current NESHAP allows commercial sterilizers to release tens of thousands of pounds of EtO annually into the communities in which they operate. We believe this must change and should be addressed by EPA in the next round of EtO regulations.

In September 2018, EPA informed the State of Illinois that EPA had started to review and update the NESHAP.¹ On May 29, 2019, EPA officials attended a community meeting in Illinois and informed thousands of residents that “regulatory action” was required and that a revised NESHAP would be proposed between July and September 2019.² However, in a recent follow-up letter to Illinois, EPA wrote that it now intends to “propose” a rulemaking “[i]n the months ahead”³—even though EPA is now more than five years behind in fulfilling its statutory obligation to review the NESHAP for EtO. While excessive amounts of EtO are constantly being released into the atmosphere, EPA continues to move much too slowly to adopt the regulations needed to protect the public from this carcinogen.

Since the time the NESHAP was adopted in 1994 (and subsequently reviewed in 2006), the evidence of the risk of EtO has increased. Scientific and technological developments in the thirteen years since the EPA last reviewed the NESHAP have firmly established the need to strengthen the standard. In December 2016, EPA completed its long-awaited Integrated Risk Information System (IRIS) assessment of EtO. This assessment confirmed that EtO is carcinogenic to humans by inhalation and declared EtO to have an inhalation cancer risk that is 30 times higher than previously estimated. The revised IRIS risk estimate was then used in the EPA’s most recent National Air Toxics Assessment (the “2014 NATA”), released in August 2018, showing that EtO is among the most hazardous air pollutants posing the greatest health risks in the largest number of urban areas in the country. Alarming, the 2014 NATA shows 58 census tracts in 18 different counties across 12 states that have EtO air emissions at levels that pose cancer risks higher than 1 in 10,000 people. Over 288,000 people live in the areas across the country that the EPA identified to be at elevated risk of EtO exposure. The potentially elevated cancer risk identified in the 2014 NATA has understandably led to heightened public concern and scrutiny of facilities that emit EtO.

¹ Letter from William L. Wehrum, Assistant Administrator to Bruce Rauner, Governor (September 27, 2018), available at https://www.epa.gov/sites/production/files/2018-10/documents/signed_response_to_hon_bruce_rauner.pdf.

² Presentation of Michael Koerber, Deputy Director, Office of Air Quality Planning & Standards, Office of Air and Radiation, U.S. Environmental Protection Agency, “Overview of Current Information” (May 29, 2019), available at <https://www.epa.gov/sites/production/files/2019-05/documents/epa-overview-current-information.pdf>.

³ Letter from Anne L. Idsal, Acting Assistant Administrator to Jay Robert Pritzker, Governor (September 13, 2019), available at https://www.epa.gov/sites/production/files/2019-09/documents/governor_of_illinois2019-09-16-103553.pdf.

There are more than 100 commercial sterilization facilities subject to the nationwide EtO standard. These facilities are located in 36 states and territories, including in many of the jurisdictions we represent. Because EPA has not updated the national standard to reflect current science, states have been required to step in and reevaluate the emissions standards for EtO. Multiple states have responded expeditiously to the 2014 NATA—and to elevated levels of EtO in communities surrounding the facilities in their states—by requiring facilities to reduce emissions of EtO. These state-led actions have resulted in a dramatic reduction in EtO emissions in those areas. Communities across the country deserve to be similarly protected from this dangerous toxin. Furthermore, EPA must move expeditiously to adequately regulate EtO, which is classified as a hazardous air pollutant (HAP) under federal law, to ensure a national minimum standard for EtO emissions. Regulating HAPs is EPA’s responsibility, and EPA owes it to the public, regulators, and the regulated community to meet its crucial obligation to protect the health and safety of the nation’s residents.

We also recognize that a critical step in reducing EtO emissions is to reduce the use of EtO. That is why we are calling on the FDA, copied on this letter, to fund research into effective alternatives to ethylene oxide sterilization. We commend the steps the FDA has already taken to identify new sterilization methods and technology to reduce EtO emissions through its public innovation challenges, but more needs to be done. Any and all strategies and technologies identified by the FDA should be considered by EPA in revising the NESHAP. EPA must also work with the FDA to ensure that the FDA adequately considers the health and environmental impacts of EtO in setting standards for sterilizing medical devices. EtO sterilization should not be used for a medical device when there is a safe alternative that does not pose a public health risk. The over-reliance on EtO sterilization must end.

The EPA is entrusted with the profound duty of safeguarding the air we breathe. We urge the EPA to fulfill its mandate and propose and finalize standards that will protect our residents from the risks posed by EtO emissions.

Respectfully,



KWAME RAOUL
Attorney General of Illinois



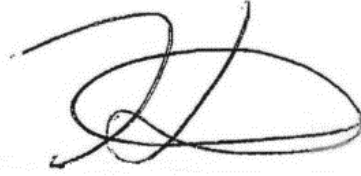
XAVIER BECERRA
Attorney General of California



WILLIAM TONG
Attorney General of Connecticut



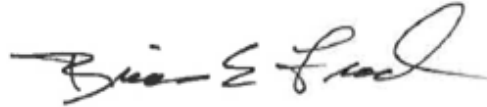
KATHLEEN JENNINGS
Attorney General of Delaware



KARL RACINE
Attorney General of the District of Columbia



TOM MILLER
Attorney General of Iowa



BRIAN FROSH
Attorney General of Maryland



MAURA HEALEY
Attorney General of Massachusetts



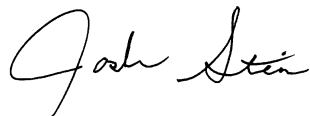
KEITH ELLISON
Attorney General of Minnesota



HECTOR BALDERAS
Attorney General of New Mexico



LETITIA JAMES
Attorney General of New York



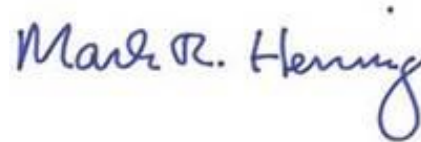
JOSHUA H. STEIN
Attorney General of North Carolina



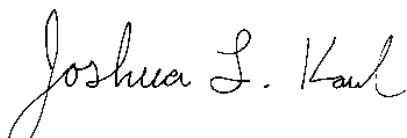
PETER F. NERONHA
Attorney General of Rhode Island



THOMAS J. DONOVAN, Jr.
Attorney General of Vermont



MARK R. HERRING
Attorney General of Virginia



JOSHUA L. KAUL
Attorney General of Wisconsin

cc: Commissioner of the FDA

Norman E. Sharpless, M.D.
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993