OFFICE OF THE ATTORNEY GENERAL
STATE OF ILLINOIS

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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. Alarmingly, 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.

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[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,

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cc: Commissioner of the FDA

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