



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

September 13, 2019

OFFICE OF  
AIR AND RADIATION

The Honorable Sean Casten  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Congressman Casten:

Thank you for your letters of February 13, 2019, and July 23, 2019, to the U.S. Environmental Protection Agency (EPA) about ethylene oxide. Addressing this chemical is a high priority for EPA, and I appreciate your interest in our ongoing work. The Administrator asked that I respond on his behalf.

As you may recall, EPA's National Air Toxics Assessment (NATA) found last year that ethylene oxide emissions may significantly contribute to potentially elevated cancer risk in several areas around the country. EPA has been taking a two-pronged approach to address these emissions. First, the Agency is reviewing its Clean Air Act (CAA) regulations for industrial facilities that emit ethylene oxide. An update on the status of our work on two National Emissions Standards for Hazardous Air Pollutants (NESHAP) addressing ethylene oxide is provided below. Second, we are working closely with our Regional offices and state and local air agencies to get additional information on facility emissions to determine whether more immediate emission reduction steps are necessary or possible in higher risk areas. This work is ongoing, and there have already been significant emission reductions in a number of areas.

### **Rulemaking Actions**

To ensure that its rules are defensible and sustainable, the Agency needs to build a solid, data-based record for its decisions. For the reviews of the NESHAP for Miscellaneous Organic Chemical Manufacturing (MON) and the NESHAP for Ethylene Oxide Commercial Sterilizers, EPA has had to compile information on emissions, potential control technology options and costs for the many potentially affected sources in these source categories. Much of this work has been, or soon will be, completed.

The Agency is under court order to issue a final risk and technology review of the MON rule by March 13, 2020. The proposed rulemaking is currently at the Office of Management and Budget (OMB) undergoing interagency review and will be issued following completion of that review.<sup>1</sup>

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<sup>1</sup> See <https://www.reginfo.gov/public/do/eoDetails?rrid=129437>

Over the past year, the Office of Air and Radiation has been gathering data to support its review of the NESHAP for commercial sterilizers. One challenge that we have identified is that about one-third of the more than 100 potentially affected facilities are small businesses. Given the potential impact of certain emission reduction strategies on these small businesses, the Agency may need to convene a Small Business Advocacy Review (SBAR) Panel before taking any significant regulatory action. EPA will soon request nominations to serve as small entity representatives as part of a possible SBAR Panel.

Currently, we are planning three upcoming actions for this source category:

1. In October, EPA intends to issue an Advance Notice of Proposed Rulemaking (ANPRM). This notice would describe and provide an opportunity for public comment on potential regulatory approaches and available control technologies and would provide an avenue for interested parties to give us additional data and information to support the future rulemaking.
2. Also, in October, EPA intends to issue a request for information under CAA section 114 to several commercial sterilization companies. This request will require companies to provide information that would support the notice-and-comment rulemaking, including data on specific facility characteristics, control devices, work practices, and costs associated with installation and operation of emission reduction strategies.
3. In the months ahead, we plan to propose a formal notice-and-comment rulemaking, informed if necessary by the SBAR Panel process. This rulemaking would begin with a proposed rule that would address the CAA-required technology review for this source category and is expected to include an assessment of the impacts of identified control strategies. This proposal will solicit public comment, and EPA will provide the opportunity for a public hearing. Once these important steps have been completed and the Agency has considered public input, then EPA would issue a final rule.

### **Area-Specific Activities**

Because our rulemaking process takes time, we decided that more immediate action may be needed in higher risk areas. Our Regional offices have been working with affected state and local air agencies to look more closely at emissions from facilities in these areas. The purpose of this work is to provide information to help us as we review our regulations and to identify whether it is possible to achieve early emission reductions. We have already seen facilities take steps, or commit to taking steps, to significantly reduce emissions and risk in a number of areas, including in Illinois, Georgia and other states. We also think it is critical to actively engage with affected communities. To this end, several of our Regional offices have conducted or participated in meetings with local elected officials and community groups. We are committed to continuing this engagement in the necessary areas.



Finally, I wish to note that some communities have asked EPA to conduct air monitoring. Because existing monitoring methods for certain air toxics, including ethylene oxide, have limitations, and because EPA's regulatory program for air toxics has traditionally relied on mathematical computer modeling to characterize outdoor air concentrations, we do not think such air monitoring is necessary to support actions to reduce emissions. As requested, however, EPA has provided technical assistance to communities wishing to conduct air toxics monitoring. In addition, in 2020, eligible localities will be able to apply for financial assistance for such monitoring through EPA's Community-Scale Air Toxics Ambient Monitoring grant competition. This program assists state, local and tribal communities in identifying air toxics sources, characterizing the degree and extent of local air toxics problems, and tracking progress of air toxics reduction activities. Information about these grants will be announced later this year and will be posted at <https://www.epa.gov/grants/air-grants-and-funding>.

I appreciate the opportunity to be of service and trust the information provided is helpful. I want you to know that EPA remains committed to its mission of protecting public health and the environment. If you have additional questions, please contact me or your staff may contact Austin Vela in the Office of Congressional Affairs at [vela.austin@epa.gov](mailto:vela.austin@epa.gov) or at (202) 564-1649.

Sincerely,

A handwritten signature in cursive script that reads "Anne L. Idsal".

Anne L. Idsal  
Acting Assistant Administrator



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

September 13, 2019

OFFICE OF  
AIR AND RADIATION

The Honorable Tammy Duckworth  
United States Senate  
Washington, D.C. 20510

Dear Senator Duckworth:

Thank you for your letters of October 12, 2018, February 13, 2019, July 18, 2019, and July 23, 2019, to the U.S. Environmental Protection Agency (EPA) about ethylene oxide. Addressing this chemical is a high priority for EPA, and I appreciate your interest in our ongoing work. The Administrator asked that I respond on his behalf.

As you may recall, EPA's National Air Toxics Assessment (NATA) found last year that ethylene oxide emissions may significantly contribute to potentially elevated cancer risk in several areas around the country. EPA has been taking a two-pronged approach to address these emissions. First, the Agency is reviewing its Clean Air Act (CAA) regulations for industrial facilities that emit ethylene oxide. An update on the status of our work on two National Emissions Standards for Hazardous Air Pollutants (NESHAP) addressing ethylene oxide is provided below. Second, we are working closely with our Regional offices and state and local air agencies to get additional information on facility emissions to determine whether more immediate emission reduction steps are necessary or possible in higher risk areas. This work is ongoing, and there have already been significant emission reductions in a number of areas.

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Over the past year, the Office of Air and Radiation has been gathering data to support its review of the NESHAP for commercial sterilizers. One challenge that we have identified is that about one-third of the more than 100 potentially affected facilities are small businesses. Given the potential impact of certain emission reduction strategies on these small businesses, the Agency may need to convene a Small Business Advocacy Review (SBAR) Panel before taking any significant regulatory action. EPA will soon request nominations to serve as small entity representatives as part of a possible SBAR Panel.

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Anne L. Idsal  
Acting Assistant Administrator





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

September 13, 2019

OFFICE OF  
AIR AND RADIATION

The Honorable Richard J. Durbin  
United States Senate  
Washington, D.C. 20510

Dear Senator Durbin:

Thank you for your letters of October 12, 2018, February 13, 2019, July 18, 2019, and July 23, 2019, to the U.S. Environmental Protection Agency (EPA) about ethylene oxide. Addressing this chemical is a high priority for EPA, and I appreciate your interest in our ongoing work. The Administrator asked that I respond on his behalf.

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Anne L. Idsal  
Acting Assistant Administrator



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

September 13, 2019

OFFICE OF  
AIR AND RADIATION

The Honorable Bill Foster  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Congressman Foster:

Thank you for your letters of October 12, 2018, February 13, 2019, and July 23, 2019, to the U.S. Environmental Protection Agency (EPA) about ethylene oxide. Addressing this chemical is a high priority for EPA, and I appreciate your interest in our ongoing work. The Administrator asked that I respond on his behalf.

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Anne L. Idsal  
Acting Assistant Administrator





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

September 13, 2019

OFFICE OF  
AIR AND RADIATION

The Honorable Daniel W. Lipinski  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Congressman Lipinski:

Thank you for your letters of February 13, 2019, and July 23, 2019, to the U.S. Environmental Protection Agency (EPA) about ethylene oxide. Addressing this chemical is a high priority for EPA, and I appreciate your interest in our ongoing work. The Administrator asked that I respond on his behalf.

As you may recall, EPA's National Air Toxics Assessment (NATA) found last year that ethylene oxide emissions may significantly contribute to potentially elevated cancer risk in several areas around the country. EPA has been taking a two-pronged approach to address these emissions. First, the Agency is reviewing its Clean Air Act (CAA) regulations for industrial facilities that emit ethylene oxide. An update on the status of our work on two National Emissions Standards for Hazardous Air Pollutants (NESHAP) addressing ethylene oxide is provided below. Second, we are working closely with our Regional offices and state and local air agencies to get additional information on facility emissions to determine whether more immediate emission reduction steps are necessary or possible in higher risk areas. This work is ongoing, and there have already been significant emission reductions in a number of areas.

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Acting Assistant Administrator



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

September 13, 2019

OFFICE OF  
AIR AND RADIATION

The Honorable Mike Quigley  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Congressman Quigley:

I would like to update you on the progress of our activities related to ethylene oxide. Addressing this chemical is a high priority for the U.S. Environmental Protection Agency (EPA), and I appreciate your interest in our ongoing work.

As you may recall, EPA's National Air Toxics Assessment (NATA) found last year that ethylene oxide emissions may significantly contribute to potentially elevated cancer risk in several areas around the country. EPA has been taking a two-pronged approach to address these emissions. First, the Agency is reviewing its Clean Air Act (CAA) regulations for industrial facilities that emit ethylene oxide. An update on the status of our work on two National Emissions Standards for Hazardous Air Pollutants (NESHAP) addressing ethylene oxide is provided below. Second, we are working closely with our Regional offices and state and local air agencies to get additional information on facility emissions to determine whether more immediate emission reduction steps are necessary or possible in higher risk areas. This work is ongoing, and there have already been significant emission reductions in a number of areas.

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### **Area-Specific Activities**

Because our rulemaking process takes time, we decided that more immediate action may be needed in higher risk areas. Our Regional offices have been working with affected state and local air agencies to look more closely at emissions from facilities in these areas. The purpose of this work is to provide information to help us as we review our regulations and to identify whether it is possible to achieve early emission reductions. We have already seen facilities take steps, or commit to taking steps, to significantly reduce emissions and risk in a number of areas, including in Illinois, Georgia and other states. We also think it is critical to actively engage with affected communities. To this end, several of our Regional offices have conducted or participated in meetings with local elected officials and community groups. We are committed to continuing this engagement in the necessary areas.

Finally, I wish to note that some communities have asked EPA to conduct air monitoring. Because existing monitoring methods for certain air toxics, including ethylene oxide, have limitations, and because EPA's regulatory program for air toxics has traditionally relied on mathematical computer modeling to characterize outdoor air concentrations, we do not think such air monitoring is necessary to support actions to reduce emissions. As requested, however, EPA has provided technical assistance to communities wishing to conduct air toxics monitoring. In addition, in 2020, eligible localities will be able to apply for financial assistance for such monitoring through EPA's Community-Scale Air Toxics Ambient Monitoring grant competition. This program assists state, local and tribal communities in identifying air toxics sources, characterizing the degree and extent of local air toxics problems, and tracking progress of air toxics reduction activities. Information about these grants will be announced later this year and will be posted at <https://www.epa.gov/grants/air-grants-and-funding>.

I appreciate the opportunity to be of service and trust the information provided is helpful. I want you to know that EPA remains committed to its mission of protecting public health and the environment. If you have additional questions, please contact me or your staff may contact Austin Vela in the Office of Congressional Affairs at [vela.austin@epa.gov](mailto:vela.austin@epa.gov) or at (202) 564-1649.

Sincerely,

A handwritten signature in cursive script, appearing to read "Anne L. Idsal".

Anne L. Idsal  
Acting Assistant Administrator





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

September 13, 2019

OFFICE OF  
AIR AND RADIATION

The Honorable Bradley S. Schneider  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Congressman Schneider:

Thank you for your letters of February 13, 2019, and July 23, 2019, to the U.S. Environmental Protection Agency (EPA) about ethylene oxide. Addressing this chemical is a high priority for EPA, and I appreciate your interest in our ongoing work. The Administrator asked that I respond on his behalf.

As you may recall, EPA's National Air Toxics Assessment (NATA) found last year that ethylene oxide emissions may significantly contribute to potentially elevated cancer risk in several areas around the country. EPA has been taking a two-pronged approach to address these emissions. First, the Agency is reviewing its Clean Air Act (CAA) regulations for industrial facilities that emit ethylene oxide. An update on the status of our work on two National Emissions Standards for Hazardous Air Pollutants (NESHAP) addressing ethylene oxide is provided below. Second, we are working closely with our Regional offices and state and local air agencies to get additional information on facility emissions to determine whether more immediate emission reduction steps are necessary or possible in higher risk areas. This work is ongoing, and there have already been significant emission reductions in a number of areas.

### **Rulemaking Actions**

To ensure that its rules are defensible and sustainable, the Agency needs to build a solid, data-based record for its decisions. For the reviews of the NESHAP for Miscellaneous Organic Chemical Manufacturing (MON) and the NESHAP for Ethylene Oxide Commercial Sterilizers, EPA has had to compile information on emissions, potential control technology options and costs for the many potentially affected sources in these source categories. Much of this work has been, or soon will be, completed.

The Agency is under court order to issue a final risk and technology review of the MON rule by March 13, 2020. The proposed rulemaking is currently at the Office of Management and Budget (OMB) undergoing interagency review and will be issued following completion of that review.<sup>1</sup>

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<sup>1</sup> See <https://www.reginfo.gov/public/do/eoDetails?rrid=129437>

Over the past year, the Office of Air and Radiation has been gathering data to support its review of the NESHAP for commercial sterilizers. One challenge that we have identified is that about one-third of the more than 100 potentially affected facilities are small businesses. Given the potential impact of certain emission reduction strategies on these small businesses, the Agency may need to convene a Small Business Advocacy Review (SBAR) Panel before taking any significant regulatory action. EPA will soon request nominations to serve as small entity representatives as part of a possible SBAR Panel.

Currently, we are planning three upcoming actions for this source category:

1. In October, EPA intends to issue an Advance Notice of Proposed Rulemaking (ANPRM). This notice would describe and provide an opportunity for public comment on potential regulatory approaches and available control technologies and would provide an avenue for interested parties to give us additional data and information to support the future rulemaking.
2. Also, in October, EPA intends to issue a request for information under CAA section 114 to several commercial sterilization companies. This request will require companies to provide information that would support the notice-and-comment rulemaking, including data on specific facility characteristics, control devices, work practices, and costs associated with installation and operation of emission reduction strategies.
3. In the months ahead, we plan to propose a formal notice-and-comment rulemaking, informed if necessary by the SBAR Panel process. This rulemaking would begin with a proposed rule that would address the CAA-required technology review for this source category and is expected to include an assessment of the impacts of identified control strategies. This proposal will solicit public comment, and EPA will provide the opportunity for a public hearing. Once these important steps have been completed and the Agency has considered public input, then EPA would issue a final rule.

### **Area-Specific Activities**

Because our rulemaking process takes time, we decided that more immediate action may be needed in higher risk areas. Our Regional offices have been working with affected state and local air agencies to look more closely at emissions from facilities in these areas. The purpose of this work is to provide information to help us as we review our regulations and to identify whether it is possible to achieve early emission reductions. We have already seen facilities take steps, or commit to taking steps, to significantly reduce emissions and risk in a number of areas, including in Illinois, Georgia and other states. We also think it is critical to actively engage with affected communities. To this end, several of our Regional offices have conducted or participated in meetings with local elected officials and community groups. We are committed to continuing this engagement in the necessary areas.



Finally, I wish to note that some communities have asked EPA to conduct air monitoring. Because existing monitoring methods for certain air toxics, including ethylene oxide, have limitations, and because EPA's regulatory program for air toxics has traditionally relied on mathematical computer modeling to characterize outdoor air concentrations, we do not think such air monitoring is necessary to support actions to reduce emissions. As requested, however, EPA has provided technical assistance to communities wishing to conduct air toxics monitoring. In addition, in 2020, eligible localities will be able to apply for financial assistance for such monitoring through EPA's Community-Scale Air Toxics Ambient Monitoring grant competition. This program assists state, local and tribal communities in identifying air toxics sources, characterizing the degree and extent of local air toxics problems, and tracking progress of air toxics reduction activities. Information about these grants will be announced later this year and will be posted at <https://www.epa.gov/grants/air-grants-and-funding>.

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Anne L. Idsal  
Acting Assistant Administrator



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

September 13, 2019

OFFICE OF  
AIR AND RADIATION

The Honorable Lauren Underwood  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Congresswoman Underwood:

I would like to update you on the progress of our activities related to ethylene oxide. Addressing this chemical is a high priority for the U.S. Environmental Protection Agency (EPA), and I appreciate your interest in our ongoing work.

As you may recall, EPA's National Air Toxics Assessment (NATA) found last year that ethylene oxide emissions may significantly contribute to potentially elevated cancer risk in several areas around the country. EPA has been taking a two-pronged approach to address these emissions. First, the Agency is reviewing its Clean Air Act (CAA) regulations for industrial facilities that emit ethylene oxide. An update on the status of our work on two National Emissions Standards for Hazardous Air Pollutants (NESHAP) addressing ethylene oxide is provided below. Second, we are working closely with our Regional offices and state and local air agencies to get additional information on facility emissions to determine whether more immediate emission reduction steps are necessary or possible in higher risk areas. This work is ongoing, and there have already been significant emission reductions in a number of areas.

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