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6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA-HQ-OAR-2018-0746; FRL-6494.1-01-OAR]

RIN 2060-AV54

Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; reconsideration of final rule.

SUMMARY: On August 12, 2020, the U.S. Environmental Protection Agency (EPA) published the final National Emission Standards for Hazardous Air Pollutants (NESHAP): Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review. Subsequently, the Agency received and granted petitions for reconsideration on two issues, specifically, the use of the EPA's 2016 Integrated Risk Information System (IRIS) value for ethylene oxide in assessing cancer risk for the source category and the use of the Texas Commission on Environmental Quality (TCEQ) risk value for ethylene oxide as an alternative risk value to the EPA's IRIS value. Here, the EPA is addressing these two issues and is also requesting public comment. The EPA is seeking comment only on the two identified petition issues. The EPA will not respond to comments addressing any other issues or any other provisions of the final rule.

DATES: *Comments.* Comments must be received on or before **[INSERT DATE 48 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

Public hearing: If anyone contacts us requesting a public hearing on or before [INSERT DATE 5 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], we will hold a virtual public hearing. See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA-HQ-OAR-2018-0746, by any of the following methods:

- Federal eRulemaking Portal: *https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- Email: *a-and-r-docket@epa.gov*. Include Docket ID No. EPA-HQ-OAR-2018-0746 in the subject line of the message.
- Fax: (202) 566-9744. Attention Docket ID No. EPA-HQ-OAR-2018-0746.
- Mail: U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA-HQ-OAR-2018-0746, Mail Code 28221T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460.
- Hand/Courier Delivery: EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m. – 4:30 p.m., Monday – Friday (except Federal holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/*, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are open to the public by appointment only to reduce the risk of transmitting COVID-19. Our Docket Center staff also continues to provide remote customer service via email, phone, and webform. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Ms. Tegan Lavoie, Sector Policies and Programs Division (E-143-01), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-5110; and email address: *lavoie.tegan@epa.gov*.

SUPPLEMENTARY INFORMATION:

Participation in virtual public hearing. Please note that because of the current Centers for Disease Control and Prevention (CDC) recommendations, as well as state and local orders for social distancing to limit the spread of COVID-19, the EPA cannot hold in-person public meetings at this time.

If requested, the virtual hearing will be held on [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The hearing will convene at 11:00 a.m. Eastern Time (ET) and will conclude at 7:00 p.m. ET. The EPA may close a session 15 minutes after the last pre-registered speaker has testified if there are no additional speakers. The EPA will announce further details at *https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission*.

The EPA will begin pre-registering speakers for the hearing upon publication of this document in the *Federal Register.* To register to speak at the virtual hearing, please use the online registration form available at *https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission* or contact the public hearing team at (888) 372-8699 or by email at *SPPDpublichearing@epa.gov*. The last day to pre-register to speak at the hearing will be [INSERT DATE 12 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Prior to the hearing, the EPA will post a general agenda that will list pre-registered speakers in approximate order at: *https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission*.

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing, if requested, however, please plan for the hearings to run either ahead of schedule or behind schedule.

If a hearing is requested, each commenter will have 5 minutes to provide oral testimony. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically (via email) by emailing it to lavoie.tegan@epa.gov. The EPA also recommends submitting the text of your oral testimony as written comments to the rulemaking docket.

The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing, if requested, will be posted online at *https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission*. While the EPA expects the hearing, if requested, to go forward as set forth above, please monitor our website to determine if there are any updates. The EPA does not intend to publish a document in the *Federal Register* announcing updates.

If you require the services of a translator or special accommodation such as audio description, please pre-register for the hearing with the public hearing team and describe your needs by [INSERT DATE 7 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The EPA may not be able to arrange accommodations without advanced notice.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA-HQ-OAR-2018-0746. All documents in the docket are listed in *https://www.regulations.gov/*. Although listed, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available

only in hard copy. With the exception of such material, publicly available docket materials are available electronically in Regulations.gov.

Instructions. Direct your comments to Docket ID No. EPA-HQ-OAR-2018-0746. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov/*, including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically any information that you consider to be CBI or other information whose disclosure is restricted by statute. This type of information should be submitted by mail as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*.

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/*, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your

comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets*.

Due to public health concerns related to COVID-19, the Docket Center and Reading Room are open to the public by appointment only. Our Docket Center staff also continues to provide remote customer service via email, phone, and webform. Hand deliveries or couriers will be received by scheduled appointment only. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets*.

The EPA continues to carefully and continuously monitor information from the CDC, local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID-19.

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404-02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA-HQ-OAR-2018-0746. Note that

written comments containing CBI and submitted by mail may be delayed and no hand deliveries will be accepted.

Preamble acronyms and abbreviations. Throughout this document wherever "we," "us," or "our" is used, it is intended to refer to the EPA. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

ACC	American Chemistry Council
AIC	Akaike Information Criterion
ATSDR	Agency for Toxic Substances and Disease Registry
CAA	Clean Air Act
CBI	Confidential Business Information
CFR	Code of Federal Regulations
DSD	Development Support Document
EPA	Environmental Protection Agency
HAP	hazardous air pollutant(s)
IRIS	Integrated Risk Information System
MACT	maximum achievable control technology
MON	Miscellaneous Organic Chemical Manufacturing NESHAP
NAICS	North American Industry Classification System
NESHAP	national emission standards for hazardous air pollutants
NIOSH	National Institute for Occupational Safety and Health
NTTAA	National Technology Transfer and Advancement Act
OAQPS	Office of Air Quality Planning and Standards
OAR	Office of Air and Radiation
OMB	Office of Management and Budget
PRA	Paperwork Reduction Act
RFA	Regulatory Flexibility Act
RFC	request for correction
RTR	residual risk and technology review
SAB	Science Advisory Board
SSM	startup, shutdown, and malfunction
TCEQ	Texas Commission on Environmental Quality
UMRA	Unfunded Mandates Reform Act
URE	unit risk estimate

Organization of this document. The information in this preamble is organized as follows:

I. General Information
A. What is the statutory authority for the reconsideration action?

B. Does this action apply to me?
C. Where can I get a copy of this document and other related information?
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III. Reconsideration Issues and Request for Public Comments
A. Use of the EPA's IRIS Value for Ethylene Oxide in Assessing Cancer Risk for the Source Category
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G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR part 51
J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

A. What is the statutory authority for the reconsideration action?

The statutory authority for this action is provided by sections 112 and 307(d)(7)(B) of the Clean Air Act (CAA) (42 U.S.C. 7412 and 7607(d)(7)(B)).

B. Does this action apply to me?

Regulated entities. Categories and entities potentially regulated by this action are shown in Table 1 of this preamble.

TABLE 1. NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS PROPOSED ACTION

Source Category	NESHAP	NAICS Code[1]
Miscellaneous Organic Chemical Manufacturing	40 CFR part 63, subpart FFFF	3251, 3252, 3253, 3254, 3255, 3256, and 3259, with several exceptions

[1] North American Industry Classification System.

Table 1 of this preamble is not intended to be exhaustive, but rather provides a guide for readers regarding the entities that this proposed action is likely to affect. To determine whether your facility is affected, you should examine the applicability criteria in the appropriate NESHAP. If you have any questions regarding the applicability of any aspect of these NESHAP, please contact the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

C. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this action is available on the Internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission*. Following publication in the *Federal Register*, the EPA will post the *Federal Register* version of the proposal at this same website.

II. Background

On December 17, 2019, the EPA published a proposed rule in the *Federal Register* addressing the risk and technology review (RTR) for the Miscellaneous Organic Chemical Manufacturing NESHAP (MON), 40 CFR part 63, subpart FFFF (84 FR 69182). On August 12, 2020, after receiving and addressing public comments, the EPA finalized determinations pursuant to CAA sections 112(d)(6) and (f)(2) for the Miscellaneous Organic Chemical Manufacturing source category and amended the rule based on those determinations (85 FR 49084). The August 2020 final action, herein referred to as the "2020 MON final rule," included amendments pursuant to the technology review for equipment leaks and heat exchange systems, and also amendments pursuant to the risk review to specifically address ethylene oxide emissions from storage tanks, process vents, and equipment leaks. In addition, the 2020 MON final rule

corrected and clarified regulatory provisions related to emissions during periods of startup, shutdown, and malfunction (SSM), including removing general exemptions for periods of SSM, adding work practice standards for periods of SSM where appropriate, and clarifying regulatory provisions for certain vent control bypasses. The final action also added monitoring and operational requirements for flares that control ethylene oxide emissions and flares used to control emissions from processes that produce olefins and polyolefins, added provisions for electronic reporting of performance test results and other reports, and included other technical corrections to improve consistency and clarity.

In the 2020 MON final rule's risk assessment,[1] we calculated cancer risks using the EPA's IRIS inhalation unit risk estimate (URE) for ethylene oxide,[2] and the risk review included a determination that the risks for this source category under the current Maximum Achievable Control Technology (MACT) provisions were unacceptable due to ethylene oxide emissions. When risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level. As such, the EPA promulgated final amendments to the MON pursuant to CAA section 112(f)(2) that require control of ethylene oxide emissions for process vents, storage tanks, and equipment in ethylene oxide service. The 2020 MON final rule reduced risks to an acceptable level that also provides an ample margin of safety to protect public health. The final rule preamble stated that "the EPA remains open to new and updated scientific information," and new dose-response values, such as those then being developed by the TCEQ (85 FR 49098). However, by the close of the public comment period for the proposed

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[1] Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review: Final Rule, August 2020. Available at: https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0189.

[2] U.S. EPA. *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) In Support of Summary Information on the Integrated Risk Information System (IRIS).* December 2016. EPA/635/R-16/350Fa. Available at: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf and in the docket for this rulemaking (see Docket ID No. EPA-HQ-OAR-2018-0746).

rulemaking (March 19, 2020), the TCEQ dose-response value had not yet been finalized and could not be considered in the final action.

Following promulgation of the 2020 MON final rule, the EPA received five separate petitions for reconsideration from four petitioners. The EPA received two petitions from the American Chemistry Council (ACC) (one petition dated October 2020, one dated December 2020), one from the TCEQ (dated October 2020), one from Squire Patton Boggs (US) LLP (submitted on behalf of Huntsman Petrochemical, LLC) (dated October 2020), and one from Earthjustice (submitted on behalf of RISE St. James, Louisiana Bucket Brigade, Louisiana Environmental Action Network, Texas Environmental Justice Advocacy Services (t.e.j.a.s.), Air Alliance Houston, Ohio Valley Environmental Coalition, Blue Ridge Environmental Defense League, Inc., Environmental Justice Health Alliance for Chemical Policy Reform, Sierra Club, Environmental Integrity Project, and Union of Concerned Scientists) (dated October 2020). Copies of the petitions are available in the docket for this rulemaking (see Docket ID No. EPA-HQ-OAR-2018-0746).

Three petitioners (ACC, TCEQ, Huntsman Petrochemical, LLC) requested the EPA reconsider the rule to reassess the risk assessment for the 2020 MON final rule using the TCEQ's alternative risk value for ethylene oxide instead of the EPA's 2016 IRIS value for ethylene oxide. These three petitioners further argued that the EPA's 2016 IRIS value for ethylene oxide is flawed, citing disagreement with the 2016 IRIS assessment's model selection and inclusion of breast cancer data. In their October 2020 petition, ACC argued that "CAA Section 307(d)(7)(B) requires EPA to convene a reconsideration proceeding where (1) it was either impractical to raise an objection during the comment period or new information becomes available after the close of the comment period; and (2) such information is of central relevance to the outcome of the rule." Earthjustice did not raise a similar issue in their petition. Two petitioners (ACC and Earthjustice) raised other issues unrelated to the use of the IRIS value or TCEQ value for assessing risk from ethylene oxide emissions (see Docket ID No. EPA-HQ-OAR-2018-0746).

On June 22, 2021, the EPA sent letters to all the petitioners informing them that: (1) the EPA was granting reconsideration requests on two specific issues (described later in this section), (2) the EPA intended to issue a *Federal Register* document initiating a notice and comment rulemaking on the issues for which the Agency granted reconsideration, and (3) the EPA was continuing to review the other issues in the petitions for reconsideration and may choose to initiate reconsideration of additional issues in the future. Copies of the letters to petitioners are available in the docket for this rulemaking (see Docket ID No. EPA-HQ-OAR-2018-0746).

Pursuant to CAA section 307(d)(7)(B), the Agency granted reconsideration of the following aspects of the 2020 MON final rule: (1) the use of the EPA's IRIS value for ethylene oxide in assessing cancer risk for the source category, and (2) the use of the TCEQ risk value for ethylene oxide as an alternative risk value to the EPA's IRIS value for purposes of evaluating risk under CAA section 112(f)(2). Reconsideration was granted on these two topics on the following bases: the TCEQ risk value for ethylene oxide was finalized after the comment period for the proposed MON rulemaking closed, and the 2020 MON final rule preamble stated that the EPA remains open to new and updated scientific information, such as the TCEQ value; and because the risk posed by ethylene oxide is of central relevance to the EPA's determination that the risks from sources in the Miscellaneous Organic Chemical Manufacturing source category remaining after imposition of the then-current CAA section 112(d)(2) MACT standards were unacceptable and that more stringent standards are required. Because the criteria for mandatory reconsideration under CAA section 307(d)(7)(B) have been satisfied, the Agency is publishing this proposed reconsideration action in the *Federal Register* and requesting public comment on the issues discussed in this action. The EPA is seeking comment only on the issues subject to mandatory reconsideration and discussed in this proposed rule. The Agency will not respond to any comments addressing other issues raised by petitioners related to the 2020 MON final rule,

or the EPA's December 13, 2021 response[3] to the Request for Correction (RFC)[4] of the IRIS value for ethylene oxide that was submitted to the EPA by petitioner ACC under the Information Quality Act, Pub. L. No. 106-554 (IQA). As discussed in section III.B of this preamble, the ACC requested correction of the ethylene oxide information in the EPA's most recent update to the National Air Toxics Assessment (NATA) released on August 22, 2018. In the EPA's response to the RFC, the EPA found that the RFC did not identify a need for correction in the 2016 ethylene oxide IRIS Assessment and determined that the inhalation URE derived in the 2016 ethylene oxide IRIS Assessment was the appropriate human health value to use for ethylene oxide in the 2014 NATA. The EPA's response to the RFC noted that the EPA's use of the IRIS value in CAA rulemakings would be addressed in the reconsideration of the 2020 MON final rule, and that the review would include consideration of additional information presented in comments on the 2020 MON rule that were not included in the 2018 RFC and addressed in the EPA's response to the RFC. As such, we are not reconsidering comments on the EPA's reliance upon the National Institute for Occupational Safety and Health (NIOSH) worker exposure studies, selection of dose-response models, and consideration of endogenous sources (*i.e.*, what the body produces) of ethylene oxide that were previously addressed in the response to ACC's RFC.

III. Reconsideration Issues and Request for Public Comments

The EPA is proposing to take comment on the two selected issues raised in the petitions for reconsideration as described in sections III.A. and III.B. below.

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[3] U.S. EPA. EPA's Response to American Chemistry Council (ACC)'s Request for Correction to the IRIS Value for Ethylene Oxide (EtO) used in the National Air Toxics Assessment (NATA) in 2018. December 13, 2021. Available at: *https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration#18003* and in the docket for this rulemaking (see Docket ID No. EPA-HQ-OAR-2018-0746).

[4] American Chemistry Council. Request for Correction under the Information Quality Act: 2014 National Air Toxics Assessment (NATA). September 20, 2018. Available at: *https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration#18003* and in the docket for this rulemaking (see Docket ID No. EPA-HQ-OAR-2018-0746).

A. Use of the EPA's IRIS Value for Ethylene Oxide in Assessing Cancer Risk for the Source Category

The EPA's IRIS program was created to provide an internal Agency database of human health effects that may result from chronic exposure to chemicals found in the environment to which the public might be exposed. The IRIS database is intended to be used by the EPA's program and regional offices in risk assessments to inform decision making.[5] The development of IRIS values includes a robust peer-review, beginning with internal reviews to reach consensus within the Agency on the scientific positions, followed by external federal agency review, an opportunity for public review and comment, and an independent, external peer-review by the EPA's Science Advisory Board (SAB).[6] During this process, the EPA considers and responds to comments received from the public and the SAB, and revises the assessment to ensure that the best available science is represented.

During development of the 2020 MON final rule, the EPA used the 2016 IRIS cancer risk value for ethylene oxide[7] in the risk review. The EPA received and responded to numerous public comments on the use of the IRIS value in the 2020 MON final rule. A summary of these comments and responses is available in the preamble of the 2020 MON final rule (85 FR 49084; August 12, 2020) and also in the "Summary of Public Comments and Responses for the Risk and

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[5] U.S. EPA. Framework for Human Health Risk Assessment to Inform Decision Making. EPA/100/R-14/001. April 2014. Available at https://www.epa.gov/sites/default/files/2014-12/documents/hhra-framework-final-2014.pdf and in the docket for this rulemaking (see Docket ID No. EPA-HQ-OAR-2018-0746).

[6] U.S. EPA. Process for Developing IRIS Health Assessments. Integrated Risk Information System (IRIS). https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process.

[7] The age-adjusted inhalation URE for ethylene oxide is 0.005 per $\mu g/m^3$. The URE is the upper-bound additional lifetime cancer risk estimated to result from continuous (24 hours/day) lifetime (70 years) exposure to ethylene oxide at a concentration of 1 $\mu g/m^3$ in air. Because ethylene oxide is mutagenic (*i.e.*, damages DNA), an age-dependent adjustment factor was applied to account for childhood exposures.

Technology Review for Miscellaneous Organic Chemical Manufacturing" document in the docket for this rulemaking.[8]

For CAA section 112(f)(2) risk reviews, the EPA performs health risk assessments for the hazardous air pollutants (HAP) that are emitted from the source category after imposition of MACT standards under CAA section 112(d)(2). Consistent with the purpose of the IRIS database for use by the EPA's program and regional offices in risk assessments and the advice from the SAB, the "Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review: Final Rule" in the docket for this rulemaking[9] described that the preferred source of chronic dose-response data is the IRIS database. If the EPA's IRIS program does not have an up-to-date hazard and/or dose-response assessment for a HAP, the EPA considers publicly available assessments that have been developed by other government agencies in a manner that is conceptually similar to the EPA's approach. This includes consistency with the EPA's risk assessment guidelines, incorporation of an independent external peer review, inclusion of a public review period, and use of the best available science with respect to dose-response information.

Application of this approach generally results in the following priority order for sources of risk values such as an inhalation URE: 1) U.S. EPA IRIS, 2) Agency for Toxic Substances and Disease Registry (ATSDR), 3) California EPA, and 4) other sources. Documentation of this approach, as applied in the CAA section 112(f)(2) reviews, is in the EPA report titled "Risk and Technology (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board: Case Studies – MACT I Petroleum Refining Sources and Portland Cement

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[8] Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing, August 2020. Available at: https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0200.

[9] Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review: Final Rule, August 2020. Available at: https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0189.

Manufacturing".[10] This approach is also documented in the risk assessment technical support document for each RTR NESHAP rulemaking and is included in the rulemaking docket for this action.[11,12]

This approach was presented to the SAB in 2009. In a May 7, 2010, memo[13] to the EPA Administrator regarding review of the EPA's RTR assessment methodologies, the SAB panel supported the EPA's approach to selecting dose-response chronic toxicity values. In the same memo, they also noted that: "The preferred database for chronic dose-response data is and should be the IRIS database. However, some chemicals of interest do not have IRIS values, and values for other chemicals have not been reviewed recently. The Panel urges the Agency to address these gaps and provide the resources necessary to maintain the updating process. Additional sources of data may also be considered if they have undergone adequate and rigorous scientific peer review." *Id.* at 5.

In the 2020 MON final rule, the EPA followed this documented approach in selecting the 2016 EPA IRIS value for ethylene oxide for use in the risk review. We have carefully reviewed the three petitioners' comments that the 2016 IRIS value for ethylene oxide should not have been used, but after careful consideration of the issues raised, we have determined that these

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[10] U.S. EPA. *Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing, June 2009.* EPA-452/R-09-006. Available at https://www3.epa.gov/airtoxics/rrisk/rtrpg.html and in the docket for this rulemaking (see Docket ID No. EPA-HQ-OAR-2018-0746).

[11] Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing, August 2020. Available at: https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0200.

[12] Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review: Final Rule, August 2020. Available at: https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0189.

[13] SAB. Recommendations of the SAB Risk and Technology Review Methods Panel are provided in their report, *Review of EPA's draft entitled, "Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies – MACT I Petroleum Refining Sources and Portland Cement Manufacturing.* Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/$File/EPA-SAB-10-007-unsigned.pdf* and in the docket for this rulemaking (see Docket ID No. EPA-HQ-OAR-2018-0746).

petitioners have not identified a basis for changing our approach to the risk assessment in the 2020 MON final rule. The substantive arguments raised by these petitioners regarding the 2016 IRIS value have been addressed in the EPA's response to the RFC, in the 2020 MON final rule's preamble (85 FR 49084; August 12, 2020), and in the response to comment document[14] for the 2020 MON final rule; beyond these alleged flaws in the 2016 IRIS value, these petitioners have presented no new arguments for why the EPA should not follow the documented approach for selecting risk values. The EPA proposes to not change its decision to use the IRIS inhalation URE for ethylene oxide in the 2020 MON final rule. Consequently, the EPA is proposing no changes to our risk assessment for the 2020 MON final rule.

B. Use of the TCEQ Risk Value for Ethylene Oxide in Assessing Cancer Risk for the Source Category

During development of the 2020 MON final rule, the EPA received and responded to numerous public comments related to the use of the TCEQ's risk value for ethylene oxide as an alternative to the EPA's IRIS value in the 2020 MON risk assessment. TCEQ submitted its draft Development Support Document (DSD), which included the dose-response analysis underlying TCEQ's draft cancer risk value, as a comment during the 2020 MON rulemaking's comment period. Because the TCEQ risk value was not final until after the close of the comment period, the EPA did not directly assess the draft DSD from TCEQ in our final rule; however, the EPA received and addressed public comments from other groups (*e.g.*, ACC) that included the same analytical approaches utilized by TCEQ. A summary of these comments and responses is available in the 2020 MON final rule's preamble (85 FR 49084; August 12, 2020) and in the response to comment document[15] for the 2020 MON final rule. In this action, the EPA reaffirms

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[14] Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing, August 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0200*.

[15] Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing, August 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0200.*

those responses in support of its decision to use the IRIS inhalation URE in the 2020 MON final rule.

As part of this proposed reconsideration of the 2020 MON final rule, the EPA reviewed the final TCEQ ethylene oxide DSD, which TCEQ referenced in its petition for reconsideration, including the assertion that the final DSD contained "additional scientific analyses". Based on this review, we have determined that TCEQ did not submit new data for the EPA's consideration that would cause us to use the final TCEQ cancer risk value instead of the IRIS cancer risk value for the MON risk review. Rather, TCEQ has pursued a different approach to analyzing the same NIOSH occupational exposure dataset that is the basis of the 2016 IRIS cancer risk value.

By using this approach, TCEQ estimated a risk value for ethylene oxide that is 2000-fold lower than that of the IRIS risk value.[16] TCEQ's analytical approach (*i.e.*, modeling mortality using a Cox proportional hazards model) closely mirrors the approach by Valdez-Flores (2010)[17] previously presented by other public commenters in the 2020 MON final rule, and which the EPA addressed in both its response to comments document[18] and its December 13, 2021 response[19] to the ACC's 2018 RFC regarding the EPA's use of the IRIS value for ethylene oxide. In addition to pursuing an analytical approach similar to that used by Valdez-Flores (2010), TCEQ went a step further and excluded women from their analysis. This exclusion included all lymphoid cancers in women, as well as the exclusion of breast cancer as an endpoint. Although modeling cancer mortality (instead of cancer incidence, which the EPA modeled) and excluding

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[16] TCEQ's age-adjusted URE is 2.3×10^{-6} per $\mu g/m^3$

[17] Valdez-Flores C, Sielken RL Jr, Teta MJ. 2010. Quantitative cancer risk assessment based on NIOSH and UCC epidemiological data for workers exposed to ethylene oxide. Regul Toxicol Pharmacol, 56(3): 312-20.

[18] Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing, August 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0200*.

[19] U.S. EPA. EPA's Response to American Chemistry Council (ACC)'s Request for Correction to the IRIS Value for Ethylene Oxide (EtO) used in the National Air Toxics Assessment (NATA) in 2018. December 13, 2021. Available at: *https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration#18003* and in the docket for this rulemaking (see Docket ID No. EPA-HQ-OAR-2018-0746).

women from the lymphoid cancer analysis impacted the final URE value, the 2000-fold difference in the IRIS versus TCEQ risk values is driven primarily by two major differences: 1) TCEQ selected a different statistical model to represent the occupational exposure data; and 2) TCEQ excluded breast cancer from the derivation of a cancer risk value based on the claim that there is insufficient weight of evidence that ethylene oxide exposure causes breast cancer.

The questions of the appropriate dose-response model to use to evaluate the risk of ethylene oxide and the strength of the evidence linking ethylene oxide exposure to breast cancer were addressed in the 2016 ethylene oxide IRIS assessment. These questions were raised again in comments on the 2020 MON final rule and responded to in both the preamble (85 FR 49084; August 12, 2020) and associated response to comments document[18] for the 2020 MON final rule. Briefly, these responses note that the EPA's 2016 IRIS risk value for ethylene oxide is based on a statistical model selected to best represent the available data on cancers in workers exposed to ethylene oxide. This model, a two-piece linear spline model, was selected after extensive review by the EPA and the SAB. The Agency and the SAB[20,21] carefully considered and evaluated multiple alternative models, including a Cox proportional hazards regression model similar to that used by TCEQ. In its response to the SAB's recommendations, the EPA noted: "The EPA has followed the SAB's recommendations for model selection. Model selection for both the breast cancer incidence (see section 4.1.2.3) and lymphoid cancer (see section 4.1.1.2) data prioritizes functional forms that allow more local fits in the low-exposure range (*e.g.*, spline

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[20] SAB. (2007). *Science Advisory Board Review of Office of Research and Development (ORD) draft assessment entitled, "Evaluation of the Carcinogenicity of Ethylene Oxide" [EPA Report].* (EPA-SAB-08-004). Washington, DC: U.S. EPA, SAB. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/368203f97a15308a852574ba005bbd01/5D661BC118B527A3852573B80068C97B/$File/EPA-SAB-08-004-unsigned.pdf and in the docket for this rulemaking (see Docket ID No. EPA-HQ-OAR-2018-0746).

[21] SAB. (2015). *Science Advisory Board Review of the EPA's Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide: Revised external review draft—August 2014 [EPA Report].* (EPA-SAB-15-012). Washington, DC: U.S. EPA, SAB. Available at: https://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/BD2B2DB4F84146A585257E9A0070E655/$File/EPA-SAB-15-012+unsigned.pdf and in the docket for this rulemaking (see Docket ID No. EPA-HQ-OAR-2018-0746).

models), relies less on AIC[22], and includes consideration of biological plausibility..." (IRIS, 2016, Appendix I, p. I-3). As such, in the 2016 ethylene oxide IRIS assessment, the EPA selected a model that best represented potential general population exposures, making it align well with the purpose of the risk assessment in the 2020 MON final rule, which sought to assess general risk exposure to the public.

Additionally, the EPA considered the weight of evidence regarding the risk of breast cancer from exposure to ethylene oxide in the IRIS process. In the 2016 IRIS ethylene oxide assessment, the EPA determined that the available epidemiological evidence for a causal relationship between ethylene oxide exposure and breast cancer was strong, and there were sufficient data to include breast cancer in the derivation of the URE. The SAB supported this determination. Comments on the evidence for breast cancer as an endpoint following ethylene oxide exposure were also addressed during the review process for the IRIS ethylene oxide assessment. For example, in response to a public comment on the IRIS 2013 draft claiming that the evidence for breast cancer is too weak to rely on in setting the URE, the EPA responded:

"Although the epidemiological database for breast cancer is more limited (*i.e.*, few studies with sufficient numbers of female breast cancer cases) than that for lymphohematopoietic cancers, the EPA determined that the available evidence is sufficient to consider breast cancer a potential hazard from ethylene oxide exposure…The 2007 SAB panel did not object to the derivation of unit risk estimates based on the available breast cancer evidence." (IRIS, 2016, Appendix K, p. K-3).[23] The IRIS cancer risk value is representative of potential health risks to the general population because it reflects the combined cancer risk of developing lymphoid cancers in all people, and breast cancer in women.

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[22] The Akaike information criterion (AIC) is a mathematical model for evaluating how well a model fits the underlying dataset from which it was generated.

[23] U.S. EPA. *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) In Support of Summary Information on the Integrated Risk Information System (IRIS).* December 2016. EPA/635/R-16/350Fa. Available at: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf and in the docket for this rulemaking (see Docket ID No. EPA-HQ-OAR-2018-0746).

After careful consideration of the TCEQ DSD and material provided in the petitions for reconsideration that requested the EPA use TCEQ's final cancer risk value, the EPA is proposing to determine that the TCEQ assessment and the petitions for reconsideration do not provide a scientifically supportable basis for relying on the URE developed by TCEQ to assess the residual risk for sources in the 2020 MON final rule. No new studies or other information have been identified by TCEQ or the petitioners requesting reconsideration that would call into question the conclusions in the 2016 IRIS ethylene oxide assessment or suggest that TCEQ's URE provides a better estimate of the risk of exposure from ethylene oxide. The 2016 ethylene oxide IRIS assessment remains the best available science, and the EPA proposes to reaffirm its decision to use the IRIS inhalation URE in the 2020 MON final rule.

IV. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected sources?

We estimate that, as of November 6, 2018, there were 201 MON facilities, nine of which reported ethylene oxide emissions to the 2014 National Emissions Inventory. However, as the EPA is not proposing any changes to the regulatory text or regulatory requirements in this action, we do not anticipate that any sources will be affected by this reconsideration. A complete list of known MON facilities is available in Appendix 1 of the document, Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2019 Risk and Technology Review Proposed Rule, which is available in the docket for this rulemaking (see Docket Item No. EPA-HQ-OAR-2018-0746-0011).

B. What are the air quality impacts?

The EPA does not project any air quality impacts associated with this action because this action does not propose any changes to the standards or other requirements on affected sources.

C. What are the cost impacts?

The EPA does not project any incremental costs associated with this action because it does not propose any changes to the standards or other requirements on affected sources.

D. What are the economic impacts?

The EPA does not project any economic impacts because there are no incremental costs associated with this action.

E. What are the benefits?

The EPA does not project any incremental benefits associated with this action because it does not propose any changes to the standards or other requirements on affected sources.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the EPA concludes that the impact of concern for this rule is any significant adverse economic impact on small entities and that the Agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities if the rule has no net burden on the small entities subject to the rule. As we are not proposing any changes to the regulatory text or regulatory requirements, we do not anticipate any economic impacts resulting from this action. We have therefore concluded that this action will have no net regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action proposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. None of the MON facilities that have been identified as being affected by this action are owned or operated by tribal governments or located within tribal lands within a 10 mile radius. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because this action does not present any changes to the rule that would affect environmental health or safety risks, including those that would present a disproportionate risk to children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR part 51

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This regulatory action acts to clarify the language in the preamble of a previously promulgated regulatory action and does not have any impact on human health or the environment.

Michael S. Regan,

Administrator.

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