and in part 570 (21 CFR part 570) for animal food. Those regulations include a voluntary procedure (''GRAS notification procedure'') through which a proponent may notify us of a conclusion that a substance is GRAS under the conditions of its intended use in human food (part 170, subpart E) or animal food (part 570, subpart E).

In some cases, the process whereby the proponent evaluates whether the available data and information support a conclusion that a substance is GRAS under the conditions of its intended use includes considering the opinion of a ''GRAS panel'' of qualified experts who independently evaluate whether the available scientific data, information, and methods establish that a substance is safe under the conditions of its intended use in human food or animal food. Depending on the outcome of the GRAS panel's analysis, the proponent could either reach a conclusion regarding the safety of the substance under the conditions of its intended use or be advised of one or more issues (such as gaps in the data and information or alternative interpretations of the available data and information) that warrant investigation before a conclusion can be drawn about whether the substance is safe under the conditions of its intended use. When the outcome of the GRAS panel's analysis supports the proponent's conclusion that a substance is safe under the conditions of its intended use, in essence the proponent then relies on the members of the GRAS panel to act as a proxy for the larger scientific community knowledgeable about the safety of substances directly or indirectly added to food and, in so doing, relies on the outcome of the GRAS panel's analysis to support the proponent's conclusion that the safety of the intended use is ''generally recognized'' by qualified experts. Whether a GRAS panel is a sufficient proxy for the larger scientific community depends on a number of factors, such as the subject matter expertise of the members of the GRAS panel and whether the members of the GRAS panel would be considered representative of experts qualified by scientific training and experience to evaluate the safety of the substance under the conditions of its intended use.

A GRAS panel is one mechanism that proponents have used to demonstrate that the safety of a substance under the conditions of its intended use is generally recognized by qualified experts. However, the use of a GRAS panel is not the only mechanism for doing so, and the use of a GRAS panel does not necessarily mean that the GRAS criteria have been met (81 FR 54960 at 54974 through 54975, August 17, 2016).

We are announcing the availability of a guidance for industry entitled ''Best Practices for Convening a GRAS Panel.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of November 16, 2017 (82 FR 53433), we made available a draft guidance for industry entitled ''Best Practices for Convening a GRAS Panel'' (''draft guidance''), which was intended for any proponent who convenes a GRAS panel and provided our current thinking on best practices to identify GRAS panel members who have appropriate and balanced expertise; to take steps to reduce the risk that bias (or the appearance of bias) will affect the credibility of a GRAS panel report, including the assessment of potential GRAS panel members for conflict of interest and the appearance of conflict of interest; and to limit the data and information provided to a GRAS panel to public information (*e.g.,* by not providing the GRAS panel with information such as trade secret information). We gave interested parties until May 15, 2018, to submit comments for us to consider before beginning work on the final version of the guidance.

We received 13 comments on the draft guidance. Most comments supported the draft guidance and offered ideas on how to improve the guidance. One comment discussed FDA's analysis of the proposed collection of information, and another comment involved issues not related to the draft guidance. We have modified the final guidance where appropriate. Changes to the guidance include:

- Emphasizing that, in many cases, a GRAS panel is not necessary, in response to comments suggesting the GRAS notification process may become too burdensome;
- Providing additional background information regarding the value of a GRAS panel in providing evidence to support the ''general acceptance'' aspect of the criteria for eligibility for GRAS status through scientific procedures;
- Clarifying the GRAS panel policy discussions around evaluating and managing conflicts of interest and appearance issues, as well as honoraria;
- Removing one reference, as it has been withdrawn since publication of the draft guidance; and
- Removing a mistaken reference to a section V.J.

The guidance announced in this notice finalizes the draft guidance dated November 2017.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in this guidance have been approved under OMB control number 0910–0911.

This guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR parts 170 and 570 have been approved under OMB control number 0910–0342.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA websites listed in the previous sentence to find the most current version of the guidance.

Dated: December 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27714 Filed 12–20–22; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2018–0746; FRL–6494.1–02–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: Final action; reconsideration of the final rule.

SUMMARY: On August 12, 2020, the U.S. Environmental Protection Agency (EPA) published the final risk and technology review (RTR) for the Miscellaneous Organic Chemical Manufacturing NESHAP (2020 MON final rule) pursuant to Clean Air Act (CAA).

Subsequently, the EPA received and granted petitions for reconsideration on two issues, specifically, on the use of the EPA's IRIS value for ethylene oxide in assessing cancer risk for the source category, and the use of the Texas Commission on Environmental Quality's (TCEQ's) risk value for ethylene oxide as an alternative risk value to the EPA's IRIS value for purposes of evaluating risk as part of the CAA residual risk review. On February 4, 2022, the EPA proposed the Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants (NESHAP): Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review to address these two issues and request public comment. This action finalizes the EPA's decision to use the IRIS value for ethylene oxide in the risk assessment for the 2020 MON final rule and our decision to reject the use of the TCEQ's risk value for ethylene oxide as an alternative risk value to the EPA's IRIS value. As such, in this final action, EPA is making no changes to the risk assessment or related regulatory text for the miscellaneous organic chemical manufacturing source category.

DATES: This final action is effective on December 21, 2022.

ADDRESSES: The U.S. Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA–HQ–OAR–2018–0746. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information 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 form. Publicly available docket materials are available either electronically through *https://www.regulations.gov/,* or in hard copy at the EPA Docket Center, WJC West Building, Room Number 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time (EST), Monday through Friday. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Ms. Susan Paret, Sector Policies and Programs Division (E–120 C), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5516; and email address: *paret.susan@epa.gov.* For specific information regarding these reconsideration decisions, contact Amy Vasu, Health and Environmental Impacts Division (C539–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0107; and email address: *vasu.amy@epa.gov.* For information about the applicability of the NESHAP to a particular entity, contact John Cox, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–1395; and email address: *cox.john@epa.gov.*

SUPPLEMENTARY INFORMATION: *Preamble acronyms and abbreviations.* 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:

CAA Clean Air Act
CRA Congressional Review Act
EtO ethylene oxide
HAP hazardous air pollutants(s)
IRIS Integrated Risk Information System
MACT maximum achievable control technology
MCPU miscellaneous organic chemical manufacturing process unit
MIR maximum individual risk
MON Miscellaneous Organic Chemical Manufacturing NESHAP
NESHAP national emission standards for hazardous air pollutants
NIOSH National Institute for Occupational Safety and Health
NTTAA National Technology Transfer and Advancement Act
PRA Paperwork Reduction Act
RFA Regulatory Flexibility Act
RTR risk and technology review
SAB Science Advisory Board
SSM startup, shutdown, and malfunction
UMRA Unfunded Mandates Reform Act
URE unit risk estimate

Background information. On February 4, 2022, the EPA proposed the Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants (NESHAP): Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review (87 FR 6466). In this action, we are finalizing decisions on the two issues for which we granted reconsideration. We summarize specific comment topics received on our proposed action and our responses central to our rationale for the decisions in this action. A summary of all public comments on the proposal and the EPA's responses to those comments is available in *Summary of Public Comments and Responses for the Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review,* Docket ID No. EPA–HQ–OAR–2018–0746.

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

I. General Information

A. What is the source of authority for this reconsideration action?

The source of 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 FINAL ACTION

NESHAP and source category	NAICS [1] code
40 CFR part 63, subpart FFFF, Miscellaneous Organic Chemical Manufacturing.	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 to provide a guide for readers regarding entities likely to be affected by the final action for the source category listed. 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 this NESHAP, please contact the appropriate 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 final action will also be available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this final 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 and key technical documents at this same website.

Copies of all oral and written comments received on the proposed rulemaking (Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants (NESHAP): Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review (87 FR 6466; February 4, 2022) are available at the EPA Docket Center Public Reading Room. Comments are also available electronically through *https://www.regulations.gov/* by searching Docket ID No. EPA–HQ–OAR–2018–0746. Additional information is available on the RTR website at *https://www.epa.gov/stationary-sources-air-pollution/risk-and-technology-review-national-emissions-standards-hazardous.* This information includes an overview of the RTR program and links to project websites for the RTR Source categories.

D. Judicial Review and Administrative Reconsideration

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit by February 21, 2023. Under CAA section 307(b)(2), the requirements established by this final action may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

II. Background Information

The EPA promulgated the Miscellaneous Organic Chemical Manufacturing NESHAP (MON) on November 10, 2003 (68 FR 63852), and further amended the MON on July 1, 2005 (70 FR 38562), and July 14, 2006 (71 FR 40316). The standards are codified at 40 CFR part 63, subpart FFFF. The MON regulates HAP emissions from miscellaneous organic chemical manufacturing process units (MCPUs) located at major sources. An MCPU includes equipment necessary to operate a miscellaneous organic chemical manufacturing process, as defined in 40 CFR 63.2550(i), and must meet the following criteria: (1) it manufactures any material or family of materials described in 40 CFR 63.2435(b)(1); (2) it processes, uses, or generates any of the organic HAP described in 40 CFR 63.2435(b)(2); and, (3) except for certain process vents that are part of a chemical manufacturing process unit, as identified in 40 CFR 63.100(j)(4), the MCPU is not an affected source or part of an affected source under another subpart of 40 CFR part 63. An MCPU also includes any assigned storage tanks and transfer racks; equipment in open systems that is used to convey or store water having the same concentration and flow characteristics as wastewater; and components such as pumps, compressors, agitators, pressure relief devices (PRDs), sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used to manufacture any material or family of materials described in 40 CFR 63.2435(b)(1). Sources of HAP emissions regulated by the MON include the following: process vents, storage tanks, transfer racks, equipment leaks, wastewater streams, and heat exchange systems.

The EPA conducted an RTR for the MON, pursuant to CAA sections 112(d)(6) and (f)(2), publishing proposed amendments on December 17, 2019 (84 FR 69182). As of November 6, 2018, the Source category covered by this MACT standard included 201 facilities, herein referred to as ''MON facilities.'' This facility population count was developed using methods described in section II.C of the RTR proposal preamble (84 FR 69182, 69186–87). 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). After soliciting and considering public comments, the EPA took final action in 2020 (85 FR 49084; August 12, 2020). The 2020 MON final rule included revisions to the NESHAP pursuant to the technology review for equipment leaks and heat exchange systems, and revisions 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] the Agency calculated cancer risks associated with emissions of ethylene oxide using the EPA's IRIS value for that pollutant,[2] [3] 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 EPA received comments from TCEQ during the public comment period that included their draft cancer dose-response assessment for ethylene oxide. The final rule preamble stated that ''the EPA remains open to new and updated scientific information'' and new dose-response values, such as the dose-response value then being developed by the TCEQ (85 FR at 49098). However, by the close of the public comment period for the proposed rulemaking, on 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 unique 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 Nos. EPA–HQ–OAR–2018–0746–0259, EPA–HQ–OAR–2018–0746–0260, EPA–HQ–OAR–2018–0746–0261, EPA–HQ–OAR–2018–0746–0262, and EPA–HQ–OAR–2018–0746–0263).

Three petitioners (ACC, TCEQ, and Huntsman Petrochemical, LLC) requested that 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 IRIS value for ethylene oxide. These three petitioners further argued that the EPA's IRIS value for ethylene oxide is flawed, citing their disagreement with the EPA Office of Research and Development's model selection and inclusion of breast cancer data in the IRIS assessment. In their petitions, ACC and Earthjustice also raised other issues unrelated to the use of the IRIS value or the TCEQ value for assessing risk from ethylene oxide emissions.

On June 22, 2021, the EPA sent letters to all of the petitioners informing them that: (1) the EPA was granting reconsideration requests on two specific issues (described in the next paragraph), (2) the EPA intended to issue a **Federal Register** document initiating a document 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 Nos. EPA–HQ–OAR–2018–0746–0249, EPA–HQ–OAR–2018–0746–0250, EPA–HQ–OAR–2018–0746–0251, and EPA–HQ–OAR–2018–0746–0252).

On February 4, 2022 (87 FR 6466), pursuant to CAA section 307(d)(7)(B), the EPA proposed to take comment on the issues for which reconsideration was granted in the June 22, 2021 letters. In the proposal, the EPA solicited public comment on 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.

[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] The IRIS value is, specifically, the inhalation unit risk estimate (URE) for ethylene oxide. 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 μg/m^3 in air. Because ethylene oxide is mutagenic (*i.e.,* damages DNA), an age-dependent adjustment factor was applied to the URE to account for childhood exposures. Therefore, the IRIS value used in the risk assessment is the age-adjusted inhalation URE for ethylene oxide, which is 0.005 per μg/m^3.

[3] 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).

Note that, for this reconsideration action, the EPA sought comment only on the two issues subject to mandatory reconsideration described in the proposal preamble for this reconsideration (87 FR 6466; February 4, 2022). Because the criteria for mandatory reconsideration under CAA section 307(d)(7)(B) have been satisfied, the Agency is publishing this final reconsideration action in the **Federal Register**.

III. Final Action

In this section of the preamble, the EPA sets forth its final decisions on the two issues for which reconsideration was granted and on which the EPA solicited comment in the proposed document of reconsideration. We also present the Agency's rationale for the decisions.

A. Issue 1: Use of the EPA's IRIS Value for Ethylene Oxide in Assessing Cancer Risk for the Source Category

1. EPA's Final Decision on the Use of the IRIS Value for Ethylene Oxide In Assessing Cancer Risk For The Source Category

After careful consideration of the comments and information submitted through the public comment process for this rulemaking, the Agency has decided that use of the EPA IRIS value for ethylene oxide for the risk assessment performed for the 2020 MON final rule was appropriate. As described in the reconsideration proposal (87 FR 6466, 6471; February 4, 2022), EPA has an established approach supported by the Science Advisory Board for selecting dose-response values for the CAA section 112(f)(2) risk reviews.[4] [5] Application of this approach generally results in an EPA IRIS value being given preference over values from other organizations or agencies. Neither the petitioners nor commenters identified a basis for the EPA to deviate from this documented approach for selecting dose-response values for use in the risk assessment for the 2020 MON final rule. Further, the EPA IRIS assessment of ethylene oxide is scientifically sound, as evidenced by the toxicological assessment itself,[6] as well as the supporting technical documentation. As described in section III.A.2 below and in greater detail in sections 4.1.1 and 4.1.2 of the response to comment document for this rulemaking, the IRIS assessment underwent an extensive peer and public review process that adhered to the guidelines in EPA's *Peer Review Handbook*[7] for peer review of highly influential scientific assessments. The IRIS assessment and supporting documentation provide evidence of full consideration of the array of scientific questions and comments presented to the EPA and addressed by the EPA prior to issuing the final assessment in December 2016. In addition, since the issuance of the final assessment, there is no new scientific information that would alter EPA's derivation of the IRIS value or other aspects of the EPA IRIS assessment for ethylene oxide. The IRIS assessment continues to provide sound scientific conclusions that are consistent with the latest scientific knowledge. For these reasons, which are addressed in section III.A.2 below, and in greater detail in the response to comment document for this rulemaking, the EPA IRIS value for ethylene oxide is the most appropriate risk value to use in assessing cancer risk for the MON Source category.

2. Comments Received on the Use of the EPA's IRIS Value for Ethylene Oxide In Assessing Cancer Risk for the Source Category

The Agency received a range of comments on the proposed rule. While many commenters agreed with the use of EPA's IRIS value for ethylene oxide, several commenters disagreed with EPA's choice to rely on the Agency's IRIS assessment, as opposed to TCEQ's assessment, as the source of the value used to calculate cancer risk from ethylene oxide exposure.

Many of the comments submitted regarding the EPA IRIS assessment of ethylene oxide have been addressed previously by the EPA as part of the extensive peer review and public review process of the draft IRIS assessment of ethylene oxide. For those comments challenging the IRIS assessment, documented in detail in the response to comment document for this rulemaking, we cite to our previous responses. For example, we again received comments claiming that potential background levels of ethylene oxide (ethylene oxide present in ambient air or produced through metabolism in a person's body (*i.e.,* endogenously)) contribute to cancer risk but were not accounted for in the calculation of the cancer risk value. We have addressed these comments previously in the 2020 MON final rule[8] and in the IRIS Assessment for ethylene oxide,[9] in addition to the EPA's December 13, 2021, response[10] to the Request for Correction (RFC)[11] of the IRIS value that was submitted to the EPA by petitioner ACC under the Information Quality Act, Public Law 106–554 (IQA). We cite these responses in the response to comment document for this rulemaking, where we explain:

> It is important to recognize that the IRIS [unit] risk estimate for EtO represents the increased cancer risk due to exposure to ethylene oxide emissions—above any potential existing risks from endogenous or ambient background levels of EtO exposure. The occupational exposures in the NIOSH study represent workplace EtO levels these workers experienced—and are in addition to any endogenous or broad population background exposures to which the workers may also have been exposed.

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[4] 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. *https://www3.epa.gov/airtoxics/rrisk/rtrpg.html.*

[5] Recommendations of the SAB Risk and Technology Review Methods Panel are provided in their report, which is available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100RODV.txt* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[6] 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).

[7] U.S. EPA, 2015. Peer Review Handbook, 4th edition. Science and Technology Policy Council. October 2015. EPA/100/B–15/001. *https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf*

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

[9] 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. *See* Appendix K, p. K–9. 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).

[10] 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-qualityguidelines-requestscorrection-and-requestsreconsideration#18003* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[11] 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-qualityguidelines-requests-correction-and-requestsreconsideration#18003* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

In this section, we describe specific comment topics central to our rationale for EPA's decision to continue to use the EPA IRIS value; detailed comment summaries and responses are presented in the response to comment document for this rulemaking.

a. Comments Concerning Selection of Dose-Response Values for CAA Section 112(f)(2) Risk Reviews

EPA received a number of comments in support of and against the use of the EPA IRIS value for ethylene oxide. As described in the reconsideration proposal (87 FR 6466, 6471; February 4, 2022), EPA has a documented approach for selecting dose-response values for the CAA section 112(f)(2) risk reviews. For these 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 and the advice from the EPA SAB, and as described in the risk assessment documentation for the 2020 MON final rule,[12] the IRIS database is the preferred source of chronic dose-response data.

Based on EPA's careful review, the Agency has determined that neither the petitioners requesting that EPA reconsider the 2020 MON final rule nor commenters on the proposed reconsideration identified a basis for EPA to change our approach generally, nor our approach to the risk assessment specifically in the 2020 MON final rule. Where commenters identified specific topics, such as new analyses or information related to the cancer risk value for ethylene oxide, we address those comments either in the preamble to this final action or in sections 3 and 4 of the response to comment document for this action.

b. Comments About the EPA IRIS Assessment of Ethylene Oxide Being Scientifically Sound and Robust

Some commenters oppose the use of the ethylene oxide IRIS value, for the most part reiterating previously provided comments (*e.g.,* on model selection) and citing information that the Agency has already considered, including in the development of the IRIS assessment or the 2020 MON final rule. Where new comments or information have been provided, we address those in this preamble or in the response to comment document for this rulemaking.

Many commenters supporting the use of the EPA IRIS value reiterated that the IRIS value must be applied because it reflects the latest scientific knowledge and is the result of an extensive review process. The EPA agrees that the EPA IRIS assessment is scientifically sound and robust and represents the best estimate of the increased cancer risk posed by inhalation exposure to ethylene oxide for use in a risk assessment. This is evidenced by the toxicological assessment itself[13] and its supporting technical documentation, as well as the extensive peer and public review process that was an integral part of the development of the final assessment.

Many of the comments received on the peer and public review of the EPA IRIS ethylene oxide assessment have been addressed previously by the EPA. Specifically, as stated in the response to comments received on the 2020 MON final rule,[14] the EPA followed its standard review process in the ethylene oxide IRIS assessment, which included multiple rounds of review and comment by experts and the public. This included internal agency review, interagency review, public external peer review, and public review. The ethylene oxide IRIS assessment underwent two peer and public review processes over a 10-year period. After the second peer and public review, the Agency followed its normal process to finalize the assessment by considering the peer and public review comments received, making final revisions to the assessment in response to those comments, and then issuing the final ethylene oxide IRIS assessment.

Given this process, the EPA stated that it disagreed with comments suggesting that scientific information and comments were not fully addressed during the IRIS assessment development and review process. In responding to these comments, the EPA further noted the Agency's adherence to the guidelines in the EPA's *Peer Review Handbook*[15] for highly influential scientific assessments. The IRIS assessment itself and supporting documentation provide evidence of full consideration of the array of scientific questions and comments presented to the EPA. Responses to new comments received regarding statistical support for the IRIS dose-response model are included in the response to comments document.

As described in the EPA's *Peer Review Handbook,*[16] there are a range of types of peer review. For the ethylene oxide IRIS assessment, the Agency requested review by the EPA SAB. The EPA's SAB is a statutorily established committee with a broad mandate to provide advice and recommendations to the Agency on scientific and technical matters. The SAB considers requests for advice and peer review from across the Agency as part of an annual process, initiated by a request from the Deputy Administrator to the EPA's senior leadership to identify requests for review by the EPA. Highly influential scientific assessments, such as IRIS assessments, or other scientific work products associated with highly visible or controversial environmental issues are most suited to review by the SAB. Much of the SAB's peer review work is done using *ad hoc* panels formed to review specific EPA draft technical products. All SAB panels provide advice through the chartered SAB, which is composed of approximately 50 nationally renowned scientists, engineers and economists who are screened for conflicts of interest. The chartered SAB further reviews reports prepared by project-specific panels, accepts further public comment, and reports final conclusions directly to the EPA Administrator.

In addition, to address concerns raised about opportunities for review of the draft IRIS assessment, it is important to note that the assessment review and revision process took place over a 10-year period, from 2006 to 2016. Stakeholders, including the American Chemistry Council, had an awareness of the Agency's IRIS assessment early in the process, as evidenced by their review of the 2006 and 2013 draft IRIS assessments and the extensive comments that the ACC and other stakeholders provided on those drafts.

After completion of an initial draft of the assessment, the EPA undertook an

[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-HQOAR-2018-0746-0189.*

[13] 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).

[14] Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing, August 2020. See section 4.1.3, response to Comment 29. Available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0200.*

[15] U.S. EPA, 2015. Peer Review Handbook, 4th edition. Science and Technology Policy Council. October 2015. EPA/100/B–15/001. *https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf.*

[16] *Id.*

extensive, transparent review process. We agree with commenters who stated that the ethylene oxide assessment underwent extensive internal EPA review, as well as external review by other federal agencies. Drafts of the assessment were available for public comment at three different times and were twice submitted for external peer review by the SAB, which is an additional round of external review than is typically received by IRIS assessments. It is correct that at least four drafts of the IRIS ethylene oxide cancer evaluation were reviewed by a wide range of ''EPA scientists, interagency reviewers from other federal agencies and the Executive Office of the President, the public, and independent scientists external to the EPA.'' [17]

Not only did the SAB reviews involve large panels of experts with diverse expertise; they also provided opportunity for public comment and SAB consideration of that comment. EPA's IRIS assessment methods and conclusions directly relied on detailed recommendations presented by the SAB (*e.g.,* SAB, 2015, page 9 presents specific recommendations on preferred dose-response models). The EPA has determined that the IRIS assessment is scientifically sound and robust and represents the best inhalation cancer risk value for ethylene oxide.

c. Comments Suggesting That There Is New Scientific Information That Would Alter Aspects of the EPA IRIS Assessment

Regarding comments questioning EPA's use of the best available and most recent scientific knowledge, EPA has carefully considered the range of information submitted to EPA on the IRIS assessment since its issuance in 2016. This includes, for example, the EPA's response to the ACC's Request for Correction of the use of the IRIS value for ethylene oxide.[18] The Agency's response documents further evidence of consideration of scientific information submitted to the EPA on the assessment of ethylene oxide since the IRIS assessment was issued in 2016. While there have been several new publications since issuance of the final ethylene oxide IRIS assessment in December 2016, those publications most pertinent to developing an inhalation cancer risk value for ethylene oxide have focused on re-analyses of published studies previously considered in the 2016 IRIS assessment and, therefore, yield no new scientific information. EPA is not aware of new epidemiological, toxicological, or basic scientific studies that suggest the current cancer risk value is no longer appropriate or that could fundamentally alter the basis for the current ethylene oxide IRIS assessment. Specifically, there is no new scientific information that would alter aspects of the EPA IRIS assessment or call into question the scientific judgements reflected in that assessment. The IRIS value for ethylene oxide continues to reflect the latest scientific knowledge.

B. Issue 2: Use of the TCEQ Risk Value for Ethylene Oxide in Assessing Cancer Risk for the Source Category

1. EPA's Final Decision on the Use of the TCEQ Risk Value for Ethylene Oxide in Assessing Cancer Risk for the Source Category

After careful consideration of the final TCEQ assessment [19] and comments and information submitted through the public comment process for this rulemaking, the Agency finds that the TCEQ risk value is unsuitable for use as an alternative to the IRIS value for ethylene oxide in assessing cancer risk under CAA section 112(f).

The EPA disagrees with several foundational aspects of the final TCEQ assessment. First, EPA disagrees with TCEQ's decision to exclude breast cancer in women as an endpoint for ethylene oxide dose response assessment. EPA finds that TCEQ's decision to exclude breast cancer in women in their derivation of the ethylene oxide risk value is not scientifically sound; this decision reduces the accuracy of, and confidence in, the TCEQ risk value as an appropriate metric of increased cancer risk from inhalation exposure to ethylene oxide. Second, with regard to TCEQ's dose-response modeling, the EPA finds that: (1) the dose-response model selected by TCEQ is unsupported by the underlying epidemiological data, and (2) TCEQ's analyses to justify their model choice were erroneous and relied on flawed assumptions. For the reasons listed here and described in detail in section III.B.2 below, as well as in the response to comment document for this rulemaking, the TCEQ risk value for ethylene oxide is not appropriate to use in assessing cancer risk for the MON Source category.

2. Comments Received on the Use of the TCEQ Risk Value for Ethylene Oxide in Assessing Cancer Risk for the Source Category

While many commenters were opposed to EPA's use of the TCEQ risk value for ethylene oxide, several commenters were in favor of the use of the TCEQ value. In this section, we describe specific comment topics key to explaining the rationale for EPA's decision to reject the use of the TCEQ risk value for assessing cancer risk for the source category; detailed comment summaries and responses are presented in the response to comment document for this rulemaking.

a. Comments on Inclusion and Exclusion of Breast Cancer as an Endpoint

While many commenters agree with the inclusion of breast cancer as an endpoint in the dose-response assessment of ethylene oxide, as was done in the EPA IRIS assessment, several commenters, including TCEQ and ACC, support exclusion of breast cancer as an endpoint, as was done in the final TCEQ assessment of ethylene oxide.

EPA disagrees with TCEQ and other commenters who support exclusion of breast cancer in women as an endpoint when assessing the cancer risk from exposure to ethylene oxide. In the IRIS assessment of ethylene oxide, the EPA determined that the available epidemiological evidence for a causal relationship between ethylene oxide exposure and breast cancer in women was strong, and there were sufficient data to include breast cancer in the derivation of the IRIS value for ethylene oxide. 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

[17] 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).

[18] 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-qualityguidelines-requests-correction-and-requestsreconsideration#18003* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[19] Ethylene Oxide Carcinogenic Dose-Response Assessment: Development Support Document, May 15, 2020. Texas Commission on Environmental Quality. *https://www.tceq.texas.gov/downloads/toxicology/dsd/final/eto.pdf.*

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.'' [20] 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.

EPA examined what TCEQ describes as new scientific information and found it to primarily consist of publications providing further reviews covering the same epidemiological data on breast cancer that had already been comprehensively reviewed in the EPA's ethylene oxide IRIS assessment. EPA's examination of these review articles finds that the authors of these journal article reviews have mostly dismissed the strongest data on ethylene oxide and breast cancer, and EPA finds these decisions to be unwarranted. Comments against the inclusion of breast cancer cite two meta-analyses addressing ethylene oxide breast cancer studies that were published after the completion of the 2016 IRIS assessment (Marsh et al. (2019). Both reviews included five breast cancer studies, all of which were examined in the IRIS assessment (Coggon, 2004; Mikoczy, 2011; Norman, 1995; Steenland, 2003; and Steenland, 2004). The conclusions of these meta-analyses are flawed for two major reasons: (1) the authors did not consider findings of increased cancer incidence or mortality in highly exposed study subgroups, and (2) the authors excluded published findings using internal comparison groups within the worker populations, which goes against best practice in epidemiology.[21] Consequently, the meta-analyses inappropriately omitted all positive findings from the Steenland et al. (2003 and 2004) and Mikoczy et al. (2011) studies for breast cancer mortality and incidence and treated these studies as providing negative evidence of an effect of ethylene oxide on breast cancer. These flawed re-analyses of data (data that had been previously reviewed in the IRIS assessment and found to provide positive evidence) led the authors to conclude that the weight of evidence does not support breast cancer as an endpoint.

EPA also examined a new study by Jain (2020) using NHANES data to investigate associations between exposure to ethylene oxide in tobacco smoke and self-reported diagnosis of cancers. The author concluded that levels of ethylene oxide in the general population in the U.S. were not found to be associated with cancers, including breast cancer. There are three major issues that call into question the interpretation of the results from this study. First, it appears that Jain misleadingly interpreted a biomarker of exposure as ''[ethylene oxide] levels in the blood''. Importantly, since NHANES did not measure ethylene oxide levels in the blood, this suggests a misunderstanding of the NHANES data consistent with Jain's overinterpretation of the results. Second, Jain failed to note the large number of unaccounted-for variables that may contribute to one's lifetime breast cancer risk, such as lifestyle, a history of breast cancer in relatives, co-exposures, and cumulative exposure to ethylene oxide and other chemicals. NHANES provides cross-sectional data representing a snapshot in time of exposure and health outcome and is not designed to establish temporal causality between chemical exposure and cancer outcomes. For this reason, NHANES data cannot be used to reliably rule out causation between chemical exposure and breast cancer. Third, biomarker measurements that offer a snapshot in time of one's exposure to chemicals are not necessarily representative of continuous, lifetime exposure leading to the development of breast cancer. Taken together, the Jain study results do not support the author's conclusion.

EPA disagrees with commenters that dismiss the breast cancer findings in the National Institute for Occupational Safety and Health (NIOSH) studies of sterilizer workers. Available epidemiologic data provide strong evidence of an elevated breast cancer risk in female workers exposed to ethylene oxide. Results from the NIOSH studies of sterilizer workers (Steenland et al., 2003, and Steenland et al., 2004) demonstrate excess breast cancer risk, substantiated through several different epidemiological analysis approaches. Other smaller studies also indicate an elevated breast cancer risk. No substantial studies challenge this conclusion. The breast cancer findings from the studies of Steenland et al. (2003, 2004) are broadly regarded as the largest and most detailed studies of this endpoint. These studies presented cancer findings for the NIOSH cohort of workers at U.S. sterilization facilities with Steenland et al. (2004) examining cancer mortality rates for breast and other cancers and Steenland et al. (2003) specifically studying incidence (occurrence of disease) of breast cancer. Particularly for breast cancer in women (who are not adequately represented in some industrial cohorts), the NIOSH study is generally regarded as preeminent. These cancer mortality and incidence studies include multiple statistical comparisons that provide evidence of the effect of ethylene oxide exposure increasing breast cancer rates. EPA reaffirms that it is sound and reasonable to include breast cancer as a major endpoint in the IRIS ethylene oxide assessment. Detailed comment summaries and responses on this subject are provided in the response to comment document for this rulemaking.

For these reasons, the EPA finds TCEQ's decision to exclude breast cancer as an endpoint in the derivation of their ethylene oxide risk value to be without adequate scientific basis.

b. Comments on Dose-Response Model Selection

EPA received a range of comments regarding the dose-response model selection for the final TCEQ assessment and for the EPA IRIS assessment. A number of the comments submitted on the reconsideration proposal were on aspects of the dose-response model that EPA had previously addressed either in the peer review of the EPA IRIS ethylene oxide assessment [22] or in the response to comment document for the 2020 MON final rule.[23] New comments regarding TCEQ's assessment focused primarily on support for, and opposition to, the model itself and TCEQ's analyses to support the model selected.

After examining the final TCEQ assessment, as well as analyses and

[20] 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. Appendix K, p. K–3. 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).

[21] Internal comparisons are particularly valuable, as they provide a basis for examining compound-related increases in cancer rates without relying on an assumption that cancer rates in the studied workers would be identical to general population average cancer rates in the absence of exposure to the compound.

[22] 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–2018–0746–0202).

[23] 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.*

arguments submitted as part of the public comment process for the MON reconsideration proposed rulemaking, the EPA disagrees with TCEQ's model selection, including TCEQ's claim that the biological evidence supports a model with a single, gradual slope through the full range of both general population and occupational exposures. For their model selection, TCEQ chose a model that is inconsistent with the underlying epidemiological data, particularly for ethylene oxide levels in the range of general population exposure (where the general population would include children and other potentially vulnerable groups), which is of most relevance for the CAA section 112 risk assessments.

The epidemiological data indicate that cancer risk rises more rapidly with increasing exposure in the lower exposure range and more gradually in the higher exposure range. TCEQ selected a model that is unable to fit the shape of the data throughout the exposure range. The slope of TCEQ's model is more representative of higher, occupational exposures. By using a single slope (a line) to project risks, TCEQ's model predicts risks at lower exposure ranges that are inconsistent with the underlying epidemiological dose-response data. EPA rejects TCEQ's model because it is inconsistent with the underlying epidemiological dose-response data and mischaracterizes risk at the lower exposure range (*i.e.,* the range representing potential general population exposures).

It is important to note that, as part of the ethylene oxide IRIS assessment, EPA considered and evaluated 12 dose-response models for lymphoid cancer mortality and 9 dose-response models for breast cancer incidence. The dose-response model selected by TCEQ (a Cox proportional hazards model) is one of the models that was considered by the EPA as part of the IRIS assessment. EPA found that the linear curve selected by TCEQ was highly influenced by the uppermost 5% of the exposure range and did not fit the full range of epidemiological data points, leading to an underestimation of risk for points below the highest exposure levels. After considering all models, EPA found that the two-piece spline model best captured the initial increase in risk at lower doses followed by an attenuation at higher doses. Spline models are generally useful for exposure-response data in which risk increases with exposure at low doses but attenuates at higher exposures, as observed in the ethylene oxide lymphoid cancer data. The plateauing exposure-response relationship has been observed for other occupational carcinogens and may be explained by the depletion of susceptible subpopulations at high exposures, mismeasurement of high exposures, or a healthy worker survivor effect (Stayner et al., 2003). The EPA subsequently rejected the model selected by TCEQ, as well as other similar models, and selected a two-piece linear spline model. In its response to the SAB's recommendations,[24] 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 models), relies less on AIC,[25] and includes consideration of biological plausibility . . .'' As such, in the 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. Importantly, EPA found TCEQ's chosen model to be a poor fit of the data in the low exposure range (*i.e.,* the range representing potential general population exposures).[26]

Unlike model selection for the TCEQ assessment of ethylene oxide, for the ethylene oxide IRIS assessment, EPA selected the model that best represented potential general population exposures, as well as higher, occupational exposures. EPA's statistical model selection was based on model fit with the observed results in the NIOSH study and was consistent with peer review advice received from the SAB. In the terminology of cancer risk assessment and EPA's Carcinogen Guidelines, the EPA two-piece linear spline model predicts a linear association between environmentally relevant ethylene oxide exposures and cancer risk.[27] SAB (2015) peer review comments noted consistency in model fit and categorical results.[28]

In addition to disagreeing with the dose-response model selected by TCEQ, EPA also disagrees with TCEQ's analytical approach to justifying its model selection. TCEQ supported their model choice using flawed calculations and inappropriate assumptions. TCEQ takes an approach that they claim allows for statistical testing of model predictions. EPA has examined TCEQ's inferences and calculations and has identified problems with: (1) TCEQ's assumption that national lymphoid cancer *mortality* rates equal rates of cancer mortality for members of the NIOSH cohort in the absence of ethylene oxide exposures; (2) TCEQ's calculation of projected cancer rates; and (3) the statistical confidence intervals TCEQ developed for the ''predicted'' numbers of cancers. These are summarized below and described in greater detail in the response to comment document for this rulemaking.

TCEQ made errors in their calculation of projected cancer rates and in the ''reality check'' calculations they used to justify their model choice. TCEQ's ''reality check'' calculations are not statistically appropriate and do not support TCEQ's claims. Further, TCEQ relied on flawed assumptions. For example, in making a claim that TCEQ's model more accurately predicts cancers attributable to ethylene oxide exposure, TCEQ incorrectly assumes that, in the absence of ethylene oxide exposure, cancer incidence rates in the worker cohort (the basis of the URE calculation in EPA's IRIS assessment) would be the same as national cancer mortality rates for the general population. This is, at best, a rough approximation and is subject to considerable error. Importantly, the development of Cox model ''internal'' risk estimates instead of a national mortality rate-based analysis by Steenland et al. (2004) reflects that comparisons to national mortality rates are not appropriate for this worker cohort. Use of an ''internal'' statistical analysis rather than an

[24] 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. See Appendix I, p. I–3. 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–2018–0746–0202).

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

[26] 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-qualityguidelines-requests-correction-and-requestsreconsideration#18003* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746–0264).

[27] Ibid.

[28] 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).

external (national mortality rate-based) analysis is broadly accepted as best practice in occupational epidemiology and was endorsed by the EPA SAB for the EtO IRIS assessment. The EPA disagrees with TCEQ's approach and these assumptions, as described in detail in the response to comment document for this rulemaking.

For the reasons stated above, the EPA finds that the dose-response model selected by TCEQ is unsupported by the data, and the analyses fail to justify the selection of the model. The TCEQ assessment, petitions, and the comments submitted as part of this rulemaking process do not provide a scientifically supportable basis for relying on the TCEQ risk value to assess the residual risk for sources in the 2020 MON final rule. No new studies or other information have been identified by TCEQ, the petitioners requesting reconsideration, or the commenters that would call into question the conclusions in the IRIS ethylene oxide assessment. The EPA reaffirms its use of the EPA IRIS value for ethylene oxide for the risk assessment performed for the 2020 MON final rule.

IV. Summary of Cost, Environmental, and Economic Impacts and Additional Analyses Conducted

A. What are the affected facilities?

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 finalizing 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 finalize 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 finalize 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 finalize any changes to the standards or other requirements on affected sources.

F. What analysis of environmental justice did we conduct?

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 reaffirm decisions made in a previously promulgated regulatory action and does not have any impact on human health or the environment.

G. What analysis of children's environmental health did we conduct?

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.

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 finalizing 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 finalizes 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)

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.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances, Intergovernmental relations.

Michael S. Regan,

Administrator.

[FR Doc. 2022–27522 Filed 12–20–22; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 107, 171, and 173

[Docket No. PHMSA–2016–0014 (HM–224I)]

RIN 2137–AF20

Hazardous Materials: Enhanced Safety Provisions for Lithium Batteries Transported by Aircraft (FAA Reauthorization Act of 2018)

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule revises the Hazardous Materials Regulations for lithium cells and batteries transported by aircraft and is consistent with the previously published Interim Final Rule, which responded to congressional mandates; prohibited the transport of lithium ion cells and batteries as cargo on passenger aircraft; required lithium ion cells and batteries to be shipped at not more than a 30 percent state of charge aboard cargo-only aircraft when not packed with or contained in equipment; and limited the use of alternative provisions for smaller lithium cell or battery shipments to one package per consignment. In response to comments, this final rule provides editorial amendments and modification of certain provisions including marking requirements, requests for an extension on the compliance date, and exception for lithium cells or batteries used for medical devices with approval by the Associate Administrator.

DATES: This final rule is effective on January 20, 2023.

FOR FURTHER INFORMATION CONTACT: Eugenio Cardez, (202) 366–9542, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

The safe transport of lithium batteries by air has been an ongoing concern due to the unique challenges they pose to safety in the air transportation environment. Unlike most other hazardous materials, lithium batteries have a dual hazard of chemical and electrical. This combination of hazards, when involved in a fire, has the potential to create a scenario that exceeds the fire suppression capability of an aircraft and lead to a catastrophic failure of the aircraft.

The Pipeline and Hazardous Materials Safety Administration (PHMSA) issued an interim final rule (IFR) [1] to amend the hazardous materials regulations (HMR; 49 CFR parts 171–180) to (1) prohibit the transport of lithium ion cells and batteries as cargo on passenger aircraft; (2) require all lithium ion cells and batteries to be shipped at not more than a 30 percent state of charge (SOC) on cargo-only aircraft; and (3) limit the use of alternative provisions for smaller lithium cells or batteries to one package per consignment. The IFR amendments predominately affected air carriers (both passenger and cargo-only) and shippers that offer lithium ion cells and batteries for transport as cargo by aircraft. The IFR amendments neither restricted passengers or crew members from bringing electronic devices containing lithium cells or batteries aboard aircraft nor restricted the air transport of lithium ion cells or batteries when packed with or contained in equipment. The IFR also fulfilled the section 333 mandates in the Federal Aviation Administration (FAA) Reauthorization Act of 2018 and amended the HMR to allow shipments of not more than two replacement lithium cells or batteries specifically used for medical devices as cargo on passenger aircraft—with the approval of the Associate Administrator—to accommodate persons in areas potentially not serviced daily by cargo aircraft. Furthermore, these lithium batteries may be excepted from the SOC requirements when they meet certain provisions.

As discussed in further detail in this final rule (see IV. Section-by-Section Review), PHMSA amends certain sections of the HMR in response to public comments received to the IFR. Overall, the comments to the IFR were supportive of PHMSA's action; however, PHMSA did receive a few comments seeking further clarification or revisions to the IFR which PHMSA also addresses in this final rule. Specifically, PHMSA revises the HMR to better ensure that it reflects the original intent of the IFR, particularly in the alignment with the lithium battery transportation requirements with the International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transportation of Dangerous Goods by Air (Technical Instructions). In addition, PHMSA clarifies the implementation of the exception, with approval of the Associate Administrator, for air transportation of lithium batteries intended for use in medical devices. Finally, PHMSA responds to comments related to the marking requirement for smaller lithium ion cells or batteries

[1] 84 FR 8006 (Mar. 6, 2019).