

MEMORANDUM

TO: Members of the Chartered SAB and SAB Liaisons

FROM: Charles Werth, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science */signed/*

DATE: June 13, 2017

SUBJECT: Preparations for Chartered Science Advisory Board (SAB) Discussions of EPA Planned Agency Actions and their Supporting Science in the Fall 2016 Regulatory Agenda

The Chartered SAB will discuss whether to review the adequacy of the science supporting planned regulatory actions identified by the EPA as major actions in the Fall 2106 semi-annual regulatory agenda at its June 29, 2017 meeting. To support this discussion a SAB Work Group was charged with identifying actions for further consideration by the Chartered SAB. This memorandum provides background on this activity, a short description of the process for identifying actions for SAB consideration, a summary of the process used by the Work Group and Work Group recommendations on the planned actions.

Background

The Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA) requires the EPA to make available to the SAB proposed criteria documents, standards, limitations, or regulations provided to any other Federal agency for formal review and comment, together with relevant scientific and technical information on which the proposed action is based. The SAB may then make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed action.

EPA's current process (Attachment A) is to provide the SAB with information about the publication of the semi-annual regulatory agenda and to provide descriptions of major planned actions that are not yet proposed but appear in the semi-annual regulatory agenda. These descriptions provide available information regarding the science informing agency actions. This process for engaging the SAB supplements the EPA's process for program and regional offices to request science advice from the SAB.

Summary of the Process Used by the SAB Work Group

The SAB Work Group followed the [process adopted by the Chartered SAB](#) in 2013¹ to initiate its review of major planned actions identified in the Unified Regulatory Agenda by EPA. The current SAB review began when the EPA Office of Policy informed the SAB Staff Office that the Fall 2016 Unified (Regulatory) Agenda and Regulatory Plan had been published on November 17, 2016. This semi-annual regulatory agenda is available at <http://www.reginfo.gov/public/>.

¹ Available at [http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/ProcScreen2017/\\$File/SABProtocol2017.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/ProcScreen2017/$File/SABProtocol2017.pdf)

This SAB Work Group was formed in January 2017 and includes SAB members with broad expertise in scientific and technological issues related to the proposed actions. The Work Group consists of Drs. Charles J. Werth (chair), Alison Cullen, H. Christopher Frey, Steven Hamburg, Denise Mauzerall, Jay Turner, Jeanne VanBriesen, and Mr. Richard Poirot.

On March 2, 2017, the Work Group received information and short descriptions from the EPA Program Offices on the major planned actions that are listed in the Fall 2016 semi-annual regulatory agenda but not yet proposed. Work Group members concurred on the recommendations presented in this memorandum after a discussion on May 18, 2017 and subsequently via email. A compiled set of the EPA descriptions of the actions and the Work Group's recommendations are provided in Attachment B.

Work Group Recommendations Regarding Planned EPA Actions of Interest to the SAB

The Work Group based the recommendations below on information received from the EPA and the Work Group's research. Of the 14 major planned actions considered, the Work Group recommends that twelve of the actions do not merit further SAB consideration.

The Work Group notes that the stage of the rulemaking for 11 of the planned actions is listed as long term actions. The Office of Management and Budget defines long term actions as planned actions "under development but for which the agency does not expect to have a regulatory action within the 12 months after publication of this edition of the Unified Agenda", and notes that some of these actions may only have abbreviated information. The SAB has considered long term actions in previous reviews of the Unified Agenda, and in some cases deferred the decision on whether the planned action merits further review until sufficient information is available. The Work Group considered the stage of rulemaking of the planned actions in making their recommendations.

A brief summary of the Work Group findings is provided and further information on each action is available in Attachment B.

Renewable Fuel Volume Standards (RFVS) for 2018 and Biomass Based Diesel Volume (BBD) for 2019 (2060 AT04) is a statutorily mandated annual rulemaking. The RFS program is a routine action that relies on the same approach and sources of data that were used in the rules establishing required standards in past years. The analytical work underlying the RFS annual rules is based on historical data regarding renewable fuel production, imports, distribution, and use. The EPA does "not currently expect to incorporate new methodological approaches that would rely on any new scientific data or touch upon novel issues" to determine the renewable fuel volume standards for 2018 and the biomass based diesel volume (BBD) for 2019. Therefore, this action does not merit further SAB consideration.

Two actions in the regulatory agenda, *Procedures for Evaluating Existing Chemical Risks Under the Toxic Substances Control Act (2070-AK20)* and *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act (2070-AK23)*, are being developed in parallel under TSCA as amended on June 22, 2016, by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which sets i) mandatory requirements for the EPA to evaluate existing chemicals with clear and enforceable deadlines, ii) new risk-based safety standards, iii) increased public transparency for chemical information, and iv) a consistent source of funding for EPA to carry out the responsibilities under the new law. The planned actions were proposed on January 19, 2017 and the *Federal Register* notices for the proposed rules identify the steps in the prioritization and risk evaluation under the

amended TSCA for chemical substances, using existing methods and the weight of evidence approach that has been applied consistently by the Agency in the past. The Work Group notes that the SAB previously reviewed planned actions for several specific TSCA chemicals using these methods and peer review and found the evaluation and peer review approach to be scientifically sound and did not recommend further review. Therefore, these actions do not merit further SAB review.

The Endangerment Finding for Lead Emissions from Piston-Engine Aircraft Using Leaded Aviation Gasoline (2060-AT10) is a long-term action that requires the EPA to evaluate whether lead emissions from aircraft operating on leaded aviation gasoline (“avgas”) cause or contribute to air pollution that may be reasonably anticipated to endanger public health. Lead is still used as an octane booster in avgas that is used in piston-engine aircraft, mostly for general aviation. EPA will use the National Emission Inventory of lead emissions from use of leaded avgas, demographic analysis of populations living or attending school near airports, surveillance monitoring data for 17 airports, and estimates of lead concentrations near airports. EPA plans to conduct a letter peer review of the nationwide analysis of lead concentrations in air at airports by five experts. EPA will provide responses to peer review comments and issue a final report. Because key elements of this action have already undergone, or will undergo, peer review, this action does not merit further review by the SAB.

Control of Air Pollution from Aircraft and Aircraft Engines: Proposed GHG Emissions Standards and Test Procedures (2060-AT26) is listed as a long term action, with a notice of proposed rulemaking due January 2018 and a final rule due December 2018. The Work Group finds that the planned action is significant and would benefit from SAB advice and comment. The Work Group notes that there are temporal constraints on completing the rulemaking and recommends the SAB provide advice on this issue, or at a minimum, the EPA should conduct a panel review that allows communication across the two proposed peer review panels in order to encourage synergistic understanding among the disciplines involved.

The Work Group notes the SAB previously reviewed *Proposed Finding that Greenhouse Gas Emissions from Aircraft Cause or Contribute to Air Pollution that May Reasonably be Anticipated to Endanger Public Health and Welfare and Advanced Notice of Proposed Rulemaking (2060-AS31)* in the Fall 2014² Regulatory Review and found that subsequent steps in the regulatory process will involve substantive scientific issues that may warrant SAB consideration. The Work Group recommends that the SAB ask the agency to regularly inform the SAB about the status of subsequent steps on this topic and also asks the EPA to provide it with briefings on the science underlying agency approaches to address greenhouse gas emissions and related climate change actions.

The Emission Guidelines for the Existing Oil and Natural Gas Sector (2060-AT29) is a long-term action, which was triggered when the EPA established New Source Performance Standards (NSPS) on new sources of emissions of greenhouse gases in the oil and gas sector. This action is in the early stages of development and the Work Group notes the agency has withdrawn the 2016 Information Collection Request (ICR) from the oil and gas industry; as a result, there is insufficient information to review. The SAB should evaluate the science supporting the planned action when more information about the proposed rule and the science supporting it are made available. At that time, the SAB will determine whether it wishes to offer advice and comment to the Administrator.

² SAB Discussions about EPA Planned Actions in the Fall 2014 Unified Agenda and their Supporting Science <https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/d789240481a106d085257dc4005dcef6!OpenDocument>

The Work Group notes that eight actions in the Fall 2016 semi-annual regulatory agenda are Risk and Technology Reviews (RTRs) for National Emissions Standards for Hazardous Air Pollutants (NESHAPs) are required by the Clean Air Act (see Table 1). Within eight years of promulgation of emission standards, EPA must assess the technology and residual risk to determine whether additional standards are needed to provide an ample margin of safety to protect public health and prevent adverse environmental effects (taking into consideration costs, energy, safety, and other relevant factors). Each RTR analysis follows a consistent risk characterization approach using methodologies that have undergone consultations, advisories and peer reviews by the SAB as the methodology is enhanced (SAB 1999, 2000, 2006, and 2010). The Work Group also notes that the EPA and SAB are planning an additional review of Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis in 2017.

The Work Group finds that there are many different sectors that use the RTR methodology. These different sectors incorporate and use data and information that are appropriate to that sector. The Work Group finds that while these eight actions do not merit further review by the SAB, the agency may benefit from SAB advice when new novel science or technologies are part of a planned action for specific sectors. The Work Group encourages the Board to recommend that the Agency provide as much sector specific information as available to assist the Board in conducting the screening review of future regulatory agendas. The Work Group also notes that the planned SAB review may provide recommendations for changes in the RTR methodology and encourages the agency to incorporate those recommendations into future RTRs.

Table 1 identifies the 14 planned actions reviewed and summarizes the Work Group’s recommendations. Attachment B provides the EPA’s descriptions of the planned actions, and the SAB Work Group’s recommendation for each of the planned actions with the supporting rationales.

Table 1: Summary of Proposed Actions that the SAB Work Group Considered for Additional SAB Comment on the Supporting Science		
RIN¹	Planned Action Title	Workgroup Recommendation
<u>2060-AT04</u>	Renewable Fuel Volume Standards (RFVS) for 2018 and Biomass Based Diesel Volume (BBD) for 2019	No further SAB consideration is merited.
<u>2070-AK20</u>	Procedures for Evaluating Existing Chemical Risks Under the Toxic Substances Control Act	No further SAB consideration is merited
<u>2070-AK23</u>	Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act	No further SAB consideration is merited
<u>2060-AT10</u>	Endangerment Finding for Lead Emissions From Piston-Engine Aircraft Using Leaded Aviation Gasoline	No further SAB consideration is merited

Table 1: Summary of Proposed Actions that the SAB Work Group Considered for Additional SAB Comment on the Supporting Science		
RIN¹	Planned Action Title	Workgroup Recommendation
2060-AT26	Control of Air Pollution From Aircraft and Aircraft Engines: Proposed GHG Emissions Standards and Test Procedures	The Chartered SAB should provide advice on this action
2060-AT29	Emission Guidelines for the Existing Oil and Natural Gas Sector	The Chartered SAB should evaluate whether to provide advice when more information are available.
2060-AT00	Stationary Combustion Turbine, National Emission Standard Hazardous Air Pollutant (NESHAP) Residual Risk and Technology Review (RTR)	No further SAB consideration is merited.
2060-AT01	Engine Test Cells National Emission Standard for Hazardous Air Pollutants (NESHAP) RTR	No further SAB consideration is merited.
2060-AT02	National Emission Standards for Hazardous Air Pollutants for Source Categories: Generic Maximum Achievable Control Technology Standards--Ethylene Production (Subparts XX and YY)	No further SAB consideration is merited.
2060-AT03	National Emission Standards for Hazardous Air Pollutants for Integrated Iron and Steel Manufacturing Facilities RTR	No further SAB consideration is merited.
2060-AT05	National Emission Standards for Hazardous Air Pollutants: Taconite Iron Ore Processing RTR	No further SAB consideration is merited.
2060-AT07	Rubber Tire Manufacturing RTR	No further SAB consideration is merited.
2060-AT08	Lime Manufacturing RTR	No further SAB consideration is merited.
2060-AT12	National Emission Standard for Hazardous Air Pollutants (NESHAP) RTR: Reinforced Plastics Composites and Boat Manufacturing	No further SAB consideration is merited.
¹ The Regulatory Identification Number provides a hyperlink to the Office of Management and Budget's webpage and information on the planned action provided in the Unified Regulatory Agenda on the OMB website http://www.reginfo.gov/		

Attachments

Attachment A: Implementation Process for Identifying EPA Planned Actions for SAB Consideration

Attachment B: SAB Work Group Recommendations on Major EPA Planned Actions Identified in the Fall 2016 Semi-Annual Regulatory Agenda.

Attachment A

Implementation Process for Identifying EPA Planned Actions for SAB Consideration

Background on the EPA Process

- ◆ The Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA, see p. 4)
 - ◆ Requires the EPA to make available to the SAB proposed criteria documents, standards, limitations, or regulations provided to any other Federal agency for formal review and comment together with relevant scientific and technical information in the possession of the agency on which the proposed action is based.
 - ◆ States that the Board may make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed actions.
- ◆ In January 2012, Office of Policy Associate Administrator Michael Goo issued a memorandum to strengthen coordination with the SAB by providing the Board with information about *proposed* agency actions. (see page p. 9)
- ◆ In February 2012, SAB Staff developed an initial proposal to provide the SAB with information about *proposed* agency actions.
 - ◆ EPA Senior Leadership concluded that providing information to the SAB for consideration at the proposal stage was *too late* in the process for meaningful involvement.
- ◆ In March 2012, the SAB held a public meeting and discussed the Goo memo and a pilot to consider the science underlying four proposed rules identified by OAR (standards for air toxics from boilers and incinerators and greenhouse gas emissions and fuel economy standards for light-duty vehicles).
 - ◆ The SAB:
 - ◆ Did not identify any science topics related to the four proposed rules warranting SAB comment.
 - ◆ Noted that the proposal stage was *too late* in the process for meaningful input.
 - ◆ Discussed the need for adequate information on the underlying science for agency actions early in the process. Information beyond the information presented in the Semiannual Regulatory Agenda is needed for this purpose.
- ◆ On January 2, 2013, Associate Administrator Michael Goo, the Administrator’s Science Advisor Glenn Paulson, and the SAB Office Director Vanessa Vu issued a memorandum (see p. 10) “Identifying EPA Planned Actions for Science Advisory Board (SAB) Consideration of the Underlying Science – Semi-annual Process” requiring EPA to provide short descriptions of *major planned actions that are not yet proposed* appearing in the semi-annual regulatory agenda

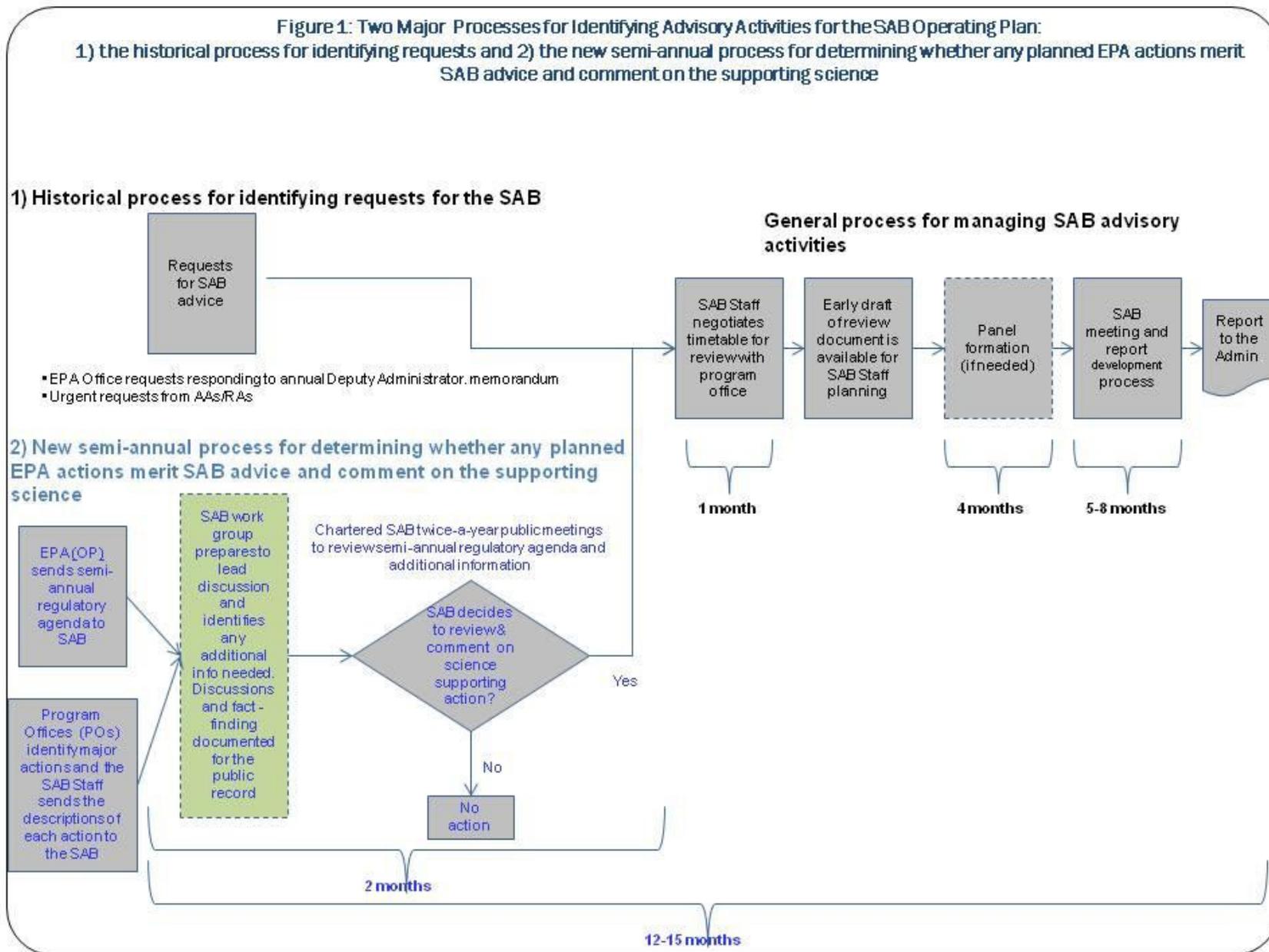
Attachment A: Identifying EPA Planned Actions for SAB Consideration

- ◆ This process supplements the Deputy Administrator's annual memorandum requesting program and regional offices to identify scientific issues that might be appropriate for SAB consideration.

SAB Process

- ◆ The SAB Staff manages the semi-annual process for determining whether any planned EPA actions merit SAB advice and comment on the supporting science as part of the entire SAB operating plan (see Figure 1).

Attachment A: Identifying EPA Planned Actions for SAB Consideration



**Environmental Research, Development, and Demonstration Authorization Act
[(ERDDAA), 42 U.S.C. 4365]**

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 55--NATIONAL ENVIRONMENTAL POLICY

SUBCHAPTER III--MISCELLANEOUS PROVISIONS

Sec. 4365. Science Advisory Board

(a) Establishment; requests for advice by Administrator of Environmental Protection Agency and Congressional committees

The Administrator of the Environmental Protection Agency shall establish a Science Advisory Board which shall provide such scientific advice as may be requested by the Administrator, the Committee on Environment and Public Works of the United States Senate, or the Committee on Science, Space, and Technology, on Energy and Commerce, or on Public Works and Transportation of the House of Representatives.

(b) Membership; Chairman; meetings; qualifications of members

Such Board shall be composed of at least nine members, one of whom shall be designated Chairman, and shall meet at such times and places as may be designated by the Chairman of the Board in consultation with the Administrator. Each member of the Board shall be qualified by education, training, and experience to evaluate scientific and technical information on matters referred to the Board under this section.

(c) Proposed environmental criteria document, standard, limitation, or regulation; functions respecting in conjunction with Administrator

(1) The Administrator, at the time any proposed criteria document, standard, limitation, or regulation under the Clean Air Act [42 U.S.C. 7401 et seq.], the Federal

Attachment A: Identifying EPA Planned Actions for SAB Consideration

Water Pollution Control Act [33 U.S.C. 1251 et seq.], the Resource Conservation and Recovery Act of 1976 [42 U.S.C. 6901 et seq.], the Noise Control Act [42 U.S.C. 4901 et seq.], the Toxic Substances Control Act [15 U.S.C. 2601 et seq.], or the Safe Drinking Water Act [42 U.S.C. 300f et seq.], or under any other authority of the Administrator, is provided to any other Federal agency for formal review and comment, shall make available to the Board such proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the Environmental Protection Agency on which the proposed action is based.

(2) The Board may make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed criteria document, standard, limitation, or regulation, together with any pertinent information in the Board's possession.

(d) Utilization of technical and scientific capabilities of Federal agencies and national environmental laboratories for determining adequacy of scientific and technical basis of proposed criteria document, etc.

In preparing such advice and comments, the Board shall avail itself of the technical and scientific capabilities of any Federal agency, including the Environmental Protection Agency and any national environmental laboratories.

(e) Member committees and investigative panels; establishment; chairmanship

The Board is authorized to constitute such member committees and investigative panels as the Administrator and the Board find necessary to carry out this section. Each such member committee or investigative panel shall be chaired by a member of the Board.

(f) appointment and compensation of secretary and other personnel; compensation of members

Attachment A: Identifying EPA Planned Actions for SAB Consideration

(1) Upon the recommendation of the Board, the Administrator shall appoint a secretary, and such other employees as deemed necessary to exercise and fulfill the Board's powers and responsibilities. The compensation of all employees appointed under this paragraph shall be fixed in accordance with chapter 51 and subchapter III of chapter 53 of title 5.

(2) Members of the Board may be compensated at a rate to be fixed by the President but not in excess of the maximum rate of pay for grade GS-18, as provided in the General Schedule under section 5332 of title 5.

(g) Consultation and coordination with Scientific Advisory Panel

In carrying out the functions assigned by this section, the Board shall consult and coordinate its activities with the Scientific Advisory Panel established by the Administrator pursuant to section 136w(d) of title 7.

(Pub. L. 95-155, Sec. 8, Nov. 8, 1977, 91 Stat. 1260; Pub. L. 96-569, Sec. 3, Dec. 22, 1980, 94 Stat. 3337; Pub. L. 103-437, Sec. 15(o), Nov. 2, 1994, 108 Stat. 4593; Pub. L. 104-66, title II, Sec. 2021(k)(3), Dec. 21, 1995, 109 Stat. 728.)



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460**

2

OFFICE OF THE ADMINISTRATOR

MEMORANDUM

SUBJECT: Identifying EPA Planned Actions for Science Advisory Board (SAB)
Consideration of the Underlying Science- Semi-annual Process

FROM: Michael Goo, Associate Administrator
Office of Policy

Glenn Paulson
Science Advisor

Vanessa Vu, Director
SAB Staff Office

TO: General Counsel
Assistant Administrators
Associate Administrators
Regional Administrators

The purpose of this memorandum is to provide guidance for implementing improved coordination with the SAB, the goal of the memorandum dated January 19, 2012 on that topic (Attachment A).

We ask that you work with the Office of Policy to provide the SAB Staff Office with information about the science supporting major planned agency actions (Tier 1 and Tier 2 actions) that are in the pre-proposal stage. The *2012 Unified (Regulatory) Agenda and Regulatory Plan* was published on December 21, 2012 on the Office of Management and Budget web site <http://www.reginfo.gov/public/>.

Please provide the SAB Staff Office (contact: Angela Nugent) by January 30, 2013, a brief description of each action along with its supporting science, following the format provided in Attachment B. Please ensure that these submissions to the SAB are consistent with information developed in the action development process.

This process supplements the Deputy Administrator's annual memorandum requesting program and regional offices- to identify scientific issues that might be appropriate for SAB consideration.

Attachment A: Identifying EPA Planned Actions for SAB Consideration

We look forward to working with you on this new process to strengthen science supporting EPA's decisions. Please contact us or Caryn Muellerleile (202-564-2855) in the Office of Policy or Angela Nugent (202-564-2218) in the SAB Staff Office, should there be questions.

Attachments

cc: Administrator
Deputy Administrator
Chief of Staff
Deputy Chief of Staff

Attachment A: January 19, 2012 Memorandum from Michal L. Goo



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 19 2012

OFFICE OF
POLICY

MEMORANDUM

SUBJECT: Coordination with the Science Advisory Board Regarding Proposed Criteria Documents, Standards, Limitations and Regulations

FROM: Michael L. Goo, Associate Administrator *MLG*
Office of Policy

TO: Assistant Administrators
General Counsel
Chief of Staff
Associate Administrators
Regional Administrators

This is to confirm the procedures that we have discussed regarding coordination with the Science Advisory Board (SAB) on the science and technical information underlying the EPA's proposed criteria documents, standards, limitations and regulations.

In addition to the current process by which program offices identify actions on which they plan to seek advice from the SAB on scientific and technical issues, OP will semiannually inform the SAB, through the SAB Staff Office, of upcoming proposed actions. This process will focus on those proposed regulations, criteria documents, standards or limitations that undergo interagency review and will operate as follows:

1. OP will submit to the SAB staff office a list, based on the Agency's *Semiannual Regulatory Agenda (Regulatory Agenda)*, augmented as necessary, of upcoming proposed regulations, criteria documents, standards or limitations that are expected to undergo interagency review. OP will work with program and regional offices to ensure that any actions not listed in the *Regulatory Agenda* that nevertheless are expected to be submitted for interagency review are included in this submission. For any of these additional actions, offices should provide a description similar to that provided for actions included in the *Regulatory Agenda*.

Attachment A: Identifying EPA Planned Actions for SAB Consideration

2. Program and Regional offices will notify the SAB staff office when proposed Agency actions that undergo interagency review become formally available for public review and comment. EPA programs are also expected to provide additional information as requested by the SAB Staff Office to facilitate the SAB's consideration of this information.

If the SAB decides to review and, as appropriate, comment on the scientific and technical basis for a proposed action, OP will work with the SAB Staff Office and the relevant program or regional office to establish the appropriate time frame for SAB review and comment.

Thank you for your assistance in adhering to this process. If you have any questions or concerns, please contact me, or your staff can contact Nicole Owens owens.nicole@epa.gov, at 202 (564-1550).

cc: Bob Perciasepe
Bob Sussman
Deputy Assistant Administrators
Deputy Associate Administrators
Deputy Regional Administrators
Assistant Regional Administrators
Alex Cristofaro
Nicole Owens
Vanessa Wu
Thomas Brennan

**Attachment B - Sample Description of Major Planned EPA Action-
Information to be Provided to the SAB**

Name of action: Development of Best Management Practices for Recreational Boats Under Section 312(o) of the Clean Water Act

EPA Office originating action: OW

Brief description of action and statement of need for the action:

This action is for the development of regulations by EPA to implement the Clean Boating Act (Public Law 110-288), which was signed by the President on July 29, 2008. The Clean Boating Act amends section 402 of the Clean Water Act (CWA) to exclude recreational vessels from National Pollutant Discharge Elimination System permitting requirements. In addition, it adds a new CWA section 312(o) directing EPA to develop regulations that identify the discharges incidental to the normal operation of recreational vessels (other than a discharge of sewage) for which it is reasonable and practicable to develop management practices to mitigate adverse impacts on waters of the United States. The regulations also need to include those management practices, including performance standards for each such practice. Following promulgation of the EPA performance standards, new CWA section 312(o) directs the Coast Guard to promulgate regulations governing the design, construction, installation, and use of the management practices. Following promulgation of the Coast Guard regulations, the Clean Boating Act prohibits the operation of a recreational vessel or any discharge incidental to their normal operation in waters of the United States and waters of the contiguous zone (i.e., 12 miles into the ocean), unless the vessel owner or operator is using an applicable management practice meeting the EPA-developed performance standards.

Timetable:

Statutory: Phase 1 - 2009, Phase 2 - 2010, and Phase 3 – 2011
Regulatory Agenda: Phase 1 NPRM - 2013, Phase 1FR - 2014

Does the action rely on science that meets the EPA *Peer Review Handbook* definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

No

Scientific questions to be addressed and approach:

Recreational boating activities can contribute to the spread of aquatic nuisance species, primarily through the secondary transport of organisms introduced to U.S. waters via other vectors. For example, recreational boating has been linked to the spread of Zebra and Quagga mussels from their initial introduction into the Great Lakes to other U.S. waters. Consequently, the Agency is considering the development of regulations designed to reduce the spread of such organisms by reducing propagule pressure from the recreational vessel vectors. Propagule pressure is a measure

Attachment A: Identifying EPA Planned Actions for SAB Consideration

of the number of individual organisms released as well as the number of discrete release events. While there is a general consensus that an increase in propagule pressure increases the probability of establishing a self-sustaining population of an aquatic nuisance species, the probability is a complex function of a wide range of variables. These variables include species traits (e.g., viability, reproductive capability, and environmental compatibility) and environmental traits (e.g., retention of propagules, and interactions with resident species). When addressing secondary transport via recreational vessels, as this project is designed to specifically do, additional variables such as vessel characteristics, voyage type, and propagule exposure need to be considered. Due to the complexity of this issue, the Agency is seeking expert scientific opinions on management practices that can reduce propagule pressure that results from recreational boating activities.

Plans for scientific analyses and peer review:

The Agency is planning to convene a workshop on secondary transport of aquatic nuisance species via recreational vessels. Invited participants will have expertise in the field of invasion biology and each participant will be charged to provide their expert scientific opinion on management practices that the Agency should consider as part of this rule making.

Attachment B

SAB Work Group Recommendations on the Major EPA Planned Actions in the Fall 2016 Semi-Annual Regulatory Agenda

The SAB formed a Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science in December 2016 to review information and short descriptions provided by the EPA Program Offices on the major planned actions that are listed in the Fall 2016 semi-annual Unified Regulatory Agenda but not yet proposed.

After reviewing the Descriptions of Tier 1 and Tier 2 Actions and additional information provided by EPA, SAB Work Group members developed and concurred on the recommendations and discussion provided in this attachment to the June 13, 2017 Work Group memorandum.

RIN ¹	Title	Stage of Rulemaking	Page
2060-AT04	Renewable Fuel Volume Standards (RFVS) for 2018 and Biomass Based Diesel Volume (BBD) for 2019	Proposal	2
2070-AK20	Procedures for Evaluating Existing Chemical Risks Under the Toxic Substances Control Act	Proposed	8
2070-AK23	Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act	Proposed	12
2060-AT10	Endangerment Finding for Lead Emissions From Piston-Engine Aircraft Using Leaded Aviation Gasoline	Long-Term	16
2060-AT26	Control of Air Pollution From Aircraft and Aircraft Engines: Proposed GHG Emissions Standards and Test Procedures	Long-Term	22
2060-AT29	Emission Guidelines for the Existing Oil and Natural Gas Sector	Long-Term	29
2060-AT00	Stationary Combustion Turbine, National Emission Standard Hazardous Air Pollutant (NESHAP) Residual Risk and Technology Review (RTR)	Long-Term	32
2060-AT01	Engine Test Cells National Emission Standard for Hazardous Air Pollutants (NESHAP) RTR	Long-Term	37
2060-AT02	National Emission Standards for Hazardous Air Pollutants for Source Categories: Generic Maximum Achievable Control Technology Standards--Ethylene Production (Subparts XX and YY)	Long-Term	42
2060-AT03	National Emission Standards for Hazardous Air Pollutants for Integrated Iron and Steel Manufacturing Facilities RTR	Long-Term	47
2060-AT05	National Emission Standards for Hazardous Air Pollutants: Taconite Iron Ore Processing RTR	Long-Term	52
2060-AT07	Rubber Tire Manufacturing RTR	Long-Term	57
2060-AT08	Lime Manufacturing RTR	Long-Term	62
2060-AT12	National Emission Standard for Hazardous Air Pollutants (NESHAP) RTR: Reinforced Plastics Composites and Boat Manufacturing	Long-Term	67

¹ Regulatory Identification Number is linked to the actions initial information on the OMB Regulatory Agenda webpage

**Recurring Action Form for Actions that
May not Merit Further SAB consideration
Description of Planned EPA Tier 1 or Tier 2 Action**

Name of action: Proposed Renewable Fuel Volume Standards for 2018 and Biomass Based Diesel Volume (BBD) for 2019

RIN Number: 2060-AS72

EPA Office originating action: OAR

Brief description of action

Section 211(o) of the Clean Air Act establishes the Renewable Fuels Standard (RFS) program, which requires that an increasing amount of transportation fuel be made from renewable feedstocks over time. The statute includes volume targets for four different categories of biofuels, for which EPA is directed to establish annual percentage standards: cellulosic biofuel, biomass-based diesel, advanced biofuel, and total renewable fuel. The statute includes tables indicating volume objectives through 2022 for cellulosic biofuel, advanced biofuel, and total renewable fuel, and through 2012 for biomass-based diesel. The Act also includes waiver authorities allowing EPA to reduce statutory volumes in appropriate circumstances. After 2012 for biomass-based diesel and after 2022 for the other fuel categories the statute provides EPA the authority to determine the volumes (the statute sets a minimum of 1 billion gallons for biomass-based diesel), and specifies factors for EPA to consider in determining the required volumes.

EPA finalized Renewable Fuel Standards regulations implementing Section 211(o) of the Clean Air Act in 2007, and also adopted substantial revisions in 2010 to implement statutory amendments enacted as part of the 2007 Energy Independence and Security Act. However, the statute requires EPA to promulgate annual rules to translate the renewable fuel volumes into percentage standards that reflect the projected gasoline and diesel fuel demand in the following year. In establishing these annual standards EPA may implement either the statutory volumes, or alternative volumes that EPA establishes using its authorities to lower statutory volumes or to set volumes for years not addressed in the statute. EPA has promulgated these annual standards every year beginning with 2007. For 2014, for the first time, EPA proposed to exercise our waiver authorities to set the applicable volumes of advanced biofuel and total renewable fuels below statutory levels, in light of the unavailability of certain types of renewable fuels and practical and legal constraints on supplying renewable fuels to consumers. The SAB reviewed this action as part of the Review of the Spring 2013 Regulatory Agenda and concluded that the action did not merit further consideration.² EPA subsequently re-proposed the 2014 annual standards along with standards for 2015 and 2016 and the biomass-based diesel applicable volume for 2017. On November 30, 2015, EPA finalized the annual standards for 2014-16 and the biomass-based diesel applicable volume for 2017; our action on 2016 standards gets us back on the statutory schedule for completing these actions. On November 23, 2016 EPA finalized the annual standards for 2017 and the applicable volume of biomass-based diesel for 2018.

² SAB [Discussions about EPA Planned Actions in the Spring 2013 Unified Agenda and their Supporting Science](#) and recommendations are available on the SAB website

The rule establishing the 2018 annual RFS standards and 2019 biomass-based diesel applicable volume is the next of these statutorily-required annual RFS rulemakings.

Justification for considering this action a recurring action.

As stated above, this is a statutorily mandated annual rulemaking. EPA is required to issue a rulemaking every year establishing applicable standards for obligated parties under the RFS program. This is a routine action that will rely on the same approach and sources of data that were used in the rules establishing required standards for recent years. The analytical work underlying the annual RFS annual rules (including for 2018) is based on historical data regarding renewable fuel production, imports, distribution, and use. That information is then used to project renewable fuel volumes for use in the proposed/final rulemakings. We then divide those volumes by gasoline and diesel projections taken from the Energy Information Agency (EIA) to calculate the percentage standards that apply directly to obligated parties like refiners.

For 2018, we will be updating all relevant data as we formulate the proposed and final rules. We do not currently expect to incorporate new methodological approaches that would rely on any new scientific data or touch upon novel issues.

For reference purposes, EPA is attaching the template we submitted to the SAB for the 2015 annual RFS volume rulemaking action. The SAB declined to select that action for in-depth review.

The SAB's decision on the earlier action (check the appropriate line and attach previous description)

The SAB did not select the earlier action for in-depth review

The SAB selected the earlier action for in-depth review.

Attachments to Proposed RFVS for 2018 and BBD Volume (BBD) for 2019 (2060-AS72): Previous Agency Description³

Name of action: Renewable Fuel Standard (RFS) Volume Standards for 2015

RIN Number: 2060-AR63

EPA Office originating action: OAR

Brief description of action and statement of need for the action:

Section 211(o) of the Clean Air Act establishes the Renewable Fuels Standard (RFS) program, which requires that an increasing amount of transportation fuel be made from renewable feedstocks over time, reaching 36 billion gallons by 2022. These 36 billion gallons are made up of four different categories of biofuels, each with its own standard: cellulosic biofuel, biomass-based diesel, advanced biofuel, and total renewable fuel. The statute includes tables indicating volume objectives through 2022 for cellulosic biofuel, advanced biofuel, and total renewable fuel, and through 2012 for biomass-based diesel. After 2012 for biomass-based diesel and after 2022 for the other standards the statute provides EPA the authority to determine the volumes (the statute sets a minimum of 1 billion gallons for biomass-based diesel), and specifies factors for EPA to consider in determining the required volumes. The Act also includes waiver authorities allowing EPA to reduce statutory volumes in appropriate circumstances.

EPA finalized Renewable Fuel Standards regulations implementing Section 211(o) of the Clean Air Act in 2007, and also adopted substantial revisions in 2010 to implement statutory amendments enacted as part of the 2007 Energy Independence and Security Act. However, the statute requires EPA to promulgate annual rules to translate the renewable fuel volumes into percentage standards that reflect the projected gasoline and diesel fuel demand in the following year. In establishing these annual standards EPA may implement either the statutory volumes, or alternative volumes that EPA establishes using its discretionary authorities to lower statutory volumes or to set volumes for years not addressed in the statute. EPA has promulgated these annual standards every year beginning with 2007. In 2014, for the first time, EPA proposed to exercise our waiver authorities to set the applicable volumes of advanced and total renewable fuels below statutory levels, in light of unavailability of certain types of renewable fuels and practical and legal constraints on supplying renewable fuels to consumers. The SAB reviewed this action in the as part of the Review of the Spring 2013 Regulatory Agenda and concluded that the action did not merit further consideration.⁴

The 2015 RFS volume rule is the next of these statutorily-required annual RFS rulemakings.

Timetable: To OMB: late fall or early winter 2014

NPRM - Signature: TBD

³ submitted with Fall 2013 Regulatory Agenda

⁴ SAB [Discussions about EPA Planned Actions in the Spring 2013 Unified Agenda and their Supporting Science](#) and recommendations are available on the SAB website

Does the action rely on science that meets the EPA *Peer Review Handbook* definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

No. The analytical work underlying the annual RFS volume rules is based on historical data regarding renewable fuel production, imports, distribution, and use, along with information on micro- and macro-economic factors affecting the underlying data. That information is then used to project renewable fuel volumes for use in the proposed/final rulemakings. This rulemaking will follow the same basic approach as prior annual rulemakings.

Scientific questions to be addressed and approach:

None – as noted above, the data and methodologies supporting this action are consistent with approaches established by previous volume standards, including the 2013 volume standard approach reviewed by the SAB.

Plans for scientific analyses and peer review:

As with previous rules, the analytical work underlying this annual RFS volume rule is based on historical data and updates to historical data regarding renewable fuel production, imports, distribution, and use, along with information on micro- and macro-economic factors affecting these underlying data. The updated information is used to conduct analyses and project renewable fuel volumes for use in the proposed/final rulemakings. This technical/analytical work, which is expected to apply approaches already established through prior volume standards, does not raise any new scientific issues. We also rely to some extent on the analyses conducted as part of the RFS2 final rulemaking released on March 26, 2010.⁵ In addition to going through the full public notice and comment process, the relevant data and methods that might have raised novel scientific issues in establishing the RFS2 final regulations in 2010 were peer-reviewed. We do not expect to conduct an additional peer review process for analyses underlying the 2015 standards rule since the decisions will be informed by analyses and employ methodologies that are not expected to present any additional novel or controversial scientific issues and/or have been previously utilized.

⁵ Materials on the RFS2 are available on the EPA web page:

- Fact Sheet: [EPA Finalizes New Regulations for the National Renewable Fuel Standard Program for 2010 and Beyond \(PDF\)](#) (7 pp, 162K, EPA-420-F-10-007, February 2010)
- Fact Sheet: [EPA Lifecycle Analysis of Greenhouse Gas Emissions from Renewable Fuels \(PDF\)](#) (4 pp, 109K, EPA-420-F-10-006, February 2010)
- [Q&A on the RFS2 http://www.epa.gov/otaq/fuels/renewablefuels/compliancehelp/rfs2-aq.htm](http://www.epa.gov/otaq/fuels/renewablefuels/compliancehelp/rfs2-aq.htm)

The FR Notice <http://www.gpo.gov/fdsys/pkg/FR-2010-03-26/pdf/2010-3851.pdf>

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Proposed Renewable Fuel Volume Standards for 2018 and Biomass Based Diesel Volume (BBD) for 2019 [RIN 2060-AT04]

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		x
Is the action primarily administrative (i.e., involve reporting or record keeping)?	x	
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		x
Is the action an extension of an existing initiative?	x	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			x
Addresses areas of substantial uncertainties			x
Involves major environmental risks			x
Relates to emerging environmental issues		x	
Exhibits a long-term outlook		x	

Recommendation: This action does not merit further SAB consideration.

Background: The Renewable Fuel Standard (RFS) program began in 2006 pursuant to the requirements in the Clean Air Act (CAA) section 211(o) that were added through the Energy Policy Act of 2005 (EPAct), and subsequently modified through the Energy Independence and Security Act of 2007 (EISA). EISA's goals include moving the United States toward "greater energy independence and security, to increase the production of clean renewable fuels." Per the CAA, section 211(o)(2), Congress specified increasing annual volume targets for total renewable fuel, advanced biofuel, and cellulosic biofuel for each year through 2022, and for biomass-based diesel through 2012, and authorized the EPA to set volume requirements for subsequent years in coordination with USDA and DOE, and after consideration of specified factors such economic impact, environmental impact, and domestic supply. Congress also recognized that under certain circumstances it would be appropriate for EPA to set volume requirements at lower levels than reflected in the statutory volume targets, and thus provided waiver provisions. For example, since 2014 the slower than expected development of the cellulosic biofuel industry and constraints in the marketplace have resulted in the use of waivers to set volume targets below congressionally specified values.

Rationale: This is a statutorily mandated annual rulemaking. EPA is required to issue a rulemaking every year establishing applicable standards for obligated parties under the RFS program. This is a routine action that relies on the same approach and sources of data that were used in the rules establishing required standards in past years. The analytical work underlying the annual RFS annual rules is based on historical data regarding renewable fuel production, imports, distribution, and use. That information is then used to project renewable fuel volumes for use in the proposed/final rulemakings. These volumes are divided by gasoline and diesel volume projections taken from the Energy Information Agency (EIA) to calculate the percentage standards that apply directly to obligated parties like refiners. The EPA does “not currently expect to incorporate new methodological approaches that would rely on any new scientific data or touch upon novel issues” to determine the renewable fuel volume standards for 2018 and the biomass based diesel volume (BBD) for 2019.

Description of Planned EPA Tier 1 or Tier 2 Action

- 1. Name of action:** Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act
- 2. RIN Number:** RIN 2070-AK20
- 3. EPA Office originating action:** Office of Chemical Safety and Pollution Prevention/Office of Pollution Prevention and Toxics
- 4. Brief description of action and statement of need for the action:** As required under section 6(b)(4) of the Toxic Substances Control Act (TSCA), EPA is proposing to establish a process for conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use. Risk evaluation is the second step, after Prioritization, in the new process of existing chemical substance review and management established under recent amendments to TSCA. This procedural rule identifies the steps of a risk evaluation process including scope, hazard assessment, exposure assessment, risk characterization, and finally a risk determination. EPA is proposing that this process be used for the first ten chemical substances to be evaluated from the 2014 update of the TSCA Work Plan for Chemical Assessments, chemical substances designated as High-Priority Substances during the prioritization process, and those chemical substances for which EPA has initiated a risk evaluation in response to manufacturer requests. This rule also includes the required “form and criteria” applicable to such manufacturer requests.
- 5. Timetable:** According to the statute, the Agency must publish the finalized risk evaluation rule 1 year after the law was enacted which would be June 22, 2017.

The proposed rule was published in the FR on January 19, 2016 and the associated comment period concludes on March 20, 2017.

<https://www.federalregister.gov/documents/2017/01/19/2017-01224/procedures-for-chemical-risk-evaluation-under-the-amended-toxic-substances-control-act>

6. Scientific products that will inform the action and plans for peer review:

6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.

This action, when finalized would establish the process for conducting risk evaluations under the amended TSCA, including steps that must be completed and associated timeframes. The process proposed here is not new, but uses processes already utilized by the Agency for evaluating chemicals. These processes have been extensively reviewed and have evolved utilizing external review and

comment. This rule itself does not contain specific scientific work products, however the result of the implementation of this rule, once finalized, may result in products.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

NA – there are no work products as a result of this rule.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

NA – there are no work products as a result of this rule.

6(d). Peer review:

This proposed rule did not require external peer review because it is not a scientific work product. The proposed rule does contain the requirement that the Agency conduct peer review for each risk evaluation as well as on any novel scientific method utilizing Agency policies and guidelines on peer review.

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Procedures for Evaluating Existing Chemical Risks Under the Toxic Substances Control Act [RIN 2070 AK20]

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties		X	
Involves major environmental risks		X	
Relates to emerging environmental issues			X
Exhibits a long-term outlook		X	

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further SAB consideration.

Rationale: This action proposes a process for conducting risk evaluations under section 6(b)4 of TSCA. Risk evaluation follows Prioritization (considered under 2070-AK23). The rule identifies the steps in a risk evaluation, using existing methods and the weight of evidence approach that has been applied consistently by the agency. The proposed rule was published in the Federal Register on January 19, 2016 and the associated comment period concludes on March 20, 2017. EPA must publish the finalized risk evaluation rule one year after enactment, which would be June 22, 2017.

The Agency’s procedures for the TSCA actions peer review include: 1) developing a Peer Review Plan for each assessment that is submitted to the public record in the docket and on the agency’s web page, 2) following a documented process for reviews of Highly Influential Science Assessments and Influential Science Assessments, and 3) announcing the peer review panel public meetings in the Federal Register. The Federal Register notice announces opportunities for public comment (at the meetings and the

docket), the public meeting logistics, and the peer review panel members. The Federal Register notice is submitted to the docket and posted on the agency's web page in addition to being published. There are also opportunities for public input on peer review plans, chemical assessments, and opportunities to submit relevant data on assessments to the EPA docket.

For the proposed action, there will be no work product for review. Instead, work products will be created during implementation (the risk evaluations). The completed risk assessment products resulting from the TSCA evaluations will meet *the EPA Peer Review Handbook definition of "an influential scientific or technical work product"* that imply a legal and/or statutory obligation to conduct a peer review. Thus, the SAB anticipates EPA will maintain the level of analysis and peer review demonstrated in previous regulatory reviews.

The Work Group notes that the SAB previously reviewed planned actions for several specific TSCA chemicals using these methods and peer review approaches and found the approach to be scientifically sound; for example, the SAB did not recommend further review for the *Trichloroethylene (TCE); Rulemaking Under TSCA Section 6(a) and N-Methylpyrrolidone (NMP) and Methylene Chloride; Rulemaking Under TSCA Section 6(a) action* included in the Spring 2015 Unified Agenda.⁶ Therefore, this action does not merit further SAB review. However, the Work Group recommends that the SAB urge EPA to retain and improve the TSCA peer review process, and to assess the adequacy of guidance documents related to risk evaluations with input from the SAB.

⁶ SAB Discussions about EPA Planned Actions in the Spring 2015 Unified Agenda and their Supporting Science available at: <https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/0e748503053ede6285257e6e0069bc5c!OpenDocument&TableRow=2.3#2>.

Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Procedures for Prioritization of Chemicals for Risk Evaluation under Toxic Substances Control Act
2. **RIN Number:** RIN 2070-AK23
3. **EPA Office originating action:** Office of Chemical Safety and Pollution Prevention/Office of Pollution Prevention and Toxics
4. **Brief description of action and statement of need for the action:** As required under section 6(b)(1) of the Toxic Substances Control Act (TSCA), EPA is proposing to establish a risk-based screening process and criteria that EPA will use to identify chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluations are not warranted at this time. This procedural rule describes the processes for identifying potential candidates for prioritization, selecting a candidate, screening that candidate against certain criteria, formally initiating the prioritization process, providing opportunities for public comment, and proposing and finalizing designations of priority. Prioritization is the initial step in this new process of existing chemical substance review and risk management activity established under recent amendments to TSCA.
5. **Timetable:** According to the statute the Agency must publish the final prioritization rule 1 year after the law was enacted, which would be by June 22, 2017.

The proposed rule was published in the FR on January 17, 2016 and the associated comment period concludes on March 20, 2017.

<https://www.federalregister.gov/documents/2017/01/17/2017-00051/procedures-for-prioritization-of-chemicals-for-risk-evaluation-under-the-toxic-substances-control>

6. Scientific products that will inform the action and plans for peer review:

6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.

This action, when finalized would establish the process for prioritizing chemicals for risk evaluation under the amended TSCA, including steps in the process and associated timeframes. Given the procedural nature of this rulemaking, no scientific work products have been or will be developed to inform the action.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

NA – there are no scientific work products as part of this action development.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"
NA – there are no scientific work products as part of this action development.

6(d). Peer review:

NA – there are no peer review plans associated with this action development.

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act [RIN 2070-AK23]

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties	X		
Involves major environmental risks		X	
Relates to emerging environmental issues			X
Exhibits a long-term outlook		X	

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further SAB review.

Rationale: From EPA’s Description of this action: “As required under section 6(b)(1) of the Toxic Substances Control Act (TSCA), EPA is proposing to establish a risk-based screening process and criteria that EPA will use to identify chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluations are not warranted at this time. This procedural rule describes the processes for identifying potential candidates for prioritization, selecting a candidate, screening that candidate against certain criteria, formally initiating the prioritization process, providing opportunities for public comment, and proposing and finalizing designations of priority. Prioritization is the initial step in this new process of existing chemical substance review and risk management activity established under recent amendments to TSCA.” The proposed rule was published in the Federal Register on January 17, 2016 and the associated comment period concludes on March 20,

2017. EPA must publish the final prioritization rule one year after enactment, which would be by June 22, 2017.

The Agency's procedures for the TSCA actions peer review include: 1) developing a Peer Review Plan for each assessment that is submitted to the public record in the docket and on the agency's web page, 2) following a documented process for reviews of Highly Influential Science Assessments and Influential Science Assessments, and 3) announcing the peer review panel public meetings in the Federal Register. The Federal Register notice announces opportunities for public comment (at the meetings and the docket), the public meeting logistics, and the peer review panel members. The Federal Register notice is submitted to the docket and posted on the agency's web page in addition to being published. There are also opportunities for public input on peer review plans, chemical assessments, and opportunities to submit relevant data on assessments to the EPA docket.

For the proposed action, EPA would use a process similar to the prioritization previously used under TSCA, and would incorporate the new requirements of the Frank R. Lautenberg Chemical Safety for the 21st Century Act enacted on June 22, 2016. Thus, the process is not new or novel. The level of interest associated with resolution of uncertainties is assessed to be high, as there are significant data gaps for some chemicals, and we do not know how great the associated potential environmental risks might be. Overall, TSCA provides authority for EPA to establish this risk-based screening process and parts of the action have been considered by the SAB in previous review of the semi-annual regulatory agenda (Spring 2016).

When finalized, the action would establish the process for prioritizing chemicals for risk evaluation under the amended TSCA. Thus, this rulemaking is of a procedural nature and no scientific work products have been or will be developed to inform the action, and therefore no peer review will be required. The completed risk assessment products resulting from the TSCA evaluations will meet *the EPA Peer Review Handbook definition of "an influential scientific or technical work product"* that imply a legal and/or statutory obligation to conduct a peer review. Thus, the SAB anticipates EPA will maintain the level of analysis and peer review demonstrated in previous regulatory reviews, and this action does not merit further SAB review. However, as explained in the recommendation for planned action *Procedures for Evaluating Existing Chemical Risks Under the Toxic Substances Control Act (2070 -AK20)*, the Work Group recommends that the SAB urge EPA to retain and improve the TSCA peer review process, and to assess the adequacy of guidance documents related to risk evaluations with input from the SAB.

Description of Planned EPA Tier 1 or Tier 2 Action

1. Name of action: Proposed Endangerment and Cause or Contribute Findings for Lead Emissions from Piston-Engine Aircraft Using Leaded Aviation Gasoline

2. RIN Number: 2060-AT10

(ANPR: <https://www.gpo.gov/fdsys/pkg/FR-2010-04-28/pdf/2010-9603.pdf>)

3. EPA Office originating action: Office of Air and Radiation, Office of Transportation Air Quality

4. Brief description of action and statement of need for the action:

The Office of Air and Radiation's Office of Transportation and Air Quality (OTAQ) is currently evaluating, under section 231 of the Clean Air Act, whether lead emissions from aircraft operating on leaded aviation gasoline cause or contribute to air pollution that may reasonably be anticipated to endanger public health or welfare. This action follows a previous [ANPRM](#) by issuing a NPRM that will describe the endangerment and cause or contribute determinations that EPA proposes for lead emissions from general aviation aircraft. Additional information on efforts to date related to this action can be found on the aviation lead emissions portion of the EPA website (<https://www.epa.gov/regulations-emissions-vehicles-and-engines/regulations-lead-emissions-aircraft>). The FAA is currently evaluating unleaded fuels for use in the piston aircraft fleet and plans to identify an unleaded replacement fuel by 2018 (<https://www.faa.gov/about/initiatives/avgas/>).

5. Timetable:

In responses to citizen petitions to make these determinations, EPA has publicly stated its intent to issue a 2017 NPRM endangerment determination, followed by a 2018 final determination. Key milestones in the current schedule include:

December 2017 - NPRM

January 2019 - Final Rule

6. Scientific products that will inform the action and plans for peer review:

6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.

- *National Emissions Inventory of lead from the use of leaded aviation fuel*

The EPA develops a national inventory of lead emissions from piston-engine aircraft as part of the National Emissions Inventory conducted every three years. This analysis provides information regarding the relative contribution of lead to the total US inventory from aircraft activity compared to other sources (e.g., industrial processes).

- *Demographic analysis of populations living or attending school near airports*
The EPA developed an analysis to characterize the number of people who live and attend school near airports. This analysis provides an estimate of the total population potentially living in or attending school in areas where emissions of lead from piston-engine aircraft may impact ambient concentrations of lead, including the number of children as well as an analysis by race. This analysis is not an exposure assessment, and thus will be used to provide estimates of the number of individuals living in areas around airports where piston-engine aircraft operate.
- *Monitored concentrations of lead in air at 17 airports*
The EPA finalized lead monitoring requirements in 2008 and 2010 which resulted in NAAQS surveillance monitoring at 17 airports. This information will be used to evaluate the question of whether aircraft emissions of lead cause or contribute to air pollution that may reasonably be anticipated to endanger public health or welfare. Information about the criteria for selection of these airports and the monitored lead concentrations are available on EPA's aircraft lead website (<https://www.epa.gov/regulations-emissions-vehicles-and-engines/airport-lead-monitoring-and-modeling>).
- *Nationwide analysis of lead concentrations at airports*
In order to characterize lead concentrations at and near airports nationwide, EPA first conducted air quality modeling at two airports using EPA's regulatory model AERMOD and evaluated the model output by comparison to airport monitoring data^{7,8}. The EPA then developed scaling factors based on air quality modeling and used these scaling factors to estimate average 3-month concentrations of lead at locations immediately adjacent to and downwind of the maximum impact site at airports nationwide. A quantitative and qualitative uncertainty analysis was conducted. The model-extrapolated lead concentrations will provide information regarding the range of potential lead concentrations attributable to piston-engine aircraft at airports nationwide.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

- *Inventory of lead emissions from use of leaded aviation fuel*
The EPA, in collaboration with the FAA, developed approaches to estimate piston-engine aircraft activity at airports in the U.S. The methods are described in full on EPA's National Emissions Inventory website (<https://www.epa.gov/air-emissions-inventories/2011-national-emissions-inventory-nei-documentation>).

⁷ Carr et al. Atmospheric Environment (2011) 45:5795-5804.

⁸ U.S. EPA (2010) EPA-420-R-10-007; available at <https://nepis.epa.gov/Exe/ZyPDF.cgi/P1007H4Q.PDF?Dockkey=P1007H4Q.PDF>

- *Demographic analysis of populations living or attending school near airports*
The EPA developed runway layers in ArcGIS using FAA input data and developed 500 meter boundaries around each runway at all airports in the U.S. Census block data from the 2010 U.S. Census was used to characterize populations living in or near the 500 meter boundaries around airports and data regarding schools and preschools located in this boundary were obtained from the Department of Education and the Department of Health and Human Services, respectively. The methodology for this study has been peer-reviewed and will be available in a forthcoming report.
- *Monitored concentrations of lead in air at 17 airports*
State and local air authorities collected and certified lead concentration data for at least one year at 17 airports. The certified data are summarized on EPA's website (<https://www.epa.gov/regulations-emissions-vehicles-and-engines/airport-lead-monitoring-and-modeling>).
- *Nationwide analysis of lead concentrations at airports*
EPA conducted a study to develop source-specific parameters that are necessary to conduct near-field air quality modeling of piston-engine aircraft. This study was conducted by collecting source-specific data (e.g., activity patterns, fuel consumption rates) and meteorology data (e.g., wind speed, wind direction, temperature) at one General Aviation (GA) airport in order to run the American Meteorological Society (AMS)/EPA Regulatory Model (AERMOD). Air quality modeling results were used to identify key sources of ground-level lead concentrations from aircraft, and to characterize the lead concentration gradient relative to locations of aircraft activity. This methodology is described in full in Carr et al., 2011⁹. The methodology described by Carr et al, 2011 was then applied to a second GA airport that served as a model facility for developing scaling factors, in the form of concentration of lead per unit of aircraft activity (i.e., ug Pb /m³ per landing-and-take-off cycle). The scaling factors were multiplied by corresponding estimates of aircraft activity at each airport nationwide in order to develop model-extrapolated concentrations of lead at U.S. airports. This analysis will be peer reviewed by five experts in a letter peer review and EPA intends to provide a response to peer review comments and final report in 2017.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

- The demographic analysis and the nationwide analysis of lead concentrations at airports are considered influential scientific information (ISI). As such, both products have, or will, undergo the appropriate peer review. The demographics analysis has gone through

⁹ [Carr et al. Atmospheric Environment: 45 \(2011\) 5795-5804.](#)

EPA's letter peer review process. EPA intends to submit the national analysis to letter peer review in 2017.

6(d). Peer review:

- National Emissions Inventory (NEI), including inventory of lead emissions from use of leaded aviation fuel
Peer review not required (data reviewed by state and local municipalities)
- Demographic analysis of populations living or attending school near airports
EPA tasked Eastern Research Group, Inc. (ERG) with organizing an independent, external peer review of a draft analysis titled, "National Analysis of the Populations Residing Near or Attending School Near U.S. Airports," to ensure that the analysis was conducted in a rigorous, appropriate, and defensible way. ERG conducted a search to identify experts with appropriate expertise and who had no conflict of interest (COI) in performing this review. Three academic researchers (Francine Laden, Harvard Medical School; James R. Roberts, Medical University of South Carolina; George D. Thurston, New York University School of Medicine) provided comments in response to charge questions on the databases used, analytical methods, assumptions, the characterization of uncertainty, and the conclusions reached through the analysis. EPA intends to make the final report, including responses to peer review comments, publically available.
- Monitored concentrations of lead in air at 17 airports
Monitoring data were collected by air monitoring agencies per 40 CFR Part 58 and submittal of all necessary data to EPA's Air Quality System and subsequent certification conforming to guidance criteria described here:
https://www.epa.gov/sites/production/files/2015-09/documents/data_certification_criteria.pdf.
- Nationwide analysis of lead concentrations at airports
Planned (contract mechanism in place for external letter peer review in 2017)

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Proposed Endangerment and Cause or Contribute Findings for Lead Emissions from Piston-Engine Aircraft Using Leaded Aviation Gasoline [RIN 2060-AT10]

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"	X	
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties		X	
Involves major environmental risks		X	
Relates to emerging environmental issues			X
Exhibits a long-term outlook		X	

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further review by the SAB.

Rationale: EPA is evaluating whether lead emissions from aircraft operating on leaded aviation gasoline (“avgas”) cause or contribute to air pollution that may be reasonably anticipated to endanger public health. Lead is still used as an octane booster in avgas that is used in piston-engine aircraft, mostly for general aviation. Avgas has a much higher octane rating than gasoline for highway vehicles. Separately, the FAA is evaluating the potential to replace leaded avgas with non-leaded avgas. EPA will use the National Emission Inventory of lead emissions from use of leaded avgas, demographic analysis of populations living or attending school near airports, surveillance monitoring data for 17 airports, and estimates of lead concentrations near airports using AERMOD. The emission inventory methods were developed with FAA and are documented online. The demographic data will be from analysis of GIS layers of airport boundaries and Census block data. Census block data are reported to have been peer-reviewed. Monitoring data for the 17 airports have been certified by state and local authorities that collected the data. EPA plans to conduct a letter peer review of the nationwide analysis of lead

concentrations in air at airports by five experts. EPA will provide responses to peer review comments and issue a final report.

EPA considers that the demographic analysis and the nationwide analyses of lead concentrations are influential scientific information (ISI). The EPA reports it has already conducted a letter peer review of the demographic data and will conduct a letter peer review of the national analysis. EPA states that peer review is not required for the NEI because data were reviewed by state and local municipalities and that peer review is not required for the measured concentrations, because the monitoring data were submitted to EPA in conformance with submittal guidance.

Although not mentioned, EPA has previously developed an Integrated Science Assessment for Lead as part of the NAAQS review process. The ISA includes causality determinations and information regarding adverse health effects from exposure to airborne lead. Three drafts of the ISA were reviewed by the EPA Clean Air Scientific Advisory Committee during the most recent review of the Lead NAAQS, completed in 2013.

Overall, it is not recommended for the Science Advisory Board to review this regulatory action, given that key elements already have undergone, or will undergo, peer review.

Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Control of Air Pollution from Aircraft and Aircraft Engines: Proposed GHG Emissions Standards and Test Procedures
2. **RIN Number:** 2060-AT26
3. **EPA Office originating action:** Office of Air and Radiation/Office of Transportation and Air Quality
4. **Brief description of action and statement of need for the action:**

This rulemaking follows on the EPA's final endangerment and cause or contribute findings for aircraft GHG emissions which were published on August 15, 2016 (81 FR 54422). As a result of these positive findings, the EPA is obligated under section 231 of the Clean Air Act to set emission standards applicable to GHG emissions from the classes of aircraft engines used in certain types of aircraft included in the contribution finding.

The EPA and the Federal Aviation Administration (FAA) traditionally work within the standard-setting process of the International Civil Aviation Organization (ICAO). ICAO's Committee on Aviation Environmental Protection (CAEP) establishes international aircraft emission standards and related requirements, which individual nations later adopt into domestic law. On July 1, 2015, the EPA issued an Advance Notice of Proposed Rulemaking (80 FR 37758) to provide an overview and seek input on a variety of issues related to the setting of an international aircraft CO₂ standard at ICAO, and the potential use of section 231 of the Clean Air Act to adopt and implement corresponding aircraft engine CO₂ emission standards domestically.

At its meeting in February of 2016, ICAO/CAEP agreed on the first-ever international standards to regulate CO₂ emissions from aircraft. The ICAO Assembly approved these CO₂ standards in October 2016, and then ICAO is expected to formally adopt these standards in March 2017. If ICAO formally adopts the final CO₂ standards in March 2017, the EPA's standards will need to be at least as stringent as the ICAO CO₂ aircraft standards for the United States to meet its treaty obligations under the Convention on International Civil Aviation. This rulemaking would meet these treaty obligations.

5. **Timetable:** As indicated in the 2016 Fall Regulatory Agenda, the EPA expects to issue a Notice of Proposed Rulemaking by January 2018 and a Final Rule by December 2018. The FAA would then adopt regulations to implement and enforce the standards. The EPA schedule has been developed in consultation with the FAA, and reflects the need for both Agencies to act prior to the January 2020 implementation date for the international aircraft CO₂ standards. We anticipate that once EPA has completed its rulemaking, FAA will then begin its rulemaking for the enforcement of the standards. Under section 232 of the Clean Air Act, FAA must enforce the emission standards that EPA sets under section 231 of the Clean Air Act. Therefore, EPA intends to complete the standard setting rulemaking by the end of 2018 in order to provide FAA sufficient time for it to finalize its rules by January 2020.

6. Scientific products that will inform the action and plans for peer review:

6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.

See section 6(c) below.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

See section 6(c) below.

6(c) For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

The EPA intends to use two scientific products to inform its decision-making in this rulemaking. Both of these products meet the definition of an influential scientific or technical work product.

The EPA is developing an aircraft GHG inventory to assess the emissions impact of this rulemaking. The aircraft GHG inventory will be based on detailed estimates of the U.S. and global fleet fuel burn and potential emission reductions, from 2010 to 2040, for different stringency and implementation timing options. The EPA utilizes an aircraft performance model, PIANO (Project Interactive Analysis and Optimization), in the development of the aircraft GHG inventory. PIANO is commercially available and widely used across the industry and academia. It contains non-manufacturer provided estimates of the performance of numerous aircraft. The EPA previously utilized PIANO as part of the EPA's technical work for the ICAO technical workgroups charged with assessing the stringency options for the international aircraft CO₂ standard.

In addition, as part of the rulemaking, the EPA is developing a technological feasibility and cost analysis that will be based on updating a March 2015 ICF report entitled, "Cost Analysis of CO₂-Reducing Technologies for Aircraft," which was a reference for the Advance Notice of Proposed Rulemaking. The new report will be an updated assessment of the latest aircraft technical improvements, their costs, and their fuel burn or emissions reduction potential. The EPA previously used the information from the March 2015 report as part of EPA's technical work for the ICAO technical workgroups tasked with assessing the technologies and costs of stringency options for the international aircraft CO₂ standard, and ICAO utilized information from this report in its analysis.

6(d). Peer review:

The EPA is developing a technical report that will document the EPA assumptions, data sources, and methods for the aircraft GHG inventory. Also, the updates to the ICF report, "Cost Analysis of CO₂- Reducing Technologies for Aircraft," will include documenting any assumptions, data sources, and methods for the technology and cost analysis.

For both of the documents described above, the EPA is seeking an independent peer review of the assumptions, data sources, and methods provided in the documents. We plan to begin the peer review in the Spring of 2017, and we expect it to be completed by the end of the Summer of 2017, before the proposed rulemaking will be issued.

The letter peer review will be led and managed by a contractor. In selecting reviewers, the contractor will avoid any reviewer with actual or apparent conflict(s) of interest that would preclude an independent review. Three peer reviewers will be chosen to review each report (there will be different peer reviewers for each report, so there will be a total of six peer reviewers). Due to the complex nature of the subjects, EPA will request that the reviewers have one or more areas of relevant expertise in order to assure an effective peer review. The combined expertise of the selected reviewers will cover the following areas: aircraft emissions inventory assessment, aircraft engine fuel efficiency technology, airframe fuel efficiency technology, aircraft economics, and aircraft industry characterization. The contractor will distribute a charge letter and collect comments from the peer reviewers. The EPA will develop a response to the peer review comments and make revisions to the reports accordingly.

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Control of Air Pollution from Aircraft and Aircraft Engines: Proposed GHG Emissions Standards and Test Procedures [RIN 2060-AT26]

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"	X	
Is the action an extension of an existing initiative?		X

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties		X	
Involves major environmental risks	X		
Relates to emerging environmental issues	X		
Exhibits a long-term outlook	X		

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: The Work Group finds that the planned action is significant and would benefit from SAB advice and comment. The Work Group notes the temporal constraints on completing the rulemaking and recommends the SAB provide advice on this issue and at a minimum EPA should conduct a panel review that allows communication across the two proposed peer review panels in order to encourage synergistic understanding among the disciplines involved.

Rationale: While the underlying rule making will follow the lead of ICAO in setting emissions standards implementation of those standards through regulation will flow from an EPA led assessment of the aircraft GHG inventory, technological feasibility and cost analysis. The assessment of the underlying science will determine the overall integrity of resulting regulations with respect to meeting the desired GHG goals. Given that these rules will impact a significant portion of the global aircraft industry and will provide the framework for any changes moving forward, ensuring the scientific integrity of these initial rules is of high importance. As is the case with development of any new rule it is critical to ensure that the range of scientific views from multiple perspectives are solicited in order to capture the

collective understanding of the relevant science. Towards that end we encourage involving a greater number of reviewers in a more integrative process using a panel review. The SAB hopes that there is time under the constraint of a December 2018 deadline for completing the standard setting ruling making to undertake this more integrative approach to a scientific review.

It is important to make the work products of the review public. Transparency can stimulate further reflection on the key science issues involved as well as precipitating advancements in the associated areas of research.

Within the temporal constraints on completing the rulemaking the SAB wishes to provide advice on this issue or at a minimum the EPA should conduct a panel review that allows communication across the two proposed panels in order to encourage synergistic understanding among the disciplines involved.

The Work Group notes the SAB previously reviewed *Proposed Finding that Greenhouse Gas Emissions from Aircraft Cause or Contribute to Air Pollution that May Reasonably be Anticipated to Endanger Public Health and Welfare and Advanced Notice of Proposed Rulemaking (2060-AS31)* in the Fall 2014¹⁰ Regulatory Review and found that subsequent steps in the regulatory process will involve substantive scientific issues that may warrant SAB consideration.

The Work Group anticipates that subsequent steps in the regulatory process will continue to involve substantive scientific issues that will warrant SAB consideration. It recommends that the SAB asks the agency to regularly inform the Board about the status of subsequent steps on this topic and also asks the EPA to provide it with briefings on the science underlying agency approaches to address greenhouse gas emissions and related climate change actions.

The Work Group submitted questions to the EPA as part of their research and fact-finding. The questions and agency responses directly follow in this attachment.

¹⁰ SAB Discussions about EPA Planned Actions in the Fall 2014 Unified Agenda and their Supporting Science
<https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/d789240481a106d085257dc4005dcef6!OpenDocument>

**Science Advisory Board Work Group’s Fact-finding Questions on
Control of Air Pollution from Aircraft and Aircraft Engines:
Proposed GHG Emissions Standards and Test Procedures (2060-AT26)**

Question: The Work Group notes that the planned action Control of Air Pollution from Aircraft and Aircraft Engines: Proposed GHG Emissions Standards and Test Procedures (2060-AT26) will require coordination with the Federal Aviation Administration and work within the standard-setting process of the International Civil Aviation Organization. Can the EPA elaborate on their portion of the schedule for the planned action that allows FAA to meet the ICAO deadlines?

Response: We do not yet have a schedule identified for this action.

Question: Has the agency initiated the peer review of the two documents, the “technical report documenting the assumptions, data sources, and methods for the aircraft GHG inventory” and the “Cost Analysis of CO₂- Reducing Technologies for Aircraft” and are the documents available?

Response: The peer review of the two documents has not been initiated, and the technical reports are not yet available.

Question: Is there additional information the EPA can provide on the planned peer reviews at this time: What is the anticipated schedule for each review?

Response: The peer review of the two documents is expected to begin later this year.

Question: Are the two documents being reviewed separately by two different panels or will the reviewers be aware of peer review comments on both documents?

Response: The two documents are being reviewed separately by two different panels, who will be unaware of the peer review comments of the other panel.

Question: Will the reviewers be different for each report, or will some reviewers review both reports?

Response: The reviewers will be different for each report.

Question: Did the agency consider conducting a panel review rather than a letter review?

Response: We determined that a letter review was appropriate for a number of reasons including time and resource constraints. Both work products are looking for perspectives from individuals with unique expertise with little-to-no subject matter overlap. For the technologies and costs analysis, we requested peer review from three subject matter experts that cover the following areas: aircraft engine technology, airframe (or whole aircraft) technology, and aircraft economics. For the GHG aircraft inventory we are requesting 3 independent subject matter experts in the field of aircraft emissions inventory modeling and

stringency analysis. In each case we believe these analyses are less complex or novel than what would typically be the subject of panel review and therefore are appropriate for letter review.

Question: If initiated, when will the peer review report be available?

Response: As described earlier, the peer review of the two documents has not been initiated.

Question: Has the agency considered expanding the number of members participating in the peer reviews (i.e., increasing the number of reviewers to address the complexity and disciplines needed)?

Response: Although the peer review of the two documents has not been initiated, we expect that six peer reviewers in total, three for each peer review, will be sufficient for the subject matter in the documents.

Question: Does the EPA plan on posting on its website or including in the docket for the proposed Control of Air Pollution from Aircraft and Aircraft Engines: Proposed GHG Emissions Standards and Test Procedures (2060-AT26) the final peer review reports and disposition of the peer review comments?

Response: If EPA uses these reports in support of a future rulemaking, we would make both reports available to the public as well as the peer review comments and how they are addressed.

Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Emission Guidelines for the Existing Oil and Natural Gas Sector
2. **RIN Number:** 2060-AT29
3. **EPA Office originating action:** Office of Air and Radiation
4. **Brief description of action and statement of need for the action:**

On June 3, 2016, EPA issued a New Source Performance Standard in the Crude Oil and Natural Gas Production source category, setting emission limits for volatile organic compounds and greenhouse gases, in the form of limitations on methane. As a result of establishing limits on non-criteria pollutants or air toxics, the NSPS triggered the Clean Air Act requirement to establish emission guidelines for this source category.
5. **Timetable:** To be determined
6. **Scientific products that will inform the action and plans for peer review:**
 - 6(a). **Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.**

The EPA is undergoing a data collection effort from oil and natural gas companies through an ICR. The ICR seeks a broad range of information, such as how equipment and emissions controls are, or can be, configured, and what installing those controls entails.

No other scientific work products have been planned at this time.
 - 6(b). **For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).**

The analysis plan for the ICR data has not yet been developed.
 - 6(c). **For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"**

To be determined
 - 6(d). **Peer review:**

To be determined

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Emission Guidelines for the Existing Oil and Natural Gas Sector [2060-AT29]

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency		X	
Addresses areas of substantial uncertainties		X	
Involves major environmental risks	X		
Relates to emerging environmental issues	X		
Exhibits a long-term outlook	X		

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: The SAB Work Group recommends that the SAB review the scientific and technical basis for the Emission Guidelines for the Existing Oil and Natural Gas Sector (2060 –AT29) when more information on the planned action is available and at that time determine if advice and comment is appropriate to provide to the Administrator. This action is still under development and the Work Group notes the agency has withdrawn the 2016 Information Collection Request¹¹ (ICR) from the oil and gas industry¹². Thus at present there is insufficient information to review.

¹¹ Background on the Information Request for the Oil and Natural Gas Industry. <https://www.epa.gov/controlling-air-pollution-oil-and-natural-gas-industry/background-information-request-oil-and>

¹² Notice Regarding Withdrawal of Obligation To Submit Information (FR. 82, 43, p 12817). March 7, 2017. <https://www.gpo.gov/fdsys/pkg/FR-2017-03-07/pdf/2017-04458.pdf>

Rationale: On March 10, 2016, the Administration and EPA announced the next step in reducing emissions of greenhouse gases (in the form of methane) from the oil and natural gas industry: moving to regulate emissions from existing sources. According to the US EPA Inventory of US Greenhouse Gas Emissions and Sinks: 1990-2015, published in April 2017, existing sources from the oil and gas industry make substantial contributions to national total methane emissions. Methane from the oil and gas industry comes packaged with other pollutants, including volatile organic compounds that contribute to the formation of ozone, a component of health, agriculture and ecosystem damaging smog, and a number of harmful pollutants known as air toxics.

This planned action follows from the New Source Performance Standards (NSPS) that set limits on new sources of emissions of greenhouse gases in the oil and gas sector. As a result of establishing limits on *new sources*, the NSPS triggered a requirement to establish emission guidelines for *existing sources* in this source category.

Although similar in type to the requirements for new sources, there are unique science questions associated with how emissions from existing sources are quantified. What type of data would best characterize leakage from existing active oil and gas extraction facilities (e.g. visual or spectrographic indication of leakage, quantitative determination of fluxes, concentration measurements above a threshold)? Would the data and measurement techniques be the same for on-shore and off-shore oil rigs? If not, how would they differ?

Scientific questions also exist on how leakage rates from existing sources would be determined, the accuracy of various measurement techniques, whether measurements would take place in close proximity to existing sources or be conducted using remote sensing instruments. Further, the current source definition does not appear to include abandoned facilities. Some abandoned oil and gas wells have been shown to emit substantial quantities of methane and other gases over multiple decades, while others emit none. Would these no longer operational or 'abandoned' wells be included in a review of existing sources of methane emissions?

Finally, an evaluation by the SAB of the scale of the impact of existing sources on: greenhouse gas emissions, volatile organic compounds that contribute to the formation of surface ozone (O₃) and have been shown to contribute to exceedance of O₃ standards, and emissions of air toxics, could also be beneficial.

Answering these science questions was intended to be informed by data provided by existing source owners through an ICR released on November 10, 2016, which sought information necessary to assist EPA in determining how to best reduce emissions of methane and other harmful emissions from existing sources in the oil and natural gas sector. However, the ICR was withdrawn by the EPA on March 7, 2017. Thus, at present there is neither data nor analysis requiring peer review.

Therefore, the SAB should evaluate the science supporting the planned action when more information about the proposed rule and the science supporting it are made available. At that time the SAB will determine whether it wishes to offer advice and comment to the Administrator. The Work Group made this decision because there was insufficient information provided by the agency to date about the scientific and technical basis for this planned action.

Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Stationary Combustion Turbine RTR
2. **RIN Number:** 2060-AT00
3. **EPA Office originating action:** EPA/OAR
4. **Brief description of action and statement of need for the action:**

The Clean Air Act (Act) establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, the Act requires the EPA to develop technology-based standards for categories of industrial sources. In the second stage of the regulatory process, EPA must review each maximum achievable control technology (MACT) standard at least every eight years and revise them as necessary, “taking into account developments in practices, processes and control technologies.” We call this requirement the “technology review.” The EPA is also required to complete a one-time assessment of the health and environmental risks that remain after sources come into compliance with MACT. This residual risk review also must be done within eight years of setting the initial MACT standard. If additional risk reductions are necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects, the EPA must develop standards to address the remaining risks. For each source category for which the EPA issued MACT standards, the residual risk stage must be completed within eight years of promulgation of the initial MACT standard. Since the initial technology review requirement coincides in deadline with the risk review requirement, the EPA generally combines these two requirements into one rulemaking activity, calling this the “risk and technology review” process, or RTR. In this way, results of the risk review can be potentially informative to the technology review process, and vice versa.

The EPA issued national emission standards for hazardous air pollutants (NESHAP) for stationary combustion turbines on March 5, 2004 (see 69 FR 10512). More information on the NESHAP can be found at <https://www.epa.gov/stationary-sources-air-pollution/stationary-combustion-turbines-national-emission-standards>.

For this action, as the second stage of the regulatory process, and as we have done for more than 55 source categories to date, we plan to conduct the residual risk review and initial technology review concurrently.

5. **Timetable:** Required proposal date and required final rule date not yet scheduled.
6. **Scientific products that will inform the action and plans for peer review:**
 - 6(a). **Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.**

The risk analysis methodologies associated with the RTR process have undergone scientific peer reviews and have been used in numerous previous RTR reviews. There are no other scientific work products that have been or will be developed to inform this planned action.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

Because RTR assessments are used for regulatory purposes, and because components of our risk analyses have evolved over time, we have, over the course of the program, conducted scientific peer reviews of the methodologies through the SAB. Through peer review of the RTR process as a whole, rather than each individual rulemaking effort, the agency is able to conduct consistent risk characterizations across all categories of industrial sources.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

While the overall RTR risk assessment methods meet the definition as "an influential scientific or technical work product", each individual RTR analysis does not.

6(d). Peer review:

Each RTR analysis follows a consistent risk characterization approach using methodologies that have undergone numerous peer reviews. Previous peer reviews have covered elements associated with the RTR process, or assessments with similar scopes or contexts. A brief summary of each peer review is provided:

- 1) The Residual Risk Report to Congress, a document describing the Agency's overall analytical and policy approach to setting residual risk standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methodology were described in this report, although individual elements have been improved over time. The Report to Congress and the final SAB advisory are available at: <https://www.epa.gov/fera/residual-risk-report-congress-1999> and [https://yosemite.epa.gov/sab/sabproduct.nsf/33598FF753C6342F852571AE0067B7D0/\\$File/ec9813.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/33598FF753C6342F852571AE0067B7D0/$File/ec9813.pdf)
- 2) A peer review of multi-pathway risk assessment methodologies for RTR was conducted by the EPA's SAB in 2000. The final SAB advisory is available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/\\$File/ecadv05.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$File/ecadv05.pdf)
- 3) A consultation on EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by SAB in December 2006. SAB provided its formal consultation in a letter to the Administrator in June 2007. The final SAB advisory is available at:

[https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/\\$File/sab-07-009.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf)

- 4) A review of the updated and expanded risk assessment approaches and methods used in the RTR program was completed in 2009. This methodology was highlighted to the SAB utilizing two RTR source categories: Petroleum Refining Sources MACT I and Portland Cement Manufacturing. The final SAB advisory is available at:
<https://yosemite.epa.gov/sab/sabproduct.nsf/0/b031ddf79cfded38525734f00649caf!OpenDocument&TableRow=2.3#2>
- 5) The individual dose-response assessment values used in the RTR assessment have themselves been the subject of peer reviews through the agencies that developed them (including EPA, through its Integrated Risk Information System, or IRIS; the California Environmental Protection Agency, or CalEPA, and the Agency for Toxic Substances and Disease Registry, or ATSDR).

EPA is currently seeking the Science Advisory Board's (SAB) input on specific enhancements made to our risk assessment methodologies, particularly with respect to screening methodologies, since the last SAB review was completed in 2009 (see above). EPA has recently submitted a draft updated methodology report to the SAB to help in panel formation. It is anticipated that an expert panel will be organized shortly and a meeting will convene by early 2017.

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Stationary Combustion Turbine RTR [RIN 2060-AT00]

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties			X
Involves major environmental risks		X	
Relates to emerging environmental issues			X
Exhibits a long-term outlook	X		

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further review by the SAB.

Background: EPA has previously developed "MACT standards" for many combinations of emission sources and hazardous air pollutants under the National Emission Standards for Hazardous Air Pollutants (NESHAP). The first phase of NESHAP consisted of setting technology-based standards that specified "maximum achievable control technology" (MACT) and are referred to as "MACT Standards." EPA is required to review the MACT standards every eight years and revise them as necessary taking into account developments in technical capability to control emissions. Furthermore, EPA is required to conduct a one-time "residual risk review" within eight years of the initial standard setting to determine if additional risk reductions are necessary to protect the public health. Thus, eight years after the promulgation of the initial standard, EPA must conduct both a risk and a technology review, referred to as "risk and technology review" (RTR). EPA states that "the risk analysis methodologies associated with the RTR process have undergone scientific peer reviews and have been used in numerous previous RTR reviews." EPA states that the RTR process has been reviewed "as a whole" rather than via each individual rulemaking. Furthermore, EPA states that "while the overall RTR

risk assessment methods meet the definition as "an influential scientific or technical work product", each individual RTR analysis does not."

While the details of each RTR are unique to the sources and pollutants being evaluated, the general approaches and methodologies employed in EPA RTRs have become standardized, and have been subject to multiple peer reviews over the past 17 years. Since the last SAB review in 2009, there have been enhancements to the RTR methodology that are being used in EPA rules and actions; these relate to enhancements in multipathway risks, environmental risks, and inhalation methodologies. EPA lists the following significant RTR review milestones: (a) SAB reviewed EPA's Residual Report to Congress in 1999; (b) SAB conducted a peer review of the multi-pathway risk assessment method for RTR in 2000; (c) SAB provided a consultation on updated methods for developing emission inventories and characterizing human exposure in June 2007; (d) SAB reviewed updated and expanded RTR methods based on two RTR source categories in 2009; (e) dose-response estimates obtained from the EPA's Integrated Risk Information System (IRIS) and from databases of other agencies have been peer reviewed; and (f) EPA is seeking review by SAB of specific enhancements made to risk assessment methods used in RTR, especially for screening methods. This latter review is pending.

Rationale: The EPA summary of this action does not provide information specific to stationary combustion turbines. Stationary combustion turbines are used at facilities such as power plants, chemical and manufacturing plants, and pipeline compressor stations. The phase one MACT standard focused on formaldehyde, toluene, acetaldehyde, and benzene. According to EPA, "exposure to emissions of these air toxics may produce a wide variety of human health effects including irritation of the eyes, skin and mucous membranes, dysfunction of the central nervous system, and narcosis. Formaldehyde exposure has been associated with reproductive effects such as menstrual disorders and pregnancy problems. EPA has classified formaldehyde as a probable human carcinogen." The expected control technology is an oxidation catalyst positioned downstream of the turbine exhaust, but other technologies may be used if they meet the emission limits. As part of the technology review, EPA will have to identify whether new technologies have emerged that can more effectively control these and other pollutants. Cost must also be considered when setting a MACT standard. Therefore, cost analysis must be conducted.

The Work Group finds that the RTR risk assessment screening methodology is broadly applicable to many source categories, and prior aspects of the data and methods identified have been subject to review by the SAB and others. The unique details of each RTR can include recommendations for new monitoring and MACTs. In general, these technologies are based on established scientific knowledge that has undergone extensive peer review. However, there can be exceptions, and the SAB encourages to EPA to continually assess and identify for SAB review any such technology recommendations that are based on new scientific knowledge. This planned RTR does not merit further review by the SAB.

Description of Planned EPA Tier 1 or Tier 2 Action

1. Name of action: Engine Test Cells NESHAP RTR

2. RIN Number: 2060-AT01

3. EPA Office originating action: EPA/OAR

4. Brief description of action and statement of need for the action:

The Clean Air Act (Act) establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, the Act requires the EPA to develop technology-based standards for categories of industrial sources. In the second stage of the regulatory process, EPA must review each MACT standard at least every eight years and revise them as necessary, “taking into account developments in practices, processes and control technologies.” We call this requirement the “technology review.” The EPA is also required to complete a one-time assessment of the health and environmental risks that remain after sources come into compliance with MACT. This residual risk review also must be done within eight years of setting the initial MACT standard. If additional risk reductions are necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects, the EPA must develop standards to address the remaining risks. For each source category for which the EPA issued MACT standards, the residual risk stage must be completed within eight years of promulgation of the initial MACT standard. Since the initial technology review requirement coincides in deadline with the risk review requirement, the EPA generally combines these two requirements into one rulemaking activity, calling this the “risk and technology review” process, or RTR. In this way, results of the risk review can be potentially informative to the technology review process, and vice versa.

The EPA issued national emission standards for hazardous air pollutants (NESHAP) for engine test cells/stands on May 27, 2003 (see 68 FR 28774). More information on the NESHAP can be found at <https://www.epa.gov/stationary-sources-air-pollution/engine-test-cellsstands-national-emission-standards-hazardous-air>.

For this action, as the second stage of the regulatory process, and as we have done for more than 55 source categories to date, we plan to conduct the residual risk review and initial technology review concurrently.

5. Timetable: Required proposal date and required final rule date not yet scheduled

Scientific products that will inform the action and plans for peer review:

6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.

The risk analysis methodologies associated with the RTR process have undergone scientific peer reviews and have been used in numerous previous RTR reviews. There are no other scientific work products that have been or will be developed to inform this planned action.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

Because RTR assessments are used for regulatory purposes, and because components of our risk analyses have evolved over time, we have, over the course of the program, conducted scientific peer reviews of the methodologies through the SAB. Through peer review of the RTR process as a whole, rather than each individual rulemaking effort, the agency is able to conduct consistent risk characterizations across all categories of industrial sources.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

While the overall RTR risk assessment methods meet the definition as "an influential scientific or technical work product", each individual RTR analysis does not.

6(d). Peer review:

Each RTR analysis follows a consistent risk characterization approach using methodologies that have undergone numerous peer reviews. Previous peer reviews have covered elements associated with the RTR process, or assessments with similar scopes or contexts. A brief summary of each peer review is provided:

- 1) The Residual Risk Report to Congress, a document describing the Agency's overall analytical and policy approach to setting residual risk standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methodology were described in this report, although individual elements have been improved over time. The Report to Congress and the final SAB advisory are available at: <https://www.epa.gov/fera/residual-risk-report-congress-1999> and [https://yosemite.epa.gov/sab/sabproduct.nsf/33598FF753C6342F852571AE0067B7D0/\\$File/ec9813.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/33598FF753C6342F852571AE0067B7D0/$File/ec9813.pdf)
- 2) A peer review of multi-pathway risk assessment methodologies for RTR was conducted by the EPA's SAB in 2000. The final SAB advisory is available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/\\$File/ecadv05.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$File/ecadv05.pdf)
- 3) A consultation on EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by SAB in December 2006. SAB provided its formal consultation in a letter to the Administrator in June 2007. The final SAB

advisory is available at:

[https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/\\$File/sab-07-009.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf)

- 4) A review of the updated and expanded risk assessment approaches and methods used in the RTR program was completed in 2009. This methodology was highlighted to the SAB utilizing two RTR source categories: Petroleum Refining Sources MACT I and Portland Cement Manufacturing. The final SAB advisory is available at:
<https://yosemite.epa.gov/sab/sabproduct.nsf/0/b031ddf79cffded38525734f00649caf!OpenDocument&TableRow=2.3#2>
- 5) The individual dose-response assessment values used in the RTR assessment have themselves been the subject of peer reviews through the agencies that developed them (including EPA, through its Integrated Risk Information System, or IRIS; the California Environmental Protection Agency, or CalEPA, and the Agency for Toxic Substances and Disease Registry, or ATSDR).

EPA is currently seeking the Science Advisory Board's (SAB) input on specific enhancements made to our risk assessment methodologies, particularly with respect to screening methodologies, since the last SAB review was completed in 2009 (see above). EPA has recently submitted a draft updated methodology report to the SAB to help in panel formation. It is anticipated that an expert panel will be organized shortly and a meeting will convene by early 2017.

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Engine Test Cells RTR

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties			X
Involves major environmental risks		X	
Relates to emerging environmental issues			X
Exhibits a long-term outlook	X		

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further review by the SAB.

Background: The EPA uses a standard process to conduct risk and technology reviews for National Emissions Standards for Hazardous Air Pollutants. This process is explained in the Background section on pages B35 and B36.

Rationale: The EPA summary of this action does not provide information specific to engine test cells. An engine test cell/stand is any apparatus used for testing uninstalled stationary or uninstalled mobile engines. EPA published MACT standards in 2003 for test cells/stands for internal combustion engines of 25 horsepower or more, internal combustion engines of less than 25 horsepower, combustion turbine engines; and rocket engines. However, the rule limits hazardous air emissions only from new or reconstructed engine test cells/stands used for testing internal combustion engines of 25 horsepower or more located at a facility considered a major source of air toxics emissions. The final rule was expected to reduce air toxic emissions by 66 tons per year using emission control devices such as a catalytic or thermal incinerator that treats the engine exhaust. As part of the technology review, EPA will have to

identify whether new technologies have emerged that can more effectively control these and other pollutants. Cost must also be considered when setting a MACT standard. Therefore, cost analysis must be conducted.

The Work Group finds that the RTR risk assessment screening methodology is broadly applicable to many source categories, and prior aspects of the data and methods identified have been subject to review by the SAB and others. The unique details of each RTR can include recommendations for new monitoring and MACTs. In general, these technologies are based on established scientific knowledge that has undergone extensive peer review. However, there can be exceptions, and the SAB encourages to EPA to continually assess and identify for SAB review any such technology recommendations that are based on new scientific knowledge. This planned RTR does not merit further review by the SAB.

Description of Planned EPA Tier 1 or Tier 2 Action

- 1. Name of action:** National Emission Standards for Hazardous Air Pollutants for Source Categories: Generic Maximum Achievable Control Technology Standards--Ethylene Production (Subparts XX and YY) RTR
- 2. RIN Number:** 2060-AT02
- 3. EPA Office originating action:** EPA/OAR
- 4. Brief description of action and statement of need for the action:**

The Clean Air Act (Act) establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, the Act requires the EPA to develop technology-based standards for categories of industrial sources. In the second stage of the regulatory process, EPA must review each MACT standard at least every eight years and revise them as necessary, “taking into account developments in practices, processes and control technologies.” We call this requirement the “technology review.” The EPA is also required to complete a one-time assessment of the health and environmental risks that remain after sources come into compliance with MACT. This residual risk review also must be done within eight years of setting the initial MACT standard. If additional risk reductions are necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects, the EPA must develop standards to address the remaining risks. For each source category for which the EPA issued MACT standards, the residual risk stage must be completed within eight years of promulgation of the initial MACT standard. Since the initial technology review requirement coincides in deadline with the risk review requirement, the EPA generally combines these two requirements into one rulemaking activity, calling this the “risk and technology review” process, or RTR. In this way, results of the risk review can be potentially informative to the technology review process, and vice versa.

The EPA issued national emission standards for hazardous air pollutants (NESHAP) for ethylene production on July 12, 2002 (see 67 FR 46257). More information on the NESHAP can be found at <https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen>.

For this action, as the second stage of the regulatory process, and as we have done for more than 55 source categories to date, we plan to conduct the residual risk review and initial technology review concurrently.

- 5. Timetable:** Required proposal date and required final rule date not yet scheduled

6. Scientific products that will inform the action and plans for peer review:

6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.

The risk analysis methodologies associated with the RTR process have undergone scientific peer reviews and have been used in numerous previous RTR reviews. There are no other scientific work products that have been or will be developed to inform this planned action.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

Because RTR assessments are used for regulatory purposes, and because components of our risk analyses have evolved over time, we have, over the course of the program, conducted scientific peer reviews of the methodologies through the SAB. Through peer review of the RTR process as a whole, rather than each individual rulemaking effort, the agency is able to conduct consistent risk characterizations across all categories of industrial sources.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

While the overall RTR risk assessment methods meet the definition as "an influential scientific or technical work product", each individual RTR analysis does not.

6(d). Peer review:

Each RTR analysis follows a consistent risk characterization approach using methodologies that have undergone numerous peer reviews. Previous peer reviews have covered elements associated with the RTR process, or assessments with similar scopes or contexts. A brief summary of each peer review is provided:

- 1) The Residual Risk Report to Congress, a document describing the Agency's overall analytical and policy approach to setting residual risk standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methodology were described in this report, although individual elements have been improved over time. The Report to Congress and the final SAB advisory are available at: <https://www.epa.gov/fera/residual-risk-report-congress-1999> and [https://yosemite.epa.gov/sab/sabproduct.nsf/33598FF753C6342F852571AE0067B7D0/\\$File/ec9813.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/33598FF753C6342F852571AE0067B7D0/$File/ec9813.pdf)
- 2) A peer review of multi-pathway risk assessment methodologies for RTR was conducted by the EPA's SAB in 2000. The final SAB advisory is available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/\\$File/ecadv05.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$File/ecadv05.pdf)
- 3) A consultation on EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by SAB in December 2006. SAB provided its formal consultation in a letter to the Administrator in June 2007. The final SAB

advisory is available at:

[https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/\\$File/sab-07-009.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf)

- 4) A review of the updated and expanded risk assessment approaches and methods used in the RTR program was completed in 2009. This methodology was highlighted to the SAB utilizing two RTR source categories: Petroleum Refining Sources MACT I and Portland Cement Manufacturing. The final SAB advisory is available at:
<https://yosemite.epa.gov/sab/sabproduct.nsf/0/b031ddf79cfffed38525734f00649caf!OpenDocument&TableRow=2.3#2>
- 5) The individual dose-response assessment values used in the RTR assessment have themselves been the subject of peer reviews through the agencies that developed them (including EPA, through its Integrated Risk Information System, or IRIS; the California Environmental Protection Agency, or CalEPA, and the Agency for Toxic Substances and Disease Registry, or ATSDR).

EPA is currently seeking the Science Advisory Board's (SAB) input on specific enhancements made to our risk assessment methodologies, particularly with respect to screening methodologies, since the last SAB review was completed in 2009 (see above). EPA has recently submitted a draft updated methodology report to the SAB to help in panel formation. It is anticipated that an expert panel will be organized shortly and a meeting will convene by early 2017.

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: National Emission Standards for Hazardous Air Pollutants for Source Categories: Generic Maximum Achievable Control Technology Standards--Ethylene Production (Subparts XX and YY) [RIN 2060-AT02]

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties			X
Involves major environmental risks		X	
Relates to emerging environmental issues			X
Exhibits a long-term outlook	X		

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further review by the SAB.

Background: The EPA uses a standard process to conduct risk and technology reviews for National Emissions Standards for Hazardous Air Pollutants. This process is explained in the Background section on pages B35 and B36.

Rationale: The EPA summary of this action does not provide information specific to ethylene production. In 2002, the EPA promulgated National Emission Standards for Hazardous Air Pollutants for Ethylene Production (subparts XX and YY). This action amended the list of emission source categories covered by "generic" MACT standards which provide a structural framework that allows source categories with similar emission types and MACT control requirements to be covered under one subpart. The ethylene production rule, amended in 2005 to clarify the applicable emission sources, applies to ethylene process vents, storage vessels, transfer racks, equipment, heat exchange systems and waste streams. The focus was on reducing emissions of benzene, 1,3-butadiene, hexane, toluene and

naphthalene. These compounds include known and probable human carcinogens and compounds with a variety of other adverse health effects. Expected control actions included, but were not limited to: leak detection and repair (LDAR) for equipment leaks; closing process vents and routing to flares or closed combustion devices; floating roofs or closed vent systems with air toxics destruction, for storage vessels; and HAP reduction from waste treatment using suppression followed by steam stripping, biotreatment, or other treatment processes. The regulation was expected to reduce air toxics emissions from ethylene production by 1,090 tons annually, representing a 60 percent reduction from levels before the rule. As part of the technology review, EPA will have to identify whether new technologies have emerged that can more effectively control these and other pollutants. Cost must also be considered when setting a MACT standard. Therefore, cost analysis must be conducted.

The Work Group finds that the RTR risk assessment screening methodology is broadly applicable to many source categories, and prior aspects of the data and methods identified have been subject to review by the SAB and others. The unique details of each RTR can include recommendations for new monitoring and MACTs. In general, these technologies are based on established scientific knowledge that has undergone extensive peer review. However, there can be exceptions, and the SAB encourages to EPA to continually assess and identify for SAB review any such technology recommendations that are based on new scientific knowledge. This planned RTR does not merit further review by the SAB.

Description of Planned EPA Tier 1 or Tier 2 Action

- 1. Name of action:** National Emission Standards for Hazardous Air Pollutants for Integrated Iron and Steel Manufacturing Facilities RTR
- 2. RIN Number:** 2060-AT03
- 3. EPA Office originating action:** EPA/OAR
- 4. Brief description of action and statement of need for the action:**

The Clean Air Act (Act) establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, the Act requires the EPA to develop technology-based standards for categories of industrial sources. In the second stage of the regulatory process, EPA must review each MACT standard at least every eight years and revise them as necessary, “taking into account developments in practices, processes and control technologies.” We call this requirement the “technology review.” The EPA is also required to complete a one-time assessment of the health and environmental risks that remain after sources come into compliance with MACT. This residual risk review also must be done within eight years of setting the initial MACT standard. If additional risk reductions are necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects, the EPA must develop standards to address the remaining risks. For each source category for which the EPA issued MACT standards, the residual risk stage must be completed within eight years of promulgation of the initial MACT standard. Since the initial technology review requirement coincides in deadline with the risk review requirement, the EPA generally combines these two requirements into one rulemaking activity, calling this the “risk and technology review” process, or RTR. In this way, results of the risk review can be potentially informative to the technology review process, and vice versa.

The EPA issued national emission standards for hazardous air pollutants (NESHAP) for integrated iron and steel manufacturing facilities on May 20, 2003 (see 68 FR 27645). More information on the NESHAP can be found at <https://www.epa.gov/stationary-sources-air-pollution/integrated-iron-and-steel-manufacturing-national-emission-standards>.

For this action, as the second stage of the regulatory process, and as we have done for more than 55 source categories to date, we plan to conduct the residual risk review and initial technology review concurrently.

- 5. Timetable:** Required proposal date and required final rule date not yet scheduled

6. Scientific products that will inform the action and plans for peer review:

6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.

The risk analysis methodologies associated with the RTR process have undergone scientific peer reviews and have been used in numerous previous RTR reviews. There are no other scientific work products that have been or will be developed to inform this planned action.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

Because RTR assessments are used for regulatory purposes, and because components of our risk analyses have evolved over time, we have, over the course of the program, conducted scientific peer reviews of the methodologies through the SAB. Through peer review of the RTR process as a whole, rather than each individual rulemaking effort, the agency is able to conduct consistent risk characterizations across all categories of industrial sources.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

While the overall RTR risk assessment methods meet the definition as "an influential scientific or technical work product", each individual RTR analysis does not.

6(d). Peer review:

Each RTR analysis follows a consistent risk characterization approach using methodologies that have undergone numerous peer reviews. Previous peer reviews have covered elements associated with the RTR process, or assessments with similar scopes or contexts. A brief summary of each peer review is provided:

- 1) The Residual Risk Report to Congress, a document describing the Agency's overall analytical and policy approach to setting residual risk standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methodology were described in this report, although individual elements have been improved over time. The Report to Congress and the final SAB advisory are available at: <https://www.epa.gov/fera/residual-risk-report-congress-1999> and [https://yosemite.epa.gov/sab/sabproduct.nsf/33598FF753C6342F852571AE0067B7D0/\\$File/ec9813.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/33598FF753C6342F852571AE0067B7D0/$File/ec9813.pdf)
- 2) A peer review of multi-pathway risk assessment methodologies for RTR was conducted by the EPA's SAB in 2000. The final SAB advisory is available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/\\$File/ecadv05.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$File/ecadv05.pdf)
- 3) A consultation on EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by SAB in December 2006. SAB provided its formal consultation in a letter to the Administrator in June 2007. The final SAB

advisory is available at:

[https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/\\$File/sab-07-009.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf)

- 4) A review of the updated and expanded risk assessment approaches and methods used in the RTR program was completed in 2009. This methodology was highlighted to the SAB utilizing two RTR source categories: Petroleum Refining Sources MACT I and Portland Cement Manufacturing. The final SAB advisory is available at:
<https://yosemite.epa.gov/sab/sabproduct.nsf/0/b031ddf79cffded38525734f00649caf!OpenDocument&TableRow=2.3#2>
- 5) The individual dose-response assessment values used in the RTR assessment have themselves been the subject of peer reviews through the agencies that developed them (including EPA, through its Integrated Risk Information System, or IRIS; the California Environmental Protection Agency, or CalEPA, and the Agency for Toxic Substances and Disease Registry, or ATSDR).

EPA is currently seeking the Science Advisory Board's (SAB) input on specific enhancements made to our risk assessment methodologies, particularly with respect to screening methodologies, since the last SAB review was completed in 2009 (see above). EPA has recently submitted a draft updated methodology report to the SAB to help in panel formation. It is anticipated that an expert panel will be organized shortly and a meeting will convene by early 2017.

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Integrated Iron and Steel Manufacturing Facilities RTR [RIN 2060-AT03]

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties			X
Involves major environmental risks		X	
Relates to emerging environmental issues			X
Exhibits a long-term outlook	X		

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further review by the SAB.

Background: The EPA uses a standard process to conduct risk and technology reviews for National Emissions Standards for Hazardous Air Pollutants. This process is explained in the Background section on pages B35 and B36.

Rationale: The EPA summary of this action does not provide information specific to integrated iron and steel manufacturing facilities. The phase one MACT standard focused on reducing air toxics emitted at a number of points at these facilities, including sinter plants that recover fine-sized materials, blast furnaces that produce iron, and basic oxygen process furnaces that produce steel. The toxic emissions of concern are metals (primarily manganese and lead with small quantities of other metals) and trace amounts of organic HAP (such as polycyclic organic matter, benzene, and carbon disulfide). According to EPA, "exposure to emissions of these air toxics is associated with cancer, central nervous system effects, kidney damage, and acute health disorders such as respiratory and skin irritation. As part of the

RTR review, EPA will have to identify whether new technologies have emerged that can more effectively control these and other pollutants. Cost must also be considered when setting a MACT standard. Therefore, cost analysis must be conducted.

The Work Group finds that the RTR risk assessment screening methodology is broadly applicable to many source categories, and prior aspects of the data and methods identified have been subject to review by the SAB and others. The unique details of each RTR can include recommendations for new monitoring and MACTs. In general, these technologies are based on established scientific knowledge that has undergone extensive peer review. However, there can be exceptions, and the SAB encourages to EPA to continually assess and identify for SAB review any such technology recommendations that are based on new scientific knowledge. This planned RTR does not merit further review by the SAB.

Description of Planned EPA Tier 1 or Tier 2 Action

- 1. Name of action:** National Emission Standards for Hazardous Air Pollutants: Taconite Iron Ore Processing Risk and Technology Review (RTR)
- 2. RIN Number:** 2060-AT05
- 3. EPA Office originating action:** EPA/OAR
- 4. Brief description of action and statement of need for the action:**

The Clean Air Act (Act) establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, the Act requires the EPA to develop technology-based standards for categories of industrial sources. In the second stage of the regulatory process, EPA must review each MACT standard at least every eight years and revise them as necessary, “taking into account developments in practices, processes and control technologies.” We call this requirement the “technology review.” The EPA is also required to complete a one-time assessment of the health and environmental risks that remain after sources come into compliance with MACT. This residual risk review also must be done within eight years of setting the initial MACT standard. If additional risk reductions are necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects, the EPA must develop standards to address the remaining risks. For each source category for which the EPA issued MACT standards, the residual risk stage must be completed within eight years of promulgation of the initial MACT standard. Since the initial technology review requirement coincides in deadline with the risk review requirement, the EPA generally combines these two requirements into one rulemaking activity, calling this the “risk and technology review” process, or RTR. In this way, results of the risk review can be potentially informative to the technology review process, and vice versa.

The EPA issued national emission standards for hazardous air pollutants (NESHAP) for taconite iron ore processing on October 30, 2003 (see 68 FR 61867). More information on the NESHAP can be found at <https://www.epa.gov/stationary-sources-air-pollution/taconite-iron-ore-processing-national-emission-standards-hazardous>.

For this action, as the second stage of the regulatory process, and as we have done for more than 55 source categories to date, we plan to conduct the residual risk review and initial technology review concurrently.

- 5. Timetable:** Required proposal date and required final rule date not yet scheduled
- 6. Scientific products that will inform the action and plans for peer review:**
 - 6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.**

The risk analysis methodologies associated with the RTR process have undergone scientific peer reviews and have been used in numerous previous RTR reviews. There are no other scientific work products that have been or will be developed to inform this planned action.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

Because RTR assessments are used for regulatory purposes, and because components of our risk analyses have evolved over time, we have, over the course of the program, conducted scientific peer reviews of the methodologies through the SAB. Through peer review of the RTR process as a whole, rather than each individual rulemaking effort, the agency is able to conduct consistent risk characterizations across all categories of industrial sources.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

While the overall RTR risk assessment methods meet the definition as "an influential scientific or technical work product", each individual RTR analysis does not.

6(d). Peer review:

Each RTR analysis follows a consistent risk characterization approach using methodologies that have undergone numerous peer reviews. Previous peer reviews have covered elements associated with the RTR process, or assessments with similar scopes or contexts. A brief summary of each peer review is provided:

- 1) The Residual Risk Report to Congress, a document describing the Agency's overall analytical and policy approach to setting residual risk standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methodology were described in this report, although individual elements have been improved over time. The Report to Congress and the final SAB advisory are available at: <https://www.epa.gov/fera/residual-risk-report-congress-1999> and [https://yosemite.epa.gov/sab/sabproduct.nsf/33598FF753C6342F852571AE0067B7D0/\\$File/ec9813.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/33598FF753C6342F852571AE0067B7D0/$File/ec9813.pdf)
- 2) A peer review of multi-pathway risk assessment methodologies for RTR was conducted by the EPA's SAB in 2000. The final SAB advisory is available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/\\$File/ecadv05.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$File/ecadv05.pdf)
- 3) A consultation on EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by SAB in December 2006. SAB provided its formal consultation in a letter to the Administrator in June 2007. The final SAB advisory is available at: [https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/\\$File/sab-07-009.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf)
- 4) A review of the updated and expanded risk assessment approaches and methods used in the RTR program was completed in 2009. This methodology was highlighted to the SAB utilizing two RTR source categories: Petroleum Refining Sources MACT I and Portland

Cement Manufacturing. The final SAB advisory is available at:

<https://yosemite.epa.gov/sab/sabproduct.nsf/0/b031ddf79cffded38525734f00649caf!OpenDocument&TableRow=2.3#2>

- 5) The individual dose-response assessment values used in the RTR assessment have themselves been the subject of peer reviews through the agencies that developed them (including EPA, through its Integrated Risk Information System, or IRIS; the California Environmental Protection Agency, or CalEPA, and the Agency for Toxic Substances and Disease Registry, or ATSDR).

EPA is currently seeking the Science Advisory Board's (SAB) input on specific enhancements made to our risk assessment methodologies, particularly with respect to screening methodologies, since the last SAB review was completed in 2009 (see above). EPA has recently submitted a draft updated methodology report to the SAB to help in panel formation. It is anticipated that an expert panel will be organized shortly and a meeting will convene by early 2017.

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Taconite Iron Ore Processing RTR [RIN 2060- AT05]

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties			X
Involves major environmental risks		X	
Relates to emerging environmental issues			X
Exhibits a long-term outlook	X		

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further SAB consideration.

Background: The EPA uses a standard process to conduct risk and technology reviews for National Emissions Standards for Hazardous Air Pollutants. This process is explained in the Background section on pages B35 and B36.

Rationale: The EPA summary of this action does not provide information specific to taconite iron ore processing. A taconite iron ore processing facility separates and concentrates iron ore from taconite (a low-grade iron ore) and produces taconite pellets, which are approximately 60 percent iron. The toxic emissions of concern include compounds containing manganese, chromium, cobalt, arsenic, and lead. Health effects from these toxic pollutants include adverse effects on the blood, central nervous system, blood pressure, kidneys, irritation of the skin and mucus membranes, and lung cancer. As part of the RTR review, EPA will have to identify whether new technologies have emerged that can more effectively control these and other pollutants. Cost must be considered when setting a MACT standard. Therefore, cost analysis must be conducted.

The Work Group finds that the RTR risk assessment screening methodology is broadly applicable to many source categories, and prior aspects of the data and methods identified have been subject to review by the SAB and others. The unique details of each RTR can include recommendations for new monitoring and MACTs. In general, these technologies are based on established scientific knowledge that has undergone extensive peer review. However, there can be exceptions, and the SAB encourages to EPA to continually assess and identify for SAB review any such technology recommendations that are based on new scientific knowledge. This planned RTR does not merit further review by the SAB.

Description of Planned EPA Tier 1 or Tier 2 Action

- 1. Name of action:** Rubber Tire Manufacturing Risk and Technology Review (RTR)
- 2. RIN Number:** 2060-AT07
- 3. EPA Office originating action:** EPA/OAR
- 4. Brief description of action and statement of need for the action:**

The Clean Air Act (Act) establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, the Act requires the EPA to develop technology-based standards for categories of industrial sources. In the second stage of the regulatory process, EPA must review each MACT standard at least every eight years and revise them as necessary, “taking into account developments in practices, processes and control technologies.” We call this requirement the “technology review.” The EPA is also required to complete a one-time assessment of the health and environmental risks that remain after sources come into compliance with MACT. This residual risk review also must be done within eight years of setting the initial MACT standard. If additional risk reductions are necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects, the EPA must develop standards to address the remaining risks. For each source category for which the EPA issued MACT standards, the residual risk stage must be completed within eight years of promulgation of the initial MACT standard. Since the initial technology review requirement coincides in deadline with the risk review requirement, the EPA generally combines these two requirements into one rulemaking activity, calling this the “risk and technology review” process, or RTR. In this way, results of the risk review can be potentially informative to the technology review process, and vice versa.

The EPA issued national emission standards for hazardous air pollutants (NESHAP) for rubber tire manufacturing on July 9, 2002 (see 67 FR 45598). More information on the NESHAP can be found at <https://www.epa.gov/stationary-sources-air-pollution/rubber-tire-manufacturing-national-emission-standards-hazardous-air>.

For this action, as the second stage of the regulatory process, and as we have done for more than 40 source categories to date, we plan to conduct the residual risk review and initial technology review concurrently.

- 5. Timetable:** Required proposal date and required final rule date not yet scheduled
- 6. Scientific products that will inform the action and plans for peer review:**
 - 6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.**

The risk analysis methodologies associated with the RTR process have undergone scientific peer reviews and have been used in numerous previous RTR reviews. There are no other scientific work products that have been or will be developed to inform this planned action.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

Because RTR assessments are used for regulatory purposes, and because components of our risk analyses have evolved over time, we have, over the course of the program, conducted scientific peer reviews of the methodologies through the SAB. Through peer review of the RTR process as a whole, rather than each individual rulemaking effort, the agency is able to conduct consistent risk characterizations across all categories of industrial sources.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

While the overall RTR risk assessment methods meet the definition as "an influential scientific or technical work product", each individual RTR analysis does not.

6(d). Peer review:

Each RTR analysis follows a consistent risk characterization approach using methodologies that have undergone numerous peer reviews. Previous peer reviews have covered elements associated with the RTR process, or assessments with similar scopes or contexts. A brief summary of each peer review is provided:

- 1) The Residual Risk Report to Congress, a document describing the Agency's overall analytical and policy approach to setting residual risk standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methodology were described in this report, although individual elements have been improved over time. The Report to Congress and the final SAB advisory are available at: <https://www.epa.gov/fera/residual-risk-report-congress-1999> and [https://yosemite.epa.gov/sab/sabproduct.nsf/33598FF753C6342F852571AE0067B7D0/\\$File/ec9813.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/33598FF753C6342F852571AE0067B7D0/$File/ec9813.pdf)
- 2) A peer review of multi-pathway risk assessment methodologies for RTR was conducted by the EPA's SAB in 2000. The final SAB advisory is available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/\\$File/ecadv05.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$File/ecadv05.pdf)
- 3) A consultation on EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by SAB in December 2006. SAB provided its formal consultation in a letter to the Administrator in June 2007. The final SAB advisory is available at: [https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/\\$File/sab-07-009.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf)
- 4) A review of the updated and expanded risk assessment approaches and methods used in the RTR program was completed in 2009. This methodology was highlighted to the SAB utilizing two RTR source categories: Petroleum Refining Sources MACT I and Portland

Cement Manufacturing. The final SAB advisory is available at:

<https://yosemite.epa.gov/sab/sabproduct.nsf/0/b031ddf79cffded38525734f00649caf!OpenDocument&TableRow=2.3#2>

- 5) The individual dose-response assessment values used in the RTR assessment have themselves been the subject of peer reviews through the agencies that developed them (including EPA, through its Integrated Risk Information System, or IRIS; the California Environmental Protection Agency, or CalEPA, and the Agency for Toxic Substances and Disease Registry, or ATSDR).

EPA is currently seeking the Science Advisory Board's (SAB) input on specific enhancements made to our risk assessment methodologies, particularly with respect to screening methodologies, since the last SAB review was completed in 2009 (see above). EPA has recently submitted a draft updated methodology report to the SAB to help in panel formation. It is anticipated that an expert panel will be organized shortly and a meeting will convene by early 2017.

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Rubber Tire Manufacturing RTR [RIN 2060-AT07]

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties			X
Involves major environmental risks		X	
Relates to emerging environmental issues			X
Exhibits a long-term outlook	X		

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further review by the SAB.

Background: The EPA uses a standard process to conduct risk and technology reviews for National Emissions Standards for Hazardous Air Pollutants. This process is explained in the Background section on pages B35 and B36.

Rationale: The EPA summary of this action does not provide information specific to rubber tire manufacturing. In 2002, EPA published MACT standards applicable operations using solvents and cements at tire production facilities; tire cord production; and puncture sealant applications. The rule was intended to reduce emissions of volatile organic compounds. The rule was expected to reduce air toxic emissions from solvents, cements and coating material used in the tire manufacturing industry by approximately 1,100 tons annually. The air toxics reduced include hexane, toluene, formaldehyde, styrene and methanol, which are associated with a variety of adverse health effects. These effects include chronic health disorders (e.g., effects on the central nervous system and reproductive system) and acute health disorders (e.g., irritation of eyes, throat, mucous membranes, headache, nausea, and blurred vision). The rule was also expected reduce volatile organic compounds (VOCs), which

contribute to the formation of ground-level ozone, the primary constituent of smog. Anticipated ways in which the standard could be met include reduced their air toxic emissions by installing controls required by state or federal new source performance standard regulations or through the elimination of, or substitution for, air toxics in cements, solvents and coating materials used as processing aides. As part of the technology review, EPA will have to identify whether new cements, solvents, coating materials, and technologies have emerged that can more effectively prevent or control these and other pollutants. Cost must also be considered when setting a MACT standard. Therefore, cost analysis must be conducted.

The Work Group finds that the RTR risk assessment screening methodology is broadly applicable to many source categories, and prior aspects of the data and methods identified have been subject to review by the SAB and others. The unique details of each RTR can include recommendations for new monitoring and MACTs. In general, these technologies are based on established scientific knowledge that has undergone extensive peer review. However, there can be exceptions, and the SAB encourages to EPA to continually assess and identify for SAB review any such technology recommendations that are based on new scientific knowledge. This planned RTR does not merit further review by the SAB.

Description of Planned EPA Tier 1 or Tier 2 Action

- 1. Name of action:** Lime Manufacturing Risk and Technology Review (RTR)
- 2. RIN Number:** 2060-AT08
- 3. EPA Office originating action:** EPA/OAR
- 4. Brief description of action and statement of need for the action:**

The Clean Air Act (Act) establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, the Act requires the EPA to develop technology-based standards for categories of industrial sources. In the second stage of the regulatory process, EPA must review each MACT standard at least every eight years and revise them as necessary, “taking into account developments in practices, processes and control technologies.” We call this requirement the “technology review.” The EPA is also required to complete a one-time assessment of the health and environmental risks that remain after sources come into compliance with MACT. This residual risk review also must be done within eight years of setting the initial MACT standard. If additional risk reductions are necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects, the EPA must develop standards to address the remaining risks. For each source category for which the EPA issued MACT standards, the residual risk stage must be completed within eight years of promulgation of the initial MACT standard. Since the initial technology review requirement coincides in deadline with the risk review requirement, the EPA generally combines these two requirements into one rulemaking activity, calling this the “risk and technology review” process, or RTR. In this way, results of the risk review can be potentially informative to the technology review process, and vice versa.

The EPA issued national emission standards for hazardous air pollutants (NESHAP) for lime manufacturing on January 5, 2004 (see 69 FR 393). More information on the Lime Manufacturing NESHAP can be found at <https://www.epa.gov/stationary-sources-air-pollution/lime-manufacturing-plants-national-emission-standards-hazardous-air>.

For this action, as the second stage of the regulatory process, and as we have done for more than 55 source categories to date, we plan to conduct the residual risk review and initial technology review concurrently.

- 5. Timetable:** Required proposal date and required final rule date not yet scheduled
- 6. Scientific products that will inform the action and plans for peer review:**
 - 6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.**

The risk analysis methodologies associated with the RTR process have undergone scientific peer reviews and have been used in numerous previous RTR reviews. There are no other scientific work products that have been or will be developed to inform this planned action.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

Because RTR assessments are used for regulatory purposes, and because components of our risk analyses have evolved over time, we have, over the course of the program, conducted scientific peer reviews of the methodologies through the SAB. Through peer review of the RTR process as a whole, rather than each individual rulemaking effort, the agency is able to conduct consistent risk characterizations across all categories of industrial sources.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

While the overall RTR risk assessment methods meet the definition as "an influential scientific or technical work product", each individual RTR analysis does not.

6(d). Peer review:

Each RTR analysis follows a consistent risk characterization approach using methodologies that have undergone numerous peer reviews. Previous peer reviews have covered elements associated with the RTR process, or assessments with similar scopes or contexts. A brief summary of each peer review is provided:

- 1) The Residual Risk Report to Congress, a document describing the Agency's overall analytical and policy approach to setting residual risk standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methodology were described in this report, although individual elements have been improved over time. The Report to Congress and the final SAB advisory are available at: <https://www.epa.gov/fera/residual-risk-report-congress-1999> and [https://yosemite.epa.gov/sab/sabproduct.nsf/33598FF753C6342F852571AE0067B7D0/\\$File/ec9813.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/33598FF753C6342F852571AE0067B7D0/$File/ec9813.pdf)
- 2) A peer review of multi-pathway risk assessment methodologies for RTR was conducted by the EPA's SAB in 2000. The final SAB advisory is available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/\\$File/ecadv05.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$File/ecadv05.pdf)
- 3) A consultation on EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by SAB in December 2006. SAB provided its formal consultation in a letter to the Administrator in June 2007. The final SAB advisory is available at: [https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/\\$File/sab-07-009.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf)
- 4) A review of the updated and expanded risk assessment approaches and methods used in the RTR program was completed in 2009. This methodology was highlighted to the SAB utilizing two RTR source categories: Petroleum Refining Sources MACT I and Portland

Cement Manufacturing. The final SAB advisory is available at:

<https://yosemite.epa.gov/sab/sabproduct.nsf/0/b031ddf79cffded38525734f00649caf!OpenDocument&TableRow=2.3#2>

- 5) The individual dose-response assessment values used in the RTR assessment have themselves been the subject of peer reviews through the agencies that developed them (including EPA, through its Integrated Risk Information System, or IRIS; the California Environmental Protection Agency, or CalEPA, and the Agency for Toxic Substances and Disease Registry, or ATSDR).

EPA is currently seeking the Science Advisory Board's (SAB) input on specific enhancements made to our risk assessment methodologies, particularly with respect to screening methodologies, since the last SAB review was completed in 2009 (see above). EPA has recently submitted a draft updated methodology report to the SAB to help in panel formation. It is anticipated that an expert panel will be organized shortly and a meeting will convene by early 2017.

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Lime Manufacturing RTR [RIN 2060-AT08]

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties			X
Involves major environmental risks		X	
Relates to emerging environmental issues			X
Exhibits a long-term outlook	X		

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further review by the SAB.

Background: The EPA uses a standard process to conduct risk and technology reviews for National Emissions Standards for Hazardous Air Pollutants. This process is explained in the Background section on pages B35 and B36.

Rationale: In 2004, EPA promulgated a final rule to reduce toxic air pollutant emissions from new and existing lime manufacturing plants. This Lime Manufacturing NESHAP established emission limitations and work practice requirements based on maximum achievable control technology (MACT) for control of hazardous air pollutants (HAP) from kilns at new and existing lime manufacturing plants. The pollutants emitted from lime manufacturing kilns include metallic HAP, hydrogen chloride, particulate matter, sulfur dioxide, nitrogen oxides and carbon dioxide. These pollutants predominantly originate from the limestone feed material and the fuels used, and are formed from the combustion of fuels and the heating of feed material in the kiln. EPA standards are required to provide an ample margin of safety to protect public health or an adverse environmental effect. EPA is required to review and revise the

MACT standards as necessary, taking into account developments in practices, processes and control technologies no less often than every 8 years. As part of the technology review, EPA will need to identify whether new approaches to lime manufacturing have emerged that can more effectively prevent or control the emission of these and other pollutants. Cost must also be considered when setting a MACT standard. Therefore, a cost analysis must also be conducted.

The Work Group finds that the RTR risk assessment screening methodology is broadly applicable to many source categories, and prior aspects of the data and methods identified have been subject to review by the SAB and others. The unique details of each RTR can include recommendations for new monitoring and MACTs. In general, these technologies are based on established scientific knowledge that has undergone extensive peer review. However, there can be exceptions, and the SAB encourages to EPA to continually assess and identify for SAB review any such technology recommendations that are based on new scientific knowledge. This planned RTR does not merit further review by the SAB.

Description of Planned EPA Tier 1 or Tier 2 Action

- 1. Name of action:** National Emission Standard for Hazardous Air Pollutants (NESHAP) Risk and Technology Review: Reinforced Plastics Composites and Boat Manufacturing RTR
- 2. RIN Number:** 2060-AT12
- 3. EPA Office originating action:** EPA/OAR
- 4. Brief description of action and statement of need for the action:**

The Clean Air Act (Act) establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, the Act requires the EPA to develop technology-based standards for categories of industrial sources. In the second stage of the regulatory process, EPA must review each MACT standard at least every eight years and revise them as necessary, “taking into account developments in practices, processes and control technologies.” We call this requirement the “technology review.” The EPA is also required to complete a one-time assessment of the health and environmental risks that remain after sources come into compliance with MACT. This residual risk review also must be done within eight years of setting the initial MACT standard. If additional risk reductions are necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects, the EPA must develop standards to address the remaining risks. For each source category for which the EPA issued MACT standards, the residual risk stage must be completed within eight years of promulgation of the initial MACT standard. Since the initial technology review requirement coincides in deadline with the risk review requirement, the EPA generally combines these two requirements into one rulemaking activity, calling this the “risk and technology review” process, or RTR. In this way, results of the risk review can be potentially informative to the technology review process, and vice versa.

The EPA issued national emission standards for hazardous air pollutants (NESHAP) for Reinforced Plastics Composites on April 21, 2003 (see 68 FR 19375) and Boat Manufacturing on August 22, 2001 (see 66 FR 44217). More information on the NESHAPs can be found at <https://www.epa.gov/stationary-sources-air-pollution/reinforced-plastic-composites-production-national-emission> and <https://www.epa.gov/stationary-sources-air-pollution/boat-manufacturing-national-emission-standards-hazardous-air>.

For this action, as the second stage of the regulatory process for these categories, and as we have done for more than 55 source categories to date, we plan to conduct the residual risk review and initial technology review concurrently.

- 5. Timetable:** Required proposal date and required final rule date not yet scheduled
- 6. Scientific products that will inform the action and plans for peer review:**
 - 6(a). Describe the scientific work products that have been or will be developed to inform decisions regarding the planned action.**

The risk analysis methodologies associated with the RTR process have undergone scientific peer reviews and have been used in numerous previous RTR reviews. There are no other scientific work products that have been or will be developed to inform this planned action.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).

Because RTR assessments are used for regulatory purposes, and because components of our risk analyses have evolved over time, we have, over the course of the program, conducted scientific peer reviews of the methodologies through the SAB. Through peer review of the RTR process as a whole, rather than each individual rulemaking effort, the agency is able to conduct consistent risk characterizations across all categories of industrial sources.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"

While the overall RTR risk assessment methods meet the definition as "an influential scientific or technical work product", each individual RTR analysis does not.

6(d). Peer review:

Each RTR analysis follows a consistent risk characterization approach using methodologies that have undergone numerous peer reviews. Previous peer reviews have covered elements associated with the RTR process, or assessments with similar scopes or contexts. A brief summary of each peer review is provided:

- 1) The Residual Risk Report to Congress, a document describing the Agency's overall analytical and policy approach to setting residual risk standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methodology were described in this report, although individual elements have been improved over time. The Report to Congress and the final SAB advisory are available at: <https://www.epa.gov/fera/residual-risk-report-congress-1999> and [https://yosemite.epa.gov/sab/sabproduct.nsf/33598FF753C6342F852571AE0067B7D0/\\$File/ec9813.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/33598FF753C6342F852571AE0067B7D0/$File/ec9813.pdf)
- 2) A peer review of multi-pathway risk assessment methodologies for RTR was conducted by the EPA's SAB in 2000. The final SAB advisory is available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/\\$File/ecadv05.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$File/ecadv05.pdf)
- 3) A consultation on EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by SAB in December 2006. SAB provided its formal consultation in a letter to the Administrator in June 2007. The final SAB advisory is available at:

[https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/\\$File/sab-07-009.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf)

- 4) A review of the updated and expanded risk assessment approaches and methods used in the RTR program was completed in 2009. This methodology was highlighted to the SAB utilizing two RTR source categories: Petroleum Refining Sources MACT I and Portland Cement Manufacturing. The final SAB advisory is available at:
<https://yosemite.epa.gov/sab/sabproduct.nsf/0/b031ddf79cffded38525734f00649caf!OpenDocument&TableRow=2.3#2>
- 5) The individual dose-response assessment values used in the RTR assessment have themselves been the subject of peer reviews through the agencies that developed them (including EPA, through its Integrated Risk Information System, or IRIS; the California Environmental Protection Agency, or CalEPA, and the Agency for Toxic Substances and Disease Registry, or ATSDR).

EPA is currently seeking the Science Advisory Board's (SAB) input on specific enhancements made to our risk assessment methodologies, particularly with respect to screening methodologies, since the last SAB review was completed in 2009 (see above). EPA has recently submitted a draft updated methodology report to the SAB to help in panel formation. It is anticipated that an expert panel will be organized shortly and a meeting will convene by early 2017.

Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

Name of planned action: Boat Manufacturing RTR [RIN 2060-AT12]

Please respond to the following questions based on the short description EPA provided for the planned action.

	Yes	No
Is the action planned or under review by the SAB? If not, has EPA identified other high-level external peer review (i.e., by the NAS, CASAC, or FIFRA SAP)?		X
Is the action primarily administrative (i.e., involve reporting or record keeping)?		X
Has EPA characterized the action as one that has "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"		X
Is the action an extension of an existing initiative?	X	

Please indicate whether the action merits a high, medium or low level of interest regarding the following historical SAB science- and problem-driven criteria, based on the short description EPA provided for the planned action.

	High	Medium	Low
Involves scientific approaches that are new to the agency			X
Addresses areas of substantial uncertainties			X
Involves major environmental risks		X	
Relates to emerging environmental issues			X
Exhibits a long-term outlook	X		

Please provide a recommendation regarding whether the SAB should consider this action for review and comment on the adequacy of the supporting science and provide a brief rationale.

Recommendation: This action does not merit further review by the SAB.

Background: The EPA uses a standard process to conduct risk and technology reviews for National Emissions Standards for Hazardous Air Pollutants. This process is explained in the Background section on pages B35 and B36.

Rationale: The EPA summary of this action does not provide information specific to boat manufacturing. In 2001, the EPA promulgated National Emission Standards for Hazardous Air Pollutants for Boat Manufacturing. The rule applies to resin and gel coat operations at fiberglass boat manufacturers, paint and coating operations at recreational aluminum boat manufacturers, and carpet and fabric adhesive operations at all boat manufacturers. The focus was on reducing emissions of styrene, methyl methacrylate, methylene chloride, toluene, xylene, and other air toxics. These compounds include possible and probable human carcinogens and compounds that cause health problems with the central nervous system, liver, and kidneys. Expected control actions included equipment and work practice requirements (e.g. use of non-spray technologies for applying resins) and

limitations on the amount of air toxics in the materials used (e.g. resins, gel coats, paints and adhesives). The regulation was expected to reduce air toxics emissions from boat manufacturers by about 3,130 tons annually, representing a 35 percent reduction from levels before the rule. As part of the technology review, EPA will have to identify whether new technologies have emerged that can more effectively control these and other pollutants. Cost must also be considered when setting a MACT standard. Therefore, cost analysis must be conducted.

The Work Group finds that the RTR risk assessment screening methodology is broadly applicable to many source categories, and prior aspects of the data and methods identified have been subject to review by the SAB and others. The unique details of each RTR can include recommendations for new monitoring and MACTs. In general, these technologies are based on established scientific knowledge that has undergone extensive peer review. However, there can be exceptions, and the SAB encourages to EPA to continually assess and identify for SAB review any such technology recommendations that are based on new scientific knowledge. This planned RTR does not merit further review by the SAB.