MEMORANDUM

TO: Members of the Chartered SAB and SAB Liaisons

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

DATE: April 25, 2019

SUBJECT: Preparations for Chartered Science Advisory Board (SAB) Discussions of EPA Planned Agency Actions and their Supporting Science in the Spring 2018 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 Spring 2018 semi-annual regulatory agenda at its June 2019 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 2013[1] 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 Spring 2018 Unified (Regulatory) Agenda and Regulatory Plan had been published on May 10, 2018. This semi-annual regulatory agenda is available at https://www.reginfo.gov/public/do/eAgendaMain. This SAB Work Group was formed in July 2018 and The SAB staff office requested information from program offices. The Work Group includes SAB members with broad expertise in scientific and technological issues related to the proposed actions. The Work Group consists of Drs. Alison Cullen (chair), Rodney

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

Andrews, Deborah Bennett, Bob Blanz, Todd Brewer, Tony Cox, Christopher Frey[2], John Graham, Merlin Lindstrom, Tom Parkerton, Richard Smith, and Mr. Richard Poirot

The Work Group considered actions in the Spring 2018 semi-annual regulatory agenda that were identified by the EPA as "major actions." The Work Group considered several factors when assessing each proposed major action, i.e., whether the action:

- already had a planned review by the SAB or some other high level external peer review [e.g., National Academy of Sciences, Clean Air Scientific Advisory Committee, Federal Insecticide, Fungicide and Rodenticide (FIFRA) Scientific Advisory Panel];
- was primarily administrative (i.e., involved reporting or record keeping);
- was an extension of an existing initiative;
- was characterized by EPA as an influential scientific or technical work product having a major impact, or involved precedential, novel, and/or controversial issues;
- considered scientific approaches new to the agency;
- addressed an area of substantial uncertainty;
- involved major environmental risks;
- related to an emerging environmental issue; or
- exhibited a long-term outlook.

On September 17, 2018, the Work Group received information and short descriptions from the EPA Program Offices on the major planned actions that are listed in the Spring 2018 semi-annual regulatory agenda but not yet proposed. Work Group members concurred on the recommendations presented in this memorandum after a discussion on September 28, 2018 and November 19, 2018 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. The Work Group submitted requests for additional information on several planned actions and held a fact-finding teleconference with EPA staff on October 31, 2018. A summary of the teleconference is provided in Attachment C.

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 12 major planned actions considered, the Work Group recommends that the SAB provide advice on three of the planned actions. Two actions had insufficient information for the Work Group to make a recommendation and seven of the actions do not merit further SAB consideration.

The Work Group notes that the stage of the rulemaking for three 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

[2] Dr. Frey's term on the Science Advisory Board ended on September 30, 2018.

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.

Miscellaneous Organic Chemical Manufacturing and Miscellaneous Coating Manufacturing Residual Risk and Technology Reviews (2060-AT85) and *National Emission Standards for Hazardous Air Pollutants: Organic Liquids Distribution (Non-Gasoline) RTR (2060-AT86)*: These planned actions do not merit further review by the SAB. The EPA uses a standard process to conduct risk and technology reviews for National Emissions Standards for Hazardous Air Pollutants. This process, "Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis (May 2017)" was reviewed by the SAB 2017 and the SAB discussions and the report are available on the SAB website:

Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Project Emissions Accounting (2060-AT89): This planned action does not merit further review by the SAB. The SAB Work Group recognizes that this regulation is intended to codify the interpretations in the March 13, 2018 Memorandum from the Administrator and does not merit further scientific review by the SAB. The Work Group notes that the scientific and technical review of NAAQS are reviewed by the Clean Air Scientific Advisory Council and this planned action is an extension of existing initiatives and primarily administrative. The SAB has considered previous planned actions regarding the NNSR and PSD[3] and found that the action did not identify new science issues and does not merit further review.

Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Review (2060-AT90): The Work Group found there was insufficient information provided for this action and suggests the SAB request updates from the agency. The Work Group recommends deferring review of the planned action until sufficient information is available.

This action will focus on the challenges of regulating multiple pollutants across multiple segments of a complex industry. One challenge pointed out by the EPA is that there are often multiple entities involved in the process of extraction of delivery of oil and natural gas. The agency needs to determine how best to integrate these entities in the law. Assuming this is done in such a way that all potential emission points are considered, this component of the action does seem likely to be a policy decision.

The second component of the proposed action is to evaluate the methods by which multiple pollutants are considered. The agency notes that many control actions reduce emissions of multiple pollutants. It appears that one of the goals is to somehow streamline the process such that fewer compounds are evaluated. While the Work Group agrees that there is a policy component to this, there is also an important science component. The methods for selecting proxy compounds to evaluate, or otherwise reducing the number of compounds tracked, must be done in consideration of the relative health impacts of the various compounds, as well as potentially accounting for exposures to mixtures of compounds with similar actions. The Agency also notes there will be analysis involving costs and benefits. The determination of costs and benefits involves the science linking emissions to health impacts. It is not

[3] See the Fall 2012 Regulatory Review and Work Group memorandum page c-18

clear if the same science will be used as in the original regulation, or if changes will be proposed. If changes are proposed, this would involve scientific evaluations.

The Work Group does not have complete information in regard to the agency's plans, and therefore requests that the Board continue to track this action to determine if it should be reviewed when more information becomes available. We note that the EPA schedule for the planned action listed the Notice of Proposed Rule Making for December 2018.

Renewable Fuel Volume Standards for 2019 and Biomass Based Diesel Volume (BBD) for 2020 (2060-AT93): This action does not merit further consideration for review by the SAB. Overall, Renewable Fuel Standards regulation is an activity covered under Section 211(o) of the CAA 2007, with the adoption of revisions in 2010 following amendments enacted as part of the 2007 Energy Independence and Security Act. Since 2007 EPA has promulgated annual rules to translate renewable fuel volumes into percentage standards reflecting the upcoming year's projection of gas and diesel demand. In 2014 for the first time the agency used its waiver authority to set applicable volumes below statutory levels as a result of the projected unavailability of some types of fuels, as well as constraints on supply. In advance of the 2014 waiver, the SAB reviewed the action as part of the Spring 2013 Regulatory Agenda and concluded that it did not merit further consideration. The current action is considered a routine and recurring action relying on the same approach and data sources.

Mercury and Air Toxics Standards for Power Plants Residual Risk and Technology Review and Cost Review (2060-AT99): This action merits review by the SAB. The Work Group notes that the action is a National Emission Standard for Hazard Air Pollutants undergoing an 8-year review required by the Clean Air Act (Risk and Technology Review). The Work Group finds that the specifics of the planned action merit review rather than deference to the standard RTR review approach.

This planned action is in response to a Supreme Court decision regarding the Mercury and Air Toxics Standards (MATS). In its ruling, the Court found that EPA did not consider cost in its "appropriate and necessary" finding supporting the MATS. In this planned action, EPA is considering whether cost of MATS compliance is reasonable when weighed against the health benefits of the rule. Per the EPA, there are no new scientific work products associated with this action. The proposal relies on existing information in the MATS rulemaking administrative record. For example, and perhaps most notably, the action relies on the existing Regulatory Impact Analysis.

The proposed action has different aspects that relate to science, policy and the law. In particular, it appears that the final disposition of the rule will depend at least in part on a court decision on the so-called co-benefits rule (i.e., that EPA includes in its cost assessment benefits due to reductions in particular matter and nitrogen dioxide as well as mercury). While the policy and legal aspects are not within the purview of SAB, SAB should provide scientific advice on the cost estimates under a variety of scenarios that both include and exclude the co-benefits to support that appropriate consideration of cost is incorporated into the new assessment. Furthermore, the SAB may provide advice on deficiencies in the cost assessment methodology that contributed t the Supreme Court ruling. . It would be of interest to know exactly how EPA determines what is a direct benefit and what is a co-benefit, and how it handles different types of human health outcomes (e.g. how to calculate the relative costs of missed work days, hospitalizations, and deaths).

A major part of the proposed action is a Residual Risk and Technology Review (RTR). It is stated that "no new scientific work products will be developed…", essentially because the methodology has been previously developed and undergone peer review. One member of the SAB Workgroup has commented that the SAB should not review actions that follow a prescribed methodology which has undergone scientific review. However, other members of the Work Group, note the distinction between the methodology used to conduct a review and the results of that review. These Work Group members find that the SAB should review whether the methodology has been correctly applied in this case.

Regarding the MATS Supplemental Cost Finding, it is stated that this "will not involve scientific work products" and in further responses by the SAB Staff Office, "EPA's review … is not based on new scientific data." Some members of the Work Group note that these statements only reinforce the need for SAB to conduct its own scientific analysis[4]. However, another member notes that this action does appear to involve new scientific work products and data (e.g., expanding the methodology to better consider cost, designating or applying "direct benefit" and "co-benefit" definitions or how health outcomes are considered in this context) and this requires a scientific review that is not planned by EPA.

It is unclear whether "peer review" (under 6(d)) refers to the work of the SAB, but we believe such peer review should be undertaken by SAB unless there are plans for this to be accomplished by another body. EPA can credibly claim to have assessed the risks and costs of the new rule only if there is a rigorous and robust peer review provided.

Rulemaking to Establish Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy (2060-AU09): This action does not warrant further review provided the EPA and CARB agree on a rule harmonized across the US. If, however, the EPA and CARB cannot agree on a harmonized rule, then the SAB is ready to review pertinent scientific data in the different rules. The Work Group conducted a non-public fact-finding meeting with EPA staff. A summary of the discussions and the EPA's responses to the Work Group's questions are provided in Attachment C of this memorandum.

In this proposal, the EPA is relying on the technical analysis performed by NHTSA which is the basis of the joint proposed standards for both CAFÉ and light-duty truck GHG standards. EPA developed extensive data, models and reports leading up to the Mid Term Evaluation, including a comprehensive Technical Assessment Report. Regardless of whether EPA relies on its own staff and analysis, or references another agency, EPA has an obligation to base its own rulemaking on appropriately reviewed scientific and technical work products.

Strengthening Transparency in Regulatory Science (2080-AA14): The SAB informed Administrator Pruitt that they wish to provide advice on this planned action in a June 28, 2018 letter. A SAB Work Group met by teleconference on May 3, 2018, to discuss its recommendations on major planned actions in the Fall 2017 semi-annual regulatory agenda and included the proposed rule Strengthening

[4] Note to members: The EPA previously considered Considering Cost in the Appropriate and Necessary Finding for the Mercury and Air Toxics Standards (MATS) (RIN 2060-AS76). The agency re-evaluated the MATS in response to a US Supreme Court decision. The agency sought public comment but did not develop any new scientific data for the action. The Work Group noted the action was supported by a SAB peer review of the Mercury Risk Assessment and the NESHAP was included in the SAB review of the Fall 2015 Regulatory Agenda. Based on the review of the Mercury Risk Assessment and the RTR Risk assessment methodologies as technical support for the MATS, the SAB agreed with the Work Group and found the action did not merit further SAB consideration. See page B22-24.

Transparency in Regulatory Science (RIN 2080-AA14) as part of the discussion. That Work Group provided the SAB with a memorandum documenting the discussion and recommending that the proposed rule merits review by the SAB. More information is available on the SAB webpage here.

Updates to Wet Weather Treatment Regulations for POTWs (2040-AF81): The Work Group notes that there was insufficient information provided for this action and suggests the SAB request updates from the agency. The Work Group recommends deferring review of the planned action until sufficient information is available. The Work Group conducted a non-public fact-finding meeting with EPA staff. A summary of the discussions and the EPA's responses to the Work Group's questions are provided in Attachment C of this memorandum.

The SAB Work Group recognizes that this regulation concerns the long-standing issue of regulatory management of wet weather flows at Publicly Owned Treatment Works (POTWs). These wet weather events have the potential to physically damage the facilities and/or "wash-out" the biological systems thereby impacting future operations. The development of the regulation is in its early stages as the agency has just completed stakeholder group meetings and gathering additional information. The SAB Work Group finds that this regulation, by necessity, will include process engineering and public health considerations and merits further consideration when additional information is available

Clean Water Act Section 404 Assumption Update Regulation (2040-AF83): The action does not merit further review by the SAB. Rationale: The SAB Work Group recognizes that this regulation is largely procedural and administrative as the 404/401 program is well established and does not merit review by the SAB.

*Treatment of Biogenic CO2 Emissions Under the Clean Air Act Permitting Programs (2060-AU03):*This planned action does not merit further review by the SAB. The proposed action relies on a policy position and does not involve any new science in this action. The *EPA's Treatment of Biogenic Carbon Dioxide (CO2) Emissions from Stationary Sources that Use Forest Biomass for Energy Production* was issued on April 23, 2018. The Work Group notes that the policy statement acknowledges the scientific complexity of the topic, the SAB's on-going work on biogenic carbon emissions and states that the "policy is not a scientific determination and does not revise or amend any scientific determinations that EPA has previously made." The Work Group received written responses from the EPA program office which are summarized in Attachment C of this memorandum.

General National Ambient Air Quality Standards Implementation Update Rule (2060-AU10): This planned action does not merit further review. The EPA describes this action as a placeholder for "one or more potential proposed rulemakings to address NAAQS implementation-related policies determined by the Administrator as necessary to fully realize the benefits of strategies to streamline and reduce burden, and in response to adverse court decisions." The EPA has not determined whether the planned action 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.

The Work Group notes that planned actions in this agenda and previous agendas addressed implementation of the NAAQS. In this regulatory agenda the Work Group found that a similar action, "*Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Project*

Emissions Accounting Proposed Rulemaking (RIN 2060-AT89), did not merit further review. Other planned actions that address the implementation of the NAAQS are listed in Attachment B

Table 1 identifies the 12 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

RIN[1]	Planned Action Title	Workgroup Recommendation
2060-AT85	Miscellaneous Organic Chemical Manufacturing and Miscellaneous Coating Manufacturing Residual Risk and Technology Reviews	No further SAB consideration is merited.
2060-AT86	National Emission Standards for Hazardous Air Pollutants: Organic Liquids Distribution (Non-Gasoline) RTR	No further SAB consideration is merited.
2060-AT89	Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Project Emissions Accounting	No further SAB consideration is merited.
2060-AT90	Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Review	Defer a determination until sufficient information is available
2060-AT93	Renewable Fuel Volume Standards for 2019 and Biomass Based Diesel Volume (BBD) for 2020	No further SAB consideration is merited.
2060-AT99	Mercury and Air Toxics Standards for Power Plants Residual Risk and Technology Review and Cost Review	Merits review by the SAB
2060-AU09	Rulemaking to Establish Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy	Merits review by the SAB
2080-AA14	Strengthening Transparency in Regulatory Science[5]	Merits review by the SAB
2040-AF81	Updates to Wet Weather Treatment Regulations for POTWs	Defer a determination until sufficient information is available
2040-AF83	Clean Water Act Section 404 Assumption Update Regulation	No further SAB consideration is merited.

[5] At its May 31, 2018 meeting the Chartered SAB discussed and identified this action (Strengthening Transparency in Regulatory Science 2080-AA14) as a planned action the SAB wishes to provide comment and advice on. The SAB sent a letter to Administrator Pruitt, available here. The SAB will be discussing this proposed action as a specific project and not part of the Spring 2018 Regulatory Deregulatory Agenda.

Table 1: Summary of Proposed Actions that the SAB Work Group Considered for Additional SAB Comment on the Supporting Science		
RIN[1]	**Planned Action Title**	**Workgroup Recommendation**
2060-AU03	Treatment of Biogenic CO2 Emissions Under the Clean Air Act Permitting Programs	No further SAB consideration is merited.
2060-AU10	General National Ambient Air Quality Standards Implementation Update Rule	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/

Work Group Recommendations Regarding Improvements to the Process for Identifying EPA Planned Actions for SAB Consideration

The Work Group thanks the EPA for providing information for consideration but emphasizes that the SAB requires more complete and timely information from the agency to make recommendations and decisions regarding the science supporting planned actions. To improve the process for future review of the semi-annual regulatory agenda, the SAB Work Group strongly recommends that EPA enhance descriptions of future planned actions by providing specific information on the peer review associated with the science basis for actions and more description of the scientific and technological bases for the actions. In reviewing the Spring 2018 Regulatory Agenda, there were several cases where key information about the planned action, its supporting science and peer review were provided only after specific work group requests. The Work Group finds that the responses to fact finding questions were not comprehensive and participation in the scheduled teleconference was limited. EPA should provide such information in the initial descriptions provided to the work group.

Effective SAB evaluation of planned actions requires the agency to characterize:

- All relevant key information associated with the planned action;
- The science supporting the regulatory action. If there is new science to be used, provide a description of what is being developed. If the agency is relying on existing science, provide a short description.
- The nature of planned or completed peer review. To the extent possible, provide information about the type of peer review, the charge questions provided to the reviewers, how relevant peer review comments were integrated into the planned action, and information about the qualifications of the reviewer(s).

This SAB made several of these recommendations in previous reviews. We request that the chartered SAB highlight to the Administrator the need for the Agency to provide more complete information to support future SAB decisions about the adequacy of the science supporting actions in future regulatory agendas.

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 Spring 2018 Semi-Annual Regulatory Agenda.
Attachment C: Summary of the October 31, 2018 Fact-Finding Teleconference

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

- 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).

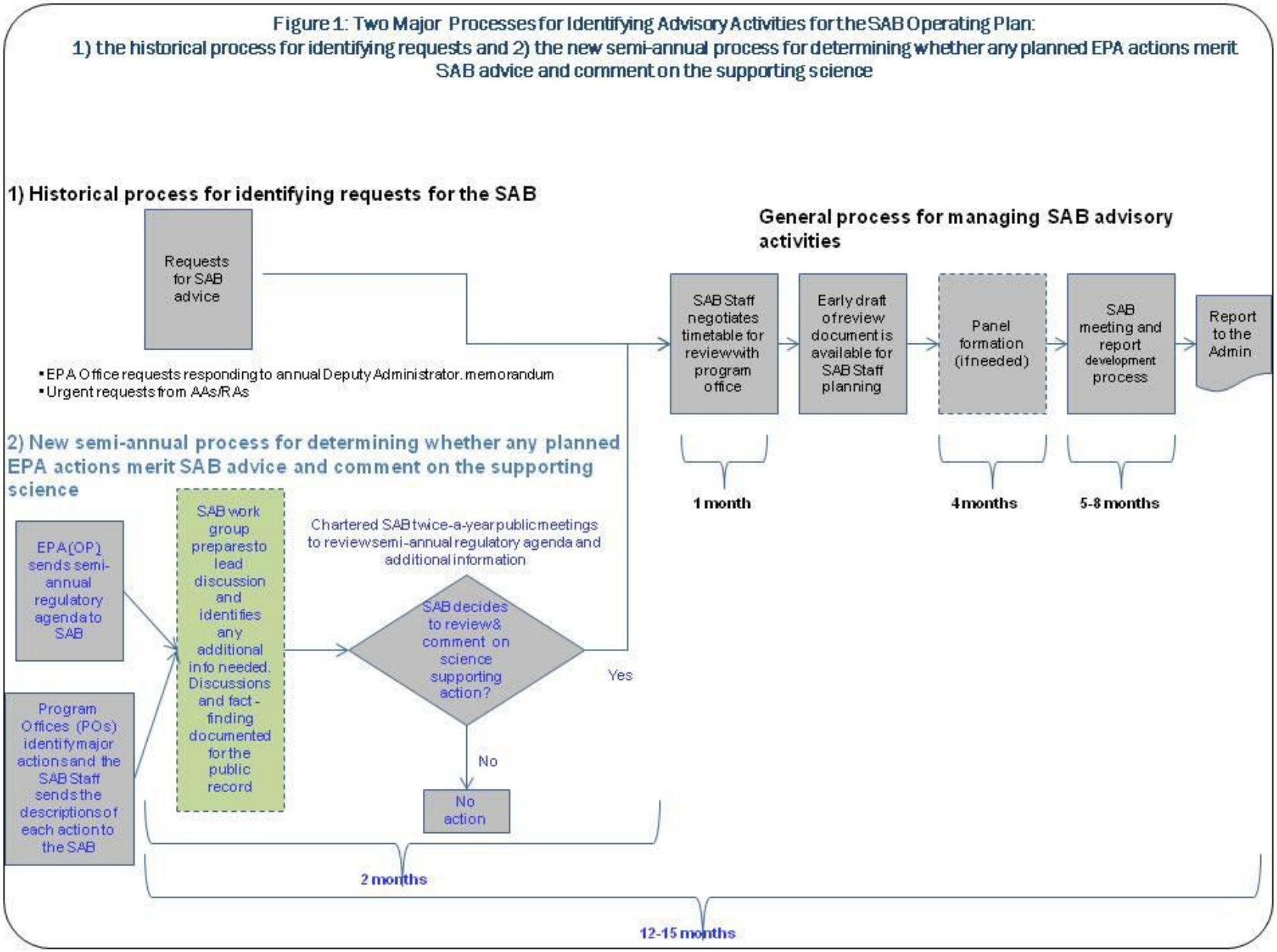
Figure 1: Two Major Processes for Identifying Advisory Activities for the SAB Operating Plan:
1) the historical process for identifying requests and 2) the new semi-annual process for determining whether any planned EPA actions merit SAB advice and comment on the supporting science
1) Historical process for identifying requests for the SAB
Requests for SAB advice
▪ EPA Office requests responding to annual Deputy Administrator. memorandum
▪ Urgent requests from AAs/RAs
General process for managing SAB advisory activities
SAB Staff negotiates timetable for review with program office
Early draft of review document is available for SAB Staff planning
Panel formation (if needed)
SAB meeting and report development process
Report to the Admin
1 month
4 months
5-8 months
2) New semi-annual process for determining whether any planned EPA actions merit SAB advice and comment on the supporting science
EPA (OP) sends semi-annual regulatory agenda to SAB
Program Offices (POs) identify major actions and the SAB Staff sends the descriptions of each action to the SAB
SAB work group prepares to lead discussion and identifies any additional info needed. Discussions and fact-finding documented for the public record
Chartered SAB twice-a-year public meetings to review semi-annual regulatory agenda and additional information
SAB decides to review & comment on science supporting action?
Yes
No
No action
2 months
12-15 months

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

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; chairmenship

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

(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

OFFICE OF THE AOMINISTRATOR

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

VanessaVu,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.

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
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*.

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

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
Major Actions in the Spring 2018
Unified Agenda of Regulatory and Deregulatory Agenda
April 25, 2019

RIN	Office	Stage of Rulemaking	Title	Page
2060-AT85	OAR	Proposed Rule Stage	Miscellaneous Organic Chemical Manufacturing and Miscellaneous Coating Manufacturing Residual Risk and Technology Reviews	2
2060-AT86	OAR	Proposed Rule Stage	National Emission Standards for Hazardous Air Pollutants: Organic Liquids Distribution (Non-Gasoline) RTR	7
2060-AT89	OAR	Proposed Rule Stage	Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Project Emissions Accounting	12
2060-AT90	OAR	Proposed Rule Stage	Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Review	16
2060-AT93	OAR	Proposed Rule Stage	Renewable Fuel Volume Standards for 2019 and Biomass Based Diesel Volume (BBD) for 2020	21
2060-AT99	OAR	Proposed Rule Stage	Mercury and Air Toxics Standards for Power Plants Residual Risk and Technology Review and Cost Review	27
2060-AU09	OAR	Proposed Rule Stage	Rulemaking to Establish Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy	33
2080-AA14	ORD	Proposed Rule Stage	Strengthening Transparency in Regulatory Science[1]	38
2040-AF81	OW	Long-Term Actions	Updates to Wet Weather Treatment Regulations for POTWs	39
2040-AF83	OW	Long-Term Actions	Clean Water Act Section 404 Assumption Update Regulation	42
2060-AU03	OAR	Long-Term Actions	Treatment of Biogenic CO2 Emissions Under the Clean Air Act Permitting Programs	45
2060-AU10	OAR	Long-Term Actions	General National Ambient Air Quality Standards Implementation Update Rule	49

[1] At its May 31, 2018 meeting the Chartered SAB discussed and identified this action (Strengthening Transparency in Regulatory Science 2080-AA14) as one the SAB wishes to provide comment and advice on. The SAB sent a letter to Administrator Pruitt, available here. The Work Group will not be discussing this action.

EPA Description of Planned Action

1. **Name of action:** National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review

2. **RIN Number:** 2060-AT85

3. **EPA Office originating action:** Office of Air and Radiation/Office of Air Quality Planning and Standards/Sector Policies and Programs Division

4. **Brief description of action and statement of need for the action:** This action will address the agency's residual risk and technology review (RTR) of the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Miscellaneous Organic Chemical Manufacturing. The Miscellaneous Organic Chemical Manufacturing NESHAP (MON), 40 CFR part 63, subpart FFFF, was promulgated pursuant to section 112(d) of the Clean Air Act (CAA) on November 10, 2003. The NESHAP established emission limitations and work practice requirements based on maximum achievable control technology (MACT) for controlling emissions of hazardous air pollutants (HAP) from continuous process vents, batch process vents, storage tanks, equipment leaks, wastewater streams, transfer racks and heat exchange systems. The HAP emitted from these sources include, but are not limited to, toluene, methanol, xylene, hydrogen chloride and methylene chloride.

   This action will implement the residual risk review requirements of CAA section 112(f)(2) and the technology review requirements of CAA section 112(d)(6). The statute directs the EPA to promulgate emission standards under CAA 112(f)(2) if such standards are required to provide an ample margin of safety to protect public health or to prevent, taking relevant factors into account, an adverse environmental effect. Any such standards are to be promulgated within 8 years after promulgation of MACT standards under CAA section 112(d). CAA section 112(d)(6) requires the EPA 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.

5. **Timetable**: Pursuant to a court order, the EPA is obligated to complete the Miscellaneous Organic chemical Manufacturing NESHAP (MON) final action by March 13, 2020. In consideration of this deadline, which also applies to 19 other RTR source categories, we established an internal schedule for this RTR to be proposed and finalized prior to the court order deadline. The EPA currently plans to complete the proposal by February 15, 2019, and final rule by March 11, 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.

The risk analysis methodologies associated with the RTR process have undergone scientific peer 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, EPA has, over the course of the program, conducted scientific peer reviews of the methodologies through the Science Advisory Board (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. As described above, the EPA also conducts a technology review to account for developments in practices, processes and control technologies.

With regard to the technology review, EPA intends to use the process outlined in the May 31, 2018, presentation to the full SAB. EPA does not anticipate the need to develop new scientific or technical information as part of this review.

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 of "an influential scientific or technical work product," each individual RTR analysis does not fit this definition.

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 final SAB advisory is available at: https://www3.epa.gov/ttn/atw/rrisk/risk_rep.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.

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.

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).

6) 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 #4 above). In May 2017, EPA submitted a report describing the updated risk screening methodologies to the SAB for review. In June 2017, the SAB expert panel met to discuss the new methodologies. In May 2018 the SAB completed the quality review of the Draft SAB report, "Review of EPA's Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis." The final SAB report was transmitted to the EPA on September 13, 2018.

SAB Work Group Recommendation on Planned Action

Name of planned action: Miscellaneous Organic Chemical Manufacturing and Miscellaneous Coating Manufacturing Residual Risk and Technology Reviews (RIN 2060-AT85)

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 planned 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, "Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis (May 2017)" was reviewed by the SAB 2017 and the SAB discussions and the report are available on the SAB website: https://yosemite.epa.gov/sab/sabproduct.nsf/0/2708C2DBC839301685258060005C87E8?OpenDocument

Rationale: This NESHAP established emission limitations and work practice requirements based on maximum achievable control technology (MACT) for controlling emissions of hazardous air pollutants (HAP) from continuous process vents, batch process vents, storage tanks, equipment leaks, wastewater streams, transfer racks and heat exchange systems. The HAPs emitted from these sources include, but are not limited to, toluene, methanol, xylene, hydrogen chloride and methylene chloride. For the technology review. EPA intends to use the process outlined in the May 31, 2018, presentation to the full SAB. EPA does not anticipate the need to develop new scientific or technical information as part of this review.

The Work Group finds that the RTR risk assessment screening methodology is broadly applicable to many source categories, 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 the EPA to continually assess and identify for SAB review any such technology recommendations that are based on new scientific knowledge.

EPA Description of Planned Action

1. **Name of action:** National Emission Standards for Hazardous Air Pollutants: Organic Liquids Distribution (Non-Gasoline) Residual Risk and Technology Review

2. **RIN Number:** 2060-AT86

3. **EPA Office originating action:** Office of Air and Radiation/Office of Air Quality Planning and Standards/Sector Policies and Programs Division

4. **Brief description of action and statement of need for the action:** This action will address the agency's residual risk and technology review (RTR) of the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Organic Liquids Distribution (Non-Gasoline). The Organic Liquids Distribution (Non-Gasoline) NESHAP, 40 CFR part 63, subpart EEEE, was promulgated pursuant to section 112(d) of the Clean Air Act (CAA) on February 3, 2004 (see 69 FR 5063). The NESHAP established emission limitations and work practice requirements based on maximum achievable control technology (MACT) for control emissions of hazardous air pollutants (HAP) from storage tanks, transfer racks and equipment leaks associated equipment. The most prevalent HAP emitted from these sources include, but are not limited to, benzene, ethylbenzene, toluene, vinyl chloride and xylenes.

   This action will implement the residual risk review requirements of CAA section 112(f)(2) and the technology review requirements of CAA section 112(d)(6). The statute directs the EPA to promulgate emission standards under CAA 112(f)(2) if such standards are required to provide an ample margin of safety to protect public health or to prevent, taking relevant factors into account, an adverse environmental effect. Any such standards are to be promulgated within 8 years after promulgation of MACT standards under CAA section 112(d). CAA section 112(d)(6) requires the EPA 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.

5. **Timetable:** Pursuant to a court order, the EPA is obligated to complete the final action by March 13, 2020. In consideration of this deadline, which also applies to 19 other RTR source categories, we established an internal schedule for this RTR to be proposed and finalized prior to the consent decree deadline.

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. 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 Science Advisory Board (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.
As described above, the EPA also conducts a technology review to account for developments in practices, processes and control technologies.

With regard to the technology review, EPA intends to use the process outlined in the May 31, 2018, presentation to the full SAB. EPA does not anticipate the need to develop new scientific or technical information as part of this review.

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 fit this definition.

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 final SAB advisory is available at: https://www3.epa.gov/ttn/atw/rrisk/risk_rep.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

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.

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).

6) The EPA is currently seeking the SAB's 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 #4 above). In May 2017, the EPA submitted a report describing the updated risk screening methodologies to the SAB for review. In June 2017, the SAB expert panel met to discuss the new methodologies. In May 2018 the SAB completed the quality review of the Draft SAB report, "Review of EPA's Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis." The final SAB report was transmitted to the EPA on September 13, 2018.

SAB Work Group Recommendation on the EPA Planned Action

Name of planned action: National Emission Standards for Hazardous Air Pollutants: Organic Liquids Distribution (Non-Gasoline) RTR (RIN 2060-AT86)

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 planned 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, "Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis (May 2017)" was reviewed by the SAB 2017 and the SAB discussions and the report are available on the SAB website: https://yosemite.epa.gov/sab/sabproduct.nsf/0/2708C2DBC839301685258060005C87E8?OpenDocument

Rationale: This NESHAP established emission limitations and work practice requirements based on maximum achievable control technology (MACT) for controlling emissions of hazardous air pollutants (HAP) from storage tanks, transfer racks and equipment leaks associated equipment. The most prevalent HAP emitted from these sources include, but are not limited to, benzene, ethylbenzene, toluene, vinyl chloride and xylenes. For the technology review, EPA intends to use the process outlined in the May 31, 2018, presentation to the chartered SAB. EPA does not anticipate the need to develop new scientific or technical information as part of this risk and technology review.

The Work Group finds that the RTR risk assessment screening methodology is broadly applicable to many source categories, 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 the EPA to continually assess and identify for SAB review any such technology recommendations that are based on new scientific knowledge.

EPA Description of Planned Action

1. **Name of action:** Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Project Emissions Accounting Proposed Rulemaking

2. **RIN Number:** 2060-AT89

3. **EPA Office originating action:** Office of Air and Radiation (OAR)/Office of Air Quality Planning and Standards/Air Quality Policy Division

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

   The NSR provisions of the Clean Air Act (CAA or Act) are a combination of air quality planning and air pollution control technology provisions that require stationary sources of air pollution to obtain a preconstruction permit prior to beginning the construction of a new major stationary source or a major modification of an existing major stationary source. Part C of title I of the CAA contains the requirements for the preconstruction review and permitting of new and modified major stationary sources of air pollution locating in areas meeting the National Ambient Air Quality Standards (NAAQS) (‘‘attainment’’ areas) and areas for which there is insufficient information to classify an area as either attainment or nonattainment (‘‘unclassifiable’’ areas). This program is known as the Prevention of Significant Deterioration (PSD) program. Part D of title I of the Act contains the requirements for the preconstruction review and permitting of new and modified major stationary sources of air pollution locating in areas not meeting the NAAQS (‘‘nonattainment’’ areas). This program is known as the Nonattainment New Source Review (NNSR) program.

   Under the current NSR regulations, a source owner determines if its source is undergoing a major modification using a two-step applicability test. The first step is to determine if there is a “significant emission increase” of a regulated NSR pollutant from the proposed modification (Step 1). If there is, the second step is to determine if there is a “significant net emission increase” (Step 2) of that pollutant. In March 2018, the Administrator issued guidance that clarified that our current regulations allow for consideration of emissions decreases in step 1 of the NSR applicability analysis (i.e. project emissions accounting or project netting). This rulemaking would codify the interpretations in the March 2018 guidance

   Timetable:

   To OMB: Fall, 2018
   Publication of NPRM: Winter, 2018

5. **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.

No scientific work products have been or will be developed to inform the decisions in this planned action because none are necessary to support this rulemaking.

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).

As stated previously, this EPA proposed rulemaking will only clarify the NSR regulations that EPA currently interprets to allow for emissions decreases and increases to be considered under Step 1 of the NSR applicability test for major modifications. No science or analysis, inter-agency collaboration, workshops or similar collaborations are necessary for the development of this action.

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?"

This action does not rely on work products involving science that meets the 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."

6(d). Peer review:

The EPA is not developing science products for this action. Therefore, no peer review is necessary.

Recommendation from the SAB Work Group

Name of planned action: Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Project Emission Accounting (RIN 2060-AT89)

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 planned action does not merit further review by the SAB.

Rationale: The SAB Work Group recognizes that this regulation is intended to codify the interpretations in the March 13, 2018 Memorandum from the Administrator and does not merit further scientific review by the SAB.

The Work Group notes that the scientific and technical review of NAAQS are reviewed by the Clean Air Scientific Advisory Council and this planned action is primarily administrative and an extension of existing initiatives. The SAB has considered previous planned actions regarding the

NNSR and PSD[2] and found that the action did not identify new science issues and does not merit further review.

[2] See the Fall 2012 Regulatory Review and Work Group memorandum page c-18

EPA Description of Planned Action

1. **Name of action:** Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Review

2. **RIN Number:** 2060-AT90

3. **EPA Office originating action:** Office of Air and Radiation/Office of Air Quality Planning and Standards/Sector Policies and Programs Division

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

   On June 3, 2016, the Environmental Protection Agency (EPA) published a final rule titled "Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources" (40 CFR Part 60 Subpart OOOOa). Following promulgation of the final rule, the Administrator received petitions for reconsideration of several provisions of the rule. The EPA is addressing those specific technical reconsideration issues in a separate proposal (RIN 2060-AT54). A number of states and industry associations sought judicial review of the rule, and the litigation is currently being held in abeyance. On March 28, 2017, newly elected President Donald Trump issued Executive Order 13783 titled "Promoting Energy Independence and Economic Growth," which directs agencies to review existing regulations that potentially burden the development of domestic energy resources, and appropriately suspend, revise or rescind regulations that unduly burden the development of U.S. energy resources beyond what is necessary to protect the public interest or otherwise comply with the law. In 2017, the EPA provided notice to initiate the policy review of the 2016 OOOOa rule and stated that, if appropriate, will initiate proceedings to suspend, revise or rescind the rule. Subsequently, in a notice dated June 5, 2017, the EPA further committed to look broadly at the entire 2016 OOOOa rule. The purpose of this action (RIN 2060-AT90) is to consider whether the 2016 rule OOOOa appropriately considered policy issues related to the challenges of regulating multiple pollutants across multiple segments of a complex industry.

   Information concerning the Oil and Natural Gas Sector is available at: https://www.epa.gov/controlling-air-pollution-oil-and-natural-gas-industry.
   Information concerning the Oil and Natural Gas 2016 Rule is available at: https://www.epa.gov/stationary-sources-air-pollution/crude-oil-and-natural-gas-facilities-which-construction.

5. **Timetable:** The 2018 Spring Regulatory Agenda publicly announced a proposed and final version of this regulation in 2018 and 2019, respectively. There are no judicial or more delineated time frames at this stage of the rulemaking.

Current Schedule:
NPRM - 12/2018
Final Rule - 05/2019

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 policy review of the 2016 OOOOa rule will be informed by the Reconsideration proposal (RIN 2060-AT54) for purposes of analyzing costs, benefits, and record keeping burden. The policy issue discussion in the Review will be informed by the following work products:

- Priorities for New Source Performance Standards Under the Clean Air Act Amendments of 1977. April 1978. EPA-450/3-78-019.
- U.S. Environmental Protection Agency. *Revised Prioritized List of Source Categories for NSPS Promulgation*. March 1979. EPA-450/3-79-023.
- Memorandum to Bruce Moore, U.S. EPA from Heather Brown, EC/R. "Composition of Natural Gas for use in the Oil and Natural Gas Sector Rulemaking". July 2011. Docket ID No. EPA-HQ-OAR-2010-0505-0084.
- "Standards of Performance for Crude Oil and Natural Gas Production, Transmission and Distribution," 77 FR 49490 (Aug. 16, 2012).

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 Reconsideration proposal (RIN 2060-AT54) will help inform this Review proposal's costs, benefits, and record keeping burden analysis.
    - Approach: This separate proposal is seeking public comment on specific issues.
    - Collaboration:
        - Formal Agency Review
        - currently undergoing OMB/interagency review
- No additional analysis was determined to be needed for the Review beyond cost, benefits, and record keeping burden. The additional work products listed in 6(a) inform discussion on policy issues such as whether the 2016 OOOOa rule appropriately considered issues related to the challenges of regulating multiple pollutants across multiple segments of a complex industry, not on technical issues such as available emission control technologies or their potential levels of effectiveness.

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?"

We do not envision this action relying on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product."

6(d). Peer review:

See related response in 6(a) above.

Recommendation from the SAB Work Group

Name of planned action: 2060-AT 90: Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Review (RIN 2060-AT-90)

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: Defer review of the planned action until sufficient information is available.

Rationale: This action will focus on the challenges of regulating multiple pollutants across multiple segments of a complex industry. One challenge pointed out by the EPA is that there are often multiple entities involved in the process of extraction and delivery of oil and natural gas. The agency needs to determine how best to integrate these entities in the law. Assuming this is done in such a way that all potential emission points are considered, this component of the action does seem likely to be a policy decision.

The second component of the proposed action is to evaluate the methods by which multiple pollutants are considered. The agency notes that many control actions reduce emissions of multiple pollutants. It appears that one of the goals is to somehow streamline the process such that fewer compounds are evaluated. While the Work Group agrees that there is a policy component to this, there is also an important science component. The methods for selecting proxy compounds to evaluate, or otherwise reducing the number of compounds tracked, must be done in consideration of the relative health impacts of the various compounds, as well as potentially accounting for exposures to mixtures of compounds with similar actions.

The Agency also notes there will be analysis involving costs and benefits. The determination of costs and benefits often involves the science linking emissions to health impacts. It is not clear if the same science will be used as in the original regulation, or if changes will be proposed. If changes are proposed, this would involve scientific evaluations.

We acknowledge that we do not have complete information in regard to the agency's plans, and therefore request that the Board continue to track this action to determine if it needs to be reviewed when more information becomes available. We note that the EPA schedule for the planned action listed the Notice of Proposed Rule Making for December 2018.

EPA Description for Recurring Action That May Not Merit SAB Consideration

Name of action: Proposed Renewable Fuel Volume Standards for 2019 and Biomass Based Diesel Volume (BBD) for 2020

RIN Number: 2060-AT93

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.[3] 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.

[3] 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 2019 annual RFS standards and 2020 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 2019) 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 2019, 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.

The SAB's decision on the earlier action (check the appropriate line)
__X__ The SAB did not select the earlier action for in-depth review
____ The SAB selected the earlier action for in-depth review.

Previously Reviewed Recurring Action

Name of action: Renewable Fuel Standard (RFS) Volume Standards for 2014

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

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

[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

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

SAB Work Group Recommendation on the Recurring Planned Action

Name of planned action: RIN 2060 – AT93 Renewable Fuel Volume Standards for 2019 and Biomass Based Diesel Volume (BBD) for 2020

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)? SAB did not select earlier action (RIN 2060-AR63) for review in 2013.		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 consideration for review by the SAB.

Rationale: Overall, Renewable Fuel Standards regulation is an activity covered under Section 211(o) of the CAA 2007, with the adoption of revisions in 2010 following amendments enacted as part of the 2007 Energy Independence and Security Act. Since 2007 EPA has promulgated annual rules to translate renewable fuel volumes into percentage standards reflecting the upcoming year's projection of gas and diesel demand. In 2014 for the first time the agency used

its waiver authority to set applicable volumes below statutory levels as a result of the projected unavailability of some types of fuels, as well as constraints on supply. In advance of the 2014 waiver, the SAB reviewed the action as part of the Spring 2013 Regulatory Agenda and concluded that it did not merit further consideration. The current action is considered a routine and recurring action relying on the same approach and data sources.

EPA Description of Planned Action

1. **Name of action:** Mercury and Air Toxics Standards for Power Plants Residual Risk and Technology Review and Cost Review
2. **RIN Number:** 2060-AT99
3. **EPA Office originating action:** Office of Air and Radiation/Office of Air Quality Planning and Standards/Sector Policies and Programs Division
4. **Brief description of action and statement of need for the action:**

Cost Review

Clean Air Act (CAA) section 112(n)(1) requires EPA to regulate electric utility steam generating units (EGUs) under CAA section 112 if the Administrator determines such regulation is "appropriate and necessary," after considering the results of a study of the hazards to public health, if any, resulting from emissions of hazardous air pollutants (HAP) from EGUs that would reasonably be anticipated to occur following implementation of the requirements of the CAA.

- On December 20, 2000, EPA issued a determination that it was appropriate and necessary (A&N Finding) to regulate coal- and oil-fired EGUs under CAA section 112 and added those EGUs to the list of source categories that must be regulated under CAA section 112(d).
- In 2012, EPA reaffirmed the 2000 A&N Finding when it promulgated National Emission Standards for Hazardous Air Pollutants (NESHAP) for Coal- and Oil-fired EGUs under CAA section 112. Those standards are commonly referred to as the Mercury and Air Toxics Standards (MATS).
- In 2015, the Supreme Court ruled in *Michigan v. EPA* that EPA was required to consider the cost of regulation in making the A&N Finding.
- In 2016, EPA finalized a Supplemental Cost Finding concluding that its consideration of cost did not change the A&N Finding. Petitions for review of the 2016 action were filed, and in an April 2017 court filing, EPA asked the Court to hold the case in abeyance while the current administration reviewed the Finding.

EPA is conducting its initial review of the MATS Supplemental Cost Finding (81 FR 24420, April 25, 2016) to determine if the finding will be reconsidered. EPA will issue the results of the review in a notice of proposed rulemaking and will solicit comment on the resulting finding.

Residual Risk and Technology Review

The CAA establishes a two-stage regulatory process for addressing emissions of HAP from stationary sources. In the first stage, the CAA requires 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 8 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 the MACT standards. If additional risk reductions are necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects, EPA must develop standards to address these remaining risks. For each source category for which EPA issued MACT standards, the residual risk stage must be completed within 8 years of promulgation of the initial MACT standard. Since the initial technology review requirement deadline coincides with the risk review requirement deadline, EPA generally combines these two requirements into one rulemaking activity, calling this the "risk and technology review" process, or simply RTR. In this way, results of the risk review can be potentially informative to the technology review process, and vice versa.

For the first stage, the EPA issued national emission standards to control hazardous air pollutants (NESHAP) from coal- and oil-fired EGUs (*i.e.*, the MATS rule) on February 16, 2012 (67 FR 9464).

For this action, as the second stage of the regulatory process, and as we have done for more than 50 source categories to date, we plan to conduct the residual risk review and initial technology review concurrently.
Information concerning MATS is available at: https://www.epa.gov/mats.

5. Timetable:

EPA's tentative schedule was to issue the proposed action in December 2018 and to issue the final action, after consideration of public comments, in 2019.

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.

No new scientific work products will be developed to inform decisions for the planned action. The RTR process will utilize existing risk analysis methodologies that have undergone scientific peer review and have been used in numerous other RTRs in a variety of industrial sectors.

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).

Review of the MATS Supplemental Cost Finding will not involve scientific work products.

The review of the Supplemental Cost Finding will not involve review of any of the key underlying technology or scientific questions related to cost of control of HAP emissions

(*e.g.*, cost and performance of different control options). Rather, the review will focus on policy questions related to how cost should be considered.

For the residual risk portion of the analysis, EPA will be using the same risk analysis methodologies and tools that have been used historically for other RTRs and that have already been reviewed by the Science Advisory Board (SAB). By conducting peer review of the methodologies and tools used for the RTR program as a whole, rather than for each individual RTR rulemaking effort, the agency is able to conduct consistent risk characterizations across all categories of industrial sources.

With regard to the technology review, EPA intends to use the process outlined in the May 31, 2018, presentation to the full SAB. In promulgating the MATS rule, EPA considered the cost and effectiveness of a wide variety of emission controls that address HAP emissions from coal- and oil-fired power plants. This included state-of-the-art particulate matter control devices (such as baghouses and electrostatic precipitators), mercury-specific control devices (such as activated carbon injection systems), and devices that control acid gases (such as scrubbers and dry sorbent injection), as well as the interaction of control devices (such as the interaction between scrubbers and selective catalytic reduction systems related to mercury control). EPA does not anticipate the need to develop new scientific or technical information as part of this review.

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?"

Review of the MATS Supplemental Cost Finding will not 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."

While the risk assessment methods for the overall RTR program do meet the definition as "an influential scientific or technical work product," those methods, as applied to each individual RTR analysis, do not fit this definition.

6(d). Peer review:

Because review of the MATS Supplemental Cost Finding will not rely on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product," peer review will not be required.

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 final SAB advisory is available at: https://www3.epa.gov/ttn/atw/rrisk/risk_rep.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.

(3) A consultation on the EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by SAB in December 2006. The 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.

(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 the 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).

(6) A review of specific enhancements made to the RTR risk assessment methodologies, particularly with respect to screening methodologies, since the 2009 SAB review (see #4 above) was completed in 2018. The final SAB advisory is available at: https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentBOARD/7A84AADF3F2FE04A85258307005F7D70/$File/EPA-SAB-18-003+.pdf.

SAB Work Group Recommendation on the EPA Planned Action

Name of planned action: Mercury and Air Toxics Standards for Power Plants Residual Risk and Technology Review and Cost Review (RIN 2060-AT99)

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 merits review by the SAB.

Rationale: The SAB should consider this action for review, following publication of the proposed rule itself.

This planned action is in response to a Supreme Court decision regarding the Mercury and Air Toxics Standards (MATS). In its ruling, the Court found that EPA did not consider cost in its "appropriate and necessary" finding supporting the MATS. In this planned action, EPA is considering whether cost of MATS compliance is reasonable when weighed against the health

benefits of the rule. There are no new scientific work products associated with this action. The proposal relies on existing information in the MATS rulemaking administrative record. For example, and perhaps most notably, the action relies on the existing Regulatory Impact Analysis.

Although this proposed new rule was not published at the time of review, it has already attracted considerable media attention.

The proposed action has different aspects that relate to science, policy and the law. In particular, it appears that the final disposition of the rule will depend at least in part on a court decision on the so-called co-benefits rule (i.e., that EPA includes in its cost assessment benefits due to reductions in particular matter and nitrogen dioxide as well as mercury). While the policy and legal aspects are not within the purview of SAB, SAB should provide scientific advice on the cost estimates under a variety of scenarios that both include and exclude the co-benefits. It would be of interest to know exactly how EPA determines what is a direct benefit and what is a co-benefit, and how it handles different types of human health outcomes (e.g. how to calculate the relative costs of missed work days, hospitalizations, and deaths).

A major part of the proposed action is a Residual Risk and Technology Review (RTR). It is stated that "no new scientific work products will be developed…", essentially because the methodology has been previously developed and undergone peer review. However, there is a distinction between the methodology used to conduct a review and the results of that review. SAB should review whether the methodology has been correctly applied in this case.

Regarding the MATS Supplemental Cost Finding, it is stated that this "will not involve scientific work products" and in further responses by the SAB Staff Office, "EPA's review … is not based on new scientific data". These statements only reinforce the need for SAB to provide advice.

It is unclear whether "peer review" (under 6(d)) refers to the work of the SAB, but we believe such peer review should be undertaken by SAB unless there are plans for this to be accomplished by another body. EPA can credibly claim to have assessed the risks and costs of the new rule only if there is a rigorous and robust peer review provided.

[Note to members: The EPA previously considered Considering Cost in the Appropriate and Necessary Finding for the Mercury and Air Toxics Standards (MATS) (RIN 2060-AS76)[6]. The agency re-evaluated the MATS in response to a US Supreme Court decision. The agency sought public comment but did not develop any new scientific data for the action. The Work Group noted the action was supported by a SAB peer review of the Mercury Risk Assessment and the NESHAP was included in the SAB review of the Fall 2015 Regulatory Agenda. Based on the review of the Mercury Risk Assessment and the RTR Risk assessment methodologies as technical support for the, SAB agreed with the Work Group and found the action did not merit further SAB consideration. See page B22-24.]

[6] Preparations for Chartered Science Advisory Board (SAB) Discussions of EPA Planned Agency Actions and their Supporting Science in the Fall 2015 Regulatory Agenda. See page B-22.
https://yosemite.epa.gov/sab/sabproduct.nsf/B55A4C6443C3838F85257F70006BA725/$File/SABWkGrpRecsFall2015RegAgenda.pdf

EPA Description of Planned Action

1. **Name of action:** The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021–2026 Passenger Cars and Light Trucks

2. **RIN Number:** 2060-AU09

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:**

   The National Highway Traffic Safety Administration (NHTSA) and the Environmental Protection Agency (EPA) propose to amend certain existing Corporate Average Fuel Economy (CAFE) and tailpipe carbon dioxide emissions standards for passenger cars and light trucks and establish new standards, all covering model years 2021 through 2026. More specifically, EPA is proposing to amend its carbon dioxide emissions standards for model years 2021 through 2026 because they are no longer appropriate and reasonable, and NHTSA is proposing new CAFE standards for model years 2022 through 2026 and amending its 2021 model year CAFE standards because they are no longer maximum feasible standards.

   The agencies must act to propose and finalize these standards and do not have discretion to decline to regulate. Congress requires NHTSA to set CAFE standards for each model year. Congress also requires EPA to set emissions standards for light-duty vehicles if EPA has made an "endangerment finding" that the pollutant in question – in this case, CO_2 – "cause[s] or contribute[s] to air pollution which may reasonably be anticipated to endanger public health or welfare." NHTSA and EPA are proposing these standards concurrently because tailpipe CO_2 emissions standards are directly and inherently related to fuel economy standards, and if finalized, these rules would apply concurrently to the same fleet of vehicles.

   The agencies' proposed preferred alternative is to retain the model year 2020 standards (specifically, the footprint target curves for passenger cars and light trucks) for both programs through model year 2026, but comment is sought on a range of alternatives. EPA also is proposing to withdraw the January 9, 2013 waiver of CAA preemption for California's Advanced Clean Car (ACC) program, Zero Emissions Vehicle (ZEV) mandate, and Greenhouse Gas (GHG) standards that are applicable to model years 2021 through 2025.

   In this proposal, EPA is relying on the technical analysis performed by NHTSA which is the basis of the joint proposed standards for both CAFE and light-duty GHG standards.

5. Timetable:

NPRM date issued: The NPRM was issued on August 2, 2018, and published in the Federal Register on August 24, 2018 [83 FR 42896]

Comment period: The comment period closed on October 23, 2018. The agencies held three public hearings on September 24, 25, and 26, in Fresno, CA, Dearborn, MI, and Pittsburgh, PA, respectively.

Final rulemaking: The agencies' goal is to issue a proposal this coming winter.

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 proposal's analysis uses the NHTSA CAFE model to estimate manufacturers' potential responses to new CAFE and CO_2 standards and to estimate various impacts of those responses. For the NPRM, the agencies are relying for the first time on two additional models newly developed by DOT/NHTSA, including a vehicle scrappage model and dynamic fleet share model. DOT is responsible for the peer review of these products.

Some other key modeling approaches and inputs to the modeling include estimates of technology cost and effectiveness, vehicle simulation results using the Argonne National Laboratory (ANL) Autonomie model (discussed further below), electric vehicle battery costs information derived from the ANL BatPac model, vehicle registration data from Polk used to assess vehicle miles traveled, and an assessment of safety attribute to vehicle mass reduction, fleet turnover, and other factors.

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).

DOT's Volpe National Transportation Systems Center (Volpe Center) develops, maintains, and applies the model for NHTSA. NHTSA has used the CAFE model to perform analyses supporting every CAFE rulemaking since 2001, and the 2016 rulemaking regarding heavy-duty pickup and van fuel consumption and GHG emissions also used the CAFE model for analysis.

This analysis also uses four DOE and DOE-sponsored models to develop inputs to the CAFE model, including three developed and maintained by DOE's Argonne National Laboratory. The analysis uses the DOE Energy Information Administration's (EIA's) National Energy Modeling System (NEMS) to estimate fuel prices, and used Argonne's Greenhouse gases, Regulated Emissions, and Energy use in Transportation (GREET) model to estimate emissions rates from fuel production and distribution processes. DOT also sponsored DOE/Argonne to use their Autonomie full vehicle simulation system to

estimate the fuel economy impacts for roughly a million combinations of technologies and vehicle types.

Comments were requested on, among other things, whether EPA should use alternative methodologies and modeling, including DOE/Argonne's Autonomie full vehicle simulation tool and DOT's CAFE model. Having reviewed comments on the subject and having considered the matter fully, the agencies have determined it is reasonable and appropriate to use DOE/Argonne's model for full vehicle simulation, to use DOT's CAFE model for analysis of regulatory alternatives.

Using the CAFE model allows consideration of the following factors: the CAFE model explicitly evaluates the cost of compliance for each manufacturer, each fleet, and each model year; it accounts for lead time necessary for compliance by directly incorporating estimated manufacturer production cycles for every vehicle in the fleet, ensuring that the analysis does not assume vehicles can be redesigned to incorporate more technology without regard to lead time considerations; it provides information on safety effects associated with different levels of standards and information about many other impacts on consumers, and it calculates energy impacts (i.e., fuel saved or consumed) as a primary function, besides being capable of providing information about many other factors within EPA's broad CAA discretion to consider.

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?"
DOT and NHTSA are also subject to guidance on the conduct of peer reviews on influential scientific and technical work products as issued by the Office of Management and Budget (OMB) through its Final Information Quality Bulletin on Peer Review (70 FR 2664). Further information can be found at:

https://www.transportation.gov/peerreview

6(d). Peer review:
Information on NHTSA's peer review of the CAFE model can be found at

https://www.nhtsa.gov/corporate-average-fuel-economy/compliance-and-effects-modeling-system

https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/812590-cafe-peer-review.pdf

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SAB Work Group Recommendation on EPA Planned Action

Name of planned action: The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021-2026 Passenger and Light Trucks. RIN Number 2060-AU09.

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 warrant further review provided the EPA and CARB agree on a rule harmonized across the US. If, however, the EPA and CARB cannot agree on a harmonized rule, then the SAB is ready to review pertinent scientific data in the different rules.

Rationale: The Work Group conducted a non-public fact-finding meeting with EPA staff. A summary of the discussions and the EPA's responses to the Work Group's questions are provided in Attachment C of this memorandum.

In this proposal, the EPA is relying on the technical analysis performed by NHTSA which is the basis of the joint proposed standards for both CAFÉ and light-duty truck GHG standards. EPA developed extensive data, models and reports leading up to the Mid Term Evaluation, including a comprehensive Technical Assessment Report. Regardless of whether EPA relies on its own staff and analysis, or references another agency, EPA has an obligation to base its own rulemaking on appropriately reviewed scientific and technical work products. EPA should, however, reconcile differences in assumptions and methods in the proposal between the EPA and the other agencies..

EPA reports that NHTSA's analysis is predicated on the following models:

1. NHTSA CAFE model to estimate manufacturers' potential responses to new CAFÉ and CO2 standards. This model is developed, maintained and applied by the DOT Volpe National Transportation Systems Center (Volpe Center). The CAFÉ model appears to have been subject to a review, but rationalization of the assumptions between the EPA models and the Volpe model has not been completed.
2. Vehicle scrappage model. More information is needed regarding the review of this model with respect to this rule making.
3. Dynamic fleet share model. More information is needed regarding the review of this model with respect to this rule making.
4. Four DOE and DOE-sponsored models, including three developed by Argonne National Laboratory (including GREET Autonomie and unspecified) and one from the Energy Information Agency (National Energy Modeling System) are being used. More information is needed regarding the review of these models with respect to their application for this rule making.
5. EPA does not describe any peer review of the input data and assumptions or results of their analysis. More information is needed in this regard.

California has an EPA waiver issued under the Clean Air Act to develop its own vehicle emissions regulations. One of the key goals of the 2017-2025 standards was to harmonize the federal standard and the California GHG standard into a Joint National Program. However, state zero emission vehicle standards were not harmonized with the EPA and NHTSA standards. California completed its own MTE and found that the California standards were appropriate. Other states on the West Coast and in the Northeast regions of the US have chosen to adopt the California standards. If the EPA grants California a waiver for separate standards, the US will have disparate standards in different parts of the country, thereby creating compliance complications for automakers. Even if EPA and CARB agree on a new harmonized rule, SAB review may be appropriate if the harmonized rule is re-proposed with a new or revised technical rationale."

Chronology and Description of Planned Action

1. **Name of action:** Strengthening Transparency in Regulatory Science
2. **RIN Number:** 2080-AA14
3. **EPA Office originating action:** Office of Air and Radiation/Office of Air Quality Planning and Standards/Sector Policies and Programs Division
4. **Brief description of action status:**

The Chartered SAB discussed and identified this action (Strengthening Transparency in Regulatory Science 2080-AA14) as one the SAB wishes to provided comment and advice at its May 31, 2018 meeting. The SAB sent a letter to Administrator Pruitt informing him of the Board's desire to review the proposed rule. The letter is available here.

Background: EPA's usual process 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, augmented to include proposed regulations, criteria documents, standards, or limitations that are expected to undergo interagency review. The EPA's descriptions provide available information regarding the science that is informing these agency actions.

SAB members and the SAB Staff Office were made aware of a proposed rule entitled *Strengthening Transparency in Regulatory Science* (RIN 2080-AA14) through an April 25, 2018, press event and an April 30, 2018, *Federal Register* notice, as well as news articles. The EPA announced the proposed rulemaking with a 30-day public comment period. SAB members had no information regarding the timeline for finalizing the rule and the proposed rule was not identified as a major action in either of the Spring 2017 or Fall 2017 semi-annual Regulatory Agendas.

An SAB Work Group met by teleconference on May 3, 2018, to discuss its recommendations on major planned actions in the Fall 2017 semi-annual regulatory agenda and included the proposed rule *Strengthening Transparency in Regulatory Science (RIN 2080-AA14*) as part of the discussion. That Work Group provided the SAB with a memorandum documenting the discussion and recommending that the proposed rule merits review by the SAB. Subsequently the SAB became aware that the proposed rule was included in the Spring 2018 semi-annual Regulatory Agenda published on May 9, 2018. A second *Federal Register* notice was published May 25, 2018 extending the public comment period to August 16, 2018 and announcing a public hearing to be held in Washington, DC on July 17, 2018. The agenda did not list a timetable for the final action.

EPA Description of Planned Action

1. **Name of action:** Peak Flows Management – formerly called Updates to Wet Weather Treatment Regulations for POTWs
2. **RIN Number:** 2040-AF81
3. **EPA Office originating action:** Office of Water, Office of Wastewater Management
4. **Brief description of action and statement of need for the action:** Wet weather events (e.g., rain, snowmelt) can impact publicly owned treatment works (POTWs) operations when excess water enters the wastewater collection system. The increased wet weather flows in the collection system can exceed the POTW treatment plant's capacity to provide the same type of treatment for all of the incoming wastewater. The treatment plant's secondary treatment units are the most likely to be adversely affected by wet weather because the biological systems can be damaged when too much water flows through them. POTWs employ a variety of operational practices to ensure the integrity of their secondary treatment units during wet weather, and this update to the regulations will clarify permitting procedures for POTW treatment plants with separate storm sewer systems under wet weather operational conditions. These updates will ensure a consistent national approach for permitting POTWs that provides for efficient treatment plant operation while protecting the public from potential adverse health effects of inadequately treated sewage.
5. **Timetable:** Public listening sessions and request for comment: Late Summer/Fall 2018; NPRM: July 2019; final rule: July 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.

   The EPA is early in the process of developing a proposal and has not yet determined the specific scientific products needed or the nature of the peer review intended. The EPA will review information on existing POTW practices to ensure the integrity of their secondary treatment units during wet weather conditions. The EPA will review literature and hold listening sessions with stakeholders and tribes.

   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 EPA is early in the process of developing a proposal and has not yet determined the specific scientific products needed or the nature of the peer review intended.

   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 is early in the process of developing a proposal and has not yet determined the specific scientific products needed or the nature of the peer review intended.

6(d). Peer review:

The EPA is early in the process of developing a proposal and has not yet determined the specific scientific products needed or the nature of the peer review intended.

Recommendation from the SAB Work Group

Name of planned action: Peak Flow Management – formerly called Updates to Wet Weather Treatment Regulations for POTWs (RIN 2040-AF81)

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: Defer SAB review of the action until sufficient information is available.

Rationale: The Work Group conducted a non-public fact-finding meeting with EPA staff. A summary of the discussions and the EPA's responses to the Work Group's questions are provided in Attachment C of this memorandum.

The SAB Work Group recognizes that this regulation concerns the long-standing issue of regulatory management of wet weather flows at Publicly Owned Treatment Works (POTWs). These wet weather events have the potential to physically damage the facilities and/or "wash-out" the biological systems thereby impacting future operations. The development of the regulation is in its early stages as the agency has just completed stakeholder group meetings and gathering additional information. The SAB Work Group finds that this regulation, by necessity, will include process engineering and public health considerations and merits further consideration when additional information is available.

EPA Description of Planned Action

1. **Name of action:** Clean Water Act Section 404 Assumption Update Regulation
2. **RIN Number:** 2040-AF83
3. **EPA Office originating action:** Office of Water, Office of Wetlands, Oceans, and Watersheds
4. **Brief description of action and statement of need for the action:**

Section 404(g) of the Clean Water Act (CWA) authorizes states [and tribes] to assume the CWA Section 404 permit program for discharges of dredged or fill material into certain waters. 33 U.S.C. 1344(g). Prior to assuming this permitting responsibility, a state or tribal program must be approved by the EPA, and be consistent with and no less stringent than requirements of the CWA and its implementing regulations. The statute and the regulations lay out the minimum requirements for assumption, the assumption process, and requirements for administration of a state/tribal CWA 404(g) program including EPA oversight. A state or tribe would be eligible to assume the program, once a state or tribe demonstrates that they meet the statutory and regulatory requirements, at 33 U.S.C. §§ 1344(h) and 40 CFR Part 233, by submitting a request for EPA approval to assume the program that includes a program description, documents and other information specified in the statute and regulations.

The Clean Water Act Section 404 Assumption Update Regulation is intended to provide general updates to the 1988 CWA section 404(g) assumption regulations and provide clarity on specific issue(s) requested by the states and tribes. Specifically, the rule would clarify and discern the extent of waters assumed by states/tribes under CWA section 404 permit responsibilities, and the extent of waters to be retained by the USACE under an approved state/tribal program. (2014 letter from state associations)

In 2015, EPA convened the Assumable Waters Subcommittee under the National Advisory Council for Environmental Policy and Technology (NACEPT), a standing federal advisory committee which addresses environmental policy, technology and management issues. Comprised of state, tribal, federal, environmental, academic and industry representatives, this twenty-two-member subcommittee was charged with providing recommendations as to how EPA could provide clarity with respect to the extent of assumable waters. NACEPT submitted their recommendations to the EPA Administrator on June 1, 2017. (NACEPT Report and Recommendations)

This rule is intended to provide clarity with respect to the extent of assumable waters following EPA's consideration of the FACA recommendations and to provide technical corrections and updates to the 1988 CWA section 404(g) assumption regulations in 40 CFR 233.

- This action fits with other agency actions to increase cooperative federalism and to assist state and tribal efforts to assume the CWA section 404 permitting program. It will

provide requested clarity and necessary updates including consideration of NACEPT's recommendations.

- This action does not affect other agency or agencies actions.

Links to key background documents in the public domain in addition to the links above, here are some additional background documents:

- ICR for the existing regulations – these will be updated for this rulemaking
- National Advisory Council for Environmental Policy and Technology (NACEPT) – see their recommendation here June 1, 2017.

5. **Timetable:**

    - September 2019 – Propose rule
    - September 2020 – 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.
    There are no scientific questions identified as needing to be addressed in advance of or as part of the proposed rule 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).
    There are no scientific questions identified as needing to be addressed in advance of or as part of the proposed rule at this time.

    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?"
    There are no scientific questions identified as needing to be addressed in advance of or as part of the proposed rule at this time.

    6(d). Peer review:
    There are no plans for peer review or scientific analysis beyond the normal economic impact analyses.

Recommendation from the SAB Work Group

Name of planned action: Clean Water Act Section 404 Assumption Update Regulation (RIN 2040-AF83)

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 action does not merit further review by the SAB.

Rationale: The SAB Work Group recognizes that this regulation is largely procedural and administrative as the 404/401 program is well established and does not merit review by the SAB.

EPA Description of Planned Action

1. **Name of action:** Treatment of Biogenic CO_2 Emissions Under the Clean Air Act Permitting Programs

2. **RIN Number:** 2060-AU03

3. **EPA Office originating action:** Office of Air and Radiation (OAR)/Office of Air Quality Planning and Standards/Air Quality Policy Division

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

   Biogenic CO_2 emissions are the CO_2 emissions related to the natural carbon cycle, as well as those from the production, harvest, combustion, digestion, fermentation, decomposition, or processing of biologically based materials ('biomass feedstocks') other than fossil fuels, peat, and mineral sources of carbon. Both the 2009 and 2016 Endangerment Findings include CO_2 within the definition of the air pollution that is reasonably anticipated to endanger public health and welfare and therefore, all CO_2 emissions are currently included in EPA's GHG regulations.

   In April 2018, the EPA issued a policy statement announcing, among other things, that EPA's policy in forthcoming regulatory actions and in various programmatic contexts will be to treat biogenic CO_2 emissions resulting from the combustion of biomass from managed forests at stationary sources for energy production as carbon neutral. This proposed rulemaking is expected to clarify how biogenic CO_2 emissions from the combustion of biomass from managed forests at stationary sources should be treated for purposes of New Source Review preconstruction permitting (specifically the Prevention of Significant Deterioration (PSD) part of the program) and title V permitting.

   The PSD provisions of the Clean Air Act (CAA) are a combination of air quality planning and air pollution control technology provisions that require stationary sources of air pollution to obtain a preconstruction permit prior to beginning the construction of a new major stationary source or a major modification of an existing major stationary source at an area attaining the National Ambient Air Quality Standards (NAAQS). Furthermore, the CAA title V permitting program requirements improve compliance with the CAA by combining all the CAA requirements a stationary source is subject to into a single permit.

   For purposes of the PSD permitting program, any facilities that use biomass feedstocks for combustion, digestion, fermentation or decomposition processes that result in CO_2 emissions could potentially be subject to Best Available Control Technology (BACT) requirements under the PSD preconstruction permitting program if the facility is subject to permitting for another regulated pollutant first. For title V purposes, a source will not be newly subject to title V permitting for its biogenic CO_2 emissions, but permitting

requirements with conditions related to biogenic CO_2 emissions could be incorporated into any title V permit if applicable.

5. Timetable:

To OMB: Fall, 2019
Publication of NPRM: Winter, 2020

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

The EPA is early in the process of developing a proposal and currently does not have information to respond to this question. The EPA is considering information related to the April 2018 Policy Statement.

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

To be determined. See previous response.

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).

To be determined.

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

Name of planned action: Treatment of Biogenic CO2 Emissions Under the Clean Air Act Permitting Program. 2060-AU03.

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 planned action does not merit further review by the SAB.

Rationale: The proposed action relies on a policy position and does not involve any new science in this action. The *EPA's Treatment of Biogenic Carbon Dioxide (CO2) Emissions from Stationary Sources that Use Forest Biomass for Energy Production* was issued on April 23, 2018. The Work Group notes that the policy statement acknowledges the scientific complexity of the topic, the SAB's on-going work on biogenic carbon emissions and states that the "policy is not a scientific determination and does not revise or amend any scientific determinations that EPA has previously made."

The Work Group received written responses from the EPA program office and they are summarized in Attachment C of this memorandum.

EPA Description of Planned Action

1. **Name of action:** General National Ambient Air Quality Standards Implementation Update Rule

2. **RIN Number:** 2060-AU10

3. **EPA Office originating action:** Office of Air and Radiation (OAR)/Office of Air Quality Planning and Standards/Air Quality Policy Division

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

   This is a placeholder for one or more potential proposed rulemakings to address NAAQS implementation-related policies determined by the Administrator as necessary to fully realize the benefits of strategies to streamline and reduce burden, and in response to adverse court decisions. This may include proposals for regulatory or policy changes related to implementation of the ozone and SO_2 NAAQS, and PSD permitting.

   Timetable:

   To be determined

5. **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.
   Not yet identified.

   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).

   To be determined.

   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?"

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

Recommendation from the SAB Work Group

Name of planned action: General National Ambient Air Quality Standards Implementation Update Rule (RIN 2060-AU10)

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 planned action does not merit further review

Rationale: The EPA describes this action as a placeholder for one or more potential proposed rulemakings to address NAAQS implementation-related policies determined by the Administrator as necessary to fully realize the benefits of strategies to streamline and reduce regulatory burden, and in response to adverse court decisions."
The EPA has not determined whether the planned action 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.

The Work Group notes that planned actions in this agenda and previous agendas addressed implementation of the NAAQS. In this regulatory agenda the Work Group found that a similar action, "Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Project Emissions Accounting Proposed Rulemaking (RIN 2060-AT89), did not merit further review by the SAB. See page B-9 of this document.

Other planned actions that address the implementation of the NAAQS are listed in the following table.

Table 1. Planned Actions in Previous Agendas Addressing NAAQS Implementation

RIN	Planned Action Title	Workgroup recommendation	SAB Disposition	Review Cycle
2060-AR34	Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements	No further SAB consideration is merited.	SAB Agreed	Fall 2012
2060-AR19	Data Requirements for Determining Attainment for the 1-Hour SO2 NAAQS.	No further SAB consideration is merited.	SAB Agreed	Fall 2012
2060-AQ47	Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Reconsideration of Inclusion of Fugitive Emissions; Reconsideration	No further SAB consideration is merited.	SAB Agreed	Fall 2012
2060-AR28	PSD for Particulate Matter Less Than 2.5 Micrometers (PM2.5)—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration: Reconsideration	No further SAB consideration merited.	SAB Agreed	Spring 2013
2060-AS05	Interstate Transport Rule for the 2008 Ozone NAAQS	No further SAB consideration is merited.	SAB Agreed	Spring 2015
2060-AS05	Interstate Transport Rule for the 2008 Ozone NAAQS	No further SAB consideration is merited.	SAB Agreed	Spring 2015
2060-AS82	Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area Classifications and State Implementation Plan Requirements	No further SAB consideration is merited.	SAB Agreed	Spring 2016

Attachment C

Summary of the Science Advisory Board Work Group Fact-Finding on EPA Planned Actions in the Spring 2018 Regulatory Agenda

October 31, 2018

The Science Advisory Board Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science held a fact-finding teleconference on October 31, 2018. EPA offices were provided questions to clarify and seek additional information on the planned actions in the Spring 2018 Regulatory agenda published on September 17, 2018. This attachment summarizes the Work Group's findings.

The Work Group submitted questions to the EPA Office of Water and the Office of Air and Radiation. The questions and responses are provided below. EPA attendees were:

John Shoaff,
Leif Hockstad
Sandy Evalenko
Caryn Muellerleile
Christine Ruf
Katherine Stebe
Tomeka Nelson
Lisa Biddle
Christopher Kloss
Kathy Hurld
Mindy Eisenberg
Michael Mcdavit
Jamie Piziali
Mike Koerber
Kevin Culligan
Benjamin Hengst
Julia Burch
Kathryn Sargeant
William Charmley
Gonzalez, Gail
Robin Moran
Michael Olechiw
Macara Lousberg
David Cozzie
Lisa Biddle
Chris Clark

Members of the SAB Work Group

Dr. Rodney Andrews
Dr. Deborah Bennett
Dr. Bob Blanz
Dr. Todd Brewer
Dr. Joel Burken
Dr. Alison Cullen (chair)
Dr. John Graham
Dr. Merlin Lindstrom
Mr. Richard Poirot
Dr. Richard Smith

Thomas Carpenter, DFO, SAB Staff Office

Questions for the Office of Water

Peak flow Management 2040-AF81

The following questions were asked by SAB members Drs. Todd Brewer and Bob Blanz. EPA staff (Lisa Biddle and Chris Clark) provided verbal responses. Written responses to the SAB questions had not been provided by EPA.

Question: How will the "consistent national approach" that provides for efficient treatment plant operations" deal with the variety of engineering processes employed at POTWs across the nation?

> *EPA Response: EPA staff indicated that the Agency had completed some stakeholder input sessions. The agency had taken six months to do outreach. Three listening sessions had been held as well as roundtables. EPA staff indicated that it was still early in the rulemaking process and the agency had not yet had a chance to flesh out stakeholder input to develop answers to the SAB question.*

Question: Since wet weather flows are usually dilute, it is often difficult, if not impossible to achieve the 85% removal of BOD5 and TSS required by the current regulations during these periods. What scientific information will EPA use to establish minimum alternative removal requirements (e.g., on duration and frequency)?

- Many small POTWs do not have timely sampling or responsiveness for stormwater events.
- What are the time frames on the averages of influent and removals?

> *EPA Response: agency staff stated that they had asked states and permittees for information on what they were seeing and how permits would be handled.*

Dr. Blanz noted that EPA had held listening sessions and he asked what kind of feedback had been received about removal efficiency.

> *EPA Response: EPA staff responded that they were still waiting to receive written comments.*

Dr. Brewer asked EPA staff whether the Agency had information about timeframe averages for influent and removal.

> *EPA Response: staff responded that they had not developed anything formal about the path forward for management of wet weather events.*

Question: How will the "potential health effects of inadequately treated sewage be quantified and compared to alternative treatment and/or operational scenarios?
- What are the specific health drivers?
- Relative to noted health concerns that are not yet quantified?
- Are health effects primary (direct) or secondary (indirect), such as harmful algal blooms that may have other drivers as well. If secondary, have health issues been apportioned?

EPA Response: agency staff stated that the engineering analysis and cost analysis must be evaluated in order to answer the SAB questions. EPA staff noted that this information had been requested from states and utilities. They indicated that the Agency was waiting to receive it.

Dr. Cullen asked what the timeframes were for receipt of this information.

EPA Response: EPA staff responded that the comment period would close soon and they expected to have a full accounting of information in the docket. EPA staff indicated that the comments being received were for the pre-proposal. Staff indicated that there would be another comment period when the rule was proposed. The proposed rule was expected to be released in the summer.

SAB members noted that they had asked some questions about specific health drivers and asked whether EPA had additional information about specific health drivers.

EPA Response: EPA staff responded that they did not have anything specific to add.

<u>Clean Water Act Section 404 2040-AF83</u>

SAB members on the call noted that they had received a written response to the following question from the Office of Water but needed some additional information on specific points.

SAB recognizes that this regulation is likely to be largely procedural and administrative in nature as the 404/401 program is well established. The EPA brief description indicates that the "rule would clarify and discern" the extent of waters assumed by states/tribes. Will the regulation be promulgated in conjunction with the USACE, and if so, or if not, what are the scientific principles that are being applied for identification of assumable retained waters?

EPA Response: No, this will not be a joint rule with the USASCE. These regulations are EPA regulations; however, we will coordinate with the USACE about the draft prior to interagency review and during review.

We will be clarifying Clean Water Act Section 404(g)(1) and will propose to establish an administrative line regarding who the permitting authority will be. The agency does not anticipate applying scientific principles to the identification of assumable/retained waters.

Dr. Blanz indicated he appreciated the written responses that had been provided and asked how EPA intended to establish administrative boundaries for permitting jurisdiction.

EPA Response: Kathy Hurld from the Office of Water responded. She indicated that an advisory committee had been convened and provided recommendations on what the administrative boundaries should be. It was recommended that the EPA take an approach similar to the one used by the State of New Jersey. Under this approach, an administrative boundary was drawn to identify wetlands and adjacent wetlands within 1000 feet of a water for which the Corps of Engineers retains permitting jurisdiction. She noted that any permit issued would comply with the Clean Water Act. The regulation would establish an administrative boundary to determine permitting jurisdiction. She stated that EPA will be taking comments on how this should be done. She stated that in this regulation, EPA was not defining waters that would be regulated, that is

another question that would be addressed in the Waters of the U.S. rule. This rule would determine who is responsible for issuing 404 permits (state or tribe or the Corps of Engineers).

Dr. Blanz thanked EPA staff for the clarification and indicated that he had no further questions.

Questions for the Office of Air and Radiation

Oil and Natural Gas Sector: Emission Standards for new, Reconstructed, and Modified Sources Review 2060-AT90

Dr. Deborah Bennett of the SAB workgroup reviewed the written responses that had been provided by EPA Staff responded to the following questions.

Can the agency provide any additional information on the scientific and technical work products that will support the adequacy of 2060-AT90?

EPA Response: The action is focused on policy issues and not technical ones, therefore the agency does not anticipate additional scientific or technical work products.

Does the agency anticipate that planned action 2060-AT90 will address all the scientific and technical issues identified in the public comments received for 2060-AT54 or are additional actions planned?

EPA Response: No, 2060-AT90 will not address scientific or technical issues identified in the public comments received for 2060-AT54. 2060-AT90 will propose regulatory changes independent of the proposed changes in 2060-AT54. The 2050-AT90 proposal is to consider whether the 2016 rule OOOOa appropriately considered policy issues related to the challenges of regulating multiple pollutants across multiple segments of a complex industry. 2060-AT54, if finalized, will address scientific or technical issues identified in the public comments received as a result of the proposed (2060-AT54) rule.

Can the agency provide any information regarding the differences in scientific and technical information that was used in the development of promulgated actions 2060-AS30 and 2060-AT29, that were previously reviewed by the SAB and identified in the June 21, 2018, letter to Administrator Pruitt and the current planned action, 2060-AT90?

EPA Response: The key difference is that 2060-AT90 is primarily a policy action that does not involve additional analysis beyond cost, benefits and recordkeeping burden. The agency anticipates soliciting comment on a lead policy option for the regulation of greenhouse gases and the sector regulatory structure and an alternative policy option under consideration. This is different from 2060-AS30 and 2060-AT29 which were primarily technical actions and had supporting information to help inform available emission control technologies or their potential levels of effectiveness.

Furthermore, OAR included an update on this action to the Clean Air Act Advisory Committee (CAAAC) at its September 26, 2018 meeting. This included an update on the oil and gas rule highlighting the targeted improvements proposal that was published on September 11, 2018, noting the proposal addressed near-term issues and additional fixes.

Dr. Bennett noted that the description of the action indicated that it was related to challenges of regulating multiple pollutants among segments of a complex industry. She commented that this should involve technical issues. She indicated that there appeared to be a need for some sort of modeling effort regarding multiple pollutants. She commented that if it just involved costs and benefits there would be technical input required for looking at those costs and benefits. She asked EPA whether there was anything technical in nature regarding the consideration of costs and benefits.

> *EPA Response: Kevin Culligan responded that the agency was looking at questions of regulatory efficiency (i.e., how best to look at regulation when there was overlap, for example, in control strategies for VOC and methane). For example, does it make sense to have a second standard when there is much overlap between two control strategies? How do you monitor? How do you set limits? The questions about complexity in the industry tend to be questions about multiple owners when you move from collection to distribution. These are not necessarily scientific questions. They are questions dealing with the best way to regulate from the perspective "what is enforceable and understandable?." There are scientific questions concerning the detection of leaks but that is not something EPA is addressing in this rule.*
>
> *EPA staff indicated that you have a mixture of pollutants that includes the methane and VOC. The methods to detect and control leaks are the same regardless of the pollutants.*

Dr. Bennett commented that it was not clear how EPA would be addressing questions about multiple owners

> *EPA Response: EPA staff responded that it was becoming clear when looking at different segments of the industry with multiple owners, it might be better not to treat them all the same way. This focuses more on corporate structure and how the industry works than science.*

Dr. Cullen noted that the EPA Clean Air Act Advisory Committee had met and received an update on the oil and gas rule. She asked whether materials were available from that meeting.

> *EPA Response: EPA staff responded that the Clean Air Act Advisory Committee (CAAAC) had met and materials were available on the CAAAC website (www.epa.gov/caac). EPA staff noted that the answers provided to the SAB workgroup provided the agency's thinking about why the issues addressed in the rule were not scientific.*

<u>Mercury and Air Toxics Standards for Power Plants Residual Risk and Technology Review Cost Review 2060-AT99</u>

Dr. Cullen noted that SAB workgroup members Drs. Smith and Graham had questions concerning this rule. Dr. Smith indicated that the following workgroup question submitted to EPA had asked whether there were additional documents available:

Are there additional documents that the SAB should review relevant to scientific and technical adequacy of the planned action in addition to those listed on the last page of EPA's description of the planned action?

Dr. Smith indicated that the additional document the workgroup wanted to see was the proposed rule. He asked whether that was available.

EPA Response: The agency's written response stated that there are no additional documents that the SAB should review relevant to scientific and technical adequacy of the planned action in addition to those listed in 6(d) of EPA's description of the planned action. However, document (6) listed in 6(d) of EPA's description has been updated to indicate that "A review of specific enhancements made to the RTR risk assessment methodologies, particularly with respect to screening methodologies, since the 2009 SAB review was completed in 2018. In response to Dr. Smith's question, EPA staff noted that a rule was going through interagency review, but it was not yet available for SAB review.

Dr. Smith indicated that the workgroup had asked the following second question and noted that he had a concern about the EPA's written response. He commented that it seemed additional scientific data would need to be considered, and he questioned whether the SAB should be reviewing new scientific information that had become available since 2012.

Are there new, unique or specific data underlying the MATS rule that have not been peer reviewed and can the agency provide any additional information on plans to review these data? Please give more detail about how EPA proposes to peer review and incorporate these data in the Risk and Technology Review.

EPA Response: EPA's written response stated that the agency was using data submitted by power companies as part of their compliance requirements. This data has been quality assured consistent with requirements that were promulgated through rulemaking processes with a public review. Further, since these data are being submitted for compliance purposes, there are legal consequences to submitting incorrect data. In response to Dr. Smith's comment, EPA staff indicated that the scope of the rulemaking was different than the 2012 rulemaking. A supplemental cost finding was being addressed and EPA was not using any new scientific information to do that. EPA was also looking at available information to look at residual risk and technology.

Dr. Smith responded that he thought the SAB should be reviewing this rule. He noted that the cost considerations included the question of co-benefits. Even without that consideration he commented that he was surprised there were no new data being considered.

EPA Response: EPA responded that the agency was responding to the court, which had asked whether the MATS rule had previously been drawn up in the right manner. The court said EPA should have considered costs and questioned what the appropriate role of costs should have been. EPA was not looking at the underlying decision.

Dr. Graham stated that it was not clear why the rule had to get into co-benefits.

EPA Response: Agency staff responded that there were a lot of different ways that people had looked at costs. The agency is considering the appropriate ways to look at costs. EPA is not addressing how to quantify co-benefits.

Dr. Graham commented that it seemed that the SAB should be looking at the proposed rule when it comes out. EPA responded that there would be a proposed rulemaking.

Mr. Poirot asked how EPA would consider the costs of an old regulation that had effective compliance. He noted that some sources had probably shut down completely. He asked how costs would be considered after many of them had already been incurred?

EPA Response: EPA staff responded that much of the analysis concerns reconciling how the court feels the agency should have done something. The next action can then start from the position of what the court thinks EPA should have done. Much of this will affect future rulemaking.

Mr Poirot asked whether the 2016 cost analysis motivates this or is it being considered as new work.

EPA Response: EPA staff responded that the agency is again looking at the issue of cost while a case is held in abeyance.

Dr. Cullen asked EPA staff when the SAB might see the rule that is currently going through interagency review.

EPA Response: EPA staff responded that they did not have a date for when the proposed rule might get signed and published.

There were no further questions on the rulemaking.

<u>Rulemaking to Establish Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy 2060-AU09</u>

Workgroup member Dr. Lindstrom indicated that he had read the EPA response to the following workgroup question and asked whether EPA and NHTSA had harmonized their assumptions, or did they have separate assumptions as they went forward with the rule in 2012.

In regard to fleet electrification, what are the key differences in assumptions underlying the fleet EV/PHEV penetration for 2026 using the Argonne National Laboratory Automonie model compared to the assumptions underlying the 2012 rule? Relatedly, what is assumed about the future of federal and state financial and non-financial incentives to commercialize EV/PHEVs?

EPA Response: The EPA's written response indicated that in the recent Safer Affordable Fuel-Efficient (SAFE) vehicles proposal, the analysis using the Argonne National Laboratory Autonomie model and its technical assumptions related to EV/PHEV penetration for 2026 were developed by NHTSA, and EPA has no further information at this time concerning technical assumptions other than what is available in NPRM and related docket materials. Similarly, EPA does not have specific information on how EV tax credits or other financial incentives may have been incorporated in the SAFE proposal analysis developed by NHTSA. EPA would be glad to provide more details regarding the assumptions made underlying previous assessments.

EPA further responded that in 2012 EPA and NHTSA made the same assumptions regarding battery pack cost and battery pack chemistry. They did independent modeling with common inputs.

Dr. Lindstrom asked whether EPA and NHTSA used the same input but might have used different models.

EPA Response: EPA responded that this was correct. For the 2012 joint rulemaking, EPA and NHTSA each used different models to project how firms might use technologies to meet the future standards. Different modeling tools were used for future projections, but they largely had common inputs.

Dr. Lindstrom asked EPA whether the agency's response to the second question (below) on price increases due to tariffs could be summarized by stating that the agency would continue to look at this issue as it went through the rulemaking process.

New vehicle cost is a key component of fleet dynamics. Is EPA taking into consideration any long-term effects of price increases due to trade/tariff economics on the vehicle prices and subsequent cost of new technology implementation. Also, is the growing global demand for rare earths and other inputs to EVs likely to change the forecasted cost of producing EVs?

EPA Response: EPA's written response was that in the SAFE NPRM, the agencies did not consider the effects of price increases due to trade/tariffs on vehicle prices. EPA is aware of at least one recent study on this issue conducted by the Center for Automotive Research in July 2018, "Trade Briefing: Consumer Impact of Potential U.S. Section 232 Tariffs and Quotas on Imported Automobiles and Automotive Parts." To the extent that EPA receives public comments on this issue related to the SAFE rule, the agency will consider how to address those comments for the final rule.

With regard to rare earth materials and other inputs to battery electric vehicles (BEVs), we note that in the 2016 Draft Technical Assessment Report (TAR), EPA included a summary of the potential for cost reductions by automakers' efforts to reduce the content of rare earths in production vehicles.

Since the 2016 TAR, EPA has followed more recent examples of auto manufacturers successfully reducing the content of rare earth minerals. For example, Tesla's induction machine designs include some of the highest power density electric machines used in automotive applications (e.g., Tesla roadster, some versions of the Model S and Model X).

Lithium supply is another area in which EPA has continued to monitor the literature and other information sources. EPA discussed this issue in the 2016 TAR at section 5.2.4.4.8 (Potential Impact of lithium Demand on Battery Costs). EPA will continue to keep abreast of the latest information on these topics.

EPA staff further indicated that the agency may have the opportunity to further consider these issues but did not yet know how all of them would be addressed in the final rule.

Dr. Lindstrom asked EPA whether these issues would be considered in the final rule.

EPA Response: Agency staff responded that the issues may be considered.

Dr. Lindstrom referred to the following question concerning how EPA, NHTSA, and California would harmonize a national program. He indicated that the agency had provided a good written response to the question.

What approaches or models will EPA, NHTSA, and California use to harmonize to a national program, and how will the assumptions underlying those approaches or models be reviewed? As efforts are made to bring EPA, NHTSA, and the California Air resources Board into a single harmonized program, will each agency undertake their own scientific and technical modeling, or will the agencies be asked to collaborate on scientific and technical modeling?

> *EPA Response: The agency's written response stated that the agency remains committed to participating in joint discussions with NHTSA and CARB and that EPA has not yet made any decisions on how the agency will approach the analysis of GHG standards that will support a final rulemaking.*
>
> *Additionally, OAR presented to the CAAAC at its September 27 meeting on the proposed SAFE rule consistent with the CAAAC's chartered objective to provide advice, information, and recommendations on policy and technical issues associated with implementation of the Clean Air Act. OAR answered CAAAC member questions and provided further clarification on this action.*
>
> *EPA staff reiterated that there was an ongoing effort to harmonize approaches, but it was not yet possible to say what the outcome would be.*

Dr. Lindstrom indicated that he had no further questions.

Dr. Cullen asked whether Dr. Graham had additional questions about this rulemaking. He responded that he had no questions.

Dr. Cullen indicated that, with regard to regulatory action 2080-AA14, Strengthening Transparency in Regulatory Science, the SAB was waiting to receive the Administrator's response to the SAB letter sent on June 28, 2018. That letter expressed the SAB's wishes to provide advice and comment on the scientific and technical adequacy of the proposed rule.

<u>Treatment of Biogenic CO_2 Emissions Under the Clean Air Act Permitting Programs 2060-AU03</u>

SAB workgroup member Dr. Andrews noted that EPA had provided the following response to the SAB question and asked EPA staff when they expected to have documents available for the SAB to review.

Does the proposed action utilize a new scientific basis, separate from the existing Framework for Assessing Biogenic CO_2 Emissions form Stationary Sources (2014) underlying the declaration of managed forest derived biomass as carbon neutral?

> *EPA Response: The EPA responded that it was early in the process of developing a proposal and the agency currently does not have information to respond to this question. EPA staff noted that this action will follow the agency's April 2018 Policy Statement, which announced the EPA's policy to treat biogenic CO_2 emissions resulting from the combustion of biomass from managed forests at stationary sources for energy production as carbon neutral.*

EPA staff further indicated that the agency was early in the process of developing a rule that would come out of the Administrator's policy statement. The policy statement followed a letter to the Governor of New Hampshire. This stemmed from language in the 2017 appropriations act which provided direction from Congress about recognizing biomass as being carbon neutral. Agency staff indicated that the rulemaking will deal with permitting. Feedback received from the SAB on the biogenic carbon framework document may or may not play a role in any rulemaking going forward because the rulemaking is centered on the policy position taken earlier. It is too early to say whether any scientific information will go into the rulemaking.

General National Ambient Air Quality Standards Implementation Update Rule 2060-AU10

Dr. Cullen called for questions from the workgroup on action 2060-AU10. Dr. Graham indicated that he was satisfied with the following answers to the workgroup questions. He had no further questions.

The workgroup notes that the agency has not determined a time table or identified scientific work products to inform decisions regarding the planned action. Has the agency received advice from any of the other high-level external review bodies (i.e., national Academy of Sciences, Clean Air Act Advisory Committee, or Clean Air Scientific Advisory Committee) on the planned action?

EPA Response: No. this action is a placeholder for one or more potential proposed rulemakings to address NAAQS implementation-related policies determined by the Administrator as necessary to fully realize the benefits of strategies to streamline and reduce burden, and in response to adverse court decisions. No specific action has been identified at this time.

Is the agency considering engaging in any of these external review bodies to review work products to support the scientific and technical adequacy of the planned action?

EPA Response: Not at this time. As noted above, this action is a placeholder for one or more potential proposed rulemakings to address NAAQS implementation-related policies determined by the Administrator as necessary to fully realize the benefits of strategies to streamline and reduce burden, and in response to adverse court decisions. No specific action has been identified at this time. Moreover, OAR provided an additional summary to the CAAAC at its September 27, 2018 meeting on the pending actions on NAAQS while noting the Clean Air Scientific Advisory Committee (CASAC) provides independent advice to the EPA Administrator on the technical bases for EPA's National Ambient Air Quality Standards.

Dr. Cullen asked EPA to describe how upcoming NAAQS reviews would be handled (given that changes were being made in the process).

EPA Response: EPA staff responded that the agency was in the process of reviewing NAAQS for several pollutants. Staff noted that: the NAAQS for sulfur dioxide was under review, a review had been initiated for ozone, and the particulate matter (PM) standard that had previously been reviewed in 2012 was also under review. The Administrator has called for completion of the ozone and PM reviews by the end of 2020. The CASAC is involved in reviewing the NAAQS for these pollutants. EPA staff noted that the seven-member CASAC would be advising EPA in the review of the PM standard. EPA staff noted that action AU10 deals with the implementation of the air quality standards. The rulemaking is a placeholder for flexibility that could be provided to states in implementing standards in order to make the process faster and more efficient.

EPA staff commented that the agency was implementing some changes in process to make the EPA-CASAC interaction more efficient and effective.

There were no further questions for EPA from workgroup members.