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 30, 2018

SUBJECT: Preparations for Chartered Science Advisory Board (SAB) Discussions of EPA Planned Agency Actions and their Supporting Science in the Spring 2017 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 2017 semi-annual regulatory agenda at its May 31, 2018 meeting. To support this discussion a SAB Work Group was charged with identifying actions for further consideration by the Chartered SAB. This memorandum provides background on this activity, a short description of the process for identifying actions for SAB consideration, a summary of the process used by the Work Group and Work Group recommendations on the planned actions.

Background

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

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

Summary of the Process Used by the SAB Work Group

The SAB Work Group followed the process adopted by the Chartered SAB in 2013¹ to initiate its review of major planned actions identified in the Unified Regulatory Agenda by EPA. The current SAB review began when the EPA Office of Policy informed the SAB Staff Office that the Spring 2017 Unified (Regulatory) Agenda and Regulatory Plan had been published on July 20, 2017. This semi-annual regulatory agenda is available at https://www.reginfo.gov/public/do/eAgendaMain. This SAB Work Group was formed in December 2017 and includes SAB members with broad expertise in scientific and technological issues related to the proposed actions. The Work Group consists of Drs. 

Discussions of EPA Planned Agency Actions and their Supporting Science in the Spring 2017 Regulatory Agenda

Alison Cullen (chair), Deborah Bennett, Joel Ducoste, Joseph Gardella, Robert Mace, Clyde Martin, H. Christopher Frey, and Mr. Richard Poirot.

The Work Group considered actions in the Spring 2017 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 January 5, 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 2017 semi-annual regulatory agenda but not yet proposed. Work Group members concurred on the recommendations presented in this memorandum after a discussion on February 16, 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 on February 16, 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 seven of the actions do not merit further SAB consideration.

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

**National Primary Drinking Water Regulations: Finished Water Storage Facility Inspection Requirements Addendum to the Revised Total Coliform Rule (RIN2040-AF37):** This action does not merit further SAB consideration. The Work Group notes that the Safe Drinking Water Act requires EPA to request comments from the Science Advisory Board prior to proposal of a maximum contaminant level goal and national primary drinking water regulation and may bring this action to the Board in the future.

**Definition of "Waters of the United States" – Recodification of Preexisting Rules (RIN 2040-AF74):** This planned action does not merit further SAB consideration. It redefines WOTUS from the current 2015 rule to the definition in place before 2015. The goal of this first step is to provide stability in the regulation of the Clean Water Act pursuant to a decision issued by the U.S. Court of Appeals for the Sixth Circuit staying the 2015 WOTUS definition, a decision that is under review by the Supreme Court.

**Second Action: Definition of "Waters of the U.S." (RIN2040-AF75):** The SAB should defer a decision on reviewing this planned action until reviewable supporting documents or draft rule language are available. A significant amount of time and effort has gone into determining the connectivity of different water bodies to downstream navigable waters. The science related to that connectivity has been well documented by well over hundreds of journal articles and technical reports. The SAB has reviewed the scientific report and the synthesis that was performed by the EPA in trying to document this extensive literature. The SAB also provided additional information and synthesis for the EPA to consider and include in that report. While the literature and the science is clear, it does not provide clear boundaries where the waters end and more importantly, where there is a significant nexus without performing detailed analyses to assess the influence of the case specific water-influencing structure. However, EPA’s Office of Water stated it does not intend to develop any new work products to support this rule, it is unclear how any development of new boundaries can be justified without the review of the science by the SAB. Therefore, the SAB should evaluate the science that would support any decision about bright-line boundaries for WOTUS jurisdiction. The Work Group recommends that the SAB request the EPA to provide briefings on the science that would underlie the agency’s selection of these boundaries and justify what is and is not jurisdictional under the revised WOTUS rule.

**Clean Water Act Hazardous Substances Spill Prevention (RIN2050-AG87):** This action does not merit further SAB consideration. EPA states that no scientific work products are being developed and standard methods for regulatory impact and economic analyses are being used. Data from existing National Response Center will be surveyed from 2007 through 2016, and impacts will be assessed with information from National Toxic Substance Incident Program. While the environmental risks are high and uncertainties growing, especially given the recent decision to open more off shore drilling across the US Coasts, there is no scientific work to be analyzed and evaluated by SAB.

**Review of the Primary National Ambient Air Quality Standards for Nitrogen Dioxide (RIN2060-AR57):** This action does not merit further SAB consideration. This action will undergo a multi-year detailed review process by the EPA Clean Air Scientific Advisory Committee and its Nitrogen Oxides Review Panel. CASAC is a FACA committee. The NOx Review Panel will be specifically constituted, in terms
Discussions of EPA Planned Agency Actions and their Supporting Science in the Spring 2017 Regulatory Agenda

of independent scientific expertise, to review this proposed action. CASAC has statutory mandate under
the Clean Air Act to advise the Administrator regarding the NAAQS.

National Emission Standards for Hazardous Air Pollutants for Iron and Steel Foundries (RIN 2060-AT30) and National Emission Standards for Hazardous Air Pollutants: Asphalt Processing and Asphalt Roofing Manufacturing Residual Risk and Technology Review (RIN 2060-AT34): The Work Group finds that these two actions do not merit further SAB consideration. While the details of each RTR are unique to the sources and pollutants being evaluated, the general approaches and methodologies employed in EPA RTRs have become standardized, have been employed in numerous previous RTRs, and have been subject to multiple peer reviews over the past 17 years, most recently in 2009. As EPA’s RTR methodologies are refined and revised over time, there is a need for periodic peer reviews of the changing methods. The SAB is currently conducting a review of recent revisions to the screening methodologies used to support RTR reviews. A final SAB report on this review is anticipated in 2018. Given the extensive past and currently ongoing peer reviews that have been conducted on RTR methodologies, the Work Group recommends that no additional SAB review is warranted for these specific RTRs at this time.

Review of the 2016 Oil and Gas New Source Performance Standards for New, Reconstructed, and Modified Sources (RIN 2060-AT54): This planned action merits review by the SAB. The SAB deferred consideration of a related rule, the Emission Guidelines for the Existing Oil and Natural Gas Sector (RIN 2060–AT29) in the Consideration of EPA Planned Actions in the Fall 2016 Unified (Regulatory) Agenda and their Supporting Science. The SAB noted the agency has withdrawn the 2016 Information Collection Request (ICR) from the oil and gas industry; as a result, there was insufficient information to review and requested that the agency provide the SAB with more information about the scientific basis. At this time, the EPA has stated a broad commitment to reviewing the whole rule during the reconsideration of additional requirements in the rule. The scientific and technical basis for identifying and evaluating measures being reconsidered for methods to reduce emissions of greenhouse gases, including methane, and volatile organic compounds (VOCs) in the oil and natural gas industry was not provided. The identification and use of influential scientific information (ISI) or highly influential scientific information (HISI) is not explained. Given that some time has elapsed since the rule-making processes for the Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Reconsideration, information regarding the scientific and technical basis for identifying alternative measures applicable to individual power plants may have changed. The previous science reviewed by the SAB supported Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Reconsideration. Therefore, the Work Group recommends that the SAB review any new science and information being considered that might change the prior justification for the rule.

Review of the Clean Power Plan (RIN 2060-AT55): This action merits review by the SAB. The review of the Clean Power Plan (CPP) pertains to a scope of scientific and technical issues that should be considered and subject to peer review. Limited information was available to the Work Group. The scientific and technical basis for identifying and evaluating measures including heat rate improvement, and other options that are applicable to individual plants, is not specified in the announcements of the planned actions. The identification and use of ISI or HISI is not explained nor defined. In the Work Group’s fact-finding, the Agency was asked to provide further details regarding what specific sources of new information will be used and how ISI or HISI will be properly vetted through a rigorous peer
Discussions of EPA Planned Agency Actions and their Supporting Science in the Spring 2017 Regulatory Agenda

review process (See attachment C). The Agency replied that public comments were being taken on “whether there are additional control measures and information beyond what was included in the original Clean Power Plan.” The Agency response did not address whether the Agency would seek updated information on measures that were included in the original CPP, nor regarding sources of such information, nor whether such information would be considered ISI or HISI, nor, if so, the nature of peer review procedures planned for ISI or HISI.

In the absence of information from the Agency, a presumption should be made that there have been updates to scientific and technical information for control measures that were included in the original CPP, and that additional measures may be identified, for which new ISI or HISI may be required. Given the potential significance of the CPP with regard to addressing GHG emissions that endanger public health and welfare, and the myriad of potential best systems of emissions reductions, further SAB attention to this matter is warranted.

Review of the Standards of Performance for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Generating Units (RIN 2060-AT56): This planned action merits review by the SAB. In its Federal Register notice EPA stated that the Agency “will review whether this Rule or alternative approaches appropriately maintain the diversity of reliable energy resources and encourage the production of domestic energy sources to achieve energy independence and security.” This implies that scientific questions will arise regarding diversity of energy sources, reliability of energy sources, or capabilities to recover or utilize energy resources domestically. These types of analyses would be novel and may require review or development of methodology and collection and evaluation of data. It is unclear how an a priori determination can be made regarding whether this planned action may require ISI or HISI. The scope of assessments needed regarding diversity of energy resources, reliability of energy resources, and domestic resources imply new analyses that were not part of the previous rule-making may be needed. The specific scope of technical issues to be addressed is not articulated, such as regarding what fuels, co-firing, firing, gasification, control, steam cycle, sequestration, and other options might form the basis of determination of best systems of emissions reduction. There is further complexity since this rule covers new, modified, and reconstructed facilities. The applicable range of options may differ depending on these stages of the plant life cycle. Based on a fact-finding query to the Agency, the Agency indicated that it plans to issue a proposed revision to the final NSPS and will consider comments it receives on that proposal.” However, no further details were provided. (See Attachment C).

In the absence of information from the Agency, a presumption should be made that there have been updates to scientific and technical information for control measures that were included in the original “New Source Rule,” that additional measures may be identified, and that additional assessments will be needed regarding energy diversity, energy reliability, and domestic energy resources, for which new ISI or HISI may be required. Given the potential significance of the Rule with regard to addressing GHG emissions that endanger public health and welfare, and the myriad of potential best systems of emissions reductions, further SAB attention to this matter is warranted. Thus, the SAB should consider this action for review.

Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h) (RIN 2070-AK34): The Work Group found that there is insufficient information to determine if the SAB should provide advice on this planned action. At this time, it is not known what information base is available for the five chemical compounds, the particulars of the peer review process, nor whether the individual
chemical assessments will be brought back to the SAB or the Scientific Advisory Committee on Chemicals. EPA is developing a plan and has indicated letter peer review will be used. Due to the timeframes established by the statute, as well as the fact that the purpose of the assessment of these chemicals is to determine the likelihood of exposure, EPA plans to use reasonably available information to complete the exposure and use assessments. Depending on the available information base the assessments may be qualitative or quantitative. The assessments are intended to support rulemaking under TSCA section 6(h) in order to reduce exposure to the extent practicable. The Work Group notes that the SAB has previously reviewed planned actions for specific TSCA chemical assessments and urged the EPA to continue this level of robust transparent peer review. Thus a final recommendation should await this timeline and any updated information that may be provided.

Review of Pesticides; Certification of Pesticide Applicators (RIN 2070-AK37) In the current context this action does not merit further SAB consideration. If EPA identifies a need for changes to the certification rule SAB review may be warranted. In a related planned action (RIN 2070-AJ20) EPA’s FIFRA Science Advisory Panel considered whether to review certification for pesticide applicators the actions and waived its review of the proposed rule on September 4, 2014, and the final rule on August 15, 2016, because the proposed revisions were administrative in nature and did not contain scientific issues that required the SAP’s consideration.

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

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¹The 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 2017 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 C: Summary of the February 16, 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).
Attachment A: Identifying EPA Planned Actions for SAB Consideration

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 OAR/OP

2) New semi-annual process for determining whether any planned EPA actions merit SAB advice and comment on the supporting science

- EPA(ORP) sends semi-annual regulatory agenda to SAB
- SAB work group prepares to lead discussion and identifies any additional information needed, discussions and fact-finding documented in public record
- Chartered SAB twice-a-year public meetings to review semi-annual regulatory agenda and additional information
- SAB decides to review and comment on science supporting action?
  - Yes
  - 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
  - 5-6 months
  - 12-15 months
- No action
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.

MEMORANDUM

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

FROM: Michael Goo, Associate Administrator
Office of Policy
Glenn Paulson
Science Advisor
Vanessa Vu, Director
SAB Staff Office

TO: General Counsel
Assistant Administrators
Associate Administrators
Regional Administrators

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

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

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

This process supplements the Deputy Administrator's annual memorandum requesting program and regional offices to identify scientific issues that might be appropriate for SAB consideration.
Attachment A: Identifying EPA Planned Actions for SAB Consideration

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

Attachments

cc: Administrator
    Deputy Administrator
    Chief of Staff
    Deputy Chief of Staff
Attachment A: January 19, 2012 Memorandum from Michal L. Goo

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 *Semianual 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*. 

Recycled/Recyclable - Printed with Vegetable Oil Based Inks on 100% Postconsumer, Process Chlorine Free Recycled Paper
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 Perciasape  
     Bob Sussman  
     Deputy Assistant Administrators  
     Deputy Associate Administrators  
     Deputy Regional Administrators  
     Assistant Regional Administrators  
     Alex Cristofaro  
     Nicole Owens  
     Vanessa Wu  
     Thomas Brennan
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 EPA Planned Actions in the Spring 2017 Semi-Annual Regulatory Agenda**

**April 30, 2018**

<table>
<thead>
<tr>
<th>RIN</th>
<th>EPA Office</th>
<th>Title</th>
<th>Agenda Stage of Rulemaking</th>
<th>Additional Available Information*</th>
<th>Page</th>
</tr>
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<tbody>
<tr>
<td>2040-AF37</td>
<td>OW</td>
<td>National Primary Drinking Water Regulations: Finished Water Storage Facility Inspection Requirements Addendum to the Revised Total Coliform Rule</td>
<td>Long-Term Actions</td>
<td></td>
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<tr>
<td>2040-AF74</td>
<td>OW</td>
<td>Definition of &quot;Waters of the United States&quot; – Recodification of Preexisting Rules</td>
<td>Proposed Rule Stage</td>
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<td>2040-AF75</td>
<td>OW</td>
<td>Second Action: Definition of &quot;Waters of the U.S.&quot;</td>
<td>Proposed Rule Stage</td>
<td>Submitted questions**</td>
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<tr>
<td>2050-AG87</td>
<td>OLEM</td>
<td>Clean Water Act Hazardous Substances Spill Prevention</td>
<td>Long-Term Actions</td>
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<tr>
<td>2060-AR57</td>
<td>OAR</td>
<td>Review of the Primary National Ambient Air Quality Standards for Nitrogen Dioxide</td>
<td>Proposed Rule Stage</td>
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<tr>
<td>2060-AT30</td>
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<td>National Emission Standards for Hazardous Air Pollutants for Iron and Steel Foundries</td>
<td>Long-Term Actions</td>
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<tr>
<td>2060-AT34</td>
<td>OAR</td>
<td>National Emission Standards for Hazardous Air Pollutants: Asphalt Processing and Asphalt Roofing Manufacturing Residual Risk and Technology Review</td>
<td>Long-Term Actions</td>
<td></td>
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</tr>
<tr>
<td>2060-AT54</td>
<td>OAR</td>
<td>Review of the 2016 Oil and Gas New Source Performance Standards for New, Reconstructed, and Modified Sources</td>
<td>Long-Term Actions</td>
<td>Submitted questions**</td>
<td>29</td>
</tr>
<tr>
<td>2060-AT55</td>
<td>OAR</td>
<td>Review of the Clean Power Plan</td>
<td>Long-Term Actions</td>
<td>NPRM: 10/16/2017 Submitted questions**</td>
<td>33</td>
</tr>
<tr>
<td>2060-AT56</td>
<td>OAR</td>
<td>Review of the Standards of Performance for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Generating Units</td>
<td>Long-Term Actions</td>
<td>Submitted questions**</td>
<td>37</td>
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<tr>
<td>2070-AK34</td>
<td>OCSP</td>
<td>Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h)</td>
<td>Long-Term Actions</td>
<td>Submitted questions**</td>
<td>41</td>
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<tr>
<td>2070-AK37</td>
<td>OCSP</td>
<td>Review of Pesticides; Certification of Pesticide Applicators</td>
<td>Long-Term Actions</td>
<td>NRPM: 12/13/2017</td>
<td>45</td>
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</tbody>
</table>

*Includes publicly available information published in the Federal Register (i.e., Advanced Notice of Public Rule Making, Notice of Data Availability, Proposed Rules) in addition to the Regulatory agenda and EPA description of the planned action

** A summary of the Work Group’s submitted questions and agency responses may be found in Attachment C
Description of Planned EPA Tier 1 or Tier 2 Action

1. Name of action: National Primary Drinking Water Regulation: Finished Water Storage Facility Inspection Requirements Addendum to the Revised Total Coliform Rule

2. RIN Number: 2040-AF37

3. EPA Office originating action: Office of Water, Office of Ground Water and Drinking Water

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

   The EPA is considering a regulation to strengthen public health protection by establishing finished water storage facility inspection (SFI) requirements. The EPA has previously requested comment on the value and cost of storage facility inspection and cleaning. EPA received comments regarding unsanitary conditions and contamination that can be found in finished water storage facilities that are not routinely inspected and cleaned, including breaches and accumulation of sediment, animals, insects, and other contaminants. The EPA intends to propose a SFI regulation and request comment on (1) requirements for public water systems to periodically inspect the interior and exterior of their finished water storage facilities and to correct any sanitary defects found, (2) any additional relevant information, including data on costs of any potential inspection requirements or guidelines and (3) public health benefits realized from a required inspection regime. EPA expects that the proposed SFI requirements would maintain or improve public health protection by reducing cases of illnesses, and possibly deaths, due to exposure to waterborne pathogens.

5. Timetable: EPA does not expect to consult with the SAB on this action in FY2018.

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.

   EPA does not anticipate developing scientific work products for the planned action in FY2018. In 2014, EPA held a public meeting to allow for public input into the Agency’s consideration of this issue. Information submitted by the public is being used to inform EPA’s development of the action.

   6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis). N/A. See item 5 above.

   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?” N/A. See item 5 above.

   6(d). Peer review: N/A. See item 5 above.
Attachment B: SAB Work Group Memorandum on the Spring 2017 Regulatory Agenda
April 30, 2018

Recommendation from the SAB Work Group

Name of planned action: National Primary Drinking Water Regulations: Finished Water Storage Facility Inspection Requirements Addendum to the Revised Total Coliform Rule (RIN 2040-AF37)

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

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>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)?</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Is the action primarily administrative (i.e., involve reporting or record keeping)?</td>
<td>X</td>
<td></td>
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<tr>
<td>Has EPA characterized the action as one that has &quot;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?”</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Is the action an extension of an existing initiative?</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Involves scientific approaches that are new to the agency</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Addresses areas of substantial uncertainties</td>
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<td>X</td>
<td></td>
</tr>
<tr>
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<td>X</td>
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<td></td>
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<tr>
<td>Relates to emerging environmental issues</td>
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<td></td>
<td>X</td>
</tr>
<tr>
<td>Exhibits a long-term outlook</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

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 any further SAB consideration. The Work Group notes that the Safe Drinking Water Act requires EPA to request comments from the Science Advisory Board prior to proposal of a maximum contaminant level goal and national primary drinking water regulation and may bring this action to the Board in the future.

Rationale: The Agency’s Revised Total Coliform Rule (RTCR) aims to increase public health protection through the reduction of potential pathways for fecal contamination in the distribution system. The EPA’s RTCR requires all public water systems to submit a coliform sample site plan and obtain state approval of startup procedures for seasonal water systems. Its purpose is to help determine if a water systems distribution network is vulnerable to microbial contamination. Storage tank deficiencies, such as vents without screens, inadequate hatches, and/or physical openings in storage tank roofs and lack of a cover, can result in the entry of contaminants. Microorganisms can also be introduced into
underground storage facilities from surface water or ground water infiltration or runoff. The EPA intends only to propose a storage facility inspection protocol to reduce the potential of microbial contaminants into the finished water distribution system. The science to support this potential route for microbial contamination is well established. The EPA does not expect to develop any scientific work products towards this effort in FY 2018. The EPA will utilize information submitted by the public to develop this protocol. Therefore, this action does not merit further SAB consideration.

The Work Group notes the Safe Drinking Water Act requires the Administrator to “request comments from the Science Advisory Board (established under the Environmental Research, Development, and Demonstration Act of 1978) prior to proposal of a maximum contaminant level goal and national primary drinking water regulation. The Board shall respond, as it deems appropriate, within the time period applicable for promulgation of the national primary drinking water standard concerned. This subsection shall, under no circumstances, be used to delay final promulgation of any national primary drinking water standard.
Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Definition of "Waters of the United States" – Recodification of Pre-existing Rules

2. **RIN Number:** 2040-AF74

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:**

   This rulemaking action responds to the February 28, 2017, Presidential Executive Order: *Restoring the Rule of Law, Federalism, and Economic Growth by Reviewing the Waters of the United States' Rule*. The February Order states that it is in the national interest to ensure that the Nation's navigable waters are kept free from pollution, while at the same time promoting economic growth, minimizing regulatory uncertainty, and showing due regard for the roles of Congress and the states under the Constitution.

   To meet these objectives, the EPA and Department of the Army (agencies) are engaged in an expeditious two-step rulemaking process. Under the first step of this rulemaking process, the proposed rule will recodify the regulatory text that was in place prior to the 2015 Clean Water Rule and that is currently in place as a result of the stay ordered by the U.S. Court of Appeals for the Sixth Circuit. The proposed rule was published in the *Federal Register* on July 27, 2017.

5. **Timetable:**

   Notice of Proposed Rulemaking: July 27, 2017
   Final Rule: 2018

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.

   In this first step, the agencies have proposed as an interim action to repeal the 2015 definition of “waters of the United States” and codify the legal status quo that is being implemented now under the Sixth Circuit stay of the 2015 definition of “waters of the United States” and that was in place for decades prior to the 2015 rule. This rule is intended simply to codify what is in place under the Court stay so that the rules are clear and certain while agencies engage in a second rulemaking to reconsider the definition. As a result, the Office of Water does not intend to rely on or develop any new scientific work products to support this rule.

   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).

   N/A: No new scientific work products have been developed.
6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that “has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?”

N/A: No new scientific work products have been developed.

6(d). Peer review:

N/A: No new scientific work products have been developed.
Recommendation from the SAB Work Group

Name of planned action: Definition of "Waters of the United States" – Recodification of Preexisting Rules (RIN 2040-AF74)

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

<table>
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</tr>
<tr>
<td>Exhibits a long-term outlook</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

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 SAB consideration.

Rationale: This planned action, requested by an Executive Order signed on February 28, 2017, is the first step in a path to redefine the waters of the United States (WOTUS) rule (the second step is posted under RIN 2040-AF75). In this first step, the EPA wants to redefine WOTUS from the current 2015 rule to the definition in place before 2015. The goal of this first step is to provide stability in the regulation of the Clean Water Act pursuant to a decision issued by the U.S. Court of Appeals for the Sixth Circuit staying the 2015 WOTUS definition, a decision that is under review by the Supreme Court.
Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Second Action: Definition of "Waters of the United States"

2. **RIN Number:** 2040-AF75

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:**

   This rulemaking action responds to the February 28, 2017, Presidential Executive Order: *Restoring the Rule of Law, Federalism, and Economic Growth by Reviewing the Waters of the United States' Rule*. The February Order states that it is in the national interest to ensure that the Nation's navigable waters are kept free from pollution, while at the same time promoting economic growth, minimizing regulatory uncertainty, and showing due regard for the roles of Congress and the states under the Constitution.

   To meet these objectives, the EPA and Department of the Army (agencies) are engaged in an expeditious two-step rulemaking process. This action follows the first step to recodify the pre-existing definition of “waters of the United States.” In this second step, the agencies are conducting a reconsideration of the definition of “waters of the United States” consistent with the Executive Order.

5. **Timetable:**
   - Notice of Proposed Rulemaking: 2018
   - Final Rule: 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.

   At this time, the Office of Water does not intend to develop new scientific work products to support this rule.

   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).

   N/A: No new scientific work products have been developed.

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

   N/A: No new scientific work products have been developed.
6(d). Peer review:

N/A: No new scientific work products have been developed.
Recommendation from the SAB Work Group

Name of planned action: Second Action: Definition of "Waters of the U.S." (RIN 2040-AF75)

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

<table>
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<tr>
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<td>Exhibits a long-term outlook</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

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

Recommendation: The SAB should defer a decision on reviewing this planned action until EPA staff produce reviewable draft rule language.

Rationale: A significant amount of time and effort has gone into determining the connectivity of different water bodies to downstream navigable waters. The science related to that connectivity has been well documented with well over 100s of journal articles and technical reports. The EPA SAB has reviewed the scientific report and the synthesis that was performed by the EPA in trying to document this extensive literature. The SAB also provided additional information and synthesis for the EPA to
consider and include in that report\(^1\), \(^2\), \(^3\). While the literature and the science is clear, it does not provide clear boundaries where the waters end and more importantly, where there is a significant nexus without performing detailed analyses to assess the influence of the case specific water-influencing structure. There is concern over the arbitrary selection of the 4,000-ft bright-line boundary mentioned in the 2015 WOTUS rule that was not provided anywhere in the scientific report or the literature. It is likely that the EPA developed this boundary to come up with some type of outer bounds to draw a jurisdictional line. However, more research or synthesis of the data may need to be performed to help develop some level of risk associated with this bright-line boundary and the determination of the impact of what is left out beyond this boundary.

In addition, the complexity of the different case specific “significant nexus” structures outlined in the rule (i.e., Prairie pothole, Carolina and Delmarva bays, pocosins, western vernal pools in California, and Texas coastal prairie wetlands) will need more clarification in the form of case studies to help strengthen the identification of these integrity-influencing waters. It is important that the SAB be involved in reviewing any science that would justify alternative bright line boundaries proposed in the revised rule by the EPA to reduce the arbitrary nature of the selection.

The planned action does not, at this point, include any proposed language; however, the proposed action states that “…the agencies are conducting a reconsideration of the definition of waters of the United States consistent with the Executive Order” where “The Executive order directs the agencies to consider a defining "waters of the United States" consistent with Justice Scalia's opinion in Rapanos.” In his opinion, Justice Scalia notes that “the phrase “the waters of the United States” includes only those relatively permanent, standing or continuously flowing bodies of water “forming geographic features” that are described simply as “streams[,] … oceans, rivers, [and] lakes.” See Webster’s Second 2882. The phrase does not include channels through which water flows intermittently or ephemerally, or channels that periodically provide drainage for rainfall.” Although Scalia’s definition is direct, it still includes ambiguity (“relatively permanent” [and how this may change with time] and “forming geographic features”) that would benefit from scientific review.

Scalia further states that “…only those wetlands with a continuous surface connection to bodies that are "waters of the United States" in their own right, so that there is no clear demarcation between ‘waters’ and wetlands, are “adjacent to” such waters and covered by the Act.” Potential definitional science issues here are (1) what defines a clear demarcation between “waters” and wetlands and (2) what defines the edge of a wetland.

\(^1\) Preparations for Chartered Science Advisory Board (SAB) March 8, 2013 Discussions of EPA Planned Agency Actions and their Supporting Science (see page 84 of attachment C. regarding review of the Connectivity /CWR search clean water protection Rule).
\(^2\) Connectivity of Streams and Wetlands to Downstream Waters: A Review and Synthesis of the Scientific Evidence.
\(^3\) “Definition of ‘Waters of the United States’ Under the Clean Water Act” - Advice and comment on science supporting the EPA’s proposed rule.
While the EPA’s Office of Water does not intend to develop any new work products to support this rule, it is unclear how any development of new boundaries can be justified without the review of the science by the SAB. Therefore, the SAB should evaluate the science that would support any decision about bright-line boundaries for WOTUS jurisdiction. The Work Group recommends that the SAB request the EPA to provide briefings on the science that would underlie the agency’s selection of these boundaries and justify what is and is not jurisdictional under the revised WOTUS rule.
Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Clean Water Act Hazardous Substances Spill Prevention

2. **RIN Number:** 2050-AG87

3. **EPA Office originating action:** Office of Land and Emergency Management (OLEM), Office of Emergency Management (OEM), Regulations and Implementation Division (RID)

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

   Section 311(j)(1)(C) of the Clean Water Act (CWA) reads, in part: “…as soon as practicable after October 18, 1972, and from time to time thereafter, the President shall issue regulations … establishing procedures, methods, and equipment and other requirements for equipment to prevent discharges of … hazardous substances from … onshore facilities … and to contain such discharges …” On September 1, 1978, the EPA proposed a regulation under this authority (43 FR 39276) but the proposal was never finalized. In 2015, the EPA was sued for failure to conduct a rulemaking for chemicals under CWA 311(j)(1)(C). This litigation was settled and a consent decree was filed with the court in February 2016 (Environmental Justice Health Alliance for Chemical Policy Reform v. U.S. EPA). The EPA is conducting this rulemaking in accordance with the consent decree and intends to issue a proposed rule by June 2018.

   The CWA hazardous substances and their associated reportable quantities (RQs) are identified in 40 CFR parts 116 and 117, respectively. The EPA will assess the consequences of hazardous substance discharges into the nation’s waters, and evaluate the costs and benefits of potential preventive regulatory requirements for facilities handling such substances.

5. **Timetable:**

   The proposed rule will be signed by June 16, 2018 (per court deadline).

   The final rule will be signed no later than 14 months after the publication of the proposed rule (per court 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.

   There are no scientific work products being developed for this action. For this action, we will use National Response Center (NRC) data as a starting point, which includes reports of all kinds of releases to the environment (including oil, chemical, radiological, biological, etc.). NRC reports will be reviewed from the years of 2007-2016 to identify CWA hazardous substances discharges to water. To assess impacts of these discharges, we will use information from the NRC and the National Toxic Substance Incident Program (NTSIP). Our target dataset to assess impacts include discharges of CWA HS reported to reach water from a non-transportation-
related source, with reported impacts, which will include injuries, hospitalization, fatalities, waterway closure, and water supply contamination. Using standard Agency methods for regulatory impact analyses (RIA) and economics analyses (EA), we assigned a cost to the impacts and are currently weighing that cost (or benefit of reducing or eliminating that cost) against the costs of regulatory options to mitigate impacts for those specific discharges. The Agency’s standard methods for RIA/EA can be found here: https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses

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).

N/A, no scientific work products are being developed.

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

N/A, no scientific work products are being developed.

6(d). Peer review:

N/A, no scientific work products are being developed.
Recommendation from the SAB Work Group

Name of planned action: Clean Water Act Hazardous Substances Spill Prevention (RIN 2050-AG87)

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

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

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

Rationale: The Description of Planned EPA Tier 1 or Tier 2 Action clearly states that no scientific work products are being developed for the required regulatory action. Standard Agency methods for regulatory impact and economic analyses are being used. Data from existing National Response Center will be surveyed from 2007 through 2016, and impacts will be assessed with information from National Toxic Substance Incident Program.

While the environmental risks are high and uncertainties growing, especially given the recent decision to open more off shore drilling across the US Coasts, there is no scientific work to be analyzed and evaluated by SAB.
Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Review of the Primary National Ambient Air Quality Standards for Nitrogen Oxides

2. **RIN Number:** 2060-AR57

3. **EPA Office originating action:** Office of Air Quality Planning and Standards in the Office of Air and Radiation

4. **Brief description of action and statement of need for the action:** Under sections 108 and 109 of the Clean Air Act, as amended, the EPA is required to review and if appropriate revise air quality criteria and national ambient air quality standards (NAAQS) every 5 years. For this review, the EPA is currently under a consent decree to take final action by April 2018. Each review generally includes the preparation of several documents (see below). These documents inform the Administrator's decision as to whether to retain or revise the current standards. The proposed decision is published in the Federal Register with opportunity for public comment. The Administrator's final decision takes into consideration these documents, CASAC advice, and public comment on the proposed decision.

5. **Timetable:** Section 109 of the Clean Air Act establishes a 5-year review cycle for the NAAQS.

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.** For each review, EPA prepares an Integrated Review Plan (IRP); an Integrated Science Assessment (ISA); a Risk/Exposure Assessment (REA) Planning Document, and, if warranted, a REA; and also a Policy Assessment (PA).

   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).** Each review generally begins with a kickoff workshop with internal and external scientific experts to solicit input on technical issues and current information relevant for the review and on the key issues that will frame the review. The workshop activity informs identification of policy-relevant issues and development of the IRP for the review. As described in the IRP, EPA prepares a series of documents, with opportunities for review by the EPA's CASAC and the public. Draft versions of the IRP, ISA, REA (if prepared), and the PA are reviewed at public meetings by a panel of the CASAC constituted for the specific NAAQS review. Final documents reflect consideration of CASAC advice and recommendations, and of comments provided by members of the public.

   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?”** Reviews of the NAAQS rely on assessment documents that are designated as “highly influential scientific assessments.”
6(d). **Peer review**: Drafts of the ISA, REA (if prepared), and PA are reviewed at public meetings by a CASAC Panel. The CASAC Panel is charged with providing written advice to the EPA Administrator, reflecting the consensus views of the Panel where appropriate. Prior to development of a REA, if one is warranted, the EPA prepares a REA Planning Document which is the subject of consultation with the CASAC Panel and on which EPA solicits public comment.

Further information: [https://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/CASAC](https://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/CASAC)
Recommendation from the SAB Work Group

Name of planned action: Review of the Primary National Ambient Air Quality Standards for Nitrogen Oxides (RIN 2060-AR57)

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

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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 by the SAB.

Rationale: This action will undergo a multi-year detailed review process by the EPA Clean Air Scientific Advisory Committee and its Nitrogen Oxides Review Panel. CASAC is a FACA committee. The NOx Review Panel will be specifically constituted, in terms of independent scientific expertise, to review this proposed action. CASAC has statutory mandate under the Clean Air Act to advise the Administrator regarding the NAAQS.
Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** National Emission Standards for Hazardous Air Pollutants for Iron and Steel Foundries

2. **RIN Number:** 2060-AT30

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

4. **Brief description of action and statement of need for the action:** The Clean Air Act (CAA) establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, the CAA requires the EPA to develop technology-based standards for categories of industrial sources. In the second stage of the regulatory process, the EPA must review each maximum achievable control technology (MACT) standards 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 MACT. This residual risk review also must be done within 8 years of setting the initial MACT standards. If additional risk reductions are necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects, the EPA must develop standards to address these remaining risks. For each source category for which the 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 coincides in deadline with the risk review requirement, the EPA generally combines these two requirements into one rulemaking activity, calling this the “risk and technology review” process, or 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) emitted from iron and steel foundries in April 2004 (69 FR 21905). Several amendments to the NESHAP were developed over the years, resulting in two final amendments (May 20, 2005 (70 FR 29400), and February 7, 2008 (73 FR 7210)).

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.

5. **Timetable:** Pursuant to a court order related to the review of 13 source categories, the EPA must complete seven final RTR actions by December 31, 2018, and six additional RTR actions by June 30, 2020. The EPA currently plans to complete this action by June 30, 2020. Tentative schedule:

NPRM: June 2019  
Final Rule: June 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.

   It is the risk analysis methodologies associated with the RTR process that 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 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, EPA also conducts a technology review to account for developments in practices, processes and control technologies. As stated in the Agency’s August 15, 2017 response to the SAB’s report on the Fall 2016 Regulatory Agenda, EPA will work with the SAB Staff Office to schedule an informational briefing on this topic.

   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 precedent, 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.


(2) A peer review of multi-pathway risk assessment methodologies for RTR was conducted by the EPA’s SAB in 2000.

Hot Link to the final SAB advisory:

(3) A consultation on the 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.

Hot Link to the final SAB advisory:

(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.

Hot Link to the final SAB advisory:
https://yosemite.epa.gov/sab/sabproduct.nsf/0/b031dd79cfded38525734f00649caf!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) The EPA is currently seeking 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, 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. SAB’s findings for this review are expected in the Fall of 2017.
**Recommendation from the SAB Work Group**

**Name of planned action:** National Emission Standards for Hazardous Air Pollutants for Iron and Steel Foundries (RIN 2060-AT30)

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

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

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

**Rationale:** EPA has developed emission standards for many combinations of stationary sources and hazardous air pollutants (HAP) under the National Emission Standards for Hazardous Air Pollutants (NESHAP). The first phase of NESHAP consists of setting technology-based standards that specify “maximum achievable control technology” (MACT). EPA is required to review the MACT standards every eight years and revise them as necessary, taking into account developments in emissions control technologies. Furthermore, EPA is required to conduct a one-time “residual risk review” within eight years of the initial standard setting to determine if additional risk reductions are necessary to protect the...
public health. Thus, eight years after the promulgation of the initial standard, EPA must conduct both a risk review and a technology review. Typically, these actions are combined as a “risk and technology review” (RTR).

The EPA summary of this RTR action does not provide information specific to iron and steel foundries. These foundries melt scrap, ingot, and other forms of iron and steel and pour the resulting molten metal into molds to produce shaped products. For iron and steel foundries that produce low alloy metal castings, metal HAP emitted are primarily Pb and Mn with smaller amounts of Cd, Cr and Ni. For iron and steel foundries that produce high alloy metal or stainless steel castings, metal HAP emissions of Cr and Ni can be significant. Organic HAP emissions include: acetophenone, benzene, cumene, dibenzofurans, dioxins, formaldehyde, methanol, naphthalene, phenol, pyrene, toluene, triethylamine, and xylene. Exposure to these substances has been demonstrated to cause adverse health effects, including cancer and chronic or acute disorders of the respiratory, reproductive, and central nervous systems. As part of the RTR review, EPA will have to assess health risks associated with current exposures to these and other pollutants from these sources and identify whether new technologies have emerged that can more effectively control these pollutants. Cost must also be considered when setting a MACT standard. Therefore, cost analysis must be conducted.

While the details of each RTR are unique to the sources and pollutants being evaluated, the general approaches and methodologies employed in EPA RTRs have become standardized, have been employed in numerous previous RTRs, and have been subject to multiple peer reviews over the past 17 years, most recently in 2009. As EPA’s RTR methodologies are refined and revised over time, there is a need for periodic peer reviews of the changing methods. The SAB is currently conducting a review of recent revisions to the screening methodologies used to support RTR reviews. A final SAB report on this review is anticipated early in 2018. Given the extensive past and currently ongoing peer reviews that have been conducted on RTR methodologies, the Work Group recommends that no additional SAB review is warranted for this specific RTR at this time.
Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** National Emission Standards for Hazardous Air Pollutants: Asphalt Processing and Asphalt Roofing Manufacturing Residual Risk and Technology Review

2. **RIN Number:** 2060-AT34

3. **EPA Office originating action:** Office of Air and Radiation, Office of Air Quality Planning and Standards, Sector Policy 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 Asphalt Processing and Asphalt Roofing Manufacturing. The Asphalt Processing and Asphalt Roofing Manufacturing NESHAP, 40 CFR part 63, subpart LLLLL, was promulgated pursuant to section 112(d) of the Clean Air Act (CAA) on May 7, 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 asphalt processing and asphalt roofing manufacturing. Asphalt processing facilities produce “blown” asphalt for use in the asphalt roofing manufacturing industry and elsewhere. Asphalt roofing manufacturing facilities produce shingles and roll roofing products by applying the “blown” asphalt to a fiberglass or felt substrate.

   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. The 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.

   We plan to conduct the residual risk review and initial technology review concurrently. The EPA has completed this process for more than 50 source categories to date.

5. **Timetable:**

Pursuant to a court order, the EPA is obligated to complete the final action by March 13, 2020.

**Tentative schedule:**
- NPRM: August 2018

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.

   It is the risk analysis methodologies associated with the RTR process that 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 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, EPA also conducts a technology review to account for developments in practices, processes and control technologies. As stated in the Agency’s August 15, 2017 response to the SAB’s report on the Fall 2016 Regulatory Agenda, EPA will work with the SAB Staff Office to schedule an informational briefing on this topic.

   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.


(2) A peer review of multi-pathway risk assessment methodologies for RTR was conducted by the EPA’s SAB in 2000.

Hot Link to the final SAB advisory: 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.


(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.

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(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) The EPA is currently seeking 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, 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. SAB’s findings for this review are expected in the Fall of 2017.
Recommendation from the SAB Work Group

**Name of planned action:** National Emission Standards for Hazardous Air Pollutants: Asphalt Processing and Asphalt Roofing Manufacturing Residual Risk and Technology Review (RIN 2060-AT34)

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

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

**Rationale:** EPA has developed emission standards for many combinations of stationary sources and hazardous air pollutants (HAP) under the National Emission Standards for Hazardous Air Pollutants (NESHAP). The first phase of NESHAP consists of setting technology-based standards that specify “maximum achievable control technology” (MACT). EPA is required to review the MACT standards every eight years and revise them as necessary, taking into account developments in emissions control technologies. Furthermore, EPA is required to conduct a one-time “residual risk review” within eight years of the initial standard setting to determine if additional risk reductions are necessary to protect the public health. Thus, eight years after the promulgation of the initial standard, EPA must conduct
both a risk review and a technology review. Typically, these actions are combined into a “risk and technology review” (RTR).

The EPA summary of this action does not provide information specific to asphalt processing and asphalt roofing manufacturing sources. A variety of HAPs are emitted from these source categories. The following HAP account for the majority (approximately 98 percent, based on the emission factors developed for the previous 2003 MACT rulemaking) of the total HAP emissions from these sources: formaldehyde, hexane, HCl (at asphalt processing facilities that use chlorinated catalysts), phenol, and toluene. Adverse health effects associated with these HAPs include both chronic health disorders (e.g., irritation of the lung, skin, and mucous membranes, effects on the central nervous system, and damage to the blood and liver) and acute health disorders (e.g., respiratory irritation and central nervous system effects such as drowsiness, headache, and nausea). The EPA has classified formaldehyde and POM as probable human carcinogens. As part of the RTR review, EPA will have to identify health risks from exposures to these or other pollutants currently emitted from these sources and determine whether new technologies have emerged that can more effectively control emissions of these pollutants. Cost must also be considered when setting a MACT standard. Therefore, cost analysis must be conducted.

While the details of each RTR are unique to the sources and pollutants being evaluated, the general approaches and methodologies employed in EPA RTRs have become standardized, have been employed in numerous previous RTRs, and have been subject to multiple peer reviews over the past 17 years, most recently in 2009. As EPA’s RTR methodologies are refined and revised over time, there is a need for periodic peer reviews of the changing methods. The SAB is currently conducting a review of recent revisions to the screening methodologies used to support RTR reviews. A final SAB report on this review is anticipated early in 2018. Given the extensive past and currently ongoing peer reviews that have been conducted on RTR methodologies, the Work Group recommends that no additional SAB review is warranted for this specific RTR at this time.
Description of Planned EPA Tier 1 or Tier 2 Action

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

2. **RIN Number:** 2060-AT54

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

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

   On June 3, 2016, the Environmental Protection Agency (EPA) finalized the Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources (40 CFR part 60, subpart OOOOa). The EPA received five petitions for reconsideration on the 2016 OOOOa rule. By a letter dated April 18, 2017, the EPA announced the convening of a proceeding for reconsideration of certain provisions in the 2016 OOOOa rule. On June 5, 2017, the EPA granted reconsideration of additional requirements in that rule. The EPA has committed to broadly reviewing the whole rule during the reconsideration.


5. **Timetable:**

   The EPA anticipates that it will take a minimum of 2 years to complete the reconsideration.
   - NPRM, 2018
   - Final Rule, 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.

   The EPA is early in the process of developing a proposal, and has not yet determined the specific scientific products needed.

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

   See related response in 6(a) above.

   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 nature of the peer review intended. 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(c) above.
Recommendation from the SAB Work Group

Name of planned action: Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Reconsideration (2060-AT54)

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

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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 merits review by the SAB.

Rationale: EPA has previously published justification and promulgated this planned action that includes technical and economic assessment of possible compliance options expected to reduce emissions of greenhouse gases, including methane, and volatile organic compounds (VOCs) in the oil and natural gas industry (FR Vol. 81, No.107). The SAB considered the proposed Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources (RIN 2060–AS30) during the Chartered Science Advisory Board (SAB) Discussions of EPA Planned Agency Actions and their Supporting Science in the Fall 2014 Regulatory Agenda⁵. The SAB review considered proposed

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⁴ The Work Group finds there is potential for influential science products. The EPA notes it has not determined scientific products, the specific nature of the peer review intended and I informed the SAB that it does not envision this planned action relying on science that is an influential scientific or technical work product.

amendments to address remaining issues raised in the petitions and to correct technical errors that were inadvertently included in the final standards. Following publication of these final standards for the oil and natural gas sector and public comment including petitions for administrative reconsideration. After reviewing the technical white papers and receiving additional information, the Workgroup concluded that the EPA conducted expert and public input and in compiling all available information to identify the most important emissions activities and processes and the most efficient control techniques to minimize those emissions.

The SAB deferred consideration of a related rule, the Emission Guidelines for the Existing Oil and Natural Gas Sector (RIN 2060–AT29) in the Consideration of EPA Planned Actions in the Fall 2016 Unified (Regulatory) Agenda and their Supporting Science\(^6\). The SAB noted the agency has withdrawn the 2016 Information Collection Request (ICR) from the oil and gas industry; as a result, there was insufficient information to review and requested that the agency provide the SAB with more information about the scientific basis for this action as soon as that information became available. At that time, the SAB would determine whether it wishes to offer advice and comment to the Administrator.

At this time, the EPA has stated a broad commitment to reviewing the whole rule during the reconsideration of additional requirements in the rule. The scientific and technical basis for identifying and evaluating measures being reconsidered for methods to reduce emissions of greenhouse gases, including methane, and volatile organic compounds (VOCs) in the oil and natural gas industry has not been provided. The identification and use of influential scientific information or highly influential scientific information is not explained. Given that some time has elapsed since the rule-making processes for the Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Reconsideration, information regarding the scientific and technical basis for identifying alternative measures applicable to individual power plants may have changed.

The previous science reviewed by the SAB supported Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Reconsideration. Therefore, the Work Group recommends that the SAB review any new science and information being considered that might change the prior justification for the rule.

\(^6\) Science Advisory Board (SAB) Consideration of EPA Planned Actions in the Fall 2016 Unified (Regulatory) Agenda and their Supporting Science. Available at: https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/33B271F19A6D3AB485258168004C30C1/$File/EPA-SAB-17-007.pdf
Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Review of the Clean Power Plan

2. **RIN Number:** 2060-AT55

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

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

   On March 28, 2017, President Trump issued an Executive Order establishing a national policy in favor of energy independence, economic growth and the rule of law. This Executive Order specifically directs the EPA to review and, if appropriate, initiate reconsideration proceedings to suspend, revise or rescind the Clean Power Plan.

   In accordance with the Executive Order and his authority under the CAA, the EPA Administrator signed a Federal Register notice on March 28, 2017, announcing the EPA’s review of the rule and noting that if the EPA’s review “concludes that suspension, revision or rescission of this Rule may be appropriate, EPA’s review will be followed by a rulemaking process that will be transparent, follow proper administrative procedures, include appropriate engagement with the public, employ sound science, and be firmly grounded in the law.” “Review of the Clean Power Plan,” 82 FR 16329 (April 4, 2017).


5. **Timetable:**

   The EPA has begun the interagency review process of a proposed regulatory action resulting from its review of the rule. The EPA has transmitted a draft proposed rule to the Office of Management and Budget’s Office of Information and Regulatory Affairs (OIRA), consistent with the review procedures that are set forth in Executive Order 12866, 58 FR 190 (October 4, 1993).

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 scientific products were developed for the proposed 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).**

   See related response in 6(a) above.
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 too early in the process of developing a proposal, and has not yet determined the specific nature of the peer review intended. 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(c) above.
Recommendation from the SAB Work Group

Name of planned action: Review of the Clean Power Plan (RIN 2060-AT55)

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

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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 merits review by the SAB

Rationale: Planned Action 2060-AT55, which is with regard to the Clean Power Plan (CPP), is a proposal to rescind an existing rule on the premise that it exceeded authority under section 111 of the Clean Air Act. The EPA appears to be planning a replacement to the CPP. The Agency appears to be proposing that the determination of “best system for emission reduction” and the authority of section 111(d) should include only measures that can be applied directly to a source, with heat rate improvements as the only example given of such measures. This interpretation of section 111(d) is not necessarily consistent with case law or the perceived Congressional intent of the language of the Act. The meaning of “best system of emission reduction” is relevant to the consideration of science issues because it affects the scope of types of measures that might be applicable. Therefore, it pertains to the scope of scientific issues that should be considered. For example, systems of emission reduction that include averaging have been within the scope of section 111(d), such as averaging and trading programs for NOx emissions from existing municipal waste combustions. The scientific issues and basis for trading programs would be different than those used only for heat rate improvements. Furthermore, it is
unclear if the scope can or should include fuel switching, co-firing, repowering, or other measures that would affect operations at an individual plant such as derating or limiting load, either in or not in combination with averaging or demand side management programs. Additional measures applicable at a new plant could include co-firing, high-efficiency supercritical steam cycles, gasification combined cycle, partial or full carbon capture, and others.

The scientific and technical basis for identifying and evaluating measures including heat rate improvement, and other options that are applicable to individual plants, is not specified in the announcements of the planned actions. The identification and use of influential scientific information (ISI) or highly influential scientific information (HISI) is not explained nor defined.

EPA stated in their description of the proposed action that a draft proposed rule has already been transmitted to the Office of Management and Budget’s Office of Information and Regulatory Affairs (OIRA), but that “the EPA is too early in the process of developing a proposal, and has not yet determined the specific nature of the peer review intended.” Nonetheless, the Agency does “not envision this action relying on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product."” It is unclear how the Agency could have a draft proposed rule and not have determined the content of that proposal.

The Agency was asked to provide further details regarding what specific sources of new information will be used and how influential scientific information or highly influential scientific information will be properly vetted through a rigorous peer review process. The agency replied that public comments were being taken on “whether there are additional control measures and information beyond what was included in the original Clean Power Plan,” per an Announcement of Proposed Rulemaking issues published on December 28, 2017. The Agency response did not address whether the Agency would seek updated information on measures that were included in the original Clean Power Plan, nor regarding sources of such information, nor whether such information would be considered ISI or HISI, nor, if so, the nature of peer review procedures planned for ISI or HISI.

In the absence of information from the Agency, a presumption should be made that there have been updates to scientific and technical information for control measures that were included in the original CPP, and that additional measures may be identified, for which new ISI or HISA may be required. Given the potential significance of the CPP with regard to addressing GHG emissions that endanger public health and welfare, and the myriad of potential best systems of emissions reductions, further SAB attention to this matter is warranted. The SAB should consider this action for review.
Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Review of the Standards of Performance for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Generating Units

2. **RIN Number:** 2060-AT56

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

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

   On March 28, 2017, President Trump issued an Executive Order establishing a national policy in favor of energy independence, economic growth and the rule of law. This Executive Order specifically directs the EPA to review and, if appropriate, initiate reconsideration proceedings to suspend, revise or rescind the New Source Rule.

   Pursuant to the Executive Order, the EPA announced in a Federal Register notice dated April 4, 2017 (82 FR 16330), that it is initiating its review of the New Source Rule. If the EPA's review concludes that suspension, revision or rescission of the New Source Rule may be appropriate, the EPA's review will be followed by a rulemaking process that will be transparent, follow proper administrative procedures, include appropriate engagement with the public, employ sound science and be firmly grounded in the law.

   Hot Link: https://www.epa.gov/Energy-Independence.

5. **Timetable:** The schedule for this action has not been determined by the Administrator yet.

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 too early in the process of developing a proposal, and has not yet determined the specific scientific products needed.

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

   See related response in 6(a) above.

   **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 too early in the process of developing a proposal, and has not yet determined the specific nature of the peer review intended. 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(c) above.
Recommendation from the SAB Work Group

Name of planned action: Review of the Standards of Performance for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Generating Units (RIN 2060-AT56)

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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 merits review by the SAB.

Rationale: EPA may “suspend, revise or rescind” the “New Source Rule” referenced above as the “Standards of Performance for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Generating Units.”

In its April 4, 2017 Federal Register notice that announced Review of these standards, EPA stated that the Agency “will review whether this Rule or alternative approaches appropriately maintain the diversity of reliable energy resources and encourage the production of domestic energy sources to achieve energy independence and security.” This implies that scientific questions will arise regarding diversity of energy sources, reliability of energy sources, and capabilities to recover or utilize energy resources domestically. These types of analyses would be novel and may require review or development of methodology and collection and evaluation of data.
In the description of the proposed action, EPA stated “the EPA is too early in the process of developing a proposal, and has not yet determined the specific nature of the peer review intended.” They further stated, “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.” However, it is unclear how an a priori determination can be made regarding whether this planned action may require influential scientific information (ISI) or highly influential scientific information (HISI) if the Agency is “too early in the process of developing a proposal.” Furthermore, the scope of assessments needed regarding diversity of energy resources, reliability of energy resources, and domestic resources imply new analyses that were not part of the previous rule-making. Furthermore, the specific scope of technical issues to be addressed is not articulated, such as regarding what fuels, co-firing, firing, gasification, control, steam cycle, sequestration, and other options might form the basis of determination of best systems of emissions reduction. There is further complexity since this rule covers new, modified, and reconstructed facilities. The applicable range of options may differ depending on these stages of the plant life cycle.

Based on a fact-finding query to the Agency, the Agency indicated that it plans to issue a proposed revision to the final NSPS and will consider comments it receives on that proposal.” However, no further details were provided.

In the absence of information from the Agency, a presumption should be made that there have been updates to scientific and technical information for control measures that were included in the original “New Source Rule,” that additional measures may be identified, and that additional assessments will be needed regarding energy diversity, energy reliability, and domestic energy resources, for which new ISI or HISI may be required. Given the potential significance of the Rule with regard to addressing GHG emissions that endanger public health and welfare, and the myriad of potential best systems of emissions reductions, further SAB attention to this matter is warranted. Thus, the SAB should consider this action for review.
**Description of Planned EPA Tier 1 or Tier 2 Action**

1. **Name of action:** Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA

2. **RIN Number:** 2070-AK34

3. **EPA Office originating action:** Office of Chemical Safety and Pollution Prevention (OCSPP), Office of Pollution Prevention and Toxics (OPPT)

4. **Brief description of action and statement of need for the action:** Section 6(h) of the Toxic Substances Control Act (TSCA) directs EPA to issue regulations under section 6(a) for certain persistent, bioaccumulative, and toxic chemical substances that were identified in the 2014 update of the TSCA Work Plan. Section 6(h) further directs EPA, in selecting among the available prohibitions and other restrictions in TSCA section 6(a), to address risks of injury to health or the environment and reduce exposure to the chemical substances to the extent practicable. EPA must develop exposure and use assessments, but the statute explicitly states that a risk evaluation is not required for these chemical substances. EPA has identified five chemical substances that meet the statutory criteria in TSCA section 6(h) and that have not been designated as priorities for risk evaluation pursuant to TSCA section 6(h)(5). These chemical substances are: decabromodiphenyl ether; hexachlorobutadiene; pentachlorothiophenol; phenol, isopropylated phosphate (3:1), also known as tris(4-isopropylphenyl) phosphate; and 2,4,6-tris(tert-butyl)phenol.

5. **Timetable:** The statute directs EPA to propose TSCA section 6(h) regulations by June 22, 2019, and to issue regulations in final form no later than eighteen months after proposal.

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.**

   For each of the chemical substances that meet the criteria set forth in TSCA section 6(h)(1)(A), EPA is directed to determine whether exposure (under the conditions of use) is likely to the general population, or to a potentially exposed or susceptible subpopulation, or the environment, on the basis of an exposure and use assessment. Due to the timeframes established by the statute, as well as the fact that the purpose of the assessment is to determine the likelihood of exposure, EPA plans to use reasonably available information to complete the exposure and use assessments. The assessments will be qualitative to the extent that the available information is insufficient to permit quantitative assessments.

   **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).**

   EPA has developed preliminary use information for each of the five chemicals and has made the information available in a public docket.
The dockets are currently open for public comment. In addition, EPA hosted a public webinar to discuss these chemical substances and to specifically request use and exposure information from stakeholders.

EPA has also been in contact with other federal, state, and local agencies, such as the Department of Defense, the Consumer Products Safety Commission, and the State of California, to inform them of our regulatory activities and to request assistance in identifying potentially-relevant data sources.

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

The exposure assessments for the five chemical substances that will be conducted under TSCA section 6(h) may be influential scientific information (ISI), and therefore OPPT is developing a plan for peer review of the individual assessments and/or underlying methodologies. These assessments will be used to support a rulemaking under TSCA section 6(h) that will reduce exposure to the subject chemical substances to the extent practicable.

6(d). Peer review: A peer review is planned, the form and particulars have yet to be determined.
Recommendation from the SAB Work Group

**Name of planned action:** Name of action: Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA (RIN 2070-AK34)

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

<table>
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<td>X³</td>
<td></td>
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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.

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

**Recommendation:** The Work Group found that there is insufficient information to determine if the SAB should provide advice on this planned action. At this time, it is not known what information base is available for the five chemical compounds, nor the particulars of the peer review process. EPA is developing a plan and has indicated letter peer review will be used. Thus a final recommendation should await this timeline and any updated information that may be provided.

**Rationale:** EPA is directed under the Toxic Substances Control Act (TSCA) to issue regulations under section 6(a) for certain persistent, bioaccumulative, and toxic chemical substances. The particular targeted compounds were identified in the 2014 update of the TSCA Work Plan. EPA is further directed to address risks of injury to health or the environment and to reduce exposure to the chemical substances to the extent practicable. Although EPA is called upon to develop exposure and use assessments, a risk evaluation is not required by statute.

³ The Work Group finds there is potential for influential science products. The EPA notes it has not determined scientific products, the specific nature of the peer review intended and informed the SAB that the planned action may rely on science that is an influential scientific or technical work product.
EPA has identified five chemical substances that meet the statutory criteria in TSCA and that have not been designated as priorities for risk evaluation. These chemical substances are: decabromodiphenyl ether; hexachlorobutadiene; pentachlorothiophenol; phenol, isopropylated phosphate (3:1), also known as tris(4-isopropylphenyl) phosphate; and 2,4,6-tris(tert-butyl)phenol.

The EPA created a summary of the available information for each of the chemicals and opened a docket requesting use information. The dockets closed on January 9, 2018. EPA is required to evaluate that information and propose regulations to reduce exposure to the extent practicable for these chemical substances by June 19, 2019.

Due to the timeframes established by the statute, as well as the fact that the purpose of the assessment of these chemicals is to determine the likelihood of exposure, EPA plans to use reasonably available information to complete the exposure and use assessments. Depending on the available information base the assessments may be qualitative or quantitative. The assessments are intended to support rulemaking under TSCA section 6(h) in order to reduce exposure to the extent practicable.

In response to questions from the Work Group the agency responded that it anticipates conducting two letter peer reviews, one for an exposure and use assessment and one for the document that describes the hazard. (See attachment C)

The Work Group notes that the SAB previously reviewed planned actions for several specific TSCA chemicals using these methods and peer review approaches and found the approach to be scientifically sound and did not recommend further review for the *Trichloroethylene (TCE); Rulemaking Under TSCA Section 6(a) and N-Methylpyrrolidone (NMP) and Methylene Chloride; Rulemaking Under TSCA Section 6(a) action* included in the Spring 2015 Unified Agenda. The Work Group recommends that the SAB urge EPA to retain and improve the TSCA peer review process to assess the adequacy of guidance documents related to risk evaluations. The SAB also notes that two TSCA actions were included in the Fall 2016 Unified agenda. In previous reviews of the regulatory agenda, the SAB found the TSCA proposed methods for evaluation and peer review panels to be scientifically sound and did not recommend further review. However, the SAB urged EPA to retain and improve the transparent peer review process used for specific chemicals evaluated under TSCA, and further encouraged the EPA to continue assessing the adequacy of guidance documents and improving the processes related to TSCA risk evaluations with input from the SAB or Science Advisory Committee on Chemicals.

The Work Group also notes that the exposure assessments for the five chemical substances may be influential scientific information and trigger more rigorous peer review needs as outlined in the EPA Peer Review Handbook.

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8 SAB Discussions about EPA Planned Actions in the Spring 2015 Unified Agenda and their Supporting Science available at: [https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/0e748503053ede625257e6e0069bc5c?OpenDocument&TableRow=2.3#2](https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/0e748503053ede625257e6e0069bc5c?OpenDocument&TableRow=2.3#2).


Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Review of Pesticides; Certification of Pesticide Applicators

2. **RIN Number:** 2070-AK37

3. **EPA Office originating action:** Office of Chemical Safety and Pollution Prevention, Office of Pesticide Programs

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

   EPA’s Certification of Pesticide Applicators rule (certification rule), 40 CFR Part 171, sets federal standards for states, tribes and federal agencies to administer programs to certify applicators of restricted use pesticides (RUPs). The certification rule establishes minimum standards of competency for pesticide applicators that apply or supervise the use of RUPs, covering private and commercial applicators, and those using RUPs under their direct supervision. The certification programs are conducted by pesticide lead agencies in states, territories, tribes and federal agencies. The certification rule has been in place since 1974; a revised rule was issued in the Federal Register on January 4, 2017 (82 FR 952).

   EPA has delayed the effective date of this final rule and initiated reconsideration proceedings in accordance with the Presidential directives as expressed in the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled "Regulatory Freeze Pending Review," and the principles identified in Executive Order 13790, entitled "Promoting Agriculture and Rural Prosperity in America.” In addition, per Executive Order 13777, EPA solicited comments this spring on regulations that may be appropriate for repeal, replacement or modification as part of the Regulatory Reform Agenda efforts. EPA received comments specific to the certification rule.

   If EPA’s efforts identify a need for changes to the certification rule, EPA will investigate the need for making changes to the rule.

   Note, the extension of the certification rule’s effective date from March 6, 2017 to May 22, 2018, is under legal challenge. No additional information can be provided at this time.

5. **Timetable:** TBD

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 scientific work products have been developed or are anticipated to be developed to inform decisions regarding the planned action.

   FIFRA requires the Office of Pesticide Programs to provide copies of proposed rules to the FIFRA Scientific Advisory Panel (SAP) for review of any scientific issues related to a proposed
rule. In a related RIN, 2070-AJ20, EPA’s FIFRA SAP considered whether to review the actions and waived its review of the proposed rule on September 4, 2014, and the final rule on August 15, 2016, because the proposed revisions were administrative in nature and did not contain scientific issues that required the SAP’s consideration. Therefore, OPP did not prepare any scientific or technical documents to support the proposed or final certification rules.

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).

N/A

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?”

N/A

6(d). Peer review:

N/A
Recommendation from the SAB Work Group

Name of planned action: Review of Pesticides; Certification of Pesticide Applicators (2070-AK37)

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

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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:** In the current context this action does not merit further SAB consideration. If EPA identifies a need for changes to the certification rule SAB review may be warranted.

**Rationale:** EPA issued a revised Certification of Pesticide Applicators rule in the Federal Register on January 4, 2017 (82 FR 952) in place of the rule that has been in place since 1974. The revised EPA Certification of Pesticide Applicators rule (certification rule), 40 CFR Part 171, sets federal standards for states, tribes and federal agencies to administer programs to certify applicators of restricted use pesticides (RUPs). The effective date of the final rule was originally March 6, 2017, but this date has been extended to May 22, 2018 as EPA reconsiders the rule under the Presidential directives expressed in the “Regulatory Freeze Pending Review” and the “Promoting Agriculture and Rural Prosperity in America” memoranda. EPA specifically received comments on this certification rule in response to a solicitation on regulations that may be appropriate for repeal, replacement or modification per Executive Order 13777. If EPA’s efforts identify a need for changes to the certification rule, EPA will investigate

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11 In a related RIN, 2070-AJ20, EPA’s FIFRA SAP considered whether to review the actions and waived its review of the proposed rule on September 4, 2014, and the final rule on August 15, 2016, because the proposed revisions were administrative in nature and did not contain scientific issues that required the SAP’s consideration.
the need for making changes to the rule. The extension is currently under legal challenge with an undetermined timeline.

No scientific work products have been developed or are anticipated to be developed to inform decisions regarding the planned action, thus there is no legal or statutory obligation to conduct a peer review.

EPA’s FIFRA SAP did consider whether to review the actions and waived its review of the proposed rule on September 4, 2014 and the final rule on August 15, 2016, because the proposed revisions were administrative and did not contain scientific issues that required SAP consideration. For these reasons OPP did not prepare scientific documents to support the proposed or final rule.
The Science Advisory Board Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science held a fact-finding teleconference on February 16, 2018. EPA offices were provided questions to clarify and seek additional information on the planned actions in the Spring 2017 Semi-Annual Regulatory Agenda published on July 20, 2018.

The Work Group submitted questions to the Office of Air and Radiation, Office of Chemical Safety and Pollution Prevention and the Office of Water. The questions and responses are provided below. Attendees were:

- Ms. Mindy Eisenberg, Office of Water
- Mr. Michael McDavit, Office of Water
- Ms. Sandy Evalenko, Office of Water
- Members of the Work Group
- Thomas Carpenter, DFO, SAB Staff Office

Questions for the Office of Air and Radiation

Review of the Clean Power Plan (RIN 2060-AT55) and Review of Standards of Performance for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Generating Units. (2060-AT56)

EPA has announced the following two planned actions: 2060-AT55 Review of the Clean Power Plan, and 2060-AT56 Review of Standards of Performance (commonly known as New Source Performance Standards) for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Generating Units. These will be referenced as CPP and NSPS, respectively.

Planned Actions 2060-AT55 and 2060-AT56 are similar in that the Agency proposes to rescind both rules on the premise that they exceed authority under section 111 of the Clean Air Act. However, the planned actions differ in that EPA appears to be planning a replacement to the CPP but appears to not be planning a replacement to the NSPS. With regard to the Clean Power Plan, for example, the Agency proposes that the determination of best system for emission reduction should include only measurements that can be applied directly to a source. Similarly, with regard to the standards of performance (commonly known as New Source Performance Standards) for greenhouse gas emissions from EGUs, EPA has announced that it "proposes to withdraw these standards on grounds that they exceed the statutory authority provided under section 111 of the Clean Air Act." EPA has indicated that the CPP may be revised, but has indicated that the NSPS will simply be rescinded.

However, the EPA has previously published justification for these rules that includes technical and economic assessment of possible compliance options that are applicable to individual power plants. These assessments include measures that can be applied directly to a source that go beyond "improving heat rate" and include, for example, the use of partial carbon capture and
sequestration. There are myriad options that can be applied at an existing power plant, such as repowering, co-firing, fuel switching, and others, or at a new power plant, such as use of high efficiency supercritical steam cycles, co-firing, and others.

The scientific and technical basis for identifying and evaluating measures including heat rate improvement, and other options that are applicable to individual plants, is not specified in the announcements of the planned actions. The identification and use of influential scientific information or highly influential scientific information is not explained. Given that some time has elapsed since the rule-making processes for the Clean Power Plan and for the Standards of Performance for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Generating Units, information regarding the scientific and technical basis for identifying alternative measures applicable to individual power plants may have changed. Furthermore, there may be options applicable to individual plants that have yet to be considered by the Agency.

Can the Agency provide further details regarding what specific sources of new information will be used and how influential scientific information or highly influential scientific information will be properly vetted through a rigorous peer review process?

Agency Response: The Agency is taking comment on whether there are additional control measures and information beyond what was included in the original Clean Power Plan in an Announcement of Proposed Rulemaking issued on December 28, 2017 (82 FR 61507).

With regard to the NSPS for greenhouse gas emissions from EGUs, and in light of the 2009 endangerment finding (https://www.epa.gov/ghgemissions/endangerment-and-cause-or-contribute-findings-greenhouse-gases-under-section-202a-clean), and the 2007 decision of the U.S. Supreme Court that greenhouse gases are air pollutants covered by the Clean Air Act, is EPA planning to replace the Standards of Performance for Greenhouse Gas Emissions From New, Modified, and Reconstructed Stationary Sources: Electric Generating Units with a revised rule, or simply to rescind the rule without replacement?

Agency Response: The Agency plans to issue a proposed revision to the final NSPS and will consider comments it receives on that proposal.

Review of the 2016 Oil and Gas New Source Performance Standards for New, Reconstructed, and Modified Sources (RIN 2060-AT54)

EPA has previously published justification and promulgated this planned action that includes technical and economic assessment of possible compliance options expected to reduce emissions of greenhouse gases, including methane, and volatile organic compounds (VOCs) in the oil and natural gas industry (FR Vol. 81, No.107). The SAB considered the proposed Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources (RIN 2060–AS30) during the Chartered Science Advisory Board (SAB) Discussions of EPA Planned Agency Actions and their Supporting Science in the Fall 2014 Regulatory Agenda⁴. The SAB review considered proposed amendments to

⁴ See the discussions for the Oil and Natural Gas Sector: Reconsideration of Remaining Provisions of New Source Performance Standards (2060- AS30). Available at:
address remaining issues raised in the petitions and to correct technical errors that were inadvertently included in the final standards. Following publication of these final standards for the oil and natural gas sector and public comment including petitions for administrative reconsideration. After reviewing the technical white papers and receiving additional information, the Workgroup concluded that the EPA conducted expert and public input and in compiling all available information to identify the most important emissions activities and processes and the most efficient control techniques to minimize those emissions.

The SAB deferred consideration of related rule the Emission Guidelines for the Existing Oil and Natural Gas Sector (RIN 2060–AT29) in the Consideration of EPA Planned Actions in the Fall 2016 Unified (Regulatory) Agenda and their Supporting Science2. The SAB noted the agency has withdrawn the 2016 Information Collection Request (ICR) from the oil and gas industry; as a result, there is insufficient information to review and requested that the agency provide the SAB with more information about the scientific basis for this action as soon as that information becomes available. At that time, the SAB will determine whether it wishes to offer advice and comment to the Administrator.

Regarding the Review of the 2016 Oil and Gas New Source Performance Standards for New, Reconstructed, and Modified Sources (RIN 2060-AT54), can the EPA provide further details regarding what specific sources of new information will be used and how influential scientific information or highly influential scientific information will be properly vetted through a rigorous peer review process?

Response: The review of the rule is a limited reconsideration building off of the information in the original rule as well as information submitted by commenters generally focused on implementation issues. We do not anticipate using new influential scientific information in this action.

Questions for the Office of Chemical Safety and Pollution Prevention

Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h) Long-Term Actions (RIN 2070-AK34)

EPA notes that the exposure assessments for the five chemical substances identified in the Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA (RIN 2070-AK34) may be influential scientific information. The Workgroup notes that dockets for decabromodiphenyl ether; hexachlorobutadiene; pentachlorothiophenol; phenol, isopropylated phosphate (3:1), also known as tris(4-isoproplyphenyl) phosphate; and 2,4,6-tris(tert-butyphenyl)phenol have been created and the agency is currently seeking public comment.

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2 Science Advisory Board (SAB) Consideration of EPA Planned Actions in the Fall 2016 Unified (Regulatory) Agenda and their Supporting Science. Available at: https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/33B271F19A6D3AB485258168004C30C/$File/EPA-SAB-17-007.pdf
The SAB previously reviewed planned actions being developed under TSCA in the consideration of the EPA Planned Actions in the Spring 2015 Unified (Regulatory) Agenda and their supporting Science\(^3\). In the reviews of trichloroethylene, N-methyl pyrrolidone, methylene chloride the SAB noted that the publicly available information, including peer review, facilitated the Board’s review of the actions and provides a strong basis for future consideration of actions developed under the Toxic Substances Control Act and encouraged “the agency to continue to use the results from research programs and the TSCA evaluations to identify risk management alternatives that include safer chemicals and greener processes and technologies.”

Will the Office of Chemical Safety and Pollution Prevention (OCSPP) use a peer review process similar to those previously reviewed by the SAB?

Does OCSPP anticipate conducting peer review by the Scientific Advisory Committee on Chemicals, contractor led panel peer reviews or letter peer reviews?

**Agency Response:** In an email OCSPP noted relative to the Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h) (RIN 2070-AK34) that the nature of a planned peer review is under management discussion. We may be able to provide you with more information after February 26th.

OCSPP staff later informed the Designated Federal Officer through email that OCSPP anticipates conducting two letter peer reviews, one for an exposure and use assessment and one for the document that describes the hazard.

**Questions for the Office of Water**

**Second Action: Definition of Water of the U.S.: (RIN 2040-AF75)**

A significant amount of time and effort has gone into determining the connectivity of different water bodies to downstream navigable waters. The science related to that connectivity has been well documented with well over hundreds of journal articles and technical reports. The EPA SAB has commented on the importance of this action\(^4\), reviewed the scientific report and the synthesis\(^5\) that was

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\(^3\) Preparations for the Chartered Science Advisory Board discussions of EPA Planned Actions in the Spring 2015 Regulatory Agenda see Page B-17 through B-26. Available at: https://yosemite.epa.gov/sab/sabproduct.nsf/F35852E8FE33175A85257EB600565D91/$File/SAB+Work+Group+Recom mendations+Spring+2015+Reg+Agenda.pdf

Science Advisory Board Consideration of the EPA Planned Actions in the Spring 2015 Unified (Regulatory) Agenda and their supporting Science. Available at: https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/0e748503053ede6285257e6e0069bc5cOpenDocument

\(^4\) Preparations for Chartered Science Advisory Board (SAB) March 8, 2013 Discussions of EPA Planned Agency Actions and their Supporting Science (see page 84 of attachment C. regarding review of the Connectivity /CWR search clean water protection Rule).

https://yosemite.epa.gov/sab/sabproduct.nsf/ACD08EC935BE248E85257B1E0066F5EC/$File/SAB+WG+Chair+memo-EPA+plnd+actns++supp+sci_Redactedv2.pdf

\(^5\) Connectivity of Streams and Wetlands to Downstream Waters: A Review and Synthesis of the Scientific Evidence.
performed by the EPA in trying to document this extensive literature. In that effort the SAB provided additional information and synthesis for the EPA to consider and include in that report to support the rule. Lastly, under the SAB’s authorizing statute, the Environmental Research, Development and Demonstration Authorization Act of 1978, the SAB provided the Administrator its advice and comments on the adequacy of the scientific and technical basis of the proposed rule.\(^6\)

The planned action does not define “relatively permanent” with respect to waters of the United States. Does the EPA anticipate (1) explicitly defining what makes a water feature “relatively permanent” and (2) including climate variability (such as past and future droughts) as part of the definition?

The planned action does not define “geographic features” with respect to water of the United States. Does the EPA anticipate explicitly defining “geographic features”?

The planned action does not define what a clear demarcation is between “waters” and wetlands. Does the EPA anticipate explicitly defining this demarcation?

The planned action does not define the landward edge of wetland. Does the EPA anticipate explicitly defining the landward edge of a wetland?

**Agency Response:** Office of Water staff stated that, overall, EPA has not determined which terms in the questions may be included and defined to provide clarity in the proposed rule for Second Action: Definition of Water of the U.S.: (RIN 2040-AF75). EPA noted that they have engaged in outreach with states, tribes, and the regulated community. The agency also opened a docket for public comments on factors that should be considered in the review. Staff are currently reviewing this information and developing options.

One member of the Work Group asked if there was any additional information on the schedule for the notice of proposed rulemaking (NPRM)?

**Agency Response:** EPA responded that the agency is working to publish the NPRM in 2018.

One member asked if the planned action addressed aquifers?

**Agency Response:** EPA responded that the statute is limited to surface water and not ground water.

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\(^6\) “Definition of ‘Waters of the United States’ Under the Clean Water Act” - Advice and comment on science supporting the EPA’s proposed rule.