MEMORANDUM

TO: Members of the Chartered SAB and SAB Liaisons

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

DATE: November 1, 2016

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

The Chartered SAB will discuss whether to review the adequacy of the science supporting planned regulatory actions identified by the EPA as major actions in the Spring 2016 semi-annual regulatory agenda at its November 30 – December 1, 2016 meeting. To support this discussion an SAB Work Group was charged with identifying actions for further consideration by the Chartered SAB. This memorandum provides background on this activity, a short description of the process for identifying actions for SAB consideration, a summary of the process used by the Work Group and Work Group recommendations on the planned actions.

Background

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

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

Summary of the Process Used by the SAB Work Group

The SAB Work Group followed the process adopted by the Chartered SAB in 2013[1] to initiate its review of major planned actions identified in the Unified Regulatory Agenda by EPA. The current SAB review began when the EPA Office of Policy informed the SAB Staff Office that the Spring 2016

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

Unified (Regulatory) Agenda and Regulatory Plan had been published on May 18, 2016. This semi-annual regulatory agenda is available at http://www.reginfo.gov/public/.

This SAB Work Group was formed in June 2016 and includes SAB members with broad expertise in scientific and technological issues related to the proposed actions. The Work Group consists of Drs. Charles J. Werth (chair), H. Christopher Frey, Kimberly Jones, Denise Mauzerall, Keith Moo Young, Surabi Menon, and Mr. Richard Poirot.

On July 18, 2016, the Work Group received information and short descriptions from the EPA Program Offices on the major planned actions that are listed in the Spring 2016 semi-annual regulatory agenda but not yet proposed. On August 23, 2016, the Work Group held a fact finding call to discuss the additional information provided by the Office of Air on the four National Emission Standards for Hazardous Air Pollutants (NESHAP) undergoing a Risk and Technology Review (RTR). The Designated Federal Officer facilitated the teleconference. Work Group members concurred on the recommendations presented in this memorandum via email. A compiled set of the EPA descriptions of the actions and the Work Group's recommendations are provided in Attachment B. Attachment C is a summary of fact finding.

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 eight major planned actions considered, the Work Group recommends that none of the actions merit further SAB consideration.

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

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

Two actions in the regulatory agenda, Polychlorinated Biphenyls (PCBs): Reassessment of Use Authorizations for PCBs in Small Capacitors (RIN: 2070-AK12) and Trichloroethylene (TCE):

Rulemaking under TSCA Section 6(a); Vapor Degreasing (RIN: 2070-AK11), will propose parts of actions considered by the SAB in previous reviews of the semi-annual regulatory agendas (Spring 2013 and 2015 respectively). In response to questions from the Work Group, the agency noted that both of these actions address issues previously presented to the SAB and no new issues are addressed in the current actions. While the rationale for narrowing the rulemakings is not clear, the EPA responses indicate that no new components outside of what was previously reviewed are being considered. Therefore, these actions do not merit further SAB review.

The two remaining actions are categorized as administrative and contain no new science. The first, Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area Classifications and State Implementation Plan Requirements, provides necessary updates to the existing implementing regulations for the ozone National Ambient Air Quality Standards (NAAQS), to address the strengthened 2015 ozone NAAQS which were issued on October 1, 2015. The second, Clean Energy Incentive Program (CEIP) Design and Implementation, provides details on design of the CEIP, as well as plans for stakeholder outreach. The details provide clarifications regarding project eligibility, including expanding eligibility to solar energy project in low-income communities, providing states with the flexibility to choose one or more existing definitions of low-income community, and show how CEIP incentives could be made available to eligible renewable energy and energy efficiency project providers.

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

Table 1: Summary of Proposed Actions that the SAB Work Group Considered for Additional SAB Comment on the Supporting Science

RIN[2]	Planned Action Title	Workgroup Recommendation
2060-AS82	Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area Classifications and State Implementation Plan Requirements	No further SAB consideration is merited.
2060-AS85	National Emission Standards for Hazardous Air Pollutants: Publicly Owned Treatment Works Risk and Technology Review	No further SAB consideration is merited.
2060-AS46	Risk and Technology Review for National Emission Standards for Hazardous Air Pollutants From the Pulp and Paper Combustion Sources	No further SAB consideration is merited.
2070-AK11	Trichloroethylene (TCE); Rulemaking Under TSCA Section 6(a); Vapor Degreasing	No further SAB consideration is merited.

Table 1: Summary of Proposed Actions that the SAB Work Group Considered for Additional SAB Comment on the Supporting Science		
RIN[2]	**Planned Action Title**	**Workgroup Recommendation**
2070-AK12	Polychlorinated Biphenyls (PCBs); Reassessment of Use Authorizations for PCBs in Small Capacitors	No further SAB consideration is merited.
2060-AS81	National Emission Standards for Hazardous Air Pollutants for Coke Ovens: Pushing, Quenching, and Battery Stacks	No further SAB consideration is merited.
2060-AS84	Clean Energy Incentive Program Design and Implementation	No further SAB consideration is merited.
2060-AS92	Portland Cement Risk and Technology Review	No further SAB consideration is merited.

[2]The Regulatory Identification Number provides a hyperlink to the Office of Management and Budget's webpage and information on the planned action provided in the Unified Regulatory Agenda on the OMB website http://www.reginfo.gov/

Attachments

Attachment A: Implementation Process for Identifying EPA Planned Actions for SAB Consideration
Attachment B: Summary of Work Group fact finding and questions sent to the Office of Air
Attachment C: SAB Work Group Recommendations on Major EPA Planned Actions Identified in the Spring 2016 Semi-Annual Regulatory Agenda.

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

Background on the EPA Process

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

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

SAB Process

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

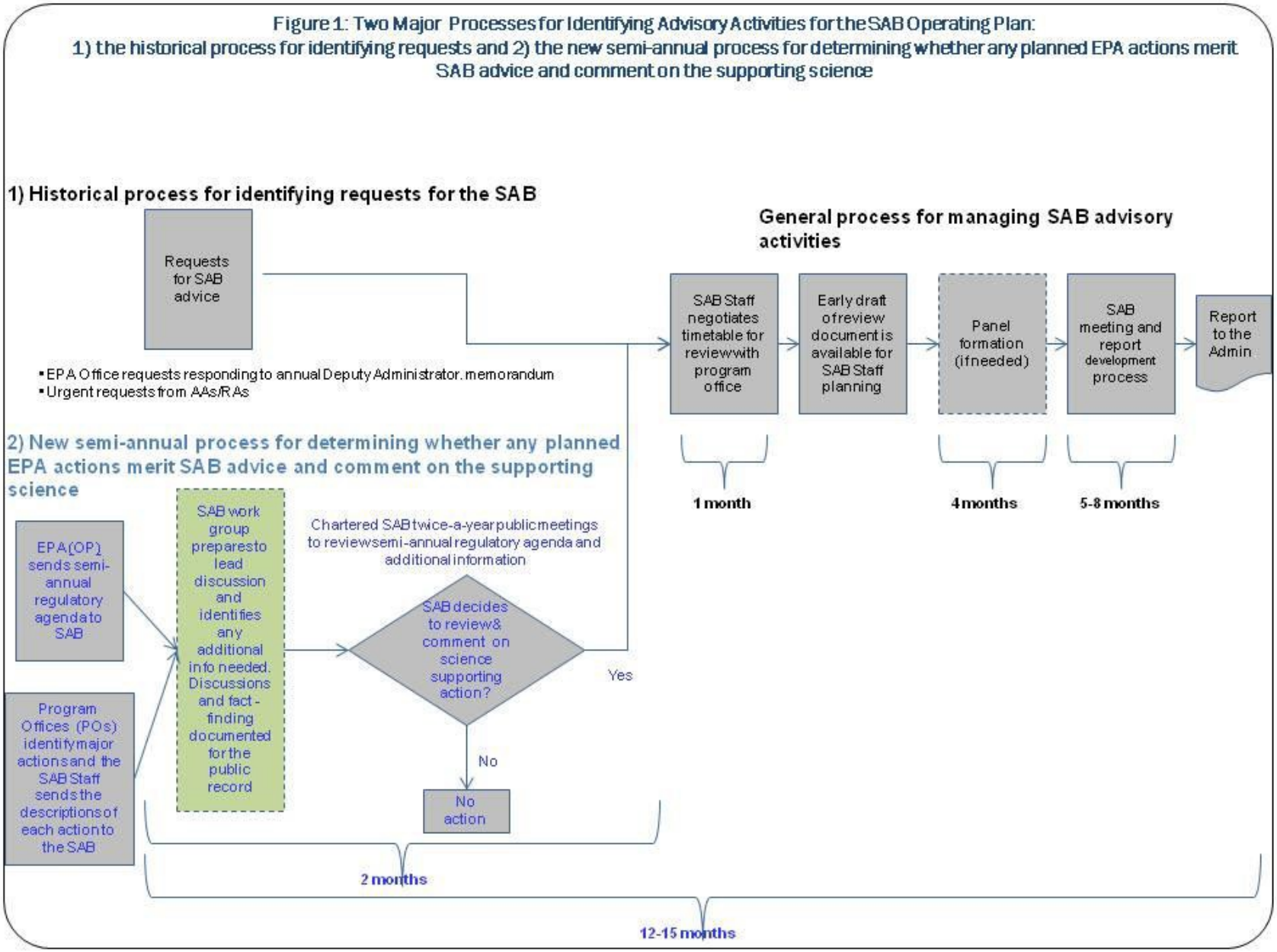
Figure 1: Two Major Processes for Identifying Advisory Activities for the SAB Operating Plan:
1) the historical process for identifying requests and 2) the new semi-annual process for determining whether any planned EPA actions merit SAB advice and comment on the supporting science
1) Historical process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

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

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 55--NATIONAL ENVIRONMENTAL POLICY

SUBCHAPTER III--MISCELLANEOUS PROVISIONS

Sec. 4365. Science Advisory Board

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(g) Consultation and coordination with Scientific Advisory Panel

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

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

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE AOMINISTRATOR

MEMORANDUM

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

FROM: Michael Goo, Associate Administrator
Office of Policy

Glenn Paulson
Science Advisor

VanessaVu,Director
SAB Staff Office

TO: General Counsel
Assistant Administrators
Associate Administrators
Regional Administrators

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

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

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

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

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

Attachments

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

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

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

JAN 19 2012

OFFICE OF POLICY

MEMORANDUM

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

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

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

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

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

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

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

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

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

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

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

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

EPA Office originating action: OW

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

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

Timetable:

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

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

No

Scientific questions to be addressed and approach:

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

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

Plans for scientific analyses and peer review:

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

Attachment B
Summary of Science Advisory Board Work Group
Fact Finding on EPA Planned Action in the
Spring 2016 Regulatory Agenda

November 1, 2016

Introduction

The Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science was formed to provide the Chartered SAB with recommendations on the actions in the Spring 2016 semi-annual regulatory agenda provided by the Agency on May 18, 2016. The chartered SAB will consider these recommendations as it determines whether it will provide "advice and comments on the adequacy of the scientific and technical basis" of agency actions, consistent with the requirements of the Environmental Research Development and Demonstration Authorization Act (ERDDAA).

On July 18, 2016 the Work Group received short descriptions from the EPA Program Offices on the major planned actions that are not yet proposed listed in the Spring 2016 semi-annual regulatory agenda. The Work Group exchanged comments via email and requested additional information from the EPA through the Designated Federal Officer. The Work Group met with EPA staff on August 23, 2016 to discuss the questions and the Agency's responses on the four Risk and Technology Reviews (RTR) in the agenda. The questions and responses are provided in this attachment.

August 23, 2016 Discussion

Members noted that EPA and SAB are planning a review of recently enhanced screening methodologies and that those methodologies will be described in a document titled: Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis. Members then asked if the agency staff could elaborate on the timeline for that review. Members also asked about the schedule for two rules that will be proposed, and possibly finalized, before the review of recently enhanced screening methodologies is completed.

EPA Staff noted that two actions: The National Emission Standards for Hazardous Air Pollutants: Publicly Owned Treatment Works Risk and The National Emission Standards for Hazardous Air Pollutants: Pulp Mill Combustion Sources Subpart MM source category are under court order deadlines to propose in 2016 and finalize the actions in 2017. They noted that the planned peer review of the recently enhanced screening methodologies could begin in early 2017. EPA staff further noted that public comments on these proposals would be considered as EPA staff work on the final rules for these source categories.

EPA staff explained that when the RTR program was designed, periodic review of RTR analytical methods by the SAB was anticipated. They noted since there are 170 source or sector categories, it would be more efficient for the agency to periodically have its RTR risk assessment methodology reviewed by SAB and then applied to individual source categories, rather than having each individual RTR source category reviewed by SAB.

One Work Group member asked if the revisions and refinements in the screening methodologies were used in the planned actions in the regulatory agenda RTRs with 2017 deadlines.

EPA Staff noted that the multipathway RTR screening methodology has three-tiers, but sometimes only one or two tiers is needed to eliminate the potential for multipathway risk. For example, if potential multipathway risk from a source category's emissions is estimated to be negligible following the tier 1 screen, there would be no reason to progress to the more sophisticated tier 2 and tier 3 screens. EPA further noted that the risk assessment and preamble for a given rule would explain whether or not emissions from a source category "screened out" with respect to potential for multipathway risk, and if so, at which tier of the multipathway screen.

Work Group members asked about the process the EPA uses to evaluate new technologies. Agency staff noted that these are conducted under the Clean Air Act Section 112(d)(6), also known as D6 technology reviews. The analysis reviews the MACT standard to determine if there have been developments in processes, practices or technologies are available and whether the MACT rule should be revised to reflect those developments. However, EPA staff emphasized that industries are not typically required to use a specific technology. Rather, the EPA establishes an emission level based on the available technologies and the facilities can comply with those emissions levels by using the referenced technology or any other means that accomplish a similar degree of emissions control. The rules do not require a specific technology, they set an emission standard that the industry/facility must meet. Staff described that the process the agency uses includes stakeholder interviews, literature searches, information collection requests, site visits and other approaches to gather and analyze emission data and other relevant information to evaluate the available technologies and achievable emissions.

One Work Group member summarized that the RTR process is undergoing continual revision and refinement. There have been refinements in the process since the SAB 2009 and those enhancements were available for public comment when the RTRs were proposed. He further noted that the periodic review of the methodology seems appropriate. The EPA staff agreed with that summary and noted that small changes are periodically made to the RTR process and when those small changes add up to an appreciable change in risk methodology the EPA initiates a review.

SAB Questions Related to EPA's RTR Methods

1. Would it be possible to get a bit more detail about the proposed SAB review of the RTR methodology in 2017?

EPA Response: Periodically, we request that the SAB review the methods that we use to estimate risk during Risk and Technology Reviews (RTR) as these methods evolve, or as new methods are developed. We are planning on having such a review in early 2017. An SAB panel will be charged with reviewing a draft report (estimated to be completed late 2016) that describes newly enhanced screening methods designed to estimate the potential risks to public health and the environment that would remain after stationary sources of hazardous air pollutants (HAP) come into compliance with EPA's MACT standards. These include screening methods to estimate the potential for multi-pathway risks (i.e., ingestion risk) from persistent and bioaccumulative HAP (see #2 below), screening methods to estimate potential environmental risks, and recent

enhancements to the inhalation risk assessment methodology. The SAB Staff Office is forming an expert panel under the auspices of the Chartered SAB to conduct this review.

2. Are the current RTRs based on the 2009 version of the RTR methodology, or are there new methodology components in the proposed rules and long-term actions?

EPA Response: Our risk assessment methodology is continually improving, and as enhancements are made, these methods are used in RTR reviews. Thus, some of the enhanced screening methods described above have been used in recently completed RTR reviews, and are being used in current RTR reviews. We consider these enhanced screens to be methodological improvements that are responsive to SAB recommendations made during previous RTR methods reviews. For example, an SAB panel previously reviewed a multipathway screening method that had the goal of quickly and cost effectively identifying facilities that may need a complete multipathway risk assessment using the TRIM model. In practice however, we found that the assumptions in this original screening method were so conservative that potential risk for individual facilities was being overestimated by a wide margin. To address this issue, we have since the last SAB review of RTR methods enhanced our multipathway screening approach by using a combination of location specific data for some of the more highly influential inputs (i.e., inputs that had the most impact on potential risk), along with conservative defaults for the remaining inputs. The result is a screening method that provides a more realistic estimate of potential multipathway risk. This enhanced approach is one of the screening methods that we would like the SAB to comment on during the 2017 review.

3. Do the current RTRs contain any rule specific information (e.g., new MACT technologies, new monitoring technologies) outside of the general RTR methodology that is considered or based on new scientific knowledge of methodologies? If so, has it undergone peer review?

EPA Response: As required under the Clean Air Act, the RTR rules set standards at the level needed to ensure that risks from a source category are acceptable and that the standards provide an ample margin of safety to protect public health. Facilities can meet those levels using whatever practices, processes, or emission control technologies they choose. As such, EPA does not typically specify what technologies must be used. Regarding monitoring technologies, EPA relies primarily on standard testing and monitoring methodologies that are well-established. While the recent petroleum refineries and ferroalloys RTR rules included new fenceline monitoring and digital camera opacity monitoring approaches, the science of those approaches is well-established and their application was tailored to the regulated industries. We plan to continue to evaluate each rule to determine what testing and monitoring should be required to ensure compliance and, if novel approaches such as fenceline monitoring or digital camera opacity monitoring are appropriate, we will work with monitoring experts to design programs on a rule-specific basis. We are not aware, at this time, of any new scientific knowledge or methodologies that would be incorporated.

Participants
SAB Work Group
Dr. Charles Werth
Dr. Kim Jones
Mr. Rich Poirot
Dr. Surabi Menon
Dr. Keith Moo-Young

EPA Staff
Dr. Michael Stewart. Office of Air and Radiation
Ms. Kelly Rimer, OAR
Mr. Brian Shrager, OAR
Mr. Charles French, OAR

Mr. Thomas Carpenter, SAB Staff Office
Designated Federal Officer

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

November 1, 2016

On July 18, 2016, the Work Group received short descriptions from the EPA Program Offices on the major planned actions that are not yet proposed and are newly listed in the May 18, 2016 semiannual regulatory agenda. The Work Group reviewed the information and researched the planned actions, identified questions for additional information about some of the planned actions, and developed draft recommendations. This document provides the EPA descriptions, recommendations developed by the Work Group on the planned actions and the rationale supporting the recommendations.

[1] The Regulatory Identification Number provides a hotlink to the Office of Management and Budget's webpage and information on the planned action provided in the Regulatory Agenda.

EPA Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area Classifications and State Implementation Plan Requirements

2. **RIN Number:**
   2060-AS82

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

4. **Brief description of action and statement of need for the action:**
   This proposed rulemaking will provide necessary updates to the existing implementing regulations for the ozone National Ambient Air Quality Standards (NAAQS), to address the strengthened 2015 ozone NAAQS which were issued on October 1, 2015. This proposed action largely retains and updates the implementation provisions for the 2008 ozone NAAQS for purposes of the 2015 ozone NAAQS. It will propose nonattainment area classification thresholds and address implementation requirements including the timing of attainment dates for each classification and a range of nonattainment area state implementation plan (SIP) requirements for the 2015 ozone NAAQS. These SIP requirements pertain to attainment demonstrations, reasonable further progress, reasonably available control technology, reasonably available control measures, nonattainment new source review permitting programs, emission inventories, and the timing of SIP submissions and of compliance with emission control measures in the SIP. Other issues also addressed in this proposed rulemaking are the revocation of the 2008 ozone NAAQS, and anti-backsliding requirements that would apply when the 2008 ozone NAAQS are revoked, and reconsideration of the ozone NAAQS interprecursor trading provisions.

   This rule is needed to provide policies on how to implement air quality programs to achieve and maintain the 2015 ozone NAAQS. The programs to be implemented and the tools to assess their effectiveness already exist. State, local and tribal agencies determine the programs that are most effective for their particular applications, use the tools to assess their effectiveness and submit those programs to the EPA in the nonattainment area SIPs.

5. **Timetable:**
   There is no court-ordered deadline for this rulemaking. However, this rule should be proposed as soon as possible, consistent with the EPA's publicly-stated intention to propose implementation rules within 1 year of issuance of the 2015 ozone NAAQS. For this reason, we are targeting September 2016 for signature of the proposed rulemaking.

6. **Scientific products that will inform the action and plans for peer review:**
   There are no new scientific analyses to be developed under this action and thus no peer

review is planned. The Clean Air Scientific Advisory Committee (CASAC) has peer reviewed the scientific basis for the Ozone NAAQS.

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

Name of planned action: Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area Classifications and State Implementation Plan Requirements

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

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

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

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

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

Recommendation: This action does not merit further SAB consideration.

Rationale: The actions primary focus is implementation of the 2015 NAAQS for ozone including nonattainment area classification and timing of SIP submissions. There is no new science or scientific analysis that is being considered. Similar actions in this rulemaking have been covered in previous 8-hour ozone NAAQS rulemakings in 1997 and 2008.

EPA Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** National Emission Standards for Hazardous Air Pollutants: Publicly Owned Treatment Works – Risk and Technology Review

2. **RIN Number:** 2060-AS85

3. **EPA Office originating action:** Office of Air and Radiation

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

   The Clean Air Act (Act) establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, the Act requires the EPA to develop technology-based standards for categories of industrial sources. In the second stage of the regulatory process, EPA must review each MACT standard at least every eight years and revise them as necessary, "taking into account developments in practices, processes and control technologies." We call this requirement the "technology review." The EPA is also required to complete a one-time assessment of the health and environmental risks that remain after sources come into compliance with MACT. This residual risk review also must be done within eight years of setting the initial MACT standard. If additional risk reductions are necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects, the EPA must develop standards to address these remaining risks. For each source category for which the EPA issued MACT standards, the residual risk stage must be completed within eight years of promulgation of the initial MACT standard. Since the initial technology review requirement coincides in deadline with the risk review requirement, the EPA generally combines these two requirements into one rulemaking activity, calling this the "risk and technology review" process, or 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, on October 26, 1999, the EPA finalized national emission standards to control hazardous air pollutants (NESHAP) emitted from publicly owned treatment works, pursuant to section 112 of the Clean Air Act (CAA). The 1999 final NESHAP can be found at: https://www3.epa.gov/ttn/atw/potw/fr26oc99.pdf.

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

5. **Timetable:**

   The EPA has a consent decree deadline for proposal of December 8, 2016. Further, the EPA must finalize any revisions by October 16, 2017, as part of this same consent decree.

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 and have been used in numerous previous RTR reviews. There are no other scientific work products that have been or will be developed to inform this planned action.

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

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

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

While the overall RTR risk assessment methods meet the definition as "an influential scientific or technical work product," and have been subject to peer review, the application of the methods to each individual RTR analysis does not fit this definition.

6(d). Peer review:

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

1) The Residual Risk Report to Congress, a document describing the Agency's overall analytical and policy approach to setting residual risk standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methodology were described in this report, although individual elements have been improved over time. The final SAB advisory is available at: http://www.epa.gov/ttn/oarpg/t3/reports/risk_rep.pdf

2) A peer review of multi-pathway risk assessment methodologies for RTR was conducted by the EPA's SAB in 2000. The final SAB advisory is available at: http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$File/ecadv05.pdf

3) A consultation on EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by SAB in December 2006. SAB provided its formal consultation in a letter to the Administrator in June 2007. The final SAB advisory is available at:

https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf

4) A review of the updated and expanded risk assessment approaches and methods used in the RTR program was completed in 2009. This methodology was highlighted to the SAB utilizing two RTR source categories: Petroleum Refining Sources MACT I and Portland Cement Manufacturing. The final SAB advisory is available at: https://yosemite.epa.gov/sab/sabproduct.nsf/0/b031ddf79cffded38525734f00649caf!OpenDocument&TableRow=2.3#2

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

6) EPA is currently seeking the Science Advisory Board's (SAB) input on specific enhancements made to our risk assessment methodologies, particularly with respect to screening methodologies, since the last SAB review was completed in 2009 (see above). EPA anticipates that SAB would establish an appropriate expert panel to convene by early 2017.

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

Name of planned action: 2060-AS85: National Emission Standards for Hazardous Air Pollutants: Publicly Owned Treatment Works Risk and Technology Review

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

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

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

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

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

Recommendation: This action does not merit further SAB review. The RTR methodology is continually evolving and can incorporate new science. However, the EPA periodically requests that the SAB convene a review of the RTR methodology, and a new panel review is scheduled for 2017. The Work Group notes that there are many different sectors in the NESHAPs and these sectors incorporate and use data and information appropriate for that specific sector. The Work Group finds that while this action does not merit further SAB review the agency may benefit from SAB advice when new novel science or technologies are part of the sector specific RTR planned actions. The Work Group also notes that the planned SAB review may provide

recommendations for changes in the RTR methodology and encourages the agency to incorporate those recommendations into future RTRs.

Background: Publicly owned treatment works (POWs) emit a number of hazardous air pollutants including xylenes, methylene chloride, toluene, ethyl benzene, chloroform, tetrachloroethylene, benzene, and naphthalene. Each of these HAPs can cause adverse health effects provided sufficient exposure. Collectively, these emissions are listed as "hazardous air contaminants" and regulated under Section 112(d) of the Clean Air Act. EPA promulgates and periodically reviews National Emissions Standards for Hazardous Air Pollutants (NESHAPS) and identifies the "Maximum Achievable Control Technology" (MACT) for these pollutants and sources. Every 8 years, EPA is required to conduct a "technology review" of each MACT standard, to assure consistency with the best current control technology. At this time, EPA is also required to conduct a "residual risk assessment" of the health and environmental risks that remain after sources come into compliance with MACT. The EPA generally combines these two requirements into one rulemaking activity, calling this the "risk and technology review" process, or simply RTR.

The initial NESHAP for publicly owned treatment works was finalized in 1999. This regulation mandated air pollution controls on new or reconstructed treatment plants at POTW that are major sources of hazardous air pollutants (HAP), including industrial POTW. In the current action, EPA is proposing to conduct the required RTR. The rulemaking process in this case entails an assessment to determine if there are residual health risks based on the current maximum achievable control technology (MACT) standards applicable to the subject source category, and to evaluate "developments in practices, processes, and control technologies" and implications for revising the MACT. The EPA is under a court order to complete the rulemaking process related to this action by October 16, 2017, and the EPA must develop a proposed rule no later than December 8, 2016.

Rationale: While the details of each RTR are unique to the sources and pollutants being evaluated, the general approaches and methodologies employed in EPA RTRs have become standardized, and have been subject to multiple peer reviews over the last 17 years. For example, the SAB reviewed the first Report on Pulp and Paper Sources NESHAP to Congress in 1999, reviewed multi-pathway risk assessment methodologies in 2000, provided a consultation on emission inventories and characterizing human exposure in 2006, and (most recently) reviewed updated risk assessment approaches in 2009. Thus, the methods used for RTR reviews have evolved over the course of time taking into account prior SAB reviews. Since the last SAB review in 2009, there have been enhancements to the RTR methodology that are being used in EPA rules and actions; these relate to enhancements in multipathway risks, environmental risks, and inhalation methodologies. The Agency is planning to seek a new SAB review of the RTR methodology enhancements, with plans to convene a panel in early 2017. It is not clear if the SAB review will be complete by the court ordered deadline for this action of October 16, 2017.

The unique details of each RTR can include recommendations for new monitoring and maximum achievable control technologies. In general, these technologies are based on established scientific knowledge that has undergone extensive peer review. However, there can be exceptions, and the SAB encourages to USEPA to continually assess and identify for SAB review any such technology recommendations that are based on new scientific knowledge.

EPA Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Pulp and Paper Combustion Sources NESHAP – Risk and Technology Review

2. **RIN Number:** 2060-AS46

3. **EPA Office originating action:** Office of Air and Radiation

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

   The Clean Air Act (Act) establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, the Act requires the EPA to develop technology-based standards for categories of industrial sources. In the second stage of the regulatory process, EPA must review each MACT standard at least every eight years and revise them as necessary, "taking into account developments in practices, processes and control technologies." We call this requirement the "technology review." The EPA is also required to complete a one-time assessment of the health and environmental risks that remain after sources come into compliance with MACT. This residual risk review also must be done within eight years of setting the initial MACT standard. If additional risk reductions are necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects, the EPA must develop standards to address these remaining risks. For each source category for which the EPA issued MACT standards, the residual risk stage must be completed within eight years of promulgation of the initial MACT standard. Since the initial technology review requirement coincides in deadline with the risk review requirement, the EPA generally combines these two requirements into one rulemaking activity, calling this the "risk and technology review" process, or 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, on January 12, 2001, the EPA finalized national emission standards to control hazardous air pollutants (NESHAP) emitted from Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills, pursuant to section 112 of the Clean Air Act (CAA). The 2001 final NESHAP can be found at: https://www.gpo.gov/fdsys/pkg/FR-2001-01-12/pdf/01-65.pdf.

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

5. **Timetable:** This rule has a court-ordered promulgation deadline of October 1, 2017. In order to meet the promulgation deadline, the EPA must propose this rule no later than mid-December 2016.

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 and have been used in numerous previous RTR reviews. There are no other scientific work products that have been or will be developed to inform this planned action.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).
Because RTR assessments are used for regulatory purposes, and because components of our risk analyses have evolved over time, we have, over the course of the program, conducted scientific peer reviews of the methodologies through the SAB. Through peer review of the RTR process as a whole, rather than each individual rulemaking effort, the agency is able to conduct consistent risk characterizations across all categories of industrial sources.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"
While the overall RTR risk assessment methods meet the definition as "an influential scientific or technical work product," and have been subject to peer review, the application of the methods to each individual RTR analysis does not fit this definition.
6(d). Peer review:

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

1) The Residual Risk Report to Congress, a document describing the Agency's overall analytical and policy approach to setting residual risk standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methodology were described in this report, although individual elements have been improved over time. The final SAB advisory is available at: http://www.epa.gov/ttn/oarpg/t3/reports/risk_rep.pdf

2) A peer review of multi-pathway risk assessment methodologies for RTR was conducted by the EPA's SAB in 2000. The final SAB advisory is available at: http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$File/ecadv05.pdf

3) A consultation on EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by SAB in December 2006. SAB provided its formal consultation in a letter to the Administrator in June 2007. The final SAB advisory is available at: https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf

4) A review of the updated and expanded risk assessment approaches and methods used in the RTR program was completed in 2009. This methodology was highlighted to the SAB

utilizing two RTR source categories: Petroleum Refining Sources MACT I and Portland Cement Manufacturing. The final SAB advisory is available at: https://yosemite.epa.gov/sab/sabproduct.nsf/0/b031ddf79cffded38525734f00649caf!OpenDocument&TableRow=2.3#2

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

6) EPA is currently seeking the Science Advisory Board's (SAB) input on specific enhancements made to our risk assessment methodologies, particularly with respect to screening methodologies, since the last SAB review was completed in 2009 (see above). EPA anticipates that SAB would establish an appropriate expert panel to convene by early 2017.

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

Name of planned action: 2060-AS46: Risk and Technology Review for National Emission Standards for Hazardous Air Pollutants from the Pulp and Paper Combustion Sources

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

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

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

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

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

Recommendation: This action does not merit further SAB review. The RTR methodology is continually evolving and can incorporate new science. However, the EPA periodically requests that the SAB convene a review of the RTR methodology, and a new panel review is scheduled for 2017. The Work Group notes that there are many different sectors in the NESHAPs and these sectors incorporate and use data and information appropriate for that specific sector. The Work Group finds that while this action does not merit further SAB review the agency may benefit from SAB advice when new novel science or technologies are part of the sector specific RTR planned actions. The Work Group also notes that the planned SAB review may provide

recommendations for changes in the RTR methodology and encourages the agency to incorporate those recommendations into future RTRs.

Background: Pulp and paper combustion sources emit a suite of hazardous air pollutants, including carcinogenic metals (e.g., chromium) and organic compounds (e.g., benzene). Collectively, these emissions are listed as "hazardous air contaminants" and regulated under Section 112(d) of the Clean Air Act. EPA promulgates and periodically reviews National Emissions Standards for Hazardous Air Pollutants (NESHAPS) and identifies the "Maximum Achievable Control Technology" (MACT) for these pollutants and sources. Every 8 years, EPA is required to conduct a "technology review" of each MACT standard, to assure consistency with the best current control technology. At this time, EPA is also required to conduct a "residual risk assessment" of the health and environmental risks that remain after sources come into compliance with MACT. The EPA generally combines these two requirements into one rulemaking activity, calling this the "risk and technology review" process, or simply RTR.

The initial NESHAP for pulp and paper combustion sources, i.e., pulping processes and chemical recovery processes for kraft, soda, sulfite, and stand alone semichemical pulp mills, were finalized in 2001. In the current action, EPA is proposing to conduct the required RTR. The rulemaking process in this case entails an assessment to determine if there are residual health risks based on the current maximum achievable control technology (MACT) standards applicable to the subject source category, and to evaluate "developments in practices, processes, and control technologies" and implications for revising the MACT. The EPA is under a court order to complete the rulemaking process related to this action by October 1, 2017, which means that EPA must develop a proposed rule no later than mid-December, 2016.

Rationale: While the details of each RTR are unique to the sources and pollutants being evaluated, the general approaches and methodologies employed in EPA RTRs have become standardized, and have been subject to multiple peer reviews over the last 17 years. For example, the SAB reviewed the first Report on Pulp and Paper Sources NESHAP to Congress in 1999, reviewed multi-pathway risk assessment methodologies in 2000, provided a consultation on emission inventories and characterizing human exposure in 2006, and (most recently) reviewed updated risk assessment approaches in 2009. Thus, the methods used for RTR reviews have evolved over the course of time taking into account prior SAB reviews. Since the last SAB review in 2009, there have been enhancements to the RTR methodology that are being used in EPA rules and actions; these relate to enhancements in multipathway risks, environmental risks, and inhalation methodologies. The Agency is planning to seek a new SAB review of the RTR methodology enhancements, with plans to convene a panel in early 2017. It is not clear if the SAB review will be complete by the court ordered deadline for this action of October 1, 2017.

The unique details of each RTR can include recommendations for new monitoring and maximum achievable control technologies. In general, these technologies are based on established scientific knowledge that has undergone extensive peer review. However, there can be exceptions, and the SAB encourages to USEPA to continually assess and identify for SAB review any such technology recommendations that are based on new scientific knowledge.

EPA Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Trichloroethylene (TCE): Rulemaking Under TSCA Section 6(a); Vapor Degreasing

2. **RIN Number:** 2070-AK11

3. **EPA Office originating action:** Office of Chemical Safety and Pollution Prevention/Office of Pollution, Prevention and Toxics

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

   Section 6(a) of the Toxic Substances Control Act (TSCA) provides authority for the EPA to ban or restrict the manufacture (including import), processing, distribution in commerce, and use of chemicals, as well as any manner or method of disposal. The EPA identified trichloroethylene (TCE) for risk evaluation as part of its Work Plan for Chemical Assessment under TSCA. TCE is used in industrial and commercial processes, and also has some limited uses in consumer products. In the June 2014 TSCA Work Plan Chemical Risk Assessment for TCE, the EPA identified risks associated with commercial vapor degreasing. EPA is initiating rulemaking under TSCA section 6 to address these risks, if the EPA finds that there is a reasonable basis to conclude that the risks to human health or the environment are unreasonable.

   This new action is a subset of the previously reviewed action, **Trichloroethylene (TCE); Rulemaking Under TSCA §6(a)** (RIN 2070-AK03) which proposed to address the risks associated with TCE when used as a spotting agent in dry cleaning and in commercial and consumer aerosol spray degreasers. The proposed rule (RIN 2070-AK03) was identified as a major action in the Spring 2015 Semi-annual Regulatory Agenda. The Work Group concluded that EPA was thorough in seeking expert and public input and in compiling all available information as they developed the TSCA Work Plan Chemical risk assessment for TCE using the best available information and approaches. They recommended that this action does not merit further SAB consideration.

   This new action addresses issues previously presented to the Work Group for TCE uses.

5. **Timetable:** EPA expects to issue a Notice of Proposed Rulemaking in 2016.

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

   Please refer to the attached template that was submitted to the SAB for the Spring 2015 Regulatory Agenda for responses to 6a, 6b, 6c, 6d**.** Also attached is the SAB Work Group recommendation. A summary of the Work Group Fact Finding questions and EPA responses were incorporated in the Work Group memorandum.

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

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

6(d). Peer review:

EPA Description Submitted for the Spring 2015 Regulatory Agenda

1. **Name of action:** Trichloroethylene (TCE); Rulemaking Under TSCA Section 6(a)

2. **RIN Number:** 2070-AK03

3. **EPA Office originating action:** Office of Chemicals Safety and Pollution Prevention/Office of Pollution Prevention and Toxics

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

Section 6 of the Toxic Substances Control Act (TSCA) provides authority for EPA to ban or restrict the manufacture (including import), processing, distribution in commerce, and use of chemicals, as well as any manner or method of disposal. EPA identified trichloroethylene (TCE) for risk evaluation as part of its Work Plan for Chemical Assessment under TSCA. TCE is used in industrial and commercial processes, and also has some limited uses in consumer products. In the June 2014 TSCA Work Plan Chemical Risk Assessment for TCE, EPA identified risks associated with commercial degreasing and some consumer uses. EPA is initiating rulemaking under TSCA section 6 to address these risks. Specifically, EPA will determine whether the continued use of TCE in some commercial degreasing uses, as a spotting agent in dry cleaning, and in certain consumer products would pose an unreasonable risk to human health and the environment. EPA expects to issue a proposed rule in early 2016. This rule will undergo public notice and comment prior to being finalized in compliance with the Agency's Action Development Process.

5. **Timetable:** EPA expects to issue a Notice of Proposed Rulemaking in 2016.

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.

TSCA Work Plan Chemical Risk Assessment for Trichloroethylene: Degreasing, Spot Cleaning and Arts & Craft Uses, June 2014

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).

Risk assessment underwent peer review in 2013. View the peer review plan, report and response to comments.

EPA also held an experts workshop on TCE alternatives and risk reduction approaches in July 2014.

- Read the Federal Register Notice announcing the meeting.

- Download the Workshop Presentation Materials.

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?"

Only the completed risk assessment product meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that has a legal and/or statutory obligation to conduct a peer review.

6(d). Peer review:

TSCA Work Plan Chemical Risk Assessment for Trichloroethylene: Degreasing, Spot Cleaning and Arts & Craft Uses, June 2014 – peer review completed.

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

Name of planned action: Trichloroethylene (TCE); Rulemaking Under TSCA Section 6(a); Vapor Degreasing

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

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

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

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

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

Recommendation: This action does not merit further SAB consideration.

Background: Section 6 of the Toxic Substances Control Act (TSCA) provides authority for EPA to ban or restrict the manufacture (including import), processing, distribution in commerce, and use of chemicals, as well as any manner or method of disposal. EPA identified trichloroethylene (TCE) for risk evaluation as part of its Work Plan for Chemical Assessments under TSCA. TCE is used in commercial and consumer degreasing, as a spotting agent in dry cleaning, and in certain consumer products.

In June of 2014, the EPA published the TSCA Work Plan Chemical Risk Assessment for Trichloroethylene (TCE). In 2015, the EPA initiated rulemaking under TSCA section 6 to address these risks by submitting their intent to issue a proposed rule in 2016. Specifically, the EPA submitted their intent to issue a proposed rule that dealt with whether the continued use of TCE in some commercial degreasing uses, as a spotting agent in dry cleaning, and in certain consumer products poses an unreasonable risk to human health and the environment. The proposed rule (RIN 2070-AK03) was identified as a major action in the Spring 2015 Semi-annual Regulatory Agenda. The Work Group concluded that EPA was thorough in seeking expert and public input and in compiling all available information as they developed the TSCA Work Plan Chemical risk assessment for TCE using the best available information and approaches. They recommended that this action did not merit further SAB consideration.

Rationale: In the newest regulatory agenda (spring 2016), the EPA has submitted their intent to publish a proposed rule that is a subset of the previously reviewed action, i.e., Trichloroethylene (TCE); Rulemaking Under TSCA §6(a) (RIN 2070-AK03). The new proposed rule will more narrowly focus only on the continued use and risks of TCE in vapor decreasing. It will not consider broader uses and risks of TCE as a spotting agent in dry cleaning, or in certain consumer products. The EPA expects to issue a Notice of Proposed Rulemaking in 2016.

The Work Group sent two questions to the EPA for additional information on how the new and more narrowly defined proposed rule will differ from the previously reviewed action (RIN 2070-AK03). These and EPA responses are noted below:

> **Are the proposed rules excerpts from the larger rules that were previously part of the SAB Regulatory Agenda review?** Yes. The proposed rules include the information that was provided to the SAB Work Group before.
>
> **Are there any new components to either of these two actions?** No, there are no new components to either of the two actions.

While the rationale for narrowing the proposed rulemaking for TCE to only consider vapor decreasing is not clear, the EPA responses indicate that no new components outside of what was previously reviewed are being considered. Therefore, this action does not merit further SAB review.

Previous Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science (Spring 2015)

Name of planned action: Trichloroethylene (TCE); Rulemaking Under TSCA Section 6(a) (2070-AK03)

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

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

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

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

Recommendation: This action does not merit further SAB consideration.

Section 6 of the Toxic Substances Control Act (TSCA) provides authority for EPA to ban or restrict the manufacture (including import), processing, distribution in commerce, and use of chemicals, as well as any manner or method of disposal. EPA identified trichloroethylene (TCE) for risk evaluation as part of its Work Plan for Chemical Assessments under TSCA. TCE is used in commercial and consumer degreasing, as a spotting agent in dry cleaning, and in certain consumer products.

In June of 2014, the EPA published the TSCA Work Plan Chemical Risk Assessment for Trichloroethylene (TCE). The EPA is initiating rulemaking under TSCA section 6 to address these risks. Specifically, the EPA is seeking to determine whether the continued use of TCE in some commercial degreasing uses, as a spotting agent in dry cleaning, and in certain consumer

products poses an unreasonable risk to human health and the environment. The EPA expects to issue a proposed rule in early 2016. This rule will undergo public notice and comment prior to being finalized in compliance with the Agency's Action Development Process.

Prior to publishing the TSCA Work Plan Chemical Risk Assessment for TCE, the EPA issued a draft version of this document for public review and comment. This was followed by a review process that consisted of internal review (EPA), a review by other federal agencies (e.g., OSHA, NIOSH), and an external peer review panel. The Workgroup confirmed in its fact finding stage that the Agency did follow Agency peer review guidelines. The Agency's procedures for the TSCA actions peer review include: 1) developing a Peer Review Plan for each assessment and that is submitted to the public record in the docket and on the agency's web page, 2) following a documented process for contractor led reviews of Highly Influential Science Assessments and Influential Science Assessments, and 3) announcing the peer review panel public meetings in the Federal Register[2]. The Federal Register notice announces opportunities for public comment (at the meetings and the docket), the public meeting logistics, and the peer review panel members. The Federal Register notice is submitted to the docket and posted on the agency's web page in addition to being published. There was a process in place for the public to comment on proposed peer reviewers and the final external review panel (which numbered 9) consisted of members affiliated with academic, industrial, and nonprofit organizations. Members of the external review panel provided written responses to a set of detailed questions. The Agency responses to the external review panel comments were also posted publicly on an EPA website along with responses to public comments. There were also opportunities for public input on peer review plans, chemical assessments, and opportunities to submit relevant data on assessments to the EPA docket.

The EPA did not include a quantitative assessment of environmental effects in this risk assessment because TCE has moderate persistence, low bioaccumulation, and low hazard for aquatic toxicity. The TCE risk assessment identified acute and chronic health risks to workers and consumers with direct (users) or indirect (bystander) exposure to TCE. Only the inhalation route of exposure was considered, as risk from dermal contact was determined to be much smaller. EPA concluded that there are both cancer and non-cancer risks associated with degreasing operations and spot cleaning.

The Work Group sent the following question to EPA for additional information on how the agency is considering alternatives and risk reduction for TCE.

> Question: EPA convened an Expert Public Workshop on "Alternatives and Risk Reduction Approaches to Trichloroethylene (TCE) Use as a Degreaser" on July 29 and 30, 2014, with the goal of supporting activities to reduce the health risks from TCE exposures to consumers using spray aerosol degreasers and the risks to workers using TCE as a degreaser in small commercial shops identified in the final TCE risk assessment. Although alternatives to TCE were identified in the Workshop, no effort was made to reach consensus or provide direct input to the proposed rule scheduled for release in early 2016. It is not clear if specific alternatives to TCE will be part of the proposed rule, or if more input will be solicited to evaluate such alternatives. More

[2] The Agency's procedures for the TSCA actions peer review include: 1) developing a Peer Review Plan for each assessment and that is submitted to the public record in the docket and on the agency's web page, 2) following a documented process for contractor led reviews of Highly Influential Science Assessments and Influential Science Assessments, and 3) announcing the peer review panel public meetings in the Federal Register

information on this would have been helpful for the Workgroup to determine the scope of the proposed rulemaking.

Could the Agency please comment on whether specific alternatives to TCE will be part of the proposed rule, and if more public and/or expert input will be solicited to evaluate such alternatives?

EPA Response: The Agency is initiating rulemaking under TSCA section 6 to address the risks identified in the Risk Assessments for certain uses of TCE, as well methylene chloride and n-methylpyrrolidone (NMP). TSCA section 6 requires the Agency to find that the chemical presents or will present an unreasonable risk of injury to health or the environment and to take action to adequately protect against the unreasonable risk using the least burdensome requirements. A proposed rule would describe the preferred risk management approach and explain how the approach achieves adequate protection using the least burdensome requirements. As part of that description, the Agency will characterize the likely alternative chemicals or processes that current producers and users of the regulated chemical could turn to as a result of the proposed risk management approach and based on market information. This information also would be included in any discussion of the costs and benefits of the selected risk management option that would be presented in the proposed rule. The public would have an opportunity to review and comment on the information considered and on the proposed rule as part of the regulatory process.

The Workgroup concluded that EPA was thorough in seeking expert and public input and in compiling all available information as they developed the TSCA Work Plan Chemical risk assessment for TCE using the best available information and approaches. These assessments focused on those TSCA uses of TCE with significant potential for exposure to humans and/or the environment. Thus, the value-added of any possible further SAB review is likely to be marginal. Accordingly, it is recommended that this action does not merit further SAB consideration.

EPA Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Polychlorinated Biphenyls (PCBs): Reassessment of Use Authorizations for PCBs in Small Capacitors

2. **RIN Number:** 2070-AK12

3. **EPA Office originating action:** Office of Chemical Safety and Pollution Prevention/Office of Pollution, Prevention and Toxics

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

   The EPA's regulations governing the use of Polychlorinated Biphenyls (PCBs) in electrical equipment and other applications were first issued in the late 1970's and have not been updated since 1998. The EPA has initiated rulemaking to reassess the ongoing authorized uses of PCBs in small capacitors. In particular, the reassessment of the use authorization will focus on the use of liquid PCBs in small capacitors in fluorescent light ballasts.

   This new action is a subset of a previously reviewed action, **Polychlorinated Biphenyls; Reassessment of Use Authorizations** (RIN 2070-AJ38) which proposed to address the following: (1) the use, distribution in commerce, marking and storage for reuse of liquid PCBs in electric equipment; (2) improvements to the existing use authorization for natural gas pipelines; and (3) definitional and other regulatory "fixes." The reassessment of use authorizations related to liquid PCBs in equipment includes small capacitors in fluorescent light ballasts, large capacitors, transformers and other electrical equipment. The proposed rule (RIN 2070-AJ38) was identified as a major action in the Spring 2013 Semi-annual Regulatory Agenda. There were no scientific issues requiring further analysis. The Work Group recommended that this action did not merit further SAB consideration.

   The new action (RIN 2070-AK12) is expected to be proposed in 2016, the former action (RIN 2070-AJ38), in 2017.

   This new action addresses issues previously presented to the Work Group for PCB uses.

5. **Timetable:** EPA expects to issue a Notice of Proposed Rulemaking in October 2016.

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

   Please refer to the attached template that was submitted to the SAB for the Spring 2013 Regulatory Agenda for responses regarding peer review. Also attached is the SAB Work Group recommendation. A summary of the Work Group Fact Finding questions and EPA responses were excerpted from a summary of the fact finding call.

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

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

6(d). Peer review:

EPA Description Template Submitted for the Spring 2013 Regulatory Agenda

1. **Name of action:** PCB Use Authorizations
2. **RIN Number:** 2070-AJ38
3. **EPA Office originating action:** Office of Chemical Safety and Pollution Prevention
4. **Brief description of action and statement of need for the action:** EPA's regulations governing the use of Polychlorinated Biphenyls (PCBs) in electrical equipment and other applications have not been updated since 1998. EPA has initiated rulemaking to reassess the ongoing authorized uses of PCBs to determine whether certain use authorizations should be ended or phased out because they can no longer be justified under section 6(e) of the Toxic Substances Control Act, which requires that the authorized use will not present an unreasonable risk of injury to health and the environment. As the first step in this reassessment, EPA published an Advanced Notice of Proposed Rulemaking (ANPRM) on April 7, 2010 and took comment through August 20, 2010. EPA reviewed and considered all comments received on the ANPRM in planning the current rulemaking. This action will address the following specific areas: (1) the use, distribution in commerce, marking and storage for reuse of liquid PCBs in electric equipment; (2) improvements to the existing use authorization for natural gas pipelines; and (3) definitional and other regulatory "fixes." The reassessment of use authorizations related to liquid PCBs in equipment will focus on small capacitors in fluorescent light ballasts, large capacitors, transformers and other electrical equipment. In addition, revised testing, characterization, and reporting requirements for PCBs in natural gas pipeline systems to provide more transparency for the Agency and the public when PCB releases occur will be considered. Consistent with Executive Order 13563, "Improving Regulation and Regulatory Review," wherever possible and consistent with the overall objectives of this rulemaking, the Agency will also eliminate or fix regulatory inefficiencies noted by the Agency or in public comments on the ANPRM.
5. **Timetable:**

   Applicable Deadlines: None

   Regulatory Agenda: NPRM publication: 07/00/2014 (Designated as a Long-Term action)

6. **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?"**

   As per the Agency's Peer Review Handbook, none of the analyses proposed are expected to require external peer review. Generally all influential scientific and technical work products used in decision making should be peer reviewed. The process of determining whether a supporting scientific and/or technical work product is "influential" takes into account circumstances surrounding the use of the work product. The Agency's Peer Review handbook provides that "the novelty or controversy associated with the work product may determine whether it is influential scientific information. Influential scientific information may be novel or innovative, precedential, controversial, or emerging ('cutting edge')." PCBs have well established and thoroughly studied adverse health effects in both humans and wildlife, with studies dating back to 1937. The scientific work products associated with this

action are not expected to present any novel or controversial issues necessitating external peer review.

Scientific questions to be addressed and approach:

N/A

Plans for scientific analyses and peer review:[3]

N/A

[3] Note that the Agency amended the Action Description template with more information and questions regarding peer review after the Spring 2013 Regulatory Review.

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

Name of planned action: Polychlorinated Biphenyls (PCBs); Reassessment of Use Authorizations for PCBs in Small Capacitors

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

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

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

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

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

Recommendation: This action does not merit further SAB consideration.

Background: Section 6 of the Toxic Substances Control Act (TSCA) provides authority for EPA to ban or restrict the manufacture (including import), processing, distribution in commerce, and use of chemicals, as well as any manner or method of disposal. EPA's regulations governing the use of Polychlorinated Biphenyls (PCBs) in electrical equipment and other applications have not been updated since 1998. The EPA initiated rulemaking in 2010 to reassess the ongoing authorized uses of PCBs to determine whether certain use authorizations should be ended or

phased out because they present an unreasonable risk of injury to health and the environment. As the first step in this reassessment, the EPA published an Advanced Notice of Proposed Rulemaking (ANPRM) on April 7, 2010 and took comment through August 20, 2010. The EPA reviewed and considered all comments received on the ANPRM in planning the current, and included a long-term action in the Spring 2013 Regulatory Agenda to issue a proposed rule on PCB Use Authorizations. The prior long-term action (RIN 2070-AJ38) proposed to address the following: (1) the use, distribution in commerce, marking and storage for reuse of liquid PCBs in electric equipment; (2) improvements to the existing use authorization for natural gas pipelines; and (3) definitional and other regulatory "fixes." The reassessment of use authorizations related to liquid PCBs in equipment includes small capacitors in fluorescent light ballasts, large capacitors, transformers and other electrical equipment. The Work Group determined that there were no new scientific issues requiring further analysis, and recommended that the prior action did not merit further SAB consideration.

Rationale: In the new Spring 2016 Regulatory Agenda, the EPA has submitted their intent to publish a proposed rule that is a subset of the previously reviewed action (RIN 2070-AJ38). Specifically, the anticipated proposed rule will more narrowly focus on the use of liquid PCBs in small capacitors in fluorescent light ballasts. The use of PCBs in "other electrical equipment", improvements to existing use authorizations for natural gas pipelines, and definitional and other regulatory fixes will not be considered.

The Work Group sent two questions to the EPA for additional information on how the new and more narrowly defined proposed rule will differ from the previously reviewed action. These and EPA responses are noted below:

Are the proposed rules excerpts from the larger rules that were previously part of the SAB Regulatory Agenda review? Yes. The proposed rules include the information that was provided to the SAB Work Group before.

Are there any new components to either of these two actions? No, there are no new components to either of the two actions.

While the rationale for narrowing the proposed rulemaking for PCBs to only consider the use of liquid PCBs in small capacitors in fluorescent light ballasts is not clear, the EPA responses indicate that no new components outside of what was previously reviewed are being considered. Therefore, this action does not merit further SAB review.

Previous Recommendation from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science (Spring 2013)

Name of planned action: Polychlorinated Biphenyls (PCBs); Reassessment of Use Authorizations (2070-AJ38)

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

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

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

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

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

This action does not merit further SAB consideration. EPA's regulations governing the use of polychlorinated biphenyls (PCBs) in electrical equipment and other applications have not been updated since 1998. EPA has initiated rulemaking to reassess the ongoing authorized uses of PCBs to determine whether certain use authorizations should be ended or phased out because they can no longer be justified under section 6(e) of TSCA, which requires that the authorized use will not present an unreasonable risk of injury to health and the environment. OCSPP confirmed that this action will address the following specific areas: (1) the use, distribution in commerce, marking and storage for reuse of liquid PCBs in electric equipment; (2) improvements to the existing use authorization for natural gas pipelines; and (3) definitional and other regulatory fixes. OCSPP confirms that the proposed rule will only address the following

specific areas of PCB use: (1) the use, distribution in commerce, marking and storage for reuse of liquid PCBs in electric equipment; (2) improvements to the existing use authorization for natural gas pipelines; and (3) definitional and other regulatory “fixes.”

EPA Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** National Emission Standards for Hazardous Air Pollutants for Coke Ovens: Pushing, Quenching, and Battery Stacks - Risk and Technology Review

2. **RIN Number:** 2060-AS81

3. **EPA Office originating action:** Office of Air and Radiation

4. **Brief description of action and statement of need for the action:**
   The Clean Air Act (Act) establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, the Act requires the EPA to develop technology-based standards for categories of industrial sources. In the second stage of the regulatory process, EPA must review each MACT standard at least every eight years and revise them as necessary, "taking into account developments in practices, processes and control technologies." We call this requirement the "technology review." The EPA is also required to complete a one-time assessment of the health and environmental risks that remain after sources come into compliance with MACT. This residual risk review also must be done within eight years of setting the initial MACT standard. If additional risk reductions are necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects, the EPA must develop standards to address these remaining risks. For each source category for which the EPA issued MACT standards, the residual risk stage must be completed within eight years of promulgation of the initial MACT standard. Since the initial technology review requirement coincides in deadline with the risk review requirement, the EPA generally combines these two requirements into one rulemaking activity, calling this the "risk and technology review" process, or 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, on April 14, 2003, the EPA finalized national emission standards to control hazardous air pollutants (NESHAP) emitted from Coke Ovens: Pushing, Quenching, and Battery Stacks, pursuant to section 112 of the Clean Air Act (CAA). The 2003 final NESHAP can be found at: https://www3.epa.gov/ttn/atw/coke2/fr14ap03.pdf

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

5. **Timetable:** An information collection request (ICR) was sent to nine coke oven companies (11 facilities) in April 2016. Responses are required by January 2017. The tentative proposal date is June 2018, and the tentative final rule date is June 2019. This action may be subject to court-ordered deadlines or consent decree deadlines in the future, as a result of pending litigation.

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 and have been used in numerous previous RTR reviews. There are no other scientific work products that have been or will be developed to inform this planned action.

6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis).
Because RTR assessments are used for regulatory purposes, and because components of our risk analyses have evolved over time, we have, over the course of the program, conducted scientific peer reviews of the methodologies through the SAB. Through peer review of the RTR process as a whole, rather than each individual rulemaking effort, the agency is able to conduct consistent risk characterizations across all categories of industrial sources.

6(c). For each work product, identify whether the action relies on science that meets the EPA Peer Review Handbook definition of "an influential scientific or technical work product" that "has a major impact, involves precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review?"
While the overall RTR risk assessment methods meet the definition of "an influential scientific or technical work product," and have been subject to peer review, the application of the methods to each individual RTR analysis does not fit this definition.

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

1) The Residual Risk Report to Congress, a document describing the Agency's overall analytical and policy approach to setting residual risk standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methodology were described in this report, although individual elements have been improved over time. The final SAB advisory is available at: http://www.epa.gov/ttn/oarpg/t3/reports/risk_rep.pdf

2) A peer review of multi-pathway risk assessment methodologies for RTR was conducted by the EPA's SAB in 2000. The final SAB advisory is available at: http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$File/ecadv05.pdf

3) A consultation on EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by SAB in December 2006. SAB provided its formal consultation in a letter to the Administrator in June 2007. The final SAB advisory is available at: https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf

4) A review of the updated and expanded risk assessment approaches and methods used in the RTR program was completed in 2009. This methodology was highlighted to the SAB utilizing two RTR source categories: Petroleum Refining Sources MACT I and Portland

Cement Manufacturing. The final SAB advisory is available at: https://yosemite.epa.gov/sab/sabproduct.nsf/0/b031ddf79cffded38525734f00649caf!OpenDocument&TableRow=2.3#2

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

6) EPA is currently seeking the Science Advisory Board's (SAB) input on specific enhancements made to our risk assessment methodologies, particularly with respect to screening methodologies, since the last SAB review was completed in 2009 (see above). EPA anticipates that SAB would establish an appropriate expert panel to convene by early 2017.

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

Name of planned action: National Emission Standards for Hazardous Air Pollutants for Coke Ovens: Pushing, Quenching, and Battery Stacks

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

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

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

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

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

Recommendation: This action does not merit further SAB review. The RTR methodology is continually evolving and can incorporate new science. However, the EPA periodically requests that the SAB convene a review of the RTR methodology, and a new panel review is scheduled for 2017. The Work Group notes that there are many different sectors in the NESHAPs and these sectors incorporate and use data and information appropriate for that specific sector. The Work Group finds that while this action does not merit further SAB review the agency may benefit from SAB advice when new novel science or technologies are part of the sector specific RTR planned actions. The Work Group also notes that the planned SAB review may provide

recommendations for changes in the RTR methodology and encourages the agency to incorporate those recommendations into future RTRs

Background: Coke ovens and associated processes emit complex mixtures of particles and gasses, including carcinogenic metals and organic compounds. Collectively, these emissions are listed as “hazardous air contaminants” and regulated under Section 112(d) of the Clean Air Act. EPA promulgates and periodically reviews National Emissions Standards for Hazardous Air Pollutants (NESHAPS) and identifies the “Maximum Achievable Control Technology” (MACT) for these pollutants and sources. Every 8 years, EPA is required to conduct a “technology review” of each MACT standard, to assure consistency with the best current control technology. At this time, EPA is also required to conduct a “residual risk assessment” of the health and environmental risks that remain after sources come into compliance with MACT. The EPA generally combines these two requirements into one rulemaking activity, calling this the “risk and technology review” process, or simply RTR.

The initial NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks was finalized in 2003. In the current action, EPA is proposing to conduct the required RTR. This was initiated by sending an information collection request (ICR) to nine coke oven companies (11 facilities) in April 2016, with responses required by January 2017. The tentative proposal date is June 2018, with a tentative final rule date of June 2019.

Rationale: While the details of each RTR are unique to the sources and pollutants being evaluated, the general approaches and methodologies employed in EPA RTRs have become standardized, and have been subject to multiple peer reviews over the past 17 years. For example, the SAB reviewed the first Report on Pulp and Paper Sources NESHAP to Congress in 1999, reviewed multi-pathway risk assessment methodologies in 2000, provided a consultation on emission inventories and characterizing human exposure in 2006, and (most recently) reviewed updated risk assessment approaches in 2009. Thus, the methods used for RTR reviews have evolved over the course of time taking into account prior SAB reviews. Since the last SAB review in 2009, there have been enhancements to the RTR methodology that are being used in EPA rules and actions; these relate to enhancements in multipathway risks, environmental risks, and inhalation methodologies. The Agency is planning to seek a new SAB review of the RTR methodology enhancements, with plans to convene a panel in early 2017. The agency anticipates that this peer review will be completed in advance of the June 2018 proposed Coke Oven RTR, so that any new scientific advances that are part of the new RTR methodology would have undergone peer review.

The unique details of each RTR can include recommendations for new monitoring and maximum achievable control technologies. In general, these technologies are based on established scientific knowledge that has undergone extensive peer review. However, there can be exceptions, and the SAB encourages to USEPA to continually assess and identify for SAB review any such technology recommendations that are based on new scientific knowledge.

EPA Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Clean Energy Incentive Program (CEIP) Design Details

2. **RIN Number:** 2060-AS84

3. **EPA Office originating action:** Office of Air and Radiation

4. **Brief description of action and statement of need for the action:** On June 16, 2016, the EPA issued proposed design details and requirements for participation in the Clean Power Plan CEIP. The framework for the CEIP was included in the final Clean Power Plan as a voluntary program that states and tribes with affected sources may use to incentivize early investments in renewable energy generation, as well as in energy-efficiency in low-income communities. We committed to a follow-on action to detail the design of the program, as well as to stakeholder outreach in advance of the follow-on action.

5. **Timetable:** The action is expected to be proposed in June 2016; timing for a final rule has not yet been determined.

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

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

   There are no scientific work products being developed for this action. The CEIP is a policy-based action, which only outlines requirements for participation in the program. This action relies on the analytical work in support of the final Clean Power Plan. The SAB reviewed EPA's analytical approach in the Boards consideration of actions to address carbon pollution under Section 111 of the Clean Air Act (CAA)

   6(b). For each work product, describe the approach the agency is taking to develop the needed science or analysis (e.g., any inter-agency collaboration, workshops to inform the analysis). There are no new scientific work products associated with this action.

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

   6(d). Peer review: No scientific products will be produced as a result of this action; therefore, no peer-review is planned.

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

Name of planned action: Clean Energy Incentive Program Design and Implementation (

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

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

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

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

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

Recommendation: This action does not merit further SAB consideration.

Background: In August 2015, the Clean Power Program was promulgated. It provides the first ever national limits on reducing carbon pollution from existing power plants. In February 2016, the Supreme Court stayed the Clean Power Plan. While the court reviews the plan, and during the stay, compliance with the Clean Power Plan is voluntary.

A framework for the Clean Energy Incentive Program (CEIP) was included as part of the Clean Power Plan. The CEIP is a voluntary program designed to help states and tribes meet the Clean

Power Plan goals by encouraging early investments in zero-emitting renewable energy generation, and by removing barriers to investment in energy efficiency in low income communities. The proposed action, published in June 2016, provides details on design of the CEIP, as well as plans for stakeholder outreach (https://www.epa.gov/cleanpowerplan/proposed-rule-about-ceip-design-details). These details provide clarifications regarding project eligibility, including expanding eligibility to solar energy project in low-income communities, providing states with the flexibility to choose one or more existing definitions of low-income community, and show how CEIP incentives could be made available to eligible renewable energy and energy efficiency project providers.

Rationale:
This action is being developed as a follow-on action for the Clean Energy Incentive Program (CEIP) established under the Clean Power Plan. The proposed action provides design details with plans to adjust the CEIP design elements pending legal resolution of the review of the Clean Power Plan under the Supreme Court's stay action on the Clean Power Plan. For states planning to participate in the CEIP, requirements for participation are specified in the Clean Power Plan Emissions Guidelines (EGs). Part of the proposed action plan for CEIP (on rate-based and mass-based trading rules) already includes feedback and new information from stakeholders after the EGs were finalized in August 2015. No new federal plans are being re-proposed. Additional details on the CEIP can be found here (https://www.epa.gov/sites/production/files/2016-06/documents/fs-ceip-proposal-061616.pdf).

The CEIP framework, included in the Clean Power Plan finalized in August 2015, does not include provisions that could have any adverse energy impacts nor any new technical standards. It is a voluntary program that offers incentives for early actions on emission reductions through renewable energy and energy efficiency plans and as such provides only design details. The final design and implementation details of the CEIP will be addressed in a subsequent action after public commentary is received – planned schedule is 60 days after publication in the Federal Register which was on June 30th 2016. Thus, no further review is needed by the SAB.

EPA Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Portland Cement NESHAP – Risk and Technology Review (RTR)
2. **RIN Number:** 2060-AS92
3. **EPA Office originating action:** Office of Air and Radiation
4. **Brief description of action and statement of need for the action:**

   The Clean Air Act (Act) establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, the Act requires the EPA to develop technology-based standards for categories of industrial sources. In the second stage of the regulatory process, EPA must review each MACT standard at least every eight years and revise them as necessary, "taking into account developments in practices, processes and control technologies." We call this requirement the "technology review." The EPA is also required to complete a one-time assessment of the health and environmental risks that remain after sources come into compliance with MACT. This residual risk review also must be done within eight years of setting the initial MACT standard. If additional risk reductions are necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects, the EPA must develop standards to address these remaining risks. For each source category for which the EPA issued MACT standards, the residual risk stage must be completed within eight years of promulgation of the initial MACT standard. Since the initial technology review requirement coincides in deadline with the risk review requirement, the EPA generally combines these two requirements into one rulemaking activity, calling this the "risk and technology review" process, or 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 Portland cement in June 1999. (64 FR 31898). Several amendments to the NESHAP were developed over the years, with litigation on the NESHAP resulting in two final amendments (September 9, 2010 at 75 FR 54970 and February 12, 2013 at 78 FR 10006). The last NESHAP amendment, which covered technical corrections, was promulgated September 11, 2015 at 80 FR 54728. Links to these actions can be found at:

   http://www.gpo.gov/fdsys/pkg/FR-2010-09-09/pdf/2010-21102.pdf

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

5. **Timetable:**

   This action is part of a larger consent decree with a court-ordered deadline of June 15, 2017, for the proposal, and June 15, 2018, for the final rule.

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

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

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

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

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

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

While the overall RTR risk assessment methods meet the definition as "an influential scientific or technical work product", and have been subject to peer review, the application of the methods to each individual RTR analysis does not fit this definition.

6(d). Peer review:

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

1) The Residual Risk Report to Congress, a document describing the Agency's overall analytical and policy approach to setting residual risk standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methodology were described in this report, although individual elements have been improved over time. The final SAB advisory is available at: http://www.epa.gov/ttn/oarpg/t3/reports/risk_rep.pdf

2) A peer review of multi-pathway risk assessment methodologies for RTR was conducted by the EPA's SAB in 2000. The final SAB advisory is available at: http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$File/ecadv05.pdf

3) A consultation on EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by SAB in December 2006. SAB provided its formal consultation in a letter to the Administrator in June 2007. The final SAB advisory is available at: https://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf

4) A review of the updated and expanded risk assessment approaches and methods used in the RTR program was completed in 2009. This methodology was highlighted to the SAB utilizing two RTR source categories: Petroleum Refining Sources MACT I and Portland Cement Manufacturing. The final SAB advisory is available at: https://yosemite.epa.gov/sab/sabproduct.nsf/0/b031ddf79cffded38525734f00649caf!OpenDocument&TableRow=2.3#2

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

6) EPA is currently seeking the Science Advisory Board's (SAB) input on specific enhancements made to our risk assessment methodologies, particularly with respect to screening methodologies, since the last SAB review was completed in 2009 (see above). EPA anticipates that SAB would establish an appropriate expert panel to convene by early 2017.

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

Name of planned action: Portland Cement Risk and Technology Review

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

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

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

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

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

Recommendation: This action does not merit further SAB review. The RTR methodology is continually evolving and can incorporate new science. However, the EPA periodically requests that the SAB convene a review of the RTR methodology, and a new panel review is scheduled for 2017. The Work Group notes that there are many different sectors in the NESHAPs and these sectors incorporate and use data and information appropriate for that specific sector. The Work Group finds that while this action does not merit further SAB review the agency may benefit from SAB advice when new novel science or technologies are part of the sector specific RTR planned actions. The Work Group also notes that the planned SAB review may provide recommendations for changes in the RTR methodology and encourages the agency to incorporate those recommendations into future RTRs.

Background: The manufacturing of Portland cement results in the emissions of numerous hazardous air pollutants, including carcinogenic metals (e.g., chromium) and organic compounds (e.g., benzene). Collectively, these emissions are listed as "hazardous air contaminants" and regulated under Section 112(d) of the Clean Air Act. EPA promulgates and periodically reviews National Emissions Standards for Hazardous Air Pollutants (NESHAPS) and identifies the "Maximum Achievable Control Technology" (MACT) for these pollutants and sources. Every 8 years, EPA is required to conduct a "technology review" of each MACT standard, to assure consistency with the best current control technology. At this time, EPA is also required to conduct a "residual risk assessment" of the health and environmental risks that remain after sources come into compliance with MACT. The EPA generally combines these two requirements into one rulemaking activity, calling this the "risk and technology review" process, or simply RTR.

The initial NESHAP for Portland cement manufacturing were finalized in 1999. Several amendments to the NESHAP were developed over the years, with litigation resulting in two final amendments (September, 2010 & February, 2013). In the current action, EPA is proposing to conduct the required RTR. The rulemaking process in this case entails an assessment to determine if there are residual health risks based on the current maximum achievable control technology (MACT) standards applicable to the subject source category, and to evaluate "developments in practices, processes, and control technologies" and implications for revising the MACT. This action is part of a larger consent decree with a court-ordered deadline of June 5, 2017 for the proposed rule, and June 15, 2018, for the final rule.

Rationale: While the details of each RTR are unique to the sources and pollutants being evaluated, the general approaches and methodologies employed in EPA RTRs have become standardized, and have been subject to multiple peer reviews over the last 17 years. For example, the SAB reviewed the first Report on Pulp and Paper Sources NESHAP to Congress in 1999, reviewed multi-pathway risk assessment methodologies in 2000, provided a consultation on emission inventories and characterizing human exposure in 2006, and (most recently) reviewed updated risk assessment approaches in 2009. Thus, the methods used for RTR reviews have evolved over the course of time taking into account prior SAB reviews. Since the last SAB review in 2009, there have been enhancements to the RTR methodology that are being used in EPA rules and actions; these relate to enhancements in multipathway risks, environmental risks, and inhalation methodologies. The Agency is planning to seek a new SAB review of the RTR methodology enhancements, with plans to convene a panel in early 2017. The agency anticipates that this peer review will be completed in advance of the June 2018 proposed Portland cement RTR, so that any new scientific advances that are part of the new RTR methodology would have undergone peer review.

The unique details of each RTR can include recommendations for new monitoring and maximum achievable control technologies. In general, these technologies are based on established scientific knowledge that has undergone extensive peer review. However, there can be exceptions, and the SAB encourages to USEPA to continually assess and identify for SAB review any such technology recommendations that are based on new scientific knowledge.