

MEMORANDUM

TO: Members of the Chartered SAB and SAB Liaisons

FROM: James R. Mihelcic, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science

DATE: September 4, 2015

SUBJECT: Preparations for Chartered Science Advisory Board (SAB) Discussions of EPA Planned Agency Actions and their Supporting Science in the Spring 2015 Regulatory Agenda

At the upcoming September 24, 2015 public teleconference, 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 2015 semi-annual regulatory agenda. 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 and improvements to the process.

Background

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

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

Summary of the Process Used by the SAB Work Group

The SAB Work Group followed the [process adopted by the Chartered SAB](#) in 2013¹ to initiate its review of major planned actions identified in the Unified Regulatory Agenda by EPA. The current SAB review began when the EPA Office of Policy informed the SAB Staff Office that the Spring 2015

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

Unified (Regulatory) Agenda and Regulatory Plan had been published on May 22, 2015. This semi-annual regulatory agenda is available at <http://www.reginfo.gov/public/>.

This SAB Work Group was formed in June 2015 and includes SAB members with broad expertise in scientific and technological issues related to the proposed actions. The Work Group consists of Drs. James R. Mihelcic (chair), Costel Denson, H. Christopher Frey, Surabi Menon, Eileen Murphy, Charles Werth and Mr. Richard Poirot.

On July 1, 2015, the Work Group received information and short descriptions from the EPA Program Offices on the major planned actions that are listed in the Spring 2015 semi-annual regulatory agenda but not yet proposed. Work Group members identified two actions that required additional information and sent those questions to EPA through the Designated Federal Officer. On August 20, 2015, the Work Group met via teleconference to discuss the seven actions. After reviewing the information provided by EPA, SAB Work Group members developed and concurred on the recommendations presented in this memorandum. A compiled set of the EPA description of the actions and the Work Group’s fact finding and recommendations are provided in Attachment B.

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

The Work Group based the recommendations below on information received from the EPA and the Work Group’s research. Of the seven major planned actions considered, the Work Group recommends that none of the actions merit further SAB consideration. However, the Work Group has identified issues that may require further discussion by the SAB.

Table 1 identifies the seven 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		
RIN²	Planned Action Title	Workgroup Recommendation
2025-AA33	Expansion of Industry Sectors Covered by the Toxics Release Inventory (TRI), Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313	No further SAB consideration is merited.
2060-AS05	Interstate Transport Rule for the 2008 Ozone NAAQS	No further SAB consideration is merited.
2060-AS47	Federal Plan for Regulating Greenhouse Gas Emissions From Electric Generating Units	No further SAB consideration is merited.
2070-AJ20	Pesticides; Certification of Pesticide Applicators	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-AK03	Trichloroethylene (TCE); Rulemaking Under TSCA Section 6(a)	No further SAB consideration is merited.
2070-AK07	N-Methylpyrrolidone (NMP) and Methylene Chloride; Rulemaking Under TSCA Section 6(a)	No further SAB consideration is merited.
2060-AS50	Review of the National Ambient Air Quality Standards for Particulate Matter	No further SAB consideration is merited.

²The 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.

The Work Group notes that several actions on the Agency’s current and previous regulatory agenda (i.e., *Interstate Transport Rule for the 2008 Ozone NAAQS [2060-AS05]* and *Greenhouse Gas New Source Performance Standard for Electric Generating Units-Emission Guidelines for Existing Sources [2060-AR33]* respectively) rely on the Integrated Planning Model (IPM) for projecting future emissions of ozone precursors or greenhouse gases from electric generating units. The Agency used the IPM in numerous regulatory and policy analyses for more than 20 years, during which time it has undergone modification and extensive external review. However, the Work Group notes that the closed-source, proprietary nature of IPM requires contractual assistance to run and is not very transparent to external testing and evaluation. The Work Group did not evaluate the IPM. It would be helpful to know if the agency conducted analyses or has (or could it develop) future plans to:

- conduct periodic retrospective analyses of historical IPM performance?
- conduct periodic comparative analyses of results from IPM and other EGU projection tools?
- work toward adoption or development of more transparent, open-source EGU projection tools?

In reviewing the information for the *Trichloroethylene (TCE); Rulemaking Under TSCA Section 6(a)* and *N-Methylpyrrolidone (NMP) and Methylene Chloride; Rulemaking Under TSCA Section 6(a)* the Work Group finds one option to mitigate risks from these compounds is to transition to safe chemicals and greener processes/technologies. Options for alternatives were extensively discussed in the information provided by the agency for TCE but not NMP or methylene chloride. In a response to questions from the Work Group (see Attachment B) the agency noted the proposed rules would describe the preferred risk management approach and alternatives explaining how the approach achieves adequate protection using the least burdensome requirements, discuss cost and benefits of alternative approaches and provide an opportunity for public comment.

The Work Group notes that the SAB has provided advice and recommendations to the agency encouraging the transition to safe chemicals and greener processes/technologies. In its recent reviews of

the agency's Strategic Research Action Plans and the six major research program areas the SAB noted that the EPA must be prepared to address questions such as: how to design and produce safer chemicals; how chemicals and their byproducts interact in the environment; how to promote safer, sustainable use of chemicals throughout their lifecycle as it addresses chemical exposure to the overall disease burden in humans (including susceptible subpopulations) and the environment. The Work Group recommends that the SAB encourage the agency to continue use the results from these research programs and the TSCA evaluations to identify risk management alternatives that include safe chemicals and greener processes /technologies.

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

The Work Group finds that the agency's descriptions for the Spring 2015 planned actions generally provided more complete information to inform the SAB's decisions than those provided for past SAB reviews of the agency's regulatory agenda. The explanation of the Peer Review process provided for the Spring 2015 planned actions was complete and helpful to our review process. The Work Group continues to strongly recommend that the EPA continue to follow this approach to include specific information on the peer review of the associated science and description of the scientific and technological bases for the planned actions in future descriptions for SAB consideration. For external peer reviews, whether conducted by EPA or by an EPA contractor, EPA should be more clear as to what criteria were used to select experts and what effort was made to address conflict of interest. The Work Group notes that the agency information provided for the two planned actions under the Toxic Substances Control Act (TSCA) Section 6(a) provided detailed information and links to the agency's websites documenting the work plan, contractor-led peer review, and public interaction for each of the chemicals considered in these actions. The information and the agency's response to questions greatly facilitated the Work Group's review of the actions and provides a foundation for future actions under TSCA Section 6(a).

Attachments

- Attachment A: Implementation Process for Identifying EPA Planned Actions for SAB Consideration
- Attachment B: Descriptions of Major EPA Planned Actions Identified in the Spring 2015 Semi-Annual Regulatory Agenda with SAB Work Group Recommendations.

Attachment A

Implementation Process for Identifying EPA Planned Actions for SAB Consideration

Background on the EPA Process

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

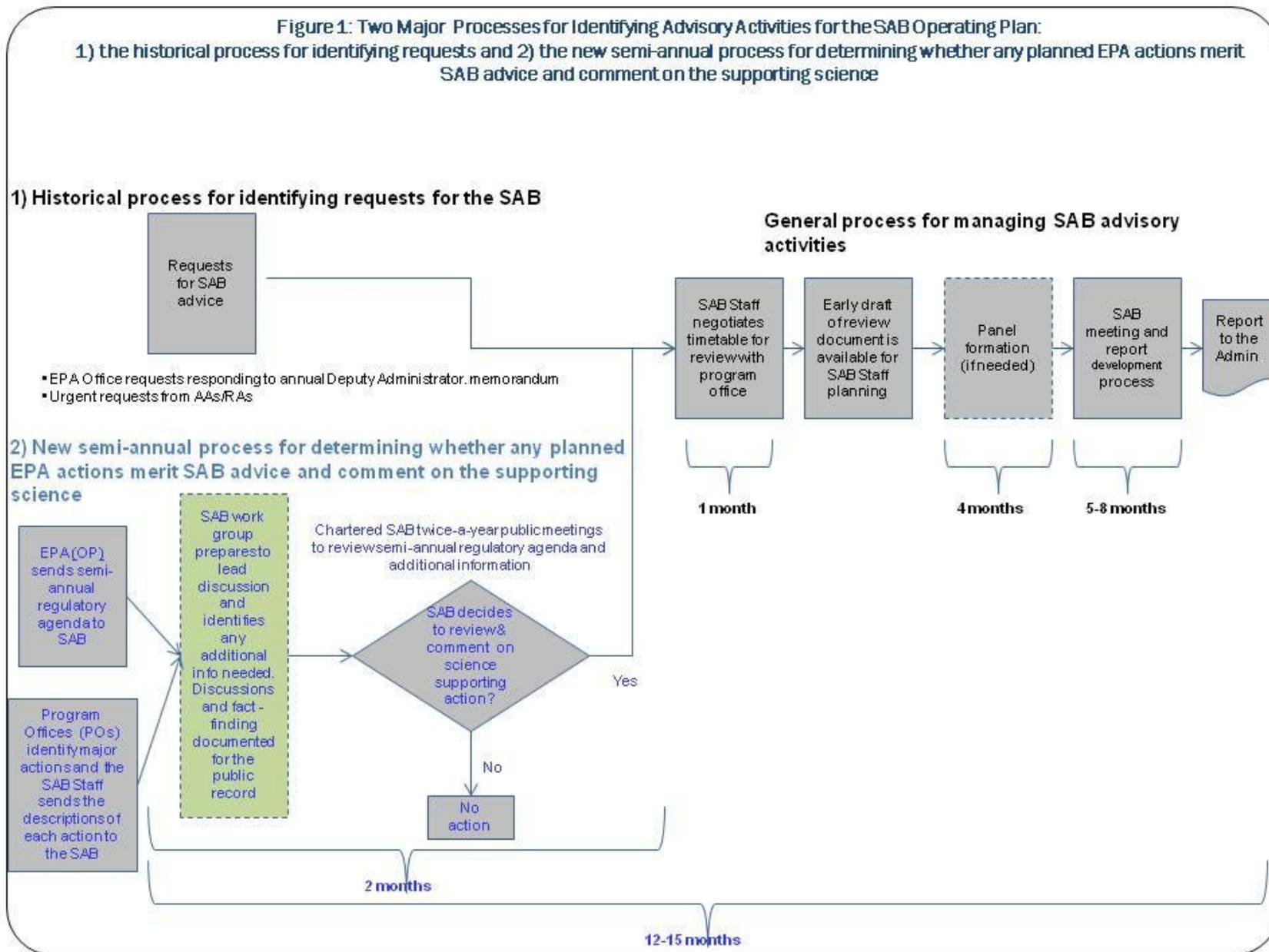
Attachment A: Identifying EPA Planned Actions for SAB Consideration

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

SAB Process

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

Attachment A: Identifying EPA Planned Actions for SAB Consideration



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

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 55--NATIONAL ENVIRONMENTAL POLICY

SUBCHAPTER III--MISCELLANEOUS PROVISIONS

Sec. 4365. Science Advisory Board

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

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

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

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

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

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

Attachment A: Identifying EPA Planned Actions for SAB Consideration

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

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

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

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

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

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

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

Attachment A: Identifying EPA Planned Actions for SAB Consideration

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

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

(g) Consultation and coordination with Scientific Advisory Panel

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

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



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

2

OFFICE OF THE ADMINISTRATOR

MEMORANDUM

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

FROM: Michael Goo, Associate Administrator
Office of Policy

Glenn Paulson
Science Advisor

Vanessa Vu, Director
SAB Staff Office

TO: General Counsel
Assistant Administrators
Associate Administrators
Regional Administrators

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

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

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

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

Attachment A: Identifying EPA Planned Actions for SAB Consideration

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

Attachments

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

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



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

JAN 19 2012

OFFICE OF
POLICY

MEMORANDUM

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

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

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

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

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

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

Attachment A: Identifying EPA Planned Actions for SAB Consideration

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

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

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

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

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

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

EPA Office originating action: OW

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

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

Timetable:

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

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

No

Scientific questions to be addressed and approach:

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

Attachment A: Identifying EPA Planned Actions for SAB Consideration

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

Plans for scientific analyses and peer review:

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

Attachment B
SAB Work Group Recommendations on
Major EPA Planned Actions in the
Spring 2015 Semi-Annual Regulatory Agenda

The SAB formed a Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science in June 2015 to review information and short descriptions provide by the EPA Program Offices on the major planned actions that are listed in the Spring 2015 semi-annual Unified Regulatory Agenda but not yet proposed.

After reviewing the Descriptions of Tier 1 and Tier 2 Actions and additional information provided by EPA, SAB Work Group members developed and concurred on the recommendations and discussion provided in this attachment to the September 4, 2015 Work Group memorandum.

<u>Office</u>	<u>Title</u>	<u>RIN</u>	<u>Page</u>
EPA/OEI	Expansion of Industry Sectors Covered by the Toxics Release Inventory (TRI), Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313	2025-AA33	1
EPA/AR	Interstate Transport Rule for the 2008 Ozone NAAQS	2060-AS05	3
EPA/AR	Federal Plan for Regulating Greenhouse Gas Emissions From Electric Generating Units	2060-AS47	9
EPA/OCSP	Pesticides; Certification of Pesticide Applicators	2070-AJ20	13
EPA/OCSP	Trichloroethylene (TCE); Rulemaking Under TSCA Section 6(a)	2070-AK03	16
EPA/OCSP	N-Methylpyrrolidone (NMP) and Methylene Chloride; Rulemaking Under TSCA Section 6(a)	2070-AK07	21
EPA/AR	Review of the National Ambient Air Quality Standards for Particulate Matter	2060-AS50	26

Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** Expansion of Industry Sectors Covered by the Toxics Release Inventory (TRI), Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313
2. **RIN Number:** 2025-AA33
3. **EPA Office originating action:** Office of Environmental Information (OEI), Office of Information Analysis and Access (OIAA)

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

In support of the goal to provide comprehensive toxic chemical release and other waste management information to communities, this rule would consider expanding the scope of industry sectors covered by Emergency Planning and Community Right-to-Know Act (EPCRA) section 313, also known as the Toxics Release Inventory (TRI). As originally enacted, EPCRA 313 applied only to the manufacturing industry sectors, i.e., sectors in Standard Industrial Classification (SIC) codes 20 through 39. The statute, however, also allows the EPA Administrator to add sectors to TRI to the extent that doing so is relevant to the purposes of EPCRA 313. Under this authority, in 1997, EPA added seven additional industry sectors to the list of sectors covered by TRI. This rule adds or expands coverage to the following industry sectors: Iron Ore Mining, Phosphate Mining, Solid Waste Combustors and Incinerators, Large Dry Cleaning, Petroleum Bulk Storage, and Steam Generation from Coal and/or Oil.

5. **Timetable:** NPRM Signature: 06/22/2016
Final Rule Signature: 06/07/2017

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.**

OEI does not expect this rule will rely on science or technical work products but on legal precedent and parameters.

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

N/A

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

OEI does not expect this rule will rely on science or technical work products but on legal precedent and parameters.

6(d). **Peer review:**

Peer reviewed is not believed to be warranted for this rulemaking.

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

Name of planned action: Expansion of Industry Sectors Covered by the Toxics Release Inventory, Emergency Planning and Community Right-to-Know Act Section 313 (RIN 2025-AA33)

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.

This rule would consider expanding the scope of industry sectors covered by Emergency Planning and Community Right-to-Know Act (EPCRA) section 313, also known as the Toxics Release Inventory (TRI). As originally enacted, EPCRA 313 applied only to the manufacturing industry sectors (i.e., sectors in Standard Industrial Classification (SIC) codes 20 through 39). This rule adds or expands coverage to the following industry sectors: Iron Ore Mining, Phosphate Mining, Solid Waste Combustors and Incinerators, Large Dry Cleaning, Petroleum Bulk Storage, and Steam Generation from Coal and/or Oil. The Office of Environmental Information does not expect this rule will rely on science or technical work products but on legal precedent and parameters.

Description of Planned EPA Tier 1 or Tier 2 Action

- 1. Name of action:** Interstate Transport Rule for the 2008 Ozone NAAQS
- 2. RIN Number:** 2060-AS05
- 3. EPA Office originating action:** Office of Air and Radiation, Office of Atmospheric Programs, Clean Air Markets Division
- 4. Brief description of action and statement of need for the action:**

This proposed rule would address Clean Air Act requirements concerning the transport of air pollution across state boundaries. This action is the next step for the EPA to move forward with eastern states to address interstate transport of ozone with respect to the 2008 ozone National Ambient Air Quality Standards. EPA is proposing to update the Cross-State Air Pollution Rule (CSAPR) to limit the interstate transport of ozone pollution caused by ozone season emissions of nitrogen oxides (NO_x) in eastern states, which affect the ability of downwind states to attain and maintain the 2008 ozone National Ambient Air Quality Standard (NAAQS). EPA is taking this action under Clean Air Act section 110(a)(2)(D)(i)(I), sometimes called the “good neighbor provision.” EPA is proposing revised state emission reduction obligations to be implemented via Federal Implementation Plans that regulate electric generating units in eastern states. This action will reduce adverse air quality impacts in downwind states from ozone pollution that crosses state lines. In conjunction with other federal and state actions, this action will help assure attainment and maintenance of the ozone standard in the eastern part of the country.

5. Timetable:

Notice of Proposed Rulemaking – December 2015
Final Rule – August 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.

The analytical framework used in developing this proposed rule has been developed and refined over many years in support of a number of major rules, starting with the NO_x SIP Call and, more recently, the Clean Air Interstate Rule and the Cross-State Air Pollution Rule (CSAPR). The CSAPR was recently affirmed by the U.S. Supreme Court¹ during judicial review of aspects of that rule. As with these past actions, this proposed rule involves evaluating the long range regional transport of air pollution in the eastern United States and developing a strategy to control upwind state contributions of air pollution to downwind states. Thus, the analytical framework and methods used to support this action are the same as were used in these past actions.

The work products created for this effort are: (1) estimates of future year ozone concentrations and individual upwind state contributions to those concentrations; and (2) estimates of available

¹ *EPA v. EME Homer City Generation, L.P. 134 S. Ct. 1584, 1606-07 (2014)*

future year emission reductions from electric generating units. Work products will be developed using existing air quality and emissions models that have been used in OAR regulatory efforts in the previous actions described above. These models have been peer-reviewed and their use in this proposed regulation is routine and consistent with past practice. Specifically, we use the Comprehensive Air Quality Model with Extensions (CAMx version 6.10) to diagnose the air quality problem and the Integrated Planning Model (IPM version 5.14) to analyze potential remedies.

The first work product created used the CAMx to estimate downwind ozone concentrations and upwind state contributions to those concentrations. CAMx is an Eulerian (grid) photochemical dispersion model that allows for integrated "one-atmosphere" assessments of gaseous and particulate air pollution (ozone, particulate matter, air toxics) over spatial scales ranging from neighborhoods to continents. It is designed to unify all of the technical features required of "state-of-the-science" air quality models into a single open-source system that is computationally efficient, flexible, and publicly available. Information on CAMx is available at <http://www.camx.com>.

The second work product created uses the Integrated Planning Model (IPM) to estimate the emissions from EGUs in the future. IPM is a multi-regional, dynamic, deterministic linear programming model of the U.S. electric power sector. It provides forecasts of least-cost capacity expansion, electricity dispatch, and emission control strategies for meeting energy demand and environmental, transmission, dispatch, and reliability constraints. IPM can be used to evaluate the cost and emissions impacts of proposed policies to limit emissions of sulfur dioxide (SO₂), nitrogen oxides (NO_x), carbon dioxide (CO₂), hydrogen chloride (HCl), and mercury (Hg) from the electric power sector. Information on IPM is available at <http://www.epa.gov/airmarkets/programs/ipm/index.html>. IPM has been used by the agency for regulatory modeling of electric power sector emissions for well over a decade.

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 several steps involved in the analytical framework used to develop this proposed rule. First, we estimate future year ozone concentrations by projecting existing ozone monitoring data using air quality modeling to identify locations that will have difficulty attaining the ozone NAAQS in a specific future year. Next, we use air quality source apportionment modeling to determine the contributions from each upwind state to each of the locations. States that contribute over a particular amount of ozone (i.e., 1% of the ozone NAAQS) are included in the rule. Next, we estimate emission reductions at various cost levels (e.g., the amount of emission reductions available at a particular marginal cost per ton of emission reduction) together with corresponding air quality modeling to select a level of emission reductions. Finally, the level of emission reduction is applied as a state budget limiting the amount of allowable seasonal emissions in each state.

As described in section 6(a), we use CAMx to identify areas and monitors that will have difficulty attaining the NAAQS in the future. This is routine for developing and implementing numerous agency rules and is done by modeling several scenarios following all applicable guidance documents (e.g., http://www.epa.gov/ttn/scram/guidance_sip.htm). First, we simulate a base year (in this case, 2011) for which a comprehensive National Emission Inventory has been

developed (see <http://www.epa.gov/ttnchie1/net/2011inventory.html> and <http://www.epa.gov/ttn/chief/emch/index.html#2011> for details on the National Emissions Inventory). The inputs of this inventory are subject to repeated review and public comment.

Next, we develop a future emission inventory (in this case, 2017) and simulate the ozone air quality. Again, development of this inventory follows the modeling guidance and the inputs are subject to extensive public comment and review. The air quality modeling is used in a “relative sense,” where the change in estimates from 2011 to 2017 is applied as a percent change to actual monitoring data from 2009-2013. The resulting air quality estimates are grounded in quality-assured air quality measurements. For the 2017 scenario, we use the source apportionment technique within CAMx to identify the contribution of pollution from ozone precursors. States and other stakeholders have utilized all of these modeling techniques and have found similar results.

Finally, we use IPM to estimate the emissions from electric generating units in the future. For this effort, we use IPM to estimate the emissions from electric generating units present in each state in 2017 at various costs per ton of emission reductions. In other words, we identify the emissions that would be achieved in a state if all EGUs greater than 25 MW in the state used all emission controls and emission reduction measures available at each of the cost thresholds. In our preliminary modeling, we examined several cost thresholds (e.g., \$500/ton, \$1300/ton, and \$3400/ton) where engineering analysis suggested that particular NOx emission reduction technology would be widespread, yielding cost-effective emission reductions.

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?”

Since EPA began using the Integrated Planning Model (IPM®) for power sector policy and regulatory analyses over 20 years ago, IPM has been periodically formally peer reviewed by multiple peer review processes. In the past 10 years alone, EPA has convened 7 separate panels of independent experts to review IPM’s coal supply and transportation assumptions, natural gas assumptions, financial and industry structure assumptions, and model formulation. In addition, SAB committees reviewed IPM and its analytical results multiple times, including the Clean Air Science Advisory Committee as a part of setting the NAAQS for particulate matter, ozone, SO₂ and NOx, and the Advisory Council on Clean Air Compliance Analysis as a part of EPA’s §812 Reports to Congress. In relation to the §812 Report, the SAB observed that “For Electrical Generating Units (EGUs), the approach to use the Integrated Planning Model (IPM) for EGU projections appears to be the most scientifically valid approach.”² IPM also underwent extensive expert review by the Council of Economic Advisors, the National Academy of Sciences, and Stanford University’s Energy Modeling Forum project. Additional expert peer reviews of IPM were conducted by regional and state planning organizations (e.g., RGGI, WRAP and OTAG),

² Source: “Advisory on Plans for Emissions Estimation in the Analytical Plan for EPA’s Second Prospective Analysis – Benefits and Costs of the Clean Air Act, 1990-2020; An Advisory by the Advisory Council for Clean Air Compliance Analysis”. Pg. 11. EPA-COUNCIL-ADV-04-001 (2004).
[http://yosemite.epa.gov/sab/sabproduct.nsf/0/61E8B48F6E9103B485256DEC004AD005/\\$File/council_adv_04_001.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/0/61E8B48F6E9103B485256DEC004AD005/$File/council_adv_04_001.pdf)

other federal agencies (FERC, GAO and DOE), and industries (e.g., TVA and SoCal), and research organizations (e.g., RFF, EPRI).

The CAMx has been and continues to be widely used by the scientific and regulatory community to estimate the impacts on ozone of changes in emissions and to quantify the contributions to ozone from emissions in particular geographic areas and from specific source categories. CAMx has been evaluated against ambient ozone measurements in multiple studies by numerous groups. Applications and evaluations of CAMx have been published in peer-reviewed scientific journals over the course of the development of this model.³ The source apportionment technique in CAMx used for calculating ozone contributions has been subject to an independent EPA-sponsored peer review by air quality modeling experts in the academic community.

Finally, as a part of a wide range of federal and state regulatory development processes, including the rules mentioned above in 6(a), IPM and CAMx have been extensively reviewed by all components of the relevant stakeholder communities, as well as during federal litigation.

6(d) Peer Review

The Office of Air and Radiation (OAR) will not be developing new scientific work products that require peer review. As noted in 6(a) and 6(b), we are using well-established models, methods and data for evaluating the downwind impacts of ozone precursors. As described in 6(c), these models and data have been subject to peer review and quality assurance procedures.

OAR considered the guidance in the peer review handbook and determined that additional peer review would not be necessary. The analytical framework used in developing this rule will not result in new scientific work products that meet the EPA Peer Review Handbook definition of "an influential scientific or technical work product." The products developed use models which have been adequately reviewed for the purposes used. According to the Handbook, "application of an existing, adequately peer-reviewed methodology or model to a situation that departs significantly from the situation it was originally designed to address may make peer review appropriate. Similarly, a modification of an existing, adequately peer-reviewed methodology or model that departs significantly from its original approach may also make peer review appropriate." As described above, the technical analyses for this action are based on models, methods and data that have been peer-reviewed in the past, do not depart in application from past uses and have not been significantly modified. Thus while the work products clearly provide a significant basis for the proposed regulation, in accordance with the EPA peer review handbook, they do not require peer review, nor do we believe such additional peer review would contribute significantly to the development of the needed products.

³ Examples of journal articles on CAMx include:

Byun, D.W., Kim, S.-T., Kim, S.-B., 2007. Evaluation of air quality models for the simulation of a high ozone episode in the Houston metropolitan area. *Atmospheric Environment* 41, 837-853.

Kemball-Cook, S., Parrish, D., Ryerson, T., Nopmongcol, U., Johnson, J., Tai, E., Yarwood, G., 2009. Contributions of regional transport and local sources to ozone exceedances in Houston and Dallas: Comparison of results from a photochemical grid model to aircraft and surface measurements. *Journal of Geophysical Research: Atmospheres* (1984–2012) 114.

Nam, J., Kimura, Y., Vizuete, W., Murphy, C., Allen, D.T., 2006. Modeling the impacts of emission events on ozone formation in Houston, Texas. *Atmospheric Environment* 40, 5329-5341.

Dunker, A.M., Koo, B., Yarwood, G. 2014. Sensitivity of atmospheric models to rate terms within complex chemical mechanisms. *Atmospheric Environment* 98, 224-230.

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

Name of planned action: Interstate Transport Rule for the 2008 Ozone NAAQS (2060-AS05)

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.

This proposed rule would limit interstate transport of ozone pollution in the eastern U.S. to areas expected to have problems attaining or maintaining the 2008 ozone National Ambient Air Quality Standard (NAAQS) by 2017. This is basically an update to EPA’s Cross-State Air Pollution Rule (CSAPR), which focused on interstate contributions to violations of the 1997 ozone NAAQS and 2006 PM_{2.5} NAAQS. The proposed rule employs emissions inventory, emissions projection photochemical modeling and source attribution tools which have previously been employed in CSAPR, and which have previously been subject to rigorous external review.

The proposed rule used the Comprehensive Air Quality Model with Extensions model ([CAMx version 6.11](#)) to identify areas with projected nonattainment and maintenance problems in 2017, and applied the CAMx Ozone Source Apportionment Technology/Anthropogenic Precursor Culpability Analysis (OSAT/APCA) technique to identify interstate contributions from ozone precursors. Meteorological data for 2011 from the Weather Research Forecast model ([WRF version 3.4](#)) was employed for both the 2011 base year and 2017 projection runs. The 2011 National Emission Inventory (2011 NEI version 2 – [2011v6.2](#)) was used for baseline modeling and as the basis for 2017 emissions projections. Projections of 2017 emissions include estimated effects from on-the-books control programs, with specific projections for electric generating units (EGU) emissions and costs developed using the Integrated Planning Model ([IPM version 5.14](#)).

These tools have been widely used in, and evaluated and refined by, the scientific community, and have been presented in a wide range of peer-reviewed scientific publications. CAMx is an open-source, [publically available](#), “state-of-the-science” air quality simulation model. The CAMx OSAT/APCA source apportionment technique used for calculating ozone contributions has been subject to an independent EPA-sponsored peer review by air quality modeling experts in the academic community. EPA has used the IPM model to project future electric power sector emissions and costs in many, various applications for more than 20 years, including NAAQS reviews overseen by the Clean Air Scientific Advisory Committee, and Clean Air Act cost/benefit analyses reviewed by the Council on Clean Air Compliance Analysis. IPM has also seen extensive review by other federal agencies, regional, state and private sector groups. EPA’s use of these tools in the current application is well documented in the technical support material, and the Agency continues to seek, and has been responsive to, public comments on the process, analysis tools, and underlying data. For the reasons indicated above, this action does not meet the criteria for SAB review, and the Work Group recommends against review at this time.

The workgroup would however like EPA to comment on their continuing, exclusive use of the IPM model for projecting future EGU emissions (and costs). While IPM has been thoroughly vetted and consistently employed in many EPA applications over the years, it remains a proprietary tool, requiring contractor assistance to implement, and with internal functions that lack transparency and are difficult to test and evaluate. The stated goals of the current application are to “to support the work states are already doing to control ozone air pollution ... and to facilitate states' submissions of transport SIPs for the 2008 ozone standards”. However, few state or regional organizations use IPM, preferring instead to employ lower cost, more flexible and more transparent EGU projection tools, such as the Eastern Regional Technical Advisory Committee Electric Generation Unit Forecast Tool ([ERTAC EGU tool](#)). Limited comparisons conducted to date between IPM and ERTAC EGU have indicated substantial differences in the projected overall timing, magnitude and spatial distributions of future EGU SO₂ and NO_x emissions. This makes it difficult for states to coordinate their planning activities with EPA, and raises questions about the relative accuracies of the different projections.

The Work Group notes that several actions on the Agency’s current and previous regulatory agenda (i.e., Interstate Transport Rule for the 2008 Ozone NAAQS [2060-AS05] and Greenhouse Gas New Source Performance Standard for Electric Generating Units-Emission Guidelines for Existing Sources [2060-AR33] respectively) rely on the Integrated Planning Model (IPM) for projecting future emissions of ozone precursors or greenhouse gases from electric generating units. The Agency used the IPM in numerous regulatory and policy analyses for more than 20 years, during which time it has undergone modification and extensive external review. However, as stated in the previous

paragraph, the Work Group notes that the closed-source, proprietary nature of IPM requires contractual assistance to run and is not very transparent to external testing and evaluation. The Work Group did not evaluate the IPM. It would be helpful to know if the agency conducted analyses or has (or could it develop) future plans to:

- conduct periodic retrospective analyses of historical IPM performance?
- conduct periodic comparative analyses of results from IPM and other EGU projection tools?
- work toward adoption or development of more transparent, open-source EGU projection tools?

While it is not critical to the current application, at some point it would be useful for EPA to conduct these retrospective analyses comparing historical IPM projections with actual EGU emissions and with the results of alternative EGU projection tools. The Work Group finds that it would be useful if the agency involved state, regional and utility industry participation in conducting this kind of retrospective model comparison analysis.

Description of Planned EPA Tier 1 or Tier 2 Action

- 1. Name of action:** Federal Plan Requirements for Greenhouse Gas Emissions from Electric Utility Generating Units Constructed on or Before January 8, 2014; Model Trading Rule
- 2. RIN Number:** 5832-AS47
- 3. EPA Office originating action:** The Office of Air Quality, Planning and Standards (OAQPS) in the Office of Air and Radiation (OAR)

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

This federal plan is an outgrowth of the Clean Power Plan for existing power plants, also called the Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Generating Units (79 FR 34830) that were proposed in June, 2014. In these emission guidelines the EPA proposed to set state goals for reducing carbon dioxide (CO₂) from fossil fuel electric generating units (EGUs) after determining the Best System of Emission Reduction (BSER). The proposed BSER is made up of four building blocks: 1) heat rate improvements at coal-fired EGUs, 2) a shift in generation from steam units to natural gas combined cycle units, 3) an increase in non-emitting generation (e.g., renewable energy), and 4) an increase in demand-side energy efficiency. The EPA has initiated this rulemaking for a federal plan as a mechanism for implementation of the emission guidelines for those states that do not develop an approvable state plan. The affected EGUs in the states that do not develop a sufficient state plan as part of the emission guidelines are the entities that will be subject to this rulemaking.

Additional information about the Federal Plan for Regulating Greenhouse Gas Emissions from Electric Generating Units is available on EPA's Clean Power Plan web site: www.epa.gov/cleanpowerplan.

- 5. Timetable:** This action is part of the President's Obama's Climate Action Plan. EPA plans to propose this action in the summer of 2015.

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

This proposed Federal Plan does not set any emission limitations or science based requirements and thus there are no new scientific products that will be created to inform this action. The standards which govern facility plans are those which were set under the 111(d) rulemaking. That proposed action was reviewed by the SAB in 2014 as part of this SAB process for review of EPA proposals. A full list of technical support documents, detailing the scientific information relied upon in the 111(d) action is available on EPA's Clean Power Plan website: <http://www2.epa.gov/carbon-pollution-standards/clean-power-plan-proposed-rule-technical-documents#cpp>. All this action does is puts in place a regulatory mechanism in the case a state fails to do so.

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

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

N/A

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

N/A

6(d). Peer review:

N/A

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

Name of planned action: Federal Plan Requirements for Greenhouse Gas Emissions from Electric Utility Generating Units Constructed on or Before January 8, 2014; Model Trading Rule (5832-AS47)

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.

This action is part of the President’s Climate Action plan announced over two years ago and aims to provide those States that do not have an approvable plan to reduce carbon emissions by 30% below 2005 levels with a federal plan as a mechanism for implementation of emission guidelines. Thus, the affected electric generating units (EGUs) will be located in states that do not develop a sufficient state plan as part of the emission guidelines. This action can be considered as an interim measure for rulemaking until states assume their own plans to reduce

emissions. The standards to be used under the planned action were covered under the 111(d) rulemaking plan that was previously reviewed by the SAB in 2014 for the adequacy of science supporting the standard for the new stationary sources (electric utility generation units). That review recommended no further consideration. Furthermore, this action does not set new emissions guidelines or any science-based requirements and no new products are to be created through this action.

Description of Planned EPA Tier 1 or Tier 2 Action

- 1. Name of action:** Pesticides; Certification of Pesticide Applicators
- 2. RIN Number:** 2070-AJ20
- 3. EPA Office originating action:** Office of Chemical Safety and Pollution Prevention, Office of Pesticide Programs (OPP)
- 4. Brief description of action and statement of need for the action:**

EPA is proposing changes to the existing regulation concerning the certification of applicators of restricted use pesticides (RUPs) in response to extensive stakeholder review of the regulation and its implementation since 1974. EPA's proposed change would ensure the Federal certification program standards adequately protect applicators, the public, and the environment from risks associated with use of RUPs. The proposed changes are intended to improve the competency of certified applicators of RUPs, increase protection for noncertified applicators of RUPs operating under the direct supervision of a certified applicator through enhanced pesticide safety training and standards for supervision of noncertified applicators, and establish a minimum age requirement for certified and noncertified applicators. In keeping with EPA's commitment to work more closely with Tribal governments to strengthen environmental protection in Indian country, certain changes are intended to provide more practical options for establishing certification programs in Indian country.

The certification regulation has been in place since the 1970s without substantial change. EPA is proposing revisions to the existing certification regulation at 40 CFR part 171 in order to reduce occupational pesticide exposure and the incidence of related illness among certified applicators, noncertified applicators working under their direct supervision, and agricultural workers, and to ensure that when used according to their labeling, RUPs do not cause unreasonable adverse effects to applicators, workers, the public, or the environment. Discussions with State regulatory partners and key stakeholders over many years, together with EPA's review of incident data, have led EPA to identify several shortcomings in the current regulation that should be addressed.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires EPA to consider the benefits of pesticides as well as the potential risks. This consideration does not override EPA's responsibility to protect human health and the environment; rather, where a pesticide's use provides benefits, EPA must ensure that the product can be used without posing unreasonable adverse effects to human health or the environment. Some pesticides may pose unreasonable adverse effects to human health or the environment without strict adherence to precise and often complex mitigation measures specified on the pesticide labeling – EPA classifies these products as restricted use. To ensure that the necessary measures are followed, EPA requires an additional level of precaution - these pesticides may be applied only by applicators who are certified or by noncertified applicators working under the direct supervision of a certified applicator. Certification serves to ensure competency of applicators to use these restricted products, and therefore to protect the applicator, persons working under the direct supervision of the applicator, the general public, and the environment through judicious and appropriate use of RUPs.

There are no previous proposals or litigation associated with this action.

5. Timetable:

NPRM expected July 2015 –

<http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201504&RIN=2070-AJ20>

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

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

No scientific work products have been developed to inform decisions regarding the planned action. FIFRA requires EPA to provide copies of proposed rules to the FIFRA Scientific Advisory Panel (SAP) for review of any scientific issues related to the proposed rule. The FIFRA SAP considered whether to review the action and waived its review on September 4, 2014 because the proposed revisions are administrative in nature and do not contain scientific issues that require the SAP's consideration. Therefore, OPP did not need to prepare any scientific or technical documents to support this proposed rule.

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

N/A

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

N/A

6(d). Peer review:

N/A

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

Name of planned action: Pesticides; Certification of Pesticide Applicators (2070-AJ20)

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 (see below)	
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.

EPA is proposing changes to the existing regulation concerning the certification of applicators of restricted use pesticides (RUPs) in response to extensive stakeholder review of the regulation and its implementation since 1974. FIFRA requires EPA to provide copies of proposed rules to the FIFRA Scientific Advisory Panel for review of any scientific issues related to the proposed rule. The FIFRA SAP considered whether to review the action and waived its review on September 4, 2014 because the proposed revisions are administrative in nature and do not contain scientific issues that require the SAB’s consideration.

Description of Planned EPA Tier 1 or Tier 2 Action

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) (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 Register⁴. 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

⁴ 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.

Description of Planned EPA Tier 1 or Tier 2 Action

1. **Name of action:** N-Methylpyrrolidone (NMP) and Methylene Chloride; Rulemaking Under TSCA Section 6(a)

2. **RIN Number:** 2070-AK07

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 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 n-methylpyrrolidone (NMP) and methylene chloride for risk evaluation as part of its [Work Plan for Chemical Assessments under TSCA](#). NMP and methylene chloride are used in commercial processes and in consumer products in residential settings. In the [August 2014 TSCA Work Plan Chemical Risk Assessment for methylene chloride](#) and [March 2015 TSCA Work Plan Chemical Risk Assessment for NMP](#), EPA identified risks associated with commercial and consumer paint removal uses. EPA is initiating rulemaking under TSCA section 6 to address these risks. Specifically, EPA will determine whether the use of NMP or methylene chloride in commercial and consumer paint removal poses 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 early 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.**

- [August 2014 TSCA Work Plan Chemical Risk Assessment for Methylene Chloride](#)
- [March 2015 TSCA Work Plan Chemical Risk Assessment for NMP](#)

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 assessments underwent peer review in 2013. [View the peer review plan, report and response to comments.](#)

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 products meet 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:

- [August 2014 TSCA Work Plan Chemical Risk Assessment for Methylene Chloride](#) - peer review completed.
- [March 2015 TSCA Work Plan Chemical Risk Assessment for NMP](#) - peer review completed.

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

Name of planned action: N-Methylpyrrolidone (NMP) and Methylene Chloride; Rulemaking Under TSCA Section 6(a) (2070-AK07)

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 n-methylpyrrolidone (NMP) and methylene chloride for risk evaluation as part of its Work Plan for Chemical Assessments under TSCA. NMP and methylene chloride are used in commercial processes and in consumer products in residential settings. In the August 2014 TSCA Work Plan Chemical Risk Assessment for methylene chloride and March 2015 TSCA Work Plan Chemical Risk Assessment for NMP, EPA identified risks associated with commercial and consumer paint removal uses. EPA is initiating rulemaking under TSCA section 6 to address these risks. Specifically, EPA will determine whether the use of NMP or methylene chloride in commercial and consumer paint removal poses 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.

EPA issued separate draft risk assessments for NMP and methylene chloride for public review and comment. This was followed by a review process that consisted of internal review (EPA), 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 both assessments 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 Register⁵. The Federal Register notice announces opportunities 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 (the combined panel was comprised of eight members) and consisted of members affiliated with academia, industry, and state government. Members of the external review panel provided written response 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.

EPA/OPPT did not include a quantitative assessment of environmental effects in this risk assessment because NMP has a low hazard profile for ecological receptors and low persistence and bioaccumulation if released into aquatic or terrestrial environments. The NMP assessment identified acute and chronic health risks to people, particularly pregnant women and women of childbearing age, who are exposed to paint and coating removal products containing high concentrations of NMP; however, EPA concluded these risks could be minimized by using NMP-resistant gloves in well ventilated work areas to reduce exposure. While the Agency wrote in the "Fact Sheet on NMP" that the option of transitioning to safe chemicals and greener processes/technologies was one option to mitigate risks from NMP, it was not clear that this option was considered.

Similarly, EPA/OPPT ruled out ecological impacts of DCM during the problem formulation and scoping process because the aquatic toxicity of DCM for fish, aquatic invertebrates and aquatic plants is low. DCM is a probable human carcinogen and exhibits acute non-cancer effects and is used widely in consumer products. It has been detected with some frequency in drinking water, indoor environments, ambient air, groundwater and soil. The EPA assessment focused on

⁵ Links to webpages for n-methylpyrrolidone

The Agency's procedures for the TSCA actions peer review include: 1) developing a [Peer Review Plan](#) for both assessments 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.

Links to webpages for methylene chloride

The Agency's procedures for the TSCA actions peer review include: 1) developing a [Peer Review Plan](#) for both assessments 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.

estimating risk due to occupational and residential use of paint strippers containing DCM. As use of DCM as a paint stripper decrease, use of substitutes like NMP has been increasing. Given that both DCM and NMP were reviewed here, it raises the issue of relative safety of substitute chemicals. As with NMP, EPA recommends the option of transitioning "...to safer chemicals and greener processes/technologies, promotion of best practices, and phase out of uses," and that the Agency is evaluating potential actions that might result in reduced risks due to DCM. However, it is not clear how far along the Agency is with this evaluation.

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

Question: The Agency wrote in the "Fact Sheet on NMP" that one option to mitigate risks from NMP was to transition to safe chemicals and greener processes/technologies, it was not clear that this option was considered. Could the Agency comment on whether this option to mitigate risk was considered at all as part of the Work Plan for Chemical Assessments for N-Methylpyrrolidone (NMP) and Methylene Chloride under TSCA?

EPA Response: Under OPPT's existing chemicals program, risk mitigation options are developed after a risk assessment is completed and only are developed if the assessment indicates that the chemical poses risks to humans or the environment. The NMP assessment did indicate risks, and therefore at this time options are being developed to mitigate those risks. Those options, which may include transition to alternatives, will be discussed and evaluated through EPA's formal action development process as it develops its proposed rule for NMP and DCM (methylene chloride) used as paint/coating removers.

Question: The agency did not identify alternatives to transition to safer chemicals and greener processes/technologies in the "Fact Sheet on DCM." Could the Agency comment on whether this option to mitigate risk was considered at all as part of the Work Plan for Chemical Assessments for Methylene Chloride?

EPA Response: See above for NMP; the same applies for DCM.

The Workgroup concluded that EPA was thorough in seeking expert, public input and in compiling all available information as they developed the TSCA Work Plan Chemical assessments for n-methylpyrrolidone (NMP) and methylene chloride using the best available information and approaches. These assessments focused on those TSCA uses of n-methylpyrrolidone (NMP) and methylene chloride 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.

Description of Planned EPA Tier 1 or Tier 2 Action

- 1. Name of action:** Review of the National Ambient Air Quality Standards for PM
- 2. RIN Number:** 2060-AS50
- 3. EPA Office originating action:** Office of Air Quality Planning and Standards in the Office of Air and Radiation

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

Sections 108 and 109 of the Clean Air Act require the EPA to set, and to periodically review, primary (health-based) and secondary (welfare-based) National Ambient Air Quality Standards (NAAQS). The EPA has established NAAQS for six common air pollutants (particulate matter, ozone, nitrogen dioxide, sulfur dioxide, carbon monoxide, lead). The Agency is currently in the early stages of reviewing the NAAQS for particulate matter (PM). The Agency's decisions in this review will be based on consideration of the available scientific evidence and technical information on PM, advice from the Clean Air Scientific Advisory Committee (CASAC), and comments from interested stakeholder groups and members of the public.

5. Timetable:

Section 109 of the Clean Air Act establishes a 5-year review cycle for the NAAQS. For PM, the last review was completed on December 14, 2012 (78 FR 3086). The EPA is currently in the planning stages for the next review.

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

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

The EPA's National Center for Environmental Assessment (NCEA) will prepare the PM Integrated Science Assessment (ISA). The PM ISA will present a rigorous assessment of the most policy-relevant scientific evidence on PM. The ISA will provide the scientific basis for the review of the PM NAAQS.

Building on the evidence assessed in the ISA, the EPA's Office of Air Quality Planning and Standards (OAQPS) will conduct quantitative analyses of PM exposures and risks and, as appropriate, will prepare a risk and exposure assessment document (REA) presenting and assessing these analyses.

The OAQPS will also prepare a Policy Assessment document (PA) synthesizing the scientific evidence from the ISA and the exposure/risk information from quantitative analyses conducted. The PA will present considerations and conclusions of the EPA staff regarding the range of policy options that could be supported by the available evidence and information.

None of these assessment documents are yet available. A first draft of the ISA is expected by the end of calendar year 2016.

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).

On February 9-11, 2015, the EPA held a kickoff workshop with internal and external scientific experts to solicit feedback on new science relevant for the PM review and on the key issues that will frame this review. Feedback received at this workshop will inform the development of the ISA, the REA (if prepared), and the PA. Draft versions of the ISA, REA (if prepared), and the PA will be reviewed at public meetings by the PM Panel of the Clean Air Scientific Advisory Committee (CASAC). Final documents will reflect staff's consideration of CASAC advice and recommendations, as well as staff's consideration of the comments provided by members of the public.

As noted above, none of these assessment documents are yet available. A first draft of the ISA is expected by the end of calendar year 2016.

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

The review of the PM NAAQS will rely on assessment documents that are designated as "highly influential scientific assessments" (HISA) and the review will encompass precedential, novel, and controversial issues.

6(d). Peer review:

As noted above, draft versions of the ISA, REA (if prepared), and PA will be reviewed at public meetings by the PM CASAC Panel. The PM CASAC Panel will be charged with providing written advice to the EPA Administrator, reflecting the consensus views of the Panel where appropriate. Information on CASAC and CASAC Panels can be found at: <http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CommitteesandMembership?OpenDocument>.

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

Name of planned action: Review of the National Ambient Air Quality Standards for PM (2060-AS50)

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

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

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

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

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

Recommendation: The SAB should not consider this action for review.

This action will undergo a multi-year detailed review process by the EPA Clean Air Scientific Advisory Committee and its PM Review Panel. CASAC is a FACA committee. The PM Review Panel will be specifically constituted, in terms of independent scientific expertise, to review this proposed action. CASAC has statutory mandate under the Clean Air Act to advise the Administrator regarding the NAAQS.