

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: December 16, 2014

SUBJECT: Preparations for Chartered Science Advisory Board (SAB) Discussions of EPA Planned Agency Actions and their Supporting Science in the Spring 2014 Regulatory Agenda

At the upcoming January 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 2014 semi-annual regulatory agenda. To support this discussion, a SAB Work Group was charged with identifying actions for further consideration by the Chartered SAB. This memorandum provides background on this activity, a short description of the process for identifying actions for SAB consideration, a summary of the process used by the Work Group, and Work Group recommendations on the planned actions 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-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 identify scientific issues that might be appropriate for SAB consideration.

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 2014

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 23, 2014. This semi-annual regulatory agenda is available at <http://www.reginfo.gov/public/>.

This SAB Work Group was formed in July 2014 and consisted of SAB members with broad expertise in scientific and technological issues related to the proposed actions. The Work Group consisted of Drs. James R. Mihelcic (chair), Taylor Eighmy, H. Christopher Frey, and Gina Solomon.

On August 8, 2014, the SAB Staff Office received descriptions of the major planned actions that were not yet proposed and are listed in the Spring 2014 semi-annual regulatory agenda. The SAB Staff Office forwarded these descriptions to the Work Group on August 10, 2014. After reviewing the information provided by EPA, SAB Work Group members developed and concurred on the recommendation presented in this memorandum.

In developing these recommendations, the Work Group considered the information and descriptions of planned actions that were identified by the EPA as “major actions.” The Work Group considered the following factors when assessing each proposed major action, i.e., whether the action:

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

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 three major planned actions considered, the Work Group recommends that two require no further SAB actions. One action, the Interstate Transport Rule for the 2008 Ozone NAAQS (2060-AS05) is not at a point in its regulatory development that the EPA could provide sufficient information for the SAB Work Group to recommend whether the action required further consideration by the SAB. The Work Group notes the EPA offered to “brief the SAB in the future” on this action. The Work Group recommends that the SAB reconsider this action when more information is available and suggests that the SAB Staff Office work with the Office of Air to provide more information on this action when it is available.

Table 1 identifies the three 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
<u>2060-AS05</u>	Interstate Transport Rule for the 2008 Ozone NAAQS	Defer SAB consideration of the planned action until more information is available.
<u>2060-AQ11</u>	National Emission Standards for Hazardous Air Pollutants: Ferroalloys Production	No further SAB consideration is merited.
<u>2060-AS22</u>	Renewable Fuel Program - 2015 Volume Standards	No further SAB consideration is merited.
² The Regulatory Identification Number provides a hyperlink to the Office of Management and Budget’s webpage and information on the planned action provided in the Unified Regulatory Agenda.		

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 2014 planned actions provided more complete information to inform the SAB’s decisions than was provided for past SAB reviews of the agency’s regulatory agenda. The Work Group recognizes the unique status of the Interstate Transport Rule for the 2008 Ozone NAAQS, appreciates the EPA acknowledging that the SAB will need more information for its consideration, and looks forward to the Agency providing additional information when it becomes available.

The SAB Work Group strongly encourages the EPA to continue including 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. Providing such specific information from the start of the SAB’s Work Group’s review will facilitate the SAB’s timely screening of the scientific and technical basis of Regulatory Agenda items.

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 2014 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

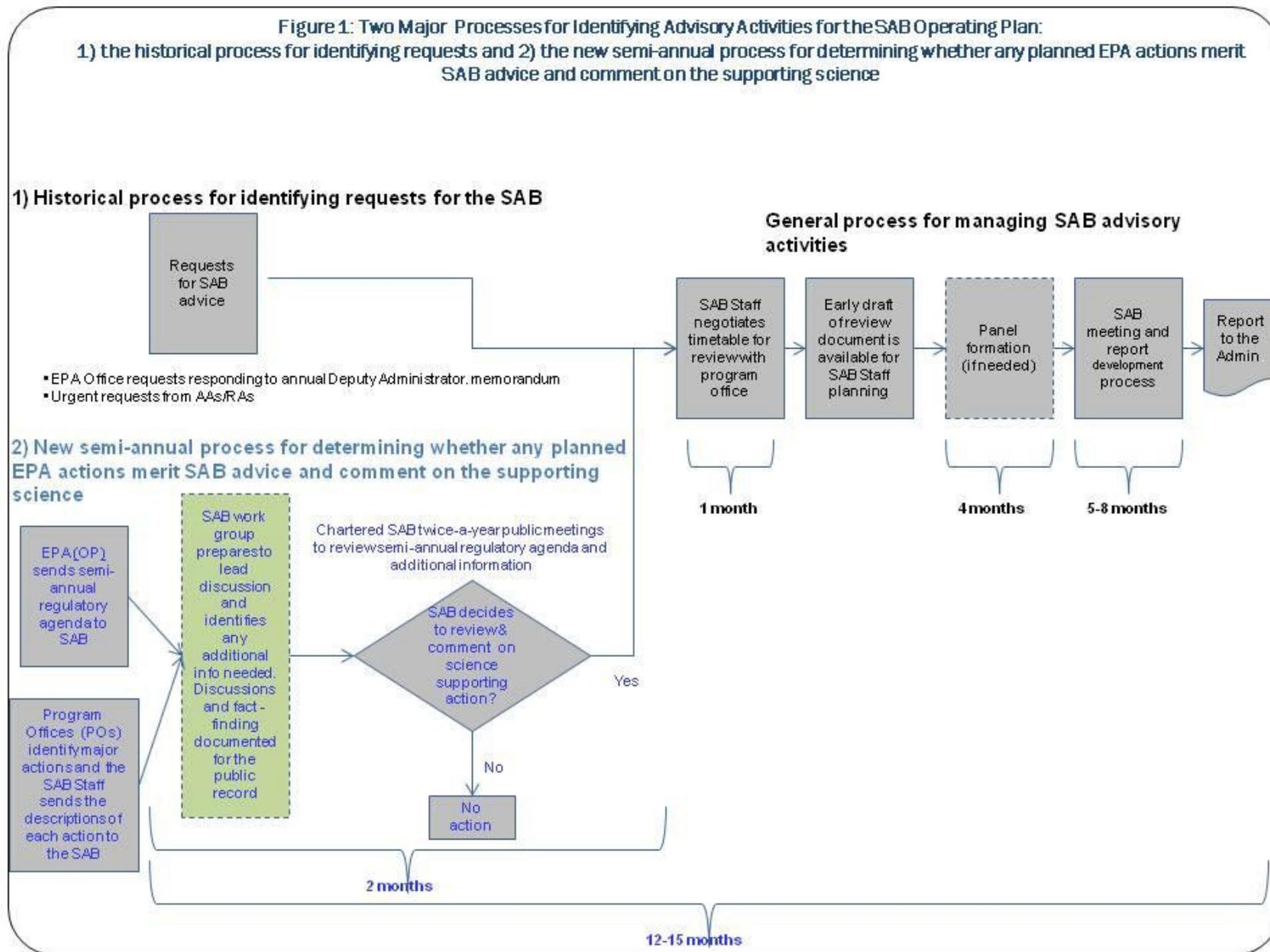
Attachment A: Identifying EPA Planned Actions for SAB Consideration

- ◆ 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**

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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
Descriptions of Major EPA Planned Actions in the
Spring 2014 Semi-Annual Regulatory Agenda

December 16, 2014

RIN	Office	Title of Planned Action	Page
2060-AS05	OAR	Interstate Transport Rule for the 2008 Ozone NAAQS	1
2060-AQ11	OAR	National Emission Standards for Hazardous Air Pollutants: Ferroalloys Production	5
2060-AS22	OAR	Renewable Fuel Program - 2015 Volume Standards	9

EPA's Description of the Planned Action

Name of action: Interstate Transport Rule for the 2008 Ozone NAAQS

RIN Number: 2060-AS05

EPA Office originating action: OAR/OAP

Brief description of action and statement of need for the action: This rule would address Clean Air Act requirements concerning the transport of air pollution across state boundaries. The rule would be the next step for the EPA to move forward with the states to address interstate transport with respect to the 2008 ozone National Ambient Air Quality Standards.

This action is impacted by the D.C. Circuit decision vacating and remanding the Cross State Air Pollution Rule (CSAPR), which established a framework to address interstate transport of air pollution in relation to attainment of the NAAQS. After the CSAPR rule was finalized in July 2011, the rule was challenged in court and the U.S. Court of Appeals for the D.C. Circuit (D.C. Circuit) stayed the rule's implementation in December 2011. In August 2012, the D.C. Circuit vacated CSAPR. Thus, the Interstate Transport Rule for the 2008 Ozone NAAQS was submitted for listing on EPA's regulatory agenda under the assumption that it would address the concerns raised by the D.C. Circuit in its opinion vacating CSAPR.

The Department of Justice subsequently appealed the decision of the D.C. Circuit and, on April 29, 2014, the U.S. Supreme Court affirmed EPA's approach for addressing pollution transport, reversing the prior D.C. Circuit opinion and remanding the case back to the D.C. Circuit for further proceedings. On June 26, 2014, the Department of Justice filed a motion requesting that the D.C. Circuit lift the stay on CSAPR and allow EPA to begin implementing the rule starting January 1, 2015. The court has not yet ruled on this request.

EPA is now actively evaluating the implications of these recent legal developments, including implications for EPA's approach and schedule for the Interstate Transport Rule for the 2008 Ozone NAAQS. Under the circumstances, EPA is not prepared at this time to address what scientific questions might be raised by a future rule; however the Agency will provide this information to the SAB in the future.

Timetable: This action was listed in the Spring 2014 Regulatory Agenda Proposal in October 2014 and as a Final Rule in December 2015. As a result of recent court actions described above, the nature and schedule for this action is under review.

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?"

[To be provided in a future submission as described above.]

Scientific questions to be addressed and approach:

[To be provided in a future submission as described above.]

Plans for scientific analyses and peer review:

[To be provided in a future submission as described above.]

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.¹

	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)?		
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?"		
Is the action an extension of an existing initiative?		

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.¹

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

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

Recommendation: The Work Group recommends that the SAB reconsider this action when more information is available.

Developing the Interstate Transport Rule for the 2008 Ozone NAAQS is motivated by a 2012 D.C. Circuit court decision to vacate the Cross State Air Pollution Rule (CSAPR). On April 29, 2014, the Supreme Court reversed the prior decision and remanded this case back to the D.C.

¹ EPA was unable to provide sufficient information to complete the tables given the current status of the Cross State Air Pollution Rule litigation and is now actively evaluating the implications of these recent legal developments including any implications for EPA's approach and schedule for the Interstate Transport Rule for the 2008 Ozone NAAQS. However, the Agency committed to providing information on this planned action to the SAB in the future.

Circuit for further proceedings. EPA is awaiting a ruling from the D.C. Circuit regarding whether the stay of CSAPR will be lifted. If so, then presumably EPA would not proceed with the planned action described here.

Given the lack of clarity regarding whether this planned action will go forward and whether it will address scientific questions if it does go forward, it is not possible to make a recommendation yet as to whether SAB should consider this action for review. EPA should provide an update to SAB regarding the status pending further developments.

EPA's Description of the Planned Action

Name of action: Residual Risk and Technology Review National Emission Standards for Hazardous Air Pollutants: Ferroalloys Production

RIN number: 2060-AQ11

EPA Office originating action: OAR

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

Hazardous air pollutants (i.e., "air toxics") are emitted from numerous industrial and other sources exposing residents downwind and, in some cases, through multimedia transfer. The Clean Air Act (CAA) requires that EPA evaluate emissions and resulting risks from these sources (by category) to determine whether exposure levels are such as to provide an "ample margin of safety" and to evaluate whether technology changes over time provide an opportunity for cost-effective emission reductions.

The RTR rules are a combined effort to evaluate both risk and technology as required by the CAA after the application of maximum achievable control technology (MACT) standards. CAA section 112(f)(2) directs EPA to conduct risk assessments on each source category subject to MACT standards within 8 years of promulgation of the MACT standards, and to determine if additional standards are needed to reduce residual risks. Section 112(d)(6) of the CAA requires EPA to review and revise any standards issued under Section 112, as necessary, taking into account developments in practices, processes, and control technologies. Technology reviews are required at least every 8 years after promulgation of MACT standards. The Risk and Technology Review (RTR) rules fulfill the requirements of both of these sections.

This action is part of the RTR rule for the National Emission Standards for Hazardous Air Pollutants (NESHAP) for ferroalloys. This supplemental proposal, currently at OMB, needs to be signed by August 21, 2014, pursuant to the terms of a consent decree to finalize the RTR. This action will present a revised risk assessment and updated technology review based on the receipt of additional data, and will also include the agency's proposal with respect to the requirements of section 112 for process stack and fugitive hazardous air pollutant (HAP) metal emissions (e.g., manganese, arsenic and nickel) and polycyclic aromatic hydrocarbons (PAH) emissions.

Timetable:

Supplemental NPRM: 08/21/2014 - Court-Ordered

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. We are conducting a RTR using well-established methods that have already been reviewed by the SAB. There is nothing unique outside of the RTR process that will be addressed in this rule.

Scientific questions to be addressed and approach:

None – as noted above, there is nothing unique outside of the RTR process that will be addressed in this rule.

Plans for scientific analyses and peer review:

The approach taken is the same approach used in other residual risk evaluations that are required under the Clean Air Act. Furthermore, any science used in the rule development has already gone through appropriate peer review, including a review of the risk methodology conducted by the SAB. We collected additional emissions test data for HAP metals and PAHs in 2012 and 2013 to augment the data set we already had for the RTR. All emissions data used in our analyses and for developing the proposed rule have undergone standard QA procedures.

The methodology for conducting the risk assessments is described in “Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA’s Science Advisory Board with Case Studies – MACT I Petroleum Refining Sources and Portland Cement Manufacturing (EPA-452/R-09-006).” The SAB reviewed this document in July 2009 and the final report of the review panel is available at:

[http://yosemite.epa.gov/sab/sabproduct.nsf/0/4AB3966E263D943A8525771F00668381/\\$File/EPA-SAB-10-007-unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/0/4AB3966E263D943A8525771F00668381/$File/EPA-SAB-10-007-unsigned.pdf).

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

Name of planned action: National Emission Standards for Hazardous Air Pollutants: Ferroalloys Production (2060-AQ11)

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.

The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ferroalloys Production is an extension of an ongoing process of risk and technology reviews (RTRs) for sources of hazardous air pollutants (HAPs) under the Clean Air Act. The SAB provided guidance and peer review of earlier NESHAPs RTR methodologies based on case studies in other sectors

(petroleum refining and Portland cement manufacturing) in May 2010,² and the NESHAP for Ferroalloys Production uses scientific methods that are consistent with these prior reviews, and with the recommendations in the 2010 SAB report. The approach described in the 2014 EPA Federal Register notice for Ferroalloys Production uses well-established risk assessment and air dispersion modeling methods.

EPA published a proposed NESHAP for Ferroalloys Production in 2011 that was not finalized. On September 4, 2014 the EPA proposed supplemental amendments to the air toxics emissions standards covering ferroalloys facilities. Based on the information in the 2011 and 2014 Federal Register notices, the Work Group categorized the health risk as “medium” in the table above. The Work Group chose this category because, although there are only two facilities located in the United States that would be covered by this proposed regulation, these two facilities do appear to pose a significant risk to local communities. According to the proposed rule for review, the cancer risk range is between 20-100 in a million, and the non-cancer acute risk (hazard quotient) is significantly above 1 (4 based on actual emissions levels, and 40 based on allowable emissions levels) for manganese.³ Although these risk levels are lower than those calculated in the 2001 document, they are still significant health risks. In the same document, these two facilities are estimated to expose about 31,000 people to cancer risks over 10^{-6} and 1,500 people to non-cancer health risk levels above 1, mostly due to emissions of manganese. Of note, the Agency for Toxic Substances and Disease Registry (ATSDR) performed an investigation in a community in Ohio near one of these facilities and found elevated ambient air concentrations of manganese that exceeded health-based benchmarks. A health study in this community also apparently identified subtle, subclinical motor alterations in community residents, as compared to a control population.⁴

The Ferroalloys Production risk and technology review is categorized by the Work Group as “medium” for addressing an area of substantial uncertainty, since there is uncertainty in the emissions and the risk estimates for these facilities. The uncertainty is not considered high because the emissions modeling uses extensive measured data from the two ferroalloys facilities, and the HAPs that are assessed generally have fairly well-established health numbers. The Work Group categorized all other areas as low, because the proposed rule does not involve scientific approaches that are new to the agency, nor does it relate to emerging environmental issues or exhibit a long-term outlook.

In summary, the Ferroalloys Production risk and technology review does not meet the criteria for SAB review, and the Work Group recommends against review.

² Review of EPA’s draft entitled, “Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA’s Science Advisory Board with Case Studies – MACT I Petroleum Refining Sources and Portland Cement Manufacturing”.

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

³ U.S. EPA. 40 CFR Part 63. National Emissions Standards for Hazardous Air Pollutants: Ferroalloys Production. Proposed Rule. 76 Federal Register 226 November 23, 2011 and Supplemental Proposed Amendments. 79 Federal Register 193 October 6, 2014.

⁴ Reports from both the air sampling and the health study are found here:
http://www.atsdr.cdc.gov/sites/washington_marietta/

EPA's Description of the Planned Action

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

RIN Number: 2060-AR63

EPA Office originating action: OAR

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

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

EPA finalized Renewable Fuel Standards regulations implementing Section 211(o) of the Clean Air Act in 2007, and also adopted substantial revisions in 2010 to implement statutory amendments enacted as part of the 2007 Energy Independence and Security Act. However, the statute requires EPA to promulgate annual rules to translate the renewable fuel volumes into percentage standards that reflect the projected gasoline and diesel fuel demand in the following year. In establishing these annual standards EPA may implement either the statutory volumes, or alternative volumes that EPA establishes using its discretionary authorities to lower statutory volumes or to set volumes for years not addressed in the statute. EPA has promulgated these annual standards every year beginning with 2007. In 2014, for the first time, EPA proposed to exercise our waiver authorities to set the applicable volumes of advanced and total renewable fuels below statutory levels, in light of unavailability of certain types of renewable fuels and practical and legal constraints on supplying renewable fuels to consumers. The SAB reviewed this action as part of the Review of the Spring 2013 Regulatory Agenda and concluded that the action did not merit further consideration.⁵

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

Timetable:

To OMB: late fall or early winter 2014

NPRM - Signature: TBD

⁵ SAB [Discussions about EPA Planned Actions in the Spring 2013 Unified Agenda and their Supporting Science](#) and recommendations are available on the SAB website

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

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

Scientific questions to be addressed and approach:

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

Plans for scientific analyses and peer review:

As with previous rules, the analytical work underlying this annual RFS volume rule is based on historical data and updates to historical data regarding renewable fuel production, imports, distribution, and use, along with information on micro- and macro-economic factors affecting these underlying data. The updated information is used to conduct analyses and project renewable fuel volumes for use in the proposed/final rulemakings. This technical/analytical work, which is expected to apply approaches already established through prior volume standards, does not raise any new scientific issues. We also reference, to a limited extent, some of the analyses conducted as part of the RFS2 final rulemaking released on March 26, 2010; that rulemaking provided the foundation and basic structure for much of the program.⁶ In addition to going through the full public notice and comment process, the methodologies that might have raised novel scientific issues in establishing the RFS2 final regulations in 2010 were peer-reviewed. We do not expect to conduct an additional peer review process for analyses underlying the 2015 standards rule since the decisions will be informed by analyses and employ methodologies that are not expected to present any additional novel or controversial scientific issues and/or have been previously utilized.

⁶ Materials on the RFS2 final rulemaking are available on the EPA web page:

- Fact Sheet: [EPA Finalizes New Regulations for the National Renewable Fuel Standard Program for 2010 and Beyond \(PDF\)](#) (7 pp, 162K, EPA-420-F-10-007, February 2010)
- The FR Notice <http://www.gpo.gov/fdsys/pkg/FR-2010-03-26/pdf/2010-3851.pdf>

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

Name of planned action: Renewable Fuel Program - 2015 Volume Standards (2060-AS22)

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	X
Exhibits a long-term outlook		NA	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 involves consulting industry, EIA and other stakeholders to determine the feasible volume of advanced renewable fuels that can be met by industry given the current state of technology. This is an ongoing activity undertaken each year by the EPA. This has an NPRM of 09/14 and a final action date of 03/2015. There is no new scientific approach underlying this action that needs to be reviewed by the SAB.

As the volume number is set, there are requirements that a statement of energy effects be provided by EPA per executive order, with this being an annual requirement as well. Though having an agency-designated priority of “other, significant,” there are no obvious “adequacy of science” issues with this annual promulgation of a volume standard.