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

February 25, 2020

THE ADMINISTRATOR

MEMORANDUM

SUBJECT: Science Advisory Board Engagement Process for Review of Regulatory Actions

FROM: Andrew R. Wheeler

TO: General Counsel
Assistant Administrators
Inspector General
Chief Financial Officer
Associate Administrators
Regional Administrators

Introduction

Federal advisory committees provide advice that is crucial to ensuring the U.S. Environmental Protection Agency's regulatory actions are sound, deliberate and transparent. The expert guidance received from advisory committees reinforces the agency's work in achieving its mission to protect human health and the environment. The EPA currently has 20 federal advisory committees, many of which are chartered to provide advice on policy issues and approximately one-third, including the Science Advisory Board, are chartered to provide the EPA with scientific advice. SAB review, in particular, is essential to guiding the agency as it develops scientific methods to assess and address key environmental and public health questions, as well as ensuring the appropriate application of those methods in a regulatory action.

For advice from the SAB (or any other advisory committee) to be truly impactful, the EPA should engage with the SAB early in the process (e.g. through reviews of methods and models that the agency believes will later be influential) and ensure that such engagement is clear in scope and timing. A recent memorandum to the programs updates the existing process[1] that should be followed for engaging with the SAB on projects not immediately tied to a proposed regulatory action and emphasizes this important point regarding early engagement.

The EPA should also more efficiently engage with the SAB on regulatory actions. To that end, this memorandum provides new guidance for engagement with the SAB once the agency has proposed a criteria document, standard, limitation or regulation. This regulatory action review

[1] Benevento, D. 2020. Request for Science Review and Advice from the EPA's Science Advisory Board for FY2020/2021.

process incorporates the principles laid out in my April 19, 2019, letter to Dr. Michael Honeycutt, Chair of the SAB, and in my comments to the SAB on June 5, 2019. Specifically, I highlighted the need for:

- *Timeliness and Early Notification* – There should be more rapid and frequent briefings or consultations on major rulemakings soon after their public release.
- *Transparency and Consistency* – Commencing engagement with the SAB upon release of a major proposed regulatory action ensures that details of the underlying scientific analyses can be openly discussed and are consistent with the public version of the regulation.
- *Inter-Committee Coordination* – The process for seeking scientific advice and establishing the scope of that advice should properly consider the full suite of important EPA advisory committees.

This new regulatory action review process institutionalizes these principles, reaffirms the EPA's commitment to obtaining impactful advice on scientific[2] aspects important to EPA regulatory actions and provides certainty and clarity to EPA programs and the SAB on the engagement process.

Process

Monthly Meetings with the Chair

The SAB Staff Office will host a standing monthly, non-public administrative meeting with the chair of the SAB. This meeting may occur in person or via teleconference. Prior to the meeting, SABSO will identify any Tier 1 or 2 proposed rules[3] that have been signed or published in the *Federal Register* since the previous monthly meeting. If no applicable regulatory actions have been signed or published, the meeting can be cancelled. SABSO will engage with staff of the program office proposing a Tier 1 or 2 rule to collect background and presentation materials. The Office of Policy can assist, as necessary. Background materials may potentially include information as outlined in the attachment to this memorandum. Any materials should be provided to the chair as far in advance of the monthly meeting as practicable to ensure a productive meeting. The chair may appoint up to eight additional SAB members with expertise on the proposed regulatory action(s) to attend the meeting and provide advice. These members are not permanent and may vary depending on the proposed regulatory action(s).

The goals of the meeting are to (a) provide an interactive briefing for the chair on the proposed regulatory action; (b) discuss any potential EPA plan for consulting with other advisory committee(s); (c) discuss whether the proposed regulatory action merits SAB review; and (d) for those proposed regulatory actions that may merit SAB review, identify specific scientific topics within the rule, a timeline for the review and whether it is best reviewed by the full SAB, standing

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[2] The SAB Staff Office Handbook states that "[t]he SAB may comment on the policy implications of scientific analyses but should not 'cross the line' into policy recommendations."

[3] EPA's Action Development Process (available at: https://yosemite.epa.gov/sab/sabproduct.nsf/5088B3878A90053E8525788E005EC8D8/$File/adp03-00-11.pdf) defines the process used to tier regulatory actions being developed within the agency. Tier 1 and 2 regulatory actions represent the Administrator's priority actions, cross-media actions or actions with significant issues.

committee or ad hoc committee. At the meeting, EPA experts will be prepared to outline the proposed regulatory action, highlighting any underlying scientific analyses, and will be available to answer any questions from the chair.

Within 10 business days of the briefing, the chair will make a determination and notify SABSO whether there are scientific aspects of the proposed regulatory action that may merit SAB review. The final decision on whether or not to review a proposed regulatory action will be tracked and communicated to the full SAB by SABSO as well as posted to the SAB public website. SABSO will schedule a public meeting (as described below) for the SAB to fully discuss the scientific aspects of the proposed regulatory action(s) that merit(s) SAB review. No further action will be taken on those proposed regulatory actions that the chair determines do not merit SAB review[4].

SAB Meetings

Within 10 business days of the chair notifying SABSO of a proposed regulatory action that merits SAB review, SABSO will begin the process of scheduling a public teleconference or meeting with the SAB. The meeting will be scheduled to accommodate at least a quorum of the SAB, but reasonable efforts will be taken to accommodate as many members as possible. EPA experts will provide any necessary background and/or presentation materials in advance of the meeting. SABSO will make this material available to the public on the SAB website ahead of the meeting. The EPA will provide a brief overview of the proposed regulatory action, highlighting key points, scientific/analytical issues, general guiding or specific charge questions, review timelines and any topics about which the SAB will coordinate their review with other committees (if applicable).

The goals of the public teleconference or meeting are to (a) provide an interactive briefing for the SAB on the proposed regulatory action, (b) provide a timeline and guidance and/or charge questions to the SAB for its review of the proposed regulatory action and (c) discuss the EPA's plan for consulting with other advisory committee(s) on the proposed regulatory action, where applicable. The SAB may deliberate on the proposed regulatory action during this meeting or may schedule a separate deliberation meeting(s), if necessary.

Conclusion

This process for engaging with the SAB is effective immediately. With these improvements, the EPA is renewing its commitment to ensuring that it remains a transparent and efficient federal agency with impactful, well-reasoned regulations. Again, this process of engaging with the SAB on proposed regulatory actions is just one of the important ways that the EPA interacts with the SAB. As previously noted, I ask that the programs continue to be forward-thinking in evaluating the science underlying the agency's actions and proactive in seeking advice

[4] For those regulatory actions that the chair determines would not benefit from full SAB scientific review, individual SAB members, utilizing their own resources and expertise and/or those of any other party, are welcome to review and submit their own public comments.

from the SAB before use of new or innovative scientific approaches in the regulatory process. Please continue to follow existing process[5] for engaging with the SAB on these matters.

Thank you for your assistance in implementing and adhering to this process. Please contact Thomas Brennan, Director of SABSO, at brennan.thomas@epa.gov or (202) 564-6953 should there be any questions.

Attachment

cc: Deputy Administrator
Chief of Staff
Deputy Chief of Staff

[5] Benevento, D. 2020. Request for Science Review and Advice from the EPA's Science Advisory Board for FY2020/2021.

Potential Information to Provide to the SAB Chair
in Preparation for the Monthly Meeting

1. Name of the proposed regulatory action
2. RIN Number
3. Federal Register publication date
4. Length of public comment period and closure date
5. EPA office originating the proposed regulatory action
6. Nature of the proposed regulatory action (e.g. administrative, renewal without significant revision, economically significant, etc.)
7. Brief description of and statement of need for the proposed regulatory action
8. Expected timeline related to the proposed and final regulatory actions and whether the timelines are driven by legal requirements
9. The key science or scientific work products pivotal to the proposed regulatory action, including:
   a. A brief description of the impact on the proposed action
   b. If the scientific approaches are new to the EPA
   c. If the science 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"
10. Dates and references to SAB reviews of previous versions of the scientific analyses and/or regulatory action
11. Other federal advisory committee consultation and rationale, where applicable

Note: These are suggestions and are provided only to assist EPA staff in preparing for the meeting with the chair. Formal responses to these questions are not expected to be provided to the chair.