



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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MEMORANDUM

SUBJECT: Science Advisory Board Engagement Process for the Review of Science Supporting EPA Decisions

FROM: Victoria Arroyo *Victoria A. Arroyo*
Associate Administrator
Office of Policy

H. Christopher Frey *H. Christopher Frey*
Deputy Assistant Administrator for Science Policy
Office of Research and Development

Thomas H. Brennan *Thomas H. Brennan*
Director
EPA Science Advisory Board Staff Office

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

Introduction

The purpose of this memorandum is to improve the process for engaging the U.S. Environmental Protection Agency Science Advisory Board in the review of the scientific and technical basis of proposed EPA decisions. This memorandum is being issued at the direction of the Administrator and supersedes prior procedures.¹ The improved process builds on the principle that early engagement with the SAB is a priority and will best enable the EPA to benefit from the expert advice received from the SAB.

Scientific and technical peer review is essential to assessing the quality of the science supporting EPA decisions and maintaining the integrity of the agency's regulatory and policy processes. The SAB provides independent scientific and technical peer review and advice to the EPA Administrator. The Environmental Research, Development, and Demonstration Authorization

¹ Specifically, these procedures replace the process set forth in the February 25, 2020, memorandum from Administrator Wheeler, "Science Advisory Board Engagement Process for Review of Regulatory Actions."

Act requires that the EPA make available certain criteria documents, standards, limitations and regulations, as well as the relevant supporting scientific and technical information, to the SAB when provided to any other federal agency for formal review and comment.² As a general matter, the SAB decides whether peer review of the supporting scientific and technical information is warranted with respect to EPA actions and provides advice to the EPA within a time frame specified by the Administrator.³ Typically, the SAB does not engage in a scientific and technical review pertaining to a planned action that is primarily administrative, that is an extension of an existing initiative, that does not involve novel scientific and technical issues, or that has already had fit-for-purpose peer review conducted in accordance with the EPA Peer Review Handbook. Consistent with its statutory role, the SAB focuses on the “adequacy of the scientific and technical basis” of EPA actions that the SAB reviews. Thus, it is not the SAB’s role to review the policy aspects of EPA actions. This improved process for engaging the SAB focuses on scientific and technical review to ensure that EPA decisions are informed by the best available science and builds on best practices from the previous years of running this process.

Process

One of the historic challenges in conducting reviews of the scientific and technical information supporting EPA decisions has been the agency’s need to receive timely expert advice from the SAB. Examination of the agency’s Semiannual Regulatory Agenda to identify planned actions requiring peer review is a “forward-looking” process that can facilitate identification of the need for the SAB to develop advice and, if there is a need, to deliver the advice to the EPA in a time frame when the advice can be most useful to the agency (i.e. no later than the end of a public comment period for a proposed action). In addition, early identification of issues requiring peer review can be facilitated by holding meetings of a small (non-quorum) SAB Work Group to receive information from the EPA about the scientific and technical basis of planned actions and prior or planned review of such scientific and technical information. An advantage of holding regularly scheduled “issue-spotting” meetings between the EPA and an SAB Work Group is the timely identification of issues that may merit attention of the Work Group or possibly the full SAB. In addition, using the Semiannual Regulatory Agenda to identify planned actions will allow the EPA to benefit from the SAB’s advice on the most significant actions. Moreover, to the extent that actions on the Semiannual Regulatory Agenda are within the scope of ERDDAA, doing so will also satisfy the procedural requirements of ERDDAA, e.g. to make such actions available to the SAB. The revised process for engaging the SAB in the review of scientific and

² The Environmental Research, Development and Demonstration Authorization Act of 1978 requires that the EPA Administrator, at the time any proposed criteria document, standard, limitation or regulation under the Clean Air Act, the Federal Water Pollution Control Act, the Resource Conservation and Recovery Act of 1976 or the Safe Drinking Water Act, 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 the relevant scientific and technical information in the possession of the agency on which the proposed action is based. See 42 U.S.C. § 4365(c)(1).

³ While the Environmental Research, Development and Demonstration Authorization Act of 1978 indicates that the Administrator can specify a time frame for receipt of such advice, it does not provide or imply that the Administrator can narrow the scope of the SAB’s review. Furthermore, the language does not imply that the SAB cannot promptly proceed to complete self-initiated reviews, consistent with its charter and purpose to provide advice to the EPA on the scientific and technical information supporting EPA actions.

technical basis of proposed EPA decisions includes the following elements described in more detail below.

- (1) Early engagement of the SAB in peer review activities.
- (2) Formation of a new SAB Work Group to examine, screen and identify potential actions proposed by the EPA that may warrant SAB review. The Work Group would then take its recommendations to the full Board for its consideration.
- (3) EPA submission to the SAB Staff Office of information regarding planned actions in the agency's Semiannual Regulatory Agenda expected to undergo interagency review.
- (4) EPA transmittal to the SAB Staff Office of all proposed actions sent to the Office of Management and Budget for interagency review, as well as the relevant supporting scientific and technical information.
- (5) Periodic internal preparatory meetings of the new SAB Work Group to: examine planned actions sent to the SAB Staff Office; receive information about planned actions from the Agency; identify aspects, if any, of the scientific and technical basis supporting the planned actions that may warrant review, or not, by the full SAB; and prepare a report to the full SAB with recommendations for or against peer review for each planned action.
- (6) Public meetings of the full SAB to decide whether to undertake SAB peer reviews recommended by the SAB Work Group and to conduct other types of peer reviews (described below) as necessary.

Early engagement of the SAB in peer review activities

In many cases, the scientific and technical information that would inform a planned action might be available in advance of policy documents that are part of a package submitted to OMB for interagency review. The SAB's review of the scientific and technical information can be informed by an understanding of the policy context in which the information is used, but the policy context can often be adequately communicated to the SAB without a full disclosure of the policy language in a proposed rule. Even if the full range of options has not been fully developed, it is best to confirm, or to develop a plan for, review of scientific and technical information in accordance with the EPA Peer Review Handbook early in the development of the action. Such review could proactively involve the SAB or other review. The EPA typically selects from many options in arranging peer review, including contractor-led letter or panel reviews, SAB reviews, reviews by other relevant federal advisory committees (e.g. the EPA Clean Air Scientific Advisory Committee in the case of criteria documents) or reviews by the National Academies of Sciences, Engineering and Medicine. Providing scientific and technical information to the SAB at a later stage, e.g. at the start of interagency review, and in the absence of a previously arranged peer review in accordance with the EPA Peer Review Handbook, can be problematic because it increases the likelihood that the SAB will not be able to complete a review, if needed, before the end of the period for receiving public comments on a proposed

action. Therefore, engaging the SAB early in the action development process is strongly recommended.

Formation of an SAB Work Group to evaluate proposed EPA actions with supporting science that may require SAB peer review

The SAB Staff Office, in consultation with the chair of the SAB, will establish the *SAB Work Group for Review of Science Supporting EPA Decisions* to manage the material provided by the EPA to the SAB for review and to evaluate the scientific and technical information supporting proposed EPA actions, with a focus on whether the supporting scientific and technical information may warrant review by the full SAB. The chair of the SAB will serve as chair of the SAB Work Group. The Work Group will have a non-quorum number of members of the Chartered SAB appointed by the SAB chair, representing key areas of relevant expertise and comprising at least 15 percent of the membership of the full SAB. Other members of the Chartered SAB may be asked by the SAB chair to augment the Work Group when additional expertise is required, but the size of the Work Group as augmented should be less than a quorum of the Chartered SAB.

EPA semiannual submission of planned actions to the SAB Staff Office

The EPA Office of Policy will semiannually submit to the SAB Staff Office lists, based on the agency's Semiannual Regulatory Agenda, of planned actions in the pre-proposal and proposal stages that are expected to undergo interagency review pursuant to Executive Order 12866.⁴ For each action included in these lists, the Office of Policy should provide the information in Attachment A items 1-6 to the SAB Staff Office. The SAB Staff Office may then contact the relevant EPA program office regarding those actions for which items 7-9 in Attachment A are of interest.

EPA transmittal to the SAB Staff Office of proposed actions sent the Office of Management and Budget for interagency review

The EPA Office of Policy will send to the SAB Staff Office all proposed actions, as well as the relevant supporting scientific and technical information, transmitted to the Office of Management and Budget for review pursuant to Executive Order 12866. This material should be sent to the SAB Staff Office shortly after the date it is transmitted to OMB so the material can be provided to the SAB Work Group for Review of Science Supporting EPA Decisions. This Science Supporting EPA Decisions process is designed to identify peer review concerns early in the process. The SAB Work Group may find that no additional action is needed by the SAB in this step.

Periodic preparatory meetings of the SAB Work Group for Review of Science Supporting EPA Decisions

⁴ In addition to actions on the Semiannual Regulatory Agenda, EPA program offices may provide information on other actions to the SAB Work Group for consideration by the full SAB consistent with the requirements of ERDDAA.

The SAB Staff Office will schedule monthly internal preparatory meetings of the Work Group for Review of Science Supporting EPA Decisions. At these meetings the Work Group will: (1) receive briefings and updated scientific and technical information from the EPA program offices pertaining to planned actions listed in the agency's Semiannual Regulatory Agenda; (2) discuss whether the scientific and technical information supporting planned EPA actions submitted to the Work Group should be reviewed by the full SAB; and (3) for the scientific and technical information supporting planned EPA actions that may warrant full SAB review, identify the specific scientific and technical topics that should be reviewed and charge questions to be considered by the full SAB.

In advance of Work Group meetings, members of the Work Group will review the scientific and technical information that EPA program offices have provided to the SAB Staff Office and may request additional written information pertaining to specific planned actions. If additional written information is requested, the EPA program offices should submit this information to the SAB Staff Office before the Work Group meetings. In addition, the EPA program offices may provide presentations at Work Group meetings to share additional background information about EPA actions and answer questions from Work Group members. It is important that the EPA program offices share information regarding the scientific and technical information underlying planned actions and the manner by which such science has been, or will be, peer reviewed with the SAB Work Group when such information is requested to enable timely engagement by the full SAB if warranted.

Unless already publicly disclosed, materials provided to the workgroup for its preparatory meetings are to be presumed to be internal deliberative and thus not intended for release to the public.

After the Work Group meets and identifies scientific and technical information supporting planned actions that may warrant review by the full SAB, the SAB Designated Federal Officer will prepare a draft report of the SAB Work Group's recommendations. The report will be provided to the full SAB after Work Group concurrence.

Chartered SAB meetings to conduct peer reviews

When the SAB Work Group completes its review and has identified supporting scientific and technical information for planned actions that may warrant full SAB review, the SAB Staff Office will promptly schedule a public meeting of the full SAB to decide whether the SAB should undertake the peer review(s) recommended by the Work Group.⁵

If the full SAB decides to conduct peer reviews recommended by the SAB Work Group, the SAB staff office will promptly schedule subsequent public meetings of the full SAB to complete

⁵ Documents prepared by or for the full SAB or shared with the full SAB must be made available to the public unless a FOIA exemption applies such that disclosure is not required. The EPA Office of Policy and EPA program offices, in consultation with the Director of the SAB Staff Office, should develop the package of materials to be provided to the full SAB. As a general matter, these materials will not include policy or pre-decisional documents. However, there may be instances where some policy documents or information that would not otherwise be disclosed are necessary to fully understand the action such that the SAB can make an informed decision on whether to engage in a review of the science and conduct a review.

the reviews. EPA program office staff should provide any necessary background and/or presentation materials in advance of the SAB meetings. The SAB staff office will make this material available to the public on the SAB website ahead of the meetings. At the subsequent meetings, the EPA program offices should present overviews of the supporting scientific and technical information being reviewed (including context with regard to planned actions) addressing the key scientific and technical issues to be considered by the SAB.⁶ The SAB will then deliberate on responses to the charge questions provided by the SAB Work Group and develop reports of their responses and advice to the EPA Administrator.

Attachment

⁶ The EPA should present an overview of key scientific and technical issues from the agency's perspective and address issues identified by the SAB Work Group.

Attachment A

Information to be Provided to the SAB Staff Office About Planned Actions

1. Name of the proposed regulatory action
2. RIN Number
3. EPA office originating the proposed regulatory action
4. Nature of the proposed regulatory action (e.g., administrative, renewal without significant revision, economically significant, etc.)
5. Brief description of the action and statement of the need for the proposed regulatory action
6. Expected timeline related to proposed and final regulatory action and whether the timelines are driven by legal requirements
7. The key science or scientific and technical work products pivotal to the planned regulatory action including:
 - a. A brief description of the scientific and technical work products that have been developed to inform decisions regarding the planned action and the impact of the science on the proposed action.
 - b. A brief description of the approach the agency is taking to develop the needed scientific or technical basis (e.g., interagency collaboration, workshops to inform the analysis) and an indication of whether the scientific and technical approaches are new to the EPA.
 - c. An indication of whether the scientific and technical basis 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.”
8. A brief description of previous peer reviews of the work products including dates and references to SAB reviews of previous versions of the scientific and technical analyses and/or regulatory action; and
9. Other federal advisory committee consultation and rationale, where applicable.