

EPA IMPLEMENTATION PLAN FOR THE NEW STRUCTURAL ORGANIZATION OF THE EPA SCIENCE ADVISORY BOARD

**A REPORT OF THE EPA SCIENCE
ADVISORY BOARD STAFF
OFFICE**

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1. INTRODUCTION

The U.S. Environmental Protection Agency (EPA) Science Advisory Board (SAB) is a chartered Federal Advisory Committee, established in 1978 by the *Environmental Research, Development, and Demonstration Authorization Act* (ERDDAA). Composed of renowned experts, the SAB provides the EPA Administrator with outside, independent advice on the scientific and technical aspects of environmental issues to help inform environmental decision-making. The SAB has a distinguished record of providing valuable and sound advice on a wide range of scientific, engineering, economics, and social science issues that impact the technical bases of EPA policies, regulations, research and science programs.

The work of the SAB is supported by the SAB Staff Office, which is housed within the Office of the Administrator. The SAB Staff Office performs management and administrative functions and provides technical assistance to the SAB, the Clean Air Scientific Advisory Committee (CASAC), and the Advisory Council on Clean Air Compliance Analysis (COUNCIL), both of which are also EPA chartered Federal Advisory Committees, established under the Clean Air Act Amendments of 1977 and 1990, respectively. The Staff Office serves as the interface for these advisory bodies for their interactions with EPA and the public. The Staff Office also ensures that the SAB, CASAC, and COUNCIL conduct advisory activities in public, and that the public has an opportunity to provide input during the advisory process.

As part of an effort to help the SAB keep pace with complex environmental challenges facing the Agency, the SAB Staff Office has recently recommended a structural and functional realignment of the SAB¹. The new SAB structure incorporates flexibility and reaffirms the importance of the advisory role of the SAB, i.e., both early, forward-looking advice and rigorous peer reviews of EPA technical and scientific work products that directly impact major EPA policies and decisions.

This document describes how the SAB Staff Office will implement the new structural and functional changes in the SAB. Processes and procedures are either currently in place, being enhanced, or added to meet these SAB changes and to ensure the delivery of timely and high quality advice. First, the document provides an overview of the new SAB organizational components, the workflow within the SAB, and an overview of the advisory process. It then details the management, administrative, and technical tasks for each of the major elements of the advisory process. Finally, it discusses the SAB structural components for FY 2004 designed to ensure an effective transition.

The focus of this report is on the changes to the SAB structure and function. It should be recognized that certain processes and procedures described in this report may or may not be applicable to the CASAC and COUNCIL. The SAB Staff Office plans to develop a series of public and internal documents that complement this report for the SAB, CASAC and COUNCIL, as deemed appropriate.

¹ See the "Reorganization of the EPA Science Advisory Board (SAB)" (November 2003)

2. OVERVIEW OF ORGANIZATIONAL COMPONENTS, FUNCTIONS AND THE ADVISORY PROCESS OF THE EPA SCIENCE ADVISORY BOARD

As shown in Figure 1, the advisory functions of the SAB will be accomplished by the Board, its Standing and *Ad Hoc* Committees, and its *De Novo* Review Panels. The advisory functions of the SAB will include the following kinds of activities:

Consultation – Provides non-consensus, oral, advice on a technical issue before EPA begins substantive work on that issue.

Advisory – Provides written advice on EPA's technical works-in-progress.

Peer Review – Conducts a review of EPA's final draft technical reports (e.g., guidelines, assessments, research strategies) or work products (e.g., analytical methods, models, databases).

Commentary – Provides forward-looking advice on an important technical or emerging issue in the form of a short communication.

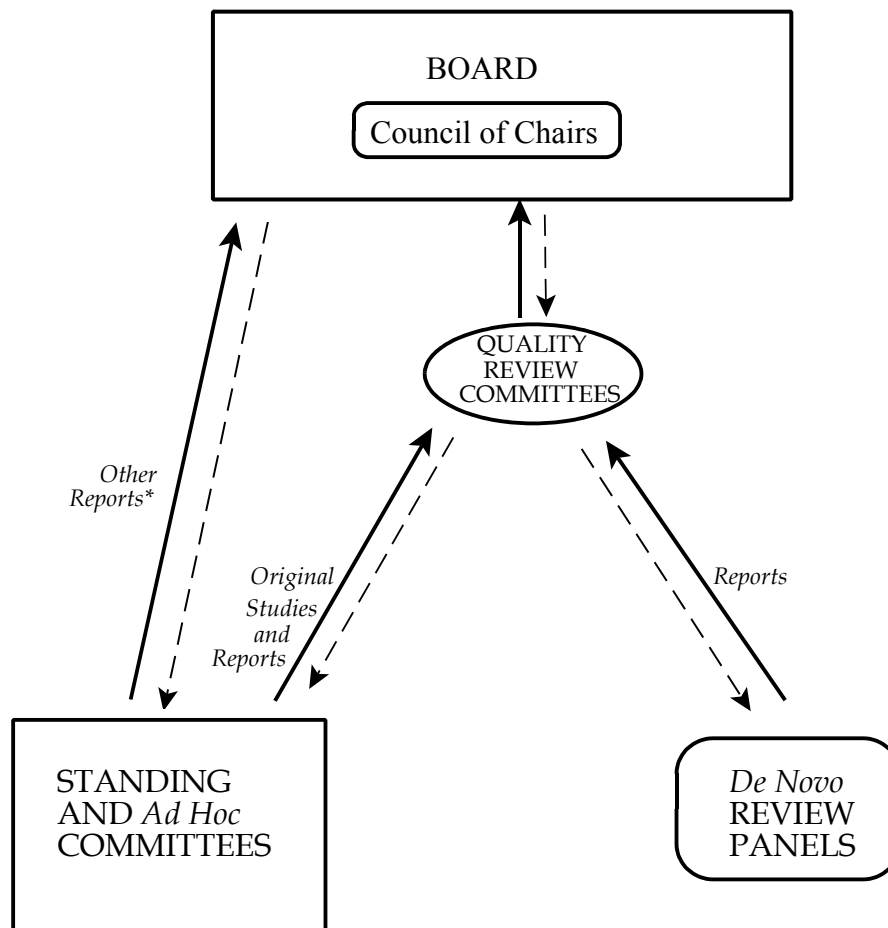
Original Study – Conducts original work on an emerging or overarching topic of importance to EPA.

Other Activity – Receives information briefings from EPA and conducts scientific workshops on specific technical subject matters.

The Board and its Standing and *Ad Hoc* Committees are a source of knowledge and continuity for the Agency, particularly as they provide early advice when requested by EPA Programs and Regions on issues related to specific disciplinary or multi-disciplinary and programmatic areas. These interactions are normally associated with early and mid-course efforts that the Agency would bring to the SAB, but also with the peer reviews of EPA final draft reports or products that provide overarching strategies, plans, or guidance on how EPA conducts its scientific and technical activities. Peer reviews of EPA final draft technical products that directly support EPA policies and/or risk management decisions will be conducted by *De Novo* Review Panels to be created for each specific peer review.

As required by the Federal Advisory Committee Act (FACA), the Board, as the parent chartered committee, must approve all advice developed by its Committees and Panels prior to transmittal to the EPA Administrator. To ensure the high quality and independence of the SAB peer review reports, a specialized Quality Review Committee will be established to review each draft report before the report is sent to the Board for final review and approval. Original works of SAB Standing or *Ad Hoc* Committees will also be reviewed by a Quality Review Committee prior to the Board's final review and approval. The Board will also provide forward-looking advice on environmental progress, trends, priorities and innovative approaches to achieve environmental challenges and on the scientific and technical investments necessary to achieve greater and more cost-effective public health and environmental protection. A Council of Chairs, composed of the Chairs of SAB Standing and *Ad Hoc* Committees and the Chairs of the CASAC, and the COUNCIL, will foster open and constructive dialogue and cross-disciplinary interactions among the committees, and advise the Board as a whole on matters that are considered important to the SAB mission.

**FIGURE 1 NEW STRUCTURE AND WORKFLOW WITHIN THE EPA
SCIENCE ADVISORY BOARD**



The dotted lines show the flow of comments and directions from the oversight and approving groups.

*Some Standing or *Ad Hoc* Committee reports may go directly to the Board for review and approval.

The mix of Standing and *Ad Hoc* committees will be based on the current and future needs of the Agency. Standing committees are expected to exist for an extended number of years while *Ad Hoc* Committees will be established for shorter periods to provide advice on matters that cannot be addressed by existing Standing Committees. As required by the enabling SAB legislation, a Board member will serve as the Chair of each SAB Committee or Panel. Board members and Committee members will be drawn from the scientific community. Collectively, they should encompass the breadth and depth of experience and expertise necessary to accomplish the anticipated work of the SAB and have a diversity of scientific perspectives. Section 3 of this report details the process for evaluating the appropriate mix of SAB Committees, and the process for nomination, selection, and appointment of Board and Committee members by the EPA Administrator.

Figure 2 depicts a SAB advisory project cycle. The SAB provides advice in response to the Agency's requests and in response to original project ideas developed by the Agency and/or the SAB. The process for the nomination and selection of SAB advisory projects is detailed in Section 4 of this report. Depending on the nature of the approved SAB projects, the Staff Office will consult with the Agency and the SAB and determine who would be the most appropriate body of experts to provide the requested advice. The process for selecting the types of SAB Committees or Panels is described in Section 5. Section 5 also outlines the many steps involved in assembling a balanced SAB Panel as required under the terms of FACA, and in accordance with federal and EPA requirements and SAB policies. Expert consultants invited to assist SAB Committees or to serve on *De Novo* Review Panels would be drawn from the scientific community and be appointed by the SAB Staff Office Director for the duration of a specific advisory activity.

A Committee or Panel will begin its advisory activity first by thoroughly reviewing and understanding its charge, and being fully prepared for the advisory meetings. Advisory meetings will be conducted in public sessions, and advisory reports will be developed as detailed in Section 6. The SAB Committee or Panel draft report will then undergo a quality review and approval process by the Board as described in Section 7. The general process for the transmittal of the approved SAB reports to the EPA Administrator and the Agency's response to the SAB advisory reports is described in Section 8.

As shown in Figure 3, depending on the nature of the Agency's request, the entire advisory process would generally take from 4 to 12 months from the initial discussion with EPA Offices and Regions to the delivery of the final SAB report. For example, a consultation to be conducted by an existing Standing or *Ad Hoc* Committee without additional expert consultants could be accomplished within 4 months. On the other hand, a peer review of a major technical work product to be conducted by a Review Panel created *De Novo* may require up to 12 months to complete. After the Agency submits the final charge questions and review materials, a draft SAB report can be available in approximately 6 months, and about 3-4 additional months for the quality review, Board approval and delivery of the final report to the Administrator.

3. SAB MEMBERSHIP

The SAB addresses a wide range of topics requiring different kinds of science advice to EPA. As the SAB continues to provide credible technical and strategic advice concerning current and future environmental challenges, it is essential that the membership of the Board and Committees encompasses the relevant breadth and depth of experience and expertise. Additionally, the SAB should reflect a diversity of scientific perspectives and demonstrate a

FIGURE 2

SAB ADVISORY PROJECT CYCLE

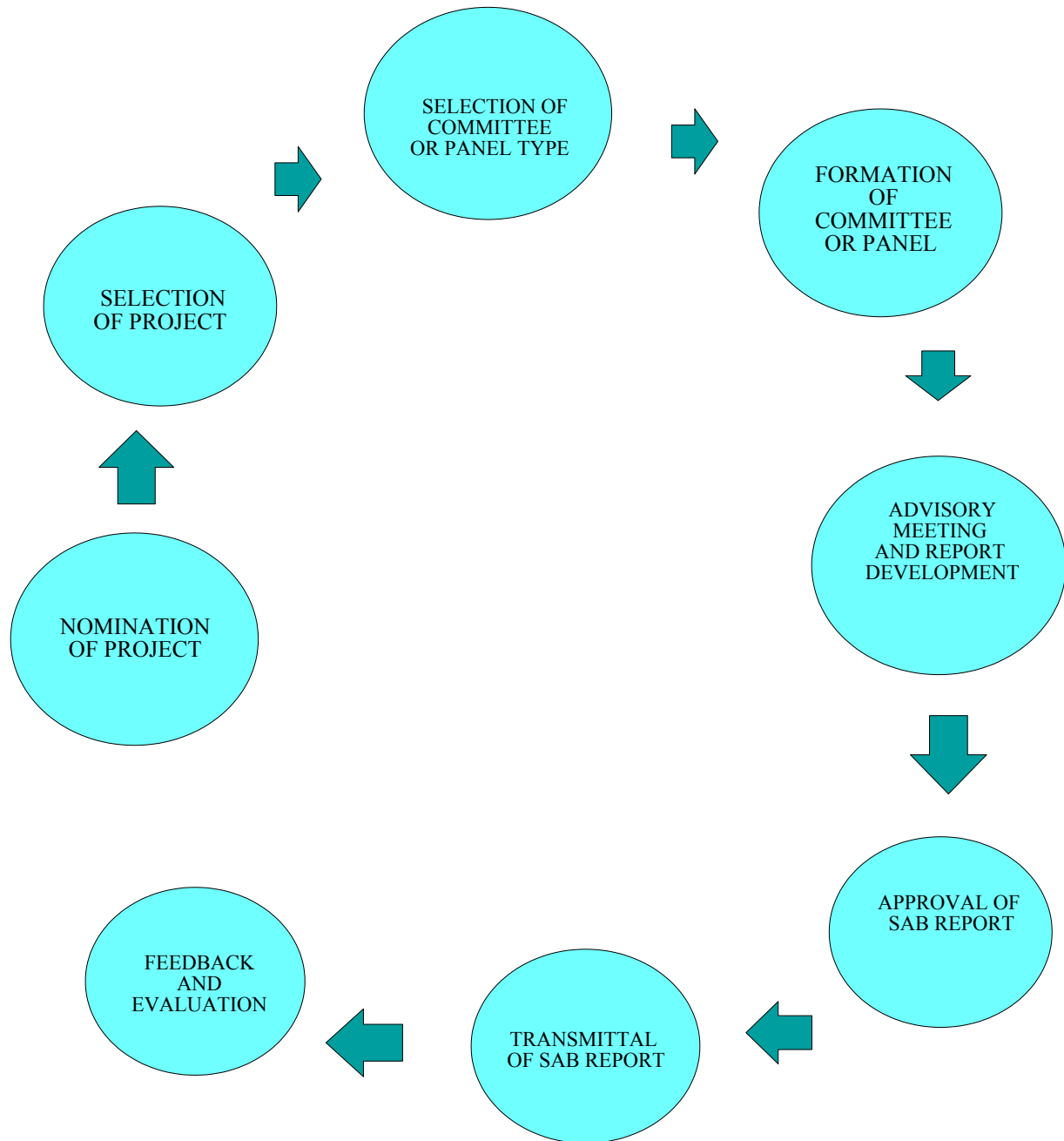
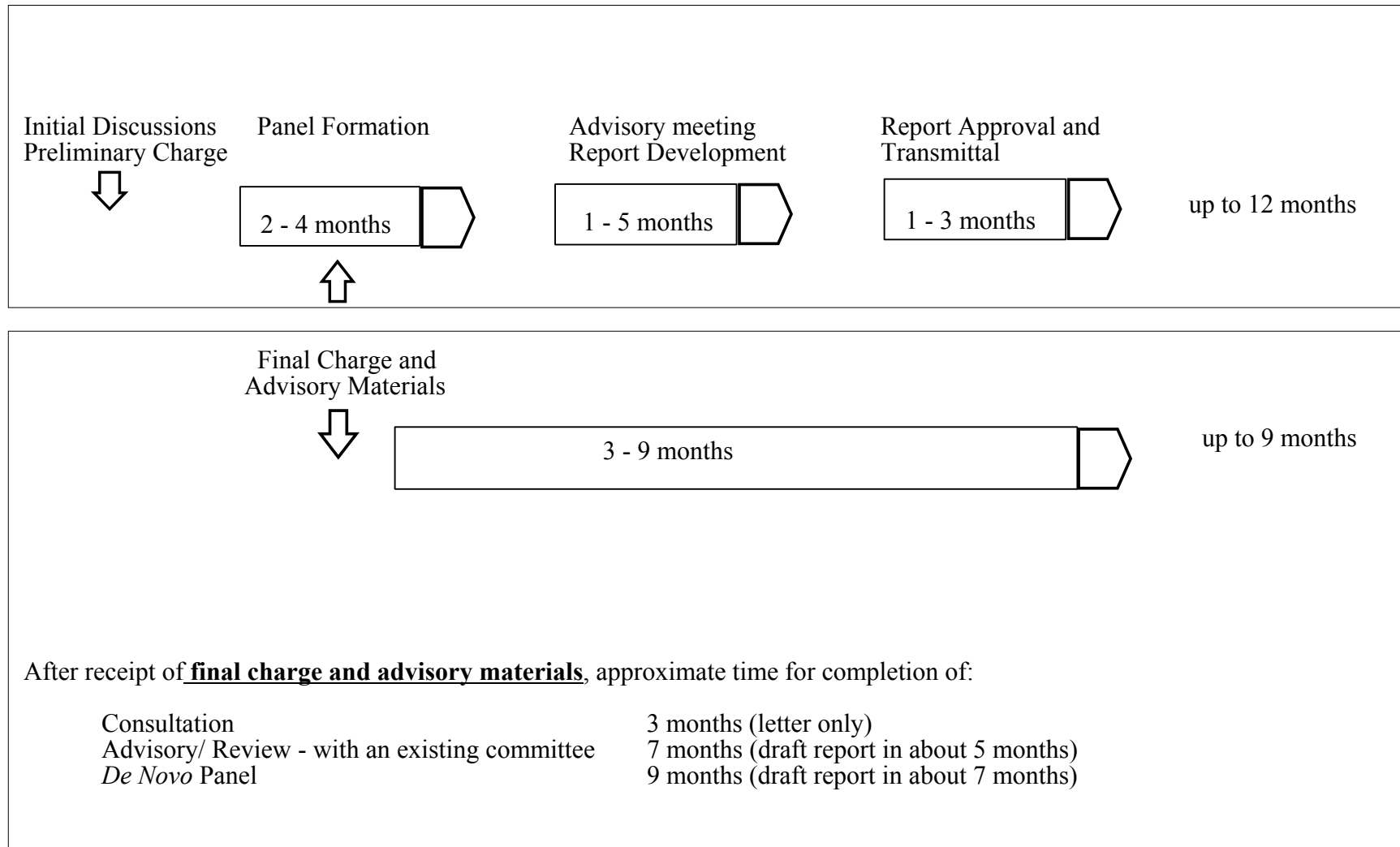


FIGURE 3 APPROXIMATE TIME LINE FOR ADVISORY ACTIVITIES



broad knowledge and appreciation of EPA's missions and environmental programs. Members of the Board and Committees (and Panels) would be drawn from academia, industry, federal, state and tribal governments, research institutes and non-governmental organizations (NGO) throughout the United States. Collectively, the SAB should constitute a distinguished body of scientists, engineers, economists and social scientists who are widely recognized for their record of scholarly and leadership achievement in their respective fields. Members of the Board, Committees and Panels should also have demonstrated ability and experience to examine and analyze issues incisively with the highest level of scientific quality, objectivity, and integrity. Furthermore, they should be known for having excellent committee-related skills and experience, including interpersonal, oral and written communication, consensus-building, and other skills necessary for working alongside their peers in committees and advisory panels.

3.1 Membership and Composition

The Board will consist of about 30 members, including a Chair and a Vice-Chair. In addition to the desired attributes as described above, Board members, in particular, should have demonstrated experience and ability to integrate and cross-connect disciplines in the pursuit of public health, ecological health and environmental protection to provide forward-looking advice to the Administrator and Agency senior leadership. The membership and composition of the Board will change over time as new environmental challenges arise and the need for a different mix of experience and expertise becomes apparent.

Because Standing and *Ad Hoc* Committees constitute the core of SAB expertise, each Committee should have the breadth of knowledge to address subjects within its purview. Committee members are expected to have the needed attributes to assimilate new information and adapt to changes in scientific knowledge and key developments in science and technology. Collectively, SAB Committees should include a wide range of scientific and technical disciplines to lead a majority of the peer reviews, advisories and consultations for the Agency. Each SAB Committee will be chaired by a Board member having appropriate stature and expertise in the relevant area. The size of each committee may vary but typically will be composed of ten to fifteen members.

3.2 SAB Committees

The SAB Staff Office, in consultation with the SAB and the Agency, will review and adjust the mix of Standing and *Ad Hoc* committees periodically. The mix of SAB Committees should reflect the needs of EPA, i.e., to protect human health and the environment and the kinds of environmental challenges facing the Agency. The mix of such committees should foster diverse perspectives across EPA national and regional environmental programs and promote interactions among SAB Committees. To minimize the overhead for supporting and maintaining the committees, Standing Committees would be organized to address the needs of the Agency in a prompt and efficient manner. *Ad hoc* Committees, on the other hand, will be created when a new need arises and will exist for a short period of time (2 to 3 years). On the other hand, if an *Ad Hoc* Committee is needed on a long-term basis, it may evolve into a Standing Committee. As discussed in Section 9, the SAB's current mix of Standing and *Ad Hoc* Committees will provide the initial basis for the new SAB Committee structure for FY 2004 and beyond.

3.3 Process for Nominations

Under the new SAB structure, Board and Committee members will be appointed by the EPA Administrator as Special Government Employees (SGEs) to serve for a term of three years

(may be renewable for an additional three-year term)². As SGEs, Board and Committee members are subject to many Federal requirements including those dealing with conflict-of-interest and ethics statutes. It is essential that the process for nomination, selection and appointment of Board members and Committee members be transparent to the public and that the public be given an opportunity to nominate individuals for SAB Board and Committee membership during the annual process, as described below.

The SAB Staff Office is responsible for making recommendations to the EPA Administrator regarding the annual updates to the membership of the Board and Committees by October of each year. The process would generally begin in April with the identification of vacancies in the coming year and the newly needed expertise for the Board and individual Committees. From May through June, the Staff Office will solicit public nominations for potential candidates via a notification in the Federal Register. The Staff Office will seek nominations from other government departments and agencies, scientific and research organizations, professional societies, and non-governmental organizations, as well as from EPA and the SAB via letters and direct contacts.

During July through August, the SAB Staff Office will contact the nominees to: (a) acknowledge the nomination; (b) ascertain their interest in serving on the SAB; (c) provide background information about the SAB; (c) inform them of the selection and appointment process; (d) acquaint them with the process involved in becoming a Special Government Employee (including the conflict of interest and ethics requirements); and (e) discuss expectations of workload, compensation and travel.

3.4 Evaluation and Selection of Board and Committee Members

Scientific and technical quality and credibility are paramount factors in selecting members for the Board and its Committees. From August through September, the Staff Office will complete an evaluation of each nominee who is interested in serving on the SAB with regard to expertise and experience, potential conflicts of interest, and bias. The Staff Office will then consult with the Agency and the SAB, in developing list of potential candidates for new members of the Board and individual Committees, taking into account the needed (a) breadth and depth of experience and expertise; (b) balance of scientific perspectives; (c) continuity of knowledge and understanding of EPA missions and environmental programs; and (d) diversity factors, including, geographical areas and professional affiliations. A similar process will also be used when Standing or *Ad Hoc* Committees are augmented with candidates that possess specific expertise needed for a particular review and when *De Novo* Panels are formed (see Section 5).

The SAB Staff Office Director will submit the recommended SAB annual membership and the rationale for each recommendation for the EPA Administrator's consideration and approval. Selected members will be notified of their appointment by a letter from the Administrator appointing them to the Board or a specific SAB Committee. New Board and Committee members will also receive a welcome letter from the SAB Staff Office Director. New appointees will comply with the federal personnel process by submitting a series of personnel forms and questionnaires and completing the "*Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency*" (EPA Form 3310-48). All SAB appointees are also required to take and certify their completion of annual ethics training programs.

² SAB Committee members appointed under the existing SAB structure will continue to be reappointed for 2 year- terms for a maximum of 6 years.

4. IDENTIFICATION AND SELECTION PROCESS FOR SAB ADVISORY PROJECTS

As described in Section 2, the SAB advisory activity may be a *consultation*, an *advisory*, a *peer review*, a *commentary* or an *original study*. The SAB Staff Office generally receives nominated advisory projects for SAB consideration from various EPA Offices including Office of Research Development, Program and Regional Offices, the Congress (through the Administrator), and the SAB. Original studies and other project types can focus on emerging or overarching scientific or technical issues. Emerging issues are those that are likely to exert a major influence on environmental policy development or research programs in the next two to five years, and hence are issues that EPA would be expected to raise to the SAB for early advice. Original project ideas could be suggested through different sources- EPA, the SAB, the scientific community and the public. The process for identifying emerging issues that can lead to an approved SAB advisory project is discussed below in section 4.2 and summarized in Table 1. Table 1 also outlines the annual process for SAB projects that are nominated by EPA Offices. However, it is important to note that the EPA Administrator always has the discretion to ask the SAB to take on any type of advisory project at anytime.

4.1 Criteria for Project Selection

Nominated advisory projects which are best suited for the SAB's consideration are those that meet several criteria. Selection criteria include the following:

- General Criterion
 - Provides an opportunity to make a difference in the science that supports the Agency's mission
- Client-related Criteria
 - Supports major regulatory or risk management initiatives
 - Serves leadership interests (e.g. the Administrator or Congress)
 - Supports EPA strategic priorities
- Science-Driven Criteria
 - Involves scientific approaches that are new to the Agency
 - Addresses areas of substantial uncertainties
- Problem-driven Criteria
 - Involves major environmental risks
 - Relates to emerging environmental issues
 - Exhibits a long-term outlook
- Organizational Criteria
 - Serves as a model for future Agency methods
 - Requires the commitment of substantial resources to scientific or technological development
 - Transcends organizational boundaries, within or outside EPA (includes international boundaries)
 - Strengthens the Agency's basic capabilities.

In addition, the SAB Staff Office will need to consider the overall mix of the nominated projects for a given fiscal year as well as the time and available resources needed to take on these projects.

TABLE 1

PROCESS FOR SELECTING SCIENCE ADVISORY BOARD (SAB) PROJECTS

<div> <div>STEPS TO SAB PROJECT SELECTION</div> <div>TYPE OF PROJECT</div> </div>	IDENTIFICATION	FORA FOR DISCUSSION AND NOMINATION	PRIORITIZATION AND SELECTION	DEFINING THE SCOPE AND CHARGE	APPROVAL
IDENTIFYING EMERGING ISSUES FOR SAB STRATEGIC ADVICE AND <i>DE NOVO</i> STUDIES	<p>Achieved through Interactions with:</p> <ul style="list-style-type: none"> EPA Program/Regional Offices Scientific Community Public Science Advisory Board SAB Staff Office 	<p>SAB Annual Meeting</p> <p>SAB Committee Meetings</p> <p>Meetings with Public</p> <p>Science Policy Council</p> <p>EPA Program/Regional Offices</p> <p>Scientific Workshops</p>	<p>Achieved through joint discussions with:</p> <ul style="list-style-type: none"> - Science Policy Council - EPA Program/Regional offices - SAB <p>To identify projects for further consideration.</p> <p>-Strategic Advice by SAB</p> <p>-<i>De novo</i> SAB project</p> <p>Selection based on:</p> <ul style="list-style-type: none"> - Impact on Agency's mission - Innovative nature of project - Agency needs 	<p>Achieved through joint discussions with:</p> <ul style="list-style-type: none"> - Designated SAB Committee - EPA Program/Regional Office 	<p>SAB Staff Office considers:</p> <ul style="list-style-type: none"> - Availability of resources
AGENCY REQUESTS	<p>Achieved through discussions within EPA Offices to determine projects which would benefit from external review.</p>	<p>Staff Office receives nominations from EPA Assistant Administrators (AAs) or Regional Administrators (RAs)</p> <ul style="list-style-type: none"> - Annually - As needed basis 	<p>Achieved through joint discussions with:</p> <ul style="list-style-type: none"> - Science Policy Council - EPA Program/Regional offices - SAB <p>Selection based on:</p> <ul style="list-style-type: none"> - Statutory Requirement - Agency needs 	<p>Achieved through joint discussions with:</p> <ul style="list-style-type: none"> - SAB Staff Office - the requesting EPA Program/Regional office 	<p>SAB Staff Office considers:</p> <ul style="list-style-type: none"> - Availability of resources

4.2 Emerging Issues

Relevant emerging and/or overarching issues for SAB project proposals may be identified by various sources including EPA, the SAB and Staff Office, EPA stakeholders and the public at large, as well as scientific organizations. Selected issues and topics relevant to EPA's mission could then be further discussed internally through the EPA Science Policy Council, and at different public fora such as the SAB Annual Meeting and Committee Meetings, EPA or SAB sponsored scientific workshops and seminars, or Staff Office sponsored public sessions. In particular, the SAB Annual Meeting would provide an opportunity to bring in all members of the Board and Committees to benefit from extended presentations and discussions of selected emerging issues. These discussions would identify the most important and relevant topics to be considered further by the Agency and the SAB. This would then result in the development of project proposals from either EPA Offices or SAB Committees to be submitted formally for SAB consideration as part of the annual nomination and selection process (see Sections 4.3).

4.3 Nomination and Selection of SAB Projects

The annual process for selecting EPA nominated SAB advisory projects for the next fiscal year normally begins in March with a formal request from the EPA Deputy Administrator to the Assistant Administrators and Regional Administrators. The Assistant Administrators and Regional Administrators are requested to send the SAB Staff Office Director a memorandum identifying a prioritized list of projects nominated for the SAB consideration. A list of high-priority science activities that do not warrant the SAB's attention are to be provided to the Staff Office for information. EPA Offices will also be asked to prepare a SAB Project Sheet for each nominated project. This project sheet describes in more detail the nature of the nominated projects. These requests will also be entered into EPA's Science Inventory database and the SAB Project Sheets will be entered into the SAB Project Database. Also in March, the Board and Committees are asked to nominate SAB project ideas on important and relevant emerging issues as identified by various mechanisms as described above (Section 4.2). Nominated SAB projects for a given fiscal year will be made available on the SAB website.

After receiving the list of requested projects, the SAB Staff Office will hold discussions with EPA Offices and identify the Agency's overall priorities via discussions with the EPA Science Policy Council. The Staff Office will also hold discussions with the Board to obtain their input and then develop a recommended final list of SAB advisory projects based on the Board and EPA rankings and the available Staff Office resources. The SAB Staff Office Director will inform the EPA Administrator and Deputy Administrator concerning the SAB operating plan particularly of projects dealing with emerging or overarching issues and highly visible peer reviews. At any time during the fiscal year, SAB projects may be added or deleted, as requested by the EPA Administrator and Deputy Administrator, Assistant Administrators, Regional Administrators, or the Congress (through the Administrator), and the SAB.

5. SELECTION AND FORMATION OF SAB PANELS FOR ADVISORY PROJECTS

The SAB Staff Office is responsible for determining the most efficient and effective way for the SAB to provide the Agency with timely and sound advice on requested projects and for selecting and assembling the most qualified body of experts. This determination would significantly influence the timing and the level of resources required to accomplish the advisory activity and would be made in consultation with the SAB and the EPA Office that requests the advice.

5.1 Selection of SAB Panels

As illustrated in Figure 4, an advisory activity as requested by EPA could be performed by an existing Standing or *Ad Hoc* Committee with or without additional expertise, or a newly created (*De Novo*) Review Panel. The determination would be based on a number of considerations and in consultation with the requesting EPA office and the SAB. These considerations may include the stages of development of the EPA work product, the subject focus and scope, the impact the advisory activity may have on an EPA action, and the level of public interest. For example, existing Standing or *Ad Hoc* Committees may provide early advice on an EPA initiative (consultation) or peer review a completed work product that is over-arching (e.g., research strategies, guidelines). In another example, a *De Novo* review panel may be created to conduct peer review of a risk assessment that may have a direct impact on EPA actions. The generic criteria described in Figure 4 are only to be used as guidelines when selecting an SAB committee or panel type.

5.2 Formation of SAB Panels

The SAB Staff Office has been implementing the SAB panel formation process (as described in the “*Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board*”, <http://www.epa.gov/sab/pdf/ec02010.pdf>) since June 2002. There are generally four basic types of Panels, each requires a different level of time and resources. The most efficient and direct way is to utilize an existing Standing or *Ad Hoc* SAB Committee, whereas the most resource intensive and time consuming is to create a *De Novo* Review Panel.

a) A Project to be performed by an existing SAB Committee

The SAB Staff Office will publish a *Federal Register* Notice announcing an advisory project to be conducted by a particular SAB Standing or *Ad Hoc* Committee and informing the public that no additional expertise is needed to augment the selected committee. The SAB Staff Office will post on the SAB Website biosketches of members of the selected committee and will request the public for information that will help in finalizing the panel. The SAB Staff Office will consider public comments and document the selection of panel members.

b) A Project to be performed by an existing Committee with additional experts from other SAB Committees and/or EPA Federal Advisory Committees

The SAB Staff Office will publish a *Federal Register* Notice announcing an advisory project to be conducted by an existing Standing or *Ad Hoc* Committee with additional appointed members of other SAB Committees and/or other EPA Federal Advisory Committees. The SAB Staff Office will post on the SAB Website biosketches of proposed Panel members and request the public for information that will help in finalizing the panel. The SAB Staff Office will consider public comments and document the selection of panel members.

**FIGURE 4 PROCESS FOR SELECTING TYPES OF SAB COMMITTEES OR PANELS :
*EPA REQUESTED PROJECTS***

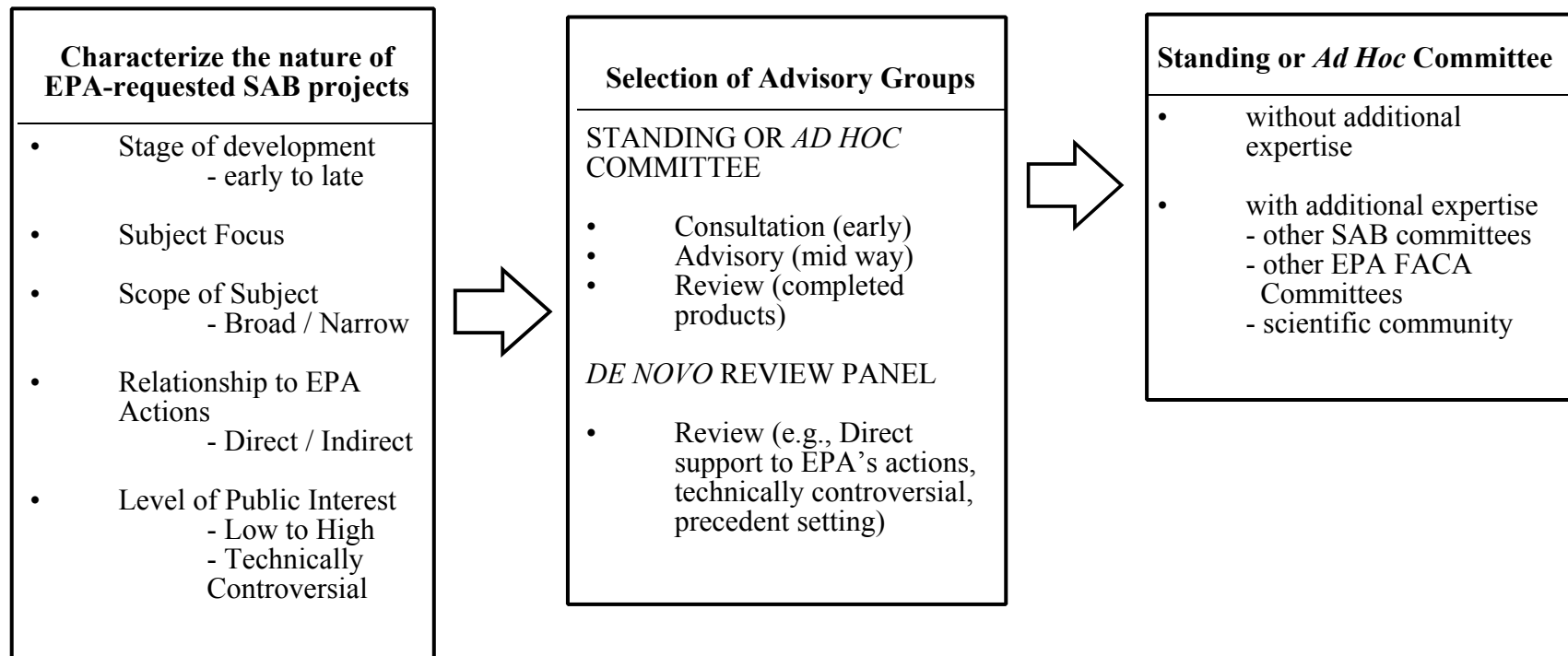
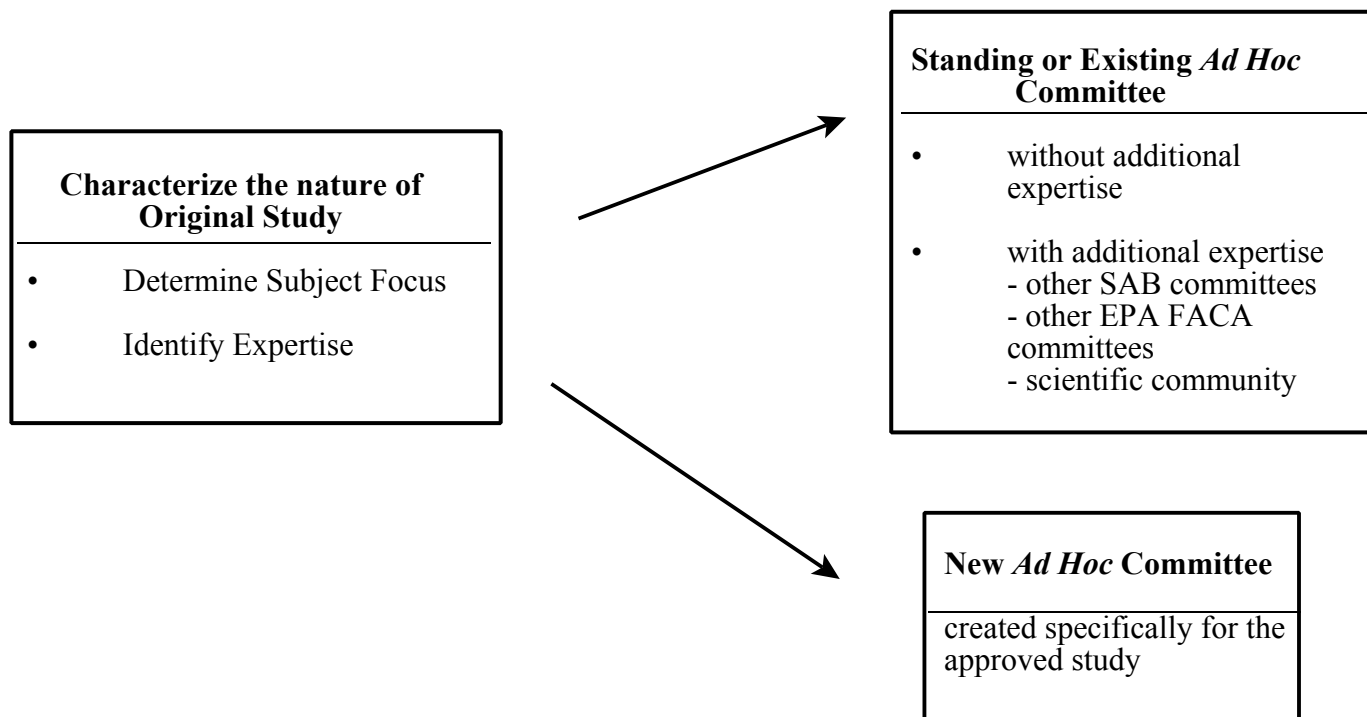


FIGURE 5 **PROCESS FOR SELECTING TYPES OF SAB COMMITTEES :**
SAB ORIGINAL STUDIES



- c) A Project to be performed by an existing Committee supplemented with additional experts drawn from the scientific community

The SAB Staff Office will announce in a *Federal Register* Notice the formation of a SAB panel and solicit public nominations for additional experts to augment the existing Standing or *Ad Hoc* Committee. The SAB Staff Office will select potential candidates from the pool of nominees needed to augment the Standing or *Ad Hoc* Committee and post biosketches for these potential candidates on the SAB website. The SAB Office will ask the public for information that will help in finalizing the panel. The SAB Staff Office will consider public comments and document the selection of panel members.

- d) A Project to be conducted by a *De Novo* Panel (see Figure 6)

The SAB Staff Office will announce in a *Federal Register* Notice the formation of a new SAB panel, identify the expertise needed for the Panel, and solicit public nominations for experts to serve on the Panel. The SAB Staff Office will select potential candidates to serve on the Panel and post their biosketches on the SAB website. The SAB Office will request the public for information that will help in finalizing the panel. The SAB Staff Office will consider public comments and document the selection of panel members.

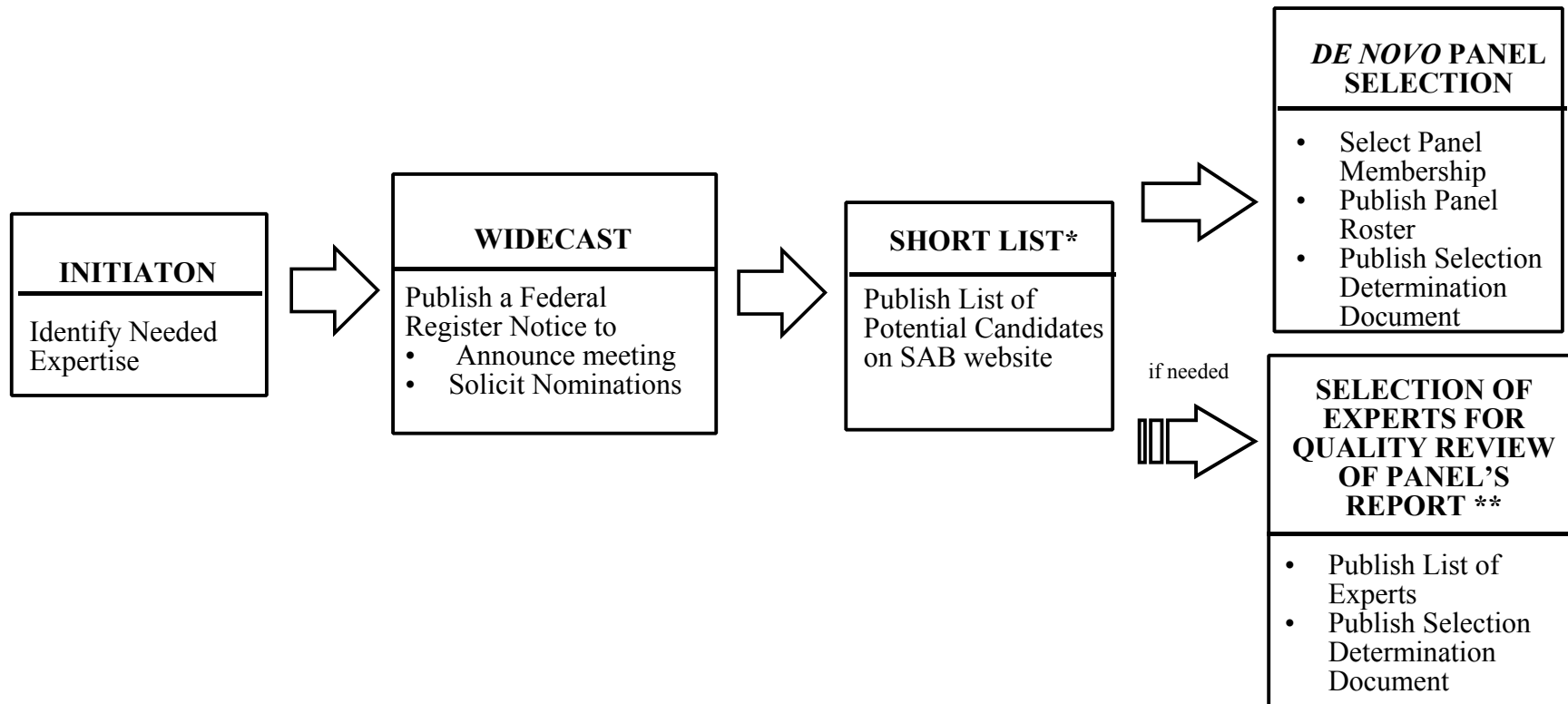
6. ADVISORY MEETINGS AND REPORT WRITING

As required under the terms of FACA, the SAB conducts advisory meetings which are open to the public. The SAB generally discusses their advice and recommendations in response to the charge questions at face-to-face meeting(s). They may conduct teleconferences as they prepare and plan for the face-to-face meetings or conduct follow up discussions to review draft reports. Except for relatively simple issues, it is likely that deliberations on the charge questions may require more than one meeting or public teleconference. Minutes of each meeting and public teleconference, approved by the Committee or Panel Chair as required by FACA, are made publicly available within 90 calendar days after the meeting date and placed on the SAB web site.

All meetings subject to FACA are formally convened by the Designated Federal Officer (DFO) who is a member of the SAB Staff Office with technical expertise related to the area of the Committee or Panel's responsibility. The DFO makes a statement certifying that the Committee or Panel membership is in compliance with Federal ethics and conflict-of-interest laws, and introduces the Chair and members of the Committee or Panel. The Chair makes some introductory remarks, reviews the meeting agenda and commences with the business of the meeting. At initial meetings of a particular advisory activity, EPA representatives may make a brief presentation on the subject matter of the meeting and the charge questions. Oral statements from members of the public usually are heard during a specific public comment portion of the meeting, and there may be an opportunity for a brief interchange of questions between public presenters and the members of the Panel or Committee. The Committee or Panel then conducts its deliberations on the charge questions.

FIGURE 6

**PROCESS FOR IDENTIFYING MEMBERS TO SERVE
ON A *DE NOVO* REVIEW PANEL**



* with public participation

**selection of experts will occur during the preparation of the final panel report (See Section 7)

6.1 Role of Key Meeting Participants

The DFO is responsible for ensuring that the legal requirements of FACA are met. This includes arranging for meetings to be open to the public at reasonably accessible and convenient locations and convenient times, ensuring that advance notice of the meeting is published in the *Federal Register*, and making available for public inspection and copying (subject to the Freedom of Information Act) documents and other materials prepared by or for the Committee or presented to the Committee, including detailed minutes of the meeting. The DFO, in consultation with the Committee or Panel Chair, develops the agenda for the meeting. It should be noted that although the DFO assists the Committee or Panel in the preparation of documents and reports, the advice and recommendations contained in those materials are solely the responsibility of the Committee or Panel.

The Committee or Panel Chair presides after the DFO convenes the meeting, and informs the public of key departures from the agenda, if there are any. The Chair assigns Committee members as discussion leaders for specific charge questions. The Chair concludes the meeting with a summary of its major outcomes – the areas of consensus, the areas where there are different views among the members, the major views expressed, and key follow-up steps. After the meeting, the Chair certifies that meeting minutes are complete and accurate and is responsible for coordinating the writing of the report (or delegating the task to another member). The Chair acts as a spokesperson for the entire Committee or Panel. Committee or Panel Members (including the chair) consider Agency presentations, public comments and background material on the subject, and then deliberate and provide advice. Members have the shared responsibility to write the report summarizing the results of their deliberations.

Representatives of EPA offices provide briefings on scientific issues and how these issues affect Agency decisions. They are a resource for the panel members, and answer questions about relevant Agency programs and policies.

Members of the public attend the meeting both as presenters of statements they wish to have considered by the panel and as members of the audience to observe the proceedings.

6.2. Deliberations and Report Development

Ideally, the deliberative process should lead to consensus conclusions. Consensus can be described as a decision that all of the members of the Committee (or Panel) can accept. At times, it may not be possible to form a consensus, and discussion will reveal the range of views held by members. Where consensus is not reached, the major substantive areas of agreement and disagreement are captured in the final report.

Report preparation is a collaborative process. Individual Committee members may write chapters or sections, which will then be integrated into a cohesive report by the Committee or Panel Chair with the assistance of the DFO. The details of the process may vary among the Committees or Panels, but the “author of record” is the entire Committee or Panel, not any particular individual member.

As the report is being developed, the members who are writing sections may communicate with each other through the DFO. Copies of this correspondence are retained by the DFO in the official file. In addition, at every major stage of report development, a draft

copy of the report is made available on the SAB web site. The public will have an opportunity to provide comments on the draft report during the SAB review and approval of the report.

7. REVIEW AND APPROVAL OF SAB REPORTS

Draft reports prepared by SAB Committees or Panels will need to be reviewed and approved by the Board before transmittal to the EPA Administrator. The Board will make a determination in an open, public meeting consistent with FACA about the quality of the draft report by answering the following questions:

- whether the original charge questions to SAB Standing or *Ad Hoc* Committees were adequately addressed;
- whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;
- whether the Committee's report is clear and logical; and
- whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

The outcome of the Board's evaluation would be one of the following:

- approve the report;
- return the draft report for further work;
- reject the work and request a reconsideration and a revised report in the future; or
- constitute an entirely new Committee or Panel.

To strengthen the quality of SAB peer review reports, a Quality Review Committee (QRC) will be established to review each SAB *De Novo* Review Panel's draft report. The Board's Vice Chair will chair all Quality Review Committees. In addition to the Vice Chair, each QRC will generally include three Board members with appropriate and relevant expertise for a particular quality review. If additional expertise is needed, three to four experts would be identified and selected from the pool of candidates as the SAB *De Novo* Review Panel is being formed. However, the selection process for the Review Panel and the QRC will not be handled by the same DFO and they will not be announced until the drafting of the peer review report is nearing completion. This process is intended to ensure the independence of the QRC from the actual peer review activities of the Panel. The overall process for selecting additional experts for the QRC will follow the same general procedures that are described in section 5.2 (also see Figure 6) for *De Novo* Peer Review Panel members. These experts will be selected based on similar criteria for selection of panel members.

Quality Review Committees will conduct their reviews of draft reports in an open, public meeting consistent with FACA. Based on its own review and written input from expert consultants, the QRC will provide the full Board with its evaluation of the draft report and its recommendations. The QRC will not repeat the work of the Peer Review Panel; rather, each QRC will only determine the quality of the draft Peer Review Report by answering the same questions as described above.

Quality Review Committees, with the assistance of additional experts, will also be established to conduct a review of original works performed by SAB Committees and to make appropriate recommendations to the Board. Additionally, some reports of Standing or *Ad Hoc* Committees that require special expertise or are particularly complex may also be reviewed by a QRC before going to the Board for approval. The Board will make the final determination before these reports are transmitted to the Administrator.

8. FEEDBACK AND EVALUATION

Depending on the nature of the advisory project, the transmittal package to the EPA Administrator generally includes a letter from the Chair of the Board which provides an overall summary of the charge and advice, and a SAB report detailing the response to the charge questions along with general and specific recommendations. In the transmittal letter to the Administrator, the SAB asks that the Agency respond to the advice within 60 days. Since this is controlled correspondence, the EPA Office preparing the response may request an extension. The response should address each recommendation and note whether it is accepted by the Agency, or the reason why it is not being accepted. The response is addressed to the Chair of the Board, at the SAB Staff Office address.

The SAB Staff Office will transmit the Agency's response to the full Board and the Committee or Panel that provided the advice. The SAB will evaluate the comments and then determine whether further analysis is needed, as appropriate. This analysis will become an important vehicle for improving the performance of the Board and its Committees to meet the needs of the Agency. The Agency's response will also be maintained in the FACA file and posted on the SAB website.

The SAB Staff Office will develop a response questionnaire that will ensure a more complete and thorough review of the SAB advice and recommendations and their likely impact on the Agency's decision-making process. The development of this survey for use by Agency officials to provide feedback will be an important priority for FY 04.

9. SAB STRUCTURE FOR FY 2004

A new Board of about 30 members will replace the existing SAB Executive Committee. The new Board's membership will cover the breadth and depth of experience and expertise needed to oversee the advisory functions of the SAB Committees, and to provide forward-looking and technical advice to the Agency on critical overarching issues in the pursuit of public health and environmental protection. The new Board will continue to benefit from having liaison members representing the other three EPA Federal Advisory Committees, i.e., EPA's Federal Fungicide, Insecticide, Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP), EPA's Children Health Protection Advisory Committee (CHPAC), and EPA's Office of Research and Development (ORD)'s Board of Scientific Counselors or (BOSC).

To ensure an effective and smooth transition, the new FY 2004 SAB committee structure will retain seven of the eight former Standing Committees and will include four *Ad Hoc* Committees, two of which are in the process of being formed (see text box). The functions of the Research Strategy Advisory Committee (RSAC), i.e., to advise the Agency on strategic plans and overall research strategies and plans and the annual review of the President's Budget Request for EPA Science and Technology, will be addressed by the new Board. Any additional changes to the SAB Committee structure will be explored during FY 2004.

SAB Committees for FY 2004

Standing SAB Committees

- Drinking Water Committee
- Ecological Processes and Effects Committee
- Environmental Economics Advisory Committee
- Environmental Engineering Committee
- Environmental Health Committee
- Integrated Human Exposure Committee
- Radiation Advisory Committee

Ad Hoc SAB Committees

- Committee on *Valuing the Protection of Ecological Systems and Services*
- Science and Technological Achievement Award Committee
- Bioethics Advisory Committee
- Homeland Security Advisory Committee