



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF THE
ADMINISTRATOR

SUBJECT: Recommended Procedures for Involving the Clean Air Scientific Advisory Committee (CASAC) in the Review Process for National Ambient Air Quality Standards

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Introduction

EPA staff have held several discussions as a follow-up to the January SAB/CASAC meeting concerning possible ways for CASAC to become involved in the review process for National Ambient Air Quality Standards (NAAQS). This memorandum contains a list of proposals and procedures arrived at during these discussions. We are hopeful that agreement can be reached with committee members on the content of these proposals at the forthcoming meeting of CASAC.

EPA is required to review and revise, if necessary, each NAAQS every five years. The current schedule for proposal of a revised standard, or reaffirmation of an existing one, is as follows:

CO	August 1979
NO ₂	November 1979
Particulates	May 1980
SO ₂	May 1980

Promulgation would occur six months after proposal. These schedules include time for SAB/CASAC to review the criteria document in a public meeting, with a contingency allowed for a second meeting, if needed. According to the Clean Air Act Amendments of 1977, the reviews must be completed, i.e. a revised standard promulgated (if needed), by December 31, 1980.

The Science Advisory Board has played a key role for some time in ensuring that the criteria document is scientifically adequate for standard setting. However, the SAB has not participated in the remainder of the

standards development process. With the establishment of the Clean Air Scientific Advisory Committee, mandated by Congress, we need to develop with CASAC procedures to define what CASAC should review, the type of output to result from such reviews, and how these reviews can be accomplished consistent with Congressionally mandated time schedules.

For the purposes of discussion, the NAAQS standards development process can be divided into the following components, each of which we suggest be considered for CASAC review:

1. Criteria document
2. Implications for standard setting of critical health studies
3. Risk assessment
4. Regulatory analysis--economic, environmental, energy, urban and community impacts
5. Overall standards development methodology

Involvement of CASAC in each of these components is discussed below.

Criteria Document

The review of criteria documents is a traditional function of the Science Advisory Board (now the SAB/CASAC) and already has been integrated into the standards development schedule. One significant issue that remains to be resolved, however, is the approach by which the Environment Criteria Assessment Office receives some written assessment from CASAC concerning the content and quality of a criteria document for its use in standards development. This issue can be termed "closure". Closure represents a "sense of the committee" determination upon the scientific adequacy of a criteria document for regulatory purposes at a specific point in time, based upon the information currently available. Closure is intended to supplement other forms of channeling advice such as transcripts, individual notes, and official committee minutes. The overall purpose of closure, therefore, is to ensure that the committee has given explicit written advice concerning a criteria document so that in the future the committee's position will not be misunderstood. Embodied within the concept of closure is that, when necessary, individual committee members can submit written minority reports if they disagree with all or part of the full committee report. A sense of the committee report would be signed by the chairman and staff officer.

Some additional suggestions for how the closure process might be accomplished are included among the appended materials which summarize the six phases now typically involved in the preparation and review of criteria documents. The last three phases outlined in the appended summary concern steps involved in the external review of the documents. This includes, as indicated under Phase IV, SAB/CASAC review of any initial external draft of a document. Also, as indicated there, it would be useful to have from the SAB/CASAC, or one of its subcommittees charged with the review, a formal staff report which details the extent to which the Committee-of-the-whole or subcommittee concurs with the contents and conclusions of the document and which also points out any specific objections or problems regarding the external draft. Phase V, following the initial SAB/CASAC meeting, would involve: (1) revision of the document by EPA/ECAO

in response to the points or issues raised by the public and the SAB/CASAC in commenting on the external draft, and (2) resubmittal of the document to SAB/CASAC for further evaluation. Phase VI, it is suggested, should involve: (1) individual SAB/CASAC committee members conveying their impressions of the revised document to the chairman and (2) the chairman, upon determining the overall sense of the committee, then initiating appropriate further steps, e.g., calling for another SAB/CASAC public review meeting or preparation of a final committee report. A proposed format for committee reports, including particular issues or questions that we feel should be focused on in their evaluations, is included on page three of the Appendix.

Please note the time periods that we estimate should be associated with accomplishing each of the six phases. In order to expedite the process of completing the final three phases, we suggest that agreement be reached between EPA and SAB/CASAC regarding a maximum time within which written committee reports would be filed following any public review meeting on initial external draft of the documents or their final committee reports regarding later, revised versions of documents resubmitted at the end of Phase V. Provision of the SAB/CASAC committee reports to EPA within a relatively short, but reasonable time frame, is crucial in order to ensure that the Agency can be responsive to the advisory group and yet still complete the criteria documents and other, subsequent steps in the standards development process in timely fashion so as to meet Congressionally-mandated or court-ordered deadlines.

Implications for Standard Setting of Critical Health Studies

Following completion of the criteria document, EPA must develop a rationale for a proposed standard. Factors which must be considered in the rationale are the relevant health studies and their quality, seriousness of health effects, identification of sensitive populations, risk to public health, averaging time, allowable exceedances of the standard, and margin of safety considerations. These factors are evaluated by the regulatory office (OAQPS) in arriving at a final recommendation to the Administrator. It is recommended that CASAC evaluate, prior to proposal, the critical health studies and their relevance in setting a standard, as well as other factors which will influence the final standard.

Risk Assessment

A risk assessment technique for application to OAQPS standards development has been under development within the Office of Air Quality Planning and Standards (OAQPS) for about two years. Ozone was the subject of the first analysis. At some future time, after interagency and peer reviews and increased public understanding and acceptance of the technique, we expect to use some form of risk assessment to help us develop ambient standards.

The OAQPS risk assessment technique was reviewed on April 19-20, 1979 by an SAB subcommittee on risk assessment. The committee felt that this technique was not yet ready for use in setting ambient standards but strongly encouraged us to continue development. EPA also was urged to structure an expanded program which would develop, evaluate, and possibly test alternative techniques applicable to the standard setting process.

The risk assessment committee had no objections to our performing a risk assessment for CO as a means of continued development of risk assessment methodology. However, we have concluded that the potential difficulty we would have in assuring the public that the results of a risk assessment would have no impact on selecting a CO standard argues for delaying this assessment until at least after proposal.

Although there is a separate SAB committee on risk assessment, we recommend that CASAC be briefed on the OAQPS methodology and future development plans since we do expect to use risk assessment at some point to help us set standards. A report on the April SAB risk assessment subcommittee meeting is on the agenda for the June CASAC meeting. We recommend that CASAC be more fully briefed in future meetings on risk assessment, future plans, and issues related to use in setting NAAQS.

Regulatory Analysis

The regulatory analysis includes economic, environmental, energy, and urban and community impact analyses. These are required for all major regulatory actions and are released in draft at the time of proposal. The results are not to be considered in setting the standard, however, and therefore should not influence SAB/CASAC in developing the advice and/or recommendations discussed in prior sections. It is planned that these documents will be made available to the CASAC at the time of proposal. It is recommended that the CASAC review a set of regulatory analysis documents for at least one standard, after which the committee can decide whether these documents should be routinely reviewed.

Overall Standard Setting Methodology

It is recommended that the CASAC consider, from time to time, the overall standard setting methodology. Of particular interest to EPA is the identification of additional analyses and research which might be needed to improve the quality of the final decision on a standard.

APPENDIX

1. PREPARATION AND INTERNAL REVIEW OF ECAO AIR CRITERIA AND HEALTH EFFECTS/RISK ASSESSMENT DOCUMENTS

o PHASE I: DOCUMENT PLANNING AND INITIATION (30 DAYS)

Assignment of Project Manager and other ECAO staff members to document preparation team

Recruitment of internal EPA Task Force and outside contributing consultants

Development of work plan and time-table for document preparation

Initiation of literature search and article procurement procedures

o PHASE II: PREPARATION OF IN-HOUSE DRAFT (60-90 DAYS)

Accumulation and analysis of pertinent literature

Writing of rough drafts of document sections

Preliminary meetings of authors and polishing of initial draft

Typing and circulation of preliminary review draft to internal task force and three to five outside reviewing consultants

o PHASE III: INTERNAL REVIEW OF IN-HOUSE DRAFT (30 DAYS)

Convening of ECAO Team, document authors, EPA internal task force and reviewing consultants at 1-day in-house review workshop

Follow-up meetings of ECAO staff, reviewers and authors as necessary

Post-workshop revision of document

Typing, editing, and printing of external review draft

2. EXTERNAL REVIEW OF ECAO AIR CRITERIA AND
HEALTH EFFECTS/RISK ASSESSMENT DOCUMENTS

o PHASE IV: PUBLIC REVIEW OF EXTERNAL DRAFT (60 - 90 days)

Publication of Federal Register Notice announcing availability of external review draft of document

Circulation of external draft to other government agencies, (SAB/CASAC) and the general public

Meeting of ECAO staff, other EPA personnel, and contributing consultants to analyze comments and prepare for SAB/CASAC meeting

Presentation and review of external draft at public SAB/CASAC meeting

SAB/CASAC committee staff report summarizing major concerns or problems

o PHASE V: POST SAB/CASAC MEETING DOCUMENT REVISION (60 DAYS)

Debriefing of ECAO staff, other EPA personnel and consultants

In-depth cataloging, review, and analysis of SAB/CASAC and public comments from before, during, and after the SAB/CASAC meeting

Assignment of specific revision responsibilities to ECAO staff members and contributing consultants

Execution of revision assignments and consultation with individual SAB/CASAC members as needed to resolve clarity and content issues

Typing, editing, and reproduction of revised draft and resubmittal of document to the SAB/CASAC

o PHASE VI: SAB/CASAC CLOSURE ON DOCUMENT STATUS (45-60 DAYS)

Report of individual SAB/CASAC committee members to chairman of group

Determination by chairman of overall sense of the committee and implementation of appropriate options based on following criteria:

Major objections/Problems remaining -- Hold public review meeting

Minor objections/Problems remaining -- Hold conference call

No substantive problems remaining -- Prepare sense of committee report

If latter, proceed with final editing, printing, and release of document

3. PROPOSED FORMAT FOR SAB/CASAC
REVIEW COMMITTEE REPORTS

- o Chairman's summary of overall concensus or majority view regarding committee's evaluation
- o Focus on evaluation of document in terms of:
 - Completeness of literature review--coverage up-to-date, key references properly considered or noted?
 - Adequacy of review and evaluation of studies--data accurately described, interpreted, reanalyzed?
 - Clarity of presentation of data and conclusions--effective presentation of text, tables, figures, summaries?
 - Accuracy of overall interpretation of data base--main conclusions well-founded and extrapolations justified?
- o Signed concurrence of committee chairman and staff officer on report--specifics of individual dissent or minority report appended.