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July 31, 1985

Honorable Lee M. Thomas
Administrator
U. S. Environmental Protection Agency
401 M Street, S. W.
Washington, D. C. 20460

Dear Mr. Thomas:

The Clean Air Scientific Advisory Committee (CASAC) has completed a report on various ways to improve the process for developing National Ambient Air Quality Standards. As you know, CASAC has been a direct participant in setting NAAQS through its reviews of their technical bases. In general, the Committee believes that the Agency has made great strides in incorporating scientific issues into NAAQS development and, as a result, both it and many members of the public believe that EPA's process for selecting levels for standards is both more widely understood and more scientifically defensible.

With this in mind, CASAC seeks, in this current report, to identify areas to further improve the standard setting process. Among the issues examined include 1) streamlining and expediting the preparation and review of air quality criteria documents and staff papers; 2) the need to develop procedures to evaluate the scientific quality of benefits analyses whose preparation is required under Executive Order 12291; and 3) improving the nature and timeliness of CASAC's advice to the Agency.

The CASAC appreciates the cooperation and input it has received from EPA staff during the preparation of this report. I look forward to learning which of the CASAC's recommendations will be accepted by EPA.

Sincerely,

Morton Lippmann, Chairman
Clean Air Scientific Advisory Committee
Science Advisory Board

cc: A. James Barnes
Charles Elkins
Bernard Goldstein
Terry F. Yosie

REPORT OF THE CLEAN AIR
SCIENTIFIC ADVISORY COMMITTEE (CASAC)
ON
IMPROVING THE PROCESS FOR SETTING
NATIONAL AMBIENT AIR QUALITY STANDARDS: AN UPDATE

Science Advisory Board
U. S. Environmental Protection Agency

July 1985

I. INTRODUCTION

One of the major responsibilities of the Clean Air Scientific Advisory Committee (CASAC), as established by the 1977 Clean Air Act Amendments, is to undertake a number of review functions associated with EPA's development, promulgation, and implementation of National Ambient Air Quality Standards (NAAQS). To this end, CASAC issued a report to the Administrator and to Congress in September 1981 entitled "Setting Ambient Air Quality Standards: Improving the Process". EPA has implemented many of CASAC's recommendations in this report. As a result, both the Committee and many members of the general public believe that the process for developing NAAQS is more widely understood and more scientifically defensible. CASAC, with four more years of experience with the process of setting NAAQS has examined several additional issues to further improve this process. These include ways to streamline and expedite the preparation and review of air quality criteria documents and staff papers, and to develop procedures for evaluating the scientific adequacy of benefits analysis. In addition, CASAC makes several recommendations for improving the quality and timeliness of its own advice to EPA.

During the preparation of this report, CASAC benefited from information gathering interviews with EPA staff as well as members of the public. In particular, the Committee wishes to express its appreciation to Alex Cristofaro, Office of Policy, Planning and Evaluation; Bruce Jordan and Harvey Richmond, Office of Air Quality Planning and Standards; Les Grant, Environmental Criteria and Assessment Office; Jack Hiding, Office of Air and Radiation; and Richard M. Dowd, R. M. Dowd, Associates.

II. CASAC FINDINGS AND RECOMMENDATIONS FOR PREPARATION OF NAAQS AIR QUALITY CRITERIA DOCUMENTS

Objective

To facilitate preparation by EPA of air quality criteria documents which present concise summaries and interpretive discussions of scientific and technological data relevant to the establishment of NAAQS.

Background

EPA has greatly improved the process by which criteria documents are prepared. This has resulted in generally high quality documents that are submitted to CASAC for review and ultimately published by the Agency.

The current process starts with development of a document preparation plan by the Environmental Criteria and Assessment Office in consultation with internal EPA task force representatives that include knowledgeable scientists from ORD research laboratories, program office (OAR, OAQPS) staff members, and staff from other interested Agency offices. Authors of criteria document chapters are selected based upon task force discussions, and the entire development plan, including selection of authors, is received and commented on by CASAC at a public meeting. After preparation of initial draft criteria document chapters, ECAO convenes expert workshops to review

their scope and quality. The criteria document development process includes the use of preliminary peer review workshops wherein EPA and non-EPA scientific experts discuss early drafts of criteria document materials, which are then revised before release for public comment and CASAC review. As a result, current criteria documents achieve a high standard for objective reporting and summarization of the pertinent scientific data bases and contain valuable critical analyses of the strengths and weaknesses of key studies leading to bottom line conclusions regarding lowest-observed effect levels and dose-response relationships.

Defects in the Current Process for Preparation of Criteria Documents

Existing criteria documents have some serious limitations which ultimately affect their value to key Agency decision makers. One problem yet to be resolved is a definition of a mechanism by which to encourage chapter authors to be brief and to focus upon key scientific studies. Difficulties are encountered, for example, in omitting or not emphasizing the work of colleagues who may be present at the workshop or on CASAC, who may be offended to find that their studies were deemed not critical to standards setting. Also, workshops held to review comprehensive draft CD chapters sometimes end up devoting too much time to editorial issues and the merits of studies that are not critical to standards setting. Finally, a workshop is an inefficient forum for adding well developed interpretive discussion if it is not already present in the draft chapter.

Current criteria documents are too encyclopedic in describing the data base, often making it difficult to identify and synthesize the data most critical to standards setting. At the same time, they have too little interpretive discussion of the critical data and their implications for standard setting purposes, e.g. explicitly identifying all low level effects that may qualify as adverse biomedical effects. In addition, the criteria documents often take too long to prepare and consume large amounts of EPA's resources.

CASAC's Proposal for an Improved Criteria Document Development Process

1. The criteria document needs to be planned better at the outset and more clearly take into account inputs from the program (OAR, QAOPS) and policy offices, as well as ECAO and other ORD components. This should include the defining of critical issues in standards setting involving: a) scientific data, its evaluation and interpretation; b) use of models in risk assessments (including exposure assessments); c) appropriate pollutant indices, averaging times, etc. and determination of which of these issues should be addressed in the criteria document and which in other standard setting materials, e.g. the QAOPS staff paper.

2. ECAO should prepare guidance to chapter managers on critical issues or topics to be addressed in criteria document chapters, and select criteria document chapter managers who are thoroughly familiar with their topics and the relevant literature. The major focus of the criteria document should be on the evaluation and interpretation of health and welfare effects data. Other background information (such as a discussion of

physico-chemical properties, sources and emissions, measurement methodologies, transport and transformation and environmental concentrations) helpful in placing the effects data in perspective should be concisely summarized in the criteria document and reference made to more detailed discussions of these issues contained in other published materials or separate background documents prepared by ECAO.

3. ECAO should direct chapter managers and other authors to prepare a comprehensive annotated bibliography for their chapters or sections of chapters. These could follow the form of some of the summary tables in recent criteria documents or, perhaps, computerized storage files (which ECAO is now establishing) containing brief summaries and critiques of studies.

4. ECAO should distribute bibliographies to anticipated workshop participants prior to the workshop and request that each expert provide to ECAO and the criteria document authors feedback on which studies are pertinent for standard setting purposes. Given the number of possible studies, ECAO may want to consider making assignments to reviewers to ensure that all of the articles are critically evaluated. This might be accomplished by means of a rating sheet on which each workshop participant would enter a score for each study listed in the bibliography. Each study would receive a score as follows:

- 1) highly relevant to standards setting
- 2) possibly relevant to standards setting
- 3) of little or no apparent relevance to standards setting
- 4) critically defective - should not be cited, except as to note why it should not be used.

5. Criteria document authors should draft their chapters by evaluating those studies most clearly identified as important for standard-setting and by presenting the principal conclusions to be drawn from those studies. The workshop convened to review the draft criteria document chapters would focus initially on the selection of pertinent studies included in the draft chapter and resolution of whether any additional studies need to be added to the chapter. Studies not selected for inclusion in the criteria document chapter would appear only in the backup annotated bibliographies cited in the criteria document as being publically available upon request (and which would be placed in the appropriate Agency docket files). Advocates of including studies with a majority of "3" or "4" scores or for excluding studies with a majority of "1" scores would have an opportunity to challenge the majority view at the workshop, along with discussion of which "2" score studies should be included in the chapter. Once the study selection issue is resolved early in the workshop discussion of the given criteria document chapter, then attention should focus on the evaluative/interpretive aspects of the draft chapter materials and what changes need to be made to reflect workshop deliberations.

CASAC understands that new studies will continue to appear in the scientific literature as the criteria document development process proceeds. Thus, the final list of studies included in the criteria document will differ somewhat from the original list.

6. The criteria document chapter managers would subsequently redraft the narrative chapters, being sure to include concise descriptions of all of the selected relevant studies but devoting most of their efforts to sharpening the interpretive discussions of the significance of the studies to the setting of NAAQS.

7. The revised draft chapters would be sent to the workshop participants for their preparation of written reviews and comments and, if found to be necessary, ECAO could convene a second workshop to resolve any significant remaining controversies concerning discussions of individual studies or overall interpretation of their collective results.

8. ECAO staff would make final editorial changes, add an executive summary incorporating overall interpretive discussions, and distribute the resulting materials as the first external review draft for public comment and CASAC review.

9. Based on public comments and CASAC review and recommendations, ECAO would then carry out, if needed, any further revisions in completing a final version of the document ready for use by OAQPS and other Agency offices (e.g. OPPE) in developing other materials used in the standard setting process.

III. CASAC RECOMMENDATIONS FOR PLANNING THE OAQPS STAFF PAPER

Objective

To achieve early identification of critical data needs to support the selection of index pollutants, adverse health effects, sensitive populations, margins of safety, most sensitive welfare effects, influence of concentration and averaging times on effects and alternate forms for standards.

Background

The OAQPS staff paper for NAAQS has proven to be a highly successful effort in bridging the gap between the scientific studies contained in the criteria documents and the public health policy judgments required of the Administrator in setting NAAQS. In particular, it has enabled both the scientific community and the general public to examine how EPA staff integrate a host of technical data into a rationale for choosing among various policy options.

The implementation of CASAC's recommendations for preparing criteria documents and the anticipated compression of the time frame may not, however, leave adequate time for OAQPS to plan the development of the

staff paper. Earlier and more focussed planning may be needed to permit the issuance of a staff paper sooner than it has in the past.

CASAC's Proposal for Staff Paper Planning

QAQPS is in the process of incorporating additional exposure analyses into its staff paper. CASAC has, for example, previously reviewed the exposure analyses for carbon monoxide and sulfur dioxide, and it encourages the development of exposure profiles and analyses for all NAAQS. These analyses will prove especially helpful as QAQPS introduces more formal methods of risk assessment and benefits analysis into NAAQS development.

By incorporating exposure assessment, risk assessment and benefits analysis, the staff paper planning process would address the following issues (most of which are already included in the existing process):

1. Identification of the sensitive individuals or population groups expected to be at risk from both acute and chronic exposures to a particular criteria pollutant.
2. Identification of the important receptors (atmospheric, aquatic and terrestrial) to evaluate and protect against welfare effects.
3. Articulation of the options from which Agency staff select the index pollutants and the averaging times for short-term and longer-term standards.
4. Evaluation of the critical effects that influence the selection of the form and the levels of primary and secondary standards.
5. Identification of the factors affecting the selection of margins of safety.
6. Assessment of factors determining the reliability of various models used in the staff paper's development. In particular, the staff paper should discuss the use of and the rationale for choosing specific models, the uncertainties associated with the chosen model, and a comparison of the results of the selected model with other models that may apply.
7. Statement of the ranges of interest within which QAQPS staff recommend standard levels to the Administrator, as supported by the available scientific data.

QAQPS should, to the extent practicable, develop exposure assessments for the populations at risk and the welfare receptors which the primary and secondary standards, respectively, are designed to protect.

In addition to these issues, QAQPS is applying methods for risk assessment and benefits analysis into the NAAQS development process. The next section of this report will address CASAC's views on these issues.

IV. THE USE OF RISK ASSESSMENT AND BENEFITS ANALYSES IN SETTING NAAQS

Objective

To establish procedures for the evaluation, inclusion and peer review of Agency risk assessments and benefits analyses during the development of NAAQS.

Background

Various EPA program offices make extensive use of risk assessment as a basis for deciding among regulatory options. A risk assessment is generally defined as including hazard identification, dose-response assessment, exposure assessment and risk and uncertainty characterization. OAQPS is seeking to apply risk assessment methodologies to the setting of NAAQS.

In parallel with this effort is the requirement under Executive Order 12291 for EPA to prepare Regulatory Impact Analyses (RIA) of the costs and benefits of significant regulatory activities. All NAAQS are defined as significant actions under this Order. OAQPS currently prepares benefits analyses for each standard but, to date, it has not utilized them as part of the scientific basis to set standard levels.

CASAC Recommendations

Since both risk assessment and benefits analysis involve the use of scientific data, EPA should attempt to systematically evaluate and integrate them into the existing process for preparing and reviewing air quality criteria documents and staff papers. EPA should develop procedures to ensure their peer review which should, at a minimum, include opportunities for CASAC and public comments. These should be no less rigorous than the procedures already in place for the review of the data bases on pollutant sources, transport, transformation, environmental concentrations and health and welfare effects. An example of peer review that EPA should consider holding from time to time is to convene scientific workshops. The objective of such peer review, which could be conducted in concert with workshops that EPA already sponsors on NAAQS related documents, is to determine which of the risk assessments and benefits analyses are scientifically adequate for inclusion in the criteria documents and staff papers.

To the extent that risk assessment and benefits analysis become part of the scientific basis for setting NAAQS, EPA should submit them for public and CASAC review. Simultaneously, CASAC should supplement its current roster to ensure that it has the appropriate scientific expertise to conduct the reviews.

V. CASAC'S ROLE IN THE NAAQS DEVELOPMENT PROCESS

CASAC's participation in the standard-setting process has evolved since its creation by the passage of the 1977 Clean Air Act Amendments.

At the present time CASAC provides its scientific advice through five distinct channels. These include 1) review of air quality criteria documents; 2) review of QAQPS staff papers; 3) review of the standards proposed in the Federal Register; 4) recommendation, on an annual basis, of the needed research to further improve the Agency's and the public's understanding of criteria pollutant mechanisms and effects; and 5) periodic reports on ways to improve the NAAQS development process.

The Committee believes, on the basis of discussions with Agency and Congressional staff and with representatives of industrial and environmental groups, that its role, in general, has wide acceptance. Like the other elements of the standard-setting process discussed previously, there is a need for CASAC to update and fine tune the way in which it prepares its scientific advice. There are several steps that CASAC plans to implement to further enhance its advisory role. These include:

- CASAC is sometimes requested by Agency staff to comment on issues which have policy as well as scientific content. One example is CASAC's advice on the scientific adequacy of the ranges of interest expressed in the staff paper which include judgments on margin of safety as well as other issues. Trying to totally separate the risk assessment and risk management components of the ranges of interest is likely to prove futile using the presently available analytical tools. Since the ranges of interest are useful to both scientists and policy makers, CASAC recommends that QAQPS retain them as a means of expressing the uncertainties in developing NAAQS. At the same time, CASAC plans to further clarify which aspects of its advice are primarily scientific versus that which is primarily policy related.

- During the course of its scientific reviews for the Agency, CASAC has continually updated its roster to adjust to the changing needs for expertise. At present, the Committee is particularly strong in the atmospheric and health sciences disciplines, and within the past year the Administrator has also appointed a biostatistician. As it forecasts its future review responsibilities, CASAC recommends that additional expertise be acquired in the fields of risk assessment, environmental effects assessment and economic analysis.

- CASAC's recommendations for streamlining various aspects of the NAAQS development process also apply to itself. The Committee believes that it has the capability to provide its written advice to the Agency more expeditiously and will strive to do so. In particular, the Committee Chair will transmit a letter summarizing its major conclusions and recommendations within thirty to sixty days of its initial review of a criteria document or staff paper. CASAC will prepare its final report on the scientific adequacy of such documents within ninety days.

January 1985

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Science Advisory Board

Subcommittee on NAAQS Process

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