Setting Ambient Air Quality Standards:

Improving the Process

A Report of the Clean Air Scientific Advisory Committee
Science Advisory Board
U.S. Environmental Protection Agency

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INTRODUCTION

Among the provisions of the 1977 Clean Air Act Amendments was a requirement that the Administrator of the U.S. Environmental Protection Agency appoint an "independent scientific review committee" to undertake a number of review functions associated with EPA's development, promulgation, and implementation of National Ambient Air Quality Standards (NAAQS). Since its original meeting in November 1978 this committee, known as the Clean Air Scientific Advisory Committee (CASAC), has held a number of public meetings with EPA staff from various program offices as well as members of the public. The Committee has directly participated in the process of developing NAAQS through its scientific review of air quality criteria documents and supplementary documents prepared by the Agency in the course of proposing and promulgating NAAQS. Due to the time constraints encountered during the review of such documents, the Committee has not had the opportunity to thoroughly investigate issues such as the role of economics in setting NAAQS, alternative strategies for attainment of air quality standards, and regulatory analysis of proposed standards. Future meetings and reports of the Committee will address these and other issues associated with NAAQS.

Based upon its experience in the scientific review process, the Committee has prepared a report, with recommendations concerning the standard-setting process, which it hopes will prove useful to the Agency in improving methods of setting scientifically supportable ambient air quality standards. Committee members have also prepared this report to supplement the discussions they have carried out in CASAC's public meetings. We believe the report will be useful to EPA and to the Congress as amendments to the Clean Air Act are considered during the coming months.

CONCLUSIONS AND RECOMMENDATIONS

- National Ambient Air Quality Standards (NAAQS) are an effective way of controlling atmospheric levels of pollutants such as carbon monoxide which are directly emitted from a variety of sources of different types. Conventional emission standards, alone, would not be sufficient for the control of atmospheric levels of such pollutants whose concentrations are superimposed in the atmosphere.

National Ambient Air Quality Standards are also a reasonable way of controlling pollutants formed in the atmosphere, such as ozone and other photochemical oxidants and nitrogen dioxide. In principle, the control of emissions of the precursors of such pollutants should be sufficient to limit atmospheric levels of the reaction products to any prescribed level. However, the available models relating air quality to emission sources are not good enough to use emission standards by themselves to protect air quality for pollutants formed in the atmosphere.

Ambient Air Standards need to be periodically reviewed to determine whether they are adequate in form or numerical values to protect the public health and welfare. The five-year review cycle established by the 1977 Clean Air Act Amendments is an appropriate time frame in relation to the rate of advance of the pertinent scientific data bases.

- CASAC's role in the standard-setting process should be expanded to include the opportunity to comment on the Regulatory Decision Package (RDP) sent to the Administrator prior to selection and publication of proposed ambient air quality standards in the Federal Register. CASAC's current responsibilities have included the scientific reviews of criteria documents and Office of Air Quality Planning and Standards' (OAQPS) staff papers, which identify key studies and evaluate other factors which are critical in setting or revising an ambient standard. CASAC's role has not included review of the Regulatory Decision Package. Since neither the criteria document nor the staff paper has specifically addressed the numerical value(s) for the standard, CASAC has not had an opportunity to advise the Administrator on the scientific aspects of the standard.[1] In seeking to comment on the RDP, CASAC does not wish to set the standard; that should remain the responsibility of the Administrator. However, the Committee believes that the Administrator can make better use of its advice on the implications of alternative forms and values of the standards for public health and environmental quality and on the implications for monitoring and pollution controls, prior to publishing a proposal.

- Research in support of standards development should be conducted on a continuing basis and for project periods appropriate to the complexity of the issues being investigated, rather than be tied to current budgetary restrictions or the timetable of a particular standard-setting cycle. Our key recommendation for improvement in the support of research for standards development is the creation of a Council for Research on Ambient Standards Development to be composed of senior scientists from outside the Agency. Council members should have scientific stature and broad perspectives of the needs of the standards program. The Council should guide the Agency's decisions on which of its peer reviewed approved grants to fund from a specific line appropriation in the Agency's budget. The Council could also periodically identify research needs to the Agency, the Office of Management and Budget, and the Congress to aid in budgetary planning.

- EPA should continue to strengthen its procedures for development of the next five-year cycle of air quality criteria documents. These procedures should continue to include early identification of critical scientific issues; assignment of

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[1] An exception to this practice was the CASAC review in July 1981 of the recent draft staff paper for particulate matter in which the Agency, as an experiment, included ranges of numbers for a twenty-four hour and an annual standard.

responsibility to a Criteria Document Manager for producing a scientifically supportable criteria document; and extensive use of workshops and public comments in the review and revision of criteria documents.

- Current criteria documents, while massive, lack many kinds of informed commentary and critical interpretation which the Administrator needs to set standards. CASAC recognizes that all pertinent studies dealing with specific pollutant effects must at least be identified in the criteria documents. However, these documents should contain a more judicious selection of studies for discussion with an emphasis on significant studies or studies of a high scientific quality. EPA has agreed in principle with this recommendation for development of the next five-year cycle of criteria documents. If the criteria document were so restructured, there would be less need for interpretation of the scientific data base in the staff paper; the staff paper could then be expanded to include a discussion of the possible forms and ranges of numerical values for the standard and the implications of each of these alternative values for the protection of the public health and welfare.

- The scientific basis for several of the NAAQS remains uncertain. Dose-response relationships, particularly at low concentration levels, are difficult to establish and are likely to remain controversial. To deal with these uncertainties, EPA should increase its efforts to develop risk assessment methodologies for quantifying the range of public health effects produced by exposure to individual or combined class(es) of air pollutants. By asking different sets of questions of available scientific data, risk assessments could assist the Administrator and the general public in evaluating the uncertainties in the medical evidence and would indicate more explicitly the health risks associated with alternative standards.

- CASAC reaffirms its policy of liberal participation at its meetings by interested members of the public. CASAC has invited individuals and groups from the public to make formal presentations before the Committee as well as to engage in the more informal question and answer sessions with Committee members and EPA staff. This process has improved the quality of the scientific dialogue on issues of national concern and has provided a forum for the exchange of sometimes differing views. By engaging in these discussions, EPA staff has had to defend their scientific assumptions and views prior to reaching decisions on standards. The result has, we believe, enhanced the decisionmaking process.

- An effective working relationship has developed between EPA and CASAC. Through the closure statement the Agency depends upon CASAC to advise it on the scientific adequacy of criteria documents and staff papers. Closure thus provides a strong incentive for cooperation between the Agency and the Committee. A similar incentive is needed for the Agency to seek CASAC advice on the scientific adequacy of standards.

DEVELOPMENT OF AMBIENT AIR QUALITY STANDARDS

A. Legislative Requirements

The Clean Air Act Amendments gave the Environmental Protection Agency the responsibility to establish nationwide ambient air quality standards requisite to protect the public health and welfare with an adequate margin of safety. Key provisions of the present Act are included in Figure 1.

In order to establish an ambient air quality standard, the Act requires a determination that a particular pollutant, which arises from diverse mobile or stationary sources, causes or contributes to air pollution which in the Administrator's judgment "may reasonably be anticipated to endanger public health or welfare." Within 12 months of the listing of a pollutant under section 108(a) of the Clean Air Act, the Administrator must publish an air quality criteria document which assesses the scientific data base underlying the ambient air quality standard. The criteria document must contain the "latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare."

Simultaneous with the publication of a criteria document, the Administrator must propose primary and secondary national ambient air quality standards, as appropriate. A primary standard must be one that, in the Administrator's judgment, is requisite to protect the public health with an adequate margin of safety. A secondary standard must be adequate to protect the public welfare from known or anticipated adverse effects. Following the proposal of any primary or secondary standard, a public comment period ensues, including the holding of a public hearing. Taking into account the public comments, the Administrator then promulgates the final standard.

The 1977 Clean Air Act Amendments retained most of the legislative requirements of the 1970 Act for the development of ambient air quality standards and specified certain additional requirements (Figure 2). For example, the 1977 Amendments require that all existing criteria documents be periodically reviewed by a newly created "independent scientific review committee." This directive was in addition to the already existing practice of having EPA's Science Advisory Board (SAB) review draft criteria documents. The SAB's authority to comment on draft criteria documents was statutorily established by the Environmental Research, Development and Demonstration Authorization Act (ERDDAA) of 1978. The CASAC, as an SAB committee, therefore retains authority to provide advice to EPA on both draft and existing criteria documents. The CASAC, like all SAB committees, is an independent body made up of scientists and other experts from outside the Agency who have substantial scientific and technical

FIGURE 1

CLEAN AIR ACT:

KEY AIR QUALITY CRITERIA AND STANDARDS PROVISIONS

- LIST UBIQUITOUS POLLUTANTS WHICH IN ADMINISTRATOR'S JUDGMENT MAY ENDANGER PUBLIC HEALTH OR WELFARE
- ISSUE CRITERIA DOCUMENTS CONTAINING LATEST SCIENTIFIC KNOWLEDGE ON IDENTIFIABLE EFFECTS OF POLLUTANT ON PUBLIC HEALTH/WELFARE
- PROPOSE NATIONAL AIR QUALITY STANDARDS WHEN CRITERIA DOCUMENTS ARE ISSUED
- PERIODICALLY REVIEW, AND WHERE APPROPRIATE, REVISE CRITERIA DOCUMENTS AND AIR STANDARDS

CLEAN AIR ACT STANDARDS PROVISIONS

- PRIMARY NATIONAL AMBIENT AIR QUALITY STANDARDS

  PROTECT THE PUBLIC AGAINST ADVERSE HEALTH EFFECTS WITH AN ADEQUATE MARGIN OF SAFETY

- SECONDARY NATIONAL AMBIENT AIR QUALITY STANDARDS

  PROTECT PUBLIC WELFARE FROM KNOWN OR ANTICIPATED ADVERSE EFFECTS

  PUBLIC WELFARE DEFINED TO INCLUDE EFFECTS ON:
  SOILS o WATER o CROPS o VEGETATION o ANIMALS
  WILDLIFE o WEATHER o VISIBILITY o CLIMATE
  MAN-MADE MATERIALS o ECONOMIC VALUES
  PERSONAL COMFORT/WELL BEING

FIGURE 2

1977 CLEAN AIR ACT AMENDMENTS:

KEY ADDITIONAL PROVISIONS BEYOND 1970 ACT

- REVIEW AND REVISE ALL EXISTING CRITERIA AND STANDARDS AS APPROPRIATE BY DECEMBER 31, 1980
- THEREAFTER REVIEW AIR QUALITY CRITERIA AT 5-YEAR INTERVALS AND REVISE STANDARDS AS NECESSARY
- ISSUE NO_2 CRITERIA (FOR UNDER 3-HOURS) AND PROMULGATE SHORT-TERM NO_2 STANDARD IF NECESSARY
- ESTABLISH A SCIENTIFIC REVIEW COMMITTEE TO REVIEW AIR QUALITY CRITERIA AND STANDARDS

expertise relevant to the mission of the Agency. The SAB is chartered by the Administrator to provide independent advice and critical review on scientific matters before the Agency.[2]

In addition to the establishment of the CASAC, section 109(d) of the 1977 Clean Air Act further directs the Administrator to complete a review of all existing criteria and standards before the end of 1980 and at five year intervals thereafter, and to revise the criteria and standards as appropriate. The Administrator is also required to issue NO_2 criteria (for under three hours) and promulgate a short-term NO_2 standard, if necessary to protect the public health.

Turning to Clean Air Act provisions for the implementation of ambient air standards, once an ambient standard is promulgated, primary responsibility under the Clean Air Act shifts from the federal government to the states. Within nine months after promulgation, each state is required to prepare and submit a State Implementation Plan (SIP) to EPA for approval. This plan must identify emission limitations and other measures to attain the primary standard "as expeditiously as practicable" but not later than three years after EPA approval, and to attain the secondary standard within a reasonable time. EPA has established primary standards solely on the basis of adequately protecting public health. Both the Agency and the courts have interpreted the Clean Air Act as forbidding the consideration of costs and feasibility of attainment in setting either the primary or the secondary standards, although such considerations are relevant in the development of State Implementation Plans.

B. The Development Process for Air Quality Criteria

During the past few years considerable change has taken place in the approach by which the Agency reviews and revises air quality criteria. These changes include reorganizations within the Office of Research and Development and alterations in the process of preparing criteria documents; more formalized review of criteria documents by the Clean Air Scientific Advisory Committee; and the development of a critical issues "staff paper" by the Office of Air Quality Planning and Standards.

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[2] An administrative decision was made by EPA to house the CASAC within the Science Advisory Board. This decision stemmed from a recognition that the activities of CASAC would necessarily overlap those areas of scientific review carried out by the Science Advisory Board in such areas as ecological effects, pollutant transport and transformation, and health effects of ambient air pollutants. By making the Committee a part of the Board, the Agency hoped to reduce administrative duplication and make optimal use of other Board committees and members. Like the Science Advisory Board, the CASAC is organizationally placed within the Office of the Administrator and reports directly to the Administrator.

The first major step in the process of formulating or revising ambient air standards is the development or a revision of a criteria document. Figure 3 summarizes six key phases or steps involved in the Agency's preparation of a criteria document. The minimum amount of time necessary to accomplish each step is indicated in parentheses.

Primary responsibility for the preparation of criteria documents rests with the Environmental Criteria and Assessment Office (ECAO), a subdivision within the Office of Research and Development (ORD). The establishment of this office in early 1978, as a successor to ORD's Criteria and Special Studies Office (CSSO), resulted from ORD's recognition of the need for a more formalized preparation of air quality criteria. This awareness stemmed, in part, from major criticisms leveled by the Science Advisory Board during its review of the lead criteria document and from 1977 Clean Air Act Amendment requirements to revise all existing criteria documents. At least four managerial changes distinguish ECAO from its predecessor office. These include 1) recruitment of a multidisciplinary staff with expertise in a range of health and ecologically-related disciplines; 2) establishment of formalized workgroups drawn from a number of Agency program offices to assist in the preparation of criteria documents; 3) extensive use of consultants to assist in the writing and review of working drafts of criteria documents both prior and subsequent to public review; and 4) use of public workshops in which Agency and non-Agency scientists debate and discuss the merits of specific studies and attempt to resolve scientific controversies over their interpretations before such matters are addressed as part of the public comment period and CASAC review of external review drafts.

C. Criteria Document Closure Process

The main features of the CASAC review of a criteria document are embodied in the process known as "closure." (See Figure 4.) Closure can be characterized in the following manner:

> 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. [3]

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[3] Letter from L. Grant, J. Padgett, T. Yosie to CASAC, June 14, 1979. See Appendix.

FIGURE 3 SUMMARY OF CRITERIA DOCUMENT PREPARATION PROCESS

PREPARATION AND REVIEW
OF ECAO AIR QUALITY CRITERIA
DOCUMENTS

- o PHASE I: DOCUMENT PLANNING AND INITIATION (60 DAYS)*

  INITIATION OF LITERATURE SEARCH AND ARTICLE PROCUREMENT PROCEDURES - NOTICE IN FEDERAL REGISTER

  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 TIMETABLE FOR DOCUMENT PREPARATION - DEFINITION OF DOCUMENT CONTENTS

  BRIEFING OF EPA SCIENCE ADVISORY BOARD (SAB/CASAC) ON DOCUMENT PLAN AND CONTENTS

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

  ACCUMULATION AND ANALYSIS OF PERTINENT LITERATURE

  WRITING OF ROUGH DRAFTS OF DOCUMENT SECTIONS - MAINLY SUMMARIZING RELEVANT PUBLISHED STUDIES

  PRELIMINARY MEETINGS OF AUTHORS TO EXPAND INITIAL DRAFTS - INITIATE CRITICAL ASSESSMENT OF STUDIES

  TYPING AND CIRCULATION OF WORKING DRAFT TO INTERNAL TASK FORCE AND OUTSIDE REVIEWING CONSULTANTS

- o PHASE III: REVIEW AND REVISION OF WORKING DRAFT (60 DAYS)

  CONVENING OF ECAO TEAM, DOCUMENT AUTHORS, EPA INTERNAL TASK FORCE, AND REVIEWING CONSULTANTS AT 1-3 DAY PUBLIC WORKSHOP

  FOLLOW-UP MEETINGS OF ECAO STAFF, REVIEWERS, AND AUTHORS AS NECESSARY TO RESOLVE REVISION ISSUES

  POST-WORKSHOP REVISION OF DOCUMENT WORKING DRAFT

  CRITICAL READING AND EDITING OF DRAFT BY ECAO STAFF

  TYPING, GRAPHICS, AND PRINTING OF EXTERNAL REVIEW DRAFT

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

  PUBLICATION OF FEDERAL REGISTER NOTICE ANNOUNCING AVAILABILITY OF EXTERNAL REVIEW DRAFT OF DOCUMENT

  CIRCULATION OF EXTERNAL DRAFT TO OTHER GOVERNMENT AGENCIES, EPA'S SCIENCE ADVISORY BOARD (SAB/CASAC), AND THE GENERAL PUBLIC

  ECAO REVIEW OF PUBLIC COMMENTS FOR POSSIBLE REVISION OF THE CRITERIA DOCUMENT PRIOR TO REVIEW BY THE CASAC

  MEETING OF ECAO STAFF, OTHER EPA PERSONNEL, AND CONSULTANTS TO PREPARE FOR SAB MEETING

  PRESENTATION AND REVIEW OF EXTERNAL DRAFT AT PUBLIC SAB MEETING

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

  DEBRIEFING OF ECAO STAFF, OTHER PERSONNEL, AND CONSULTANTS

  IN-DEPTH CATALOGING, REVIEW, AND ANALYSIS OF SAB/CASAC AND PUBLIC COMMENTS DELIVERED AT 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

  TYPING, EDITING, AND REPRODUCTION OF REVISED DRAFT AND RESUBMITTAL OF DOCUMENT TO THE SAB/CASAC

- o PHASE VI: FINAL SAB CLOSURE AND PUBLICATION (60 DAYS)

  RECIRCULATION OF EXTERNAL REVIEW DRAFT FOR PUBLIC COMMENT AND SAB REVIEW

  ECAO REVIEW OF PUBLIC COMMENTS FOR POSSIBLE REVISIONS OF CRITERIA DOCUMENT PRIOR TO REVIEW BY CASAC

  PRESENTATION AND REVIEW OF EXTERNAL DRAFT AT PUBLIC SAB/CASAC MEETING

  SUBMITTAL OF WRITTEN SAB/CASAC COMMITTEE REPORT ON DOCUMENT TO EPA ADMINISTRATOR

  TYPING, EDITING AND PRINTING OF PREPRINT AND PUBLICATION OF CRITERIA DOCUMENT

* Minimum time necessary to complete phase shown in parentheses.

FIGURE 4

FORMAT FOR SAB/CASAC CLOSURE MEMORANDUM FOR CRITERIA DOCUMENTS

- CHAIRMAN'S SUMMARY OF OVERALL CONSENSUS OR MAJORITY VIEW REGARDING COMMITTEE'S EVALUATION
- 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?

- SIGNED CONCURRENCE OF COMMITTEE MEMBERS OR CHAIRMAN ON REPORT--SPECIFICS OF INDIVIDUAL DISSENT OR MINORITY REPORT APPENDED

The practice of closure represents a marked improvement in the review of criteria documents compared to previous reviews conducted prior to the establishment of CASAC. For example, it avoids the confusion that surrounded the review of the oxidant criteria document by the Science Advisory Board. In the review of that document, charges that the Agency ignored its scientific advisors have surfaced in litigation brought against EPA on the ozone standard. This controversy might have been avoided had the Agency and the review committee employed present reporting procedures.

D. Staff Paper

Once the criteria document has been reviewed by the public and the CASAC, the staff of the Office of Air Quality Planning and Standards prepares a paper which evaluates the key studies in the criteria document and identifies critical elements to be considered in the development of the standard. In addition, the paper provides a discussion of uncertainties in the medical evidence and other factors which the staff believes should be considered in selecting an adequate margin of safety and a final standard level. The staff paper also evaluates studies which should be used in making scientific judgments on the level at which there are effects on public welfare. Previous staff papers for carbon monoxide and nitrogen dioxide did not present a judgment on what concentration level(s) should be established for the standard, although the recent draft staff paper for particulate matter did discuss possible ranges for a revised standard. The paper does help to bridge the gap between the science contained in the criteria documents and the judgment required of the Administrator in setting ambient air quality standards.

Although not required by statute, the staff paper is reviewed externally by the public and the CASAC. CASAC holds a public meeting to provide its comments and to solicit comments from the public. Once the paper has been reviewed by the CASAC, the scientific judgments made in the paper form the basis for the OAQPS staff's recommendation to the Administrator for a proposed standard.

CASAC ROLE AND RESPONSIBILITIES

Section 109(d)(2) of the Clean Air Act, as amended, provides CASAC with a broad mandate to conduct scientific reviews in a number of areas related to EPA's development of air quality criteria and the promulgation and implementation of primary and secondary ambient air quality standards. Quoting from the statute, the Committee's duties include the following:

> "Not later than January 1, 1980, and at five-year intervals thereafter, the committee...shall complete a review of the criteria published under section 108 and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the

Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate....

Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards."

In addition to these statutory requirements, CASAC's designation by EPA as a standing committee of the Science Advisory Board has conferred other responsibilities. Quoting from CASAC's Science Advisory Board charter, the Committee

"shall hold meetings, perform studies, make necessary site visits and undertake other activities necessary to meet its responsibilities. The Committee will coordinate its activities with other committees of the Science Advisory Board and may, as it deems appropriate, utilize the expertise of other committees and members of the Science Advisory Board. Establishment of subcommittees is authorized for any purpose consistent with this charter. The Committee will report to the Administrator of the U.S. Environmental Protection Agency....

Members shall be persons who have demonstrated high levels of competence, knowledge, and expertise in scientific/technical fields relevant to air pollution and air quality issues. Members of the Committee become members of the Science Advisory Board, and the Chairman of the Committee, or his designee, shall serve as a member of the Executive Committee of the Science Advisory Board. The Committee will meet three to six times per year. Support shall be provided by EPA through the offices of the Science Advisory Board. The annual operating cost will not exceed $150,000 and three man-years."

And, as previously noted, as a committee of the Science Advisory Board, CASAC, pursuant to section 8(e) of the Environmental Research, Development and Demonstration Authorization Act of 1978, may make available to the Administrator its advice and comments on the scientific and technical basis of proposed criteria documents and standards.

How has the Committee addressed these responsibilities? The Clean Air Act requires that the Committee review all of the air quality criteria documents published under section 108 of the Act. Since the Agency had already announced its plans to revise existing criteria documents, the Committee decided that the most useful approach was to review the scientific and technical adequacy of new criteria documents. This course of action has provided the Committee with greater opportunity to exercise its influence in reviewing the scientific basis for new criteria documents. Discussion of this and other issues pertaining to the Committee's role occurred in public meetings with participation by EPA's Office of Air Quality Planning and Standards, Office of Research and Development, Office of General Counsel, and interested members of the public. To date, CASAC has reviewed four sets of criteria documents. These include carbon monoxide (CO), hydrocarbons (HC), nitrogen oxides (NO_x), and sulfur oxides/particulate matter (SO_x/PM). A summary of CASAC meetings, agendas, and major recommendations is provided in Figure 5.

Throughout its review of a variety of scientific issues, CASAC has stressed the need for EPA to address effects on public health or welfare produced by exposures to a mix of air pollutants. Examples include the following:

- At the first meeting of CASAC in November 1978, Committee members recommended that the Agency issue a combined sulfur oxides/particulate matter criteria document. The Committee reaffirmed this advice in August 1980.

- CASAC has noted the significance of health effects produced by combined SO_x/PM exposures or with pollutants combined with NO_x or O_3.

- The Committee has recommended to the Administrator that EPA prepare an integrated and interpretive scientific document that reviews the causes and effects of acidic deposition. Such a document should evaluate the state of scientific knowledge with regard to precursor emissions, transport of acidic compounds, pollutant deposition (both wet and dry), and the effects (both measured and potential) of acidic deposition. The Administrator has reviewed this recommendation and has directed Agency staff to prepare such a document, which will be reviewed by the Committee.

- CASAC has suggested the incorporation of information, in various criteria documents, on the role of hydrocarbons in ozone formation and their role as generators of chemical species that also affect other atmospheric processes, so that control strategies are formulated with the several impacts of hydrocarbons in mind.

FIGURE 5

Chronology of CASAC Meetings, Agendas, and Major Recommendations

Date	Agenda	Major CASAC Conclusions/Recommendations
November 1-2, 1978	Process of Setting NAAQS and Standards Currently Being Developed	
	Schedule and Procedures for Preparing Criteria Documents	
	Development Plan for SO_x/PM Criteria Document	CASAC endorses joint criteria document approach
January 29-30, 1979	Review of NO_x criteria document	CASAC recommends substantial revisions in assessments of scientific studies of health and welfare effects from NO_x. EPA agrees to revise and resubmit criteria document for CASAC review.
January 30-31, 1979 (CO Subcommittee)	Review of CO criteria document	CO Subcommittee advises revision of criteria document to amplify comments on certain issues and studies, but Subcommittee is in general agreement with criteria document conclusions.
June 14-15, 1979	Revised CO criteria document	CO Subcommittee concludes revised CO criteria document is scientifically adequate for standard setting.
	CO Staff Paper	1. Critical COHb level reached at 2.7-3.0%. 2. Modeling techniques acceptable. 3. Exercise level assumptions reasonable. 4. Averaging times appropriate. 5. Aggravation of angina described as adverse health effect. 6. Use 1978 Aronow passive smoking study in considering margin of safety.

FIGURE 5 (Continued)

Chronology of CASAC Meetings, Agendas, and Major Recommendations

Date	Agenda	Major Conclusions/Recommendations
June 15-16, 1979	Report to CASAC of CO Subcommittee on criteria document and staff paper reviews	CASAC authorizes preparation of memo to the Administrator affirming conclusions of CO Subcommittee
	Committee Procedures	CASAC adopts "closure" process.
March 17, 1980	Review of EPA Issues Paper, "Facts and Issues Associated with the Need to Develop a Hydrocarbon Criteria Document"	CASAC agrees with the conclusion of the EPA issues paper that, at ambient levels, HC as a class does not cause adverse health or welfare effects. Committee recommends that individual hydrocarbons need careful evaluation, however. CASAC authorizes preparation of a memo to the Administrator summarizing its conclusions.
	Briefing by EPA Oxidants Research Committee Cochairmen	
August 20-22, 1980	SO_x/PM Criteria Document Review	1. Retain combined SO_x/PM criteria document. 2. Neither BS, COHS, or TSP adequately reflect key physical or chemical properties of PM; inter-conversion among BS, COHS, and TSP is not scientifically acceptable. 3. Adopt guidelines for selection of key epidemiological studies. 4. Short-term peak exposures of SO_2 of more concern than low, chronic level exposures. 5. Expand acidic deposition research. EPA should prepare separate integrated document on acidic deposition. 6. Revise criteria document and resubmit for CASAC review.
	Outlines of staff papers for SO_2 and PM	

FIGURE 5 (Continued)

Chronology of CASAC Meetings, Agendas, and Major Recommendations

Date	Agenda	Major Conclusions/Recommendations
November 13-14, 1980	Revised NO_x criteria document	Document adequately addresses previous CASAC criticisms and is scientifically adequate for standard setting. Authorization provided to inform Administrator of CASAC conclusions through preparation of a closure memorandum.
	NO_2 staff paper	Welfare effects data adequately presented and interpreted. Health effects studies over-interpreted. Health studies need further discussion by CASAC.
	Briefing on proposed revisions to ambient CO standard	
February 6, 1981 (Subcommittee on Health Effects of NO_2)	NO_2 staff paper	1. No clear-cut evidence of adverse health effects in clinical studies at NO_2 levels below 1 ppm. 2. No single study seen as providing a quantitative basis for selecting effects levels, EPA should draw from a composite of animal, clinical, and epidemiological data to determine an effects level. 3. Subcommittee recognized the need to protect against both short and long-term health effects, but no consensus was drawn on the form of a standard. 4. Staff paper will be revised and resubmitted to CASAC.
March 10-11, 1981	Preparation of report to Administrator and Congress of principal findings and recommendations.	1. Re-affirm use of ambient standards to control criteria pollutants. 2. Expand CASAC review role in NAAQS development. 3. Establish new research grant program specifically to support standards development. 4. Strengthen procedures for development of next five-year cycle of criteria documents. 5. Prepare more interpretive criteria documents and include discussion of the possible forms, ranges, and numercial values for the standard in the staff paper. 6. Continue development of risk assessments for use in setting standards. 7. Public participation in CASAC meetings has improved the NAAQS standard-setting process. 8. EPA-CASAC working relationship is constructive.

FIGURE 5 (Continued)

Chronology of CASAC Meetings, Agendas, and Major Recommendations

Date	Agenda	Major Conclusions/Recommendations
July 7-9, 1981	Revised SO_x/PM Criteria Document	1. With revisions suggested by CASAC to be incorporated in Vols. II-V, and with the preparation of a revised Vol. I which the Committee will receive by mail, CASAC agrees in principle that the criteria document is scientifically adequate for use in standard setting.
	Particulate Matter Staff Paper	1. CASAC recommends a 10 micrometer size cut for a revised ambient particulate standard. 2. EPA staff should develop a stronger case in support of a secondary standard for fine particles. 3. The numerical ranges stated in the staff paper are reasonable, but more work is needed to supplement epidemiological studies with human clinical and animal toxicological data at both the upper end and lower end of the ranges. 4. The case for a 3 mile aircraft visibility standard has not been made. 5. Duplications and inconsistencies between the staff paper and various sections of the criteria document should be resolved; also, further modifications in the criteria document suggested by CASAC should result in similar revisions in the staff paper.

FINDINGS, RECOMMENDATIONS, AND COMMENTS OF THE CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE

1. National Ambient Air Quality Standards

The Clean Air Act calls for the development and promulgation of National Ambient Air Quality Standards for ubiquitous pollutants which, in the Administrator's judgment, have adverse effects on public health or welfare. The Act also provides for the establishment of technology-based emission standards to control pollutants. Thus, Congress decided to utilize two distinctive yet complementary approaches to standards for pollution control, i.e., an ambient standards approach to be implemented by the states, and a technology performance approach, utilizing emission standards, to be applied to selected categories of mobile and stationary sources. Hazardous pollutants are to be controlled through emission standards applied to both existing and new sources.

Both approaches have advantages and disadvantages. Ambient air quality standards are most appropriate for pollutants which originate from numerous, varied, and widespread sources such as furnaces for heat and power production. They are also useful for pollutants such as ozone and nitrogen dioxide which form in the atmosphere. Technology-based emission standards are most appropriate for new sources, which can more readily apply the latest control technology, and for sources of hazardous air pollutants, where the major sources are limited in number and readily identifiable.

National Ambient Air Quality Standards are an effective way of controlling atmospheric levels of pollutants such as carbon monoxide and sulfur dioxide which are directly emitted from a variety of sources of different types. Conventional emission standards, alone, would not be sufficient for the control of atmospheric levels of such pollutants, whose concentrations are superimposed in the atmosphere.

National Ambient Air Quality Standards are also a reasonable way of controlling pollutants formed in the atmosphere, such as ozone and other photochemical oxidants and nitrogen dioxide. In principle, the control of emissions of the precursors of such pollutants should be sufficient to limit atmospheric levels of the reaction products to any prescribed level. However, the available models relating air quality to emission sources are not good enough to use emission standards by themselves to protect air quality for pollutants formed in the atmosphere.

For some pollutants, both approaches are utilized simultaneously. Emission controls on motor vehicles are needed to approach or achieve the ambient air quality standards for carbon monoxide and ozone, whose atmospheric concentrations are primarily attributable to motor vehicle emissions. In the areas where the

standards are exceeded, other control approaches can be utilized to supplement the emissions controls, such as restrictions on motor vehicle usage, mandatory inspection and maintenance of control device performance, etc. This may be preferable and more cost effective than a uniform, national tightening of the performance requirements for emission controls.

The NAAQS's need to be periodically reviewed to determine whether they are adequate in form or numerical values to protect the public health and welfare. The five-year review cycle established by the 1977 Clean Air Act Amendments is an appropriate time frame in relation to the rate of advance of the pertinent scientific data bases.

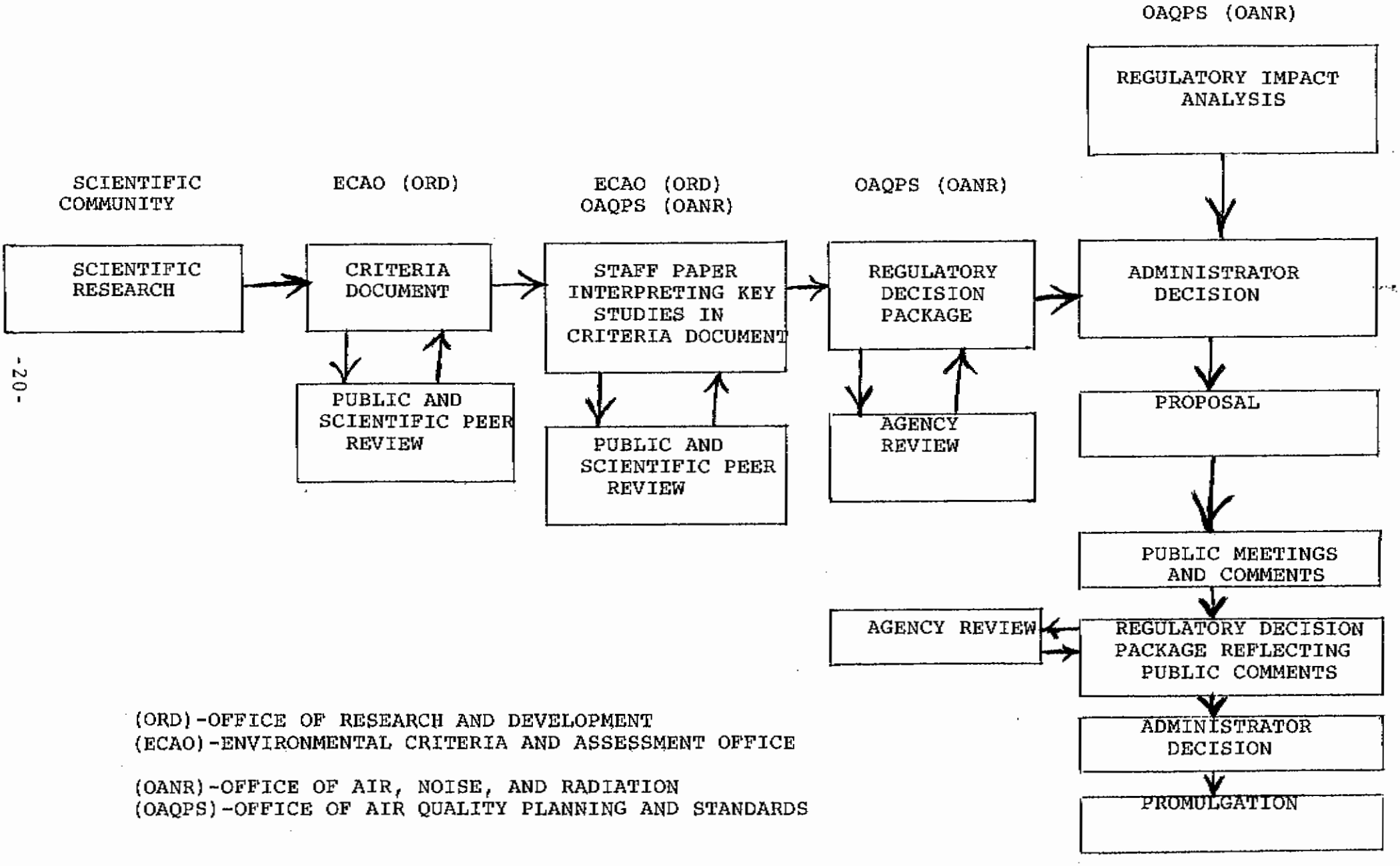
2. Current Limitations on the Role of CASAC in Reviewing Ambient Air Quality Standards

Most of CASAC's efforts, to date, have been devoted to the review of draft criteria documents, one of its major responsibilities as established by statute. To bridge the gap between the large volumes of scientific data summarized in the criteria documents and the critical evaluation of these data needed by the Administrator in developing a standard, the EPA's Office of Air Quality Planning and Standards (OAQPS) has prepared a "staff paper" for each criteria pollutant. The staff paper discusses those data, cited in the criteria document, which OAQPS believes provide the best scientific basis for a standard. At the request of OAQPS, CASAC has also reviewed its staff papers. The CASAC input to the standard-setting process has, to date, been largely limited to these document reviews, which are part of the overall process illustrated in Figure 6. In this figure, CASAC's input is included in the two boxes labelled "Public and Scientific Peer Review."

Following the review of a criteria document and its associated staff paper by CASAC, OAQPS prepares a Regulatory Decision Package (RDP) which, for the first time, addresses the issue of one or more numerical values for the air quality standard. EPA has not sought CASAC advice on the RDP perhaps because it believes that CASAC input at this stage would involve the Committee in policy as opposed to scientific issues and would limit the freedom of the Administrator to select the form and/or the numerical values of the proposed standards.

CASAC believes that EPA should take more advantage of CASAC's extensive knowledge of pollutant effects gained through its reviews of the criteria document and staff paper. CASAC does not seek to select the form or values of the standard. That is the responsibility of the Administrator. However, CASAC believes that the Administrator can benefit from its advice on the implications of alternative forms and values of the standard to public health, environmental quality, and the technological feasibility of monitoring and controls.

FIGURE 6 NATIONAL AMBIENT AIR QUALITY STANDARDS SETTING PROCESS



(ORD)-OFFICE OF RESEARCH AND DEVELOPMENT
(ECAO)-ENVIRONMENTAL CRITERIA AND ASSESSMENT OFFICE

(OANR)-OFFICE OF AIR, NOISE, AND RADIATION
(OAQPS)-OFFICE OF AIR QUALITY PLANNING AND STANDARDS

Although CASAC can comment on the proposed standard after it has been published in the Federal Register, EPA's credibility would be damaged unnecessarily by public criticism from CASAC on a proposed standard. In addition, CASAC's input on the RDP would improve the scientific quality of decisionmaking on NAAQS.

To summarize, CASAC believes that it should review RDP's in the current, uncompleted round of NAAQS reviews. If, however, there are legal or scheduling impediments to its participation in the review of the RDP in this round, CASAC believes that these impediments should be removed, so that it can contribute to future reviews.

3. Need for Long-Term Commitment to Research in Support of Air Quality Standards Development

In recent CASAC reviews of the air quality criteria documents, it became clear that major gaps remain in current knowledge about the nature of the health effects, the dose-response relationships and the temporal and spatial variations in the concentrations of criteria air pollutants. Furthermore, for pollutant classes such as NO_x and SO_x, there are major temporal and spatial variations in the proportions present as vapors and those present as particles. Some of these chemicals are primary pollutants (e.g., NO and SO_2) which serve as precursors for atmospheric transformations to more toxic pollutants (e.g., NO_2 and H_2SO_4), which in turn are transformed to less toxic pollutants (NH_4NO_3,$(NH_4)_2SO_4$). For the pollutant class known as particulate matter which includes secondary aerosols resulting from the oxidation of NO_x and SO_x as well as ash, soil, diesel exhaust particles, etc., there are substantial variations in particle size distribution and trace cocontaminants which affect health and welfare.

The gaps in our knowledge make the selection of NAAQS's very difficult. In the face of the scientific uncertainties, the Administrator may feel impelled to utilize a greater margin of safety in selecting an NAAQS than would be necessary and prudent if there were a more adequate and reliable scientific data base. An excessively stringent NAAQS can impose enormous incremental societal costs in terms of the installation and maintenance of emission controls, additional monitoring of ambient air, and governmental enforcement activities.

The information gaps can be addressed by research programs which focus on the critical scientific questions. However, some of the information needs identified in the recent round of criteria document reviews are too large to be readily filled by short-term, highly targeted research projects. There is a need for long-term programs which enlist a broad range of investigators willing to make a continuing commitment to research in areas related to setting ambient standards.

A long-term commitment of support by EPA is essential to an effective program. It not only takes time to formulate programs designed to address some of the complex issues in standards development, but it takes time, even for the best investigators, to develop the background, specialized techniques, and perspectives needed to perform the series of experiments and studies which can resolve these issues. In the past, crash programs have been initiated only two years or less before the data were needed for decisions. Such a time frame makes it difficult to enlist the services of the kinds of research talents needed to address the fundamental questions. Some of the research needs which face EPA today were apparent when the initial air quality criteria documents were prepared in 1969. These information gaps might have been resolved had there been a commitment of resources guided by a standards development policy and overseen by a suitable group of senior scientific advisors.

EPA does have mechanisms for performing and supporting research needed for ambient air quality standards development. Intramural research performed in its Health Effects Research Laboratory and Environmental Sciences Research Laboratory has made, and will continue to make, important contributions. In addition, some of the newly created university-based EPA-sponsored research centers have program elements which involve research related to the development of NAAQS's. Unfortunately, these various research activities, valuable and important as they are, fall short in terms of developing the broad scientific data base needed for establishing NAAQS's which are both cost-effective and protective of human health and environmental quality. Such research cannot, by itself, do the job because it is too restricted in scope and level of effort. It fails to enlist the talents of the larger scientific community, especially in terms of support of innovative, investigator-initiated research of the type supported by the National Institutes of Health (NIH) and the National Science Foundation (NSF). Some support for research related to the development of NAAQS is available from NIH and NSF, but these agencies tend not to support research perceived as "practical" or program-oriented, preferring studies perceived as "basic research."

EPA is an agency which always has been and probably always will be on the "firing line." Public and Congressional pressures cause it to divert funds and personnel to investigate and control the "crisis-of-the-month." There is, therefore, concern about its ability to effectively manage long-term research programs. On the other hand, EPA is the logical federal agency to support long-term research on standards development, since standards development will continue to be a major statutory responsibility of the Agency.

A. Effective Patterns of Research Support

There are several patterns of long-term research support within and outside of EPA which provide proven mechanisms for a research program in support of standards development. Within EPA,

there is the highly successful peer review grants program which was initiated about two years ago. In this system, the Agency has solicited the submission of investigator-initiated research grant applications directed at specific broad categories of Agency program needs. These grant applications are evaluated for scientific merit by a review panel composed primarily of academic researchers, but also including some EPA research personnel. There are currently four panels and they meet three times each year. In the first full year of application, the panels reviewed 658 grant applications and approved 207 of them. Those that were approved were given a scientific rating. These ratings and the relevance of the research to EPA program needs were evaluated by Agency personnel in deciding which of the approved grants to fund. Of the approved grants, 103 were funded.

The EPA extramural grants program is similar to, and in many respects is patterned after, the highly successful extramural grants programs of the National Institutes of Health. In terms of the scientific peer review procedures, there are not important differences; those differences that do exist are reasonable given the differing responsibilities of the agencies. On the other hand, in terms of the secondary reviews, there are substantial and significant differences. Each NIH Institute (NCI, NIEHS, etc.) has a scientific council composed of extramural senior scientists. Each council meets three times a year to evaluate the grants assigned to that Institute and previously reviewed by one of the discipline-oriented peer review panels (study sections). They weigh the scientific merits of each grant, as outlined to them in the summary statements prepared by the study section, and the relevance of the proposed work to the mission of that particular Institute. As Institute advisors are not employees, they can and do take a long-range view of the needs of the Institute program.

By contrast, the summary statements prepared by the program area peer review panels of EPA (review panels) are reviewed by Agency scientists, who are, of necessity, more influenced by perceived short-term needs of the Agency and whose perspectives may be more limited than those who would be chosen to serve on an NIH-type council.

A further critical difference is the length of time that research support can be committed. NIH Councils can make five-year commitments of support for approved research grants (subject, of course, to continued funding of the Institute by Congress). On the other hand, EPA is limited by Congress to funding research projects for a maximum of two years.

B. Need for a Special Long-Term Commitment for Support of Research on Standards

Many research programs in support of standards development need a commitment of more than two years, and mechanisms should be established to permit such support. Also, recommendations about which of the peer-review approved grants to fund should be made by

a group of senior scientists who have broad perspectives of the needs of the standards program and who are not influenced by the short-term program needs and budgetary exigencies of the Agency. Therefore, our key recommendation for improvement in the support of research for standards development is the creation of a Council for Research on Ambient Standards Development to oversee the research to be supported on a long-term and continuing basis by a specific line appropriation separate and independent of other EPA research programs.

It may be desirable to constitute this Council as a subcommittee or affiliate of CASAC since CASAC has the necessary program perspectives and intimate familiarity with the research needs in support of standards acquired in the course of its reviews of the criteria documents. CASAC's major concern, however, is not that it be involved in the activities of the Council, but that such a mechanism be created to assure timely delivery of scientific results. This mechanism could also be helpful in communicating research needs to EPA, the Office of Management and Budget, and the Congress to help in their budgetary analyses.

Our specific recommendations for a new extramural research program to support the development of ambient air quality standards are summarized in figure 7.

4. Strengthening of Improved Procedures for the Preparation of the Next Five-Year Cycle of Criteria Documents

The preparation of the current round of criteria documents and staff papers was not always expeditious and efficient. Some of these documents will be completed after the December 31, 1980 deadline specified in the 1977 Clean Air Act Amendments, and they will cost much more to prepare than had been anticipated. Furthermore, the form and content of some initial drafts were deficient. Some of the problems in schedule resulted from litigation and were, therefore, beyond the direct control of EPA. However, the problems of form and content were primarily derived from the EPA's conception of the documents.

EPA staff are already well aware of most of CASAC's concerns and have already initiated procedures to improve the development of the next five-year cycle of air quality criteria documents. The following represents CASAC's recommendations for the revised procedures which the Environment Criteria and Assessment Office should continue to implement in the preparation of criteria documents.

Recommendations:

A. Identification of Critical Issues to be Addressed by Criteria Documents

1. ECAO and OAQPS should prepare a compilation of the critical unresolved issues relative to the setting of an NAAQS for each of the criteria pollutants. For a given

FIGURE 7

CASAC Recommendations for Establishing a Long-term Ongoing Research Program in Support of the Development of Ambient Air Quality Standards

I. Suggested Mechanisms for Support of Research

1. Solicitation of long-term (up to 5 years) research grant applications (patterned after the systems used by NIH, i.e., Request for Application (RFA), based upon broad description of research needs).

2. Peer Review of applications by current EPA supported Review Panels, or by special review panel with similar quallfications, providing summary statement on approval and priority score or disapproval.

3. Review of summary statements by a Council for Research on Ambient Standards Development for relevance to standards setting (similar to the advisory role of an NIH Council in the NIH Grants Program).

4. EPA commitment to continuing support of the approval applications for up to 5 years, contingent upon satisfactory progress.

II. Major Areas of Needed Research for Ambient Standards Development

1. Fundamental Studies of Exposure-Response for Criteria Pollutants
   a. Animal toxicology--short-term and chronic exposures
   b. Clinical studies--short-term exposures of human volunteers
   c. Population studies--epidemiology of exposed humans

2. Fundamental Studies of Atmospheric Composition
   a. Primary pollutants--temporal and spatial distributions downwind of sources and potential for population exposure
   b. Atmospheric transformations--temporal and spatial distributions of secondary pollutants, their chemical and physical properties, and their atmospheric lifetimes under various conditions of temperature, humidity, actinic radiation, transport, etc.
   c. Spatial variations within an airshed
      1. center city vs. suburb
      2. ground level vs. elevated sites
      3. outdoor vs. indoor

3. Development and Improvement of Air Samplers, Monitors and Devices for Determining Personal Exposures
   a. Samples for size-selective sampling of aerosols--for both fixed station and personal sampling
   b. Improved samplers and/or monitors for reactive species, such as H_2SO_4, NO_2, HNO_3, volatile and/or reactive organics in or on aerosol particles and in gases, etc.

pollutant the list should be prepared as soon as reasonably possible after the completion of each criteria document and standard for the pollutant. In this manner, the lists can guide EPA's research program in support of standards development, as well as take advantage of the staff's familiarity with the issues acquired during the preparation of the criteria documents.

2. The critical issues lists should be refined in consultation with CASAC.

3. At the beginning of each five-year review cycle of a criteria document, ECAO should conduct a public workshop to develop, update, and refine the critical issues to be addressed in preparing the criteria document. The workshop panel should include a cross-section of scientists and engineers having broad perspective and experience in the field, and should not exceed twenty-five. The workshop should develop a concise summary and list of recommendations.

B. Assignment of Responsibilities for Producing a Criteria Document

1. ECAO, with the advice of CASAC, should identify one or more individuals having the appropriate background and perspective to serve as the Criteria Document Manager (CDM). This person should spend full-time on this activity, on leave of absence from his or her permanent position within EPA, or from a university on a leave of absence and on temporary EPA assignment.

2. The CDM, appointed by ECAO, should prepare a document outline and identify suitable authors for the chapters in the document.

3. The CDM should coordinate development of the individual chapter outlines for addressing the critical issues with the chapter authors.

C. Review and Revision of Draft Criteria Document

1. The initial draft should be reviewed at a public workshop including the CDM and the chapter authors.

2. The chapters should be revised by the authors to incorporate the input from the authors' workshop.

3. The revised draft of the document should then be reviewed at a workshop attended by the participants in the original critical issues workshop.

4. The document should be revised by ECAO to incorporate the input of the critical issues workshop panel and be issued as the first external review draft.

5. OAQPS should prepare a staff paper to highlight the critical issues and information identified in the external review draft which provide a scientific basis for proposal of an air quality standard by the Administrator.

6. The external review draft, and changes in the document which ECAO plans to make as the result of public comments, should be reviewed by CASAC.

7. The criteria document should be revised, as necessary, to obtain closure by CASAC.

5. Form and Content of Ambient Air Quality Criteria Documents and Staff Papers

The 1970 Clean Air Act specifies that criteria documents must contain the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare. The criteria documents prepared by the Environmental Criteria and Assessment Office of EPA during the current review cycle have been criticized by CASAC as being overly inclusive compilations of all available data on the subject pollutant, much of which is of little relevance to standard-setting. The documents, while massive, have been lacking in many kinds of informed commentary and critical interpretation which are needed by the Administrator in setting standards. CASAC recognizes that all pertinent studies dealing with specific pollutant effects must at least be identified in the criteria document. However, the document should contain a judicious selection of studies for extended discussion with an emphasis upon significant studies or studies of high scientific quality. The remaining studies could be referenced in a bibliography. EPA has agreed in principle with this recommendation for development of the next five-year cycle of criteria documents.

If the criteria document were so restructured there would be less need for interpretation of the scientific data base in the staff paper. The staff paper could then be expanded to include a discussion of the possible forms and ranges of numerical values for the standard and the implications of each of the alternatives for the protection of the public health and welfare.

6. Risk Analysis and Air Quality Standards

In carrying out the Clean Air Act requirement to develop ambient air quality standards, EPA must evaluate the "latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare which may be expected from the presence" of pollutants in the ambient air. Pursuant to this Congressional mandate the Agency must also set the standards to protect against adverse effects, protect persons in sensitive groups, and include an adequate margin of

safety to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of scientific uncertainty.

One approach that has evolved to address these issues is known as risk analysis. Risk analysis is a methodology used to determine the probability that specified events will occur given particular concentration levels of pollutants, and it attempts to define the significance of the consequences to public health and welfare following such occurrences. It consists of scientific data collection; assessment of the probabilities of risk based upon available scientific data; and the evaluation of risks based upon their probabilities as governed by the risk assessment process and their value as determined by the policymaker.[4]

EPA has initiated a Risk Analysis Program in its Strategies and Air Standards Division (SASD) to evaluate alternative risk assessment methods with the aim of eventually incorporating risk analysis into the process for setting ambient air quality standards. A Subcommittee on Health Risk Assessment of the Science Advisory Board has recommended that SASD develop and "establish the credibility" of these methods, and it is currently advising that office on the identification and review of alternative risk assessment approaches.

CASAC recommends that EPA should continue its efforts to apply risk analysis in assessing and quantifying the range of public health effects produced by exposure to individual or combined class(es) of air pollutants. Such scientific/decision analysis technique(s) offer promise in defining which of the range of air pollution effects are adverse. By asking alternative sets of questions of available scientific data, risk analysis could assist the Administrator and the general public in evaluating uncertainties in the medical evidence and would indicate more explicitly the health risks associated with alternative standards. The Committee also recommends that it be periodically briefed on the degree of the Agency's progress toward incorporating risk analysis into the standard-setting process.

7. Public Participation in Scientific Reviews

Throughout all of its meetings, CASAC has invited the participation of individuals and groups representing the public. Their input, in the form of formal presentations as well as more informal question and answer sessions with the Committee and EPA staff, has considerably enhanced the quality of the scientific dialogue on issues of national concern. Committee meetings have

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[4] For a recent discussion of the role of risk analysis in standard-setting see Richard Wilson and Joseph J. Harrington "The Role of Risk Analysis in Setting Ambient Air Quality Standards," Business Roundtable Air Quality Project, Vol. I.

provided a forum for the exchange of sometimes differing views. By engaging in these discussions with CASAC and the public, EPA staff have had to defend their assumptions and their interpretations of scientific data and issues. The result has, we believe, enhanced the decisionmaking process.

These discussions have not occurred without a certain amount of confusion or frustration, particularly when legal conflicts have surfaced which have affected the Committee's work. CASAC, however, is committed to the public review process and it reaffirms its policy of liberal participation by interested members of the public.

8. The Working Relationship Between EPA and CASAC

An effective working relationship has developed between EPA and CASAC. Through the closure statement the Agency depends upon CASAC to advise it on the scientific adequacy of criteria documents and staff papers. Closure thus provides a strong incentive for cooperation between the Agency and the Committee. A similar incentive is needed for the Agency to seek CASAC advice on the scientific adequacy of standards.

Appendix of Major CASAC Documents

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

ADVISORY COMMITTEE CHARTER

ORGANIZATION AND FUNCTIONS - COMMITTEES, BOARDS, PANELS AND COUNCILS

CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE

OF THE SCIENCE ADVISORY BOARD

1. PURPOSE. This charter is reissued for the Clean Air Scientific Advisory Committee (of the Science Advisory Board) in accordance with the requirements of section 9(c) of the Federal Advisory Committee Act, 5 U.S.C. (App. I) 9(c).

2. AUTHORITY. The Committee is authorized under section 109 of the Clean Air Act, as amended on August 7, 1977, (42 U.S.C. 7401 et seq.).

3. OBJECTIVE AND SCOPE OF ACTIVITY. The Committee shall provide independent advice on the scientific and technical aspects of issues related to the criteria for air quality standards, research related to air quality, sources of air pollution, and the strategies to attain and maintain air quality standards and to prevent significant deterioration of air quality. The Committee shall hold meetings, perform studies, make necessary site visits and undertake other activities necessary to meet its responsibilities. The Committee will coordinate its activities with other committees of the Science Advisory Board and may, as it deems appropriate, utilize the expertise of other committees and members of the Science Advisory Board. Establishment of subcommittees is authorized for any purpose consistent with this charter. The Committee will report to the Administrator of the U.S. Environmental Protection Agency.

4. FUNCTIONS. The Committee will review criteria documents for air quality standards and will provide independent scientific advice in response to the Agency's request and, as required by the Clean Air Act Amendments of 1977, it shall:

- Not later than January 1, 1980, and at five-year intervals thereafter, complete a review of the criteria published under section 108 of the Clean Air Act and the national primary and secondary ambient air quality standards and recommend to the Administrator any new national ambient air quality standards or revision of existing criteria and standards as may be appropriate,

- Advise the Administrator of areas where additional knowledge is required concerning the adequacy and basis of existing, new, or revised national ambient air quality standards,

- Describe the research efforts necessary to provide the required information,

- Advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and

- Advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

5. COMPOSITION AND MEETINGS. The Administrator will appoint a Chairman and six members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies for terms up to four years. Members shall be persons who have demonstrated high levels of competence, knowledge, and expertise in scientific/technical fields relevant to air pollution and air quality issues. Members of the Committee become members of the Science Advisory Board, and the Chairman of the Committee, or his designee, shall serve as a member of the Executive Committee of the Science Advisory Board. The Committee will meet three to six times per year. A full-time salaried officer or employee of the Agency will be present at all meetings and is authorized to adjourn any such meeting whenever this official determines it to be in the public interest. Support shall be provided by EPA through the offices of the Science Advisory Board. The estimated annual operating cost will not exceed $150,000 and two work-years of staff support.

6. DURATION. The Committee will be needed on a continuing basis. This charter will be effective until August 7, 1983, at which time the Committee charter may be renewed for another two-year period.

JUN 2 6 1981
Approval Date

Administrator

Date Filed with Congress

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

June 14, 1979

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

FROM: Lester D. Grant, Ph.D.
Director, Environment Criteria and Assessment Office
Office of Research and Development

Mr. Joseph Padgett
Director, Strategies and Air Standards Division
Office of Air Quality Planning and Standards

Mr. Terry F. Yosie
Staff Officer, Clean Air Scientific Advisory Committee
Science Advisory Board

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 consistant 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.

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

- 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

- 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

- 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

- Chairman's summary of overall concensus or majority view regarding committee's evaluation

- 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?

- Signed concurrence of committee chairman and staff officer on report—specifics of individual dissent or minority report appended.

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

October 9, 1979

OFFICE OF THE
ADMINISTRATOR

SUBJECT: Findings, Recommendations, and Comments of the Subcommittee on Carbon Monoxide of the Clean Air Scientific Advisory Committee (CASAC) Concerning the Revised Criteria Document for Carbon Monoxide

FROM: Harry H. Hovey, Jr.
Chairman, Subcommittee on Carbon Monoxide

THRU: Sheldon K. Friedlander
Chairman, Clean Air Scientific Advisory Committee

TO: The Administrator

Introduction

The Clean Air Act Amendments of 1977 directed the Agency to establish an independent scientific review committee to complete a review of the criteria published under Section 108 and the national primary and secondary ambient air quality standards promulgated under Section 109. Pursuant to this requirement, the Agency chartered the Clean Air Scientific Advisory Committee of the Science Advisory Board (SAB).

On June 14-15, 1979, a subcommittee of CASAC completed its review of two documents that address the major scientific issues associated with exposure to CO. These documents were: 1) the Air Quality Criteria Document for Carbon Monoxide, and 2) a Preliminary Assessment of Adverse Health Effects from Carbon Monoxide and Implications for Possible Modifications of the Standard (referred to henceforth as Adverse Health Effects memorandum). The purpose of this memorandum is to summarize the major findings, recommendations, and comments provided by the subcommittee to assist you in reviewing the data necessary for proposing an ambient air quality standard for carbon monoxide as required by law.

Major Issues Pertaining to the Criteria Document

Five major issues pertaining to the CO criteria document were discussed by subcommittee members. These issues include:

1. Does the criteria document adequately identify, discuss, and evaluate the critical health studies for CO?

2. Does the document address and assess in sufficient detail the methodologies for measuring CO?

3. Does the document adequately identify exposure conditions for the population as can best be ascertained from presently available information?

4. Does the criteria document adequately address and evaluate the global cycle of carbon monoxide?

5. Does the criteria document fulfull the requirements of law set forth in Section 108 of the Clean Air Act Amendments of 1977?

ISSUE #1: Identification, Discussion, and Evaluation of Critical Health Studies for CO.

In general, the subcommittee concluded that the criteria document represents a comprehensive and balanced presentation and interpretation of the information contained within the literature of critical health studies for carbon monoxide. Specific comments were made in relation to the role and importance the Agency should attribute to particular studies and to related health issues. Those studies and issues of a major concern to the subcommittee included:

- the role of the 1978 Aronow study on passive smoking

Evaluation of the Aronow study was discussed within the context of relating critical levels of blood carboxyhemoglobin (COHb) to adverse health effects. Specifically, the subcommittee was requested to advise whether Aronow's conclusion that a concentration of 1.8% COHb produced aggravation of angina pectoris should be relied upon by the Agency in determining the threshold level for adverse health effects. In addressing this question, subcommittee members commented upon the methodology of the Aronow study. In measuring COHb levels in patients seated in an enclosed room, Aronow did not account for individuals who were smoking; consequently, he did not measure and did not account for other components of cigarette smoke in the air. The health effects of CO exposure alone upon COHb levels of the patients, therefore, is in doubt. The conditions of this study, as well as Aronow's 1972 freeway study, raise but do not resolve the issue of whether there are interactions or synergisms between CO and other pollutants. The subcommittee recommended, however, that the Agency retain the use of the 1978 Aronow study in considering adverse effects.

o populations at risk

The subcommittee concluded that the criteria document adequately identifies the sensitive population groups at risk from ambient CO concentrations. The subcommittee recommended that members of the smoking population not be listed as a sensitive group which a proposed standard would be specially designed to protect.

ISSUE #2: Methodologies for Measuring CO

The subcommittee concurred that the criteria document adequately addresses and evaluates in sufficient detail the models for measurement of carbon monoxide in the air and in the blood. Individual members did suggest, however, that some minor editorial or clarifying statements be incorporated that pertain to measurement procedures and detectable levels of CO.

ISSUE #3: Identification of the Exposure Conditions for the Population Based upon Existing Information

The subcommittee concluded that, based upon existing information, the criteria document contains the most practicable analyses in identifying and assessing population exposure conditions from CO, but it observed that the paucity of such information limits a more precise understanding of health effects that occur at ambient levels of CO. Pursuant to addressing this problem of insufficient data, the subcommittee made the following comments: (1) an apparent contradiction exists between measured CO levels in cities and overall emission levels. In urban areas, where monitoring stations are located, measured levels of ambient CO has shown a decreasing trend. On a nationwide scale, however, CO emissions continue to increase due to the greater number of aggregrate vehicle miles traveled. The criteria document should address this issue. (2) CO concentrations represent a health concern chiefly to population groups residing in cities. Most available data utilized by the Agency, however, project nationwide CO concentrations. Consequently, there is a need to obtain a better profile within specific urban areas, at the neighborhood or street level, to assess the health effects of CO exposures at such "hotspots." The subcommittee recommended that the Agency devote increased resources in the future to attain such profile improvements in order to obtain a more realistic scientific appraisal of urban CO exposures. (3) the criteria document should place a greater emphasis upon the problem identified in item 2 above, and (4) a section on exposure concentrations resulting from cigarette smoking should be included within the criteria document.

ISSUE #4: Global Cycle of Carbon Monoxide

The subcommittee concluded with a unanimous consensus that the criteria document adequately addresses, presents, and interprets information concerning the various sources and sinks of CO in the global atmosphere.

ISSUE #5: Fulfilling the Requirements of Section 108 of the Clean Air Act Amendments of 1977

Section 108 of the Clean Air Act Amendments requires the Agency to establish national primary and secondary ambient air quality standards for air pollutants based upon air quality criteria that "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities. The criteria for an air pollutant, to the extent practicable, shall include information on:

(A) those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant;

(B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and

(C) any known or anticipated adverse effects on welfare."

The subcommittee, after reviewing the scientific information as identified, discussed, and evaluated in the criteria document for carbon monoxide, and after receiving a reading of Section 108 of the Clean Air Act Amendments, reached a consensus that the criteria document adequately fulfills the requirements of law.

Major Issues Pertaining to the Adverse Health Effects Memorandum

The subcommittee addressed a number of issues that will influence a proposed ambient air quality standard for carbon monoxide. The issues addressed and the recommendations include the following:

- the role of the 1978 Aronow study in standard setting. The subcommittee recommended that the Agency should continue to rely upon the Aronow study in developing an ambient CO standard but, given the uncertainties stemming from the methodological approach, it should utilize the

study for margin of safety considerations rather than using it for the determination of a threshold value.

- the subcommittee discussed a range of COHb concentration levels addressed in the criteria document. A majority consensus was reached that: 1) aggravation of angina pectoris represents an adverse health effect, and 2) the critical COHb level at which adverse health effects do occur falls within a range of 2.7% - 3.0% COHb. One member of the subcommittee dissented from this finding and advised that the critical level was reached at approximately 4.0% COHb.

- the available health effects evidence indicates that the population groups at greatest risk to low level CO exposures include coronary artery and peripheral vascular disease individuals.

- the principal mechanism of toxicity for standard setting purposes at this time is hypoxemia.

- the Coburn model provides the best availabe tool for predicting COHb levels resulting from CO exposures.

- the findings of animal studies suggest that CO produces detrimental effects on human fetal development. This evidence relates primarily to animal studies showing that the developing fetus is exposed to COHb concentrations considerably higher than the pregnant mother for long-term CO exposures. However, such findings cannot be extrapolated directly to identify specific human effects levels.

- the one hour and the eight hour averaging times in the current ambient standard for CO should be retained because they provide an appropriate time frame from which to evaluate health effects from both short-term and continuous exposures, respectively. In particular, the one and eight hour standards provide reasonable protection against the bolus effect (high spikes of short duration) in the urban ambient environment.

- the reduced 0_2 pressure at higher altitudes can result in hypoxemia that may interact with the effect of CO exposures upon persons with impaired cardiovascular systems. The key issue of concern is adaptability. While a healthy young person might adapt to hypoxic stress, for example, an elderly person with coronary disease might be adversely affected. The possible

adverse effects on non-adaptable population groups should be considered in selecting an adequate margin of safety for the proposed CO standard.

Minority Report

As part of the working procedures adopted by the Clean Air Scientific Advisory Committee, individual members may submit a minority report to address those major issues or problems which they believe remain unanswered or unresolved within the criteria document.

The subcommittee on Carbon Monoxide achieved consensus on each of the five major issues listed above, but such consensus was not always unanimous. Dr. Domingo Aviado has participated in both reviews of the criteria document and believes that major scientific problems remain to be resolved before it can be used as a scientific basis for proposing an ambient air quality standard for carbon monoxide. His report is appended to the report of the subcommittee.

Minority Report by Domingo M. Aviado

This member of CASAC would like to file an objection to the final subcommittee report because the Criteria Document on Carbon Monoxide has failed to place in proper perspective the observations on exercising subjects. Results from only a few subjects, suggesting that exposure to carboxyhemoglobin levels as low as 1.8 to 3.0% for less than one hour can influence the heart, cannot be used to determine the threshold for adverse effects. Animal studies of daily exposure to carbon monoxide for several hours or even up to 24 hours daily for weeks or months indicate that there are no adverse cardiovascular effects with 5.0% carboxyhemoglobin saturation.

Almost all of my written suggestions (7 pages and 13 pages) have been rejected by the staff responsible for the Criteria Document. I am not contesting this because our group is entirely advisory in nature. However, the Criteria Document of Staff Paper might include a quotation from the National Academy of Sciences Report on Carbon Monoxide on the significance of the exercise studies:

"If the results of the clinical studies are applicable to this large population at risk, then a major public health problem exists. Taking the current results at face value suggests only that, when patients with angina are exposed to low carbon monoxide concentrations for short periods, they cannot exercise as long on a bicycle or treadmill before developing chest pain as those breathing compressed air. There is no evidence from these results that the exposure to carbon monoxide increases the frequency and severity of chest pain or the development of other complications or that it shortens life expectancy among patients with angina pectoris or other clinical manifestations of heart disease. We can only infer the existence of such a relationship."

There are other portions of the National Academy of Science Report which would be helpful in the preparation of the Staff Paper, particularly the determination that 4.0 or 5.0% carboxyhemoglobin is the threshold for adverse effect on human health.

DMA, 8/6/79

SCIENCE ADVISORY BOARD
CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE

SUBCOMMITTEE ON CARBON MONOXIDE

CHAIRMAN

Mr. Harry H. Hovey, Jr., New York Department of Environmental Conservation, 50 Wolf Road, Albany, New York 12233

MEMBERS/CONSULTANTS

Dr. Domingo M. Aviado, Allied Chemical, P. O. Box 1021 R, Morristown, New Jersey 07960

Dr. Stephen M. Ayres, St. Louis University, School of Medicine, Department of Internal Medicine, 1325 S. Grand, St. Louis, MO 63104

Dr. Ronald F. Coburn, University of Pennsylvania, School of Medicine, Department of Physiology, 200 Richards Bldg, Philadelphia, PA 19104

Dr. Edward Ferrand, Assistant Commissioner for Science and Technology, New York City Department for Air Resources, 51 Astor Place, New York, New York 10003

SAB STAFF OFFICER

Mr. Terry F. Yosie, EPA Staff Officer, Science Advisory Board (A-101), 401 M Street S.W., Washington, D.C. 20460

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

August 22, 1980

OFFICE OF
THE ADMINISTRATOR

Honorable Douglas M. Costle
Administrator
Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460

Dear Mr. Costle:

The Clean Air Scientific Advisory Committee of the Science Advisory Board has reviewed External Review Draft No. 1, April, 1980 - Air Quality Criteria for Particulate Matter and Sulfur Oxides at its meeting August 20-22, 1980. The results of this review will be available in due course.

However, in our review of the technical area entitled in the document "acidic precipitation" it became evident that:

1. This is an area of extreme scientific complexity in establishing firm, quantitative relationships between emissions of relevant pollutants, formation of acidic dry and wet deposition products, and the effects on terrestrial and aquatic ecosystems.

2. U. S. research in this area has been scanty but is now burgeoning. New and relevant research results are emerging almost daily.

3. Documentation of the contemporary character of "wet" deposition is, as yet, incomplete. There are only about three years of reliable network data in the northeastern U.S., but this data base expands daily. The spatial coverage in the mid-west and western areas is gradually expanding.

4. Data available thus far show that influences on acidity include not only sulfur compounds but also nitrogen and chloride materials as well as the buffering role of substances such as ammonia, calcium, magnesium and potassium.

5. The ecosystem effects now seem to be related to very complicated interactions with soils and waters with a strong dependence on molecular forms, especially aluminum.

We could expand further on these complexities including, especially, the currently unquantified atmospheric transformation processes that change primary emissions to secondary products which are transferred in the atmosphere and subsequently deposited on land, water and vegetation. However, we believe the special character of acidic deposition has been described. It involves, as a minimum, the criteria pollutants of oxides of sulfur, oxides of nitrogen, hydrocarbons and the fine particle fraction of suspended particulates.

We suggest that, with the above complexities in mind, the Environmental Protection Agency prepare a separate document that can recognize and incorporate the new information on causes, effects and data bases for all of the various pollutants relevant to acidic deposition (e.g., land, air, water interactions).

We recognize the need to incorporate existing information, probably in somewhat abbreviated form, in the present TSP and Sulfur Oxides Criteria Document but we believe that EPA and public interests would be well served by the preparation of a document that would integrate the problem of dry and wet deposition of acidic products that could result in deleterious ecological effects.

We suggest this document address "Acidic Deposition" in a complete sense. As such, it would support and augment criteria documentation for formulation of sound standards.

Sincerely,

Sheldon K Friedlander

Sheldon K. Friedlander, Chairman
Clean Air Scientific Advisory Committee
Science Advisory Board

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

OCT 22 1980

THE ADMINISTRATOR

Mr. Sheldon K. Friedlander
Chairman, Clean Air Scientific Advisory Committee
Science Advisory Board
401 M Street, S. W.
A-101
Washington, D. C. 20460

Dear Mr. Friedlander:

In your letter of August 22, 1980 you suggested that EPA prepare a document that can recognize and incorporate the new information on causes, effects and data bases for all of the various pollutants relevant to acidic deposition. You rightfully point out that acidic precipitation is a complex phenomenum about which we learn more almost daily. Because of this I have asked my staff to pull together a comprehensive document which lays out the state of our knowledge with regard to precursor emissions, pollutant transformation to acidic compounds, pollutant transport, pollutant deposition and the effects (both measured and potential) of acidic deposition. I have asked my staff to outline at the appropriate level of detail the contents of such a document for the review of your committee.

Sincerely yours,

Douglas M. Costle

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

OFFICE OF
THE ADMINISTRATOR

Honorable Douglas M. Costle
Administrator
Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460

Dear Mr. Costle:

Throughout our review of the Draft SO2/PM Criteria Document one continuing frustration was the lack of peer review of this document. Previous documents had such review and were subsequently revised before submission to the Clean Air Scientific Advisory Committee. These reviews had been done through "Technical Experts Workshops" in the past. Such a workshop scheduled for Spring of 1979 was cancelled because of a suit by an industry group.

Because of the valuable contributions of such workshops we ask that they be reinstituted for all future criteria documents. Whether in an open forum or behind closed doors makes little difference to us, but such a workshop is needed.

Sincerely,

Sheldon K. Friedlander

Sheldon K. Friedlander, Chairman
Clean Air Scientific Advisory
Committee

7/15/80
cc
Dr. T.F Yosie

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

December 10, 1980

OFFICE OF
THE ADMINISTRATOR

SUBJECT: Scientific Review by the Clean Air Scientific Advisory Committee of the Air Quality Criteria for Hydrocarbons

FROM: Sheldon K. Friedlander, Chairman
Clean Air Scientific Advisory Committee
Science Advisory Board

TO: Douglas M. Costle
Administrator

On March 17, 1980, the Clean Air Scientific Advisory Committee reviewed a scientific document that addressed the major scientific issues associated with ambient level exposures of hydrocarbons. The document entitled, Facts and Issues Associated with the Need for a Hydrocarbon Criteria Document, was produced by the Office of Research and Development to fulfill section 109(d)(1) of the 1977 Clean Air Act requirement to update the air quality criteria for the national ambient air quality standard for hydrocarbons. The purpose of this memorandum is to summarize the major findings, recommendations, and comments provided by the Committee to assist you in reviewing the data necessary for reaching regulatory decisions on gas-phase hydrocarbons in the ambient air.

Major Issues Pertaining to the Hydrocarbon Document

Three major scientific issues regarding the hydrocarbon document were discussed and evaluated by the Committee. These included:

1. Do gas-phase hydrocarbons, as a class, contribute to the formation of ozone and other photochemical oxidants?

2. Can the attainment and maintenance of a uniform, nationwide ambient air concentration of volatile nonmethane hydrocarbons ensure the attainment and maintenance of the ambient ozone standard?

3. Do gas-phase hydrocarbons, as a class, cause adverse effects on public health or welfare at or near ambient air levels?

Issue #1 Gas-phase hydrocarbons and the formation of ozone and other photochemical oxidants

The Committee agreed that the scientific evidence supports the premise that gas-phase hydrocarbons, as a class, do contribute to the formation of ozone and other photochemical oxidants. The data indicate that all hydrocarbons participate in these chemical reactions but the reactivities of the various hydrocarbons differ with respect to the different oxidant products. As a result, a general relationship between oxidant formation and total hydrocarbon (or non-methane hydrocarbon) concentrations, valid across the nation, cannot be obtained.

The Committee requested incorporation of information in this and other documents (e.g. the sulfur oxides/particulate matter criteria document now in progress) on the role of hydrocarbons in ozone formation and their role as generators of chemical species that also affect other atmospheric processes, such that control strategies are formulated with the several impacts of hydrocarbons in mind. In particular, the action of various radicals on the oxidation of methane in the presence of nitrogen dioxide, and the process by which peroxide radicals act in the formation of acidic precipitation by oxidation of sulfur dioxide in cloud and rain water should be included in any evaluation of controls required for hydrocarbons.

Issue #2 Attainment and maintenance of an ambient air concentration of volatile non-methane hydrocarbons and its relationship to attainment and maintenance of an ambient ozone standard.

This issue is closely related to issue #1. Hydrocarbon emissions and ambient air levels are only two of many variables in the atmospheric processes that result in the formation of ozone and other photochemical oxidants. Other variables include the emissions of other reactive gas-phase organics, and meteorological and geographical factors such as temperature, humidity, wind speed, latitude and longitude, and topography. Because of the many variables and uncertainties discussed under issues #1 and #2, no fixed level of gas-phase nonmethane hydrocarbons can be used to ensure the attainment and maintenance of the ozone standard. However, based upon the evidence which the Committee reviewed in the document, the Committee concluded that the document adequately identifies, discusses, and evaluates studies in the current literature. The Committee identified some minor issues regarding presentation of the information, but these comments are included in the transcript.

Issue #3 Health and welfare effects of ambient level hydrocarbons.

There was general agreement among Committee members that hydrocarbons at ambient levels, with the exception of benzene and ethylene, do not cause adverse health and welfare effects, respectively. Benzene has been listed as a hazardous air pollutant under section 112 of the Clean Air Act and regulatory actions are proceeding. There are adverse effects upon vegetation from ethylene, but, even though ethylene is ubiquitous, these effects have not been measured in all parts of the country, partly because the more susceptible species (ornamentals) are not grown in all parts of the country; the issue should not be dismissed, however, on the basis that adverse vegetative effects from ethylene are not a national problem.

Summary

The Clean Air Scientific Advisory Committee agrees with the Agency's conclusion that, in the absence of a uniform quantitative relationship nationwide between hydrocarbon emissions and ambient air levels and resulting ozone-oxidant ambient air levels, there is no scientific basis for maintaining a national ambient air quality standard for hydrocarbons. The Committee also agrees with the Agency's conclusion that, because of the absence of ambient-level adverse health or welfare effects from hydrocarbons, no new basis exists for an ambient air quality standard for hydrocarbons. Public health and welfare will continue to be protected even in the absence of a national ambient air quality standard for hydrocarbons. Recision of a national ambient hydrocarbon standard should also beneficially act to streamline the regulatory process.

The Committee urges, however, that efforts continue to assess and where necessary to control harmful compounds. The control of emissions for hydrocarbons as a class remains essential as a convenient method of controlling ambient levels.

The Committee made additional comments of an editorial nature and requested further information on the results of source reconciliation studies showing contributions of various source categories to hydrocarbons in ambient air in one or more cities or airsheds. They also requested the inclusion of information on (1) the possible role of the oxidation of methane and carbon monoxide in the photochemical production of ozone; (2) the effect of radicals generated from hydrocarbons

on the conversion of sulfur dioxide to sulfate; and (3) the identification of specific gas-phase hydrocarbons known to be precursors to secondary organic aerosols. With the understanding that the requested changes are included in the revised document, the Committee is satisfied that the document meets the requirements of section 108 of the Clean Air Act as amended.

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

February 4, 1981

OFFICE OF
GENERAL COUNSEL

MEMORANDUM

SUBJECT: Review and Revision of National Ambient Air Quality Criteria and Standards; Draft Guidance Document

FROM: Matthew B. Van Hook, Attorney
Air, Noise & Radiation Division (A-133)

TO: Terry F. Yosie, Staff Officer
Clean Air Scientific Advisory Committee (CASAC)

Enclosed as you requested is a draft of the guide EPA has been preparing to statutory and judicial authorities bearing on EPA's periodic review and, as appropriate, revision of criteria and standards under Sections 108 and 109 of the Clean Air Act, 42 U.S.C. §§ 7408, 7409. The document is intended to provide a brief but useful source of reference on these matters, and is being prepared by the Office of General Counsel in conjunction with the Environmental Criteria and Assessment Office (ECAO) of the Office of Research and Development and the Office of Air Quality Planning and Standards (OAQPS) of the Office of Air, Noise and Radiation.

The document is being prepared because questions regarding legal aspects of the review and revision process have often arisen during the many public workshops, meetings and hearings that have occurred in connection with EPA's review of the current criteria and standards. Although the document is not ready for release in final form, the draft may provide useful information for members of CASAC and interested members of the public. EPA would appreciate any comments CASAC or the public may have on the draft. As indicated on the cover page, the paper is intended to be a convenient source for reference but is necessarily rather general. Accordingly, ECAO, OAQPS or the Office of General Counsel should be consulted if more detailed or definitive information is necessary.

DRAFT

ESTABLISHMENT AND REVISION OF NATIONAL AMBIENT AIR QUALITY STANDARDS:

An Overview of Statutory and Judicial Guidance

January 1981 Draft

United States Environmental Protection Agency

NOTE

This paper presents a brief review of statutory and judicial guidance concerning establishment and revision of national ambient air quality standards (NAAQS) by EPA under Sections 108 and 109 of the Clean Air Act, and of statutory authorities bearing on the role of the Clean Air Scientific Advisory Committee of EPA's Science Advisory Board in that process. The paper and its several appendices are intended as a convenient source for reference on these matters but are necessarily rather general. EPA's Office of General Counsel should be consulted if more detailed or definitive interpretations are necessary.

DRAFT

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B. "Research Authorization Act of 1978," Section 8 of the Environmental Research, Development and Demonstration Authorization Act of 1978, P.L. 95-155, Nov. 8, 1977 (Statutory basis for the Science Advisory Board, and authority for the Board's advice and comments to EPA on proposed criteria documents and standards).

C. Legislative History of the Clean Air Act Amendments of 1970 and the Research Authorization Act of 1978 (excerpts).

D. "Lead Decision," excerpts from a decision of the U.S. Court of Appeals for the District of Columbia Circuit in a case involving NAAQS for lead: Lead Industries Association et al v. EPA, ___ F.2d ___, ___ ERC ___ (D.C.Cir.1980), cert. denied ___ U.S. ___ (1980).

E. Charters of the Science Advisory Board and Clean Air Scientific Advisory Committee.

I. EPA's AUTHORITY TO ESTABLISH AND REVISE NAAQS

A. Air Quality Criteria

Criteria documents are the basis for the NAAQS, and are required to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare from pollutants in the ambient air." (Section 108(a)(2), Appendix A). Criteria documents are not intended to contain conclusions concerning which "identifiable" effects are "adverse." As discussed below, such judgments are made by the Administrator in establishing NAAQS, based on the criteria document. However, criteria documents should contain information helpful in assessing the relative significance ("kind and extent") of the various reported effects.

B. Primary NAAQS

Primary standards "shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health." (Section 109(b)(1), Appendix A). They are to be uniform, nationwide standards, applicable every place in the country, and are to be attained within three years from the date state implementation plans are approved. (Section 110(a)(2)(A), Appendix A).

Major elements of EPA's interpretation of its authority to establish and revise NAAQS were recently upheld by the U.S. Court of Appeals for the District of Columbia Circuit in a case involving NAAQS for lead. Lead Industries Association et. al. v. EPA, ___F.2d ___, ___ERC___(D.C.Cir. 1980), cert. den. ___ U.S.___ (1980) (hereafter "Lead Decision"). Several of these elements are discussed below:

i. Adverse Effects

The primary standards are not intended to protect against all identifiable effects, only those judged by the Administrator to be "adverse." However, because the primary NAAQS were intended by Congress to be precautionary and preventive, the Administrator is not free to define as adverse only those effects which are clearly harmful or for which there is a medical consensus about the degree of harm. Rather, the Administrator must evaluate reasonable medical concerns and theory in deciding which effects are significant enough to be considered adverse. (Lead Decision, Appendix D).

The health effects Congress was concerned about at the time the 1970 amendments were enacted ranged from cancer, metabolic and respiratory diseases, and impairment of mental

processes, to "headaches, dizziness, nausea . . . ." (Legislative History, Appendix C). To put the health effects intended to be protected against by the NAAQS in some perspective, Congress elsewhere directed that if a pollutant is found to result in an increase in "serious irreversible, or incapacitating reversible, illness," it would qualify for regulation as a hazardous pollutant under Section 112 (42 U.S.C. §7412).

ii. Sensitive Population Groups

Congress did not intend that only healthy persons be protected by the NAAQS. At the same time, the standards were not intended to protect those dependent on a controlled internal environment, such as persons in intensive care units. Instead, Congress emphasized that the standards shoud protect "particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment." (Legislative History, Appendix C). The standard is statutorily sufficient whenever there is "an absence of adverse effect on the health of a statistically related sample of persons in sensitive groups from exposure to the ambient air." (Id.). Congress defined a statistically related sample as "the number of persons necessary to test in order to detect a deviation in the health of any person within such sensitive group which is attributable to the condition of the ambient air." (Id.).

iii. Margin of Safety

Congress specified that the primary NAAQS include an "adequate margin of safety" to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement. (Lead Decision, Appendix D). The requirement for a margin of safety underscores that the primary NAAQS are not simply intended to protect against health effects that are known to be clearly harmful; Congress authorized the Administrator to exercise his judgment in setting NAAQS precisely to permit him to act in the face of uncertainty. (Id.).

iv. Economic Considerations / Feasibility

Primary NAAQS are to be based solely on the protection of human health; economic considerations play no part in the setting of these standards. (Lead Decision, Appendix D). The criteria on which the standards are based likewise do not address such factors as economic and technological feasibility. (Id.). In short, the Administrator is not required, and in fact is not even permitted, to consider economic or technological factors in setting NAAQS. (Id.). The regulatory analysis which accompanies NAAQS rulemaking packages is intended to comply with the directives of several executive orders, and serves to inform the States, the public, and

Congress of the expected impact of the NAAQS; however the Administrator may not consider or base his decisions regarding levels on the regulatory analysis.

C. Secondary NAAQS

Secondary standards "shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air." (Section 109(b)(2), Appendix A). Like the primary standards, the secondary NAAQS are to be nationally applicable, uniform standards. However, they are to be attained within a "reasonable time," in contrast to the specific three year timetable set forth for primary NAAQS. (Section 110(a)(2)(A), Appendix A).

The welfare effects to be protected against include but are not limited to effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility, climate, damage to and deterioration of property, hazards to transportation, as well as effects on economic values and on personal comfort and wellbeing. (Section 302(h), Appendix A). The reference to economic values does not include the costs of compliance with NAAQS; it refers only to the economic costs of pollution. (Lead Decision, Appendix D). Thus, like the primary NAAQS, secondary standards are to be based on the effects information detailed in the criteria document, with the Administrator making a judgment concerning what level of effect is to be considered adverse.

II. CASAC'S AUTHORITY TO PROVIDE ADVICE ON DRAFT CRITERIA DOCUMENTS AND PROPOSED NAAQS

The Clean Air Scientific Advisory Committee (CASAC) has two sources of authority: (1) Section 109(d)(2) of the Clean Air Act, and (2) the Research Authorization Act of 1978 (pertinent parts of both statutes are reproduced in Appendices A and B). Reflecting its dual authorities, CASAC is a constituent committee of EPA's Science Advisory Board (SAB) (the charters of both CASAC and the SAB are included in Appendix E).

A. Existing Criteria Documents and NAAQS

CASAC's authority under the Clean Air Act concerns review of existing criteria documents and NAAQS, and the giving of advice to the Administrator on a broad range of matters including research needs and the health, economic and energy effects of various strategies for attaining the NAAQS. (Section 109(d)(2), Appendix A). Accordingly, under Section 109(d)(2)(B) of the Act CASAC is to review existing criteria documents and NAAQS

and recommend appropriate changes to the Administrator one year before the agency completes its own periodic review under Section 109(d)(1). (Appendix B).

B. Proposed Criteria Documents and NAAQS

As the committee of the Science Advisory Board charged with responsibility for matters concerning NAAQS, CASAC exercises the Board's authority under the Research Authorization Act of 1978 to review proposed criteria documents and NAAQS. (Appendix B).

Section 8(e) of that Act provides that any time a proposed criteria document or standard is provided to any other Federal agency for formal review or comment, such document or standard is to be made available to the Board. Thereafter, the Board (CASAC) "may make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis" of the proposed criteria document or NAAQS.

cc: Dr. Hernandez

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

19 JUN 1981

OFFICE OF
THE ADMINISTRATOR

SUBJECT: CASAC Review of the Air Quality Criteria Document for Nitrogen Oxides

FROM: Sheldon K. Friedlander, Chairman
Clean Air Scientific Advisory Committee

TO: The Administrator

Introduction

On November 13, 1980, the Clean Air Scientific Advisory Committee of the Science Advisory Board completed its review of the revised air quality criteria document for the oxides of nitrogen. This was the second review of the criteria document by the Committee. The first review, held January 29-30, 1979, resulted in major CASAC recommendations for revisions in the criteria document. In its most recent meeting the Committee concluded that its recommendations had received a fair and thorough evaluation by the Agency, evidenced in the changes incorporated into the criteria document. The purpose of this memorandum is to summarize for you the Committee's major conclusions to assist you in reviewing the scientific data necessary for proposing an ambient air quality standard for nitrogen dioxide as required by law. This memorandum further advises you of the Committee's conclusion that the criteria document fulfills the criteria set forth in section 108 of the Clean Air Act as amended, which requires that such a document accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare from pollutants in the ambient air.

A separate memorandum which will address the review of the Staff Paper for nitrogen oxides will be sent to you following completion of the Committee's review of that document.

Major Issues Pertaining to the NOx Criteria Document

Air Quality

Nitrogen Cycle--There is much duplication of information concerning the nitrogen cycle throughout the document which could be presented more succinctly in Chapter 4. Nevertheless, Chapter 4 itself is well written.

Sources and Emissions--As requested by CASAC, the revised document contains more information on NO/NO_2 ratios and this is adequately presented.

Environmental Transport & Transformation--The criteria document adequately addresses current knowledge in this area. Very importantly, it discusses the need for additional information on NOx--organics chemistry and the dearth of quantitative knowledge of wet and dry removal processes and rates for NOx.

Sampling and Analysis for Ambient NO_2 and NOx--Derived Pollutants--This section of the criteria document describes the methods, procedures, and problems in the determination of the ambient levels of NOx in a useful and complete fashion. Of particular importance is the identification of uncertainties in the earlier measurements of NO_2 (Jacobs-Hochheiser method), and for nitrate (artifact formation). Characterization of such uncertainties should ensure against the use of suspect data in setting the standard.

Welfare Effects

Perturbations of the Stratospheric Ozone Layer--The relevant studies are included in this section of the document. It brings out the important point that NO and NO_2 released from surface sources are not expected to significantly effect stratospheric ozone.

Effects of Nitrogen Oxides on Visibility--The chapter presents a good review of the scientific issues related to visibility. The role of NO_2 in atmospheric discoloration is well described. The chapter also adequately points out the multi-pollutant aspects of the regional haze problem.

Acidic Precipitation--Chapter 11 is to be retitled "Acidic Deposition" to better define its contents and to ensure that the role of dry deposition is recognized. The information presented in the criteria document is a useful tutorial for understanding acidic deposition. As requested by CASAC the very importance of multi-pollutant aspects of this environmental problem are being addressed by a separate document that is now in preparation; thus, for the purpose of this criteria document this chapter is adequate in ensuring that the role that nitrogen compounds play in acidic deposition reactions is recognized.

Effects on Natural Ecosystems, Vegetation, and Microorganisms--The criteria document provides a good review of background information concerning potential effects on ecosystems as well as the relations of the nitrogen cycle. Regarding potentially harmful effects of NOx, the document correctly emphasizes NO_2 since this is the most harmful oxide for the effects of concern. Both visible effects and effects not readily perceptible are discussed thoroughly.

Threshold doses are given for the inhibition of photosynthesis under laboratory conditions. However, it would be desirable if sensitivity under these predisposing conditions could be compared with sensitivity under field conditions. The plant varieties used for these studies are relatively sensitive, but how does this compare with more important and widely planted species? Taylor, et. al. reported mostly no effects occurred on several field crops exposed to 10 ppm for 90 minutes.

From the document, we can conclude that sensitive plant species may be injured by one-half hour to eight-hour exposure to concentrations of 10 to 2 ppm, respectively. If exposed for several days, concentrations as low as 0.15 ppm may have some effect, but a safe limit seems to be in the neighborhood of 0.5 to 1 ppm NO_2. It would be helpful if these values were compared with ambient baseline concentrations as reviewed in Chapter 8.

Toxicity of NO_2 seems to be enhanced when SO_2 also is present. However, much of the laboratory research is inconsistent and cannot provide a sound basis for criteria. The relations are especially indefinite in the field. This issue is discussed well in the document.

Finally, the Committee would prefer to see the bibliography of this and other chapters arranged alphabetically.

Health Effects

Effects of Nitrogen Compounds on Animals-There are some problems with the overall format. There is both detailed description of individual papers and an unreferenced interpretive discussion of the patterns of cellular and tissue response to oxides of nitrogen. What appears to be missing is interpretation of individual papers and groups of papers. There is little attempt to reconcile, or even point out, seemingly contradictory findings. Nor does the review come to grips with the implications of the findings. One also expects a critique of those findings reported to occur at relatively low levels of nitrogen dioxide. Also of value would be some discussion of species difference in findings, particularly as this would pertain to generalization in humans. With the understanding that these issues will be resolved in this chapter in the revision of this draft document, the Committee will advise that the chapter is scientifically acceptable.

Effects on Humans of Exposure to Oxides of Nitrogen--The discussion primarily focused on the revisions made to the document since the last CASAC meeting, and whether those revisions adequately dealt with previous comments from CASAC and the public. In reviewing Chapter 15, the Committee specifically addressed the question of whether the chapter adequately identified, discussed, and evaluated the critical health studies for the oxides of nitrogen.

In general, it was concluded that the current revision of the criteria document presented a balanced and comprehensive critical review of the pertinent literature on human health effects of the oxides of nitrogen. It was agreed that new literature is continually being added to the subject, but that an arbitrary limit had to be set for the current document and that no studies unpublished at the time of the meeting should be included.

The emphasis placed upon specific studies was appropriately altered from the previous draft criteria document following comments by CASAC. Specifically, it was concluded that the current document adequately de-emphasized the significance of the Chattanooga studies of Shy, et al. The Committee also believed that the study by Orehek had been appropriately considered as relevant to safety factor considerations, and that it should not be used for identifying a specific level for setting a standard.

CASAC also concluded that the discussion of gas stove studies was scientifically acceptable. The Committee believed that there might be a more concise summary of the indoor NO exposurers relevant to the gas stove studies, but this represents only a minor refinement in the chapter.

The criteria document appropriately separated effects on sensory organs, pulmonary function and respiratory systems or infection. When possible, most of these effects were considered separately in healthy and sensitive populations. The limitations of the different types of studies (human exposure, epidemiologic) were also considered.

The studies relevant to the critical issue of level of lowest observed effect were discussed in the document in a balanced manner. It was recognized by CASAC that no body of data is perfect and, subject to the recommendations suggested in the paragraphs above, the criteria document had critically and satisfactorily reviewed the existing data on human health effects of the oxides of nitrogen.

Summation

The Committee made additional comments of an editorial nature. These remarks, as well as a more detailed discussion of the recommendations and review provided above, are included in the transcript. With the understanding that the advised changes are incorporated in the revised criteria document, the Committee is satisfied that the air quality criteria document for the oxides of nitrogen is scientifically adequate for use in standard setting.

Clean Air Scientific Advisory Committee
Science Advisory Board

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF THE
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July 9, 1981

Dr. Lester Grant, Director
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Research Triangle Park, NC 27711

Dear Dr. Grant:

The Clean Air Scientific Advisory Committee has completed its second review of EPA's combined air quality criteria document for sulfur oxides and particulate matter. The Committee notes with satisfaction the significant improvements in the document in air quality, health effects, and welfare effects data made since the Committee's review of the first external review draft in August, 1980.

The Committee has concluded that, with incorporation of changes as suggested in the transcript, Volumes II through V are scientifically adequate for use in standard setting. Another version of Volume I, reflecting these and previous revisions of Volumes II through V needs to be prepared. The Committee requests that copies of these latter volumes as further revised be sent to the members for their reference in reviewing the revised Volume I. When the revised Volume I is considered acceptable, an official closure memorandum will be prepared reflecting CASAC's action on the entire criteria document.

Sincerely,

Sheldon K. Friedlander

Sheldon K. Friedlander, Chairman
Clean Air Scientific Advisory
Committee

Clean Air Scientific Advisory Committee, Subcommittee on Health Effects of SOx/PM

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