Review of the Process for Setting National Ambient Air Quality Standards

Prepared by the NAAQS Process Review Workgroup

for the Assistant Administrators of the
Offices of Air and Radiation and Research and Development
U.S. Environmental Protection Agency

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This report was prepared by the NAAQS Process Review Workgroup, which was formed at the request of Deputy Administrator Marcus Peacock, U.S. Environmental Protection Agency (EPA), for the purpose of providing recommendations on the process used by the Agency for setting National Ambient Air Quality Standards (NAAQS). Workgroup efforts have been led by Lydia Wegman, Office of Air Quality Planning and Standards (OAQPS) in EPA's Office of Air and Radiation (OAR), and Kevin Teichman, Office of Science Policy (OSP) in EPA's Office of Research and Development (ORD). Workgroup members include John Bachmann, Karen Martin, and Harvey Richmond in OAQPS/OAR; Jason Burnett and Carl Mazza in OAR; John Vandenberg in the National Center for Environmental Assessment (NCEA)/ORD; Bob Fegley in OSP/ORD; Gerry Gleason, John Hannon, and Steve Silverman in EPA's Office of General Counsel (OGC); and Al McGartland in EPA's Office of Policy, Economics, and Innovation (OPEI). The workgroup's recommendations presented in this report were prepared for Bill Wehrum, Acting Assistant Administrator for OAR, and George Gray, Assistant Administrator for ORD, to help inform their recommendations to the Deputy Administrator.

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EXECUTIVE SUMMARY

In response to a request from the Deputy Administrator of the Environmental Protection Agency (EPA), the Assistant Administrators for the Offices of Air and Radiation and Research and Development formed this intra-agency workgroup to conduct a "top-to-bottom" review of the process used by the Agency to periodically review and, as appropriate, revise the air quality criteria and national ambient air quality standards (NAAQS) as required by the Clean Air Act (CAA). This NAAQS review process has evolved since it was instituted in 1970, with many of the current features having been in place for over 20 years. The present review is aimed at examining whether and, if so, how the process can be further strengthened, and at identifying ways of streamlining the process so that EPA can achieve more timely NAAQS reviews. We have concluded that the process can be strengthened and have identified specific recommendations as summarized below.

Past reviews of the process have addressed a number of issues, including the difficulty EPA has had historically in completing NAAQS reviews at 5-year intervals as required by the CAA, resulting in litigation-driven review schedules; the statutory role of the Clean Air Scientific Advisory Committee (CASAC) in providing scientific and policy-relevant advice to the Administrator; concerns about the "encyclopedic" nature of EPA's science assessment documents (referred to as “Criteria Documents”) and support for a more integrative synthesis of the science; and general support for the introduction and subsequent evolution of a policy-oriented “Staff Paper” to help bridge the gap between the science presented in the Criteria Document and the policy judgments required of the Administrator in reaching decisions on the NAAQS. While many improvements have come about as a result of these past reviews, some of the same issues remain relevant today, and are addressed again in this process review.

Consistent with meeting the April 3, 2006 deadline for this report, we focused on the following key issues identified as being of most interest to the Deputy Administrator: timeliness of the NAAQS review process; consideration of the most recent available science; distinctions between science and policy judgments; and addressing uncertainties in scientific information. To help inform our review, we solicited input from a number of outside parties who have been actively engaged in the process over time, including all current and former CASAC members, who were asked to provide their individual views. While the time frame for this report precluded broad solicitation of public comments, we did engage in a limited set of consultations with representatives of various stakeholder groups, including representatives of industry groups, environmental and public health groups, States, and the chairs of National Academy of Sciences (NAS) committees that have addressed NAAQS-related issues.

For purposes of this review, we have focused on the basic functional elements of the NAAQS process and on the nature of and linkages between the contents of documents that are currently prepared as part of the NAAQS review. These key functional elements include planning, science assessment, risk/exposure assessment, policy assessment, and rulemaking. Overlaid on these functional elements throughout the process are the involvement of CASAC in

providing review and advice on the air quality criteria and the standards and numerous opportunities for public participation.

In considering the questions that framed this process review, and taking into account the views expressed by individual CASAC members and other outside parties, the workgroup identified a number of options for changing the NAAQS review process. Options were identified for each of the key functional elements and also addressed CASAC involvement and public participation in the process. On the basis of our examination of the NAAQS review process, and considering the resulting options for change, we have reached several key conclusions, as summarized below:

- Past NAAQS reviews demonstrate that, in the absence of unusual developments, it is possible to complete the current process for reviewing a NAAQS within the statutory 5-year review cycle. However, the likelihood that the process *will* be completed in that time frame, in the absence of court-imposed schedules, can be increased by making changes that generally create a more policy-relevant focus and a more internally coordinated, consultative approach to each of the process elements.

- NAAQS decisions could be based on more recent science than has historically been available for consideration by adopting changes that provide a continual compilation/evaluation of science, enhance linkages between science and risk/exposure assessments, facilitate reaching proposed policy decisions as quickly as possible after the completion of those assessments, and expedite provisional assessment of "new" science, when appropriate, during the rulemaking process.

- Distinctions between science and policy judgments made by EPA and by CASAC throughout the NAAQS review process can be clarified and made more transparent, in part, by adopting changes that facilitate the preparation and review of a policy assessment document that is based on, but separate from, the science and risk/exposure assessments.

- Changes that enhance the linkages between the preparation of the science assessment and risk/exposure assessment, which in turn would enhance the linkages between CASAC reviews of these two documents, can also help to ensure that more complete, policy-relevant characterizations of uncertainties are incorporated into these assessments.

To effect these improvements, we recommend implementing changes to the NAAQS process, as summarized below. The extent to which the projected improvements are likely to be realized depends not only on which changes and related options are adopted, but also on the extent to which adequate resources and continued management support are provided for the effective and ongoing implementation of any such changes.

- Combine the current separate planning activities into the preparation of one integrated planning document that focuses the science, risk/exposure, and policy assessments on a set of policy-relevant issues. This plan should maximize the amount of time allotted to the science and risk/exposure assessments; more closely link these assessments through a more coordinated, consultative process; minimize the time between the completion of these assessments and reaching proposed decisions on the NAAQS; and allow for provisional assessment of "new" science, as appropriate, during the rulemaking process.

- Restructure the science assessment document to be a more concise evaluation, integration, and synthesis of the most policy-relevant science (with comprehensive annexes with generally descriptive information), and to include key science judgments that are integral to the risk/exposure assessments. This document should present the synthesis of policy-relevant science not only for a scientific audience, but also in language that will be understood and meaningful to policy makers, perhaps in the form of a "plain-English" executive summary.

- Develop and implement a continuous process to identify, compile, characterize, and prioritize new scientific studies with the assistance of state-of-the-art electronic databases developed by the Office of Research and Development. Recognizing that the development of such a system is complex and potentially resource-intensive, we believe that additional time is needed to explore various approaches, options, and resource requirements for its development.

- Develop a more concise risk/exposure assessment document focused on key results, observations, and uncertainties (similar to the risk/exposure chapter(s) that are now included in Staff Papers), with comprehensive annexes that include all relevant information, assumptions, results, and assessments of variability and uncertainty (similar to the information now included in contractor reports).

- To the extent that the changes recommended above are adopted and effectively implemented, replace the Staff Paper with a more narrowly focused policy assessment document, based on the science and risk/exposure assessments and including policy-relevant air quality analyses. This document could focus on identifying approaches for reaching policy judgments; considering the adequacy of the current standards and whether alternative standards should be assessed for consideration; and identifying a range of options for alternative standards (in terms of indicators, averaging times, forms, and ranges of levels) that might be considered by the Administrator in making policy choices. We recognize that important and complex issues are involved in deciding the scope of such a document; whether such a document would continue to reflect staff views, EPA senior management views, or both; and how that choice may affect the process by which such a document would be reviewed by CASAC and the public.

- Work with the Science Advisory Board (SAB) Staff Office to consider the formation of a CASAC subcommittees on risk/exposure assessment, when appropriate; to examine additional measures that can be taken to orient new CASAC panel members; and to give further consideration to the issue of CASAC "closure" in its review of key documents.

We also offer additional recommendations for continuing this examination of the NAAQS process beyond April 3, 2006, as summarized below:

- Continue a dialogue with the public in the coming months on the issues addressed in this review of the NAAQS process.

- Continue to examine more specific options for implementing those changes that are adopted, or that remain under consideration, as well as their organizational, staffing, and resources implications.

- More broadly, consider the organizational and resource implications for EPA of coordinating and conducting reviews of all NAAQS on 5-year cycles, and work with the SAB Staff Office to consider the implications of constituting CASAC Panels and managing the CASAC review process for all such NAAQS reviews.

1. INTRODUCTION

On December 15, 2005, the Deputy Administrator of the Environmental Protection Agency (EPA) asked the Assistant Administrators for the Offices of Air and Radiation (OAR) and Research and Development (ORD) to conduct a "top-to-bottom" review of the process used to periodically review and, as appropriate, revise the air quality criteria and national ambient air quality standards (NAAQS), as required by sections 108 and 109 of the Clean Air Act (Attachment 1). The principal purpose of this review was to ensure that the best available science guides and informs decision making within EPA. Although previous reviews of the NAAQS process have led to significant changes and improvements, many of its current features have been generally followed for over 20 years. The present review is aimed at examining whether and, if so, how the process can be further strengthened, and at identifying ways of streamlining the process so that EPA can achieve more timely NAAQS reviews.

1.1 Scope and Approach

To carry out this review, an intra-agency workgroup was formed and charged with preparing a report on the NAAQS process to include specific recommendations for possible changes to that process. Our workgroup recommendations are intended to help inform the recommendations to be made by the Assistant Administrators for OAR and ORD to the Deputy Administrator, as requested, by April 3, 2006. In defining the scope for this review, consistent with meeting this deadline, we prepared a set of key questions to focus the review on those issues identified by the Deputy Administrator as being of particular interest (Attachment 2).

To help inform our workgroup's examination of the current NAAQS process, we have solicited input from a number of outside parties who have been actively engaged in the process over time. In recognition of the statutory role that the Clean Air Scientific Advisory Committee (CASAC) plays in the NAAQS review process, and the unique perspective that members of CASAC have on the process, we invited all current and former CASAC members to provide their individual views on the current process. Using the set of key questions to help focus their responses, we asked them to identify what is currently working well and what recommendations they might have to improve the process for achieving a comprehensive and timely review of the NAAQS. While the time frame initially allotted for this review precluded the solicitation of broad public comments at this time, we engaged in a limited set of consultations with representatives of various stakeholder groups that have been actively involved in NAAQS reviews. We invited representatives of industry groups, environmental and public health groups, States, and the chairs of National Academy of Sciences (NAS) committees that have addressed NAAQS-related issues to participate in teleconference meetings with us that focused on the set of key questions and to provide written comments.

While our workgroup defined the scope and approach used to conduct this review so as to meet the immediate goals and deadline set by the Deputy Administrator, we also recognized that efforts to review the NAAQS process beyond that date could well be worthwhile. This report presents a set of general conclusions and recommendations for possible changes to the NAAQS

process, but additional time would be needed to more fully explore the implications of various options that have been identified. In addition, we recognize the potential value in extending the scope of this effort beyond looking at the process for conducting the review of the NAAQS for any individual pollutant to more broadly considering the implications of a process that would ensure meeting the statutory 5-year review cycle for all of the NAAQS pollutants. Further, we note that continuing this effort beyond April 3, 2006 would allow time for broader input from interested parties and for examining processes used by other organizations to conduct complex science-based assessments.

1.2 Statutory requirements for NAAQS reviews

The Clean Air Act (CAA) calls for EPA to issue and periodically review air quality criteria (AQC) and NAAQS for the "criteria" pollutants that now include particulate matter (PM), ozone (O_3), carbon monoxide (CO), sulfur dioxide (SO_2), nitrogen dioxide (NO_2), and lead (Pb). Section 108 of the CAA requires that EPA issue AQC for each criteria pollutant and that the AQC "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 AQC are to include information on:

- "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;"
- "the types of air pollutant which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare;" and
- "any known or anticipated adverse effects on welfare."

Section 109 of the CAA requires that EPA issue primary and secondary NAAQS for each criteria pollutant, as appropriate. Primary (health-based) NAAQS are to be ambient air quality standards which in the judgment of the Administrator, based on the AQC and allowing an adequate margin of safety, are requisite to protect public health. The courts have ruled that such primary standards are not intended to be "risk free," nor are they to be based on the cost associated with their implementation. The standards must be requisite to protect public health, allowing for an adequate margin of safety. They must be sufficient but not more than necessary to meet this criterion, requiring the Administrator to make judgments of degree. Making this determination requires public health policy judgments as to what level of air quality is required to protect sensitive groups within the population, although not the most sensitive individual within that group, from adverse health effects. The approach to providing an adequate margin of safety is a public health policy choice left to the Administrator's judgment. Secondary (welfare-based) NAAQS are to specify a level of air quality which in the judgment of the Administrator, based on the AQC, is requisite to protect the public welfare from any known or anticipated adverse effects. Welfare effects as defined by the CAA include effects on vegetation, crops, soils, water, wildlife, man-made materials, and visibility, among others.

Section 109 of the CAA also requires EPA to review the AQC and NAAQS at 5-year intervals, and to make such revisions in the AQC and NAAQS and promulgate such new

NAAQS as may be appropriate. Section 109 further requires that EPA appoint an independent scientific review committee to be composed of seven members that include at least one member of the NAS, one physician, and one person representing State air pollution control agencies. This committee, the Clean Air Scientific Advisory Committee (CASAC), is required to complete a review of the AQC and NAAQS at 5-year intervals and to recommend to the Administrator any new NAAQS and revisions of existing AQC and NAAQS as may be appropriate. Section 307 of the CAA requires that EPA explain in the rulemaking the reasons for any differences between proposed or final NAAQS and CASAC recommendations.

Another statute, the Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA), which established EPA's Science Advisory Board (SAB), applies to the review of the NAAQS under the CAA as well as more broadly to standards set under several other EPA statutes. Under ERDDAA, the Administrator is to make available to the SAB any proposed criteria document or standard at the time it is provided to any other Federal agency for formal review and comment. Further, the SAB 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 for any proposed criteria document or standard. The EPA has historically relied upon the review process conducted by CASAC, which is administered by EPA's SAB Staff Office, to address these ERDDAA provisions.

1.3 Historical perspective and previous NAAQS process reviews

A general overview of the history of setting and reviewing NAAQS is shown in Figure 1. The initial NAAQS were set in 1971, as required by CAA amendments in 1970, for O_3, PM, SO_2, NO_2, CO, and hydrocarbons (HC), based on air quality criteria completed in 1969. The original requirement for periodic reviews of the air quality criteria and NAAQS was modified to specify 5-year intervals by the CAA amendments of 1977. In 1976, EPA laid out a schedule to review all of the NAAQS, with review of O_3 first (1976-79), followed by NO_2, HC. and CO (1977-1985). The PM and SO_2 reviews, initiated in 1979, were linked through an integrated review of the PM/SO_2 air quality criteria, although decisions on the PM and SO_2 standards were made separately. New PM standards were promulgated in 1987, even as review of the primary SO_2 standards continued. An initial review of Pb was started in 1975, and lead standards were first set in 1978.

In the 1980s, EPA initiated new reviews of the O_3, NO_2, CO, and Pb standards within about 1 to 2 years of the previous decisions. Ozone and Pb reviews began in the early 1980's. The O_3 review concluded in 1993 (under court order) with a decision not to revise the NAAQS, but to accelerate the next review as much as possible to consider new scientific studies that had become available since completion of the revised air quality criteria for O_3. The Pb review ended in 1991 without a published rulemaking decision, but with the Agency's announcement and implementation of an integrated lead strategy that focused on other sources of lead exposures, reflecting the dramatic decrease in airborne lead resulting from the phaseout of leaded gasoline. The CO and NO_2 reviews began in the late 1980s and were completed in the mid-1990s with decisions to reaffirm the standards.

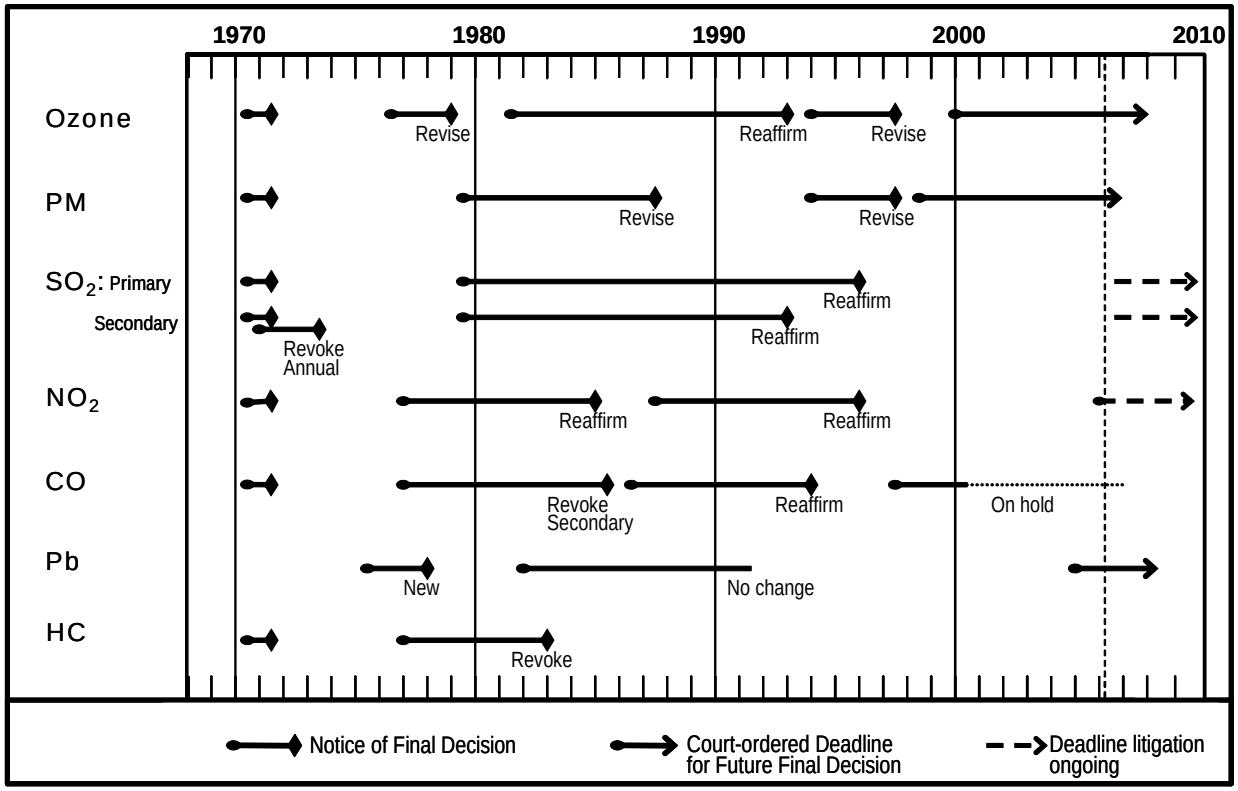

Figure 1. History of NAAQS Reviews: 1970 – Present

EPA initiated new reviews of the standards for O_3, PM, and CO in the 1990s, and the ongoing reviews of the SO_2 primary and secondary standards were completed in the mid-1990s (although the Agency is continuing to consider the primary SO_2 standard in response to a remand of that decision). The new O_3 and PM reviews began in 1993 and the review schedules were linked in the expectation that if the standards for both pollutants were revised, promulgating those revisions at the same time could facilitate the development of integrated implementation strategies. New O_3 and PM standards were promulgated on the same day in 1997 (pursuant to a court-ordered schedule). The CO review was put on hold in 2000 while a Congressionally mandated NAS study of CO-related issues was conducted, and that review has not yet been completed.

Following the 1997 O_3 and PM decisions, EPA initiated a new PM review within months, and started a new O_3 review in 2000. These staggered PM and O_3 schedules were established so that the ozone review could benefit from the review of new epidemiologic studies that addressed both PM and O_3 in the context of the PM criteria review, and also reflected EPA resource limitations that precluded starting both reviews at the same time. Both reviews have been substantially extended due in part to protracted litigation involving the 1997 decisions (final resolution of which did not occur until 2002 when the U.S. Court of Appeals for the D.C. Circuit, on remand from the Supreme Court, upheld both standards), and in part to the need to account for new findings regarding statistical methodology, which required reanalysis of a

number of epidemiological studies in 2002. In addition, there has been an unprecedented volume of new scientific studies on PM due in large part to the substantial increase in PM research funding mandated by Congress during this time. The schedules for the PM and O_3 reviews are now governed by a court order, calling for completion of the PM review by September 2006 and of the O_3 review by the end of 2007. A new Pb review was initiated in 2004 in response to litigation, and a court order calls for completion of that review in 2008. The schedules for the NO_2 and SO_2 reviews are now the subject of litigation.

Over the last 25 years, many reviews of the NAAQS process have been undertaken both by EPA and CASAC, leading to a number of changes and significant improvements. A former CASAC chair published an article in 1987 that presented an overview of reviews done to that date, discussed how the NAAQS process had evolved in part in response to those reviews, and offered additional recommendations for further changes to improve the process.[1] These past reviews of the process have addressed a number of issues, including the difficulty EPA has had historically in completing NAAQS reviews at 5-year intervals, resulting in litigation-driven review schedules; clarification of the role of CASAC in reviewing the AQC and the NAAQS and in providing scientific and policy-relevant advice to the Administrator; concerns about the "encyclopedic" nature of EPA's science assessment document (referred to as “Criteria Documents”) and support for a more integrative synthesis of the science; and general support for the introduction in the early 1980s and subsequent evolution of a policy-oriented “Staff Paper” to help bridge the gap between the science presented in the Criteria Document and the policy judgments required of the Administrator in reaching decisions on the NAAQS. While many improvements have come about as a result of these past reviews, some of the same issues remain relevant today, and are addressed again in this process review.

[1]Lippmann, Morton (1987) *Role of Science Advisory Groups in Establishing Standards for Ambient Air Pollutants*. Atmospheric Science and Technology 6:93-114.

2. CURRENT NAAQS PROCESS

The current process for periodic review of the AQC and NAAQS, as it has evolved over the years, is typically described by reference to a series of sequential activities that starts with the publication of scientific studies in peer reviewed journals and ends with final EPA decisions on the standards. A frequently used flow chart (Figure 2) highlights key steps and products in the process, including the preparation and review of two documents: (1) an ORD Criteria Document, a comprehensive characterization and integrative assessment of relevant scientific studies; and (2) an OAQPS Staff Paper, which identifies the most policy-relevant science drawn from the Criteria Document, presents results from quantitative risk and/or exposure assessments, describes how the science and risk/exposure assessment results can be considered as a basis for making decisions on whether to retain or revise the standards, and includes staff conclusions and recommendations regarding the key components of an air quality standard – indicator, averaging time, statistical form, and level. Since 1980, these recommendations have been in the form of ranges of alternative standard options for the Administrator's consideration. Early steps in the preparation of the Criteria Document broadly involve the scientific community, including workshops with scientific experts that are open to the public, and reviews by CASAC and the public are part of the development of the Criteria Document, Staff Paper, and related risk and/or exposure assessment reports. In conducting these reviews, the seven-member CASAC is supplemented with additional subject-matter experts, as appropriate, forming a CASAC Review Panel, to address the range of scientific information and issues that are expected to be important in any given review. The Agency then initiates notice-and-comment rulemaking, based on the information in the Criteria Document, Staff Paper, and quantitative risk and/or exposure assessments, after an interagency review process. The rulemaking includes both a public comment period and public hearings. EPA takes the comments received through this process into consideration in reaching final decisions on the NAAQS.

In the current process, the information presented in the Criteria Document, as well as the related risk and/or exposure assessments and some of the information included in the Staff Paper address the statutory provisions requiring EPA review and, as appropriate, revision of AQC. The statutory provisions requiring CASAC review and recommendations to the Administrator concerning appropriate revisions of existing AQC and NAAQS are addressed through CASAC's reviews of drafts of the Criteria Document and Staff Paper. The final documents, taken together, present an updated assessment of the science as well as a policy assessment leading to staff and CASAC recommendations on alternative standards for consideration by the Administrator.

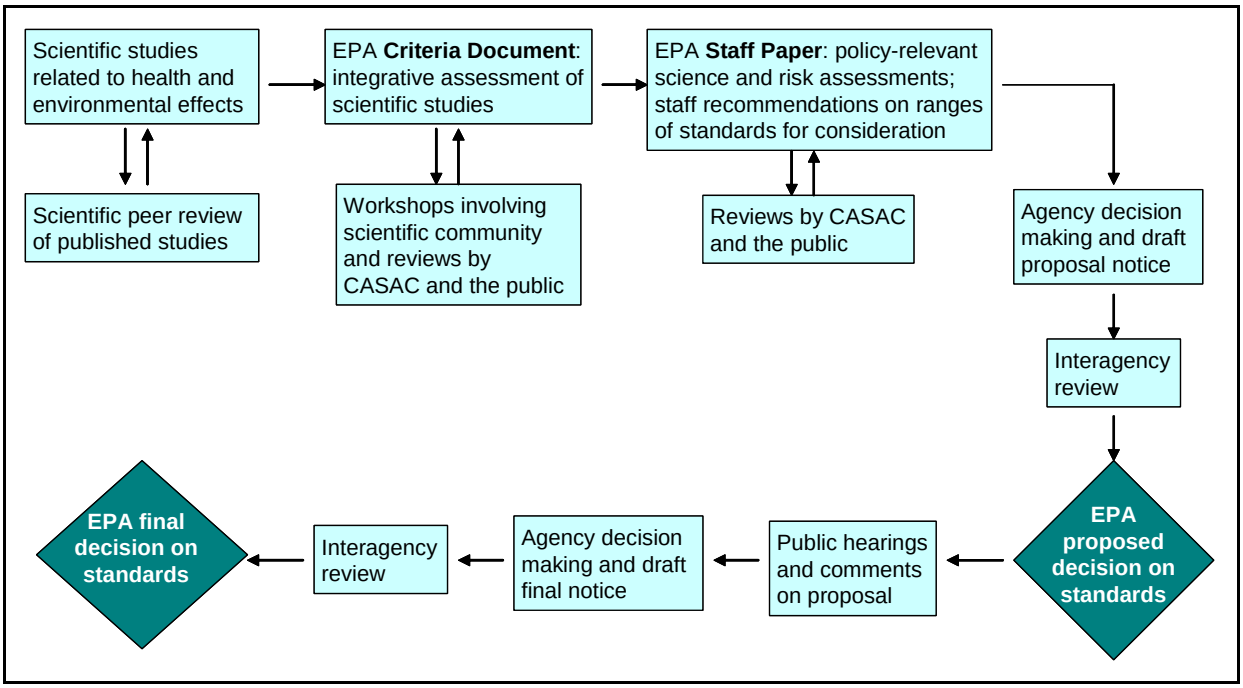

Figure 2. Current NAAQS Review Process

2.1 Key Elements of the NAAQS Process

For proposes of this review, we have prepared a somewhat different chart that focuses on the basic functional elements of the NAAQS process and on the nature of and linkages between the contents of documents that are currently prepared as part of the NAAQS review (Figure 3). The time frames typically allotted to each of these elements within a generic 5-year review cycle, and the extent to which work on these documents is done concurrently or sequentially, can vary substantially from one review to another. Differing time frames for these elements and documents come about, for example, as a result of differences in the volume and nature of the new science available in any given review, differences in the nature and complexity of the issues that must be addressed, and differences in the scope and nature of any risk and/or exposure assessments conducted, as well as from constraints arising from litigation and agency staffing and budget limitations.

As discussed below, the key functional elements are identified as planning, science assessment, risk/exposure assessment, policy assessment, and rulemaking. Overlaid on these functional elements throughout the process are the involvement of CASAC in providing review and advice on the AQC and standards and numerous opportunities for public participation.

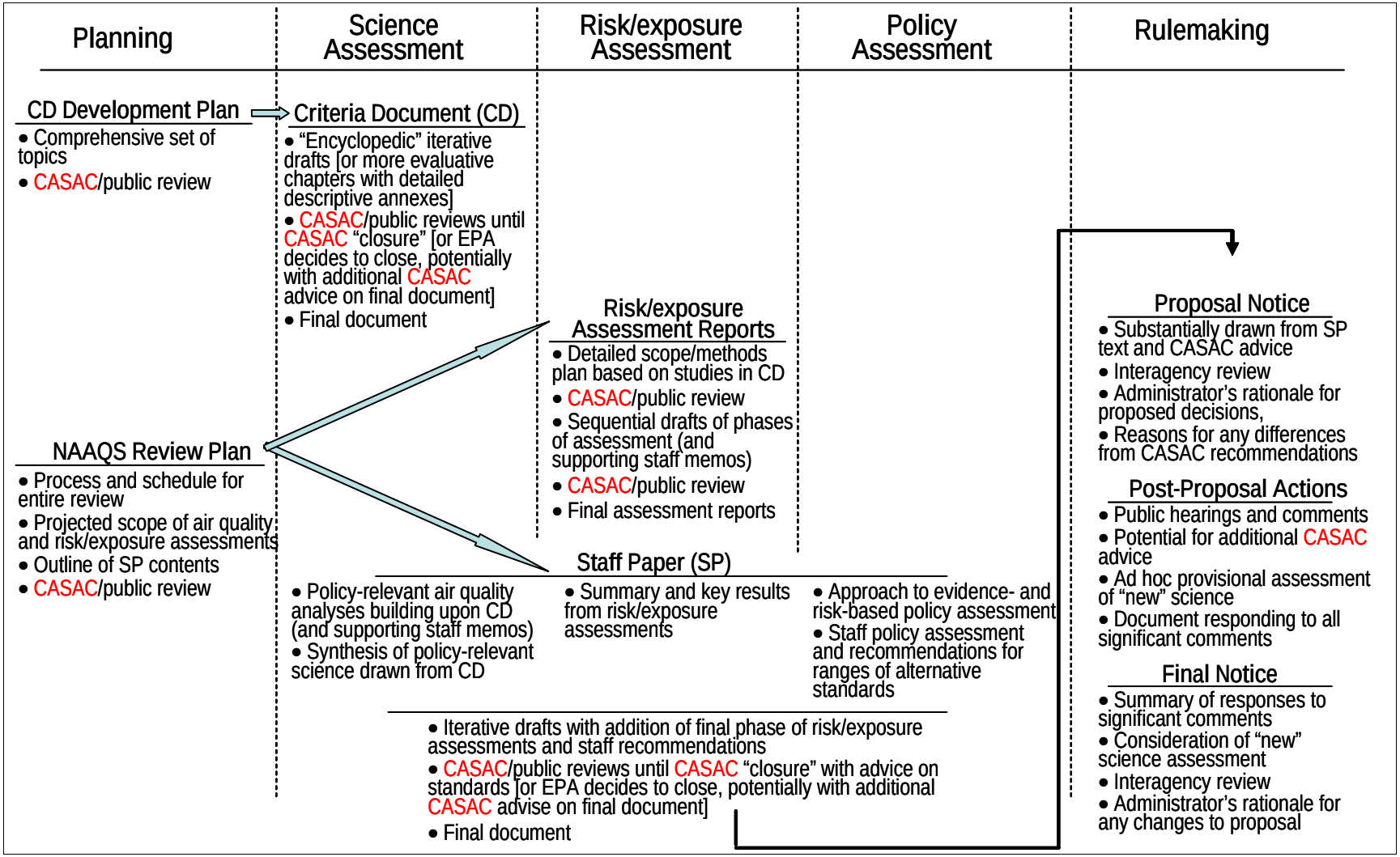

Figure 3. Key Functional Elements of Current NAAQS Review Process

2.1.1 Planning

At the beginning of a NAAQS review, under the current process the first planning document, prepared by NCEA/ORD, is a Development Plan for the Criteria Document. This plan is a comprehensive set of scientific topics and issues that are likely to be relevant for a review of the AQC for the pollutant in question. The plan also discusses the organization of the prospective Criteria Document, identifies key authors for each of the subject-specific chapters, and provides a projected schedule that includes iterative reviews of draft documents by CASAC and the public. A draft of this plan is the subject of a public consultative meeting with CASAC that generally occurs before the full CASAC Review Panel is formed, such that the broader group of experts who will be reviewing the draft Criteria Document generally do not have an opportunity to comment on the development plan.

A second planning document is prepared generally around the time that the first draft of the Criteria Document is being developed. This NAAQS Review Plan, prepared by OAQPS/OAR, discusses the overall process and schedule for the review of the AQC and the NAAQS. It discusses in general terms initial plans for various quantitative assessments, including air quality analyses, human health exposure and risk assessments, and any environmental assessments that may be done, and focuses on the policy-relevant issues that the Staff Paper will address. These policy-relevant issues are related most generally to the choices that need to be made in deciding whether to retain or revise the current NAAQS, including choices about the indicators, averaging times, forms, and levels of the primary and secondary NAAQS. This plan is typically the subject of a consultation with the CASAC Review Panel and public comments are solicited.

2.1.2 Science Assessment

In this report, the term "science assessment" refers to a range of activities that includes the identification of peer-reviewed publications related to the pollutant in question in the scientific literature, the description and evaluation of these studies' methods and findings, and the synthesis of the entire body of evidence to develop an integrated, generally qualitative assessment designed to inform the central policy-relevant issues. The results of the science assessment serve as the foundation for the subsequent quantitative risk/exposure and policy assessments.

In the current process, the bulk of the science assessment activities are undertaken by NCEA in the development of the Criteria Document. Using the Criteria Document Development Plan as a guide, EPA convenes a series of technical workshops to bring together experts from throughout the scientific community to discuss important scientific and technical issues identified in that plan. These public workshops are designed to help focus the presentation of each subject-specific chapter in the Criteria Document on the key issues. Before the workshops, lead authors (typically academics under contract to EPA) are identified for each of these chapters and asked to prepare initial draft materials to frame the workshop discussions. These chapters are generally organized by academic discipline, such as air quality, epidemiology or toxicology, and

have typically been comprehensive and "encyclopedic" in nature.[2] In addition to these subject-specific chapters, EPA staff also prepares an integrative synthesis chapter that brings together information from the various disciplines to reach conclusions that are central to the review, for example, about the extent to which the weight of the evidence supports inferences of causality in the relationships between various health-related endpoints and exposures to the pollutant in question and about the subpopulations that are likely at increased risks for various health effects.

After initial chapters are drafted by lead authors and reviewed by EPA staff, they are released for CASAC and public review. Under the current process, this first External Review Draft of the Criteria Document may not contain an integrative synthesis chapter. After receiving CASAC and public comments, lead authors, working with NCEA staff, revise the draft chapters as appropriate. In addition, NCEA staff develop an integrative synthesis chapter based on the conclusions from the individual chapters and the comments received to date. Following internal review, the resultant Second External Review Draft of the Criteria Document is released for CASAC and public review, following which final changes are made to the document to address comments received. In some cases, NCEA has prepared additional drafts (*e.g.*, four drafts of the most recent PM Criteria Document, with further iterations on certain chapters, including the integrative synthesis), or, if significant time has elapsed since the cut-off date for studies to be included in the Criteria Document, EPA has sometimes prepared a Supplement or Addendum that evaluates new science (*e.g.*, as was done in the mid-1980s for the PM/SO_2 and CO Criteria Documents).

While the science assessment is primarily presented in the Criteria Document, that document has generally been written for a scientific audience rather than being oriented toward policy makers. To help bridge the gap between the scientific information, as conveyed in the Criteria Document, and the judgments required in making policy decisions on the NAAQS, an integrated presentation of the most policy-relevant scientific information is included in the Staff Paper in terms that are intended to be understandable and meaningful for policy makers and a broad public audience. This activity essentially winnows down the voluminous material in the Criteria Document to address the critical needs of decision makers in addressing issues central to promulgating a NAAQS, including in particular issues related to choosing the indicator, averaging time, statistical form, and numerical level for each standard. This policy-oriented presentation of scientific information is distinct from the other two major functions of the Staff Paper: (1) reporting the major findings of the risk/exposure assessment and (2) the integration of scientific evidence and quantitative risk-based information into a policy assessment upon which staff-recommended ranges of specific policy options and alternative standards, as appropriate, are based. These latter two functions are described in the following sections.

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[2]Consistent with recommendations from past NAAQS process reviews, NCEA departed from preparing an "encyclopedic" set of chapters with its most recent Ozone Criteria Document, in which comprehensive descriptive materials were presented in a series of annexes, with the main body of the document being much more concise and evaluative in nature.

2.1.3 Risk/Exposure Assessment

Based on the information in the science assessment, OAQPS typically conducts quantitative assessments of public health risks, human exposures, and/or risks, exposures, and impacts on the environment. Together with the information in the Criteria Document, an issue-oriented discussion in the Staff Paper presents the foundation and criteria for decisions about the scope and methods to be used in the assessments. To obtain input on the scope and methods prior to conducting the assessments, OAQPS prepares a detailed Scope and Methods Plan for each assessment that builds upon the general plan included in the initial NAAQS Review Plan. This detailed plan is the subject of consultation with CASAC and is made available for public review and comment.

The Scope and Methods Plan addresses various aspects of the assessment design, including the selection of categories of effects, geographic study areas, and sensitive populations for which EPA will do a quantitative assessment. This plan also addresses key methodological issues related to: developing estimates of background air quality levels; approaches to simulating air quality levels that would meet the current standard and an appropriate range of possible alternative standards; various aspects of selecting appropriate concentration- and/or exposure-response functions; quantifying relevant baseline incidence rates and sensitive populations; and approaches to characterizing uncertainty and variability across all the elements of the assessment.

Taking into account CASAC advice and public comments on the plan, OAQPS directs work on the assessments, typically using contractors to carry out the main components and to prepare complete documentation in the form of contractor-authored reports. OAQPS staff then prepares for inclusion in the Staff Paper an overview of the assessment, a discussion of the criteria and assumptions that led to the assessment design and selection of scope and methods, and a presentation of the results and key observations with a focus on the uncertainties and variability in the assessment results. The contractor reports serve as technical support documents for the presentation of the risk/exposure assessments in the Staff Paper

The risk/exposure assessments are reviewed by CASAC and the public through review of iterative drafts of both the Staff Paper and the technical support documents. The first drafts typically contain the first phase of the assessment results which include risk/exposure estimates associated with recent ambient air quality levels and estimated risk/exposure reductions associated with just meeting the current NAAQS. The second drafts typically also contain the second phase results which include risk/exposure estimates associated with just meeting alternative standards identified by OAQPS staff based on the information in the science assessment and the results of the first phase of the risk/exposure assessment.

2.1.4 Policy Assessment

The primary purpose of the OAQPS Staff Paper (subtitled: Policy Assessment of Scientific and Technical Information) is to evaluate the policy implications of the scientific information contained in the Criteria Document and the results of the quantitative risk/exposure

assessments. In addition to the sections of the Staff Paper that discuss the science and risk/exposure information, there is also a section that presents air quality analyses conducted by staff that help to interpret that information in a policy-relevant context. These sections serve as the basis for subsequent sections that discuss approaches to evaluating whether the current NAAQS are adequate or whether any revisions are appropriate, and to developing staff recommendations on the elements of possible alternative standard options (in terms of the indicator, averaging time, form, and ranges of levels) for consideration by the Administrator. This policy assessment seeks to identify a broad range of reasonable approaches for taking into account both evidence-based (*e.g.*, epidemiologic evidence in the form of short- and long-term exposure studies) and quantitative risk-based considerations in reaching policy judgments about the current and possible alternative standards. Public health policy judgments about standards that are requisite to protect public health with an adequate margin of safety generally involve consideration of a number of factors, such as the nature and severity of the health effects involved, the degree to which those effects are judged to be adverse, the nature and size of the sensitive population(s) at risk, and the kind and degree of uncertainties that must be addressed. Characterization and consideration of the various types of uncertainties that are inherent in any such assessment are highlighted, including both qualitative uncertainties about the likelihood that reported associations are causal in nature and quantitative uncertainties in estimated risks that reflect not only statistical confidence intervals but also the sensitivity of results to different modeling approaches and to underlying assumptions.

Under the current process, this policy assessment includes staff recommendations, and the associated rationales, as to whether the Administrator should consider retaining or revising the current NAAQS, and if appropriate, what alternative standard options and ranges of levels he might consider. Such recommendations are based on various types of judgments about the scientific evidence, quantitative risk and/or exposure estimates, and alternative ways to weigh uncertainties in making policy choices. A summary of key uncertainties and research recommendations related to setting NAAQS are included at the end of the policy assessment to help inform the next review. Iterative drafts of this policy assessment are reviewed by CASAC and the public as part of their review of the Staff Paper, providing an opportunity for input on the range of policy-relevant judgments that will need to be made by the Administrator in reaching his proposed NAAQS decisions.

2.1.5 Rulemaking

The rulemaking process begins with the preparation of a notice of proposed rulemaking (NPR), which is based on the information in the Criteria Document and Staff Paper and on CASAC advice and recommendations, with consideration also given to input received from stakeholders and through an interagency review process. Interagency review is a mechanism that provides other federal agencies, including the Office of Management and Budget (OMB), an opportunity to review and comment on a draft proposal notice, with comments received during this process being placed in the public docket for the rulemaking. The preamble discussion in the NPR draws heavily from text in the final Staff Paper and further articulates the Administrator's rationale for his proposed decisions on the NAAQS. These decisions include whether the standards should be retained or revised, and if the proposal is to revise them, what

revised standards are requisite to protect public health with an adequate margin of safety and what secondary standards are requisite to protect public welfare from known or anticipated adverse effects. To the extent that any of these decisions differ from advice received from CASAC, the reasons for the differences are clearly explained in the preamble. In addition to soliciting comment on all aspects of the Administrator's proposed decisions, the proposal notice often solicits comments more broadly on a range of alternative standards that may have been recommended by CASAC or advocated by other parties, or on alternative interpretations of the underlying scientific information that may have been advanced by other parties.

Following publication of the NPR in the *Federal Register*, a public comment period is provided that typically extends for at least 90 days. During this time, public hearings are generally held to provide opportunities for interested parties to present their comments on the proposed rule in person to agency officials as well as in written comments. There have been instances in which CASAC has met during this period to review the proposed decisions and provide further advice to the Administrator. All comments received during this comment period are placed in the public docket, including transcripts of public hearings, and are considered by the Agency in reaching final decisions. If relevant "new" scientific studies (*i.e.*, studies not published in time to be included in the Criteria Document) are identified by the Agency or submitted in public comments, EPA may provisionally assess them, as appropriate, so that the Administrator is aware of the latest scientific information before reaching a final decision.

Based on a consideration of all significant comments received during the comment period, and with an awareness of the latest scientific information, the Administrator reaches final decisions on the NAAQS. The preamble to the notice of final rulemaking (NFR) articulates the Administrator's rationale for his final decisions and summarizes the most significant comments on the proposed rule and the Agency's responses to them. All significant comments and responses are documented more fully in a separate document that is placed in the public docket. These responses may draw upon any provisional assessment of "new" science that may have been done to provide a more up-to-date context for considering specific comments, although the provisional assessment has not been relied upon as a basis for the final decisions. The draft NFR also goes through interagency review. Upon completion of this process, the final rule is promulgated and the NFR is published in the *Federal Register*.

2.1.6 CASAC Review

As is clear from the above discussions of each NAAQS review element, CASAC plays a central role throughout the review of the AQC and NAAQS. Through its public consultations with EPA staff on draft review and assessment plans, and its review and advice and recommendations on iterative drafts of the Criteria Document, Staff Paper and related risk/exposure assessments, CASAC fulfils its statutory responsibilities to review the AQC and NAAQS and to provide advice to the Administrator on any revisions to the AQC and NAAQS as may be appropriate.

The process by which CASAC reviews these documents and provides its final advice to the Administrator has for many years included the step of CASAC reaching "closure" on both

the Criteria Document and Staff Paper, as reflected in a “closure” letter to the Administrator. That is, CASAC "closes" its review of each of these documents when it deems that the document is adequate for use as a basis for reaching decisions on the NAAQS. By continuing to revise and make additional drafts of these documents available for CASAC and public review until CASAC reaches "closure," EPA has sought to implement a process that produces high quality assessments and that makes CASAC's advice and recommendations clear and transparent. On the other hand, this CASAC "closure" step can lengthen the time to complete the review, in some instances beyond court-ordered deadlines. In such instances, EPA has at times requested from the court an extension in the schedule to allow for additional review. However, in the case of the most recent Staff Paper for PM, for example, EPA determined that it was appropriate to publish a final document that reflected CASAC input on the second draft of the document by the court-ordered deadline, even though CASAC felt that the necessary changes were substantial enough to warrant its reviewing an additional draft. Both to allow EPA to meet the deadline and to ensure that the Administrator had the benefit of whatever further advice CASAC wanted to provide, EPA's SAB Staff Office convened a meeting of the CASAC Review Panel after the final Staff Paper was published and facilitated the preparation of a letter to the Administrator that conveyed CASAC's views on the final Staff Paper. This additional advice from CASAC was then considered by the Administrator in reaching his recently proposed decisions on the PM NAAQS.

The CASAC and its NAAQS Review Panels are administered by EPA's SAB Staff Office and are subject to the provisions of the Federal Advisory Committee Act (FACA), which requires that advisory panels be fairly balanced in terms of the points of view represented and the functions to be performed. EPA’s SAB has a formal process for forming advisory panels and making decisions about conflict of interest and balance among panelists. All CASAC meetings to discuss the NAAQS reviews are public meetings, and include public comment periods to provide CASAC Panel members an opportunity to hear comments from the public on the documents under review during their deliberations.

2.1.7 Public Participation

Opportunities for public participation are provide throughout the NAAQS review process, including opportunities coincident with CASAC reviews and consultations on EPA draft documents. Prior to rulemaking, the public can participate by providing written comments to EPA and CASAC on all draft documents and can also provide oral comments at CASAC meetings. As noted above, the public comment periods during CASAC meetings provide an opportunity for CASAC to hear the views of interested parties on the documents under review, as supplemented by whatever written comments are provided, and to question the commenters for clarification of their views. During rulemaking, the public can provide comments during the public comment period, both in writing and orally at public hearings.

2.2 Comments on the NAAQS Process from Outside Parties

2.2.1 Views of Current and Former CASAC Members

Individual views of current and former CASAC members who provided comments on the current process are summarized below and included as Attachments 3-A to 3-D. Areas in which several of the individual commenters expressed similar views are summarized first, followed by a listing of issues that were raised by one or another of the CASAC members who commented.

All individual comments received were consistent with the view that EPA should take actions that would improve the timeliness and efficiency of the process. The CASAC commenters generally felt that EPA could bring about these improvements in part by ensuring that adequate time and resources are devoted to producing initial draft documents that are of high quality. With regard to the Criteria Document, virtually all CASAC commenters expressed strong support for restructuring the document to make it far more concise and focused on evaluation and synthesis of the science. Several CASAC commenters expressed the view that the synthesis of scientific information in the Criteria Document should be focused on policy-relevant issues to better inform EPA's policy decisions. A number of comments addressed the importance of ensuring that uncertainties are fully characterized in a balanced way, both in the more qualitative discussions of scientific evidence in the Criteria Document and in the quantitative risk/exposure assessments. The CASAC commenters generally supported the preparation of the type of policy assessment currently presented in the Staff Paper, which provides a framework for CASAC to provide advice on ranges of alternative standards.

Most of the CASAC commenters expressed strong support for reinstating the "closure" process that CASAC has historically used to advise the Administrator when the document under review is judged to be adequate to be used as a basis for regulatory decision making. Some individuals expressed the view that CASAC's ability to fulfil its statutory responsibilities as an independent committee charged with providing its advice directly to the Administrator is compromised by a discontinuation of the "closure" process.

Several CASAC commenters addressed the issue of distinguishing science and policy judgments throughout the process. Some expressed the view that EPA should more clearly articulate the policy considerations central to its decision making, both early in the review process (*e.g.*, through charge questions to CASAC) and as part of its regulatory decision making.

With regard to consideration of the most recent science, some individual CASAC commenters expressed the view that "new" studies rarely have major impacts on an integrated interpretation of the entire body of scientific evidence. In those cases where circumstances warrant consideration of exceptionally important new studies, several commenters felt that CASAC should review any such studies and that CASAC could accomplish that review quickly without unduly delaying the review process.

Individual CASAC members offered a number of additional comments, including the following:

- EPA should give more careful consideration to secondary standards.
- NCEA should enlist workshops and/or CASAC consultations to identify important issue at the beginning of the process to help frame the integrative science assessment.
- The basic compilation of scientific literature should be reviewed by CASAC subcommittees (by teleconferences) so as to allow more time for CASAC to focus its review on the integrative synthesis of the science in the Criteria Document and the policy assessment in the Staff Paper.
- EPA could use a process more similar to that used by the National Research Council (NRC) to produce the science assessment; alternatively, EPA might consider asking NRC to conduct the science assessment.
- EPA should more fully incorporate modern information tools and processes into the review process.
- EPA should more clearly and consistently define key policy-relevant concepts (e.g., adequate margin of safety, sensitive populations, adverse health effects, susceptible individuals, population-based thresholds, acceptable level of population risk).
- OAQPS should not issue the first draft of the Staff Paper until the Criteria Document is final.
- The Staff Paper should be incorporated into a restructured Criteria Document, and that single document should focus only on policy-relevant studies.
- CASAC should focus its advice on ranges of alternative standards that are supported by the science and not recommend specific policy choices.
- EPA's risk assessments tend to under-state scientific uncertainty; EPA should consider expanding the risk assessments (*e.g.*, by having multiple parties, including EPA staff, produce potentially "dueling" assessments) so as to more thoroughly characterize uncertainties; comparative risk information should be presented to put air pollution risks into a broader context.
- Uncertainties in epidemiological estimates of effect are not adequately reflected in the current risk assessment; a formal probabilistic risk assessment is needed.

- Public comments on draft documents should be made available to CASAC earlier to allow time for members to review the comments in advance of the CASAC meetings; EPA should formally respond to these comments.

- CASAC procedures should be modified in a number of ways; for example, provide transcripts of all CASAC meetings; minimize or eliminate teleconferences; invite CASAC members to participate in legal negotiations to ensure that regulatory schedules are consistent with a full science review.

- The Administrator should work with Congress to lengthen the NAAQS review cycle from five to ten years.

2.2.2 Views of Various Stakeholders

Views of various stakeholder groups on the current process are summarized below and more fully in Attachment 4, which includes all written comments submitted by commenters. A number of overarching comments were received from the stakeholder groups that were consulted with in the preparation of this report. In particular:

- There was broad recognition among all the outside parties consulted that there are problems with the process taking too long, which generally led to questions about the adequacy of the resources being allocated. Many commenters expressed the view that EPA presently allocates insufficient resources to consistently produce documents, especially science assessments, that are both timely and of optimal quality.

- Aside from the issue of timeliness, some commenters believe that the process generally works well and is not structurally "broken," and would not want to see major structural changes. Virtually all of these commenters nonetheless recognize that some changes in the process would be beneficial, with different commenters focusing on changes to different elements of the process, as discussed below.

- Some other commenters believe that there are several areas where the process could and should be structurally improved to address the key questions that frame this review, as discussed below.

- Varying views were expressed with regard to the distinctions made throughout the review between science and policy, with some feeling that such distinctions were currently being made to the extent necessary. Others expressed the view that such distinctions are somewhat artificial, whereas still others felt that the distinctions could and should be made more transparent.

- More generally, one commenter expressed the view that a statutory change is warranted to allow for a longer than 5-year NAAQS review cycle. Another

commenter felt that this review of the NAAQS process should be extended beyond April 3, 2006, allowing for a more transparent review and for more informed and inclusive involvement of the scientific community and the public.

With regard to the planning element, commenters expressed the following views:

- Some felt that the process would be improved by identifying key policy-relevant issues at the beginning of the process and using those issues to frame the science assessment and the quantitative risk/exposure assessment.

- Some expressed the view that criteria should be presented at the beginning of the process for how key studies will be selected for "policy-relevance" and for how those studies, and the entire body of evidence, will be evaluated and integrated in the Criteria Document.

Views on the science assessment took the form of comments on the Criteria Document, and included the following:

- There was broad recognition that the Criteria Document is typically "encyclopedic" in nature, which is seen by many as contributing to an unnecessarily lengthy process for preparing document drafts and for reviews by CASAC and the public, and obscuring a focus on the most policy-relevant scientific information.

- Very broad support was expressed for moving to a more continuous process for identifying and characterizing new scientific studies. Some commenters provided detailed suggestions for the development and use of an electronic database that would catalogue descriptive documentation of scientific studies. Some commenters noted that such a database would facilitate the development of a more focused evaluative and integrative assessment document for each 5-year NAAQS review cycle, and that it could also be used to facilitate the preparation of more frequent periodic updates of the new science for the full set of criteria air pollutants. These periodic updates could, in turn, facilitate the development of pollutant-specific documents to support specific NAAQS reviews.

- Some commenters expressed the view that the contrast between what was known in the previous review, and the key uncertainties at that time, and what is now known, and what are now the key uncertainties, should be a major focus of the Criteria Document.

- Some commenters felt that the evaluation of the science should be made more transparent by more clearly defining and following sets of criteria for identifying and evaluating individual studies and for synthesizing scientific information across disciplines in the Criteria Document.

With regard to the risk/exposure assessment, commenters expressed the following views:

- Several commenters viewed the assessments as being thorough and transparent, and as serving as a bridge between science and policy, whereas others saw a need for more transparency with respect to some of the analytical choices made in the assessments.

- Some viewed the current assessments as generally being well done and transparent in addressing uncertainties, while others expressed the view that transparency should be improved and uncertainty analyses should be broadened.

Views on the policy assessment element took the form of comments on the Staff Paper, and included the following:

- Some commenters expressed the view that the Staff Paper was generally well done and was an appropriate mechanism to lay out policy options.

- Some commenters expressed the view that the discussions of health and welfare effects in the Staff Paper are duplicative of material that is or could be covered in the Criteria Document.

- Some commenters felt that the first draft of the Staff Paper was often incomplete and thus prematurely offered for CASAC and public comment.

- Several commenters expressed the view that it was desirable to have a document that reflects staff views (to avoid the perception of political influences) made available for CASAC and public review. In sharp contrast, others felt that it would be desirable to have a document that represented EPA senior management views made available for CASAC and public review earlier in the process, before Agency decisions are proposed. One commenter suggested that this could be accomplished by eliminating the Staff Paper and placing its contents into an advance notice of proposed rulemaking (ANPR).

Some views were expressed that related to the rulemaking stage of the process, including the following:

- There was broad recognition that regulatory decisions are necessarily made without the very latest science having been integrated into the science assessment. Some commenters felt that this was not generally a problem in NAAQS reviews, in that a small number of new studies rarely have a large impact on the overall weight of evidence. Others felt that this concern could be addressed through some type of provisional assessment during the rulemaking phase. It was noted that any such provisional assessment would be facilitated by a continuous process for identifying, compiling, and characterizing new emerging scientific studies.

- Concern was expressed by some commenters that the interagency review process that occurs before proposed and final decisions are published allows for potentially inappropriate changes to EPA's assessment of the science that reflected CASAC's review and advice.

With regard to CASAC's role in the process, commenters expressed the following views:

- Some felt that CASAC Panel members could be better guided with regard to their statutory responsibilities and important distinctions between providing policy-relevant advice and making specific policy recommendations. Some commenters expressed the view that it was appropriate for CASAC to offer advice as to the adequacy of the current standard or a range of alternative standards, but that it was important that the rationale for its advice be based on scientific evidence and judgments, not policy preferences.

- Concern was expressed by some commenters that EPA may be too deferential in instances when individual CASAC Panel members press EPA to do more work or analyses on particular issues, especially when the issue in question is not important from a policy perspective. This concern was cited as an issue that can add to problems with the timeliness of the review.

- Sharply contrasting views have been expressed on the issue of allowing the review process to continue until CASAC reaches "closure" on a document under review. As noted above, many CASAC members expressed strong views about the importance of their reaching "closure" before EPA finalizes documents, whereas some stakeholders see "closure" as a means by which CASAC Panel members can inappropriately extend the length of (and their influence upon) the NAAQS review.

- One commenter raised questions about real or perceived bias with regard to issues such as the choice of CASAC/Panel members; members reviewing chapters that include their own studies; members coming in with their own policy goals; inappropriate conduct or contact between EPA staff and CASAC/Panel members; and inadequate time for CASAC/Panel members to hear and give appropriate consideration to public comments.

With regard to public participation in the NAAQS review process, there was broad recognition that there are frequent opportunities for public participation and comment throughout the process. Nonetheless, some stakeholders expressed the view that in some instances the time allotted to review documents has not been sufficient. Some commenters felt that it would be desirable to have more time to present public comments during CASAC meetings and that EPA should fully respond to public comments provided on draft documents that are made available for public review.

3. OPTIONS FOR CHANGES TO THE NAAQS PROCESS

3.1 Framework for Consideration of Options

In considering potential options for changes to the current NAAQS process, the workgroup has examined each of the functional elements and the nature and linkages among the key documents, as described above. Our examination has focused on the key questions that frame this review, and has taken into consideration the comments and recommendations received from current and former CASAC members and from stakeholder groups. As a first step, we derived an alternative framework for addressing each of the key functional elements through the preparation of somewhat differently structured documents that would be less overlapping in content and could be developed through more efficient approaches. This alternative framework is shown in Figure 4, which highlights changes from the current process as depicted in Figure 3 above.

The time frames that might reasonably be allotted to each of the elements within this alternative framework, and the extent to which work on the significant documents could be done concurrently or sequentially, are shown in Figure 5. While recognizing that the relative timing of the elements of a review will inevitably vary somewhat from one review to another, and depend in part on what options may be adopted for changes to the NAAQS process, we judged that this general time line provided a useful mechanism for examining potential efficiencies to be gained from the changes contemplated by this alternative framework.

A range of options for each of the key elements is discussed below in the context of the alternative framework presented in Figures 4 and 5. We believe that many of the options discussed below have the potential to bring about increased efficiency and other improvements to the process and are responsive to the key questions that frame this review. It is important to note that the time frames described in Figures 4 and 5 are such that a review of the NAAQS would typically take a full five years. The increased timeliness and efficiency expected under the alternative framework derive from making it more likely that a coordinated, comprehensive, and policy-relevant review can be conducted in that time frame, while reducing the likely amount of time between the science assessment and the issuance of the proposal, increasing the likelihood that the proposed decision will be based on the most recent science.

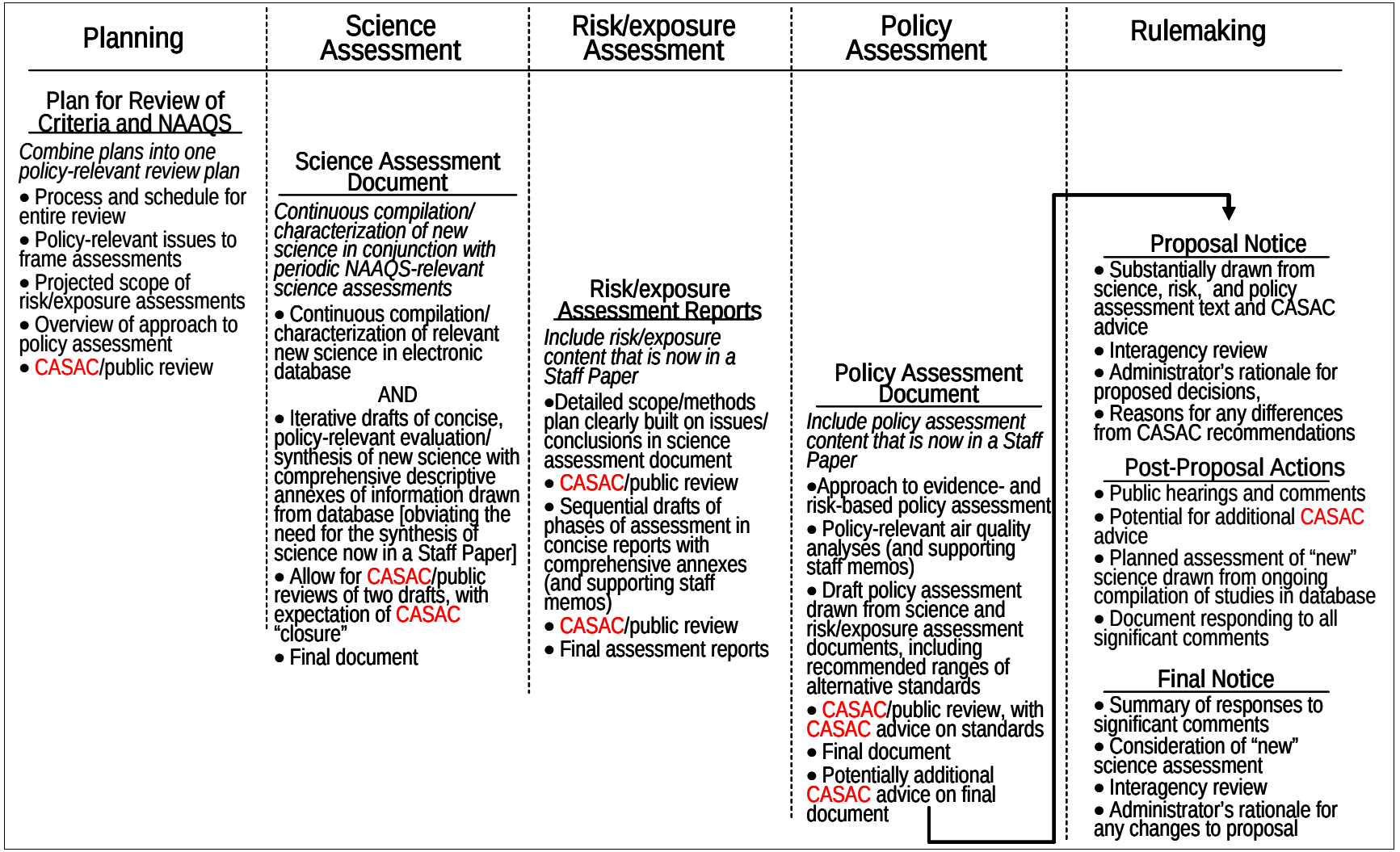

Figure 4. Key Functional Elements in Alternative NAAQS Review Framework

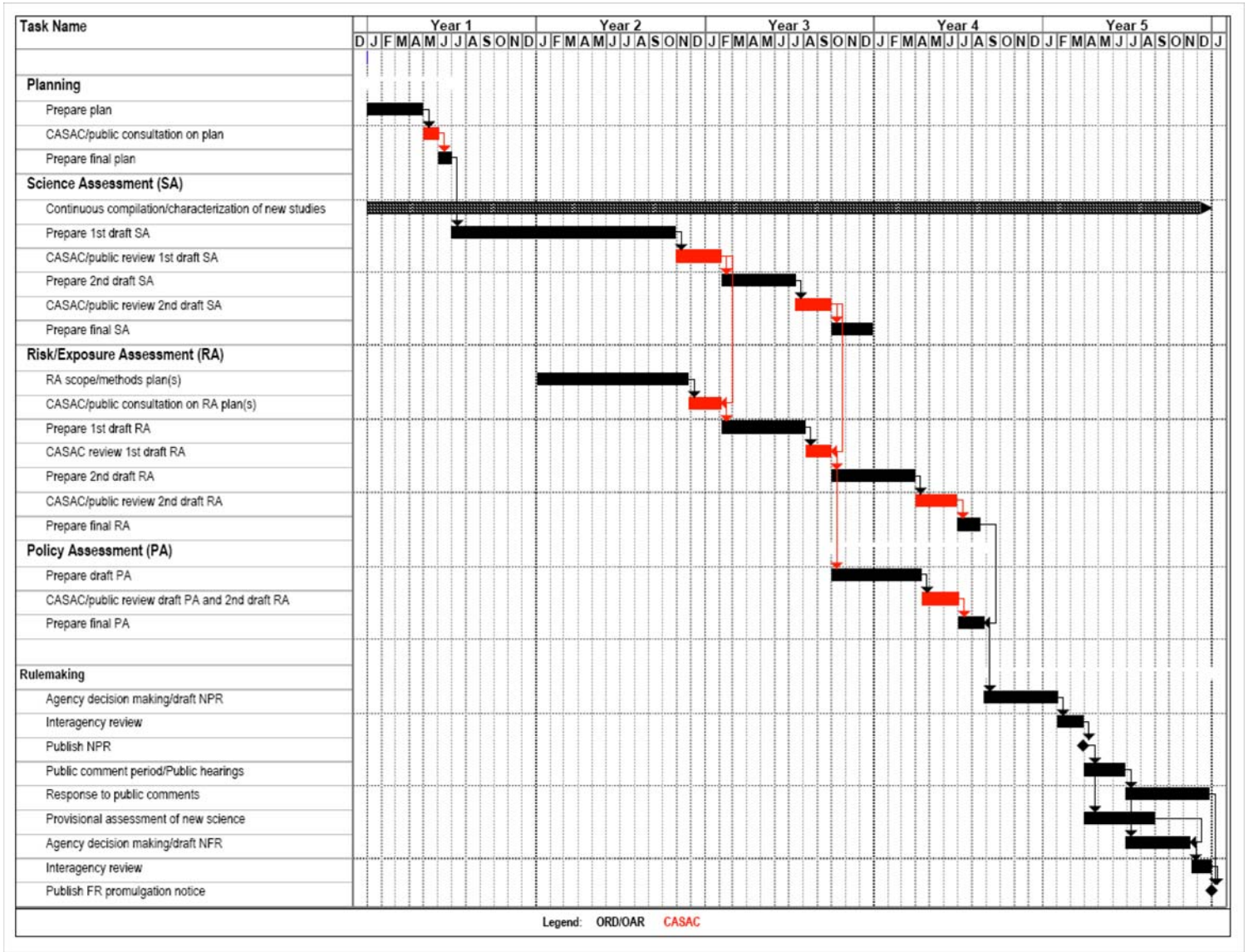

Figure 5. Timeline for Alternative NAAQS Review Framework

3.2 Options for Changes to the Key Elements

3.2.1 Planning

The implementation of some or all of the following options for changing the nature of the current planning process could enhance the efficiency and timeliness of the process for preparing each of the assessment documents and for CASAC and public review of those documents. These options could also facilitate early input from EPA senior management and outside parties on important policy issues that could then serve as a basic integrative framework for the science, risk/exposure, and policy assessments to be prepared in the course of the NAAQS review.

- ORD and OAR could collaborate on combining the current Criteria Document Development Plan (prepared by ORD/NCEA) and the NAAQS Review Plan (prepared by OAR/OAQPS) into one integrated plan for the review of both the AQC and the standards.

- The focus of such an integrated planning document could change from (1) identifying a comprehensive set of scientific topics to be addressed in a science assessment document to (2) identifying key policy-relevant issues that would generally be used to frame the science assessment, risk/exposure assessment, and policy assessment documents. These policy-relevant issues would reflect the key uncertainties, gaps in knowledge, and research needs identified at the end of the previous NAAQS review. It would also be appropriate to recognize in the plan that new issues could arise and would need to be addressed during the course of the current review.

- In discussing policy-relevant issues, this plan could help clarify appropriate distinctions between science and policy judgments and/or elaborate on important concepts and terms that have both science and policy components.

- The set of policy-relevant issues identified in this plan could include those science judgments that are an integral part of the projected risk/exposure assessment. Such a plan would link the preparation of a draft science assessment document with the development of methodologies for the risk/exposure assessments.

- The plan could include criteria for the identification and selection of policy-relevant scientific studies as well as criteria for how the science assessment will evaluate the weight of the evidence for purposes of drawing inferences about causal relationships.

- The plan could allow for provisional assessment of "new" science (*i.e.*, new studies that have appeared in the peer-reviewed literature after the presumptive cut-off date for the science assessment document), as appropriate, to be prepared following proposed rulemaking. Such an assessment would serve to make the

Administrator aware of the most recent science beyond that which is incorporated into the science assessment document prior to his reaching final decisions.

3.2.2 Science Assessment

The implementation of some or all of the following options for changing the nature of the assessment of the science done by ORD, as typically documented in a Criteria Document, could enhance the efficiency and timeliness of the preparation of the document and of its review by CASAC and the public. These options could further streamline the overall NAAQS review by obviating the need for some of the work that is now done as part of the development of a Staff Paper.

- The Criteria Document could be substantially restructured in a number of ways. For example, the material included in the main body of a science assessment document could be much more concise and evaluative and integrative in nature, and focus more clearly on characterizing the strengths and uncertainties of the available scientific evidence. Such a document would appropriately be supported with comprehensive annexes that include generally descriptive information, the preparation of which would require judgments about study selection, characterization, and prioritization consistent with the criteria laid out in the planning document. We note that the current Ozone Criteria Document generally reflects this type of restructuring. Further, the presentation and final synthesis of information could be organized to more directly address key policy-relevant issues, as identified in an initial integrative plan. To the extent that a restructured document identified and focused on the most policy-relevant science, there would not be a need for the type of synthesis of the science that is now included in a Staff Paper.

- The timely development of such a science assessment document would be facilitated by the use of a continuous process (including the use of up-to-date electronic methods and searchable databases) for identifying, compiling, characterizing, and prioritizing relevant new scientific studies. In developing and implementing such a continuous process, several factors would need to evaluated and addressed, including: the scope of information to be included in such a database(s); whether pollutant-specific databases or one multi-pollutant database should be developed; the range of *descriptive information* to be included (*e.g.*, key elements of the study design; environmental variables such as air quality statistics or dose levels; relevant results and authors' conclusions); whether any *evaluative judgments* about each study should be included, and if so, the nature of such information; approaches that might be used for the development of such a database(s), taking into account resource considerations and the use of EPA staff and/or consultants/contractors; and the extent to which CASAC and the public would be asked to play a role in the development of such a process.

Consideration would also need to be given to options for staffing the ongoing maintenance of such a process. In addition, the desired output of information from the database(s) would need to be determined in terms of what is needed to support the science assessment done as part of 5-year NAAQS review cycles, and whether more frequent periodic (*e.g.*, annual) updates on emerging new science across all criteria pollutants would be useful and appropriate and with what type of peer review. Periodic updates on emerging science have the potential to raise new policy-relevant issues that could be factored into the review and to facilitate the development of pollutant-specific science assessments.

- The breadth of conclusions reached in the science assessment document could be extended beyond what is currently done in the Criteria Document to explicitly address many of the types of science judgments that are integral to the planned quantitative risk/exposure assessments. To the extent that this is done, there would be less need for these types of judgments to be made separately in conjunction with the development of methods for risk/exposure assessments.

- ORD could produce the science assessment document through a more coordinated, consultative internal process, consulting with subject experts across ORD, OAR, and other offices, as appropriate, across the Agency. This approach would help to ensure the policy-relevance of the assessment and would facilitate consideration of the newest scientific data and methods.

- Consider changing the name of the document (*e.g.*, "Assessment of Scientific Information") to emphasize the restructured and refocused content. Avoiding the use of the word "criteria" in the name of the document could help to clarify that the "air quality criteria" called for in the CAA may include information beyond that which is presented in the science assessment document (*e.g.*, the risk/exposure assessments).

3.2.3 Risk/Exposure Assessment

The implementation of some or all of the following options for changing the risk/exposure assessments conducted by OAR/OAQPS (including both human health and environmental assessments) could enhance the efficiency and timeliness of the overall NAAQS review process. Structuring the process to facilitate the completion of the risk/exposure assessments closer in time to the completion of the science assessment would also allow the policy assessment to be done closer in time to the science assessment. Thus, such changes would help to minimize the time between completion of the science assessment and reaching proposed decisions on the standards.

- The detailed scope and methods plan for the risk/exposure assessments, which builds upon the more general discussion in the initial NAAQS Review Plan, could be developed through a more coordinated, consultative process with ORD, in conjunction with the preparation of relevant sections of the science assessment

document. This approach would facilitate concurrent peer and public review of (1) the underlying science judgments and assessment models presented in the science assessment document and (2) the scope and methods plan that projects how such science judgments would be incorporated into the risk/exposure assessment, how the assessment models would be applied, and how uncertainties would be characterized. This approach would be expected to improve the quality of the reviews of these documents and, hence, the quality of the documents themselves.

- The risk/exposure assessment report could be restructured to be a more concise assessment focused on key results, observations, and uncertainties (similar to the risk/exposure chapter(s) that are now included in a Staff Paper). Such a document would be supported with comprehensive annexes that included all relevant technical information and results to make the assessment methods, results, and uncertainties transparent. The annexes would include all the information that is now presented in the comprehensive risk/exposure report(s) that are prepared in conjunction with a Staff Paper. We note that this change would parallel the restructuring of the Criteria Document discussed above, and would obviate the need for this material to be separately summarized as part of a Staff Paper.

- A Risk/Exposure Subcommittee of the CASAC NAAQS Review Panel could be established, when appropriate, to provide broader and more focused expertise on the risk/exposure assessment. This approach would help to ensure that the latest assessment methodologies and approaches to characterizing uncertainties are incorporated into the assessments.

3.2.4 Policy Assessment

The implementation of some or all of the following options for changing the policy assessment developed by OAR/OAQPS, as currently documented in a Staff Paper, could potentially enhance the efficiency and timeliness of the review. These changes could also include providing for input from OAR and/or EPA senior management to be reflected in a policy assessment that is made available for CASAC and public review, prior to the selection of policy choices as presented in a proposed rulemaking.

- To the extent that science assessment and risk/exposure assessment documents are restructured as discussed above, the Staff Paper as currently structured could be replaced with a more concise policy assessment document. This document would not need to include the synthesis of policy-relevant science and the key observations from the risk/exposure assessment that are now included in Staff Papers; instead, it would include only the policy-relevant air quality analyses and policy assessment content. This content includes discussion of evidence-based and quantitative risk-based approaches for making policy choices and the identification of ranges of alternative standards that reflect alternative policy judgments. Such ranges of alternative standards would continue to provide a

framework for CASAC advice and recommendations and for public comment. This document would be based primarily and directly on the information in the final synthesis chapter of the science assessment and in the risk/exposure assessment report. This document could further elaborate on important concepts and terms that have both science and policy components, building upon a discussion of these concepts in the initial planning document. To the extent that such a document included research recommendations, as are included in current Staff Papers, it could provide important input to the identification of policy-relevant issues for incorporation in the integrated plan for the next review.

- Since all the relevant science and risk/exposure assessment information would already have been reviewed by CASAC and the public by the time such a policy assessment document would be prepared, it might be reasonable to make only one draft of the policy assessment document available for CASAC and public review. This approach would shorten the time between the completion of the science and risk/exposure assessments and publication of a NPR. Following review, comments received could be incorporated into a final policy assessment document, or alternatively could be addressed directly in the NPR, without taking time to prepare a separate final policy assessment document.

- Such a policy assessment document could reflect staff views, as does the current Staff Paper, EPA senior management views, or both. Ranges of alternative standards could continue to reflect staff recommendations for the Administrator's consideration, or alternatively could be presented as a set of options defined by staff and/or senior management for the purpose of eliciting more focused comments on alternative standards. To the extent that the policy assessment reflects senior management views, consideration could also be given to the option of publishing the document in the form of an ANPR, which would solicit comment from CASAC and the public, rather than as a report.

3.2.5 Rulemaking

The following options would help improve the Agency's ability to use the most recent science and to ensure that the assessment of the science that forms the basis for the Administrator's decisions is appropriately transparent.

- Prior to initiating an interagency review, the role of the interagency review process in reviewing the science, risk/exposure, and policy assessments upon which EPA's proposed decisions are based could be more clearly defined for all participants in the review. The transparency of whose views are being expressed in the preamble to the rulemaking notices could be enhanced, in part through a more clearly defined interagency review process.

- Both an improvement in the timeliness of the other components of the review, as well as development of an ongoing survey of scientific information, would serve

to reduce the amount of new science that might need to be examined during the public comment period. A survey and provisional assessment of "new" science could be prepared, as appropriate, following proposed rulemaking.

3.2.6 CASAC Review

We believe that the effectiveness of the CASAC review process would be enhanced if many of the options identified above for changes to the science, risk/exposure, and policy assessments were adopted. Many of these options are consistent with the comments offered by individual CASAC members for ways to improve the NAAQS review process. In addition, we believe that the following options would also serve to enhance the effectiveness of CASAC reviews:

- EPA could prepare more comprehensive information and guidance on CASAC's statutory roles and responsibilities to enhance the orientation of CASAC panel members to the NAAQS review process. Among other things, this information and guidance could serve to increase awareness of the importance of maintaining the distinction between science and policy judgments in the advice and recommendations prepared by CASAC.

- With regard to the issue of "closure," we believe that this is an important issue that warrants further consideration by EPA and perhaps communication with CASAC so it can be addressed in a manner that meets both CASAC's and EPA's needs.

- The SAB Staff Office could consider issues raised by some commenters during this process review with regard to the selection and management of CASAC NAAQS review panels to identify any areas where changes are warranted or where current procedures could be made more transparent.

3.2.7 Public Participation

We make the following observations about public participation in the context of an alternative framework for the NAAQS process:

- Opportunities for public participation are available throughout the current process and such opportunities would remain in the alternative framework and with any of the options for change discussed above.

- While responses to public comments received on draft documents prior to publication of the NPR could be more clearly documented, which could serve to enhance the transparency of the process, such an effort would add to the time for the review and would require additional resources.

4. WORKGROUP CONCLUSIONS AND RECOMMENDATIONS

In considering the questions that framed this process review, and the options for changing the NAAQS review process discussed above, we have reached the following conclusions:

- Past reviews demonstrate that, in the absence of unusual developments, it is possible to complete the current process for reviewing a NAAQS within the statutory 5-year review cycle. However, the likelihood that the process *will* be completed in that time frame, in the absence of court-imposed schedules, can be increased by making changes that generally create a more policy-relevant focus and a more internally coordinated, consultative approach to each of the elements of the process. While this conclusion applies to the process for reviewing the NAAQS for any one pollutant, it does not address important resource-related issues that would arise in considering the likelihood that all of the NAAQS can regularly be reviewed within 5-year review cycles (as noted below under recommendations for continuing work).

- Within the review cycle, NAAQS decisions could be based on more recent science than has historically been available for consideration by adopting changes that provide a continual compilation/evaluation of science, enhance the linkages between the science and risk/exposure assessments, facilitate reaching proposed policy decisions as quickly as possible after the completion of those assessments, and expedite provisional assessment of "new" science, when appropriate, during the rulemaking process (as noted below under recommendations for continuing work).

- Distinctions between science and policy judgments made by EPA and by CASAC throughout the NAAQS review process can be clarified and made more transparent, in part, by adopting changes that facilitate the preparation and review of a policy assessment document that is based on, but separate from, the science and risk/exposure assessments. This can also be done by increasing the awareness of CASAC Review Panel members of the importance of this distinction and the need for a science-based review of policy issues. Additionally, this can be done by clarifying to the public the role of the interagency review process in reviewing EPA's discussion and views on science and policy issues in the rulemaking notices.

- Changes that enhance the linkages between the preparation of the science assessment and risk/exposure assessment, which in turn would enhance the linkages between CASAC reviews of these two documents, can also help to ensure that more complete, policy-relevant characterizations of uncertainties are incorporated into these assessments.

To effect these improvements, we recommend implementing the general changes to the NAAQS process identified below. The extent to which the projected improvements are likely to be realized depends not only on which changes and related options are adopted, but also on the extent to which adequate resources and continued management support are provided for the effective and ongoing implementation of any such changes.

- Combine the current separate planning activities into the preparation of one integrated planning document that focuses the science, risk/exposure, and policy assessments on a set of policy-relevant issues, which reflect key uncertainties and gaps in knowledge identified at the end of the last review, and that includes criteria for identifying key policy-relevant studies and for assessing the weight of the evidence for important scientific issues. Include in this plan a schedule for the review that maximizes the amount of time allotted to the science and risk/exposure assessments; that more closely links these assessments through a more coordinated, consultative process; that minimizes the time between the completion of these assessments and reaching proposed decisions on the NAAQS; and that allows for provisional assessment of "new" science, as appropriate, during the rulemaking process. The preparation of such an integrated, policy-relevant plan would provide an opportunity for early involvement of EPA senior management and/or outside parties in the framing of policy-relevant issues.

- Restructure the science assessment document to be a more concise evaluation, integration, and synthesis of the most policy-relevant science (with comprehensive annexes that include generally descriptive information), and to include key science judgments that are integral to the risk/exposure assessments. This document should include a presentation of the synthesis of policy-relevant science not only for a scientific audience, but also in language that will be understood and meaningful to policy makers, perhaps in the form of a "plain-English" executive summary.

- Develop and implement a continuous process to identify, compile, characterize, and prioritize new scientific studies with the assistance of state-of-the-art electronic databases developed by ORD. We recognize that the development of such a system is complex and potentially resource-intensive, and believe that additional time is needed to explore various approaches, options, and resource requirements for its development. Consideration of the extent to which such a system would facilitate a survey of "new" science during the rulemaking and/or preparation of more frequent periodic updates should be done in conjunction with efforts to develop such a system.

- Develop a more concise risk/exposure assessment document focused on key results, observations, and uncertainties (similar to the risk/exposure chapter(s) that are now included in Staff Papers). This document would be supported with comprehensive annexes that include all relevant background information, assumptions, results, and assessments of variability and uncertainty to ensure the

transparency of the assessment (similar to the information now included in contractor reports).

- To the extent that the changes recommended above are adopted and effectively implemented, replace the Staff Paper as currently structured with a more narrowly focused policy assessment document. This document would be based on the information contained in the science and risk/exposure assessments, and would also include the results of policy-relevant air quality analyses. This document could focus on identification of a set of evidence- and risk-based approaches for reaching policy judgments; consideration of the adequacy of the current standards and whether alternative standards should be assessed for consideration; and identification of a range of options for alternative standards (in terms of indicators, averaging times, forms, and ranges of levels) that might be considered by the Administrator in making policy choices. We recognize that important and complex issues are involved in deciding the scope of such a document, as well as deciding whether such a document would continue to reflect staff views, EPA senior management views, or both, and how that choice may affect the process by which such a document would be reviewed by CASAC and the public.

- Work with the Science Advisory Board (SAB) Staff Office to consider the formation of a CASAC subcommittees on risk/exposure assessment, when appropriate; to examine the extent to which additional measures can be taken to orient new CASAC panel members to the NAAQS review process and to increase awareness of the importance of maintaining the distinction between science and policy judgments in the Committee's advice and recommendations; and to give further consideration to the issue of "closure." Request that the SAB Staff Office consider issues raised by some commenters during this process review with regard to the selection and management of the CASAC NAAQS review panels.

We also offer the following additional recommendations for continuing this examination of the NAAQS process beyond April 3, 2006:

- Continue a dialogue with the public in the coming months on the issues addressed in this review of the NAAQS process. As indicated above, we consulted with a limited set of stakeholder groups that have been actively involved in NAAQS reviews to solicit the views of knowledgeable individuals on how the NAAQS process might be improved. However, time constraints for this initial report precluded the broader involvement of many other parties who may also have valuable insights as to how the NAAQS process might be improved and a strong interest in providing comments on it.

- Continue to examine more specific options for implementing those changes that are adopted, or that remain under consideration, as well as their organizational, staffing, and resources implications. In particular, as noted above, continue to explore various approaches, options, and resource requirements for the

development of a state-of-the-art electronic database system to facilitate the continuous identification, compilation, characterization, and prioritization of relevant published scientific studies. With regard to assessing "new" science during rulemaking, continue to examine the questions of when and how assessment of "new" science could appropriately be performed and used during the rulemaking.

- More broadly, consider the organizational and resource implications for EPA of coordinating and conducting reviews of all NAAQS on 5-year cycles, and work with the SAB Staff Office to consider the implications of constituting CASAC Panels and managing the CASAC review process for all such NAAQS reviews. This broader examination of how EPA plans for and implements reviews of all the NAAQS might include consideration of some or all of the following issues:

  - The variable nature of the amount and complexity of the work involved in reviewing the NAAQS for the different criteria pollutants, based in part on the volume and nature of available new science, beyond that included in the last science assessment, and how these factors relate to the amount of time and resources needed to conduct each review.

  - The value of conducting various NAAQS reviews on somewhat different schedules, within the statutory 5-year review cycle, taking into account the factors identified above.

  - The desirability of building more flexibility into the planning of NAAQS reviews to allow for integration across pollutants when the nature of the available science suggests that some degree of integration could result in a more scientifically sound and/or efficient review process.

- To the extent that any recommendations for continuing this examination of the NAAQS process beyond April 3, 2006 are accepted, we will prepare a plan for the development and implementation of the continuing actions, including target dates and organizational responsibilities for interim progress reports and for the phase-in and implementation of the actions.