

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.