



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

**OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD**

December 16, 2008

The Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Dear Administrator Johnson,

As the new Chair of the Clean Air Scientific Advisory Committee (CASAC or Committee), I am writing on behalf of the Committee to reiterate and expand on our recommendations regarding implementation of the Agency's revised process for reviewing the National Ambient Air Quality Standards (NAAQS) for criteria air pollutants. The CASAC's mandate under the Clean Air Act is to provide independent scientific advice and recommendations on the adequacy and basis of existing, new, or revised NAAQS that are needed to protect both public health and public welfare, and, in the case of the protection of public health, to do so with "an adequate margin of safety." CASAC and the EPA have now worked within this new process for sufficient time to consider how further improvements can be achieved. Several changes could be made in the current NAAQS process that would facilitate carrying out our shared mission.

The Agency announced its new five-step NAAQS process in Deputy Administrator Marcus Peacock's memo of December 2006. Since then, CASAC has offered comments and suggestions which resulted in the Agency's modifications of the NAAQS process as expressed in the Deputy Administrator's additional memoranda of January 3, 2008 and September 8, 2008. Now that CASAC has had the opportunity to complete the first four steps of the new NAAQS review process (workshop, Integrated Plan, Integrated Science Assessment (ISA), Risk and Exposure Assessment (REA) for public health effects of Oxides of Nitrogen (NO₂), we suggest additional modifications that will further improve the process and enhance the scientific foundation for EPA's decisions. We would like to commend the EPA for its final version of the REA for health effects of NO₂. This REA succeeded in linking the scientific evidence in the ISA and the REA to science supporting the four elements of NAAQS (indicator, level, statistical form, and averaging time) all of which will be discussed in the forthcoming Advanced Notice of Proposed Rulemaking (ANPR).

At this juncture we recommend careful documentation of the new process for revising the NAAQS as this process has evolved since the original memo from Deputy

Administrator Peacock in 2006. More specific guidance should be provided to better standardize the implementation of various parts of the new NAAQS review process. With experience gained to date using the revised NAAQS process, we recommend that a clear description of the purpose, contents, and approach for developing each document be prepared in written form and provided for public and CASAC review.

While we recognize that the pace of the required NAAQS reviews is demanding, we request strict adherence to the NAAQS review schedule for each criteria pollutant. During the review of the public-health based NAAQS for Oxides of Nitrogen, the final summary chapter was not available to us until release of the final REA and thus it did not receive CASAC review before publication. Moreover, the final REA for public-health effects of Oxides of Nitrogen Primary NAAQS was delayed beyond the time of the face-to-face meeting that had been previously scheduled for its review. Without insistence by CASAC on reviewing the entirety of the final REA, we would not have been able to offer our scientific input into the most critical part of the REA. We are concerned that any slippage in schedules – which we recognize to be demanding both for EPA and for CASAC -- may jeopardize the quality of CASAC's input. In turn, inadequate review by CASAC would reduce the quality of the scientific foundation that EPA uses to support NAAQS revisions. As with NO₂, such input is particularly critical as the review process moves to its end and the ANPR builds on the findings and alternative policy options under consideration within the REA and further described in the ANPR. In the specific, recent example of NO₂, CASAC requested and received the opportunity to review the final chapter of the REA for Oxides of Nitrogen, but last-minute schedule improvisations are not optimal for a thorough scientific review. With adequate time, we can serve you and the public better.

Additionally, we suggest that the policy-relevant considerations be developed earlier in the new NAAQS review process -- perhaps as early as the *Scope and Methods Plan for the REA* since this is the first document that lays out EPA's plans for conducting its risk assessment. By outlining specific alternative policy options in first REA drafts, much of the discussion around subsequent drafts of the *Risk and Exposure Assessment* (REA) and the *Integrated Science Assessment* (ISA) would be better focused. Delineation of alternative policy choices would also help to better frame charge questions for CASAC's consideration and establish appropriate linkages between the REA and the ISA for each Criteria Pollutant.

We recommend further specificity and clarity in the formulation of EPA's suggested charge questions. For example, a recent charge question read as follows: "To what extent is the assessment, interpretation, and presentation of the results of the exposure analysis technically sound, clearly communicated, and appropriately characterized." This rather vague kind of charge question is far too general and thus very difficult to answer with precision. The EPA should develop its charge questions with emphasis on the key elements of the documents that will figure in revisions to the NAAQS. Attention by EPA to the formulation and clarity of charge questions will result in a better focus of the review process on the key policy-relevant issues.

We also ask that EPA adopt a practice of responding more specifically to CASAC's major concerns summarized in our letters to the EPA Administrator. In standard peer reviews, authors generally prepare a "response to peer review comments" that addresses major issues raised by the reviewers. To date, we typically receive general feedback from EPA on how our comments have been addressed in revised drafts. In fact, CASAC typically is not provided with a document indicating what has been changed from the prior draft; this makes it necessary for CASAC members to laboriously review and compare lengthy text, tables and figures to identify changes that have been made and others that perhaps have not been made. If possible, a "track changes" kind of revision process would be very helpful.

As always, CASAC appreciates the opportunity to provide independent advice to the Agency as it pursues its mission to safeguard the nation's air quality. We look forward to working with the Agency in strengthening the NAAQS process.

Sincerely,

/Signed/

Dr. Jonathan M. Samet, Chair
Clean Air Scientific Advisory Committee

cc: Marcus Peacock, Deputy Administrator