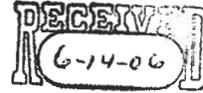




**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
Washington, D.C.



**MEMORANDUM**

**SUBJECT:** Additional Input from the Clean Air Scientific Advisory Committee on the Agency's Process for Reviewing National Ambient Air Quality Standards

**FROM:** William Wehrum  
Acting Assistant Administrator  
for Air and Radiation

A handwritten signature in black ink, appearing to read "W. Wehrum".

George Gray  
Assistant Administrator  
for Research and Development

A handwritten signature in black ink, appearing to read "G. Gray".

**TO:** Vanessa Vu, Director  
Science Advisory Board Staff Office

In conducting a "top-to-bottom" review of the process used to periodically review and revise, as appropriate, the air quality criteria and national ambient air quality standards (NAAQS), as requested by Deputy Administrator Marcus Peacock, we solicited input from members of the Clean Air Scientific Advisory Committee (CASAC) in February 2006, recognizing CASAC members' unique perspective and role in the NAAQS review process. Our request at that time focused on several key questions related to the timeliness of the NAAQS review process, consideration of the most recent available science, distinctions between science and policy judgments, and characterizing uncertainties in scientific information. The responses provided by several current and former CASAC members on March 16, 2006, have been very useful in our examination of the NAAQS review process, and are reflected in the March 2006 report of the NAAQS Process Review Workgroup.

On April 3, 2006, we communicated to the Deputy Administrator our endorsement of the Workgroup recommendations put forward in that report and offered our additional recommendations. In particular, we recommended that consideration be given to additional changes to the policy assessment/rulemaking activity, including reflecting the Agency's views in the policy assessment document and publishing that document as an advance notice of proposed rulemaking. We noted that various components of these recommendations would benefit from additional consideration, including further consultation with CASAC members—past and current—and the public.

With the support of the Deputy Administrator, we are seeking additional input from CASAC and the public on various components of these recommendations, even as we are now taking actions to begin implementing a number of basic structural Workgroup recommendations in upcoming NAAQS review activities. In this regard, we appreciate the preliminary thoughts on the recommended changes to the process that the current CASAC provided to Administrator Johnson on May 12, 2006.

We are looking forward to the meeting with CASAC that you are convening on June 29, 2006, to facilitate additional input on the NAAQS review process. To help focus our discussion at the meeting, we have prepared some background information on our current plans for incorporating basic structural changes into NAAQS reviews, as well as a set of discussion questions that address the various structural elements of the NAAQS review process (attached). Further, as the responses previously provided by current and former CASAC members have been very useful in our examination of the NAAQS review process, to the extent practicable, we would encourage CASAC to draw upon the expertise of its past members in addition to its own as the committee develops its input.

We appreciate the CASAC's time in considering these questions and in meeting with us on this important matter.

Attachment

## Attachment

### **Background Information and Discussion Questions on the Review of the Process for Setting NAAQS**

#### **Prepared for a Meeting on June 29, 2006, with the Clean Air Scientific Advisory Committee (CASAC)**

The following provides background information on our recommended structure for the NAAQS review, encompassing four activities: planning, science assessment, risk/exposure assessment, and policy assessment/rulemaking. As discussed below, the basic structural changes that we intend to start incorporating into NAAQS reviews include combining separate planning activities into one integrated plan that focuses on policy-relevant issues; restructuring the Air Quality Criteria Document into a more concise science assessment document; preparing more concise risk/exposure assessment documents with an enhanced focus on characterizing uncertainties; and, to the extent that these changes are implemented, replacing the Staff Paper as currently structured with a more narrowly-focused policy assessment document.

Questions for discussion are included to help focus the Agency's upcoming consultation with CASAC members on various components of these recommendations, drawing upon the preliminary thoughts of the current CASAC members as expressed in their May 12, 2006, letter to Administrator Johnson.

- **NAAQS Review Plan**

As recommended in the Workgroup report, we plan to 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, reflecting key uncertainties and gaps in knowledge identified at the end of the last review. This plan would include criteria for identifying key policy-relevant studies and for assessing the weight of the evidence for important scientific issues. This plan would also include 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, CASAC and/or outside parties in the framing of policy-relevant issues.

- What key issues can and should be addressed in a NAAQS review plan, recognizing that this plan will be developed before the science assessment?

- Taking into consideration your preliminary thoughts on a joint NCEA/OAQPS science workshop as the first step in the NAAQS review process, what are your views on the role of CASAC and the public in providing input and/or review of such plans?

- Science Assessment

As recommended in the Workgroup report, we plan to restructure the Air Quality Criteria Document into a science assessment document that is 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.

- Taking into consideration your preliminary thoughts on creating a highly streamlined science assessment that is not comprehensive in nature, what are your thoughts on how such a document would best assess all relevant information, recognizing that the air quality criteria are to “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”?
- With regard to your preliminary thoughts on combining the science assessment and policy assessment into one document, how might such a document best make clear distinctions between science and policy judgments?
- If such a combined document were to be prepared, how might your advice to the Administrator best distinguish between science and policy issues?
- What types of science judgments are integral to conducting risk/exposure assessments and to what extent do you think those judgments are best made in the science assessment?
- What are your views on the projected timeline for developing the risk/exposure assessment methodologies concurrent with the preparation of the first draft science assessment, and for conducting the first phase risk/exposure assessment (projecting risk/exposure associated with recent air quality and with just attaining the current standards) concurrent with the preparation of the second draft science assessment?

We have endorsed the recommendation in the Workgroup report to 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. 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. Further, we have concluded that consideration of the extent to which such a system would facilitate a survey of "new" science during the NAAQS rulemaking and/or preparation of more frequent periodic updates should be done in conjunction with efforts to develop such a system.

- What are your views on how best to provide for a more continuous process of identifying, compiling, characterizing, and prioritizing new scientific studies that does not begin and end with the preparation of each science assessment done as part of periodic NAAQS reviews?
- To what extent would it be practical and/or useful for such a continuous process to have a multi-pollutant focus rather than focusing on each pollutant separately?
- Can you suggest any examples that the Agency might consider in designing and implementing such a process?
- Taking into consideration your preliminary thinking on this issue, when and how could assessment of "new" science appropriately be performed and used during the NAAQS rulemaking process?

- Risk/Exposure Assessment

As recommended in the Workgroup report, we plan to 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 technical support documents currently reviewed by the CASAC and public). We plan to work with the Science Advisory Board Staff Office to consider the formation of a CASAC subcommittee on risk/exposure assessments, when appropriate, to provide more focused feedback and advice on planning these assessments, including input on the methodology used and the characterization of uncertainties.

- What are your views on forming a CASAC subcommittee to provide more focused feedback and advice on the risk/exposure assessments?
- How might such a subcommittee best function and interact with the full CASAC and/or the broader CASAC Panels that are constituted to advise the Agency on the NAAQS reviews for individual criteria pollutants?

- Policy Assessment/Rulemaking

As recommended in the Workgroup report, we plan to replace the Staff Paper as currently structured with a more narrowly focused policy assessment document to the extent that the changes discussed above are adopted and effectively implemented. 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 would 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.

- What steps can be taken to ensure that the roles previously played by the Staff Paper are effectively addressed in the science assessment, risk/exposure assessment, and the policy assessment?
- What are your views on whether and how CASAC's role of providing advice to the Administrator on the standards would be affected by having an opportunity to review just one draft of the policy assessment, as envisioned in the recommended timeline?

We have additionally concluded that it is appropriate for the final policy assessment to reflect the Agency's views, consistent with EPA practice in other rulemakings. We also believe that further consideration should be given to publishing the policy assessment through an advance notice of proposed rulemaking (ANPR) that solicits review and comment from CASAC and the public. Comments received on an ANPR would be taken into consideration in developing the proposal notice. Unlike the process of preparing both a draft and final assessment document that addresses such comments prior to the preparation of a proposal notice, the use of an ANPR may eliminate the preparation of a "final" policy assessment.

- To what extent, if at all, do you think that it would affect your role in providing advice to the Administrator if the draft and/or final policy assessment reflects Agency rather than staff views?
- To what extent, if at all, do you think it would affect your role if the policy assessment were to be published in conjunction with an advance notice of proposed rulemaking rather than in the form of both a draft and final assessment document?

- General Issues

- The generic NAAQS review timeline presented in the Workgroup report is intended to maximize the time allotted to conducting the science and risk/exposure assessments within a 5-year review cycle, and to allow EPA to reach proposed decisions as close in time to the completion of the science and risk/exposure assessments as possible. As a general matter, what are your views on these goals?

- To what extent do you feel that the relative amount of time allotted to each activity in the generic timeline, and the degree to which certain activities are projected to be done concurrently, is appropriate?
- The Workgroup report noted that most CASAC commenters had previously expressed strong support for the historic closure process. CASAC used this process to reach consensus on advising the Administrator when a Criteria Document and Staff Paper under review were judged to provide an adequate review of the available science and an adequate summary of our understanding of the scientific basis for making regulatory NAAQS decisions, respectively. To what extent do you believe that the recommended generic timeline provides adequate and appropriate opportunities for CASAC to reach consensus so as to be able to provide this type of advice to the Administrator?