



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

DEC 7 2006

MEMORANDUM

FROM: Marcus Peacock
Deputy Administrator

A handwritten signature in black ink that reads "Marcus Peacock".

DEPUTY ADMINISTRATOR

TO: Dr. George Gray
Assistant Administrator
Office of Research and Development

Bill Wehrum
Acting Assistant Administrator
Office of Air and Radiation

RE: Process for Reviewing National Ambient Air Quality Standards

On December 15, 2005, I requested that you establish and co-chair an Agency working group to conduct a top-to-bottom review of the process the Agency uses in setting and reviewing the National Ambient Air Quality Standards (NAAQS). To fulfill this request, you formed an intra-agency working group, which sought advice and recommendations from current and former members of the Clean Air Scientific Advisory Committee (CASAC) and other stakeholder groups that have substantial experience with the NAAQS process. Based in large part on this input, the Agency working group developed a report containing a set of recommendations for possible changes to the NAAQS process. On April 3, 2006 you forwarded this workgroup report to me with your endorsement together with your additional recommendations that Agency views should be reflected in any policy assessments made available for public comment, that serious consideration should be given to publishing a policy assessment document as an advance notice of proposed rulemaking (ANPR), and that the Agency would benefit from further consultation with CASAC and the public prior to my reaching final decisions on the NAAQS review process.

In the months following the release of this report, you and your senior staff held additional stakeholder meetings, including both a general public workshop and a meeting with CASAC in recognition of CASAC members' unique perspective and role in the NAAQS review process. Based on your advice to me following these public meetings and additional discussions with the internal working group, I have decided to institute a number of changes to the NAAQS review process. These changes reflect many of the recommendations contained in the working group's April report. Specifically, I direct your offices to proceed with the general structure recommended in your April 3, 2006 memo, as discussed below, which involves four major components: planning, science assessment, risk/exposure assessment, and policy assessment/rulemaking.

- *Planning*: The preparation of an integrated, policy-relevant plan as described in the workgroup report should immediately follow the completion of the prior NAAQS

review. Consistent with the advice and recommendations received from CASAC, during this phase the Agency should conduct an early workshop to get input from CASAC, EPA-contracted outside scientists, and the public regarding policy-relevant questions from the prior review and/or new policy-relevant science issues that should be addressed in the current review. Following this workshop, a draft integrated science/policy plan outlining schedule, process, and a set of key policy-relevant issues should be developed to guide the full review process. CASAC must be consulted on the draft integrated plan prior to the issuance of a final plan, and Agency management will also provide advice and guidance throughout the planning phase.

- *Integrated Science Assessment:* The Agency should restructure the science assessment document to be a more concise evaluation, integration and synthesis of the most policy-relevant science, including key science judgments that will be used in conducting the risk and exposure assessments. CASAC and the public must have an opportunity to evaluate and comment on up to two drafts of the integrated science assessment (ISA) document. The ISA will be supported by a more detailed and comprehensive science assessment support document, which will eventually be linked to an electronic database of scientific studies. The development and implementation of such a database will facilitate a more continuous process to identify, compile, characterize, and prioritize new scientific studies.
- *Risk/Exposure Assessment:* The Agency should develop a more concise risk/exposure assessment document focused on key results, observations, and uncertainties. The development of methodologies to be used in the risk/exposure assessment, should be closely linked to the preparation of the ISA and should continue to be reviewed by CASAC and the public to ensure the characterization of risk and exposure are informed by the clearest possible understanding of the available scientific information. Therefore, the risk/exposure methodologies should be prepared in concert with the development of the first draft ISA. Final application of the methodologies to particular air quality levels should follow and be informed by the final ISA. In addition, the Agency's Science Advisory Board Staff Office should focus on strengthening the risk/exposure expertise on CASAC Panels by selecting additional members with knowledge of these areas.
- *Policy Assessment/Rulemaking:* Following the ISA and the Risk/Exposure Assessment, the Agency will develop a policy assessment that reflects the Agency's views, consistent with EPA's practice in other rulemakings. This document, in conjunction with the ISA and the Risk/Exposure Assessment, will replace the Staff Paper. Moreover, the policy assessment should identify conceptual evidence- and risk-based approaches for reaching policy judgments, discuss what the science and risk/exposure assessments say about the adequacy of the current standards, and present any preliminary risk/exposure information associated with alternative standards. This policy assessment should also describe a range of options for standard setting, in terms of indicators, averaging times, form, and ranges of levels for any alternative standards, along with a description of the alternative underlying interpretations of the scientific evidence and risk/exposure information that might support such alternative standards and that could be considered by the Administrator

in making NAAQS decisions. Such an assessment should help to “bridge the gap” between the Agency’s scientific assessment and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the standards. This policy assessment should be published in the Federal Register as an Advance Notice of Proposed Rulemaking (ANPR), with supporting documents placed in the rulemaking record as appropriate. The use of an ANPR will provide an opportunity for both CASAC and the public to evaluate the policy options under consideration and offer detailed comments and recommendations to inform the development of a proposed rule. Issuance of a proposed and final rule will complete the rulemaking process.

I believe these changes will help to improve the efficiency of the NAAQS review process while ensuring that the Agency’s decisions are informed by the best available science and broad participation among experts in the scientific community. These improvements will help the Agency meet the goal of reviewing each NAAQS on a 5-year cycle as required by the Clean Air Act without compromising the scientific integrity of the process. It is imperative that the NAAQS process continue to adhere to the highest scientific standards to ensure adequate protection of public health and welfare.

In moving forward, I urge you to apply these revisions to the NAAQS review process to all upcoming NAAQS reviews and to any ongoing reviews. As to the latter, I would like these revisions to apply to the review of lead, which is currently underway. The last formal draft Staff Paper for lead, adhering to the previous standard setting process, has been transmitted to CASAC, and therefore the relevant changes noted above should apply to the remainder of the lead review.

I wish to thank both of you for the leadership you have demonstrated in moving this process forward, and to thank each member of the working group for providing invaluable assistance in helping to revitalize a process which forms the cornerstone of EPA’s air quality programs. I feel confident that the changes we are instituting in the NAAQS review process will ensure that the Agency can meet the Administrator’s goal of using the best available science to protect public health and the environment.