

Additional CASAC Member Individual Comments on EPA's NAAQS Process

Dr. James Crapo

March 20, 2006

The following are my thoughts about how the NAAQS process could be improved:

Timeliness and Efficiency of the Current Process for both EPA's and CASAC's Review of the Air Quality Criteria and the NAAQS

Having served on CASAC during the recent and ongoing reviews of ozone, PM, and lead, it is my observation that the current process has evolved into an inefficient and ineffective process. This leads to major delays and reduces the ability of CASAC to provide rigorous scientific input into EPA staff recommendations and policy decisions. The most critical discussions of each topic are often delayed until the process is under court order to proceed and adequate time is not available for effective and thoughtful interactions.

The current process requires that a first and second draft of the air quality criteria document (AQCD) be prepared [by NCEA-RTP for a given criteria air pollutant] and discussed by CASAC, which is then followed by a first and second draft of staff papers which are discussed by CASAC, leading to a final CASAC letter to the Administrator. This process produces expansive review documents on the literature underlying each subject area but adds years to the review cycle and inhibits effective discussion of the critical issue, *i.e.*, whether or not there are adverse health effects at current air quality standards. The AQCDs contain no conclusions regarding the air quality standard and CASAC is inhibited from meaningfully discussing this issue during the process of reviewing the AQCD. The majority of CASAC time is often spent on reviewing literature rather than discussing the critical issue of whether or not adverse health effects exist at current air quality standards. Finally, the majority of the literature discussed in the AQCD focuses on levels that are not relevant to current environmental conditions in the United States or the air quality standards. In each review cycle there are only a small number of critical scientific studies that address the form and standard of the current NAAQS. These critical articles are nearly lost in the massive size of the current AQCD and the process established for its review.

The current review of the air quality standard for lead illustrates the above problems. The current air quality standard for lead was set in 1978 and EPA has not conducted a review of this standard in the past 15 years. The World Health Organization has set an air quality standard for lead that is 3 times lower than the current U.S. standard. This was done in the 1980s. The most recent AQCD for lead is a massive document requiring enormous time by the EPA staff to prepare and which is still not comprehensive. In addition, after weeks of review and a two-day meeting discussing this document, CASAC has not yet discussed the question of whether or not the current NAAQS for lead is adequately protective of human health. I would conclude that the current process does not allow the EPA and its [Clean Air] Scientific Advisory Committee to

effectively address their charge to carry out a timely and effective review of air quality standards for the United States.

I would recommend that the entire process be changed along the following guidelines:

- Requirement for a comprehensive AQCD should be eliminated.
- A short AQCD (page-limited) focused only on scientific studies that address relevant air pollutant levels in the United States and which address adverse health effects at those levels should be prepared.
- The staff papers should be incorporated into the AQCD reducing this to one document which could undergo two or at most three reviews.
- The air quality document should begin with an interpretation (staff recommendation) on the quality of current science relative to the question of adverse health effects at the existing air quality standard. The document should then defend that staff interpretation of the scientific literature through its summary of studies that directly address the critical question.
- Comprehensive summaries of the literature should be placed in an appendix and only articles deemed to be relevant to the question of the current form and standard for each regulated air pollutant should be included in the primary document.
- The discussions at CASAC meeting should focus on whether or not the current air quality standard is adequately protective of human health.

The above recommended process would be far more efficient in both the use of EPA staff time and the time of CASAC members. It would dramatically reduce current inefficiencies and allow the EPA to meet its obligation for a timely review of air quality criteria and NAAQS. It would also allow CASAC to have a more effective role in defining the scientific basis for changing or not changing current NAAQS.

Consideration of the Most Recent Available Science

The above recommended change in the process for EPA and CASAC review of air quality criteria and NAAQS will substantially enhance our ability to consider the most recent available science. No cut-off for a published article to be discussed in the preparation of the final document would need to be imposed. Because critical articles relevant to the final decision would be considered up to and including the final draft of the document, there would be opportunity for them to be considered by EPA staff and discussed by CASAC. By restricting the focus to only articles that directly deal with the question of current air quality levels and the presence or absence of adverse health effects at current air quality standards, there would be no need to impose a cut-off for consideration of best science.

In summary, the EPA NAAQS review process and policy judgments can be made far more efficient if changes are made to require preparation of smaller documents that focus on the

question of the adequacy of current air quality standards to protect human health and to allow both staff and CASAC to focus on this question from the inception of each review cycle. The process could ideally be completed in less than one year, requiring two and at most three cycles of discussions with CASAC and should result in a more effective statement to the Administrator regarding the science that should be used as a factor in making policy judgments.

Sincerely,

James D. Crapo, M.D.
Professor of Medicine
National Jewish Medical and Research Center
and
Director, Clinical Science Ph.D. Program
University of Colorado Health Sciences Center

National Jewish Medical and Research Center
1400 Jackson Street, Denver, CO 80206
Tel: 303-398-1436; Fax: 303-270-2243; E-mail: crapoj@njc.org
<http://www.NationalJewish.org>