

Dr. Frederick J. Miller

Comments on the NAAQS process

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Over the last 30 years, I have seen the NAAQS process unfold from both sides of the table – first as an EPA employee coauthoring chapters in Criteria Documents (CD) and interacting with members of CASAC, later as an ad hoc CASAC reviewer, and since 2000 as an EPA appointed regular member of CASAC. Others who have served on CASAC have provided their insights and suggestions for improving the NAAQS process. I offer the following comments on the strengths and weaknesses of the NAAQS process and how, in my opinion, this process needs to be changed.

Timeliness and Efficiency of the Current NAAQS Review Process

With each review cycle for a NAAQS pollutant, the number of available scientific publications has grown exponentially. Because the Agency has viewed the CD as needing to be exhaustive in the review of all available peer-reviewed papers, the NAAQS CDs have greatly expanded in size, thereby requiring longer and longer periods of time for review and more iterations if the documents are not of high quality or if they contain biased discussions of the studies. This has led to court ordered time schedules and a less than desirable process – in short, the current process is broken and needs to be fixed.

Recommendation – Change the structure and focus of the CD

We need to know if effects are occurring below the levels of current NAAQS standards and if current standards are adequately protective of public health. Thus, the main focus of the CD should be to identify and discuss any new studies, for which there will usually be few, that establish effects below the levels of current standards. In addition studies that are relevant to the indicator for the standard, the averaging time, and the statistical form should be included. All other studies should be relegated to appendices tables if the Agency is required to or wants to be “complete” in its review of the literature.

If the structure and focus of the CD were done as suggested above, CASAC and Agency staff could have more interactive discussions on these results and interpretations of these critical studies. CASAC would be in a better position to identify if there are other studies that are relevant to the indicator variable, averaging time, numerical level, or statistical form. And most importantly, discussions at CASAC meetings could focus on whether or not current standards protect public health with an adequate margin of safety. This new focus might also enable the CD and Staff Paper to be combined into a single document, as has been recommended by CASAC member, Dr. James Crapo.

Consideration of the Most Recent Available Science

Since scientific research is iterative, there is no magical date when all is known about an issue. The lengthy time for preparation and review of the CD and Staff Paper for a

NAAQS pollutant is a by-product of the current process. If the CD structure and focus is changed as suggested above, the ability to incorporate the most recent available science would be greatly improved because the time interval for the process would be significantly shortened compared to what it is now.

Recommendation – Incorporate critical new science

If the CD focuses on studies that impact our knowledge about pollutant effects at or below the levels of current standards, there should be ample time in the review cycle to consider critical new science. The new science must, however, meet the following criteria: (1) be judged to be of such a nature that it could change the indicator variable, averaging time, numerical level, or statistical form of the standard, and (2) have been reviewed and vetted by CASAC. The second criterion is absolutely essential for maintaining the objectivity, credibility, and integrity of CASAC in fulfilling its statutory mandate. I agree with others who have noted that the recent EPA management change eliminating the long-standing finalization of the CD and the Staff Paper via a CASAC closure letter was unwise. The inclusion of newly available science should not be done by bypassing CASAC review of this new science.