NAAQS Update: PM, Ozone, and the Review of the NAAQS Review Process

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PM NAAQS Review

PM NAAQS Rulemaking

- Proposals: signed on December 20, 2005, covering PM_{2.5} and PM_{10-2.5}
 - PM NAAQS, Federal Reference Method, & Data Handling (Part 50)
 - Air Monitoring Regulations: Requirements for Reference and Equivalent Methods, Network Design Requirements (Parts 53 & 58)
- Public comment period: 90 days, ended April 17, 2006
- Public Hearings: March 8 in Philadelphia, Chicago and San Francisco
- Final Rule: Must be signed by September 27, 2006
- Current Tasks:
 - Consider and respond to public comments
 - Finish evaluation of new studies completed since close of criteria document, including any key studies submitted during comment period
 - Develop final Regulatory Impact Analysis
- For more information go to http://www.epa.gov/air/particles/actions.html

Ozone NAAQS Review

Status of Ozone NAAQS Review

- Final Criteria Document released March 21, 2006
 - Conference call with CASAC scheduled for May 12 to discuss additional CASAC comments on integrative health chapter
- Second draft Ozone (O₃) Staff Paper and exposure, health risk, and environmental effects assessments being revised/updated
 - Conference call with CASAC scheduled for May 12 to discuss additional CASAC comments on integrative health chapter
 - Targeting release in June 2006
 - August 24 and 25, 2006 CASAC meeting scheduled
- Final Staff Paper targeted for release by the end of September 2006
- Proposal March 2007
- Final December 2007

Overview of Exposure and Health Risk Assessment

- For 1997 NAAQS review:
 - Evaluated exposure and health risks in excess of "background" O₃ levels in 9 urban areas
 - Exposure estimates for "outdoor children"
 - Health risk estimates for decreased lung function and increased respiratory symptoms in children and respiratory hospital admissions
- For the current review:
 - Methods build on general approaches used in last review, with significant improvements in exposure model and inputs to the model
 - In Spring 2005, a draft Health Assessment Plan (included both exposure and risk assessment) was released for consultation with CASAC and for public comment
 - Plan significantly expanded coverage from last review:
 - More health endpoints (e.g., mortality)
 - Larger set of health studies providing exposure-response and concentrationresponse relationships
 - More urban areas included
 - Focus on characterizing uncertainty/variability in inputs and results

Ozone Health Effects

- Recent epidemiology studies provide highly suggestive evidence that ambient O₃ exposure contributes to premature mortality.
- Evidence of premature mortality remains uncertain but is much stronger and more extensive than the evidence that was available during the 1997 NAAQS review.
- In addition, ambient O₃ exposures potentially contribute to adverse cardiovascular effects.
- Overall, the epidemiologic findings of O₃-related health effects may be attributed to the direct effects of O₃ alone and/or in combination with co-pollutants (other photochemical oxidants, NO₂, SO₂, and fine PM).

Review of the NAAQS Review Process

Ongoing EPA Efforts to Improve the NAAQS Review Process

- "Top-to-bottom" review of the process by which NAAQS are reviewed and revised was requested by EPA Deputy Administrator Marcus Peacock in Dec. 15, 2005 memo
- Internal EPA workgroup formed to address key issues and make recommendations on the standard-setting process by April 3, 2006
- Key issues:
 - Timeliness (i.e., how to complete NAAQS reviews on a 5-year cycle as required by Clean Air Act)
 - Consideration of the most up-to-date scientific information
 - Differences between scientific and policy judgments
 - Defining and expressing uncertainties in scientific and technical information
- Meetings held with CASAC, stakeholders, and congressional staff
- Workgroup report and cover memo from Bill Wehrum and George Gray, along with stakeholder comments, available online at: http://www.epa.gov/ttn/naaqs/naaqs_process_report_march2006.pdf

Summary of Workgroup Recommendations and Key Issues

- Planning: one integrated plan; focus on key policy-relevant issues
- Science Assessment: restructure Criteria Document to be a concise synthesis of most policy-relevant science
 - Develop continuous survey/evaluation of new science; use of state-ofthe-art electronic databases
- Risk/Exposure Assessment: more concise document to focus on key results and uncertainties
- Policy Assessment: replace broader focused Staff Paper with more narrowly focused policy assessment document
 - Further consider whether to reflect views of staff, management, or both
- CASAC-related issues (work with SAB Staff Office)
 - Consider formation of risk/exposure subcommittee
 - Consider procedural issues (orientation of members; CASAC "closure")
 - Refer CASAC selection/management issues to SAB Staff Office
- Resource implications: need further consideration

Framework for Considering Options for Changes to the NAAQS Review Process

Planning	Science Assessment	Risk/exposure Assessment	Policy Assessment	Rulemaking
Plan for Review of Criteria and NAAQS Collaborate on one policy-relevant review plan Process and schedule for entire review Policy-relevant issues to frame science assessment Projected scope of risk/exposure assessments Overview of approach to policy assessment CASAC/public review	Science Assessment Continuous compilation/ characterization of new science in conjunction with periodic NAAQS- relevant integrative assessment • Continuous compilation of relevant new science in searchable database AND • Iterative drafts of concise, policy-relevant evaluation/ synthesis of new science with annexes of comprehensive descriptive information drawn from database [obviating the need for the synthesis of science now in a Staff Paper] • Allow for CASAC/public reviews of two drafts, with expectation of CASAC "closure" • Final document	Risk/exposure Assessments Include risk/exposure content that is now in a Staff Paper • Scope/methods plan clearly built on issues/ conclusions in science assessment document • CASAC/public review • Sequential drafts of phases of assessment in concise reports with comprehensive annexes (and supporting staff memos) • CASAC/public review • Final assessment reports	Policy Assessment Include policy assessment content that is now in a Staff Paper • Approach to evidence- and risk-based policy assessment • Policy-relevant air quality analyses (and supporting staff memos) • Draft policy assessment drawn from science and risk/exposure assessment documents, including recommended ranges of alternative standards • CASAC/public review, with CASAC advice on standards • Final document • Potentially additional CASAC advice on final document	Proposal Notice • Substantially drawn from science, risk, and policy assessment text and CASAC advice • Interagency review • Administrator's rationale for proposed decisions, • Reasons for any differences from CASAC recommendations Post-Proposal Actions • Public hearings and comments • Potential for additional CASAC advice • Planned assessment of "new" science drawing from ongoing compilation of studies in database • Document responding to all significant comments Final Notice • Summary of responses to significant comments • Consideration of "new" science assessment • Interagency review • Administrator's rationale for any changes to proposal

Additional recommendations from George Gray and Bill Wehrum

- Cover memo issued by Wehrum and Gray on April 3, 2006 endorsing workgroup recommendations.
- Two additional recommendations:
 - Agreed with workgroup that staff paper should be replaced with a more narrowly focused policy assessment document and concluded that "it is appropriate for the policy assessment document to reflect the Agency's views, consistent with EPA practice in other rulemakings."
 - Indicated that serious consideration should be given to publishing the policy assessment as an ANPR, which would also be reviewed by CASAC.

Next Steps

- Further consultation with CASAC and members of the public being planned to solicit additional input before moving forward to fully implement changes.
- Further consideration being given in particular to the additional recommendations offered by Bill Wehrum and George Gray.