7/10/2007

Review of the National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM)

Workshop to Discuss Policy-Relevant Science to Inform EPA's Integrated Plan for the Review of the Primary PM NAAQS

U.S. EPA
109 T.W. Alexander Drive
Research Triangle Park, North Carolina 27711
Building C – Auditorium

July 11-13, 2007

Background/Workshop Objective

This workshop is designed to inform the planning for EPA's next review of the primary (health-based) national ambient air quality standards (NAAQS) for particulate matter (PM) which EPA intends to complete in 2011.[1] This workshop will provide an opportunity for EPA to begin implementing a new, more efficient NAAQS review process[2] and highlight key policy issues around which EPA would structure the PM NAAQS review. Workshop participants will be asked to highlight significant new and emerging PM research and make recommendations to the Agency regarding the design and scope of this review. The goal of the workshop is to ensure that this review focuses on the key policy-relevant issues and considers the most meaningful new science to inform our understanding of these issues.

Workshop participants will be encouraged to think broadly about the body of new scientific evidence and how it can best be used to build upon the scientific evidence that supported the last PM NAAQS review. They will be invited to participate in an open dialogue regarding ways in which this new science could most effectively be used in the assessments that will serve as the foundation for the Agency's decisions. Specifically, the workshop discussions will provide important input as EPA considers the appropriate design and scope of the major elements of the PM review that will inform the Agency's policy assessment under the new NAAQS process: an integrated plan highlighting the key policy-relevant issues; an integrated science assessment; and a risk and/or exposure assessment.

Participants in the workshop will consist of a wide range of external experts as well as EPA staff representing a variety of areas of expertise (e.g., epidemiology, human and animal toxicology, statistics, risk/exposure analysis, atmospheric science). The workshop discussions are planned to build upon three prior publications or events:[3]

1. *Provisional Assessment of Recent Studies on Health Effects of Particulate Matter Exposure.* This assessment, which was completed by EPA's National Center for Environmental Assessment (NCEA) in July 2006, evaluated studies published too late for inclusion in the final PM criteria document in the last review.

[1] A similar workshop to discuss planning for the review of the secondary PM NAAQS will be held on July 16, 2007 in Research Triangle Park.
[2] Please see http://www.epa.gov/ttn/naaqs/ for more information on the new NAAQS review process.
[3] Please see http://www.epa.gov/air/particlepollution/actions.html to obtain a copy of the provisional science assessment, the notice of final rulemaking, and other related documents.

2. *National Ambient Air Quality Standards for Particulate Matter: Final Rule* (71 FR 61144, October 17, 2006). The preamble to the final rule included detailed discussions of policy-relevant issues central to the last review.

3. Materials from a December 2006 workshop sponsored by NCEA, entitled "Interpretation of Epidemiologic Studies of Multi-pollutant Exposure and Health Effects." The workshop dealt with important issues relevant to this review, such as the interpretation and understanding of criteria air pollutant health effects analyses in population-level epidemiologic studies, with a focus on multi-pollutant exposures.[4]

Workshop participants are encouraged to review each of these documents and/or supporting materials thoroughly before the meeting, as they provide important insights into new scientific advances and key policy-relevant questions.

Based in large part on the guidance received during this workshop, EPA will develop a draft integrated PM NAAQS review plan that will outline the schedule, process, and approaches for evaluating the relevant scientific information and addressing the key policy-relevant issues. The Clean Air Scientific Advisory Committee (CASAC) will be asked to conduct a consultation with the Agency on the draft integrated plan later this year, and the public will have the opportunity to comment on it as well. The final integrated plan will be used as a framework to guide the review. Our current schedule targets the release of a first draft PM integrated science assessment (ISA) in the summer of 2008 and completion of this ISA in the fall of 2009. We anticipate publishing a final PM risk/exposure assessment report and the Agency's policy assessment (in the form of an advance notice of proposed rulemaking [ANPR]) in the spring of 2010. CASAC and public review and comment will be solicited at several times during the development of these critical documents, which will provide the foundation upon which Agency decision-makers will ultimately base their decisions on the PM NAAQS. We currently anticipate that proposed decisions will be made around the end of 2010, with final decisions in the fall of 2011.

Proposed Meeting Structure

The workshop will begin with an introductory session in which EPA will highlight the significant features of the new NAAQS review process, specifically emphasizing key opportunities to improve the review process, and key policy-relevant issues, building on the experiences gained in the last PM NAAQS review. The meeting will then proceed with specific panel sessions, each facilitated by two co-chairs, addressing the following topic areas:

- Defining particle pollution
- Planning for the review of the health effects evidence
- Risk characterization - planning for quantitative risk and/or exposure assessments and characterizing the broader public health impacts of particle pollution

[4] The presentation materials from the epidemiological workshop will be provided to all panelists for the PM workshop as well as other participants upon request. The proceedings of the epidemiology workshop will be published in an upcoming special edition of *Journal of Exposure Science and Environmental Epidemiology* which will not be available prior to this workshop.

At the start of each session, the panel co-chairs will highlight appropriate background information and policy issues that were most critical for the 2006 PM NAAQS decisions. Other panel members and interested participants will be invited to join in a structured discussion of the topic. The co-chairs will moderate each session to ensure the discussion remains focused on providing guidance to help EPA plan the PM NAAQS review.

The detailed agenda below provides a starting point for each session. The questions presented in this agenda are not intended to be prescriptive; rather, they are intended to be illustrative of the types of issues that may be discussed. They represent a broad range of issues and we fully anticipate that some issues will warrant much more discussion time than other issues. This agenda is a "strawman" to guide the workshop discussions. We anticipate that this agenda will continue to evolve as panel members and other workshop participants provide input and respond to the comments of others during the course of the workshop.

Workshop to Discuss Policy-Relevant Science to Inform EPA's Integrated Plan for the Review of the Primary PM NAAQS

Wednesday, July 11, 2007

11:30 – 1:00 **Registration**

1:00 – 1:10 **Welcome/Purpose of Meeting**
Ila Cote, U.S. Environmental Protection Agency

1:10 – 1:30 **Restructuring the NAAQS Review Process: Opportunities for Improvement**
Lydia Wegman, U.S. Environmental Protection Agency
John Vandenberg, U.S. Environmental Protection Agency

1:30 – 2:00 **Building on the Last PM NAAQS Review: Focus on Key Policy-Relevant Issues**
Karen Martin, U.S. Environmental Protection Agency

2:00 – 5:30 Session I: Defining Particle Pollution

2:00 – 2:30 **Background/Introductory Remarks**
Co-Chairs: **William Wilson, U.S. Environmental Protection Agency**
Ronald Wyzga, Electric Power Research Institute

2:30 – 5:30 **Panel Discussion** (Break to be taken, as needed)

Panel Members: **Robert Devlin, Environmental Protection Agency; Neil Donahue, Carnegie Mellon University; Joe Mauderly, Lovelace Respiratory Research Institute; Lucas Neas, Environmental Protection Agency**; **Kent Pinkerton, University of California-Davis; Joel Schwartz, Harvard University School of Public Health; Barbara Turpin, Rutgers University**

In the last PM NAAQS review, EPA focused on particle mass and primarily distinguished between two categories of particle pollution based on size (i.e., fine- and thoracic coarse-fraction particles), and conducted parallel evaluations of the available scientific evidence relating to each category. The importance of specific PM components and sources was evaluated within the context of this basic size differentiation.

This session will include consideration of the extent to which key research is becoming available to meaningfully revisit how particle pollution is defined. More specifically:

- **Looking broadly at the scientific evidence, what does the newly available evidence suggest about the appropriateness of continuing to maintain the basic mass size-fraction approach used in the last review as compared to adopting an alternative approach for defining particle pollution, including other size fractions and/or indicators other than mass?**

- **Beyond this basic distinction, how might any additional factors, such as considering the relative toxicity of various PM components or mixtures and/or emissions associated with particular sources and/or environments (e.g., urban and non-urban areas), be incorporated into the assessment and characterization of particle pollution in this review?**

- **How might correlations between levels of PM and the levels of other key pollutants influence the approaches used for setting the NAAQS for PM (or other pollutants)?**

Examples of factors to consider:

Size/Mass

- To what extent is key evidence becoming available regarding health effects associated with particular *PM size fractions*, either those that have been focused on in the past (e.g., $PM_{2.5}$, PM_{10}, $PM_{10-2.5}$) or *alternative size fractions* (e.g., ultrafines)?

- To what extent does the new evidence inform whether it is appropriate to focus on *particle surface area* or *particle number* rather than particle mass?

Composition

- To what extent is critical evidence becoming available to inform the understanding of the *role and relative public health importance of specific components within the ambient mix of particles*? More specifically, how can the new scientific evidence inform the understanding of *potential differences in toxicity* for individual PM components as well as the interactions of these components in the ambient mix?

- Are there key *interactions with gaseous pollutants* or other particulate pollutants that would affect the toxicity of specific PM components and/or mixtures of PM?

- To what extent is key evidence becoming available to assess *specific PM components or gaseous pollutants* that may serve as *surrogates for other toxic components/mixtures* or to identify *new toxic species or mixtures of PM* that may be of concern?

Sources /Environment

- To what extent is critical evidence concerning *specific sources of PM* becoming available and how might EPA best incorporate the results of this information into its assessments? For example, how can EPA most effectively use evidence from *source apportionment analyses* and *near-roadway studies* and *other assessments* of *specific PM sources*?

- To what extent is key scientific evidence becoming available on PM components (including consideration of primary and secondary particles) and mixtures of particles found in *various regions* of our country and/or in *urban versus non-urban environments*?

- To what extent are key research and methodologies becoming available to improve our understanding of the *spatial and temporal distribution* of PM including different size classes or components of PM?

5:30 Adjourn

Thursday, July 12, 2007

8:30-9:00 Recap Session I: Defining Particle Pollution

Session I Co-Chair: Ronald Wyzga, Electric Power Research Institute

9:00 – 12:30 Session II: Planning for the Review of the Health Effects Evidence

9:00 – 9:30 Background/Introductory Remarks

Co-chairs: Daniel Costa, U.S. Environmental Protection Agency
Douglas Dockery, Harvard School of Public Health

9:30 – 12:30 Panel Discussion (Break to be taken, as needed)

Panel Members: Wayne Cascio, East Carolina University; Robert Devlin, U.S. Environmental Protection Agency; W. James Gauderman, University of Southern California; Terry Gordon, New York University; Morton Lippmann, New York University; Michael Kleinman, University of California-Irvine, Sverre Vedal, University of Washington

Scientific studies have previously reported associations between short- and/or long-term exposures to PM and a wide range of health endpoints. The purpose of this session is to discuss how best to focus the review of the health effects evidence to integrate the new and emerging evidence with the existing PM scientific evidence to inform the understanding of the health effects associated with PM exposures and the populations that are most sensitive to these exposures. This discussion will include consideration of key uncertainties identified in the last review and the extent to which new scientific evidence may be available to substantially inform our ability to characterize and/or reduce these uncertainties.

Examples of key questions to consider:

Interpretation of Epidemiologic and Experimental Evidence

- Past reviews have highlighted various issues associated with the interpretation of PM epidemiologic studies. In what ways are critical research and/or analytical tools becoming available to inform the understanding of these issues? For example, topics to be discussed could include: d*ifferent modeling strategies for time-series studies; different modeling approaches to address spatial correlation in long-term exposures studies; influence of exposure error; associations of health effects with PM as part of a broader mixture of pollutants, particularly with gaseous co-pollutants (e.g., NO_2, SO_2, and O_3)?*

- In what ways can existing and/or new analytical tools best be used in interpreting epidemiologic evidence to address potential *effect modifiers* such as education level, socioeconomic status *(*SES), weather and *potential confounders* such as gaseous co-pollutants, weather, and smoking status? To what extent might the use of such analytic tools inform the understanding of effect modification and confounding that may vary for *different size fractions, sources, or components of PM*?

- What critical research is becoming available that characterizes how *particle composition changes* based on various sample collection methods and treatment as it pertains to the interpretation of toxicological and human clinical studies? For example, what new evidence exists that demonstrates *composition differences between atmospheric particles and those collected on filters* (which are often used in animal toxicological research) or those used in *concentrated ambient particles* (CAPs) studies? In addition, are there anticipated panel or intervention studies that may improve our understanding and linkages of empirical findings of the CAPs studies with the findings from epidemiological study designs?

Time Periods of Exposure

- To what extent is key scientific evidence becoming available to improve the understanding of the effects associated with *various time periods of PM exposures*, including not only daily and chronic exposures, but also specifically evaluating *peak PM exposures (less than 24-hour)*?

- Time-series studies have observed PM health effects at *various temporal lags*. To what extent is critical research becoming available that could improve the understanding of the relationship between various health endpoints and different lag periods (e.g., single day, multi-day distributed lags)?

Sensitive Subpopulations and Health Endpoints

- To what extent is key evidence becoming available that could inform the understanding of *subpopulations* that are particularly *sensitive* to PM exposures? Furthermore, is there new or emerging evidence on health effects beyond cardiovascular and respiratory endpoints (e.g., systemic effects, developmental effects) that suggest *additional sensitive subpopulations* should be given increased focus in this review (e.g., fetuses, neonates)?

- What is known about common attributes of varied susceptible groups (e.g., COPD, CVD, diabetes) that link across groups and give insight into responsivity or risk of health outcomes?

- What is known about genetic traits that underlie susceptibility?

- Are new animal models becoming available to better characterize sensitive subpopulations?

Mechanistic Evidence and Biological Plausibility

- What key *animal toxicology* and *controlled human exposure studies* are becoming available to inform the understanding of the *mechanisms* of action by which *short- and long-term exposures* to PM may result in health effects, especially with regard to cardiovascular effects?

- In what ways could this information be most effectively *integrated* with additional health evidence to inform the understanding of the *biological plausibility* of the observed effects?

Integration of Health Evidence

- In what ways could the new and emerging research be most effectively used to inform the understanding of associations between PM exposures and health effects, especially likely *causal associations* that might extend to air quality levels that are as low as or lower than had previously been observed, particularly in sensitive subpopulations?

- In what ways can the new scientific evidence related to *sensitive subpopulations, mechanisms,* and *biological plausibility* be most effectively integrated with the entire body of scientific evidence to inform the understanding of the public health impacts associated with PM exposures?

12:30 – 1:30 Lunch

1:30 – 5:00 Session IIIA: Risk Characterization - Planning for Quantitative Risk and/or Exposure Assessments

1:30 – 2:00 Background/Introductory Remarks
Co-Chairs: Harvey Richmond, U.S. Environmental Protection Agency
Bart Ostro, California Environmental Protection Agency

2:00 – 5:00 Panel Discussion (Break to be taken, as needed)

Panel Members: Ed Avol, University of Southern California; Montserrat Fuentes, North Carolina State University; Henry Gong, University of Southern California; Haluk Ozkaynak, U.S. Environmental Protection Agency; Joel Schwartz, Harvard School of Public Health; Linda Smith, California Air Resources Board; Sverre Vedal, University of Washington

The quantitative risk assessment (QRA) conducted for the last review evaluated a limited number of urban areas to illustrate potential risks associated with a limited set of health endpoints in conjunction with both short-and long-term PM exposures. This QRA relied upon concentration-response functions estimated in epidemiological studies using ambient air quality data from fixed-site, population-oriented ambient monitors and, thus, a quantitative exposure analysis was not conducted. The discussions in this session will focus on the extent to which new research and/or improved methodologies may be available to inform how EPA designs a QRA, whether it is appropriate to conduct a quantitative exposure assessment, and, if so, how the assessment might be structured. These discussions will include consideration of key uncertainties identified in the last review and the extent to which new scientific evidence may be available to substantially inform our ability to characterize and/or reduce these uncertainties.

Examples of key questions to consider:

Quantitative Risk Assessment

- The previous risk assessment included the following outcomes: mortality from long- and short-term exposure, hospital admissions and respiratory symptoms. Are estimates for additional endpoints warranted by the new and emerging scientific evidence?

- To what extent does new scientific evidence support developing quantitative estimates for either different size cuts (e.g., coarse, ultrafines, PM_1) or components of PM (e.g., EC, OC, nitrates, sulfates, metals) or sources to inform decisions on the PM NAAQS?

- An important aspect in characterizing risk and making decisions regarding air quality standard levels is the shape of the *concentration-response (C-R) functions* for PM. To what extent is key evidence

becoming available on the following issues: (1) assessment of potential thresholds and lowest concentrations for extrapolation; (2) non-linear functions at either low or high concentrations; (3) appropriate lags to use? To what extent does this new evidence address previously recognized uncertainties related to the shape of the C-R functions for PM?

- How should multiple long-term exposure mortality studies be utilized to develop C-R functions? Does new evidence from long-term exposure studies provide guidance on cessation lags?

- In what ways could the QRA be structured to best utilize existing or new approaches to inform the characterization of *uncertainties* associated with public health risks of PM? For example, should EPA consider using *expert elicitation* in this review to address the broader range of uncertainties?

Quantitative Exposure Assessment

- What *critical factors* should be considered by EPA in determining whether a quantitative exposure assessment should be conducted for this review? What purposes might such an assessment serve (e.g., to provide insight on population exposures with respect to interpreting epidemiological findings; to serve as an input to risk assessment based on evidence from clinical studies, to provide a basis for adjusting C-R relationships to account for exposure error)?

- To what extent is key scientific evidence becoming available from *controlled human exposure studies* to inform the understanding of *exposure-response relationships* or *exposure levels of concern* for various health endpoints of concern?

- If an exposure assessment were conducted for this review, how might EPA define the *scope* of such an analysis to appropriately incorporate the new and emerging scientific evidence, addressing *individual and population-level PM exposure, including consideration of indoor vs. outdoor contributions to exposure, regional differences, sensitive subpopulations, and the role of exposures to correlated gaseous co-pollutants?*

5:00 Adjourn

Friday, July 13, 2007

8:00 – 8:30 Recap of Session II: Planning for the Review of the Health Effects Evidence

Session II Co-Chairs: Daniel Costa, U.S. Environmental Protection Agency
Douglas Dockery, Harvard University School of Public Health

8:30 – 9:00 Recap of Session IIIA: Risk Characterization - Planning for Quantitative Risk and/or Exposure Assessments

Session IIIA Co-Chairs: Harvey Richmond, U.S. Environmental Protection Agency
Bart Ostro, California Environmental Protection Agency

9:00 – 11:30 Session IIIB: Risk Characterization - Characterizing the Broader Public Health Impacts of Particle Pollution

9:00 – 9:30 Background/Introductory Remarks

Co-Chairs: Bryan Hubbell, U.S. Environmental Protection Agency
Daniel Greenbaum, Health Effects Institute

9:30 – 11:30 Panel Discussion (Break to be taken, as needed)

Panel Members: Michelle Bell, Yale University; Michael Kleinman, University of California-Irvine; Petros Koutrakis, Harvard School of Public Health; Michal Krzyzanowski, World Health Organization; George Thurston, New York University

EPA recognizes, consistent with previous comments from CASAC, that the public health impacts associated with PM exposures in the U.S. are broader than those risks that were estimated in the last QRA, which was limited in geographical scope and in the range of health endpoints considered. This session will explore ways in which this review could more broadly and comprehensively characterize the *nature, magnitude, extent, variability,* and *uncertainty* of the public health impacts associated with PM exposures on a *national* scale and, specifically, the extent to which these impacts might occur in *sensitive subpopulations*.

Examples of key questions to consider:

- In what ways could existing and/or new methodologies or tools be effectively utilized to *qualitatively* extend the results of *quantitative risk* and/or *exposure assessments* for selected locations to more *broadly characterize PM risks* and/or *public health impacts across the nation*?

- What existing and/or new methods or tools are available to inform the characterization of the *broader set of health endpoints* associated with PM exposures? How could these approaches be most appropriately used to inform the understanding of *nationwide PM risks*?

- In what ways could currently available or new tools be applied in a *national context* to inform the understanding of *differences in PM risks observed in various locations*? In what ways could these approaches be used to conduct analyses that would *complement QRA* conducted for a limited number of locations to better characterize the *variability of PM risks* between cities and/or regions? Specifically, how could these analyses be used to inform the understanding of regional PM differences taking in consideration the following factors:

    - *variations in individual and/or population susceptibility* including consideration of *population demographics*
    - *variations in particle size, composition*, and/or *levels*;
    - *impacts of potential effect modifiers* (e.g., weather)

- To what extent are there key methods becoming available to meaningfully apply risk estimates derived from effects observed in controlled human exposure studies (e.g., changes in lung

function, heart rate variability) to inform the *estimation of relevant public health impacts*, such as work loss days?

11:30 – 12:00 Closing Remarks

Ila Cote, U.S. Environmental Protection Agency
Lydia Wegman, U.S. Environmental Protection Agency

12:00 Adjourn