



September 8, 2009

MEMORANDUM

SUBJECT: CASAC Review of *Risk Assessment to Support the Review of the PM Primary National Ambient Air Quality Standards - External Review Draft* and *Particulate Matter Urban-Focused Visibility Assessment – External Review Draft*

FROM: Lydia N. Wegman, Director /s/
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Office of Air Quality Planning and Standards
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TO: Holly Stallworth
Designated Federal Officer
Clean Air Scientific Advisory Committee
EPA Science Advisory Board Staff Office

Attached are two draft assessment documents: (1) *Risk Assessment to Support the Review of the PM Primary National Ambient Air Quality Standards - External Review Draft* (September 2009) and (2) *Particulate Matter Urban-Focused Visibility Assessment – External Review Draft* (September 2009), prepared by the Environmental Protection Agency's (EPA) Office of Air Quality Planning and Standards (OAQPS) staff as part of EPA's ongoing review of the primary (health-based) and secondary (welfare-based) national ambient air quality standards (NAAQS) for particulate matter (PM). These documents will be the focus of a review by the Clean Air Scientific Advisory Committee (CASAC) PM NAAQS Review Panel (the CASAC PM Panel) at a public meeting to be held in Chapel Hill, NC on October 5–6, 2009. In addition, on or about September 15, 2009, we plan to release a very preliminary draft of another document, *Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards: Preliminary Draft* (Policy Assessment), to facilitate discussion with the CASAC PM Panel on our ongoing efforts to prepare an external review draft Policy Assessment. I am requesting that you forward these draft documents to the CASAC PM Panel to prepare for the October meeting.

As part of EPA's review of the PM NAAQS, the Agency is conducting quantitative assessments characterizing (1) the health risks associated with exposure to ambient PM and (2) urban visibility impairment associated with ambient PM. The two attached draft assessment documents convey the approaches taken to assess and characterize PM-associated health risks and urban visibility impairment. These documents include descriptions of the scope of the assessments and the methodologies used as well as the initial key results, observations, and related uncertainties associated with the quantitative analyses conducted.

The EPA's plans for conducting the health risk and urban-focused visibility assessments, including the proposed scope and methods of the analyses, were presented in two planning documents, *Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment* (February 2009) and *Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Urban Visibility Impact Assessment* (February 2009), henceforth, Scope and Methods Plans, see http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pd.html. These planning documents were the subject of a consultation with CASAC on April 2, 2009. Comments from the CASAC PM Panel as well as public comments were considered in developing the draft assessment documents being released at this time.

These draft documents draw upon information presented in the *Integrated Science Assessment for Particulate Matter: Second External Review Draft* (ISA, July 2009) prepared by EPA's National Center for Environmental Assessment, Research Triangle Park, NC (NCEA-RTP), which the CASAC PM Panel will review at the same meeting. The CASAC and public comments on the draft assessment documents will be taken into consideration in making revisions to the draft assessment documents and in the preparation of an external review draft Policy Assessment.

Draft documents are being made available to the CASAC PM Panel in the form of attached electronic files. The documents are also available from the EPA website at http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_pd.html. Printed copies of these documents will be sent to CASAC PM Panel members via Federal Express. With regard to the Risk Assessment document, we will mail a printed copy of the main body of the document only. The appendices can be accessed electronically as noted above and printed copies of the appendices will be made available to Panel members upon request.

Charge to the CASAC PM Review Panel

We ask the CASAC PM Panel to focus on the charge questions listed below in their review of two draft assessment documents, but we would appreciate comments on any other topics as well.

- ◆ **Risk Assessment:** *Risk Assessment to Support the Review of the PM Primary National Ambient Air Quality Standards - External Review Draft* (September 2009)

Following an introductory chapter, this document discusses the scope of the risk assessment, including modifications based on CASAC consultation and public comment on the Scope and Methods Plan; the methods used to estimate risks associated with recent air quality and with air quality concentrations simulated to just meet current and alternative standards; the results including core analyses and alternative estimates based on a number of sensitivity analyses, as well as an evaluation of the representativeness of the urban study areas in a national context; and a national-scale assessment of premature mortality associated with long-term PM_{2.5} exposures based on recent air quality. Throughout these chapters, key issues and uncertainties are discussed.

Chapters 2 and 3 – Scope of the assessment and Methods used for the urban case studies

- 1) After careful consideration of evidence provided in the second draft ISA and of the views expressed by the Panel in consulting on the Scope and Methods Plan, we have decided to quantitatively assess risk associated with both short- and long-term exposure to PM_{2.5} only. Based on our consideration of the evidence for health effects potentially associated with short-term exposure to PM_{10-2.5}, as well as to ultrafine particles and specific components, and in recognition of the limited available air quality data, we decided not to assess risk quantitatively for PM_{10-2.5}, ultrafine particles, or specific PM components as part of the current assessment. Is the Panel generally supportive of this scope? To what extent is the rationale for this decision clear and appropriate?
- 2) The final set of health effect categories included in the risk assessment for PM_{2.5} are consistent with those outlined in the Scope and Methods Plan (i.e., those classified as having a *causal or likely causal* association with PM_{2.5} exposure, as presented in the second draft ISA). We decided not to include any of the health effect categories classified as *suggestive* of a casual association in the second draft ISA, based on a number of considerations as described in section 3.3.1. Please comment on the approach taken and on the clarity of the rationale for selecting health effect categories for inclusion in the quantitative risk assessment.
- 3) Based on consideration of evidence presented in the second draft ISA, we have identified four combinations of 24-hour and annual alternative standard levels for analysis in the risk assessment. Please comment on the extent to which the rationale provided in section 2.5 appropriately supports these combinations of alternative standard levels for this assessment.
- 4) General approach
 - a) For this assessment, we have developed a primary set of risk results based on the application of modeling element choices (e.g., concentration-response (C-R) functions, lag periods) that we believe have the greatest overall support in the literature (referred to as the “core” results). As discussed in sections 2.4.1, 3.1 and 4.0, while it is not possible at this time to assign quantitative levels of confidence to these core risk estimates, staff believes that these estimates are generally based on inputs having higher overall levels of confidence, relative to risk estimates that could have been generated using other inputs identified in the literature. Consequently, the core risk estimates receive greater focus when we present, summarize and discuss risk estimates. What is the Panel’s view on the approach used and does the Panel consider it to be described appropriately and clearly?
 - b) Based on consideration of uncertainties associated with specifying C-R functions below the lowest measured level (LML) from a particular epidemiological study, we have decided to model risk for long-term PM_{2.5} exposures down to the LML, but not to extrapolate down to policy-relevant background (PRB). In contrast, when estimating risk associated with short-term PM_{2.5} exposures, because the LML is generally below the range of PRB values on some days during the study periods evaluated, we decided to model short-term risk down to PRB (see section 3.1). Is the Panel generally supportive of these approaches?

5) Air quality inputs

For this assessment, we have included an alternative approach for simulating air quality levels that just meet either current or alternative suites of standards in addition to the proportional analysis that has been used in previous analyses. Specifically, we have employed a hybrid (non-proportional) air quality adjustment procedure which simulates a combination of regional and local controls. The non-proportional rollback approach was used as part of a sensitivity analysis to examine uncertainty associated with this aspect of the risk assessment, while the historical proportional approach was used for the core analysis. To what extent does the Panel support the use of the alternative non-proportional rollback approach in the context of the sensitivity analyses? Please provide comments on the alternative approach as presented in section 3.2.3 and Appendix B.

6) Selection of urban study areas

We have included 15 urban study areas in the risk assessment, with the selection of these areas being based on a number of criteria as presented in section 3.3.2. To what extent does the Panel support the rationale provided for selection of the urban study areas and the specific locations considered?

7) Selection of epidemiological studies and C-R functions within those studies:

In estimating risks associated with $PM_{2.5}$ exposures, we focused on selecting C-R functions from large multi-city studies based on staff's conclusion that these studies provided more defensible effect estimates (see section 3.3.1). Concentration-response functions from several single-city studies evaluating short-term $PM_{2.5}$ exposures were also included to provide coverage for additional health effect endpoints (e.g., emergency department visits). To what extent is the Panel supportive of this approach for selecting C-R functions for modeling risk related to short-term and long-term $PM_{2.5}$ exposures?

- a) Specifically with regard to short-term exposure-related mortality, focusing on a study of 112 US cities by Zanobetti and Schwartz (2009), we obtained Empirical Bayes "shrunk" city-specific estimates from the study authors that provided a distinct C-R function for each urban study area location. For short-term exposure-related morbidity, focusing on a study of 202 U.S. counties by Bell et al. (2008), we used regionally-differentiated effect estimates provided by the study authors. Please comment on the selection of C-R functions for evaluating short-term morbidity and mortality effects. To what extent do the Panel members consider the rationales supporting the selection of C-R functions to be clearly and appropriately presented?
- b) Specifically with regard to long-term exposure-related mortality, we identified a number of effect estimates using the extended follow-up of the American Cancer Society (ACS) study to use in the core analysis (Krewski et al., 2009). These effect estimates include standard Cox proportional hazards models, with 44 individual and 7 ecologic covariates, derived using two separate $PM_{2.5}$ monitoring data sets (i.e., 1979-1983 and 1999-2000) (see section 3.3.3 of the RA). To what extent is the rationale for these choices clear and sufficiently justified as the basis for the core analysis involving long-term $PM_{2.5}$ -related mortality?

8) Addressing uncertainty and variability

- a) The treatment of uncertainty and variability in the analysis is based on the multi-tiered approach presented in a recent WHO document (WHO, 2008). Specifically, as outlined in section 3.5, we have included qualitative analysis of both variability and uncertainty (WHO Tier 1), as well as single-factor and multi-factor sensitivity analyses aimed at identifying which potential sources of uncertainty have the greatest impact on the core risk estimates (WHO Tier 2). In addition, the sensitivity analyses have been designed to provide a reasonable set of alternate risk estimates to supplement the core risk estimates and inform consideration of uncertainty associated with the core analysis. To what extent does the Panel support the overall approach for addressing uncertainty and variability? To what extent does the Panel agree that the overall approach is appropriate and consistent with the goals of the risk assessment as outlined in chapter 1? Does the Panel have any recommendations for improving the characterization of variability and/or uncertainty?
- b) The qualitative discussion of key sources of variability, and the degree to which the analysis design captures those sources of variability, are presented in section 3.5.2. Please provide comments on the approach used. Specifically, do the analyses sufficiently address the issue of variability? Are there key sources of variability that have not been addressed within the qualitative analysis but which could have an important impact on modeling population-level risk associated with PM_{2.5} exposure?
- c) Table 3-13 provides a qualitative characterization of uncertainties including the potential direction, magnitude, and degree of confidence associated with our understanding of the sources of uncertainty. To what extent does the Panel support the characterizations of the key sources of uncertainties identified and the relative rankings of the importance of those sources of uncertainty? Are there additional uncertainties that should be considered?
- d) The results of the sensitivity analyses have been used to gain insights into which sources of uncertainty significantly impact the core risk estimates and to provide a reasonable set of alternate risk estimates to supplement the core analysis. We are mindful that these estimates do not represent a true uncertainty distribution. With regard to the single- and multi-factor sensitivity analyses, to what extent is the Panel supportive of the approach used to conduct and characterize the results of the sensitivity analyses? Please provide comments on the extent to which the presentation of the results of the sensitivity analyses are clearly and reasonably described? Does the Panel have any recommendations for how the results of the sensitivity analyses could be used more effectively or appropriately in characterizing uncertainty associated with the core risk estimates?

Chapter 4 – Results

- 9) A number of risk metrics as well as different approaches for presenting these metrics are included in tabular and graphical format for both the core analysis and sensitivity analyses. Please comment on the extent to which the risk estimates are clearly and appropriately characterized and presented.

10) Evaluation of the representativeness of the urban study areas in the national context

We completed a comparison of the 15 urban study areas against national distributions for key PM risk-related attributes. The goal of this analysis was to determine whether the urban study areas are more nationally-representative of these attributes, or are more focused on a particular portion of the distribution for a given parameter. In particular, given that one of the goals of the risk analysis is to provide estimates of risks for those areas likely to experience high levels of PM exposure and risk, this assessment provides insights as to the extent to which the assessment represents high PM_{2.5} risk locations. The results of this analysis were then used to evaluate, in part, whether the set of 15 urban study areas is likely to reflect the broader U.S. population with regard to PM_{2.5}-related risk, including coverage for those locations that represent specific at-risk populations. To what extent does the Panel support the approaches used? Please provide comments on the clarity with which the methods, results, and insights gained from this analysis are described.

Chapter 5 – National-Scale Assessment of Long-Term Mortality Related to PM_{2.5} Exposures

11) We completed a national scale assessment focused on long-term mortality associated with recent air quality conditions. To what extent does the Panel support the approach used? Please comment on the clarity and appropriateness with which the methods, results, and insights gained from this analysis are described.

12) The national-scale long-term mortality risk assessment provides perspective for where the 31 counties associated with our 15 urban study area analysis fall along the national distribution of mortality risk. We note that this analysis is distinct from the representativeness analysis referenced above (and described in section 4.4) in that this analysis focuses on coverage of the 15 urban study areas for long-term mortality risk, while the earlier representativeness analysis focuses on coverage for PM risk-related factors. To what extent is the Panel supportive of this specific analysis and its intended use to provide insights into the extent to which the urban study area analysis broadly represents urban PM_{2.5}-related risk in the U.S?

◆ **Visibility Assessment** *Particulate Matter Urban-Focused Visibility Assessment – External Review Draft* (Visibility Assessment, September 2009)

Following an introductory chapter, this document discusses the current scope of the urban focused visibility assessment, including modifications based on CASAC consultation and information provided through public comment; the results of a reanalysis of urban visibility preference studies; the methods used to evaluate recent PM_{2.5} air quality and light extinction levels with PM_{2.5} air quality concentrations simulated to just meet current and alternative PM_{2.5} and PM light extinction standards; and results of the evaluations. Throughout these chapters, key issues and uncertainties are discussed.

Chapter 1 – Scope of Visibility Assessment

1) After careful consideration of the evidence provided in the second draft ISA, and in particular the significant body of work that has been conducted by the Regional Planning Organizations under the Regional Haze Rule, (i.e. information on urban and rural PM concentrations and compositions), we have decided to continue to focus this assessment on

the PM induced visibility impairment that is occurring in urban areas. What is the Panel's view on this approach? Is the rationale supporting the selected approach clear and appropriate?

- 2) After further considering the nature of urban versus more remote area PM, and in light of discussions with CASAC at the April 2, 2009 meeting, we have decided not to develop an urban optimized algorithm at this time, but instead to rely on the original IMPROVE algorithm to relate urban PM to local haze (PM light extinction). Is the Panel generally supportive of this approach? Is the rationale supporting this decision appropriate and clearly presented?
- 3) In a change from the planned approach presented in the Scope and Methods Plan, we have decided to conduct a reanalysis of the urban visibility preference studies available at the time of the 2006 PM NAAQS review, rather than conducting new public preference studies since it is highly unlikely that the results of new studies could be completed in time to inform this review. This reanalysis was designed to explore the similarities and differences (comparability) between the current studies and to assess what information could be drawn from these results to inform the selection of visual air quality (VAQ) candidate protection levels (CPLs) to be used in subsequent impact assessments. This reanalysis also includes a recent study by Smith and Howell (2009) for Washington, D.C. which was presented to the CASAC during the public comment phase of the April 2, 2009 meeting and later provided to EPA staff. Does the Panel agree that the information provided by this reanalysis is useful to inform the selection of CPLs? Does the Panel agree that inclusion of the Smith and Howell (2009) is appropriate in both the ISA and Visibility Assessment? To what extent does the Panel consider that the reanalysis of the urban visibility preference studies is clearly and appropriately characterized?
- 4) We have chosen to use the range that represents the 50th acceptability criteria across the four cites studied (i.e., the VAQ level that best divides the photographs shown into two groups: those with a VAQ rated as acceptable by the majority of the participants, and those rated not acceptable by the majority of participants) as CPLs to characterize the nature of the impact on urban VAQ associated with current PM levels. Please comment on the clarity and appropriateness of the rationale supporting this decision. Does the Panel have suggestions for alternative ranges to consider?
- 5) A new indicator relating ambient PM to urban VAQ (i.e., PM light extinction) has been evaluated to improve our characterization of the relationship between ambient PM and visibility impairment. Is the Panel generally supportive of this approach? To what extent have we provided an adequate justification for the new indicator used?
- 6) An averaging time of one hour as a practical minimum time period was used in this assessment in recognition that, while the visibility impacts are nearly instantaneous, the urban VAQ does not generally change significantly from minute to minute, but does vary from hour to hour. To what extent does the Panel support this approach? Does the Panel consider the rationale supporting this approach to be clearly and appropriately presented?
- 7) We have chosen to use the 90th and 95th percentile forms in our assessment of alternative secondary (welfare-based) standards. Please comment on the use of these alternative forms.

Chapter 2 – Urban Visibility Preference Studies

- 8) To what extent does the Panel support the graphical displays presented in this chapter? As currently presented, do these figures clearly summarize the assessment results? We have combined data from multiple studies for two locations - British Columbia and Washington, D.C. - (Abt Associates, 2001; Smith and Howell, 2009 test 1) as presented in Figure 2-14. Does the Panel agree with developing a composite dataset for each of these two urban areas?
- 9) Despite significant differences in study characteristics (e.g., size, location), to what extent does the Panel support combining and comparing the results from the four cities, as shown in Figure 2-14? What is the Panel's view on the clarity and adequacy of the descriptions of the uncertainties and limitations associated with such a combined assessment and the conclusions that can be drawn from the assessments? Please provide comments on additional insights, uncertainties, or caveats that should be considered.
- 10) We have used the combined results presented in this chapter to develop a range of CPLs that are used in subsequent steps of the assessment. To what extent does the Panel support the range of CPLs used and the justification provided for selecting this range? Does the Panel recommend consideration of any alternative approaches or criteria for selecting CPLs?
- 11) Overall, we consider this assessment useful for providing information for the design of future urban visibility preference studies. Does the Panel support this conclusion and does the Panel have any recommendations for changes that could be made in the discussions of this information to enhance its usefulness for this purpose?

Chapter 3 – Estimation of Current PM Concentrations and Light Extinction

- 12) Are the goals articulated in the first paragraph of this chapter achieved in the remainder of the assessment? If not, does the Panel have suggestions for additional assessments that should be done?
- 13) Are the methods and approaches taken in these assessments, including those for monitor site selection, incomplete data adjustments, and the use of the CMAQ model to augment speciation data, appropriate and is the rationale for their selection clearly articulated?
- 14) Is the approach used to estimate PRB as described in chapter 3 and Appendix C appropriate?
- 15) We consider the results generated by these analyses to be reasonable based on PM composition and relative humidity data. Does the Panel agree? Are there other tests of reasonableness that could be applied?
- 16) In addition to a qualitative discussion of possible sources of uncertainty and variability, are there quantitative methods for addressing uncertainty and variability associated with these assessments that the Panel would recommend?
- 17) A number of appendices are provided at the end of this document. Does the Panel agree that this information is useful to retain? Does the Panel agree with the level of detail provided in the body of the report and its organization and distribution throughout the document?

Chapter 4 – Total Light Extinction Under “What If” Conditions of Just Meeting Specific Alternative Secondary NAAQS

- 18) Does the Panel agree with the approaches used to simulate just meeting air quality conditions for the current and alternative PM standards? In particular, is use of the proportional rollback approach appropriate in the context of the urban PM visibility assessment?
- 19) To what extent does the Panel consider the presentation of "what if" scenarios for retention of the current secondary PM_{2.5} NAAQS and consideration of alternative, more protective secondary NAAQS in sections 4.2 and 4.3 to be clearly written with an appropriate level of detail? Do the correlation analyses presented in Appendix D provide sufficient insight into the suitability of alternative indicators based on sub-24 hour averaging periods for PM_{2.5}? Are there additional alternative standard scenarios that should be evaluated?

We look forward to discussing these issues with the CASAC PM Panel at our upcoming meeting. Should you have any questions regarding these draft documents, please contact Dr. Zach Pekar regarding the draft risk assessment (919-541-3704; email pekar.zachary@epa.gov) or Ms. Vicki Sandiford regarding the draft visibility assessment (919-541-2629; email sandiford.vicki@epa.gov).

Attachments

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