



February 9, 2010

MEMORANDUM

SUBJECT: CASAC Review of *Quantitative Health Risk Assessment for Particulate Matter -- Second 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
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Attached is the second draft assessment document: *Quantitative Health Risk Assessment for Particulate Matter* (February 2010), 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) national ambient air quality standards (NAAQS) for particulate matter (PM). This document will be one of the documents to be reviewed 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 March 10-11, 2010. I am requesting that you forward this draft document to the CASAC PM Panel to prepare for the March meeting.

The other document to be reviewed at the March meeting, *Particulate Matter Urban-Focused Visibility Assessment – Second External Review Draft*, was sent to you on January 20, 2010. As I noted at that time, we are also preparing another draft document, *Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards – First External Review Draft*, to be reviewed by the CASAC PM Panel by teleconference on April 8-9, 2010. I expect to send the draft Policy Assessment to you around the beginning of March, in advance of the March meeting.

This draft document draws upon information presented in the final *Integrated Science Assessment for Particulate Matter* (ISA, December 2010) prepared by EPA's National Center for Environmental Assessment, Research Triangle Park, NC (NCEA-RTP). It also reflects consideration of comments from the CASAC PM Panel, as well as public comments, on the first draft PM Risk Assessment, which was reviewed by the Panel at a meeting on October 5-6, 2009.

The CASAC and public comments on this second draft Risk Assessment will be taken into consideration in preparing the final PM Risk Assessment.

The main comments from the CASAC PM Panel on the first draft Risk Assessment, provided to us in a November 24, 2009 letter (Samet, 2009), are briefly summarized below together with a brief description of how we have considered the comments in preparing this second draft PM Risk Assessment.

- The Panel recommended that we include an integrated discussion that draws on the uncertainty and variability analyses as well as the various national-scale analyses completed as part of this assessment, to interpret the core risk estimates.

RESPONSE: We have added a new chapter 6 to provide an integrative discussion of the risk-related analyses presented throughout this second draft Risk Assessment, including the PM_{2.5}-related risk estimates generated for the set of urban study areas and the related uncertainty and sensitivity analyses, the representativeness analyses, and the national-scale long-term exposure PM_{2.5} mortality assessment. The goal of this integrative discussion is to inform our understanding of important policy-relevant risk-based questions.

- Regarding EPA staff's decision to focus the first draft risk assessment on PM_{2.5} and not to estimate risk for coarse-fraction PM, the Panel generally agreed that the focus on PM_{2.5} was appropriate, although the Panel suggested that consideration be given to ways to carry out some form of exploratory analyses related specifically to PM_{10-2.5}. While acknowledging the uncertainty that would be involved, the Panel also recommended that we generate semi-quantitative risk estimates for both reproductive effects and lung cancer.

RESPONSE: We have not included a quantitative assessment of risk associated with PM_{10-2.5} due to continued concerns that the uncertainty in any such estimates that we could generate would be so great that they would not serve the purpose of informing our review of the PM NAAQS. We discuss the basis for this decision briefly in section 2.3 of the document with additional discussion provided in Appendix H. We also note that the evidence-based considerations to be presented in the upcoming draft Policy Assessment document will address PM_{10-2.5} exposure and risk. Regarding reproductive and developmental effects and lung cancer, we note that the risk assessment does include estimates of lung-cancer mortality as part of modeling long-term exposure-related mortality. However, in the case of reproductive and developmental effects, we continue to believe that there are insufficient data at this time (particularly with regard to identifying appropriate exposure windows) to support quantitative risk assessment. Nonetheless, these endpoints will be covered as part of the evidence-based considerations to be presented in the draft Policy Assessment.

- The Panel expressed the view that stronger justification was needed for designating some of the risk estimates as core estimates. The Panel also recommended that we provide further explanation for how specific long-term and short-term multi-city epidemiological studies were selected for inclusion in the risk assessment and why other studies of potential interest were not included. For long-term exposure-related risk, the Panel suggested that we provide additional rationale for the specific set of C-R functions and effect estimates selected from the Krewski et al. (2009) study for modeling long-term exposure-related mortality for the core and sensitivity analyses.

RESPONSE: We have expanded the discussion (in section 3.3.3) of our rationale for identifying modeling choices comprising the core risk model, including both the selection of specific epidemiological studies for use in deriving C-R functions as well as specific choices made in specifying those functions. In addition, we have added clarification for why alternative candidate epidemiological studies and alternative C-R function specifications were not included in the core risk assessment.

- Regarding the characterization of variability, the Panel recommended that additional detail be provided on how different sources of variability were compared and prioritized. In addition, the Panel suggested that the sources of variability considered in the analysis be augmented to include differences in PM copollutant concentrations and discussion of land use, source locations, housing stock, and SES.

RESPONSE: We have added clarification for the process used to evaluate sources of variability as part of section 3.5.2 of the document. In addition, we added coverage for the specific sources of variability referenced in the Panel's comments.

- With regard to the qualitative assessment of uncertainty, the Panel recommended that additional detail be provided on the method used to rank and categorize sources of uncertainty, and that we discuss implications for interpreting the urban study area risk estimates. The Panel encouraged us to comment on the degree to which dependencies exist between pair-wise combinations of sources of uncertainty. The Panel also recommended that we address more directly the potential for exposure misclassification (in the epidemiological studies providing the C-R functions) to introduce uncertainty into the risk assessment.

RESPONSE: We have expanded our discussion of the qualitative analysis of uncertainty (in section 3.5.3) to more explicitly describe the process used. The integrative discussion in the new chapter 6 includes consideration for how the qualitative analysis of uncertainty impacts the interpretation of core risk estimates. We have also included comparisons of selected pair-wise interactions of sources of uncertainty that have the potential to impact risk estimates.

- Regarding the sensitivity analysis, the Panel made two specific recommendations for additional analyses: consider alternative lags for short-term morbidity endpoints based on Bell et al. (2008) and consider risk for short-term mortality using regional effect estimates from Zanobetti and Schwartz (2009). More generally, the Panel recommended that we compare the impact of uncertainty in the statistical fit of the effect estimates used in the core analysis with the impact of other sources of uncertainty considered in the sensitivity analysis. The Panel also suggested that we do the following: 1) provide additional rationale for focusing on long-term exposure-related mortality in using the results of the sensitivity analysis to inform consideration of uncertainty in the core risk estimates; 2) discuss whether the lower and upper bounds of the sensitivity analysis represent plausible upper and lower bounds on the core risk estimates; and 3) consider the results of the sensitivity analysis together with the results of the qualitative uncertainty analysis to inform interpretation of the core risk estimates.

RESPONSE: We have expanded the sensitivity analysis to include consideration for alternative lag periods in modeling risk for short-term morbidity using Bell et al., 2008 (see section 3.5.4). However, we concluded that expanding the sensitivity analysis to include coverage for regional effect estimates (in addition to the city-specific effect estimates used in the core risk assessment) was not warranted in light of the resources and time that would

have been required. We have expanded our discussion of uncertainty (in section 3.5.3) to include explicit consideration for uncertainty in the statistical fit of the C-R functions and specifically how this compares to other factors assessed as part of the sensitivity analysis. The discussion of the sensitivity analysis has been expanded to address the use of the results as an alternative set of reasonable risk estimates for informing consideration of uncertainty in the core risk estimates (including the degree to which we believe the sensitivity analysis captured plausible high- and low-bound risk estimates – see section 4.3.2). The integrated discussion in the new chapter 6 integrates consideration of the sensitivity analysis results with other analyses completed for the risk assessment, including the qualitative uncertainty analysis as noted above, to inform consideration of overall confidence in the core risk estimates.

- With regard to the national-scale long-term exposure-related mortality analysis, the Panel recommended that risk estimates be generated for the full set of air quality scenarios included in the risk assessment (i.e., current and alternative suites of standards, in addition to a recent conditions analysis) and that additional health effect endpoints matching those modeled for the 15 urban study areas be included in the national-scale analysis.

RESPONSE: Following deliberative review of available data and methods, combined with consideration for the policy goals of the national-scale mortality analysis (as differentiated from the health benefits assessment that the Agency conducts as part of a Regulatory Impact Analysis), and taking into consideration the resources and time needed for such an expanded assessment, we have decided not to expand the national-scale mortality analysis to include consideration of either alternative suites of standards or additional health endpoints. We have included our rationale for this decision in section 5.1.

Document Availability

The draft document is being made available to the CASAC PM Panel in the form of the attached electronic file. The document is also available from the EPA website at http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_risk.html. Printed copies of this document will be sent to CASAC PM Panel members via Federal Express. 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 the *Quantitative Health Risk Assessment for Particulate Matter*, but we would appreciate comments on any other topics as well.

Chapter 3 – Urban Case Study Analysis Methods

- 1) Air quality inputs (section 3.2): We have expanded the consideration of alternative approaches to simulating just meeting the current and alternative suites of PM_{2.5} standards

(i.e., rollback approaches) to include a peak shaving approach, in addition to the hybrid and proportional approaches considered in the first draft assessment. This peak shaving approach is intended to represent more localized, rather than regional, patterns of PM_{2.5} reductions (discussed in section 3.2.3.3).

- a) To what extent does the Panel believe that the use of the peak shaving approach provides useful additional exploration of variability associated with how ambient PM_{2.5} concentrations are simulated to change upon just meeting the current and alternative suites of standards?
 - b) We have used comparisons of composite monitor annual averages generated using the different rollback approaches as a surrogate for differences in long-term exposure-related mortality in looking across all three rollback approaches. To what extent does the Panel believe that this is a reasonable approach for assessing the impact of variability associated with simulating changes in air quality patterns on estimates of long-term exposure-related mortality?
- 2) Selection of model inputs (section 3.3): We have expanded and clarified the discussion of our rationale for identifying modeling choices comprising the core risk model, focusing in particular on selection of C-R functions (section 3.3.3). To what extent does the Panel consider this discussion to be clear and the model selections appropriate?
 - 3) Addressing uncertainty and variability (section 3.5): We have clarified the process used to evaluate sources of variability and added coverage for specific sources of variability (section 3.5.2); expanded our discussion of the qualitative analysis of uncertainty (section 3.5.3); and included analyses of pair-wise interactions of sources of uncertainty (section 3.5.4). To what extent does the Panel consider these discussions to be clear and appropriate?

Chapter 4 – Urban Case Study Results

- 4) Sensitivity analysis results (section 4.3): We have included a discussion of how the results of the sensitivity analysis can be used as an additional set of reasonable risk estimates to inform consideration of uncertainty in the core risk estimates (see section 4.3.2). What are the Panel's views on how we have used the sensitivity analysis results to support consideration of uncertainty in the core risk estimates?
- 5) Consideration of design values and patterns of PM_{2.5} monitoring data in interpreting core risk estimates (section 4.5): To enhance our interpretation of the patterns of core risk estimates generated for both the current and alternative suites of standards, we have included analyses of 24-hour and annual design values together with patterns of PM_{2.5} monitoring data for the 15 urban study areas. This reflects the fact that these two factors play a key role in determining the degree of risk reduction estimated upon just meeting the current and alternative suites of standards under alternative rollback approaches. As part of the consideration of design values, we have also contrasted the 15 urban study areas with patterns of design values seen for the broader set of urban areas in the U.S. in order to help place the urban study area in a broader national context
 - a) To what extent is the Panel supportive of these additional assessments?

- b) Does the Panel have any recommendations for additional insights based on consideration of patterns in design values and PM_{2.5} monitoring data across the 15 urban study areas and at the national level?

Chapter 6 – Integrative Discussion of PM_{2.5}-related Risks

- 6) We have developed an integrated discussion of the PM_{2.5}-related risk estimates which considers the results of the qualitative and quantitative treatment of uncertainty and variability together with the various national-scale assessments completed for the analysis to support interpretation of the core risk estimates. As part of the integrative discussion, we also provide key observations that bear on policy-relevant risk-based questions.
 - a) To what extent does the Panel believe that we have captured the key policy-relevant questions that can be addressed by this risk assessment?
 - b) We provide a set of key observations related to estimates of risk associated with simulations of just meeting the current and alternative suites of standards. These observations are based not only on consideration of trends in risk reduction across alternative suites of standards and residual risk remaining after simulation of just meeting specific suites of standards, but also on additional factors that can impact risk (e.g., the role of annual and 24-hour design values, the peakiness of PM_{2.5} distributions within a study area, and application of different rollback approaches). To what extent do the Panel members believe that the observations presented in section 6.2 are well supported by the results of the analyses? Are there other observations that might be made that would help to address the policy-relevant questions identified at the beginning of the chapter?
 - c) Part of our interpretation of the core risk estimates presented in section 6.2 is our characterization of confidence in the core risk estimates and in observations made based on those estimates. These assessments of confidence are based on consideration of the results of the sensitivity analysis as well as on the qualitative assessment of uncertainty and variability. To what extent does the Panel believe that the characterizations of confidence in the core risk estimates and associated policy-related observations are reasonable given available information?
 - d) As part of the integrative discussion, we use the results of several national-scale analyses (i.e., the national scale PM_{2.5} mortality analysis, the representativeness analysis, and the new exploration of design values and patterns of PM_{2.5} monitoring data presented in section 4.5) to place the results of the risk assessment in a broader national-context. What are the Panel members' views on appropriateness of this effort to place results of the analysis in a national context?
 - e) We conclude chapter 6 with a list of key observations. Does the Panel believe that we have appropriately highlighted key findings of the risk assessment in these observations? Of particular note is the observation that, while alternative 24-hour standard levels can be used to reduce annual-average PM_{2.5} concentrations and thus to reduce estimated risk, the results are likely to be highly variable across urban areas. More consistent lowering of annual-average PM_{2.5} concentrations across study areas, and thus more consistent reductions in estimated risk, may result from application of alternative annual standard levels. We also note that simulation of the alternative 24-hour standard level of 25 µg/m³

resulted in reductions in annual-average PM_{2.5} levels for some study areas that were well below the lowest annual standard level assessed (i.e., below 12 µg/m³). As a consequence, we observed risk reductions reflecting these changes in annual-average PM_{2.5} levels below 12 µg/m³. Given these results, does the Panel believe that there is utility in estimating risks for alternative annual standard levels below 12 µg/m³?

We look forward to discussing these issues with the CASAC PM Panel at our upcoming meeting. Should you have any questions regarding this draft document, please contact Dr. Zach Pekar (919-541-3704; email pekar.zachary@epa.gov).

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