

3-30-09 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel. These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

**Compendium of Preliminary Pre-Meeting Comments
CASAC Particulate Matter Review Panel on
PM NAAQS: Scope and Methods
Plan for Health Risk and Exposure Assessment (Feb. 2009)**

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Comments from Dr. Douglas Crawford-Brown

Review of the Document: Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment

Douglas Crawford-Brown
03-20-09

This review considers specific issues related to Chapter 3: Scope and Approach for the Health Risk Assessment.

1. The risk assessment makes use of an appropriate selection of information from the draft ISA, both in regards to effects examined – morbidity and mortality - and exposure pathways that dominate. The decision to focus primarily on the 2.5 fraction is consistent with the ISA as well.
2. It was good to see that the assessment will consider how to place the limited sample size of cities into a broader judgment of national risks. I will need to reserve judgment as to how well that is done, as the draft document provides only a hint as to the general approach, and the details will be significant. But this is an issue for which I have had concern in the past, and so it is heartening to see that it is being addressed directly.
3. I found pages 3-1 and 3-3 to be somewhat inconsistent in regards to the composition of particles. The authors seem to first suggest that composition will be considered, and then on 3-3 state that the risk assessment will use only the mass fraction. I suppose this could be counted as being “considered”, in the sense that such a composition approach is rejected, but the discussion as to why it is rejected is so cursory that the two pages end up seeming to be inconsistent.
4. I disagree with the statement on 3-4 that Equation 3-1 does not require more detailed individual-specific exposure data. It certainly is true that 3-1 can be applied to populations even with exposure distributions, but it can equally be applied to studies where detailed individual-specific exposures are used to stratify the population. In fact, it is more accurate in the latter case. So I don't know what the authors mean by this statement.
5. I support the use of the 2005-2007 monitoring data as the basis for the exposure assessment. This is a reasonably complete dataset and relevant to current conditions.
6. The modeling approach outlined on page 3-6 is consistent with REAs conducted for other contaminants, and so is appropriate here.

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7. In addition, the proportional roll-back and the modeling approaches have both been used in other REAs, and we have approved these through the CASAC. As a result, I am comfortable with the approach being applied here.
8. The categories of effects noted on pages 3-7 and 3-8 are consistent with those mentioned as prominent in the summaries in the ISA, and so are appropriate ones for this REA. This applies to both the short and long-term exposures. I am less comfortable with the inclusion of birth outcome effects, unless a more compelling case is made for including suggestive effects in ALL REAs as a matter of policy.
9. The criteria for study selection on page 3-9 are appropriate and consistent with past REAs. I don't, however, understand the paragraph beneath this listing of criteria. I have read it several times and can't determine what the authors are trying to say, or why this issue is being raised.
10. The decision on page 3-10 to include both single and multi-pollutant models is a good one, and can be used as a form of sensitivity analysis. Where the two approaches lead to very different results that would have policy implications, however, there will be a need to better specify which approach is preferred. The same comment applies to the other categories of different modeling approaches on page 3-17. Taken as a whole, these various approaches should provide a reasonable exploration of the uncertainty introduced by the availability of alternative approaches.
11. On the issue of cut-points raised on 3-18, the authors should be prepared to offer a scientifically cogent reason for selection of a specific cut-point, and not simply try different cut-points to see what effect this has on the analysis. The draft ISA was clear that there is little evidence for a population threshold in the C-R function.
12. The criteria for city selection on pages 3-18 and 3-19 are appropriate and should lead to a reasonable set of such cities.
13. I am less comfortable with the ways in which the baseline rates are to be determined, or at least how I think they will be determined given what is in the text. It sounds to me as if data on the county containing a city, or even the state, will be used. Given differences in background incidence of many effects in rural and urban areas, I worry if background incidence for an urban area is determined from a geographic area with a large rural population. I will withhold judgment on this until I see what is actually employed.
14. I support the general idea of separating variability and uncertainty in the assessment. The listing of sources of variability on 3-22 and 3-23 is a good one, but I am not sure how the authors plan to separate out these sources, or use the multiple cities in the assessment to get an understanding of this variability. At present, the list strikes me as more aspirational than something that can be built into the methodology.
15. I support the use of a qualitative methodology for uncertainty analysis as a first step. And then I like the idea of a quantitative assessment of uncertainty described in the

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document. I worry, however, that the fully quantitative approach described may prove infeasible (I hope not, but that possibility remains). If that is the case, I wouldn't want the default position to be the qualitative analysis alone. There have been quite a few studies of uncertainty in PM risk assessment, including subjective probability encoding. I agree that having a high/medium/low categorization of the impact of specific parameters or model choices will be useful, and so support this idea. But it also occurs to me that something more can be said for each of these about the general magnitude of the uncertainty introduced (i.e. factor of 1.5, 2, 10, etc) even if the formal quantitative approach described does not work in the end. The authors should further consider whether a more quantitative metric – but not the full sensitivity approach described - can be developed as an adjunct to the qualitative one (not as a replacement). If the full sensitivity approach can be developed, though, this is the approach that will have the most utility.

16. On pages 3-26 and 3-27, I am not sure what is meant by “core” risk assessments. Is this meant to be something like “best estimate”? I think it is. If so, just use that phrase, as “core” is not standard terminology.

17. As I read through subsequent pages, I became less convinced I understood the way in which the authors intend to separate the sensitivity and uncertainty analyses. These are not the same kind of analysis. A sensitivity analysis adjusts each parameter by some fixed fraction and examines the influence on the outcome. An uncertainty analysis employs information on the actual degree of uncertainty in each parameter. But the discussion seems to conflate these two, and so I am left unsure whether an actual uncertainty analysis is being proposed, or only a sensitivity analysis. This must be clarified.

18. I support the approach to presenting the results. It has been effective in other REAs and should continue to serve the purpose here. I liked the mention on page 3-29 of considering the representativeness of a particular geographic area, even if I am not sure how this will be done operationally. But it is certainly an important way of viewing the information.

19. The national approach mentioned is ambitious, and in many ways is another level of complexity to the analyses described in earlier parts of the chapter. As it is so complex, I was struck by the lack of detail provided. I cannot judge the feasibility of the approach given this sketchy description, and so will withhold judgment until the approach is described in detail. It just seems to me a LOT of work to do as an adjunct to the other analyses being conducted, and I don't yet see the reason for it.

20. I agree both that the PM10-2.5 approach should be similar to that for 2.5 and that the uncertainty will be larger.

Comments from Dr. David Grantz

David A. Grantz, University of California, 25 March 2009

REGARDING February 2009 draft of

USEPA PM NAAQS: Scope and Methods Plan for Health Risk and Exposure Assessment

1. Include, or better justify exclusion of, “exposure assessment of simulated air quality that meets current or alternative PM standards”.

The Plan repeatedly declines to conduct such an analysis, but the reasons are not apparent. They should be made explicit, as it seems that such an analysis would be a useful and even obvious goal. The authors appear to have serious misgivings about excluding it, since it is restated several times (e.g. at page 1-9, lines 15-16; page 1-12, lines 12-14; and page 4-2, lines 12-15). This seems to contrast with the explicitly stated goal (Figure 3-1) of making quantitative risk estimates at these simulated levels of air quality.

2. Better justify exclusion of air quality data from health endpoint analyses (exceptional events, indoor, personal cloud), that are reasonably excluded from regulatory analysis.

As exceptional events subject populations to exceptional levels of PM exposure, these events may have health endpoint consequences. Their exclusion from exposure modeling (page 2-3, lines 22-27) may inappropriately underestimate exposure, and bias selection of a health protective standard. It may also introduce avoidable variability between C-R relationships obtained at contrasting locations.

The proposed exposure analysis explicitly ignores indoor PM, while giving careful consideration to time spent indoors and therefore partially shielded from outdoor PM (page 4-14, lines 6-12). Assuming that health impacts of indoor and outdoor PM are similar, exclusion of indoor sources will inappropriately underestimate exposure. Similarly, exclusion of the PM contribution of the personal cloud, particularly in the unstirred air indoors, requires justification. At a minimum, the suggested offset of 2-4 $\mu\text{g m}^{-3}$ (page 4-14, lines 13-23) could be incorporated in indoor exposure estimation, while suggesting that further research is required.

3. Evaluate but do not rely on the proposed model (CMAQ)-based-rollback to simulate air quality just meeting current or alternative NAAQS.

The application of CMAQ to this problem has considerable merit. However, there is little evidence presented that serious error will be inserted into the analysis by using the historical data and a proportional rollback approach. At this time it seems prudent to

3-30-09 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel. These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote. continue the conceptually straightforward practice of assuming historical continuity in the patterns of PM reduction, while using the current review to demonstrate the power of the new technique.

4. The Plan can be condensed for clarity and ease of reading.

Many sections of the text can be condensed. Others are partially redundant. For example, the description of the APEX model can be made much more straightforward (Page 4-4, line 16-23, can be combined with page 4-3, lines 5-16). Consideration of alternative models can be much reduced with inclusion of appropriate references.

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Comments from Dr. Frank Speizer

Pre-meeting Comments on PM NAAQS: Scope and Methods Plan for Health Risk and Exposure Assessment, Dated: February 2009

Submitted by Frank E. Speizer

March 25, 2009

Chapter 1:

Page 1-6, Last sentence beginning line 21. I believe this is somewhat revisionist history. The Administrator not only “more heavily weighed...” than did almost everyone else, he essentially bowed to pressure from the White House Offices to redefine any scientific considerations of the meaning of margin of safety to make the definition of uncertainty fit the political needs of his bosses. I suggest a more thorough chronology of the facts be presented, perhaps including the recent court ruling that rejected his logic.

Page 1-8, Section 1.2: As part of the goals of this REA I believe it would be appropriate to re-introduce the concept of “margin of safety”. As this section is written it appears the thinking is continuing along the line of “uncertainty” as the objective itself (and thus a reason set less stringent standards) rather than uncertainty being used to inform the margin of safety.

Page 1-10, Line 10. What about total mortality for PM_{2.5}? More generically should these risks be assessed for all those specific categories in which the data summarized in the ISA identified as “suggestive of causal” rather than just those in which causal is likely or firm? Although this might broaden the work load considerably it would provide a more thorough picture of certainty and uncertainty of risks. (It probably makes more sense biologically and scientifically than focusing on birth outcomes).

Page 1-11, line 7: What does “sufficiently suggestive” mean. The ISA uses suggestive without the adverb.

Page 1-11, Paragraph beginning line 9. Although I would tend to agree I THINK CASAC AS A GROUP NEEDS TO SIGN OFF ON THIS. IN PARTICULAR I AM CONCERN THAT MORE MIGHT BE SAID ABOUT ULTRAFINES

Page 1-12, Figure 1-2: Because of the way the chapter 8 in the ISA is organized should there be a separate line in the APEX model for Vulnerable Groups to go along with Sensitive Populations? For example, urban/downtown centers or near stationary power sources may have significantly greater impact on a sub segment with closer proximity than the entire metropolitan district, which might include suburbs as well. In fact the rest of the page essentially says that is what will be done!

Chapter 2—Useful summary of plan.

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Page 2-9, paragraph 2.5. Not mentioned here but probably to be considered is the variation in seasonal effects across regions. If data exist suggest it also should be considered.

Chapter 3

General Comment: As indicated above I am biased toward accepting “suggestive of causal” for evaluation. This will need to be discussed more fully among the members of CASAC with staff as to what it will mean to add this category to the risk assessment. The summary tables suggest that there might be additional endpoints, which have not made it into the categories of causality (e.g. cancer). The details of the methods seem reasonable but I leave to others with more expertise to comment.

Specific Comments;

Page 3-3, last two sentences beginning line 7: This presents an interesting problem. It seems that this says we must throw out the bulk of the data we have to make estimates with a very weak set of data that can only lead to substantial uncertainty in what gets done. Would it not be better to explore more fully ways in which the PM10 data (in conjunction with the PM2.5 data) could be more effectively used to make estimates for PM10-2.5? I admit I do not know how to do this but have we really explored all possibilities?

Section 3.2.2 Needs to be expanded to include suggestive causal categories.

Page 3-21, Section 3.3 This is an important and appropriate section. Either up front in this introductory section or certainly in the section later that deals with uncertainty, some discussion need to deal further with what happens with the uncertainty, particularly to the degree that it can be quantified. Surely an alternative, or as part of the discussion of what to do with the uncertainty must relate to how it is used in estimating the appropriate margin of safety. Can we begin to decide on how much uncertainty needs to be considered in constructing an adequate margin of safety? Or how much uncertainty results in setting the standard at a level that is not too stringent, given the law states with an adequate margin of safety?

Page 3-33 Section 3.6: Agree with plan to use, if possible suggestive causal data for long term PM10-2.5 as outlined in this section. Reasonable set of studies as outline in Table 3.3. However, as indicated above suggest explore other possible approaches to use PM2.5 and PM10 data to make estimates of PM10-2.5 to expand potential health data base for these analyses. (Maybe this will come up as option in Chapter 4).

Chapter 4. I applaud the effort to do this, and the chapter provides sufficient information to suggest that data do exist. The problem will be both having the time and expertise to carry out the appropriate analyses. I lack the technical expertise to know how many of the procedures proposed are “off the shelf” and already in the appropriate literature. If this is the case than I encourage staff to go ahead. The issue will be to the degree that the analyses are novel they should be peer reviewed and at least in press by the time they are used.

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Comments from Dr. Rogene Henderson

Draft Comments on Scope and Methods Plan for Health Risk and Exposure Assessment, February, 2009

Rogene Henderson

Response to charge questions

1. Selection of health effects

- a. I agree with the endpoints selected.
- b. I see the quantitative risk assessment for birth outcome as potentially quite problematic. The timing of the exposure would be important and this type of exposure information would be difficult to obtain. I am not enthusiastic about this approach.
 - c. I agree with the approach presented on page 3-3, lines 1-4, in which a limited quantitative risk assessment would be conducted for short-term exposures to PM_{10-2.5}

2. Specification of concentration-response functions

- a. Agree
- b. I am not qualified to comment here. I am not familiar with Empirical Bayes.
- c. Agree
- d. Agree, especially because various cut-points will be considered (Page3-18, lines 5-7.

3. Selection of urban study areas

- a. I think the selection criteria are complete and appropriate. I was curious as to what urban areas would be representative of vulnerable populations.
- b. I think the agency has done as well as they can considering the limited data. I wondered why Table 3-3 did not include the studies on coarse particles conducted in the Coachella Valley of California by Lipsett and Ostro.

4. Addressing uncertainty and variability

- a. I agree with it.
- b. I think a major uncertainty is how to deal with co-pollutants and how they contribute to the health effects attributed to PM. The document discusses this well.

5. National patterns of risk

- a. I think it is good to attempt this. There will be many uncertainties, but this is discussed in the document.
- b. I like this idea.

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Comments from Mr. Rich Poirot

R. Poirot Comments on Chapter 2 (Air Quality Considerations) of EPA PM Health Assessment Plan, February 2009.

1. Do Panel members generally agree with the planned approach for obtaining and analyzing the air quality data that will be used in the risk and assessments?

Yes, I think the proposed approach for obtaining and analyzing data for the risk assessments is reasonable.

You indicate that the 2005-2007 data have been filtered by application of the Exceptional Events (EE) Rule for 24-hour NAAQS designations. Does this mean that no data were found to qualify for exceptional event status relative to the annual standard (or is there no policy for this)? It might be informative for the panel if you provided some examples of how the EE screening affects the resulting data and metrics like the 98th or 99th percentiles at selected sites. I wonder how EE-type events were handled in the epidemiological studies?

You indicate that continuous PM data from non FRM/FEM samplers may be used for risk assessments at locations where epidemiological studies were based on such monitors. If that's the case, what procedures, if any, will be applied to convert the non-FRM/FEM data and response functions to "FRM-like" units?

Given that the availability of PM_{10-2.5} data are already quite limited, what approaches, if any, will be considered to account for what may be assumed is the large spatial variability in coarse particle concentrations and exposures?

Given the typically different sources for fine and coarse particles, I'm not sure its logical to assume EEs for PM_{2.5} would also be EEs for PM_{10-2.5}. Forest fires, for example, may result in relatively small contributions to coarse mass.

2. With regard to approaches for simulating air quality that just meets the current or alternative standards under consideration:

a. What are the Panel members' views on the planned use of a proportional (i.e., linear) approach to adjusting air quality (proportional rollback)?

I think the proportional rollback approach has been reasonable in the past given the absence of viable alternatives for estimating a "more realistic" shift in the distribution of concentrations below the standard(s). It would be useful to include this approach in the current assessment, for comparison with both historical results as well as those from other methods of reducing concentrations – such as those based on historical trends or modeling future emissions changes.

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b. What are the Panel member's views on also considering the alternative rollback approach being considered for PM_{2.5} (model-based rollback)?

I like the proposed alternative rollback approach, based in part on logical assumptions about emissions controls pending and/or likely in the relatively near future. It should be cautioned though that sometimes the best laid plans...don't always work so well. For example, a year before the 1996 PM NAAQS revisions, EPA had already issued the final CAIR Rule (Clean Air Interstate Rule - for which the first phase reductions were to commence in 2009 for NO_x and 2010 for SO₂), but the current status of those reductions is uncertain. Still, I think this (modeled) approach could be a useful current and future tool. It might allow, for example, consideration of differential effects of different PM species, sources, or pollutant mixtures, comparisons of alternative control strategies, and assessments of benefits gained or lost by speeding or delaying the implementation

For example, EPA had estimated that CAIR would reduce acidification, improve visibility, and result in \$85-100 billion in health benefits each year, preventing 17,000 premature deaths, 22,000 non-fatal heart attacks, 12,300 hospital admissions, 1.7 million lost work days and 500,000 lost school days. If all this is true, then why was it prudent to phase in the program so gradually over a 10 to 15 year period and to limit it to the Eastern US only (and what are the health costs of further delaying its implementation)? Maybe a modeled rollback approach could be used to evaluate benefits of more rapid or larger-scale emissions reductions.

It isn't clear to me how estimated reductions of specific future controls could be linked to the concept of just attaining the annual or 24-hour standards, as it seems likely such programs would tend to undershoot or overshoot the 24-hr or annual NAAQS. The approach seems promising, but more detail would be helpful.

3. What are the Panel members' views on the planned approach for estimating and using policy-relevant background concentrations?

I think the proposed approach (GEOS-Chem + CMAQ) for estimating policy relevant background seems reasonable. I assume this approach can be demonstrated to work significantly better than use of GEOS-Chem alone? Is it also assumed that this approach is superior to the use of data from selected IMPROVE sites and species (excluding sulfate or sulfate & nitrate) that was considered in the last review cycle?

A relatively poor model performance (underestimates) in the West – if such results are due, as suggested, to failure of the relatively coarse 36 Km grid structure to capture influence of local emissions in mountain valleys - doesn't necessary reflect poorly on the model's estimates of Western PRB. To evaluate this you might stick to comparisons with only higher (relative) elevation ridge-top monitors. It would also be interesting to compare these modeled PRB calculations (or the natural source component of PRB) with the estimates of natural background (mean and deviations) that have been made for the IMPROVE sites.

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Presumably, the PBR calculations include many site-days that might have qualified as exceptional events, had they been measured and caused violations. How do these influences relate to use of measurement data with EEs removed? Are there PRB calculations for $PM_{10-2.5}$?

As indicated by CASAC comments in the last PM review, PRB is un-measurable and therefore fundamentally unknowable, and might most efficiently be handled by using health assessment metrics that minimize its importance.

Comments from Dr. Helen Suh

Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment and Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Urban Visibility Impact Assessment

Comments

Helen H. Suh
Associate Professor
Harvard School of Public Health
Boston, MA 02215

March 25, 2009

Chapter 4: Population Exposure Analysis

- 1) What are panel members' views on the general structure and overall design of the exposure assessment to provide insight on population exposures with respect to informing the interpretation of available epidemiological studies?*

The inclusion of a quantitative exposure assessment is an important component of the health risk assessment. The proposed exposure assessment rightly focuses on PM_{2.5} and its intent is appropriate – to provide insight on population exposures with respect to informing the interpretation of available epidemiological studies. Specifically, the exposure assessment is intended to help identify various personal and building-related factors that may account for some of the variability in PM_{2.5}-associated health risks. To do so, the exposure assessment will predict 24-h population exposures for each of ten cities using the APEX model. The focus on 24-h PM_{2.5} concentrations is appropriate given the importance of community time-series study findings; however, given the likely causal relations between PM_{2.5} and mortality, it is also important to characterize annual exposures for the interpretation of chronic PM_{2.5} studies.

Population exposure assessment will be useful in characterizing the relation between the ambient concentration and mean population exposure (or the ambient exposure factor) and the variability in population exposures – both of which are important to the interpretation of community time series studies. Since APEX is able to estimate both, it has the potential to achieve the goals proposed for this exposure assessment. Before APEX can be used, however, it should be validated and its performance assessed for each city, beginning with the pilot study in Detroit. In addition, the added value of APEX over other more simple exposure assessment methods should be assessed and described. This added value should be balanced with the model complexity and its many data inputs and

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assumptions and also should be balanced with the fact that exposures given future or projected scenarios will not modeled. Simple methods to be considered may include (but are not limited to) GIS-based linear regression or spatial models to estimate impacts of location on outdoor spatial variability, statistical models examining the relation between measured exposures, indoor, outdoor, and ambient concentrations for distinct population sub-groups, and/or analytical models accounting for the influence of different exposure-related variables on pollution-effect associations. While not perfect, some of the simpler methods may be equally or more effective in identifying factors affecting population PM_{2.5} exposures and their relation to corresponding ambient concentrations and health risks. If so, these simpler methods may be preferable to the more complicated model. .

In addition, although the document provides a good and thorough description of the APEX model structure and data inputs, the document does not provide a framework for how the model and its results will be integrated and used to interpret epidemiological studies. As currently presented, the APEX model and its results are disconnected from the basic intent of the work. To maximize the effectiveness and usefulness of the population exposure assessment, a data analysis plan should be developed that describes how the model results and calculated personal exposure factors will be used to (1) explain observed health risk variability and (2) identify and quantify the influence of important personal and building factors on this variability. In addition, the plan should propose an approach to integrate results within and across cities.

In this regard, the pilot exposure assessment to be conducted for Detroit presents a valuable opportunity to refine aspects of the proposed exposure assessment framework and approach. Results from this pilot study should be connected to a time-series health study to examine whether and how health risks obtained using ambient concentrations as the exposure measure differ from those using the estimated population exposures for the entire city, by season, for different susceptible age groups, and for different SES groups.

2) *What are panel members' views regarding the planned measures of exposure?*

As above, the exposure assessment is focused on 24-h population exposures, which is appropriate given the importance of time-series study findings in the causal determinations. Since long-term PM_{2.5} exposures were also found to be “likely causal” of adverse health impacts, it would also be important to develop a plan to characterize annual exposures to help in the interpretation of chronic PM_{2.5} studies.

While interesting, the consideration of additional indicators of exposure (as indicated magnitude and duration of exposures, frequency of repeated high exposures, and ventilation rate) will not likely inform the interpretation of time-series epidemiological studies. These efforts, however, will be useful in explaining variability in autonomic function and other intermediate marker studies that show sub-daily exposures to be important exposure windows.

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- 3) *EPA is planning to focus the exposure assessment on a subset of the urban study area evaluated in the risk assessment. What are panel members' views regarding the selection of these study areas and the planned time periods to be modeled?*

EPA proposes to select ten cities and time periods to correspond to the cities used in the health risk assessment. These cities will also be selected to be diverse, as assessed by geographic location, PM_{2.5} composition, air conditioning use, demographics included SES, and/or baseline health rates. This strategy is appropriate and coordinates well with the planned health risk assessment.

- 4) *Regarding the approach for addressing uncertainty and variability, are Panel members generally supportive of the planned approach?*

The approach used to address uncertainties and variabilities in the model and its inputs is well thought, thorough, and builds upon previous work and findings.

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Submitted by Frank E. Speizer

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General Comment: As indicated above I am biased toward accepting “suggestive of causal” for evaluation. This will need to be discussed more fully among the members of CASAC with staff as to what it will mean to add this category to the risk assessment. The summary tables suggest that there might be additional endpoints, which have not made it into the categories of causality (e.g. cancer). The details of the methods seem reasonable but I leave to others with more expertise to comment.

Specific Comments;

Page 3-3, last two sentences beginning line 7: This presents an interesting problem. It seems that this says we must throw out the bulk of the data we have to make estimates with a very weak set of data that can only lead to substantial uncertainty in what gets done. Would it not be better to explore more fully ways in which the PM10 data (in conjunction with the PM2.5 data) could be more effectively used to make estimates for PM10-2.5? I admit I do not know how to do this but have we really explored all possibilities?

Section 3.2.2 Needs to be expanded to include suggestive causal categories.

Page 3-21, Section 3.3 This is an important and appropriate section. Either up front in this introductory section or certainly in the section later that deals with uncertainty, some discussion need to deal further with what happens with the uncertainty, particularly to the degree that it can be quantified. Surely an alternative, or as part of the discussion of what to do with the uncertainty must relate to how it is used in estimating the appropriate margin of safety. Can we begin to decide on how much uncertainty needs to be considered in constructing an adequate margin of safety? Or how much uncertainty results in setting the standard at a level that is not too stringent, given the law states with an adequate margin of safety?

Page 3-33 Section 3.6: Agree with plan to use, if possible suggestive causal data for long term PM10-2.5 as outlined in this section. Reasonable set of studies as outline in Table 3.3. However, as indicated above suggest explore other possible approaches to use PM2.5 and PM10 data to make estimates of PM10-2.5 to expand potential health data base for these analyses. (Maybe this will come up as option in Chapter 4).

Chapter 4. I applaud the effort to do this, and the chapter provides sufficient information to suggest that data do exist. The problem will be both having the time and expertise to carry out the appropriate analyses. I lack the technical expertise to know how many of the procedures proposed are “off the shelf” and already in the appropriate literature. If this is the case than I encourage staff to go ahead. The issue will be to the degree that the analyses are novel they should be peer reviewed and at least in press by the time they are used.

Comments from Dr. Ted Russell

Review of EPA PM Scope and Methods Plan- Health Risk and Exposure Assessment Armistead (Ted) Russell

I am generally pleased with the PM NAAQS Scope and Methods Plan for Health Risk and Exposure Assessment (hereafter, SM). It lays out a reasonable path that will provide desirable information on the potential risks from and exposures to PM, how those risks may respond to revised PM NAAQS (both PM_{2.5} and PM_{10-2.5}).

I do note a few deficiencies, both in the document as well as the plan.

First, it would have been very nice if the document had a section summarizing criticisms by CASAC and others on the prior risk and exposure assessments, and how they have responded. This could be done by grouping the types of comments made, and how they plan to address them, and where in the current document the planning takes on those criticisms, very much like a typical response to review document. This should become standard in the process.

Chapter 1

On page 1-8, they are considering a nationwide assessment of the potential magnitude of premature mortality. This should definitely be more than a consideration, and should be done. This analysis should, likewise, provide comparisons of the potential risks of meeting the current and alternative standards. I am actually less keen on the exposure analysis next discussed (though still believe it should be done), unless there is a clearer linkage identified between the results of that analysis and how consideration of those results would be reflected in the decision process of revising the NAAQS. We have used those results in the past, though particularly when there was clinical data to suggest exposure levels of concern. Besides additional understanding of the epidemiologic results, what is to be gained? This analysis may prove to be very resource intensive, so additional thought needs to be given as to what aspects of the product would be of use. I personally find the distribution of exposures, both between individuals and by location and source, to provide insight, and to assess the potential of certain subpopulations or individuals to be particularly exposed. I would actually like to have this extended to simulating meeting the standard/alternatives.

Chapter 2:

The air quality considerations chapter adequately lays out the data needed, though the treatment of compositional data should be strengthened. There is growing evidence of the differences in health impacts between PM components, and those components vary spatially and respond differently to controls. Yes, the data to address compositional

3-30-09 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel. These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote. differences is less extensive, but I think still adequate to consider a more thorough treatment.

In this SM, they will use estimates of PRB in their adjustment of PM levels. One question this brings up is what is the correlation between estimated PRB and the observed concentrations? There is reason to suggest that there will be some correlation (possibly negative). For example, natural dust is likely to be higher on windy days when anthropogenic PM levels are low. This has potentially important implications in terms of rolling back 24-hour levels. It is true, however, that given that the PRB levels are typically rather low, so the concern might be minor. This should be assessed.

On page 2-7, they consider using a data melding process using CMAQ and observations to estimate how PM levels should be adjusted. I can agree that this might be “better”, but they need to identify how they will identify if the results are, indeed, better.

On page 2-8, they ascribe a potential issue with the poor performance of CMAQ in the West to model resolution. This should not be said without some further foundation. There are a variety of other possible reasons as well. One question this brings up is does the poorer performance impact the analysis significantly.

Chapter 3.

As noted above, I think there is sufficient information to begin addressing how composition may play a role in the PM risks, and that they can start to address this. It may be that, in the end, the decision is that there is such uncertainty as to not place much emphasis on the results using composition, but the information is still informative, and lays the foundation for the next review. Compositional information is going to be used in the Visibility SM, and it can be used here as well.

On page 3-29, they note that they have greater confidence in the risk estimates for the base case than for the other cases. However, the estimate of difference in risk may not be. This should be assessed.

As noted previously, I strongly encourage EPA to move the national-level assessment from being considered to being a central part of the REA. Also, they suggest they will use a CMAQ model run for one year, and then add parenthetically, e.g., 2005. Given that they are going to use 2004 in their PRB calculation, I would consider doing the same for consistency, all else equal.

Specific: Page 3-19: Do you mean vulnerable and/or susceptible populations?

Chapter 4.

As noted previously, I would think long and hard about how the results from the detailed exposure modeling will be used in the decision process to possibly revise the NAAQS.

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This might impact how the modeling is done and which results are highlighted. I was hoping for a more extensive plan to evaluate the model results.