

10-10-19 Preliminary Draft Comments from Members of the Independent Particulate Matter Review Panel (IPMRP).
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**Preliminary Comments from Members of the
Independent Particulate Matter Review Panel**

on

**EPA’s Policy Assessment for Review of the National Ambient Air
Quality Standards for Particulate Matter (External Review Draft –
September 2019)**

Received as of 10-10-19

Dr. Rob McConnell..... 2

Dr. Rob McConnell
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EPA-3. Chapter 3 – Review of the Primary PM_{2.5} Standards: What are the CASAC views on the approaches described in Chapter 3 to considering the PM_{2.5} health effects evidence and the risk assessment in order to inform preliminary conclusions on the primary PM_{2.5} standards? What are the CASAC views regarding the rationales supporting the preliminary conclusions on the current and potential alternative primary PM_{2.5} standards?

Overall, this is a very solid review and synthesis of literature and policy alternatives and implications.

SCQ-3.2 What are the panel's views on the relative weight that the draft Policy Assessment gives to the evidence-based (i.e. draft PA, section 3.2) and risk-based (i.e. draft PA, section 3.3) approaches in reaching conclusions and recommendations regarding current and alternative PM_{2.5} standards?

There is appropriate focus on the evidence that has emerged since the last PM review for the key outcomes, including mortality and cardiovascular disease. Evidence is well summarized incl cross discipline, low level effects and accountability studies. The risk-based approach provides complementary information relevant to policy.

The summary of the changing conclusions regarding causality in Table 3-1 largely reflects the emerging scientific consensus based on a stronger evidence base. However, I am puzzled that there was not further consideration of likely causal relationships with premature birth and low birth weight. There is also rapidly emerging evidence from epidemiological and toxicological studies indicating that PM_{2.5} exposure causes insulin resistance, impairs beta-cell function and causes Type 2 diabetes. The criteria for the conclusions that these were not likely causal might be explained in more detail.

One disturbing feature of Table 3-1 is the footnote indicating that the CASAC that reviewed the ISA found that the evidence that evidence was not sufficient to conclude that the relationship was likely causal between PM_{2.5} exposure and nervous system effects; between long-term ultrafine particulate (UFP) exposure and nervous system effects; or between long-term PM_{2.5} exposure and cancer". While it is within the purview of the CASAC to make such a determination, did not the CASAC itself acknowledged that it lacked the expertise to do so?

SCQ 3.3 What are the panel's views on the evidence-based approach, including:

- a) The emphasis on health outcomes for which the draft ISA causality determinations are "causal" or "likely causal"?

This is a reasonable approach. See also response to SCQ 3.2

- b) The identification of potential at-risk populations?

The PA acknowledges susceptibility of children, the elderly, the poor and ethnic and racial minorities based on increased exposure, people with pre-existing conditions, in short a large proportion of the population. There is voluminous data on exposure and environmental justice that was not

reviewed in any detail. Also, there was little discussion of genetic susceptibility and the implications for causal inference. Where variants in pathways predicted to be targeted by exposure modify effects, these results can provide a very strong argument for causality.

- c) Reliance on key multicity epidemiology studies conducted in the US and Canada for assessing the PM_{2.5} levels associated with health effects?

These are the most relevant to exposures to the U.S. population. Although it might be argued that the composition of European PM_{2.5} is different than in the U.S., PM_{2.5} composition also differs across the U.S. and Canada, and there is strong evidence of health effects from The ESCAPE studies, for example, and other European studies (as well as elsewhere). The approach should not preclude review of selected studies from elsewhere that provide compelling evidence based on novel design or relevance to questions of interest to the PA.

- d) Characterizing air quality in these key studies using two approaches: is the overall mean and 25th/75th percentiles of the distribution and the “pseudo design value” reflecting a monitor with the highest levels in an area?

I look forward to the committee discussion of this question.

- e) The preference for continuing the use of an annual PM_{2.5} standard as the principle means of providing public health protection against the bulk of the distribution of short- and long-term PM_{2.5} exposures?

The PA makes a credible argument for this approach.

- f) The draft PA conclusions on the extent to which the current scientific information strengthens or alters conclusions reached in the last review on the health effects of PM_{2.5}?

The PA makes a strong case that health effects are occurring at concentrations below the current long-term standard, based on studies showing effects among populations exposed at levels at or below the standard, and the supportive evidence from the design and pseudo-design values. The PA justifies a lower alternative standard to levels around 10 ug/m³, levels below 10 (to as low as 8 ug/m³), and levels between 10 and 12.

- g) Whether the discussions of these and other issues in Chapter 3 accurately reflect and clearly communicate the currently available health effects evidence, including important uncertainties, as characterized in the ISA?

There is appropriate consideration of the uncertainties.

EPA-4. Chapter 4 – Review of the Primary PM₁₀ Standard: What are the CASAC views on the approach described in Chapter 4 to considering the PM_{10-2.5} health effects evidence in order to inform preliminary conclusions on the primary PM₁₀ standard? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current primary PM₁₀ standard?

SCQ-4.1 To what extent does the panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the PM₁₀ NAAQS review? Are there additional policy-relevant questions that should be addressed?

SCQ-4.2 What are the panel's views of the draft PA assessment of the currently available scientific evidence regarding the health effects associated with exposures to thoracic course particles, PM_{10-2.5}?

SCQ-4.3 What are the panel's views on the draft PA preliminary conclusion that the available evidence does not call into question the adequacy of the public health protection afforded by the current primary PM₁₀ standard and that evidence supports consideration of retaining the current standard?

The PA makes a case that, in spite of additional epidemiological studies, key uncertainties in the evidence that precluded a determination of causal role for PM_{10-2.5} by itself or a justification for considering alternative standards for PM₁₀ in the last PM review. Additional research is needed: toxicological effects of coarse-thoracic PM; inhalation challenge studies to characterize acute effects and pathways and subclinical effects; studies of susceptible populations, especially asthmatics. Appropriate methods for exposure assessment of PM-2.5 and for analysis of exposure assigned using different methods, and of co-pollutant effects, rare acutely in need of further investigation. This is not to say that current levels of exposure to PM_{10-2.5} are safe, rather that there is not enough evidence to make a determination.

EPA-6. Chapters 3 to 5: What are the CASAC views regarding the areas for additional research identified in Chapters 3, 4 and 5? Are there additional areas that should be highlighted?

Response to follow.