

05-19-16 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Particulate Matter 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 Do not cite or quote.

**Preliminary Comments from Dr. Rob McConnell on
EPA's *Integrated Review Plan for the National Ambient Air Quality Standards
for Particulate Matter (External Review Draft – April 2016)*
05-19-16**

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The chapter clearly and adequately describes the scope, specific issues to be considered, and organization of the ISA.

What are the panel's views on the overall scope of the ISA? Does the planned scope ensure that the EPA will capture the scientific literature most pertinent to the ISA's focus, which is answering the question, "Is there an independent effect of PM on health and welfare at relevant ambient concentrations?"

In general, the strategy proposed to identify the relevant literature is appropriate. One potential reconsideration might be the automatic exclusion of all commentaries. Although these might not generally contain new primary data, some selected ones might provide novel insights into mechanisms or interpretation of the literature.

Some additional questions that merit consideration:

The impact of recent revelations of uncertainties in emission profiles, especially for diesel exhaust particulate, is not identified as a potentially relevant issue. Allegations that the emissions from some vehicles have not been appropriately reported by the manufacturers or adequately characterized in emissions assessments may be relevant to the ISA.

The scope of work does not exclude consideration of on-road (eg. commuting) exposures, which are increasingly recognized to result in health-relevant exposures, but they are not mentioned. These might appropriately be included in the review. There are other recently recognized sources of heavy PM exposure, such as ultrafine particles from large airports.

As a minor clarification, the distinction of effects of short-term exposure studies ("i.e., exposures ranging from hours to days to weeks") that primarily rely on temporal variation in exposure from effects of long-term exposure studies ("i.e., 13 exposures ranging from months to years") that rely on spatial variability of exposure is, in general, appropriate. Conceptually, however, exposures that vary seasonally over months may reflect temporal variation with high relevance for some outcomes, for example trimester-specific gestational effects of exposure. To the extent possible, harmonization of evaluation of effects across temporal windows of exposure would be helpful.

Does the restriction to studies of exposures below 2 mg/m³ preclude inclusion of studies that would help strengthen causal inference based on an evaluation of concentration-response or dose-response

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relationships, for example studies of effects of occupational exposures to diesel exhaust particulate components of the PM mixture? To the extent recent studies attempting to examine the integrated exposure response relationship across a range extending to secondhand or personal tobacco smoke exposure is relevant to the ISA, the 2 mg/m³ restriction should be loosened. A related issue is the apparent restriction of toxicological studies to those below 2 mg/m³ PM, if I understood correctly. This seems likely to preclude assessment of dose-response relationships and to dramatically reduce power to identify effects in animal studies.

Finally, it is not clear to me why studies evaluating risk of cancer will not include studies that use PM filter extracts (“because they may not mimic what is bioavailable in vivo”), or on studies of individual PM components (“due to the inability to compare effects to the current mass-based PM indicator”). Does the focus on size preclude an integrated assessment of the role of some key components, for examples metals, that are found in multiple size fractions?

What are the panel’s views on the approaches outlined in Chapter 3 to streamline the discussion in some sections of the ISA? What are the panel’s views on EPA’s plans to produce an assessment that is concise and forms an adequate scientific foundation for subsequent steps of the NAAQS review process?

In general, the approach to streamlining the discussion seems reasonable, as long as there is a clear rationale for excluding literature that is not relevant to the development of a standard.