

## Questions for Non-Member Consultants on the PM PA from Dr. Mark Frampton

1. The EPA concluded in the 2009 PM ISA, and reconfirmed in the 2018 ISA, that the scientific evidence is sufficient to conclude that the relationship between PM<sub>2.5</sub> exposure and mortality is causal. Previous CASACs have concurred with this conclusion. This finding, among other causality determinations expressed in the ISA, forms a key basis for the risk assessments presented in the current PA. However, the current CASAC was not able to reach agreement on this important issue, as indicated in the letter to the Administrator ([April 11, 2019](#)). Some CASAC members are of the opinion that the scientific evidence base is insufficient to support a causal relationship between PM exposure and mortality. Is there evidence that would support a reconsideration of the current and long-held views of this causal relationship as expressed in the PA and ISA?
2. In the long-term epidemiological studies of PM mortality, heterogeneity between and within cities has been cited as a source of uncertainty in drawing conclusions about causality. Please opine on the level of uncertainty that is represented by this heterogeneity, and the impact if any, on the conclusions in the PA.
3. Dr. Cox, Chair of CASAC, has introduced concepts of causality determination that differ from the framework established by the EPA in prior ISAs, used in the current PM ISA, and reiterated in section 3.2 of the current PA. This was a topic of discussion during CASAC's recent review of the PM ISA. Please opine on the adequacy of the causality analysis framework currently used by the EPA, and whether and how the concepts espoused by Dr. Cox should, or should not, be incorporated into the NAAQS causality framework. Also please comment on the implications, of any changes in the causality framework that you would recommend, for the analyses and conclusions in this current PA. For background, see the following documents:
  - 1) Preamble to the Integrated Science Assessments, November 2015, pages 18 to 25 ([https://yosemite.epa.gov/sab/sabproduct.nsf/78476291901FF5AE8525835F00634158/\\$File/ISA\\_PREAMBLE\\_FINAL2015.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/78476291901FF5AE8525835F00634158/$File/ISA_PREAMBLE_FINAL2015.pdf));
  - 2) Follow-up Questions for John Vandenberg from Dr. Cox, letter of 12/17/2018 ([https://yosemite.epa.gov/sab/sabproduct.nsf/B28289529495F929852583660057A3EE/\\$File/Follow-up+questions+for+John+Vandenberg-rev.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/B28289529495F929852583660057A3EE/$File/Follow-up+questions+for+John+Vandenberg-rev.pdf));
  - 3) Responses from John Vandenberg, letter of 2/20/2019 ([https://yosemite.epa.gov/sab/sabproduct.nsf/B48131F413362439852583A7005FDFDA/\\$File/JVandenberg+response+to+TCox+ltr+of+121718.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/B48131F413362439852583A7005FDFDA/$File/JVandenberg+response+to+TCox+ltr+of+121718.pdf));
  - 4) CASAC letter to the Administrator, April 11, 2019 - Dr. Cox comments, pages A8 to A27 ([https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/6CBCBBC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002+.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002+.pdf)).
4. The CASAC letter to the Administrator ([April 11, 2019](#)) states, "There is inadequate evidence for the 'likely to be causal' conclusion for long-term PM<sub>2.5</sub> exposure and cancer." This is based on epidemiological studies that do not appear to adequately differentiate incident cancer and cancer-related mortality because the exposure time frames for most of these studies are insufficient to draw conclusions about incident cancer. Do you agree with the CASAC's findings in this matter? Please discuss the evidence (or lack thereof) that supports your opinion.
5. Please comment on the appropriateness and completeness of the approaches used in this PA to assess the risks of exposure, and the assessments of risk reduction of alternate standards, for PM<sub>2.5</sub> and PM<sub>10</sub> (sections 3 and 4, respectively).

6. Are there additional key studies that should be considered in sections 3 and 4 of the PA?