

Comments on the CASAC Draft Letter to the Administrator on Its Review of US EPA's Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018)

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March 28, 2019

Thank you for the opportunity to speak today. I am an epidemiologist and board-certified toxicologist at Gradient, an environmental consulting firm. I am speaking on behalf of Gradient, but my time spent preparing these comments and attending this teleconference has been supported by the American Petroleum Institute. I appreciate all the efforts that went into the CASAC responses to charge questions. In my written comments, I discuss a few areas in which I think CASAC could consider providing more detail.

Several people have taken issue with CASAC's expertise. Setting aside the question regarding expertise, CASAC has provided many valid critiques of several analyses in the Draft ISA. EPA should consider and address these comments, particularly with regard to evaluations of individual studies. Also, there is a lack of consensus among the CASAC members regarding EPA's evaluation of the concentration-response relationships, which indicates more discussion is needed on this very important topic.

Several people, including Dr. John Vandenberg from EPA, have indicated that it is not appropriate for the ISA to rely solely on epidemiology studies that use "causal methods" and ignore the plethora of available epidemiology evidence on PM and health effects. Dr. Vandenberg has also noted that EPA does not focus only on epidemiology evidence when making causal determinations, but also exposure, dosimetry, and experimental evidence.

I completely agree with Dr. Vandenberg and others that studies that use causal methods should not form the sole basis for casual conclusions. However, as I have pointed out in comments to EPA, even though the Draft ISA considers many studies across several disciplines, it does not do so in a systematic, unbiased, or transparent manner.

This is at least partly because while the Draft ISA does have a protocol, the protocol lacks sufficient detail. The protocol should include well-developed methods for the literature search strategy; study inclusion and exclusion criteria; a process for data extraction and quality control; specific, prescriptive criteria for evaluating study quality; data analysis methods; and PM-specific methods for evidence integration and causality determinations.

In particular, while the Draft ISA provides very detailed study quality criteria, the list of criteria is incomplete and does not include any criteria for *in vitro* studies. There is also no documentation of a study quality assessment in the Draft ISA, and the results of many studies were discussed without any indication of how study quality may have impacted the interpretation of results.

In the absence of a detailed protocol and robust study quality evaluation, the Draft ISA does not evaluate and integrate the evidence in a transparent, systematic, and unbiased manner. As such, the causal determinations for health effects from PM exposure are biased towards causation, and undue confidence is placed in observational concentration-response data that contain substantial uncertainties.

In closing, the CASAC letter and responses to charge questions are extremely thoughtful and thorough, although additional details in a few areas would be helpful. Setting aside the issues with CASAC's expertise and recommendations regarding casual methods, EPA should consider and address CASAC's comments regarding the ISA review process and evaluation.