

I'm Giffe Johnson and I'm speaking on behalf of the National Council for Air and Stream Improvement or NCASI. Before joining NCASI, I spent about 10 years as faculty in the Toxicology and Risk Assessment program at the University of South Florida and served as the Assistant Director of Research at the Center for Environmental and Occupational Risk Analysis during this time. I hold graduate degrees in Epidemiology and Toxicology and have engaged in primary research in these fields for about 12 years.

The focus of my comments today is on the use of scientific research in the draft particulate matter policy assessment. The draft policy assessment relies on the review of scientific literature conducted in the draft integrated science assessment for particulate matter. However, as reflected in my Dec 2018 comments on the draft ISA for particulate matter, the approach used in the ISA review lacks several critical features of a systematic review framework.

Systematic review frameworks serve to uniformly address uncertainty and bias within a set of literature, weight and integrate lines of evidence within the context of bias and uncertainty and provide a more realistic characterization of confidence in the conclusions drawn from a literature review. Lacking this, the draft ISA and the draft policy assessment for particulate matter does not adequately characterize uncertainty and bias that exists across lines of evidence. These assessments, in many cases, also don't contemplate the adequacy of the reviewed literature for addressing specific, policy relevant, research questions.

NCASI, in collaboration with subject matter experts, has developed a systematic review protocol for evaluating the potential impact of PM<sub>2.5</sub> on mortality and ischemic heart disease at policy relevant exposure scenarios, to stimulate dialog and demonstrate the benefits of a systematic review approach. This protocol relies on both contemporary systematic review practices, as well as risk of bias and evidence integration criteria tailored specifically to the needs of the NAAQS PM rulemaking process. The protocol has been submitted to the EPA and CASAC as part of written comments to the policy assessment.

As appendices to this protocol, two articles highlighted in the ISA that impact the policy assessment, Kloog et al. 2014 and Cesaroni et al. 2013, have been taken through the process of data extraction, risk of bias evaluation, and discussed in terms of evidence integration as prescribed by our protocol. This systematic evaluation demonstrates that these sentinel articles, although being relied upon for conclusions of causation between PM<sub>2.5</sub> and mortality or ischemic heart disease at policy relevant exposure scenarios, are contextualized with poor confidence due to uncertainty and bias. Time constraints prevented us from developing more examples or undertaking a complete review of the literature using this protocol. However, these two examples serve to illustrate how other articles heavily relied upon by the draft policy assessment would be evaluated under this protocol. Many studies that rely on linear models, use insufficiently individualized exposure assessments and fail to adequately consider the impact of unmeasured confounding would likely be ranked and integrated similar to Kloog et al. 2014 and Cesaroni et al. 2013. This includes other heavily cited studies such as Di et al. 2017 and Shi et al. 2016.

The goal of these comments is not to impugn the science in the articles previously mentioned but to illustrate the drawbacks of the approach used to review the scientific literature. The lack of specificity in the research questions asked during the review process causes studies to be brought in without an appropriate characterization of their ability to answer the scientific questions relevant to policy setting. A systematic review approach, as presented in our written comments, avoids these pitfalls and can

rigorously evaluate the current body of literature. An approach that uniformly and consistently weighs health-related findings for uncertainty, bias, and policy relevance is critical for concluding that adverse health effects occur below current exposure standards.

I'd like to thank the CASAC and EPA staff for their time in listening to these comments and reviewing our written comments. We welcome any comments or questions relevant to our technical work in this area.