

Summary of Testimony to The Clean Air Scientific Advisory Committee:
The CASAC Meeting on the Draft Particulate Matter ISA December 12-13, 2018

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While the mission of the Environmental Protection Agency (EPA) under the Clean Air Act to protect public health by setting National Ambient Air Quality Standards (NAAQS) is critical, we believe that this policy should be based on the best available science, using the best systematic and transparent review process to produce a reliable characterization of the relationship between particulate matter and potential health effects.

Increasingly institutions that conduct science-based policy assessment have instituted more rigorous systematic review methodologies. These institutions include the National Toxicology Program (NTP) under the Toxic Substances Control Act (TSCA), the National Academies of Sciences (NAS), and EPA's Integrated Risk Information System (IRIS) program. These methodologies have been adopted in order to more accurately rank, weight, and evaluate quality of individual studies within a framework to more reliably and transparently draw conclusions related to exposure/disease relationships.

Using a systematic review framework that includes pre-specified eligibility criteria, all empirical evidence can be evaluated to answer a specific research questions. The methodology relies on explicit, systematic methods that minimize bias, thus providing a more reliable evaluation for drawing conclusions and decision-making.

The key elements of a systematic review include:

- a clearly stated set of objectives with pre-defined eligibility criteria for studies;
- an explicit, reproducible methodology;
- a systematic search that attempts to identify all studies that would meet the eligibility criteria;
- an assessment of the validity of the findings of the included studies, for example through the assessment of risk of bias; and
- a systematic presentation, and synthesis, of the characteristics and findings of the included studies.

Although the EPA NAAQS Framework for Causal Determination, includes some of these elements, many of them are missing, resulting in an assessment that lacks transparency and is prone to risk of bias and potentially unreliable conclusions.

For example, the research questions in the Draft ISA are not specific enough to inform the development of review criteria and study inclusion/exclusion and for study quality evaluation. The imprecise framing of research questions and this can lead to inappropriate selection of literature terms for establishing relevance and assessing study quality.

In addition, the literature selection process lacks critical elements of systematic review. For example, the Draft ISA does not clearly present the methodology details for the literature search and how the studies were selected or excluded from the review (i.e., in terms of flow charts etc.). The lack of specific details inhibits the ability to reproduce the science assessment leading to poor transparency.

In relation to the assessment of study quality, this is entirely missing from the Draft ISA. There is no guidance for establishing the criteria for study quality. One example of this is in the evaluation of the epidemiological literature. One important limitation in the air quality studies that are included in the review is the issue of confounding. This issue is not adequately evaluated in the Draft ISA. We found that key studies were absent from the review that highlighted this important issue. Without a systematic approach that provides specific criteria for study selection and evaluation, there is a substantial risk of bias that can compromise the reliability of the ISA findings.

Another study quality feature with regards to the epidemiological evidence relates to the impact of model selection and other assumptions in the key studies identified in the Draft ISA. EPA does not have a systematic approach to evaluate the impact of model specifications and underlying model assumptions in each of the studies. Model specification can have a large impact on the underlying results of an epidemiological study, and if model assumptions are inaccurate this calls into question the reliability of the study results. The ISA lacks a pre-defined systematic approach to evaluate this important issue.

Another issue that is absent from consideration in the ISA is the issue of publication bias. New meta-analyses that have been recently conducted have highlighted this important issue, yet EPA has not addressed it in the ISA. A pre-defined systematic approach should include the consideration of this issue as part of the scientific evaluation of the health impacts of particulate matter.

The integration of the evidence in the ISA also is lacking. There is no pre-defined methodology for integration across all lines of scientific evidence. Instead, the Draft ISA appears to rely almost entirely on evidence from epidemiological studies, giving little weight to other lines of scientific evidence that may provide alternative views or challenge the conclusions from the epidemiology studies. In addition, without a framework for weighing the quality of the studies it is unclear how the evidence can be ranked across all lines of evidence. One important consideration is the integration of Mode of Action studies and the reconciliation of concentration-response associations in epidemiological studies compared to dose-response associations observed in toxicological studies. Without an established systematic approach for integrating these lines of evidence the reliability of the conclusions presented in the Draft ISA can be called into question.

The establishment of a systematic review process that includes pre-defined, objective criteria to reach judgements of causality would improve the scientific rigor of the ISA. The lack of objective

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criteria or well-defined criteria to reach conclusions of causality impairs the reliability of the scientific judgements.

Overall the Draft ISA process currently introduces uncertainty and bias at every stage of the review process and is unable to adequately characterize the relationship between particulate matter and health outcomes. The ISA should be conducted applying a systematic approach.

We appreciate the time provided to give testimony on these issues, however, we are allotted to short an amount of time to adequately present our comments. Please refer to our written comments for a more detailed review of the issues presented here.