

**Testimony of the
American Petroleum Institute
Oral Comments before the Clean Air Scientific Advisory Committee
on the
National Ambient Air Quality Standards:
Integrated Science Assessment for Particulate Matter (External Review Draft)
[83 *Fed. Reg.* 534,71 (October 23, 2018)], Docket ID: EPA-HQ-ORD-2014-0859
December 12, 2018**

Thank you for the opportunity to provide public comment today. My name is Ted Steichen, a Senior Policy Advisor at the American Petroleum Institute (API).

API is the only national trade association representing all facets of the oil and natural gas industry, which supports 10.3 million U.S. jobs and nearly 8 percent of the U.S. economy. Our over 620 corporate members – from large integrated oil and gas companies to small independent companies – comprise all segments of the industry. API member companies are producers, refiners, suppliers, retailers, pipeline operators and marine transporters, as well as service and supply companies providing much of the nation’s energy. Science that informs the development of policy and regulations impacts all aspects of API member business.

The members of API are dedicated to continuous efforts to improve the compatibility of their operations with the environment while economically developing energy resources and supplying high quality products and services to consumers. Our members recognize their responsibility to work with the public, the government, and others to develop and to use natural resources in an environmentally sound manner while protecting the health and safety of our employees and the public.

I offer the follow comments on the Draft Integrated Science Assessment for Particulate Matter (External Review Draft) (herein referred to as the "draft ISA") issued in October 2018 (US EPA, 2018).

There are several overarching issues in the draft ISA evaluation that undermine its conclusions:

- **The draft ISA lacks a sufficiently detailed systematic review protocol.** The lack of a protocol which sufficiently details literature search strategy, inclusion and exclusion criteria, methods for evaluating study quality, evidence integration and causality determinations, and so on, has led to an evaluation that was not conducted in a systematic, unbiased, or transparent manner.

- **Study quality is not sufficiently addressed.** The draft ISA provides a list of important study quality aspects in Appendix 1 but acknowledges that the list is not complete. As it stands, one cannot ascertain how the draft ISA determined the quality of any individual study based on this list.
 - Quality aspects should be tabulated for each individual study.
 - High-quality studies should be given more weight.
 - Quality of all studies should be considered.
- **Study relevance criteria should be explicitly stated.** The draft ISA should explicitly state the criteria that must be met for study results to be considered relevant and representative of the US population as a whole and to "at-risk" populations.
- **The causal framework is not adequate.** The causal framework is structured in such a way that biases towards a causal conclusion. It should be revised to be more balanced, such as the original Institute of Medicine framework.

Because of these overarching issues, the available evidence is not reviewed and integrated in a consistent, systematic way, and consequently, the causal conclusions are not supported by the weight of scientific evidence.

While the draft ISA includes potentially useful information, the unsystematic review and inadequate evaluation of study quality argue that this draft is not fit for purpose. Coupled with the use of a biased causal framework, the draft ISA conclusions are not informative to this NAAQS review.

The last PM NAAQS review ended with the publication of a final rule in January 2013. EPA has stated its commitment to meet the statutory five-year review going forward, and for PM is targeting getting as close as possible to that intention by establishing December 2020 as the target for completion of this rule. As you, CASAC, now evaluate this draft ISA, with that deadline in mind, there is a dilemma as to how you are able to advise on this process. On one hand, this draft ISA needs significant revisions to provide the information needed to move the review forward; however, the wholesale reworking of the document could necessitate a substantial delay the review.

API therefore asks CASAC to recommend EPA work diligently to revise the draft ISA starting with objectively reevaluating any change in a causal determination since the 2009 final ISA, as well as highlighting in the Executive Summary and subsequently in the document, the substantial uncertainties remaining due to the lack of a documented transparent framework to evaluate the

studies and a consistent process to assess and consider study quality. Specifically, CASAC should include in their Report to the Administrator:

- 1.) The draft ISA lacks a sufficiently detailed systematic review protocol, it does not sufficiently detail the literature search strategy, inclusion and exclusion criteria, methods for evaluating study quality, evidence integration and causality determinations, therefore the evaluation was not conducted in a systematic, unbiased, or transparent manner.
- 2.) The draft ISA lacks a systematic review of the studies and therefore does not highlight which of the studies are of the best quality and therefore to be most heavily relied upon. To partially address this deficiency, EPA could use Gradient's approach, including spreadsheets and heat maps as a guide to assessing study quality; these documents¹ have been provided to CASAC and the Docket.
- 3.) Replace Table P2 in the draft ISA listing the modified five causal classifications, with the four causal classifications in the original Institute of Medicine (IOM) framework to eliminate some of the bias. Such a framework, when accurately employed, could better ensure evidence is reviewed systematically and consistently by these well-specified criteria, so that causality can be objectively assessed.

Addressing these three findings would provide a final ISA that could be useful in completing this NAAQS review in a timely manner.

¹ Note this material is confined to mortality and cardiovascular morbidity because these endpoints have great policy-relevant significance in that they are the basis of the concentration-response assessment.