

COMMENTS CONCERNING EPA'S INTEGRATED SCIENCE ASSESSMENT (ISA) FOR
PARTICULATE MATTER (EXTERNAL REVIEW DRAFT-OCTOBER 2018)

Prepared by:

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Background

I write these comments from the professional perspective of being a pulmonary physician and epidemiological researcher who has carried out research on the health effects of indoor and outdoor air pollution for decades. My research has used the full range of epidemiological methods to assess associations of air pollution with health. As a consequence of my research background, I have been a member of numerous national and international committees concerned with the translation of scientific evidence into policy, including serving on various committees of the Environmental Protection Agency's (EPA) Science Advisory Board. With regard to Particulate Matter (PM), I was one of the Consultants to the Clean Air Scientific Advisory Committee (CASAC) for the review of the Criteria Document and Staff Paper that led to the 1997 PM_{2.5} National Ambient Air Quality Standard (NAAQS). I chaired CASAC from 2008 through 2012 and, while in this role, I led the reviews carried out for the PM NAAQS. During that review, the transition to the current suite of documents related to the NAAQS review process was completed, resulting in the Integrated Science Assessment (ISA), the Risk and Exposure Assessment (REA), and the Policy Assessment (PA). I provided guidance to the EPA staff concerning frameworks for assembling and evaluating evidence, drawing on my experience as editor and author for the reports of the Surgeon General on smoking and health and various committees of the National Academies of Science, Engineering and Medicine that I chaired. Of these committees, the Committee on Research Priorities for Airborne Particulate Matter is particularly relevant, as the committee was tasked to identify the most critical scientific uncertainties around PM following the PM_{2.5} NAAQS, to develop a research agenda addressing these uncertainties, and to track progress in resolving these uncertainties.

Since my term on CASAC ended, the EPA's approach for assembling and interpreting evidence with review from CASAC has proved effective. The approach is well-established (Figure 1); provides a transparent record of the concerns raised during the review, summarized in a letter to the Administrator; and changes in response to review are documented with a rationale provided. The scope of the documents reviewed and the breadth of the scientific evidence has necessitated the augmentation of the seven Chartered CASAC members with additional panelists and several cycles of revision and review of each consecutive document have been needed. The practice of expanding the panel beyond the Chartered CASAC members is long-standing. For example, I attach a table taken from the June 13, 1996 Closure Letter on the Staff Paper from Dr. George Wolff, CASAC Chair, to Administrator Browner ([Link to Letter](#)). This informative table lists the 21 panel members and their expertise, reflecting the broad range of disciplines required for comprehensive review of the lengthy documents assembled for reconsidering a NAAQS (Table 1). That scope cannot be captured with the seven members of the Chartered CASAC.

The sequence of the documents is consistent with usual risk assessment approaches: the ISA is concerned with hazard identification, providing an assessment of the strength of evidence for causation and a suite of outcomes for consideration in the REA. The approach to making judgments as to the causal nature of associations of PM with health outcomes draws on widely used approaches, embedded within various EPA guidelines and used by other entities, e.g., the

Centers for Disease Control and Prevention in evaluating the evidence on smoking and health. The REA considers selected health outcomes and assesses the burden of disease attributable to PM at current levels and levels that would prevail under various scenarios associated with changes in the NAAQS. The REA is a critical step in moving from the ISA and its identification of hazard to the PA, which guides the Administrator's decision-making.

This process has been in place for about a decade, undergoing small refinements. Generally, there is agreement that it has proved a workable approach to the complex task of moving from myriad scientific papers to the evidence that is most critical for possible revisions to the NAAQS. The Appendix to these comments includes a letter from seven former Chartered CASAC members, supporting the current approach and offering concern about not expanding beyond these seven individuals.

The Current ISA Review

Over two days, December 12 and 13, the charter CASAC members face the task of reviewing the draft PM ISA, numbering 1881 pages and occupying 19.4 megabytes. It was first released on October 23, allowing approximately 6 weeks for review by CASAC and the public. The CASAC has five general charge questions stemming from the "Back to Basics Process for Review of the National Ambient Air Quality Standards" and an additional eight, more specific, albeit challenging, questions. Examining the agenda, setting aside the time for administrative matters, presentations, and public comments, approximately 11 hours remain for the committee to do its work, including a writing session. The CASAC members will likely continue to refine their comments following the meeting, but this schedule for reviewing an enormous document cannot support the needed in-depth review.

With deference to the CASAC members, this mandated approach can at best result in a more superficial review and more cursory comments than achieved with the prior approach. As a first item on its agenda, CASAC should question the EPA staff on the new review approach and, specifically, how the consequences of this abbreviated process will be evaluated. Such questioning is justifiable, given how the review process has been altered and the implications of a hurried evaluation. The import of this first testing of the new review process needs to be fully understood.

The Current ISA

As noted, the current ISA is lengthy, reflecting the enormity of the literature. Quoting the ISA (P-10, line 18): "This ISA evaluates relevant scientific literature since the 2009 PM ISA...". Over that time period, the growth of the literature on PM and health alone has been substantial (Table 2). This table provides article counts from broad searches conducted on December 10, 2018 on topics relevant to this ISA. The scope of the literature available and considered is enormous with 2656 references cited in the first draft ISA.

Consider Chapter 5, *Respiratory Effects*, for example. This 340 page chapter covers a broad set of outcomes that are critically relevant to public health; the relevant literature covers particle characteristics and dosimetry, and findings from mechanistic, toxicological and epidemiological research. It covers not only PM_{2.5}, but also PM_{10-2.5} and ultrafine particles (UFP) across an array of health outcomes. There are 425 citations. The various lines of evidence are considered for each outcome and synthesized following the principles laid out in the Preface of the ISA. The ISA's findings reaffirm those of the 2009 ISA, without advancing conclusions with regard to the strength of evidence.

The CASAC review of this chapter should include panel members with expertise in lung toxicology, mechanisms of lung injury and epidemiology. Given the breadth of the outcomes considered, more focused expertise in some areas, e.g., asthma, is warranted. And, reviewers will likely need to examine some of the critical studies cited to assure that they have been correctly represented or to address study-specific concerns.

Are Refinements Needed?

Inevitably, any process for gathering, reviewing, and synthesizing evidence can be improved as experience is gained. While I have been supportive of the ISA as a format for gathering and reviewing evidence, new and more efficient approaches may be needed, particularly for PM and ozone, given the scope of the relevant literature. In the case of PM, by 2009, substantial evidence causally linked PM to a number of short-term and long-term adverse effects. These became the basis for the REA, an analysis supporting the PA and ultimately the Administrator's decision on NAAQS revision. When adverse effects of major public health concern have well documented causal links to PM, should the emerging literature be reviewed exhaustively? Could screening approaches be used to limit the number of comprehensive reviews considered in the ISA?

The REA remains a key step in developing evidence-based guidance for the Administrator. It would best be maintained as a free-standing document.

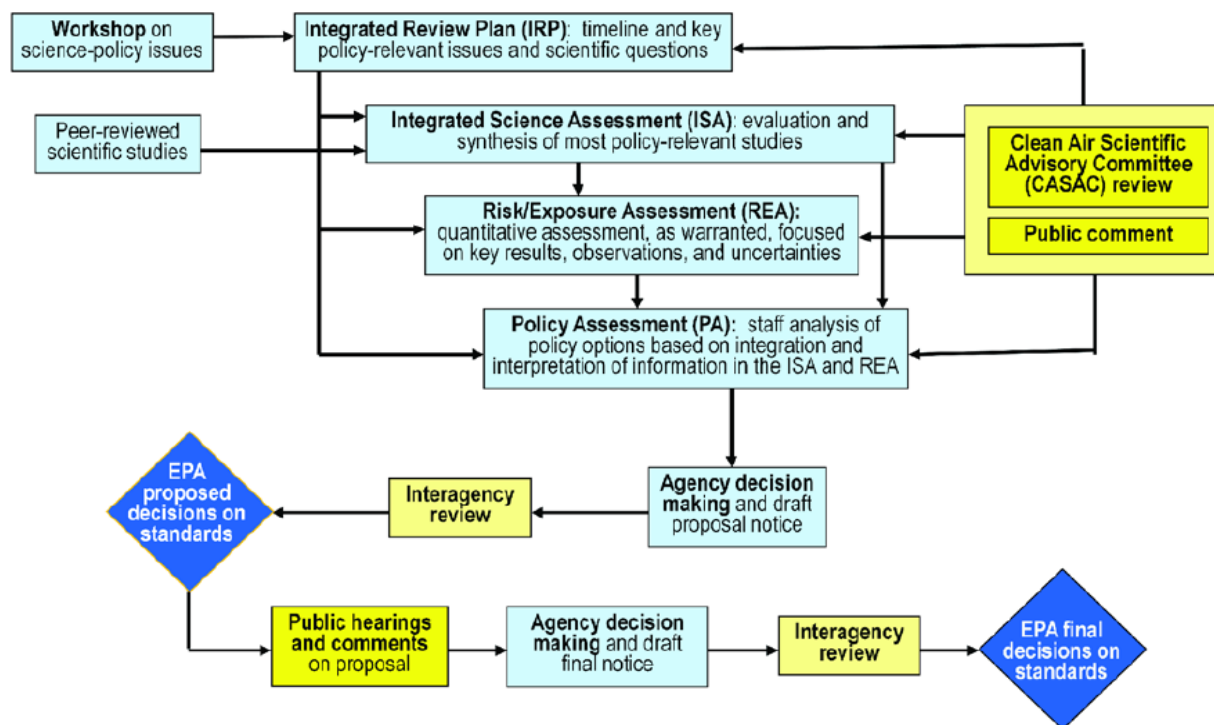
Conclusions and Recommendations

My comments concerning the formidable, if not impossible challenge, posed by review of the draft PM ISA have been echoed by others. Thus, with regard to the process for this review of the PM ISA, I recommend the following:

1. CASAC should provide its assessment of the feasibility and effectiveness of this accelerated review process, coinciding with not appointing consultant members to the PM panel. This first application of a new process should be closely scrutinized for its consequences.

2. The Science Advisory Board should undertake its own evaluation of the sweeping changes made to its review processes for the PM NAAQS and the consequences for the quality of its work.
3. The EPA staff need to continue to provide a written response to CASAC's principal comments; such documentation is critical if CASAC has only a single review meeting.
4. The size of the draft PM ISA contributes to the complexity of review, even without the changes to the review processes. The ISA was intended to be briefer and more integrative than the previous Criteria Documents. In that regard, the ISA has succeeded, but this approach to evidence gathering, evaluation, and synthesis is challenged by the enormity of the literature. Discussion is warranted as to how to scope the literature relevant to updating a NAAQS and to produce a sufficiently informative, but smaller document.

Figure 1. Schematic of the key steps in review of the National Ambient Air Quality Standards



U.S. EPA (U.S. Environmental Protection Agency). (2015). Preamble to the Integrated Science Assessments [EPA Report]. (EPA/600/R-15/067). Research Triangle Park, NC: U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment—RTP Division. <https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244>.

Table 1. [Summary of CASAC Panel Members Recommendations \(all units \$\mu\text{g}/\text{m}^3\$ \), 1996](#)

		PM _{2.5} 24-hr	PM _{2.5} Annual	PM ₁₀ 24-hr	PM ₁₀ Annual
Current NAAQS		N/A	N/A	150	50
EPA Staff Recommendation		18 - 65	12.5 - 20	150 ¹³	40 - 50
Name	Discipline				
Ayres	M.D.	yes ²	yes ²	150	50
Hopke	Atmos. Sci.	20 - 50 ³	20 - 30	no	40 - 50 ⁴
Jacobson	Plant Biologist	yes ²	yes ²	150	50
Koutrakis	Atmos. Sci.	yes ^{2,5,6}	yes ^{2,5,6}	no	yes ⁴
Larntz	Statistician	no	25-30 ⁷	no	yes ²
Legge	Plant Biologist	≥ 75	no	150	40 - 50
Lippmann	Health Expert	20 - 50 ³	15 - 20	no	40 - 50
Mauderly	Toxicologist	50	20	150	50
McClellan	Toxicologist	no ⁸	no ⁸	150	50
Menzel	Toxicologist	no	no	150	50
Middleton	Atmos. Sci.	yes ^{2,3,12}	yes ^{2,5}	150 ^{3,13}	50
Pierson	Atmos. Sci.	yes ^{2,9}	yes ^{2,9}	yes ⁴	yes ⁴
Price	Atmos. Sci./ State Official	yes ^{3,10}	yes ¹⁰	no ^{3,4}	yes ⁴
Shy	Epidemiologist	20 - 30	15 - 20	no	50
Samet ¹	Epidemiologist	yes ^{2,11}	no	150	yes ²
Seigneur	Atmos. Sci.	yes ^{3,5}	no	150 ¹³	50
Speizer ¹	Epidemiologist	20 - 50	no	no	40 - 50
Stolwijk	Epidemiologist	75 ⁷	25-30 ⁷	150	50
Utell	M.D.	≥ 65	no	150	50
White	Atmos. Sci.	no	20	150	50
Wolff	Atmos. Sci.	≥ 75 ^{3,7}	no	150 ³	50

¹ not present at meeting; recommendations based on written comments

² declined to select a value or range

³ recommends a more robust 24-hr. form

⁴ prefers a PM standard rather than a PM standard 10-2.5 10

⁵ concerned upper range is too low based on national PM /PM ratio 2.5 10

⁶ leans towards high end of Staff recommended range

⁷ desires equivalent stringency as present PM standards 10

⁸ if EPA decides a PM NAAQS is required, the 24-hr. and annual standards 2.5 should be 75 and 25 $\mu\text{g}/\text{m}^3$, respectively with a robust form

⁹ yes, but decision not based on epidemiological studies

¹⁰ low end of EPA's proposed range is inappropriate; desires levels selected to include areas for which there is broad public and technical agreement that they have PM pollution problems 2.5

¹¹ only if EPA has confidence that reducing PM will indeed reduce the components 2.5 of particles responsible for their adverse effects

¹² concerned lower end of range is too close to background

¹³ the annual standard may be sufficient; 24-hr level recommended if 24-hour standard retained

Table 2. PubMed Literature Search Results for Report Key Terms, 2009 – present

Search Term(s)	Number of Citations
Epidemiology and particulate matter	6639
Epidemiology AND particulate matter AND respiratory effects	1461
Epidemiology AND particulate matter AND respiratory health	1231
Epidemiology AND particulate matter AND cardiovascular disease	1406

APPENDIX

Andrew Wheeler

Acting Administrator

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW, Washington, DC 20460

RE: Proposed changes to Clean Air Scientific Advisory Committee (CASAC) review process

December 10, 2018

Acting Administrator Wheeler:

We write as past members of the Clean Air Scientific Advisory Committee (CASAC) of the Science Advisory Board of the US Environmental Protection Agency (EPA) to express concern about the announced approach for CASAC review of the National Ambient Air Quality Standards (NAAQS), which eliminates the comprehensive peer review process that evaluates evidence related to the NAAQS and replaces the process with a single seven-person panel, comprised of the Charter CASAC members. Several of those signing this letter have served as Chair of CASAC (Samet, Frey, Hopke, Diez Roux), and we have expertise in the health effects of air pollution, coming from our research and patient care activities, as well as a range of disciplines pertinent to the NAAQS review. As a primary concern, we are united in suggesting that a seven-person panel cannot review and evaluate the documents prepared by the Agency in the process for consideration of revisions to the NAAQS. We are deeply concerned that eliminating the CASAC panels will lead to superficial reviews that will not have the needed scientific depth. The Charter CASAC, simply based on its number, cannot span the scope of science considered by the EPA as it guides the Administrator in assuring that the NAAQS will protect human health with an adequate margin of safety, as mandated by the Clean Air Act. Furthermore, for the current ozone and particulate matter reviews, the EPA is proposing a rushed schedule, which will reduce transparency, opportunity for public input, and the quality of the review.

Those signing this letter are in agreement that the CASAC peer review process was not “broken”; quite to the contrary, an effective process had been established that led to high-quality and timely peer review that has directly informed NAAQS revisions. Scientific evidence has been the foundation for NAAQS revision and peer review is fundamental to the translation of scientific evidence into standards to protect the public health. The CASAC panels have typically included 14-15 members beyond the Charter CASAC to have the full range of expertise needed to cover the Integrated Science Assessment (ISA), Risk and Exposure Analysis (REA), and Policy Analysis (PA) documents. The range of topics to be covered includes atmospheric sciences, exposure sciences, toxicology, epidemiology and statistics, risk assessment, and

ecological and human welfare effects. For the most critical areas, such as epidemiology, several expert panel members have been included in the pollutant-specific review panels.

With these numbers and breadth of expertise, CASAC panels have provided comprehensive reviews that are then summarized by the CASAC Chair and approved by the Chartered CASAC before transmittal to the Administrator. CASAC has been augmented with additional expert scientists to form review panels for over three decades. The role of the Charter CASAC, and additional scientists added to complete pollutant-specific panels, is well specified in the series of documents developed by the EPA in support of NAAQS revision (see Figure 1 below from the 2013 ISA for Ozone). CASAC has recognized that the EPA documents need to be adequate for their intended purpose. In our experience, peer review by CASAC has resulted in substantial revisions by the EPA. In the past, CASAC typically provided two cycles of peer review per document, as each document was revised in response to CASAC comments.

We are deeply concerned that eliminating these levels of peer review and expertise will deprive the EPA of essential, independent scientific guidance that is needed to set NAAQS that are protective of human health. We request the opportunity to speak with the EPA's leadership on the process by which CASAC provides scientific input to the agency as the NAAQS are revised. Collectively, we have provided years of service to the agency on CASAC and its panels. We are hopeful that the tradition of assuring the best possible peer review will be maintained.

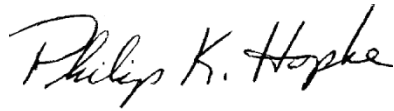
Sincerely,



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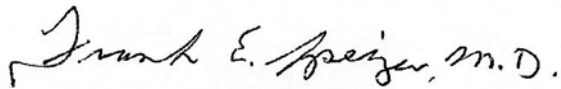
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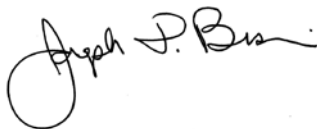
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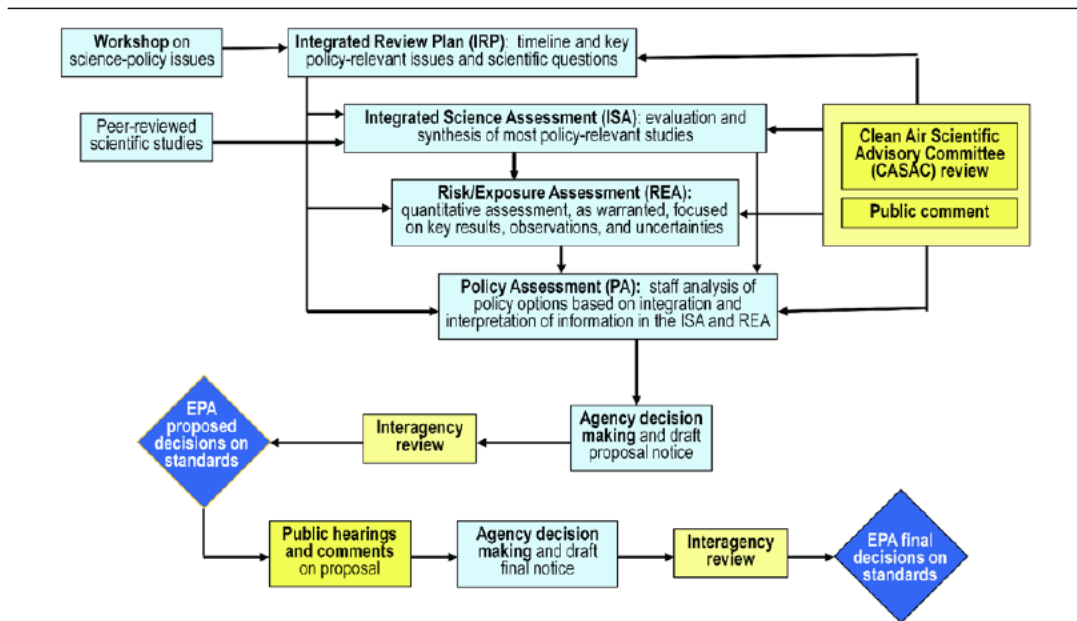


Figure 1 Illustration of the key steps in the process of the review of National Ambient Air Quality Standards.