

8 November 2019

US Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Docket Number: EPA-HQ-OAR-2015-0072

EPA Administrator Andrew Wheeler and the Clean Air Scientific Advisory Committee (CASAC):

On behalf of more than half a million citizens and scientists, we advocate for the use of science for a healthy planet and a safer world. The Center for Science and Democracy works to advance the roles of science and public participation in policy decision-making. We have never advocated for an ambient air quality standard different from the CASAC recommendation, only to ensure a robust, transparent process is followed and independent scientific advice is heeded.ⁱ

The Clean Air Act requires that the EPA set particulate matter (PM) standards at levels that protect public health and welfare with an adequate margin of safety. CASAC is charged with considering all available evidence and providing science advice on the standards. At this stage in the PM standard update, there are significant challenges to both the science and process that CASAC is following. These issues are undermining the agency's ability to set science-based standards to protect public health and welfare.

Process Issues

Thus far, CASAC has not followed a process that is likely to lead to a science-based recommendation to the EPA Administrator.

EPA leadership has failed to provide the agency and CASAC with an opportunity to obtain the robust science advice it has always received on National Ambient Air Quality Standards (NAAQS), given the significantly reduced expertise the agency is now receiving (See Figure). In addition to the significant gaps in expertise that have resulted from EPA leadership's choice of CASAC members, dismissal of the PM review panel has severely limited the degree of independent expertise the EPA and CASAC are receiving on the PM ISA and subsequent documents that inform the standard.

CASAC itself recognized the need for additional expertise to inform their review of the PM standards. In an April 11, 2019 letter, the committee wrote in its consensus statements, "The CASAC recommends that the EPA reappoint the previous CASAC PM panel (or appoint a panel with similar expertise) as well as adding expertise..."ⁱⁱ

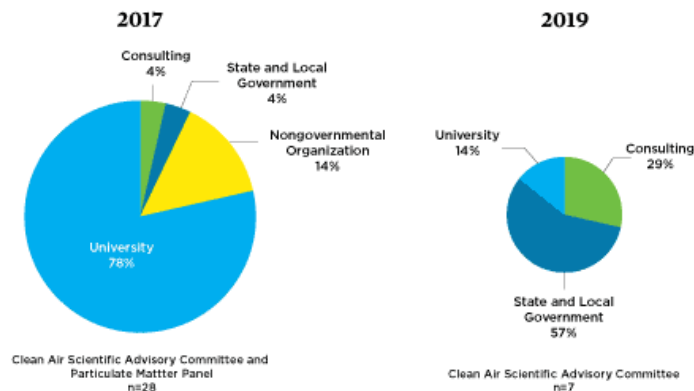
Despite this call for additional expertise, echoed by public comments, Administrator Wheeler has failed to fill the gap in expertise and is allowing the PM NAAQS review to proceed without the science advice needed to ensure health-protective standards. In September 2019, Administrator Wheeler appointed a pool of consultants to aid CASAC in its review of the PM standards; however, this group and context in which they are appointed is wholly inadequate.ⁱⁱⁱ The consultants were chosen by the administrator, without input from EPA career staff and without an opportunity for public comment on the nominations.^{iv} In contrast to the open, robust, and interactive process by which pollutant review panels of experts would engage with CASAC in public meetings on past NAAQS reviews, the consultants have instead only been provided the opportunity to provide written comments to narrow questions posed by CASAC in advance of their meeting. The appointment of consultants also happened far too late in the NAAQS PM review cycle to provide any substantive benefit, given CASAC has already provided advice on the EPA Integrated Science Assessment (ISA) and CASAC has not been granted an opportunity to review a second draft. If the goal of the consultant pool was to bolster the expertise of CASAC, this is far too little, too late.

Further, the greatly expedited schedule to complete the PM review by 2020 is limiting the ability of the EPA and CASAC to follow a science-informed process.^v Historically, the robust science-informed process of EPA staff, CASAC, and the PM Review Panel compiling, reviewing, and revising multiple drafts of the ISA, Risk and Exposure Assessment (REA), and Policy Assessment (PA) required far more time than this schedule allows. Under the current PM NAAQS review, CASAC was not provided with an opportunity to review a second draft ISA before being asked to deliberate on the first draft PA. This 11th hour toss-in is a poor substitute for the rigorous, public review that has, until now, always taken place between CASAC, the Review Panel, the public, and EPA staff. Such a situation is inappropriate and sets a dangerous precedent that blurs the line between science and policy advice.

The dismissal of the Particulate Matter Review Panel, the accelerated timeline with limited drafts and opportunity for public input, and the absurdity of asking experts to deliberate on policy without a final ISA have all diminished the long-standing robust science-based process EPA has followed on NAAQS reviews for many years.

Figure.

Changes to EPA Science Advice on Ambient Particulate Pollution Standards



Science Issues

Despite this dismantling of the science-based and time-tested process followed by EPA for decades to ensure health-protective standards and despite its own unanswered request for additional expertise, CASAC has proceeded with the review. However, the committee should instead insist on receiving the additional expertise they requested last April and insist on the opportunity to review a second draft ISA before developing consensus comments of their recommendations on the PM standards. In general, CASAC should refuse to comply with the unreasonable timeline imposed on the committee and the lack of support it has been given to complete its charge.

Given the committee's refusal to heed this advice, it is left with no choice but to follow the advice of the larger, more experienced Independent Particulate Matter Review Panel. The panel has the expertise that CASAC requested and is well-positioned to provide robust science advice to the administration. Despite its dismissal by EPA in October 2018, the panel has reconvened, conducted a full review of the EPA Policy Assessment, and developed a consensus report in a formal letter to the Administrator.^{vi}

Specifically, the Panel found that the current particulate matter standards are inadequate to protect public health and welfare. Given the weight of the evidence from new studies across scientific disciplines and consistent with the peer-reviewed decision-making process that EPA and its science advisers have used for many years, the Panel recommends a tightening of the primary PM_{2.5} daily and annual standards, citing, "New and compelling evidence that health effects are occurring in areas that already meet or are well below the current standards." Notably, this evidence cuts across different locations with different study populations, different study designs, and different statistical approaches.

The draft policy assessment offers an alternative rationale for maintaining the current standards. The independent panel roundly rejected this justification as "not scientifically justified" and "specious."

CASAC should take these recommendations seriously. And if the committee disagrees with the Panel's recommendations, it should justify in its letter to the administrator why it disagrees with a larger, more experienced, and more scientifically diverse set of experts.

In its consideration of the science, CASAC should consider all available science at its disposal and it should rely on the established approach for assessing the causal links between particulate pollution and health impacts, as detailed in the preamble to the ISAs.^{vii} The causal framework employed by the EPA has evolved over the past decade, has been endorsed by 11 prior CASACs and 138 experts, and has been deemed adequate in the courts.^{viii, ix}

While CASAC chair has proposed upending this scientifically backed and time-tested approach, it is crucial that the EPA reject reliance on methods that have not been scientifically vetted and endorsed by the scientific community.^{x,xi,xii} Such a proposal would create an unattainable burden of proof on the scientific community to demonstrated causal links between PM reductions and changes in health outcomes, as it is not feasible or ethical to design and carry out population-level manipulative causation studies.^{xiii}

Importantly, following such a proposal is incompatible with CASAC's charge to recommend PM standards that protect public health with an adequate margin of safety including sensitive subpopulations. Protecting groups such as the elderly, children, and those with lung diseases,

with an adequate margin of safety requires the EPA to consider all evidence and use expert judgement. Relying on a framework that discounts epidemiologic evidence and requires manipulative causation for all causal determinations made by the agency is unlikely to meet this Clean Air Act mandate.

The EPA Administrator's decision on particulate matter will be consequential for public health. More than 23 million Americans live in areas with particulate pollution levels that exceed the current standard,^{xiv} with serious public health consequences, including premature death, cardiovascular effects, and respiratory effects.^{xv} Given the advice of the Independent Panel, many more people are likely at risk of adverse health effects from particulate matter exposure. The public deserves a decision based on the best available science advice on a regulation with such far-reaching health impacts.

It is the job of CASAC to make recommendations consistent with the best available science on the links between PM and health and welfare effects. Although it wasn't their job, the Panel has done the work of CASAC and provided the independent robust science that is legally necessarily and desperately needed on this PM NAAQS Review. I urge the members of CASAC and the EPA administrator to follow this science advice in order to ensure PM standards that protect public health and welfare, as required under the Clean Air Act.

Sincerely

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ⁱ Goldman, G.T. 2015. Union of Concerned Scientists. Comment on EPA-HQ-OAR-2008-0699-2472: Proposed Rule: National Ambient Air Quality Standards for Ozone. <https://www.regulations.gov/document?D=EPA-HQ-OAR2008-0699-2472>

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ⁱⁱⁱ <https://www.epa.gov/newsreleases/administrator-wheeler-announces-new-casac-member-pool-naaqs-subject-matter-experts>

^{iv} <https://blog.ucsusa.org/gretchen-goldman/wheeler-worsens-particulate-pollution-review-process>

^v <https://www3.epa.gov/ttn/naaqs/standards/pm/data/201612-final-integrated-review-plan.pdf>

^{vi} <https://ucs-documents.s3.amazonaws.com/science-and-democracy/IPMRP-FINAL-LETTER-ON-DRAFT-PA-191022.pdf>

^{vii} https://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=526136

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^{ix} US EPA. Particulate Matter (PM) Standards - Documents from Review Completed in 2012 – Litigation. (2012)

https://www3.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_lit.html

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^{xi} The National Academies of Sciences, Engineering, and Medicine, Using 21st Century Science to Improve Risk-Related Evaluations (National Academies Press, 2017). <http://www.toxicologia.org.ar/wp-content/uploads/2017/02/Risk-Book-2017.pdf>

^{xii} The National Academies of Sciences, Engineering, and Medicine, Scientific Evidence for Causation in the Population 7, 150 (2008) <https://www.nap.edu/read/11908/chapter/10>

^{xiii} Goldman, G.T. and F. Dominici. (2019) Don't abandon evidence and process on air pollution policy. *Science*. 21 March. DOI: 10.1126/science.aaw9460. Online at <http://science.sciencemag.org/content/early/2019/03/20/science.aaw9460>

^{xiv} <https://www3.epa.gov/airquality/greenbook/popexp.html>

^{xv} <https://www.epa.gov/pm-pollution/health-and-environmental-effects-particulate-matter-pm>