

3 February 2020

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

Docket IDs: EPA-HQ-OAR-2018-0279; EPA-HQ-ORD-2018-0274

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 formal science advice provided to the administrator, only to ensure a robust, transparent process is followed and independent scientific advice is heeded.<sup>i</sup>

### **Process Issues and Ozone Integrated Science Assessment**

Under the National Ambient Air Quality Standards (NAAQS), the Clean Air Act requires that the EPA set ozone standards at levels that protect public health and welfare with an adequate margin of safety, including sensitive subpopulations. CASAC is charged with considering all available evidence and providing science advice on the standards. The EPA has not instituted a process that ensures robust science advice to the EPA Administrator and this is undermining the agency's ability to set science-based standards to protect public health and welfare.

The ozone NAAQS review is proceeding under an unreasonably expedited and arbitrary timeline, resulting in limited drafts and limited opportunity for public comment. Alarming, this situation is blurring the line between science and policy as CASAC reviewed a first draft ISA and a first draft PA in the same December 3-6, 2019 meeting and is now considering draft letters for both the ozone ISA and PA at the same time. This is a far cry from the careful, robust review the EPA has followed for years to ensure adequate science advice.

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, its failure to convene an Ozone Review Panel has severely limited the degree of independent expertise the EPA and CASAC are receiving on the science and policy documents that inform the standard.

In its final letter on the ozone ISA, CASAC should acknowledge its need for additional expertise to adequately review the ozone ISA, as the committee did in its April 11, 2019

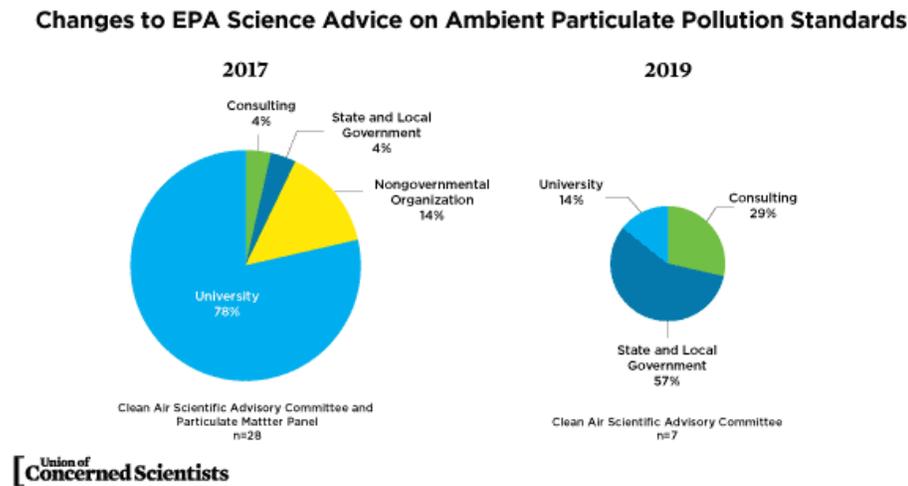
letter regarding the Particulate Matter (PM) standards, where the committee wrote in its consensus statements, “The CASAC recommends that the EPA reappoint the previous CASAC PM panel (or appoint a panel with similar expertise) as well as adding expertise...,”<sup>ii</sup> Given the current gaps in expertise on CASAC and the failure of the EPA to convene an ozone review panel, it is clear that there is also not adequate expertise on this committee to conduct the ozone review and CASAC should acknowledge this in its letters to the administrator.

Despite previous calls for additional expertise, echoed by public comments, Administrator Wheeler failed to fill the gap in expertise and is allowing the PM and ozone NAAQS reviews 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 and ozone standards; however, this group and context in which they are appointed is wholly inadequate.<sup>iii</sup> The consultants were chosen by the administrator, without input from EPA career staff and without an opportunity for public comment on the nominations.<sup>iv</sup> 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. If the goal of the consultant pool was to bolster the expertise of CASAC, this was far too little, too late.

Further, the greatly expedited schedule to complete the ozone review by the end of 2020 is limiting the ability of the EPA and CASAC to follow a science-informed process.<sup>v</sup> Historically, the robust science-informed process of EPA staff, CASAC, and the ozone Review Panel compiling, reviewing, and revising multiple drafts of the ISA, Risk and Exposure Assessment (REA), and PA required far more time than this schedule allows. Under the current ozone NAAQS review, CASAC is being asked to deliberate on advice for the administration on the ISA and PA at the same time. Such a situation is inappropriate and sets a dangerous precedent that blurs the line between science and policy advice.

The failure to convene an Ozone Review Panel, the accelerated timeline with limited drafts and opportunity for public input, and the absurdity of asking experts to deliberate on policy concurrent with deliberating on the science have all diminished the long-standing robust science-based process EPA has followed on NAAQS reviews for many years. In its final letters to the administration, CASAC should acknowledge these exceptional and unsupportive conditions under which it is being asked to complete its charge.

Figure.



Many of these process concerns are echoed in a letter from 18 members of the previous ozone review panel from 2009-2015. They write that until these process issues can be addressed, “The NAAQS review for ozone should be suspended.”<sup>vi</sup> With respect to the quality of the draft ISA, the former panelists find that EPA staff “have undertaken a good faith effort” however, this document was produced under tremendous time pressures.

### Science Issues

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 air pollution and health impacts, as detailed in the preamble to the ISAs.<sup>vii</sup> 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.<sup>viii, ix</sup>

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.<sup>x, xi, xii</sup> Such a proposal would create an unattainable burden of proof on the scientific community to demonstrated causal links between ozone reductions and changes in health outcomes, as it is not feasible or ethical to design and carry out population-level manipulative causation studies.<sup>xiii</sup>

Importantly, following such a proposal is incompatible with CASAC’s charge to recommend ozone 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.

## Ozone Policy Assessment

In its final letter, CASAC should consider and heed the input of relevant experts on ozone pollution and health and welfare effects, such as the previously convened ozone review panel. In its draft letter, CASAC requests input from experts “outside of the NAAQS community.” While it may at times be appropriate and beneficial for the National Academies of Sciences, Engineering, and Medicine to review and advise on EPA’s approaches to NAAQS updates, CASAC should, in this review, prioritize consideration of advice from those with direct expertise in ozone pollution and its health and welfare effects.

In particular, CASAC should consider the input of the 18 members of the previous ozone review panel that functioned 2009-2015. This group has affirmed the EPA’s choice to retain the current causality determination frameworks and noted that the EPA ozone PA represents a good faith document, despite the time pressures under which it was produced.<sup>xiv</sup>

When it was active, this panel informed CASAC, which in 2014 recommended a primary ground-level ozone standard of 60 to 70 ppb, citing “substantial scientific evidence of adverse effects ... including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation.”<sup>xv</sup> On the ozone NAAQS prior, back in 2007, CASAC also recommended a primary ozone standard of 60 - 70 ppb.<sup>xvi</sup> In the current ozone PA, EPA staff have affirmed that health effects evidence continues to be strongest for respiratory effects.

Additionally, in its 2014 letter to the administration, then-CASAC stated that although 70 ppb was included in its recommended range, such a standard would not provide an “adequate margin of safety,” noting that with a 70-ppb standard there is “substantial scientific evidence of adverse effects ... including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation.”

Therefore, when formulating its final primary standard recommendations, this committee should consider this growing body of evidence of health impacts of ozone below 70 ppb and that several prior CASACs, informed by an independent Ozone Review Panel of experts representing the breadth, depth and diversity of expertise relevant to the ozone NAAQS, have recommended a standard at least as strong as the current 70 ppb standard and indicated that this level may not be protective of public health with an adequate margin of safety, particularly for sensitive groups such as children and asthmatics. There is large body of robust science and science advice preceding the current CASAC. The committee should follow it, especially given their shortcomings in size, expertise, and experience.

## Public Interest

The EPA Administrators decision on ozone will be consequential for public health. Some 124 million Americans live in areas with ozone pollution levels that exceed the current standard, with serious public health consequences for many, including those with lung diseases such as asthma, children, and the elderly.<sup>xvii</sup> 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 ozone and health and welfare effects. CASAC and the EPA administrator should follow this science advice in order to ensure ozone standards that protect public health and welfare, as required under the Clean Air Act.

Sincerely,

Gretchen T. Goldman, PhD

Research Director  
Center for Science and Democracy  
Union of Concerned Scientists

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<sup>i</sup> 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>

<sup>ii</sup>

[https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002+.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002+.pdf)

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

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

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

<sup>vi</sup> <https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0279-0022>

<sup>vii</sup> [https://ofmpub.epa.gov/eims/eimscomm.getfile?p\\_download\\_id=526136](https://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=526136)

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[https://yosemite.epa.gov/sab/sabproduct.nsf/44E735B0EB05DACD852583B500714CA2/\\$File/JVandenberg+response+to+TCox+ltr+of+121718.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/44E735B0EB05DACD852583B500714CA2/$File/JVandenberg+response+to+TCox+ltr+of+121718.pdf)

<sup>ix</sup> 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](https://www3.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_lit.html)

<sup>x</sup>

[https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentCASAC/FE50D8FD06EA9B17852583B6006B7499/\\$File/03-07-19+Draft+CASAC+PM+ISA+Report.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentCASAC/FE50D8FD06EA9B17852583B6006B7499/$File/03-07-19+Draft+CASAC+PM+ISA+Report.pdf)

<sup>xi</sup> 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>

<sup>xii</sup> 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>

<sup>xiii</sup> 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>

<sup>xiv</sup>

[https://yosemite.epa.gov/sab/sabproduct.nsf/B2AF0B23ABE6A60E852584C4007312E3/\\$File/EPA+CASAC+O3+Review+ISA+PA+Letter+191202+Final.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/B2AF0B23ABE6A60E852584C4007312E3/$File/EPA+CASAC+O3+Review+ISA+PA+Letter+191202+Final.pdf)

<sup>xv</sup> [https://yosemite.epa.gov/sab/sabproduct.nsf/5EFA320CCAD326E885257D030071531C/\\$File/EPA-CASAC-14-004+unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/5EFA320CCAD326E885257D030071531C/$File/EPA-CASAC-14-004+unsigned.pdf)

<sup>xvi</sup> [https://yosemite.epa.gov/sab/sabproduct.nsf/FE915E916333D776852572AC007397B5/\\$File/casac-07-002.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/FE915E916333D776852572AC007397B5/$File/casac-07-002.pdf)

<sup>xvii</sup> <https://www3.epa.gov/airquality/greenbook/popexp.html>