

**EPN Comments on the Draft EPA Policy Assessment  
for Particulate Matter**  
November 17, 2021

**To:** EPA Administrator Michael Regan and the Clean Air Scientific Advisory Committee (CASAC):

This is John Bachmann. I want to thank the CASAC and EPA for this opportunity. I represent the Environmental Protection Network, a volunteer organization of over 550 former EPA employees and others concerned about public health and the environment. I worked in EPA's Air Office for 33 years in Science/Policy, with a lead role in all reviews of the PM NAAQS through 2006.

Having participated in the most recent PM review, we're grateful that Administrator Regan decided to reconsider the unfounded decision not to strengthen the PM standards. We're also aware of the additional burden this has placed on EPA staff to update the science and policy assessments in just a few months. We believe EPA staff have done a creditable job on both.

That said, we have some issues that CASAC and EPA should consider in reviewing and completing these documents. Today, I outline evidence and perspectives we believe should lead CASAC and EPA to consider recommending significant revisions to both primary fine particle standards.

The Clean Air Act gives CASAC a unique responsibility to review the scientific criteria and recommend appropriate revisions to the criteria as well as the ambient standards themselves. The Policy Assessment is intended to assist you and the Administrator in determining whether and how standards should be revised. This CASAC/PM panel includes experts well qualified to consider the extent to which recent studies have added to the weight of evidence, and to recommend inclusion of any new significant studies that may have been overlooked.<sup>1</sup>

*Daily Standard:* We agree the averaging time and form of the daily standard should be retained, but believe the record supports strengthening the level. The staff assessment of controlled human studies focused on a theoretical 2-hour standard, missing an opportunity to examine the implications of controlled human and panel studies with longer averaging times. We now have two controlled studies<sup>2</sup> that find that 4-5 hour exposures to ambient levels of PM<sub>2.5</sub> (24 and 38 ug/m<sup>3</sup>) produce cardiopulmonary responses. By force fitting such results into an equivalent 2 hour exposure, the PA ignores the implications of whether seeing effects at such low levels for 4-5 hours might carry over to 24-hour ambient exposures. Dr. Costa's comments today cite several panel studies in the 2019 ISA and a new study that found daily and hourly effects on inflammatory and cardiac variables in elderly and at risk people exposed to ambient air at or

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<sup>1</sup> Examples of relevant missing studies include Zigler CM, C Choir, F Dominici. 2018. Impact of National Ambient Air Quality Standards nonattainment designations on particulate pollution and health. *Epidemiology* 29(2):165-172. doi: 10.1097/EE9.000000000000052 and a new study: Schwartz JD, Yitshak-Sade M, Zanobetti A, Di Q, Requia WJ, Dominici F, Mittleman MA. A self-controlled approach to survival analysis, with application to air pollution and mortality. *Environ Int.* 2021 12. 157:106861. PMID: [34507231](https://pubmed.ncbi.nlm.nih.gov/34507231/)

<sup>2</sup> PA Table 3-4 Hemmingsen et al., 2015a,b; Wyatt et al., 2020.

below the daily standard.<sup>3</sup>

Taken together, these lines of evidence buttress the results of large epi-studies in which restricted analysis found mortality and other serious effects at levels below the current daily standard.<sup>4</sup> While we agree that more stringent annual standards would provide substantial protection against the cumulative exposures to repeated daily peaks over a year, the relative risk to individuals of a more limited number of peaks where the annual is not controlling should also be considered. Higher peak exposures from local sources to people of color means this also has implications for environmental justice.<sup>5</sup> EPA should give more consideration to the level of the daily standard that is intended to reduce the risk of such exposures to the most exposed populations.

*Annual Standard:* The PA develops appropriate questions and useful summaries for key US and Canadian epidemiology studies in the ISA, sorting them by exposure methods, with attention paid to those using causal modelling methods, accountability studies, restricted exposures and assessing uncertainties. Recognizing that newer work serves to reduce some past uncertainties, this section focuses most on uncertainties in hybrid vs. monitoring-based studies. While this is appropriate, the discussion places too much emphasis on the importance of relating hybrid exposures to U.S. design values, when the most important statistic should be an estimate of the overall mean concentration reflecting the levels with the highest number of people exposed (PA Figure 2-3). As in the 2012 standard decision, the standard level should reflect the central tendency of exposures, not the study design value.<sup>6</sup>

The alternative justifications for standards “as low as 10” and 8 should be reconsidered. It’s hard to look at the results in the PA figures and tables and agree that levels above 10 ug/m<sup>3</sup> should be considered at all. Based on the 2020 review, the Independent PM Panel recommended a maximum of 10. The PA suggestion that only one US study found effects below 10 ug/m<sup>3</sup> is inconsistent with data from several figures and tables presented earlier, unless only studies based on monitoring count. Similarly, the basis for levels as low as 8 should consider results from the accountability, causal methods, and restrictive analysis studies, for example the restricted result from Wu et al. 2020 at 8.4 ug/m<sup>3</sup>.

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<sup>3</sup> See Comments submitted by Dr. Dan Costa. The newest relevant panel study noted above was not included in the PA: Zhang S, et al.. Association between short-term exposure to ambient fine particulate matter and myocardial injury in the CATHGEN cohort. *Environ Pollut.* 2021 Apr 15;275:116663. doi: 10.1016/j.envpol.2021.116663. Epub 2021 Feb 5. PMID: 33581627.

<sup>4</sup> PA Table 3-10, e.g. Di et al., 2017a; Shi et al., 2016; Wei et al 2019. Table 3-11 Schwartz et al, 2018a

<sup>5</sup> The new demographic risk assessment is an important innovation for examining this issue. However, the approach long-used for NAAQS risk assessment may bias the result in a manner that reduces the disparity among most exposed groups. By moving everyone up (or down) to just meet the current standard of 12, the demographic disparity in current exposures is erased, and subsequent differences may reflect only the relative difference in responses instead of the relative benefit to disadvantaged groups.

<sup>6</sup> Appendix B of the 2020 and current PA shows EPA staff did significant work on addressing these issues, including contacting authors of at least one study for additional data. If there are uncertainties in determining population weighted exposures for newer US or Canadian studies with respect to population weighted exposures, it might be appropriate to request additional information from the respective investigators.