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EPN Comments on the Draft EPA Policy Assessment for Particulate Matter

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The Environmental Protection Network (EPN), thanks EPA Administrator Michael Regan, the Clean Air Scientific Advisory Committee (CASAC), and EPA staff for the opportunity to provide these written comments at this important stage of the current reconsideration of the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM). EPN is a volunteer organization of former EPA employees and others concerned about public health and the environment.

These comments expand on the oral remarks on the draft EPA PM Policy Assessment (PA) delivered by John Bachmann at the November 17th CASAC meeting. They are influenced by the extended discussions and written comments by the CASAC Panel and the public at four subsequent meetings. We appreciate the insights and interchanges provided by CASAC on the PA as they addressed EPA's expansive charge questions, as well as the Panel's efforts to develop an initial consensus on whether and how the $PM_{2.5}$ standards should be revised.

Overview: While we agree with CASAC that EPA staff has done a good job in identifying key studies and updating their risk and other analysis, we take issue with aspects of the presentation of alternative rationales for selecting levels for a more protective annual standard,[1] and disagree with the basis for their provisional conclusion to retain the daily standard.[2] We agree with those on CASAC suggesting a range of 8 to 10 ug/m^3 for the annual standard, and also with those suggesting that EPA provide a more considered review of the information most relevant to considering a more stringent 24-hour standard.

Annual Standard: The PA evidence-based assessment develops appropriate science/policy questions and useful summaries of results from key U.S. and Canadian epidemiology studies in the Integrated Science Assessment (ISA), sorting them by exposure methods, with additional tabular summaries for causal modelling studies, accountability studies, and restricted exposures, and a summary section on key uncertainties. Recognizing that newer work serves to reduce past uncertainties,[3] the latter section focuses mostly on uncertainties in exposure estimates for hybrid vs.

[1] PA, **Section 3.5.2.4 Level**, *Alternative Annual Standard Levels,* pp 3-197 to 3-200.
[2] Ibid. *Alternative 24-Hour Standard Levels,* pp 3-200 to 3-203.
[3] PA**, Section 3.5.1.4, Uncertainties in the Health Effects Evidence**, pp 3-168 to 3-171.

monitoring-based studies. While these differences are relevant, the discussion places too much emphasis on the importance of relating hybrid exposure estimates to U.S. design values, when the most important and relevant information for selecting standard levels is the population-weighted exposure.

The use of design values in considering studies for standard setting is one of several problems in the PA's provisional rationale for considering levels below 12 and above 10 ug/m^3. The PA notes that reductions with a standard at 10 ug/m^3 would result in risk reductions for larger areas that would be "within the range of overall means for which key epidemiologic studies indicate consistently positive and statistically significant health effect associations (≥ about 8 ug/m^3)."[4] Yet, as noted in our clarifying remarks on December 2nd and in comments by Dr. Weisskopf, if key studies show an association between significant adverse health effects and lower mean levels, the standard should be set at those levels taken from those studies, so that the most exposed groups living near design value (DV) monitors get the appropriate level of protection. The most exposed groups need protection from effects associated with the lower mean levels, and a standard based on the DVs for the studies would fail to provide appropriate protection because it allows exposure to higher levels. This would ignore the evidence regarding higher exposures and risks to people of color. Such considerations were the basis for the 2012 decision to do away with spatial averaging, which the PA rationale above would effectively reinstate.[5] Setting a standard at a level such that the highest monitors are well above the means found to produce health effects is simply inconsistent with the Clean Air Act requirement to protect the most sensitive populations with an adequate margin of safety.

The rationale for levels below 12 ug/m^3 should be rewritten so as not to limit the presentation to supportive studies at higher levels and include results consistent with the rest of the PA presentation on the evidence from key epidemiology studies. It is hard to look at the results in the PA's many figures and tables and agree that levels above 10 ug/m^3 should even be considered.[6] The PA summary of levels in key studies suggests a limited number of studies finding effects below 10 ug/m^3 down to 9.3 and 9.9 ug/m^3, inconsistent with results from several figures and tables presented earlier in the document. Notably, restricted analyses for several epidemiology studies have

[4] PA, Lines 16-17, pp 3-198.

[5] Dr. Weisskopf took issue with the approach in his written comments (pps 59-60) and in a colloquy with Dr. Boylan, who used the argument as support for standard levels of 10 to 11 ug/m^3. Dr. Weiskopf noted that if the purpose of the standard is to protect everyone, setting it at a high level equivalent to a DV for the study would ignore the risk to the most exposed groups when the standard is implemented. As discussed above, this approach would allow the most exposed group to be subject to levels well above the population means in those studies, which were linked to significant adverse health effects.

[6] The Independent Particulate Matter Research Panel recommended a maximum annual level of 10 ug/m^3. IPMRP, 2019. https://yosemite.epa.gov/sab/sabproduct.nsf/81DF85B5460CC14F8525849B0043144B/$File/Independent+Particulate+Matter+Review+Panel+Letter+on+Draft+PA.pdf

averages less than 10 ug/m^3, e.g., a causal inference study, Wu *et al.*[7] with a restricted average at 8.4 ug/m^3, and Shi *et al.*[8] at 8.1 ug/m^3. The rationale also ignores Canadian studies that used monitors to measure exposures.[9] Notably, while mentioning accountability studies, this portion of the rationale does not note one such study in which the *initial* level is 10 ug/m^3 and the intervention reduces exposures to 7.2 ug/m^3.[10] The PA should make 10 ug/m^3 the upper bound of the range of levels considered based on the evidence. The subsequent discussions of lower bounds should provide a more balanced assessment of the uncertainties and basis for levels down to 8 ug/m^3 or below, considering specifics from the accountability, causal methods, and restrictive analysis results.

24-Hour Standard: The PA's review of the short-term standard fails to adequately take into account the range of evidence suggesting the need for greater protection from short-term exposures allowed by the current 24-hour standard. Despite providing summaries of short-term epidemiology studies, the PA does not use them as a basis for evaluating the current 24-hour standard. Instead, the PA's conclusion that the current short-term standard is adequate rests largely on an assessment and analysis based on controlled human studies.

The PA analysis focuses on studies of 2-hour exposures with effects levels generally greater than 100 ug/m^3. In doing so, it treats as outliers the results from other controlled human studies that suggest cardiopulmonary responses can occur in healthy individuals after 4 to 5 hours of exposure at near ambient levels (24 and 37.5 ug/m^3). As we have noted in some detail, these results appear credible as they are supported by the results of several panel studies in outdoor environments.[11] During the CASAC meetings, we learned that Dr. Peele's research group had found multiple effects in controlled 2-hour human exposures at $PM_{2.5}$ levels of around 8 and 46 ug/m^3 produced by burning propane and wood chips in two different burners. These results further strengthen concerns about ignoring effects at lower short-term peak levels. Moreover, information presented by two public commenters at the meeting calls into question the PA analysis regarding the rarity of 2-hour levels at or above 120 ug/m^3 in areas meeting the current standards.[12,13]

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[7] Wu, X, et al., (2020). Evaluating the impact of long-term exposure to fine particulate matter on mortality among the elderly. *Science Advances* 6(29): eaba5692.

[8] Shi, et al. (2016). Low-concentration PM2.5 and mortality: estimating acute and chronic effects in a population-based study. *Environmental Health Perspectives* 124(1): 46-52.

[9] PA Table 3-6 includes a long-term mortality study monitor mean 8.7 ug/m^3 and the annual monitored averages for several short studies with levels of 8.2 to 8.8 and above. EPA and CASAC have considered annual levels from short-term studies based on monitors from the U.S. and Canada as relevant to considering levels of the annual standard.

[10] PA Table 3-12. Henneman *et al.*, (2019). Accountability assessment of health improvements in the United States associated with reduced coal emissions between 2005 and 2012. *Epidemiology* 30(4): 477-485.

[11] See oral comments of EPN member Dan Costa, Sc.D., former National Program Director, Air, Climate, and Energy Research Program, EPA Office of Research and Development, before the CASAC on Particulate Matter Panel, November 17, 2021 and EPN's written comments on the draft Supplemental to the Integrated Science Assessment.

[12] Ned Mulchahy of the Group Against Smog and Pollution in clarifying comments reported that Pittsburgh has experienced 2-hour peaks above 120 ug/m^3 on several days over the last three years, despite meeting the standard.

[13] John Graham of the Clean Air Task Force in clarifying comments provided graphs that examine the distribution of Maximum 2- and 4-hour levels sorted by daily design values. The results suggest the 2- and 4-hour peaks above 100 drop significantly at sites with design values at 25 to 31 ug/m^3.

While we agree these studies would not justify a shorter averaging time, they certainly suggest the need for a more thorough consideration of the evidence that might support a more protective 24-hour standard, including that from the short-term epidemiology studies. We are pleased that a number of CASAC panelists suggest that a harder look at the evidence, including the short-term epidemiology studies, is appropriate.

We recognize the PA risk assessment finds considerably larger effects for tighter annual levels than for an alternative daily standard. Yet there are some issues with using the estimates for quantitative comparisons. Although it is the largest PM assessment to date, it omits the Northwest U.S., a region more likely to have higher peak-to-mean ratios. Moreover, by design, the risk assessment does not reflect what would happen in the real world once standards are set. Today, few areas violate the current annual standard, and as Dr. Boylan noted, the actual risk reductions for a lower annual standard of, e.g., 10 ug/m^3 levels would be much smaller than is suggested by the risk assessment. Due to the inherent uncertainties and structure, EPA has not relied on past PM Risk Assessment results as a primary or main basis for selecting specific standard levels. The assessment of the evidence has provided the main basis for selecting a level, with the risk assessment providing secondary, supporting information for making this choice.

Nevertheless, the approach used in PM risk assessments can provide important insights of expected trends or directions in public health effects that could occur, which can support evaluations of what the evidence indicates about alternative future standards. Estimating the risk, assuming all areas in the analysis just meet the current and alternative standards, has provided important information in prior PM NAAQS reviews. Beginning with the review leading to the first $PM_{2.5}$ NAAQS in 1997, the risk assessments have found that 1) assumed $PM_{2.5}$ exposures may result in a substantial number of premature deaths in areas included and 2) annual risk estimates based on cohort studies are considerably higher than those derived from the sum of daily mortality from short-term studies. These results prompted the approach of using the annual standard as the primary vehicle for addressing both short- and long-term effects.[14]

Past reviews have also recognized that the annual standard by itself may fail to prevent high risks to sensitive populations from short-term peaks. Recent evidence suggests such peaks can occur in areas with strong sources of primary $PM_{2.5}$ (e.g., Pittsburgh) or areas where seasonal sources cause high short-term peaks part of the year (e.g., areas with substantial use of wood stoves for heating). It is important to have a short-term standard that adds to the protection from the annual standard, preventing high risks to sensitive populations living in these areas where even a tighter annual standard might fail to address this risk.

[14] For this reason, the level of the original annual standards were based on the annual levels observed in short-term mortality studies, which were lower than those of contemporary cohort studies. In subsequent reviews ending in 2006 and 2012, EPA staff and CASAC have considered the annual levels in daily standard in recommending levels for the annual standard. E.g., see EPA-CASAC-LTR-06-002 Rogene Hendersson, March 21, 2006, Letter to Honorable Stephen L. Johnson Administrator, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460. Subject: Clean Air Scientific Advisory Committee Recommendations Concerning the Proposed National Ambient Air Quality Standards for Particulate Matter.

We believe the proper consideration of controlled human exposure studies, related panel studies, and evidence on the potential for high short-term peaks, combined with an examination of epidemiology studies showing mortality and morbidity at levels below the current daily standard, provide a strong basis for a more protective 24-hour standard.[4] 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 from periodic exposure to peaks where the annual standard is not controlling must be considered. Protection against potential higher peak exposures from local sources to people of color and people of lower socioeconomic status is consistent with the need to address environmental justice disparities.[5] EPA should consider a level for the daily standard in a range of 25 to 30 ug/m^3 to address the risk of such exposures to the most exposed sensitive groups.