

# **Comments on CASAC's November 13, 2019 Review of EPA's "Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019)"**

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The Chartered Clean Air Scientific Advisory Committee (CASAC) met in October 2019 to peer review the EPA's "Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019)." CASAC drafted a letter summarizing a consensus response to EPA's charge questions (CASAC, 2019).

The CASAC letter brings up several important points with regard to the assessment of fine particulate matter (PM<sub>2.5</sub>). For example, the letter indicates the draft Particulate Matter Policy Assessment (PM PA) should have a balanced summary of study results for each health endpoint and that the causality determinations for cancer and nervous system effects should be revised.

A key conclusion in the CASAC letter, which merits significant emphasis, is that "CASAC recommends that the PM PA explicitly state the implicit assumption that regression coefficients can be used to quantify causality, noting that it is not necessarily a valid assumption, and provide information about whether the assumption has been tested and what the results were." CASAC further notes that describing associations as if they were causal C-R functions is "technically unsound."

The CASAC letter also recommends that uncertainty be analyzed quantitatively and account for model uncertainty, exposure estimation error, and internal and external validity. It also recommends that the final PA provide quantitative uncertainty and sensitivity analyses to provide a clearer technical and scientific basis for data interpretation and policy making.

While most CASAC members concluded the new scientific evidence and data do not call into question the adequacy of the PM<sub>2.5</sub> standard, other members concluded this was not the case based primarily on epidemiology studies reporting statistically significant associations in areas with mean concentrations below the current standard. As discussed in detail in Gradient's written comments on the draft PM ISA and PA (Gradient, 2018, 2019), conclusions regarding these specific epidemiology studies are unwarranted. These and a few other issues that could be included in the CASAC letter are discussed below.

The first issue is the use of mean exposures from epidemiology studies in the risk assessment. The mean values in a study are not an indication of the exposure concentration at which adverse effects are most likely to occur in that study and should not be treated as such. Importantly, mean values are not comparable to design values that are used to determine compliance with a standard. Thus, analyses with mean values can be misleading.

Second, the draft PA calculates pseudo-design values to determine whether an area is in compliance with the National Ambient Air Quality Standards (NAAQS). This is more appropriate than using means, because pseudo-design values are more comparable to design values. Still, the pseudo-design values likely overestimated the extent to which study areas met the current standards because of the way they were calculated and the lack of near-road monitors. The observed distributions of pseudo-design values indicate that a large proportion of the study populations in the key epidemiology studies were likely in areas that did not meet the current standard. These results indicate that the key studies do not provide sufficient evidence against the adequacy of protection provided by the current PM<sub>2.5</sub> standard. The CASAC letter states that EPA's PM PA "should clarify the use and interpretation of pseudo-design values," and goes on to state, "The pseudo-design values are also assumption-laden and have not been validated; hence, their relevance for real-world health effects of real-world exposures remains unknown." However, a more in-depth discussion of pseudo-design values is warranted.

Third, the draft PM PA directly evaluates "current" (2015) air quality conditions, a hypothetical air quality scenario in which air quality just meets the current annual standard of 12 µg/m<sup>3</sup>, and a hypothetical air quality scenario in which air quality just meets an alternative annual standard of 10 µg/m<sup>3</sup>. EPA then uses an unvalidated approach to evaluate air quality scenarios just meeting alternative standards of 11 µg/m<sup>3</sup>

using linear extrapolation and  $9 \mu\text{g}/\text{m}^3$  using linear interpolation. However, there is no evidence that  $\text{PM}_{2.5}$  concentrations would scale linearly between modeled alternative standards. The  $8 \mu\text{g}/\text{m}^3$  alternative standard was not evaluated at all. The CASAC letter should indicate that the  $8 \mu\text{g}/\text{m}^3$  alternative should not be considered because it was not analyzed, and emphasize that estimates at other alternative standards have a large degree of uncertainty.

The CASAC letter notes that study areas with poor model performance should not be used in the risk assessment. The letter should have also noted that the risk assessment was performed for only a small fraction of the US that does not necessarily correlate with the areas in epidemiology studies on which the risk assessment was based. There is also a high degree of uncertainty in modeled  $\text{PM}_{2.5}$  concentrations and unconventional rounding choices and compounding levels of conservatism in the modeling. These factors all preclude drawing fine-scale distinctions between proposed alternative standards. That is, these issues make the risk assessment inadequate to evaluate any differences between proposed standards that only differ by  $1 \mu\text{g}/\text{m}^3$ . The CASAC letter should have emphasized how these issues limit the confidence that should be placed in the risk assessment results.

Overall, the CASAC letter address the key issues regarding the evaluation of  $\text{PM}_{2.5}$  in the draft PM PA, but there are a few other issues that could be emphasized that support the position of several CASAC members that the currently available scientific evidence and risk-based information does not call into question the adequacy of the public health protection afforded by the current annual and 24-hour  $\text{PM}_{2.5}$  standards or indicate that alternative standards will increase public health protection.