Preliminary Comments from Members of the Independent Particulate Matter Review Panel on

EPA's Policy Assessment for Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019)

Received as of 10-07-19

Mr. George Allen
October 6, 2019

General comment. It remains unclear how EPA will address the CASAC=s April 11, 2019 comments on the draft PM ISA in the final ISA. These comments assume there will not be any substantial changes to the causal findings as presented in the draft ISA that would result in how the draft ISA findings are used in the REA presented as part of this draft PA.

These comments are limited to the assigned charge question topics. Additional comments will follow later.

Chapter 2, Air Quality.

This chapter provides a useful summary of the 2018 draft PM ISA section on air quality. Trends for PM2.5 and PM10 are presented, showing general downward movement over the last 2-3 decades, driven primarily by lower concentrations of PM2.5 sulfate as a result of substantially lower SO2 emissions, especially in the eastern US. Figure 2-2 shows 2014 NEI PM2.5 with 32% from fires (mostly wild) and 18% from dust; these are surprisingly high. Page 2-50 (last line) says wildfire smoke is 10 to 20% of primary PM emissions, which is what I would have expected. Data from speciation networks and from IMPROVE sites considered to represent background PM are presented.

Hybrid Modeling.

In the context of this review of health based standards, the air quality section on hybrid modeling approaches to PM2.5 is the most important, since this is the area where substantial improvements in characterizing ambient PM2.5 exposures over large areas have been made since the last PM NAAQS review. The performance of four different approaches are summarized, with the Baysian downscaler 12 km model and the machine learning 1 km model having better overall performance. All models had degraded performance at low PM concentrations and in rural areas, although for use in health effect studies, uncertainties in annual average concentrations below ~ 6 to 7 µg/m3 are less important.

Of particular relevance for this review is the performance of the machine learning approach for daily PM2.5 with a 1 km grid used by Di et al. from the Harvard-Chan School of Public Health, since this was used in the pair of Di et al. chronic and acute mortality papers from 2017. The ability to predict PM2.5 at the 1 km scale provides improved estimates in urban areas, which is important since much of the US population is urban and PM2.5 tends to be higher in urban areas (much of the signal in PM epidemiology studies covering the continental US comes from urban populations).

Near-road PM.

A useful summary of the increase in PM2.5 at near-road sites is given, showing an average increment over urban background of less than 1 µg/m3. Brief noted in section 2.2.5 are other particle measurements at some of the near-road network sites, including black carbon (BC) and ultra-fine particle concentration measurements. It is worth noting that although BC is being measured at many near-road sites, it is not required to be reported to AQS under current regulations, and some agencies still do not report it.

Re-purposing the near-road network from NO2 to PM.

There are approximately 75 near-road monitoring sites that were originally deployed with NO2 as the primary pollutant of interest. That turned out to be a mistake, since there are no near-road sites even close to being out of NO2 compliance. Even exceedances of the 1-h 100 ppb standard are unusual. This doesn=t mean there is no issue with near-road pollution health effects though, with particles being the most likely driver of the observed increase in several different health endpoints. EPA should reconsider how to use the existing near-road monitoring network infrastructure in the context of characterizing a range of particle metrics at a subset of near-road sites, including UFP, lung-deposited surface area (using charge-based measurements), total aerosol carbon, and speciation of tire and brake wear emissions (including iron and copper).

Relationship between annual and daily PM2.5 design values.

This is an important analysis, given that EPA continues to recommend that the daily PM2.5 NAAQS not be changed and continued to be used only as a backstop, with the annual PM2.5 NAAQS as the primary control mechanism. While it is true that most sites that are in compliance with the current annual NAAQS of 12 have daily design values less than 35, there is a subset of sites where the daily NAAQS DV is greater than 35 and the annual is less than 12. A common driver of this situation is winter woodsmoke from residential space heating, where elevated levels of PM2.5 occur only during the heating season. The poster child for this scenario is the North Pole (Fairbanks) AK valley monitoring site, in severe non-compliance for PM2.5 because of winter woodsmoke. The ratio of the 2014-2018 daily DV to annual average is 5.1, substantially larger than the 35/12 ratio of 2.9. For the annual NAAQS to provide equivalent protection of the daily NAAQS at this location, it would have to be 7 µg/m3. If the annual PM NAAQS is reduced, the daily should not be left unchanged unless an annual NAAQS of less than 8 µg/m3 is chosen.

Issues with FRM and FEM PM2.5 monitor comparisons.

Monitoring agencies continue to struggle with getting their continuous FEM PM2.5 monitor performance within acceptable levels for them to be used to demonstrate compliance with the PM2.5 NAAQS. This problem goes back to how the FRM is run for FEM testing requirements; it is well known that FRM filters can lose up to 10% of their non-water mass over the 177 hours allowed before post-sampling weighings are done. As noted by Dirk Felton many years ago, it is time to fix the FRM, or at least fix how FEM equivalency testing is done.

Background PM.

This section covers sources of background (non-anthropogenic, domestic) PM well, with estimates of background PM from 0.5 to 3 µg/m3, with the upper end of that range probably driven by secondary organic aerosol (SOA). Other than wind-blown dust, SOA is the largest source, especially in the southeast from the reaction of photochemical oxidants with biogenic hydrocarbons (isoprene, terpenes). This document treats all of this source as natural, but since some of the photo-oxidant load is anthropogenic, perhaps some of the SOA should be considered that as well.

Chapter 3, Section 3.4.2, Potential PM2.5 alternative standards

Most of my response will be about alternative annual PM2.5 standards, since that is the major metric under consideration. There is little new information since the last review to support serious consideration of changes to the indicator, form, or averaging times for the annual and daily NAAQS. There is some discussion of UFP as an additional indicator since it is described as Likely to be causal for long-term nervous system effects, but it is unclear if this association is independent of PM2.5 which is also Likely to be causal. As noted in the draft PA, there is a very large body of research showing PM2.5 mortality effects since the last PM review. The most robust work is the pair of chronic and acute studies of the medicare population by Di et al. from the Harvard-Chan School of Public Health. In addition to having a 61 million person cohort with a median follow-up of 7 years and hybrid-modeled daily PM2.5 1x1 km exposure estimates for the entire continental US, the combination of chronic and acute mortality analysis on the same data set provides increased confidence that the analytical methods used are robust, since potential confounders for the chronic and acute analysis are different. These two studies are game changers for PM2.5 mortality effect estimates. Just like the Harvard 6-City Study was the driver behind the 1998 PM2.5 NAAQS, these studies are the drivers for serious consideration of annual PM2.5 values down to 8 µg/m3. While these studies are an important part of EPA=s analysis, the agency is still using the nn study area approach for the REA. When you have robust mortality estimates for the entire country, this approach seems too limited.

The draft PA looks at a range of annual PM2.5 between 8 and less than 12 (e.g., 11), and performs risk assessments at 11, 10, and 9 µg/m3 (Table 3-7, page 3-88). Table 3-8 presents % risk reduction for these concentrations relative to 12. Since the CR curve is assumed to be linear within this range, the reductions are not large: 21 to 27% across all table categories. The Di and Pope all-cause mortality estimates for the 47 urban study areas are ~ 50,000/year - a very large number from a public health perspective. Reducing this by ~ 25% is still a very large number, and does not reflect mortality on a national scale; the 47 urban study areas represent about 1/3 of the total population (Table C-2).

The risk analysis mostly ignores or de-emphasizes study data below 8 to 9 µg/m3, saying there is insufficient information from studies at those low concentrations. However, figure 3-8 shows that average pm2.5 for 25% of the Di et al. chronic mortality study population was below 7 µg/m3. This represents 115 million person-years of follow-up, a very large sample size that results in relatively robust mortality estimates even at levels below 7 µg/m3 (see Di et al., NEJM 2017 Figure 3a). There is a very large population with current annual PM exposures less than 8 µg/m3, and while the effect is lower with lower concentrations and there is a suggestion of flattening of the CR curve below 7 µg/m3, the overall mortality is large in this group because of its size. This issues is not clearly addressed in the draft PA.

The Di et al. 2017 NEJM chronic mortality study, Figure 2, presents another measure of concern: the three times higher risk for Blacks compared to the general population. (dashed line is overall population risk)

This is not addressed in the risk assessment. If we set standards for what we think is appropriate for the general population, the 13% of the over 65 population that is black will be at substantially elevated risk. EJ anyone?

Daily PM2.5 NAAQS.

There is no rationale to leave the daily PM2.5 NAAQS unchanged if the annual is reduced to 10 µg/m3 or lower. If the 35/12 ratio was good enough in 2012, why isn=t it good enough now? Yes, it is appropriate to have the annual NAAQS be the primary control, but one of the more important reasons to keep the daily NAAQS at least somewhat relevant is that EPA=s PM2.5 health messaging (AQI) is based only on the daily standard. Other than for wildfire events, at 35 µg/m3 health messaging is almost never more than yellow/moderate. That messaging communicates little to no risk at concentrations that EPA says causes more than 50,000 premature deaths annually. The messaging is broken.

Typo: Thurston 2015 in many tables should be 2016.

Dr. Kevin J. Boyle
September 22, 2019

Here, I refer to the charge questions for Chapter 5 of the report.

PA-5. Chapter 5 – Review of the Secondary Standards: What are the CASAC views on the approach described in Chapter 5 to considering the evidence for PM-related welfare effects in order to inform preliminary conclusions on the secondary standards? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current secondary PM standards?

SCQ-5.1 To what extent does the panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the secondary PM standards? Are there additional policy-relevant questions that should be addressed?

Comment: I think that it is good that additional attention was given to urban areas where the largest share of the populace resides without overlooking rural residents (p. 5-14, lines 1-6) Consideration of regional variation is also important (p. 5-14, 5-15).

However, there are important missing components to adequately consider public welfare that I outline below.

SCQ-5.2 What are the panel's views of the draft PA evaluation of the currently available scientific evidence with respect to the welfare effects of PM. Does the assessment appropriately account for any new information related to factors that influence:

a) Quantification of visibility impairment associated with PM2.5 and examination of methods for characterizing visibility and its value to the public?

Comment: The use of "*acceptable*" visibility is a fundamentally flawed policy concept (p.15, line 25 – p. 17, line 9). What is acceptable in an urban area with a certain baseline visibility may not be acceptable in a rural area with a higher baseline of visibility. This is not just a dichotomy between urban and rural residents. Urban residents may expect greater visibility when they travel to a rural area for vacation, and rural residents may consider urban visibility a forgone condition. An additional question is whether the visibility standard should be higher in some locations such is already the case in Class I visibility areas, national parks and wilderness areas.

The more concerning element is that while people may rate a certain level of visibility as acceptable, this does not imply that they would not realize a welfare gain from further improvements in visibility (Boyle et al., 2016; Haider et al., 2019; Yao, 2019). Compromised visibility can also affect property values (Walls, Kousky and Chu, 2015). In short, the question is never posed or answered to consider if there are net public benefits, improved welfare, for enhancing visibility beyond the acceptable level.

Further. the acceptability studies were focus groups with small numbers of participants.

- Ely et al. (1991) conducted 17 focus groups of members of civic organizations in Denver, CO for a total of 214 participants (about 12-13 people per group).
- BBC Consulting (2002) conducted 27 focus groups in Phoenix, AZ for a total of 385 participants (about 14 people per group).
- Pryor (1996) conducted four classroom exercises in British Columbia, CAN with 180 university students (about 45 students per class).
- Abt (2001) conducted a single focus group in Washington< DC with nine participants.

The Ely and BBC studies represent initial research that would be conducted at the beginning of a well-designed national preference study with one exception. The focus groups would be conducted at several locations around the U.S., not in single cities. The Pryor study presents an interesting investigation to learn about preferences for visibility, but is not indicative of national preferences in the U.S. Finally, the Abt study represents the first step in study design from which no firm policy implications could be drawn. Johnston et al. (2017) discuss best practices in the conduct of an economic preference study to evaluate public welfare gains and losses and the use of focus groups in the design of such studies.

The American Association for Public Opinion Research's Best practices for Survey Research include the recommendation that "(a)*ll questions should be pretested to ensure that questions are understood by respondents, can be properly administered by interviewers or rendered by web survey software and do not adversely affect survey cooperation*" (https://www.aapor.org/Standards-Ethics/Best-Practices.aspx#best6, accessed September 23, 2019). The conduct of focus groups is a key step in this process to learn how best to present visibility images and query subjects about visibility in the implementation of a national visibility preference study. Thus, the above studies present evidence of the importance of visibility but do not present enough information to support national policy decisions.

The report states that the "… *preliminary conclusions for the Administrator's consideration is that it 22 is appropriate to consider retaining the current secondary PM standards, without revision. In so concluding, we recognize, as noted above, that the final decision on this review of the secondary PM standards to be made by the Administrator is largely a public welfare judgment, based on his judgment as to the requisite protection of the public welfare from any known or anticipated adverse effects*." (p. 39, lines 21-26) This

conclusion is based on flawed logic because an implicit premise of the report is that there a no societal benefits beyond what some small and incomplete studies found as acceptable.

b) The effects of PM2.5 components on climate?
Comment: The report concludes that "(w)*hile evidence in this review suggests that PM influenced temperature trends across the southern and eastern U.S. in the 20th 26 century, uncertainties continue to exist and further research is needed to better characterize the effects of PM on regional climate in the U.S*." (p. 28, lines 25-28). It seems questionable to me to treat ecological effects and climate separately, which has been done by partitioning ecological impacts to a separate assessment. While this is not my area of expertise, it seems logical to ask if induced changes in climate over time will have ecological impacts that are not observed today.

c) The effects of fine and coarse particles on materials?

Comment: The report concludes that "(w)hile some new evidence is available with 21 respect to PM-attributable materials effects, the data are insufficient to conduct quantitative analyses for PM effects on materials in the current review" (p. 5-35, line 20-22). The report is unclear on what literature was reviewed and there is evidence outside of the U.S. on the cost of soiling from air pollution (e.g., Besson, 2017; Grøntoft, 2019

SCQ-5.3 What are the panel's views of the draft PA preliminary conclusion that the currently available scientific evidence does not call into question the protection afforded by the current secondary PM standards against PM welfare effects and that it is appropriate to consider retaining the current secondary PM standards without revision?
Comment: I have several major concerns.
First, the framing of the policy from a welfare perspective using "acceptable", by default, leads to the conclusion that no further protection is required. From a welfare perspective, the question is never posed to ask if welfare would be enhanced if protection was increased.
Second, given the uncertainties in the current state of knowledge the question is never posed to inquire if further protection is warranted until the uncertainties are resolved. The "what if nothing is done" question is never explored in any substantial manner to explore how large or small the consequences might be from holding the current standard.
Finally, in addition to advocating for a "better characterization" of the scientific knowledge, it would be appropriate to recommend a precautionary principle in setting policy until the visibility impacts and resulting welfare impacts are better understood (Kiebel et al., 2001). A safe minimum standard would call greater emphasis on protection of the environment, visibility here, so long as the social costs of doing so are not unreasonable (Bishop, 1978).

References

Abt Associates, Inc. 2001. Assessing Public Opinions on Visibility Impairment Due to Air Pollution: Summary Report. Prepared for EPA Office of Air Quality Planning and Standards, EPA Contract No. 68-D-98-001. See: https://www3.epa.gov/ttn/naaqs/standards/pm/data/vis_rpt_final.pdf, accessed September 23, 2019.

BBC Research & Consulting. 2003. Phoenix Area Visibility Survey: Final Report. See: https://repository.asu.edu/attachments/77581/content/PhxVisibilitySurvey.pdf, accessed September 23, 2019.

Besson, P., Munoz, C., Ramírez-Sagner, G., Salgado, M., Escobar, R. and Platzer, W. 2017. Long-Term Soiling Analysis for Three Photovoltaic Technologies in Santiago Region. *IEEE Journal of Photovoltaics*, 7 (6): 1755-1760.

Bishop, R.C. 1978. Endangered species and uncertainty: the economics of a safe minimum standard. *American Journal of Agricultural Economics*, 60 (1): 10-18.

Boyle, K.J., Paterson, R., Carson, R., Leggett, C., Kanninen, B., Molenar, J. and Neumann, J. 2016. Valuing shifts in the distribution of visibility in national parks and wilderness areas in the United States. *Journal of Environmental Management*, 173: 10-22.

Ely, D.W., Leary, J. T., Stewart, T.R. and Ross D.M. 1991. The Establishment of the Denver Visibility Standard. Presented at the 84th Annual Meeting & Exhibition of the Air and Waste Management Association, June 16-21, 1991. See: https://www.albany.edu/cpr/stewart/Papers/T0210-ElyDenverVisStandard-1991cap.pdf, accessed September 23, 2019.

Grøntoft, T., Verney-Carron, A. and Tidblad, J. 2019. Cleaning costs for European sheltered white painted steel and modern glass surfaces due to air pollution since the year 2000. *Atmosphere*, 10 (4): 167.

Johnston, R.J., Boyle, K.J., Adamowicz, W., Bennett, J., Brouwer, R., Cameron, T.A., Hanemann, W.M., Hanley, N., Ryan, M., Scarpa, R. and Tourangeau, R. 2017. Contemporary guidance for stated preference studies. *Journal of the Association of Environmental and Resource Economists*, 4 (2): 319-405.

Kriebel, D., Tickner, J., Epstein, P., Lemons, J., Levins, R., Loechler, E.L., Quinn, M., Rudel, R., Schettler, T. and Stoto, M. 2001. The precautionary principle in environmental science. *Environmental Health Perspectives*, 109 (9): 871-876.

Haider, W., Knowler, D., Trenholm, R., Moore, J., Bradshaw, P. and Lertzman, K. 2019. Climate change, increasing forest fire incidence, and the value of visibility: evidence from British Columbia, Canada. *Canadian Journal of Forest Research*, 49 (999): 1242-1255.

Pryor, S.C. 1996. Assessing Public Perception of Visibility for Standard Setting Exercises. *Atmospheric Environment*, 30 (15): 2705-2716.

Walls, M., Kousky, C. and Chu, Z. 2015. Is what you see what you get? The value of natural landscape views. *Land Economics*, 91 (1): 1-19.

Yao, L., Deng, J., Johnston, R.J., Khan, I. and Zhao, M. 2019. Evaluating willingness to pay for the temporal distribution of different air quality improvements: Is China's clean air target adequate to ensure welfare maximization? *Canadian Journal of Agricultural Economics*, 67 (2): 215-232.

Dr. Judith Chow
October 7, 2019

EPA-2. Chapter 2 – PM Air Quality: To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for the review?

SCQ-2.1 What are the panel's views regarding whether the draft Policy Assessment accurately reflects and communicates the air quality related information most relevant to its subsequent evidence-based assessment of the health and welfare effects studies, including uncertainties, as well as the development of the risk assessment for current and alternative standards? In particular, do the following sections accurately reflect and communicate current scientific understanding, including uncertainties, for: (a) relationships between annual and daily distributions of PM; (b) the review of hybrid modelling approaches used to estimate exposure in some studies and the risk assessment; and (c) information on background level of various measures of PM?

Chapter 2 documents particulate matter (PM) emission sources, ambient monitoring methods and networks, as well as ambient air concentrations and background PM. The chapter provides useful information, however, several key areas deserve additional discussion including: 1) clarification of discrepancies in source types and percent contributions to precursors (i.e., SO_2, NO_x, NH_3, and VOCs) and PM emissions; 2) documentation of the zones of representation of sampling sites for PM exposure assessments; 3) specification of the relationship between annual average and 98^{th} percentile 24-hour $PM_{2.5}$ concentrations; and 4) exclusion of exceptional events in the PM_{10} analysis.

- **Sources of PM Emissions (Section 2.1.1)**

Total $PM_{2.5}$ emissions are estimated at ~5.4 million tons/year (similar to the <5400 KTons/year in the draft ISA with different units), but the aggregation of the seven source types in the draft PA (U.S. EPA, 2019) varies from that in the draft ISA (U.S. EPA, 2018a); both are based on the 2014 National Emissions Inventory (NEI, U.S. EPA, 2018b). Figure 2-2 (page 2-5) shows that "Dust" (including agriculture, construction, and road dust) and "Agriculture" (tilling) sources each account for 18% of the total $PM_{2.5}$ emissions in the PA, which differs from the 13% "Unpaved Road Dust" and 19% "Agriculture- Crops & Livestock Dust") sources in the ISA. As agriculture tilling results in suspended PM dust, it should be part of the agricultural dust. The rationale to assign agricultural dust to "Dust" and agricultural tilling to "Agriculture" sources need to be explained.

Aggregation of different dust categories should be documented. Separation of "Dust" emissions into paved and unpaved road dust and construction dust provides insight on the magnitude of suspended PM for each source subtype, this information is useful to evaluate source contributions by receptor modeling source apportionment and has been applied in the development of State Implementation Plans (SIPs).

Table 1 compares the percent contributions of seven source types between the draft PA and ISA for both annual $PM_{2.5}$ and PM_{10} emissions. It shows the inconsistency in definition of source types and source subtypes between the PA and ISA. Similar discrepancies are found for the percent distribution of PM_{10} emissions. Given that ~75% of the PM_{10} emissions are attributed to "Dust" and "Agriculture" sources, it would be helpful to illustrate the source subtype contributions. As PM_{10} consists of $PM_{2.5}$, the percent distribution of major emission sources in $PM_{10-2.5}$ should be given to provide some perspectives on major source types in the coarse particle size fraction. It should also be noted that fugitive dust emission estimates are highly inaccurate and are not reflected in source apportionment of PM data (Watson and Chow, 2000). Emissions of precursor gases (i.e., SO_2, NO_x, NH_3, and VOCs) also differ between the draft PA and ISA. For SO_2, the 79% "Stationary Fuel Combustion" source in Figure 2-5a (page 2-10) is 6% higher than the 73% "Fuel Combustion" source (sum of Electric Generation and Industrial Boilers in Figure 2-4 [page 2-15] of the draft ISA); for NO_x, the 58% "Mobile" source in Figure 2-5b is 4% higher than the 54% in the draft ISA (Figure 2-4b); and for NH_3, the 80% "Agriculture" source (Figure 2-5c) is 22% higher than the 58% "Agriculture- Livestock Waste" source in the draft ISA (Figure 2-4c).

The most confusing discrepancies concern VOC emissions. The naming convention changes from "VOC" in the ISA to "Anthropogenic VOCs" in the PA. Both documents report annual average VOC emissions of 17 million tons per year (page 2-9 of draft PA and page 2-13 of draft ISA). Figure 2-5d of the PA attributes 24% of VOC to "Mobile" sources, this is four times higher than the 6% in the ISA (Figure 2-4d). The 71% of VOCs attributed to "Biogenics-Vegetation and Soil" source in the draft ISA is not included in the draft PA. Differences between the two EPA reports need to be resolved.

Since these emission estimates serve as input to air quality models, consistent source types and emission estimates should be used. Reasons for different percent contributions of precursor gases and PM emissions, based on the same 2014 NEI should be clarified.

- **Ambient PM Monitoring Methods and Networks (Section 2.2)**

Discussions of the spatial scales and monitors that characterize mobile and stationary source emissions (pages 2-12 and 2-13) are not consistent with the community monitoring zones (CMZ) defined by the US EPA (1998) network design document. Zones of representation are defined as: microscale (<100 m), middle scale (~100-500 m), neighborhood scale (0.5-4 km), and urban scale (4-50 km) (40 CFR, Part 58, Appendix D). The statement that "…the network design criteria emphasize monitoring at middle and neighborhood scales to effectively characterize the emissions from both mobile and stationary sources…" from pages 2-12 and 2-13 for PM_{10} monitoring is misleading as most of the PM_{10} sites represent urban-scale community exposures. Only the near-road $PM_{2.5}$ sites can represent micro- and middle-scale monitoring.
The zone of representation for each monitor is important for exposure assessment and epidemiology studies that use data from compliance monitoring stations. Emissions source zone of influence and receptor site zones of representation need to be defined for exposure assessment.

It appears that network-wide annual $PM_{2.5}$ concentrations have been reduced from 8.6 $\mu g/m^3$ during 2013-2015 (Table 2-4, pages 2-48 of ISA) to 8.0 $\mu g/m^3$ during 2015-2017 (page 2-24 of

PA). Apparently, $PM_{2.5}$ concentrations have continuously declined nationwide. It would be helpful to provide statistics on the number of sites included in each concentration bracket for the annual and 98th percentile 24-hour $PM_{2.5}$ concentrations in Figure 2-8 (page 2-23), especially for locations with averages between 8-10 and 10-12 $\mu g/m^3$.

Not much information is given to illustrate relationships between annual and daily $PM_{2.5}$ distributions. It is not clear why most sites exhibit high correlation coefficients between the trends in annual average $PM_{2.5}$ concentrations and trends in 98th percentile of 24-hour $PM_{2.5}$ concentrations at individual sites (Figure 2-10, page 2-25). The implications of these high correlations, especially for eastern U.S. and in coastal California sites, need to be explained.
The 24 hour PM_{10} NAAQS is 150 $\mu g/m^3$, not to be exceeded more than once per year averaged over three years. However, only the average second highest 24-hour PM_{10} concentrations during 2015-2017 (Figure 2-16, page 2-33) and 2000-2017 national trends (Figure 2-17, page 2-34) are presented. As many western sites exceeded the 150 $\mu g/m^3$ PM_{10} NAAQS, days with exceptional events should be excluded in these presentations to provide a better perspective of potential areas with elevated PM_{10} concentrations.
Although it appears that the majority of the PM_{10} sites showed levels <75 $\mu g/m^3$ during 2015-2017, maximum 24-hour PM_{10} concentrations over the 2015-2017 period should be given to provide information on sites and locations with potential exceedances of 24-hour PM_{10} NAAQS over the three year period.

References

U.S. EPA (1997). Guidance for network design and optimal site exposure for PM2.5 and PM10. U.S. Environmental Protection Agency, Research Triangle Park, NC. http://www.epa.gov/ttn/amtic/files/ambient/pm25/network/r-99-022.pdf

U.S. EPA (2018a) Integrated Science Assessment for Particulate Matter, External Review Draft. U.S Environmental Protection Agency, Research Triangle Park, NC, USA.

U.S.EPA, (2018b). 2014 National Emissions Inventory (NEI) data. U.S. Environmental Protection Agency, Research Triangle Park, NC. https://www.epa.gov/air-emissions-inventories/2014-national-emissions-inventory-nei-data

U.S. EPA (2019) Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft. U.S Environmental Protection Agency, Research Triangle Park, NC, USA.

Watson, J.G., Chow, J.C., (2000). Reconciling urban fugitive dust emissions inventory and ambient source contribution estimates: Summary of current knowledge and needed research. Desert Research Institute, Reno, NV. http://www.epa.gov/ttn/chief/efdocs/fugitivedust.pdf

Table 1
Comparison of percent source type contributions to total $PM_{2.5}$ and PM_{10} emissions between draft PA[a] and ISA[b]

Total $PM_{2.5}$ Emissions (5.4 million tons/year)

Source Type	Draft PA (U.S. EPA 2019)[a]	Source Type	Draft ISA (U.S. EPA 2018)[b]	Difference PA minus ISA
Fires	32%	Wildfires	17%	--
		Prescribed Fires	15%	--
Dust	18%	Unpaved Road Dust	13%	+5%
Agriculture (Tilling)	18%	Agriculture- Crops & Livestock Dust	19%	-1%
Stationary Fuel Combustion	14%	Fuel Comb- Residential Wood	6%	+8%
Industrial Processes	5%		0%	+5%
Mobile Sources	7%		0%	+7%
	0%	Waste Disposal	4%	-4%
Misc.	6%	Other	26%	-20%

Total PM_{10} Emissions (13 million tons/year)

Source Type	Draft PA (U.S. EPA 2019)[a]	Source Type	Draft ISA (U.S. EPA 2018)[b]	Difference PA minus ISA
Fires	11%	Wildfires	6%	--
		Prescribed Fires	5%	--
Dust	47%	Unpaved Road Dust	39%	-8%
	0%	Paved Road Dust	5%	-5%
Agriculture (Tilling)	28%	Agriculture- Crops & Livestock Dust	30%	+2%
Stationary Fuel Combustion	5%	Fuel Comb- Residential Wood	0%	+5%
Industrial Processes	4%		0%	+4%
Mobile Sources	3%		0%	+3%
Misc.	2%	Other	15%	-13%

[a]U.S. EPA (2019) Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft. U.S. Environmental Protection Agency, Research Triangle Park, NC, USA; based on Figures 2-2 and 2-3.

[b]U.S. EPA (2018) Integrated Science Assessment for Particulate Matter, External Review Draft. U.S. Environmental Protection Agency, Research Triangle Park, NC, USA; based on Figures 2-2 and 2-6

EPA-4. Chapter 4 – Review of the Primary PM_{10} Standard: What are the CASAC views on the approach described in Chapter 4 to considering the $PM_{10-2.5}$ health effects evidence in order to inform preliminary conclusions on the primary PM_{10} standard? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current primary PM_{10} standard?

SCQ-4.01 To what extent does the Panel find that the key policy questions posed in this chapter appropriately reflect the important policy-relevant issues for the PM_{10} NAAQS review? Are there additional policy-relevant questions that should be addressed?

SCQ-4.02 What are the panel's views of the draft PA assessment of the currently available scientific evidence regarding the health effects associated with exposures to thoracic course particles, $PM_{10-2.5}$?

SCQ-4.03 What are the panel's views on the draft PA preliminary conclusion that the available evidence does not call into question the adequacy of the public health protection afforded by the current primary PM_{10} standard and that evidence supports consideration of retaining the current standard?

Little information is given in Chapters 2 and 4 to evaluate the adequacy of the 24-hour PM_{10} NAAQS. Nationwide, there are 391 FRM and 365 FEM PM_{10} sites as compared to 624 FRM and 579 FEM $PM_{2.5}$ sites for integrated 24-hour and hourly PM concentrations, respectively. In addition, there are 361 $PM_{2.5}$ monitors, not approved as FEMs, operated to report the AQI. Therefore, the total number of PM_{10} sites are less than 50% of the $PM_{2.5}$ sites. This results in a dearth of PM_{10} data, and is therefore, $PM_{10-2.5}$ (coarse) concentrations.
Although the $PM_{10-2.5}$ FRM was posed in the 2006 PM NAAQS review, little effort has been made over the last decade to better understand the temporal and spatial variations or the composition of $PM_{10-2.5}$. As of 2018, there are only 279 $PM_{10-2.5}$ sites in the AQS database, less than 20% of the $PM_{2.5}$ sites.

Figure 2-16 (page 2-33) shows the 2015-2017 average of second highest 24-hour PM_{10} concentration at 56 $\mu g/m^3$ (ranging 18-173 $\mu g/m^3$) with the majority of the sites measuring below 75 $\mu g/m^3$, with the exception of those in the southwest U.S. Figure 2-17 (page 2-34) shows that the annual second highest 24-hour PM_{10} concentrations decreased by ~30% from 2000-2017, and are below 75 $\mu g/m^3$ after 2007. The 98th percentile $PM_{10-2.5}$ concentrations for 2015-2017 (Figure 2-20, page 2-36) are mostly less than 30 $\mu g/m^3$, consistent with nationwide $PM_{2.5}/PM_{10}$ ratios of 0.5-0.6 for the second highest PM_{10} concentrations during 2015-2017 (Figure 2-19, page 2-35). Therefore, 24-hour average PM_{10} concentration of 75 $\mu g/m^3$ with a 24-hour $PM_{10-2.5}$ of 30 $\mu g/m^3$ most represents community exposure.

Equal weight and effort should be dedicated to each criteria pollutant in evaluating the NAAQS. It is not clear why the draft PA did not include evaluations of PM_{10} distributions in locations

with individual epidemiologic studies; comparison of experimental exposures with ambient air quality; or the quantitative assessment of $PM_{10-2.5}$ health risks. Given the lack of measurements and resources, it is not surprising that the same key limitations (e.g., approaches to estimate $PM_{10-2.5}$, measurement errors, potential for confounding by co-pollutant, and lack of biological plausibility) were given in the previous (U.S. EPA, 2009) and current (U.S. EPA, 2018) assessments.

Given that 24-hr PM_{10} concentrations have decreased by ~30% since 2000 and a positive association between PM_{10} and health effects is still present, it is hard to justify retaining the 24-hour PM_{10} NAAQS at the current level (150 $\mu g/m^3$) and form (not to be exceeded more than once per year on average over a three-year period), which have not changed since 1987 (see Table 1-1, pages 1-6).

More analyses are needed to test the association of lower (e.g., 75 $\mu g/m^3$) 24-hour PM_{10} concentrations with health effects and to demonstrate that the 150 $\mu g/m^3$ 24-hour PM_{10} NAAQS promulgated over 30 years ago is still adequate to protect public health.

References

U.S. EPA (2009). Integrated Science Assessment for Particulate Matter (Final Report). U.S. Environmental Protection Agency, Washington, D.C. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=216546

U.S. EPA (2018) Integrated Science Assessment for Particulate Matter, External Review Draft. U.S Environmental Protection Agency, Research Triangle Park, NC, USA.

U.S. EPA (2019) Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft. U.S Environmental Protection Agency, Research Triangle Park, NC, USA.

EPA-5. Chapter 5 – Review of the Secondary Standards: What are the CASAC views on the approach described in Chapter 5 to considering the evidence for PM-related welfare effects in order to inform preliminary conclusions on the secondary standards? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current secondary PM standards?

SCQ-5.01 To what extent does the Panel find that the key policy questions posed in this chapter appropriately reflect the important policy-relevant issues for the secondary PM standards? Are there additional policy-relevant questions that should be addressed?

SCQ-5.02 What are the panel's views of the draft PA evaluation of the currently available scientific evidence with respect to the welfare effects of PM. Does the assessment appropriately account for any new information related to factors that influence:

a) Quantification of visibility impairment associated with $PM_{2.5}$ and examination of methods for characterizing visibility and its value to the public?

b) The variable effects of $PM_{2.5}$ and it's light absorbing and scattering components on climate?
c) The effects of fine and coarse particles on materials?

SCQ-5.03 What are the panel's views of the draft PA preliminary conclusion that the currently available scientific evidence does not call into question the protection afforded by the current secondary PM standards against PM welfare effects and that it is appropriate to consider retaining the current secondary PM standards without revision?

- **Visibility Effects (Section 5.2.1)**

The analysis of visibility effects is mainly based on the outdated (2005-2008 vs. 2011-2014) data and doesn't provide new information that might influence light extinction and visibility. To achieve consistent and objective quantification of regional haze, the Regional Haze Rule (Section 308 of Protection of Visibility, 40 CFR Part 51, Subpart P, Sections 51.300-51.309) calls for the use of $PM_{2.5}$ chemical components to estimate particle light extinction (Watson 2002). Information on spatial interpolation of average light extinction for most recent period (e.g., 2015-2017) should be compared with that from the last review to provide some perspective on overall changes.

As shown in Hand et al (2019), the organic mass (OM) to OC ratio increased across the network after 2011, highest in the east during summer, unrelated to the influence of particle bound water. The effects of visibility from changes in $PM_{2.5}$ composition over the past decade needs to be addressed. The reanalysis of three versions of IMPROVE light extinction algorithms should provide IMPROVE 2015-2017 reconstructed light extinction coefficients (b_{ext}, Mm^{-}) by chemical components with monthly average $PM_{2.5}$ concentrations, to compare with those of 2005-2008 period.

The revised IMPROVE algorithm (Pitchford et al, 2007) uses different scattering coefficients for the large and small sulfate, nitrate, and organic mass. The 20 $\mu g/m^3$ cut-off was selected to separate the large vs. small components. Owing to the nationwide reduction in $PM_{2.5}$ mass and sulfate concentrations, the "20 $\mu g/m^3$" cut-off in the revised IMPROVE algorithm (Pitchford et al., 2007; Lowenthal and Kumar, 2016) may no longer be applicable. A reexamination with concentration levels more relevant to current air quality should be used to develop a more representative IMPROVE light extinction algorithm.

The draft PA suggests expanding the number and geographic coverage of "Preference" studies in urban, rural, and Class I areas to account for differences in population preference based on the scenic views. The "magnitude of scenic values" or the "ability of the public perception on visibility degradation" is judgmental and qualitative at best. Efforts should be put on science-based visibility estimates.

- **Key Uncertainties and Areas for Future Research (Section 5.4)**

New measurement techniques that can be used to estimate the radiation balance or climate change should be discussed. The newly developed multiwavelength (e.g., 405, 532, and 870 nm)

Photoacoustic Extinctiometer (PAX) provides high resolution aerosol optical measurements (Droplet Measurement Technologies, Boulder, CO) and is more advanced than the teleradiometers and telephotometers listed in the draft PA. Both the photoacoustic system and the dual and seven wavelength aethalometer (AE22 [370 and 880 nm] and AE33 [370 to 950 nm], Magee Scientific, Berkeley, CA, USA) can be used to estimate brown carbon (BrC), organic carbon that absorbs light at a low wavelength (~300-400 nm). Estimates of BrC are included in the most recently released report by the Intergovernmental Panel on Climate Change (IPCC, 2019)

Starting with $PM_{2.5}$ filter samples from January 2016, the IMPROVE network reports seven wavelength (i.e., 405-980 nm) optical measurements along with the OC and EC analysis (e.g., Chen et al, 2015; Chow et al, 2015; 2018; 2019) that demonstrate the impact of BrC during fire episode. These data can be used to address changes in OM/OC ratios; develop revised IMPROVE algorithms; improve emissions inventory estimates; and provide data for climate assessment.

These data are also useful for determining natural visibility conditions related to the U.S. Regional Haze Rule; examining the effectiveness of emission reduction strategies for wood burning; and identifying exceptional events that cause exceedances of air quality standards. The draft PA should most represent state-of-the-art measurement techniques.

References

Chen, L.-W.A., Chow, J.C., Wang, X.L., Robles, J.A., Sumlin, B.J., Lowenthal, D.H., Zimmermann, R., Watson, J.G., (2015). Multi-wavelength optical measurement to enhance thermal/optical analysis for carbonaceous aerosol. Atmospheric Measurement Techniques, 8, 451-461. http://www.atmos-meas-tech.net/8/451/2015/amt-8-451-2015.html

Chow, J.C., Wang, X.L., Sumlin, B.J., Gronstal, S.B., Chen, L.-W.A., Trimble, D.L., Kohl, S.D., Mayorga, S.R., Riggio, G.M., Hurbain, P.R., Johnson, M., Zimmermann, R., Watson, J.G., (2015). Optical calibration and equivalence of a multiwavelength thermal/optical carbon analyzer. Aerosol and Air Quality Research, 15, 1145-1159. doi:10.4209/aaqr.2015.02.0106. http://aaqr.org/VOL15_No4_August2015/1_AAQR-15-02-OA-0106_1145-1159.pdf

Chow, J.C., Watson, J.G., Green, M.C., Wang, X.L., Chen, L.-W.A., Trimble, D.L., Cropper, P.M., Kohl, S.D., Gronstal, S.B., (2018). Separation of brown carbon from black carbon for IMPROVE and CSN $PM_{2.5}$ samples. Journal of the Air & Waste Management Association, 68, 494-510.

Chow, J.C., Wang, X.L., Green, M.C., Watson, J.G., (2019). Obtaining more information from existing filter samples in PM speciation networks. EM, 23, 15-19. https://www.researchgate.net/publication/332878240_Obtaining_More_Information_from_Existing_Filter_Samples_in_PM_Speciation_Networks

Hand, J.L., Prenni, A.J., Schichtel, B.A., Malm, W.C., Chow, J.C., (2019). Trends in remote PM2.5 residual mass across the United States: Implications for aerosol mass reconstruction in the IMPROVE network. Atmospheric Environment, 203, 141-152. 10.1016/j.atmosenv.2019.01.049.

IPCC (2019). 2019 refinement to the 2006 IPCC guidelines for national greenhouse gas inventories: Switzerland. https://www.ipcc.ch/report/2019-refinement-to-the-2006-ipcc-guidelines-for-national-greenhouse-gas-inventories/

Lowenthal, D.H., Kumar, N., (2016). Evaluation of the IMPROVE Equation for estimating aerosol light extinction. Journal of the Air & Waste Management Association, 66, 726-737. 10.1080/10962247.2016.1178187.

Pitchford, M.L., Malm, W.C., Schichtel, B.A., Kumar, N.K., Lowenthal, D.H., Hand, J.L., (2007). Revised algorithm for estimating light extinction from IMPROVE particle speciation data. Journal of the Air & Waste Management Association, 57, 1326-1336.

Watson, J.G., (2002). Critical review: Visibility: Science and regulation. Journal of the Air & Waste Management Association, 52, 628-713. http://www.tandfonline.com/doi/pdf/10.1080/10473289.2002.10470813

Dr. H. Christopher Frey
October 7, 2019

These comments build upon written comments that I submitted to CASAC and EPA as an attachment to a consensus letter from the Independent Particulate Matter Review Panel (IPMRP) on December 10, 2018,1 as individual comments to CASAC and EPA on March 26, 2019,2 and as part of a consensus letter from the IPMRP on March 27, 2019.3

Process Issues

Since 2017, numerous changes have been made to the scientific review process for the National Ambient Air Quality Standards (NAAQS), including changes that affect the membership and composition of the EPA Clean Air Scientific Advisory Committee (CASAC). These changes have been made without advance notice to, or input from, the full chartered CASAC, EPA staff, or the public. The changes include: (a) imposing non-scientific criteria for appointing CASAC members related to geographic diversity and affiliation with governments; (b) replacing the entire membership of the chartered CASAC in a period of one year; (c) banning recipients of scientific research grants while allowing persons affiliated with regulated industries to be members of CASAC; (d) ignoring statutory requirements for the need for a thorough and accurate scientific review of the NAAQS in setting a review schedule; (e) reducing the number of drafts of a document for CASAC review irrespective of whether substantial revision of scientific content is needed; (f) commingling science and policy issues; (g) depriving CASAC of the needed breadth, depth, and diversity of scientific expertise for the PM NAAQS review by disbanding the CASAC PM Review Panel; (h) depriving CASAC of the needed breadth, depth, and diversity of scientific expertise for the ozone NAAQS review by refusing to form a CASAC Ozone Review Panel; and (i) creation of an ad hoc "pool" of consultants that fails to address the deficiencies created by disbanding the CASAC PM Review Panel and not forming a CASAC Ozone Review Panel. Each one of these changes harms the quality, credibility, and integrity of the NAAQS review for both PM and ozone.

EPA should appoint members to CASAC and its review panels based on the need for breath, depth, and diversity of scientific expertise, not geographic diversity and government affiliation. Consistent with Federal peer review guidance, EPA should allow leading researchers who hold

---

[1] Frey, H.C., A.V. Diez Roux, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and S. Vedal, "CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018)," 34 page letter and 100 pages of attachments submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA–HQ–ORD–2014-0859, December 10, 2018. https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/$File/PMRP+Letter+to+CASAC+181210+Final+181210.pdf

[2] Frey, H.C., "Public Comment: Deficiencies of Procedure and Expertise Must Be Corrected," Written Comment to the Clean Air Scientific Advisory Committee," U.S. Environmental Protection Agency, Washington, DC, March 26, 2018, https://yosemite.epa.gov/sab/sabproduct.nsf/46BBA443B9D953A9852583C9004F1F00/$File/Frey+Written+Public+Comments+to+CASAC+190326+Final.pdf

[3] Frey, H.C., A.V. Diez Roux, P. Adams, G. Allen, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R. McConnell, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and S. Vedal, "03-07-19 Draft CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018)," 19 page letter submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency,Washington, DC, March 27, 2019. https://yosemite.epa.gov/sab/sabproduct.nsf/A491FD482BB83BEE852583CA006A2548/$File/Written+Comments+from+17+Members+of+the+CASAC+PM+Review+Panel+that+was+Disbanded+on+October+11+2018+rev.pdf

EPA scientific research grants to serve, subject to previously existing requirements that such persons do not deliberate on their own work. EPA should recognize that there is a learning curve to service on CASAC and, therefore, value in appointing members to staggered terms and reappointing members to a second three-year term. EPA should allow adequate time for the scientific review. EPA should not combine assessment documents in a review unless this is consistent with a final Integrated Review Plan that has been agreed to by CASAC. EPA should allow for the likelihood that complex scientific and policy documents such as an Integrated Science Assessment, Risk and Exposure Assessment, and Policy Assessment may need substantial revision and re-review. EPA should better manage the timing of key milestones in the NAAQS review process so as not to selectively take time away from CASAC as a means to compensate for delays created by EPA elsewhere in the review. EPA should not introduce policy considerations until the scientific issues have been adequately settled. EPA should continue to follow the successful practice, proven for four decades, of augmenting CASAC with the expertise it needs via review panels that deliberate interactively with members of the chartered CASAC. EPA should not make ad hoc changes to the NAAQS review process in the middle of a review. If EPA wishes to make changes to the NAAQS review process, it should do so in a systematic manner similar to that employed in 2006, when EPA staff, CASAC, and others had an opportunity to provide input.

CASAC does not have adequate breadth, depth, and diversity of scientific expertise and experience needed to conduct thorough reviews based on the latest scientific knowledge of the kind and extent of scientific issues that pertain to the Particulate Matter NAAQS.

Emphasis has been placed on geographic diversity, not scientific expertise, in appointing members of CASAC, per an October 31, 2017 memorandum by former Administrator Scott Pruitt.[4] This policy has been implemented by Administrator Scott Wheeler in appointing members to CASAC on October 31, 2017 and by Administrator Andrew Wheeler in appointing five members to CASAC on October 10, 2018.[5] In revising criteria for membership on EPA Federal Advisory Committees, the October 31, 2017 memorandum from former Administrator Pruitt, EPA should have recognized that such committees may serve different purposes, and should have acknowledged Federal guidance on peer review. The membership criteria for a scientific review committee should not be the same as the membership criteria for a stakeholder committee.

Emphasis has been placed on affiliation with state, local, and tribal governments, not scientific expertise, in appointing members of CASAC, per October 31, 2017 memorandum by former Administrator Scott Pruitt. Although by law CASAC must have at least "one person representing State air pollution control agencies," CASAC must also have sufficient expertise to do its job. As of October 10, 2018, with the new appointments by Administrator Wheeler, CASAC had four members from state agencies (Georgia, Texas, Alabama, and Utah) and had another appointee who was affiliated with a Federal agency. Having four members from state agencies does not make CASAC four times better. CASAC is less scientifically qualified than it

[4] Pruitt, E.S., "Strengthening and Improving Membership on EPA Federal Advisory Committees," Memorandum, U.S. Environmental Protection Agency, October 31, 2017. https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf

[5] EPA, "Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee Tasks Chartered Panel to Lead Review of Ozone & Particulate Matter Standards Under Reformed Process," News Release, U.S. Environmental Protection Agency, Washington, DC, October 10, 2018, https://www.epa.gov/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee

would otherwise have been had the appointments been made, instead, based on selecting the best scientists.

A policy to have more member turnover on CASAC, per the October 31, 2017 memorandum by former Administrator Scott Pruitt, has led to 100% turnover in just one year. In his October 10, 2018 appointments to CASAC, Administrator Wheeler replaced five CASAC members with five people who had never served on the chartered CASAC. Coupled with the appointments a year earlier by Administrator Pruitt of a chair and a member with no prior CASAC experience, as of October 2018 the chair and members of the chartered CASAC had a grand total of two person-years of experience on the CASAC, and little to no institutional memory of how CASAC operates. The new policy to enhance member turnover fails to acknowledge that there are benefits of continuity and knowledge provided by having some previous members continue to serve. Under this new policy, **well-qualified scientists have been "rotated" off of the CASAC, in favor of new members without needed subject matter expertise and without prior experience** on CASAC or CASAC review panels, selected instead for their affiliation or geographic location. CASAC is now the most inexperienced and unqualified that it has been in its history.

Banning recipients of EPA research grants from serving on CASAC, per the October 31, 2017 memorandum by former Administrator Scott Pruitt, is clearly intended to keep top academic researchers from serving on CASAC. The memorandum states that "no member of an EPA federal advisory committee currently receive EPA grants," but that this "principle should not apply to state, tribal, or local government agency recipients of EPA grants." This is inconsistent with the Federal Advisory Committee Act and inappropriate for four reasons. One is the obvious inconsistency of implying that receiving a grant creates a conflict of interest for one but not another class of persons. The second is the longstanding recognition that **receipt of a peer-reviewed scientific research grant, for which the Agency does not manage the work nor control the output, is not a conflict of interest**. Per the Office of Management and Budget (OMB): "When an agency awards grants through a competitive process that includes peer review, the agency's potential to influence the scientist's research is limited. As such, when a scientist is awarded a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist's ability to offer independent scientific advice to the agency on other projects."[6] A 2013 report by the EPA Office of Inspector General reaffirmed that receipt of an EPA research grant is not a conflict of interest.[7] However, there can be situations in which a member of an advisory committee should recuse themselves from discussions that might pertain to their own work. Thus, third, the CASAC has had recusal policies in place for dealing with this issue and situations in which a member's work may come up for deliberation. Fourth, **the memorandum does not acknowledge that persons with financial or professional ties to regulated industries have, at the very least, the appearance of conflict of interest**.

Former EPA Administrator Pruitt signed a memorandum on May 9, 2018 that made major changes to the scientific review process for the NAAQS.[8] The memo is replete with cherry-

[6] Office of Management and Budget, "Final Information Quality Bulletin for Peer Review," *Federal Register*, 70(10):2664-2677 (January 14, 2005) . https://www.govinfo.gov/content/pkg/FR-2005-01-14/pdf/05-769.pdf

[7] EPA, "EPA Can Better Document Resolution of Ethics and Partiality Concerns in Managing Clean Air Federal Advisory Committees," Report No. 13-P-0387, Office of Inspector General, U.S. Environmental Protection Agency, Washington, DC, September 11, 2013. https://www.epa.gov/sites/production/files/2015-09/documents/20130911-13-p-0387.pdf

[8] Pruitt, S.E., "Back to Basics Process for Reviewing National Ambient Air Quality Standards," Memorandum, U.S. Environmental Protection Agency, Washington, DC, May 9, 2018. https://www.epa.gov/sites/production/files/2018-

picking of incomplete information that fails to accurately characterize the previously existing NAAQS review process, including its strengths. The memorandum emphasizes that the Clean Air Act requires that NAAQS be reviewed every five years, but fails to emphasize the statutory mandate for a thorough and accurate scientific review. For those NAAQS reviews for which EPA entered into a consent decree or was under court order to complete a review, the court-supervised schedules have taken into account the need for EPA staff to develop assessment documents and for CASAC to review the documents and advise the Administrator. Thus, the memorandum fails to acknowledge that courts have recognized that the time needed for a thorough and accurate scientific review can be taken into account in setting schedules that go beyond the five year time frame. Instead, EPA is self-imposing a schedule that compromises the quality, credibility, and integrity of the scientific review and is doing so in a manner beyond what courts have historically imposed.

The memorandum gives the misleading impression that delays in the review process are attributed to CASAC. Based on analysis that I submitted as part of my individual member comments attached to the IPMRP's December 10, 2018 letter to CASAC, I showed that the duration of CASAC activities in a NAAQS review cycle is far less than the total duration of the review cycle. A key factor that increases the duration of CASAC's involvement in a review cycle is delay in EPA providing CASAC with assessment documents for review. Furthermore, the memorandum omits any discussion of the more salient factors that have led to delays in the NAAQS review process related to decisions made by the EPA, not CASAC, as detailed below. EPA should not impose a reduced duration schedule for the scientific review that compromises the scope and quality of the scientific review. The duration of a review cycle is dependent on the following:

(1) EPA controls the duration of time between the conclusion of a prior review cycle and the initiation of the subsequent review cycle;
(2) EPA decides the allocation of resources for development of assessment reports by EPA staff that are part of the scientific review process;
(3) EPA decides when to release a draft document for CASAC review;
(4) EPA has been responsible for delays in providing draft assessments to the CASAC for review;
(5) Whether a draft EPA document requires further iteration depends on its initial scientific quality; and
(6) EPA has control over the timing of the NAAQS review process from the time that it receives closure on advice from CASAC until it promulgates a final decision.

Although the May 9, 2018 memorandum gives some attention to the last point in the list above, it fails to account the first five listed EPA-driven factors that lead to delays in review cycles. **Based on incomplete and erroneous diagnosis of leading causes of delay,** and without due consideration for statutory requirements as described above, including the need for a "thorough review" based on the "latest scientific knowledge" of the "kind and extent of… effects," **the May 9, 2018 memorandum inappropriately targets measures to reduce the duration of CASAC's engagement in the review process**.

The late 2020 deadline for completing the particulate matter review given in the May 9, 2018 memorandum is contrary to EPA's own final Integrated Review Plan for the PM NAAQS review[9]

05/documents/image2018-05-09-173219.pdf

[9] EPA, "Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter," EPA-452/R-16-005, U.S. Environmental Protection Agency, Research Triangle Park, NC, December 2016.

and does not provide sufficient time to complete the "thorough review" of the "latest scientific information" of the "kind and extent" of "all identifiable effects" mandated by the Clean Air Act for the review of NAAQS, even if the CASAC were supported by a robust panel of experts in the multiple disciplines involved. Furthermore, the quality and credibility of the review depends on whether CASAC is augmented with an appropriately constituted PM Review Panel.

On October 10, 2018, then acting EPA Administrator Wheeler eliminated the CASAC PM Review Panel by press release,[10] with a follow-up email from the SAB office on October 11, 2018. This was done without advance notice and without prior consultation with the panel or the CASAC. There is no precedent for disbanding a review panel in the middle of a review cycle.

The actual reason as to why Administrator Wheeler disbanded the PM Review Panel and refused to form an Ozone review panel has likely not yet been publicly disclosed. Two general talking points have emerged from EPA leadership regarding the elimination of review panels for PM and ozone. One is that the CASAC is the sole advisory body charged with advising EPA per the Clean Air Act. The other is that the panels needed to be eliminated to 'streamline' the review process. Both of these talking points are specious.

The talking point that only CASAC should advise the Administrator is specious because in fact it has only been the CASAC that has advised the Administrator throughout the history of CASAC. Per CASAC's charter with the U.S. Congress:[11]

"EPA, or CASAC with the Agency's approval, may form subcommittees or workgroups for any purpose consistent with this charter. Such subcommittees or workgroups may not work independently of the chartered committee and must report their recommendations and advice to the chartered CASAC for full deliberation and discussion. Subcommittees or workgroups have no authority to make decisions on behalf of the chartered committee, nor can they report directly to the EPA."

Thus, **it has always been the chartered CASAC, not its panels, that advise the EPA**. It has been long-standing practice since the 1970s to augment the 7-member CASAC with additional independent experts, so as to have the breadth and depth of expertise required to conduct a "thorough review" based on the "latest scientific knowledge," consistent with requirements of the Clean Air Act, as detailed in my individual comments attached to the IPMRP letter to CASAC dated December 10, 2018. **It is not sufficient, as the Administrator suggested, to state that the 7 member committee meets the minimum requirements of the law**.

The talking point that panels must be eliminated to streamline the review process is specious because, without the panels, CASAC does not have the breadth, depth, and diversity of expertise to conduct scientific review consistent with the Clean Air Act requirements for being

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

[10] EPA, "Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee Tasks Chartered Panel to Lead Review of Ozone & Particulate Matter Standards Under Reformed Process," News Release, U.S. Environmental Protection Agency, Washington, DC, October 10, 2018, https://www.epa.gov/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee

[11] United States Environmental Protection Agency Charter, Clean Air Scientific Advisory Committee, Filed with Congress, June 5, 2019, https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf

accurate and thorough. Thus, the panels are essential. Secondly, the panels do not slow down CASAC's review time. They work in parallel and concurrently with the chartered CASAC.

The EPA released the external review draft of the Integrated Science Assessment (ISA) on October 15, 2018, five days after disbanding the CASAC PM Review Panel.[12] The Federal Register notice announcing that the draft ISA was available for public review was dated October 16, 2018 and published on October 23, 2018.[13]

Compared to the chartered CASAC, the PM review panel had more experts, covered more scientific disciplines, and had multiple experts who provide diversity of perspectives in many key disciplines, such as epidemiology, toxicology, and human clinical studies, among others.

After receiving public comments at its December 2018 and March 2019 public meetings on the draft ISA, CASAC requested in its April 11, 2019 letter to the Administrator that it review a second draft of the Integrated Science Assessment for Particulate Matter, and that it be augmented with the expertise necessary for such a review by either reappointing the disbanded PM review panel or appointing a similar panel.[14] In a July 25, 2019 letter to CASAC, the Administrator refused these requests.[15] **The Administrator stated that there will not be a second external review draft of the ISA.** The Administrator did not directly address any rationale for why he did not reappoint the disbanded panel or form a similar panel. Instead, the Administrator decided to appoint a "pool" of "subject matter" consultants. As described below, **the "pool" of consultants does not address deficiencies created by the same Administrator when he disbanded the PM review panel.**

The lack of a second draft of the ISA is highly problematic, particularly because the draft Policy Assessment is based on scientific evidence from the ISA. In prior NAAQS reviews, it has been typical practice that CASAC reviews a second and sometimes third draft (as in the cases of the most recent lead and ozone reviews) of the ISA. It has been typical practice that CASAC has had the opportunity to review a draft Policy Assessment **AFTER** it has completed reviews of draft ISAs. This sequence was by design. A key principle of the 2006 revisions to the NAAQS review process, which were modified in part in 2007 and 2009, is that the scientific foundation of

[12] EPA, "Integrated Science Assessment for Particulate Matter (External Review Draft)," EPA/600/R-18/179, U.S. Environmental Protection Agency, Research Triangle Park, NC, October 2018. https://yosemite.epa.gov/sab/sabproduct.nsf/0/932D1DF8C2A9043F852581000048170D/$File/PM-1STERD-OCT2018.PDF

[13] EPA, "Integrated Science Assessment for Particulate Matter (External Review Draft)," *Federal Register*, 83(205):53471-53472 (October 23, 2019). https://www.govinfo.gov/content/pkg/FR-2018-10-23/pdf/2018-23125.pdf

[14] Cox, L.A. (2019), "CASAC Review of the EPA's Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018)," EPA-CASAC-19-002, Letter to A. Wheeler, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, April 11, 2019. https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002+.pdf

[15] Wheeler, A.R. (2019), Letter to L.A. Cox, EPA Clean Air Scientific Advisory Committee, from Administrator, U.S. Environmental Protection Agency, Washington, DC, July 25, 2019, https://yosemite.epa.gov/sab/sabproduct.nsf/0/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002_Response.pdf

the review must be established before addressing policy issues.[16,17,18] Failure to do this risks commingling policy issues prematurely before the science issues are adequately vetted and settled, which in turn creates the potential for policy choices to be made irrespective of the science. Thus, **the integrity of the process is harmed when policy issues are addressed before the science issues are adequately settled**.

In this review cycle for PM, there are significant areas of indicated need for revision for the draft ISA based on comments from the Independent Particulate Matter Review Panel and members of the public. Thus, neither CASAC nor the public will have an opportunity to see how unresolved issues in the draft ISA that might have impacted the PA will be handled in a final version of the ISA. The final version of the ISA will not be available until after this EPA forces CASAC to conclude its involvement in this review cycle.

The Administrator announced a "pool" of 12 subject matter experts in an EPA press release on September 13, 2019.[19] The pool of 12 are intended to respond to written questions from the chartered CASAC for both the PM and ozone NAAQS reviews. In contrast, the disbanded PM review panel had 20 experts in addition to the chartered CASAC. At the same time that the Administrator disbanded the CASAC PM Review Panel on October 10, 2018, he also announced that he would not form a CASAC Ozone Review Panel. This was despite the fact that EPA had requested nominations for a CASAC Ozone Review Panel in a Federal Register notice on July 27, 2018.[20] In the prior ozone NAAQS review, which was completed in 2015, the CASAC was augmented with 15 additional experts to form an ozone review panel. Thus, **the total number of augmented experts for the prior ozone review and the current PM review through 2018 was 35. Twelve people is not an adequate number to cover the breadth, depth, and diversity of scientific expertise and experience needed for review of both ozone and PM**.

The use of a "pool of subject matter experts" rather than a review panel to augment the chartered CASAC is unprecedented. Review Panels augment and report through the chartered CASAC, working in parallel and in collaboration with the members of the chartered CASAC. Members of review panels are nominated by the public and the nominations are subject to public comment. The SAB staff office reviews, vets, and appoints members of review panels. Members of review panels participate in meetings with members of the chartered CASAC, and deliberate interactively with members of the chartered CASAC on complex subject matter. The chartered CASAC is ultimately responsible for the content of advice sent to the Administrator, but the formulation of that advice is informed based on deliberations with panelists who provide the breadth, depth, and diversity of needed scientific expertise.

---

[16] Peacock, M., "Process for Reviewing National Ambient Air Quality Standards," Memorandum to George Gray and Bill Wehrum, U.S. Environmental Protection Agency, Washington, DC, December 7, 2006.

[17] Peacock, M., "Modifications to Process for Reviewing National Ambient Air Quality Standards," Memorandum, U.S. Environmental Protection Agency, Washington, DC, April 17, 2007

[18] Jackson, L., "Process for Reviewing National Ambient Air Quality Standards," Memorandum, U.S. Environmental Protection Agency, Washington, DC, May 21, 2009. https://www3.epa.gov/ttn/naaqs/pdfs/NAAQSReviewProcessMemo52109.pdf

[19] EPA, "Administrator Wheeler Announces New CASAC Member, Pool of NAAQS Subject Matter Experts," News Release, U.S. Environmental Protection Agency, Washington, DC, September 13, 2019. https://www.epa.gov/newsreleases/administrator-wheeler-announces-new-casac-member-pool-naaqs-subject-matter-experts.

[20] EPA, "Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel," *Federal Register*, 83(145): 35635- 35636 (July 27, 2018). https://www.govinfo.gov/content/pkg/FR-2018-07-27/pdf/2018-16116.pdf

In contrast, **there was no opportunity for public comment on the nominees for the pool of subject matter experts**. The decision regarding appointments of ad hoc consultants to serve as subject matter experts was made by the Administrator, not by the SAB Staff Office. The General Accountability Office has documented irregularities in the process since 2017 by which appointments have been made to EPA advisory committees, including the CASAC.[21] **Appointments made directly by the Administrator are subject to political considerations** and can disregard input from EPA career staff in the Science Advisory Board Staff Office regarding scientific considerations in selecting members and consultants. All interactions between CASAC and the subject matter experts are done only in writing. **Subject matter experts are not allowed to participate in deliberative meetings with CASAC**. For example, subject matter experts are not allowed to, unless invited in writing by the chair or designees of the chair, respond to all charge questions that might be of interest to the consultant. If a member of the pool of experts offers written comments that are inaccurate, are out of scope, or have other problems, there is not an effective mechanism for interaction that might have led to more relevant and refined input. Moreover, the composition of the pool of consultants does not provide CASAC the breadth, depth, and diversity of expertise needed for review of either the ozone or the PM NAAQS. **The appointment of consultants by the Administrator is not correcting the deficiencies in CASAC's ability to conduct a thorough review that have resulted from disbanding the PM Review Panel**.

EPA should reinstate the disbanded PM review panel and appoint an ozone review panel. These panels should be appointed by the director of the SAB staff office, not by the Administrator, per established procedures in place prior to interference by the current EPA Administrator.

In attempting to alter the NAAQS review process, if any changes are warranted, EPA should have followed the kind of open and transparent process undertaken in 2006, which included input from EPA career staff, the chartered CASAC, and members of the public. Such a process would lead to a better understanding of the key needs and challenges of NAAQS review and perhaps effective ideas for reviews which are more timely.

As a result of the many deleterious, unprecedented, and unwarranted changes to the CASAC described above, CASAC has transitioned from a committee of nationally and internationally recognized researchers at the leading edge of their fields toward a committee composed predominantly of stakeholders chosen based on geographic location and affiliation with state government, rather than scientific expertise first and foremost. **CASAC does not have adequate breadth, depth, and diversity of scientific expertise and experience needed to conduct thorough reviews based on the latest scientific knowledge of the kind and extent of scientific issues that pertain to the Particulate Matter NAAQS**. This is generally true given that CASAC is comprised of only seven members, whereas these reviews require multiple experts in each of many scientific disciplines. This is even more true given that the current CASAC was appointed based primarily on geography and affiliation, and not by scientific discipline, in accordance with the October 31, 2017 memo by former Administrator Pruitt. According to November 7, 2018 "determination" memorandum from the EPA SAB office, the CASAC has no epidemiologists,[22] even though epidemiology is a key scientific discipline related

[21] GAO, EPA Advisory Committees: Improvements Needed for the Member Appointment Process, GAO-19-280, General Accountability Office, Washington, DC. https://www.gao.gov/assets/710/700171.pdf

[22] Yeow, A., "Determinations Associated with the Clean Air Scientific Advisory Committee (CASAC) Review of the Particulate Matter (PM) National Ambient Air Quality Standards (NAAQS)," Memorandum to T.H. Brennan, Science

to both the ozone and PM reviews. The CASAC lacks adequate coverage of many other disciplines, such as exposure assessment, welfare effects, and other areas, and lacks depth in areas for which CASAC has historically and necessarily engaged multiple experts, such as toxicology and controlled human studies.

The Administrator should reinstate the disbanded CASAC PM Review Panel or should form a similar panel to augment CASAC for the current review of the PM NAAQS. The Administrator should form a CASAC Ozone Review panel to augment the CASAC for the current review of the ozone standard. The EPA should reaffirm and continue the established and successful practice, demonstrated for four decades, of augmenting CASAC with expert panels for each NAAQS review.

To promote transparency of the review and opportunity for public input consistent with long-standing practice, the CASAC should have a longer time frame for its deliberations, consistent with historic practice in the last decade, and should not have the public meeting process truncated to meet shortened deadlines that resulted from EPA delays in starting the current review. The current self-imposed review schedule for the PM NAAQS review is contrary to the final PM IRP. It has fewer public meetings of CASAC and, therefore, fewer opportunities for public comment. For the ozone NAAQS review, the EPA is planning that CASAC will have only one face-to-face meeting to simultaneously review the draft ISA and draft PA, which even more severely limits opportunities for public comment compared to prior review cycles.

EPA's focus on rushing the scientific review of both the PM and Ozone NAAQS is clearly hypocritical. Although the Administrator has emphasized the need to meet the five year statutory mandate of the Clean Air Act for NAAQS review, not only has the Administrator not acknowledged that courts have allowed adequate time for scientific review when EPA has missed such deadlines, but the Administrator has been silent regarding the timing of reviews for carbon monoxide, lead, nitrogen dioxide, and sulfur oxides. For example, the most recent review of the carbon monoxide NAAQS concluded on August 31, 2011. The most recent lead review concluded on October 18, 2016. The most recent nitrogen dioxide review concluded on April 6, 2018. Why has the EPA not started new review cycles for these pollutants? **Delays by EPA in starting review cycles or developing assessment documents should not infringe on the duration of review and comment activities by CASAC and the public**.

Decision Context for NAAQS Review May Not Be Redefined by CASAC

CASAC may not redefine the policy and decision context of NAAQS review. This context is set forth by Congress in the Clean Air Act, including but not limited to the following excerpts. From Section 108:

The NAAQS must address "air pollution which may reasonably be anticipated to endanger public health or welfare"

"Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities." and "any known or anticipated adverse effects on welfare"

Advisory Board, U.S. Environmental Protection Agency, Washington, DC, November 7, 2018. https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentCASAC/64C246444C9CC319852584430045E365/$File/Determination%20memo-Chartered%20CASAC%20PM-110718.pdf

And from Section 109:

The Administrator "shall complete a thorough review of the criteria" published under Section 108.

"National primary ambient air quality standards, prescribed under subsection (a) shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health."

Note that nowhere does the Clean Air Act state that EPA should take a risk-neutral or risk-seeking attitude toward risk, nor that EPA should limit its assessment only to those studies that individually can demonstrate manipulative causality consistent with particular quantitative causal tests and inference methods. The language of the Clean Air Act means that EPA cannot throw out studies according to arbitrary "quality" criteria if that would compromise the ability to conduct a thorough review and account for the full scope of review as mandated in the Act.

The Role of Expert Judgment in Scientific Review of the NAAQS

In the current review process the Administrator has arbitrarily and capriciously done away with the CASAC PM Review Panel. Given the important role of expert judgment in CASAC's work, it is essential that CASAC be augmented with additional experts in the multiple scientific disciplines needed for this review. Furthermore, there must be multiple experts in key areas, such as air quality physics and chemistry, exposure assessment, toxicology, controlled human studies, epidemiology, and others, to have a diversity of perspectives to assure that judgment is based on the large body of relevant scientific evidence using accepted inference methods. For four decades, CASAC has been augmented with expert panels as documented by Frey et al. (2018) and others[23,2425]. Augmented panels advise the CASAC and supplement it with the expertise it needs. Absent such augmented expertise, the chartered CASAC is scientifically unqualified to conduct a review consistent with language in the Clean Air Act.

Expert judgment requires judgment by domain experts.[26,27] Given that this CASAC lacks experts in the appropriate scientific domains, it is unqualified to offer such judgments. Given

[23] Frey, H.C., A.V. Diez Roux, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and S. Vedal, "CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018)," 34 page letter and 100 pages of attachments submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA–HQ–ORD–2014-0859, December 10, 2018, Appendix E. https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/$File/PMRP+Letter+to+CASAC+181210+Final+181210.pdf

[24] Bloomer, L., and J. Goffman, "The Legal Consequences of EPA's Disruption of the NAAQS Process," Environmental and Energy Law Program, Harvard Law School," undated, http://eelp.law.harvard.edu/wp-content/uploads/Legal-Consequences-of-NAAQS-Changes.pdf, accessed 10/7/19

[25] Bachmann, J., "Written Statement for the Public Meeting of the EPA Chartered Science Advisory Board, Re: 5/31 SAB Discussions about EPA Planned Actions and their Supporting Science," Environmental Protection Network, May 29, 2018, http://www.scientificintegrityinstitute.org/EPATransBachmann052918.pdf

[26] EPA, Expert Elicitation Task Force White Paper, Science and Technology Policy Council, U.S. Environmental Protection Agency, Washington, DC, August 2011. https://www.fwspubs.org/doi/suppl/10.3996/052017-JFWM-041/suppl_file/10.3996052017-jfwm-041.s7.pdf

[27] Morgan, M.G., and M. Henrion, Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis, Cambridge University Press, 1990.

that this CASAC lacks expertise in many key disciplinary areas, especially epidemiology, and that EPA arbitrarily and capriciously disbanded the CASAC PM Review Panel a few days before the Draft ISA was released, thereby depriving CASAC of the needed expertise, this CASAC is not in a credible position to offer judgments regarding causal determinations.

Expert judgment should be based on conditioning of available evidence and inference methods. The conditioning step is substantially more credible when it is based on a group of experts with breadth and depth of expertise, and diversity of perspectives. EPA had such a group in the form of the CASAC PM Review Panel and yet arbitrarily and capriciously dismissed that panel without prior notice and without public consultations with CASAC.

There are well known biases in expert elicitation, some of which are cognitive and some of which are motivational. An example of a motivational bias is the so-called "expert bias," which is when people who are not the relevant experts pretend that they are to make themselves appear to be important experts. Another well-known motivational bias is when an "expert" wants to influence the outcome of a scientific review process to achieve a particular policy or regulatory outcome. Such biases might be indicated, for example, when members of a scientific review committee earn their living based on funding from regulated industries, and offer opinions that are consistent with policy outcomes of interest to their funders. Motivational biases also arise when an expert has taken strongly stated public positions previously, as a result of which it becomes more difficult for that person to change their views.

Biases can be counter-acted. The approach to counter-act "expert" bias is to engage experts who have relevant expertise and to make sure that there is breadth and depth of needed expertise, as well multiple experts in key scientific disciplines who have diverse opinions. In contrast, if the goal is to undermine the science review process, efforts could be made to promote and enhance "expert" bias. This can be done, for example, by doing away with a group of domain experts, as EPA has done by eliminating the CASAC PM Review Panel, and instead placing the review in the hands of a group that lacks the breadth and depth of expertise, and diversity of perspectives, to properly condition the review. A corollary is that "true" experts are usually the first to admit that they are not qualified to undertake a particular review and to call for the inclusion of additional experts. Persons who are over-confident of their own expertise or who seek to be perceived as an expert in an area for which they are not are unlikely to want to cede their position to experts.

An example of over-confidence is the inability of a person to admit to any limitations of methodologies that they advocate while emphasizing only limitations but not strengths of other methodologies. For example, advocates of new quantitative methods should acknowledge limitations related to problem selection, data selection, limitations of the methodology itself, and challenges with interpretation of results. As a simple example, consider the use of statistical methods to making inferences regarding a statistic. There is judgment regarding how to structure the analysis, what data to select (including geographic area, time period, spatial and temporal resolution, and so on), what analysis methods to use, what criteria to use in hypothesis testing, and how to interpret the results.

One way to counter-act motivational biases related to experts who want to influence the outcome is, preferably, to not include persons with clear conflicts of interest as part of an expert advisory committee, especially in a regulatory context. This would typically exclude people with financial ties to regulated industries who have a vested interest in the outcome of the review process, and would also include people who have strongly stated prior positions that imply pre-judgment of the policy-relevant outcomes and people who work at agencies with publicly stated

perspectives on issues under deliberation for which there is also a close reporting and line of management relationship. Such persons could still participate in the process as stakeholders via public comments.

In contrast, if the goal is to undermine the science review process, efforts could be made to promote and enhance motivational bias. A way to promote and enhance motivational biases is to have fewer experts and include among them persons who are susceptible to such biases. This is what EPA has done in doing away with the CASAC PM Review Panel and with recent changes to the composition of the CASAC.

It is evident that the recent changes to the NAAQS review process have undermined prior measures that were in place to avoid or mitigate motivational biases. Changes to the NAAQS review process and to the CASAC since 2017 clearly produce bias.

Integrated Science Assessment

In our December 10, 2018 letter to CASAC and the EPA docket for the draft Integrated Science Assessment, we offered consensus advice on numerous issues related to the draft ISA. The failure of EPA to provide a second external review draft of the ISA compromises the credibility and integrity of the NAAQS review process. This is because there were many important scientific issues raised regarding the first external review draft that require revision and iteration prior to their application in risk and exposure assessment and prior to their interpretation in the policy assessment. Although we found that the draft ISA was a comprehensive scientific document, we identified numerous areas for which refinement or revision was needed as detailed in our December 10, 2018 letter to CASAC. These areas include low cost sensors, air quality, contrasts between $PM_{2.5}$ and UFP, coarse PM, PM components, onroad and near-road microenvironments, mixtures and copollutants, study selection, transparent application of the causal framework, more in-depth treatment of specific issues related to $PM_{2.5}$ and mortality, more explanation and possible reconsideration of the causal determination for short-term exposure to coarse PM and respiratory adverse effects, more explanation and possible reconsideration of the causal determination for long-term exposure to UFP and central nervous system effects, and reconsideration of the at-risk causal finding for populations with pre-existing cardiovascular or respiratory disease. Members of the IPMRP also provided extensive individual comments that were attached to the December 10, 2018 letter from the panel.

In our March 27, 2019 letter to CASAC, we noted that “the framework for causal determination, including terminology, and the overall plan for development of the ISA, was reviewed by CASAC in 2016.” However, we strongly disagreed with statements in CASAC’s draft letter to the Administrator “that the Draft ISA lacks explicitly stated principles for drawing conclusions or lacks operational definitions.” We noted that “the various considerations in developing causal determinations are explained in the Preamble to the ISAs and have been considered already in CASAC’s review of the Draft Integrated Review Plan.” We further noted that “[w]hile there may be opportunities for EPA staff to improve the clarity and transparency of the explanations of the inferences it makes and the conclusions it draws, this is not a fundamental limitation of the underlying framework but rather a matter of routine scientific review and iteration to improve the clarity and transparency of the final document.”

The chartered CASAC developed comments that in many cases appeared to exclusively focus on doubt-raising without acknowledgment of inferences that can be supported by the scientific evidence. In our March 27, 2019 letter, the IPMRP stated that “it is inappropriate to over-

emphasize or exclusively focus on discordant results and ignore the overall preponderance of the evidence when making inferences."

The IPMRP further stated that the draft ISA "follows methods previously reviewed by CASAC, including the approach to literature review, the causal determination framework, the framework for assessing at risk populations and life stages, and assessment of concentration-response functions, consistent with the Preamble to the ISAs and the 2016 Integrated Review Plan for the current review cycle." Consistent with our December 10, 2018 comments, we noted on March 27, 2018 that "the ISA takes into account poverty, temperature, and season, including lags related to temperature, and makes inferences regarding whether ambient PM concentration independently causes adverse effects and whether concentration and response relationships are either confounded or modified by other variables. Some of these inferences could be explained more clearly or in more detail."

The draft PA appears to accept the draft ISA as it was prior to external review by CASAC and the public, including the IPMRP. There is no summary in the draft PA of any changes that are being made to the draft ISA as a result of comments from CASAC and the public, including the IPMRP. Normally, in prior review cycles, there is a second external review draft of the ISA concurrent with a first review draft of the Risk and Exposure Assessment (REA). In this review cycle for PM, EPA has not produced a separate draft REA, but instead has subsumed the REA into the draft PA. Typically, in a normal review cycle, the draft PA would not be released until after EPA has finalized the ISA and completed a second draft of the REA. The typical sequence in a normal review cycle was intended to protect the science assessments from being commingled with the policy assessment, so that the scientific basis could be established irrespective of later policy interpretations. In the current review cycle, the fact that the ISA is not completed prior to external review of the draft PA provides EPA leadership with the opportunity to change the ISA to support pre-determined policy outcomes in the final PA. This is a completely unacceptable situation.

Based on the content of the draft PA, it is clear that EPA staff have elected to retain the causal determination framework for health effects attributed to exposures of varying durations to particular indicators, and to retain the causal framework for at-risk populations. This is an appropriate choice. Although the chair of CASAC has aggressively advocated that EPA adopt quantitative causal tests for individual studies based on the chair's own work, such methods have not been adequately vetted and are not ready for widespread use at this time. The merits of such proposals could be a research topic that may be informative in future review cycles. It is certainly the case that leading edge research in the field of air pollution epidemiology is concerned with potential threats to validity of making inferences as well as adoption of improved techniques that better account for confounding and modification and that help support inferences regarding causality. However, because CASAC does not have epidemiologists among its seven members, and does not have access to a sufficient number of epidemiologists with breadth, depth, and diversity of expertise and experience, this CASAC is hardly an appropriate authority on the state of epidemiological practice and science and the directions it should go.

EPA-1. Chapter 1 – Introduction: To what extent does the CASAC find that the information in Chapter 1 is clearly presented and that it provides useful context for the review?

The draft PA, Chapter 1, fails to document the ad hoc changes to the NAAQS review process and to the CASAC that have been made since the final Integrated Review Plan (IRP) was published in 2016.[28] Table 1-3 of the final IRP laid out the following schedule for the review of the PM NAAQS:

- Fall 2017: Release of first external review draft of the ISA
  Release Risk and Exposure Assessment (REA) planning document(s)
- Winter 2018: CASAC Review of First Draft ISA, REA Planning Documents
- Fall 2018: Release of second external review draft of the ISA
  Release of First Draft REAs
  Release of First Draft PA
- Winter 2019: CASAC Review of Second Draft ISA, First Draft REAs, and First Draft PA
- Fall 2019: Release Final ISA
  Release of Second Draft REAs
  Release of Second Draft PA
- Winter 2020: CASAC Review of Second Draft REAs, Second Draft PA
- Fall 2020: Final REAs, Final PA
- 2021 Proposed Rule
- 2022 Final Rule

Compared to the IRP, the following steps have been omitted in the current review: (a) no REA planning document(s); (b) no second external review draft of the ISA; (c) no external review drafts of the REAs; (c) no provision for a second draft of the PA; (d) no final REA as a separate document; and (e) no final ISA until after CASAC has completed its review of the draft PA.

Although the IRP is cited on page 1-1, line 7, the deviations of the current review from the IRP are complete omitted. This is inappropriate and should be corrected. The chapter should enumerate all of the changes to the NAAQS review process, the CASAC, and the PM NAAQS review since 2016. See my detailed comments above on process issues.

The schedule in the final IRP specified two drafts of each of the ISA, REA, and PA. However, the final IRP indicated that the drafts of the REA and PA would be concurrent. This differs from the schedule in the external review draft of the IRP that was reviewed by CASAC earlier in 2016.[29,30] In the external review draft of the IRP, EPA had proposed to sequence the release of first drafts of the ISA, REAs, and PA such that CASAC would review them sequentially on a staggered schedule. Thus, under the initial proposed schedule, CASAC would have been able

[28] See Reference 9.

[29] EPA, Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter, EPA-452/D-16-001, U. S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711. https://www3.epa.gov/ttn/naaqs/standards/pm/data/201604-draft-integrated-review-plan-casac-review.pdf

[30] Diez Roux, A., "CASAC Review of the EPA's Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016)," EPA-CASAC-16-003, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, August 31, 2016. https://yosemite.epa.gov/sab/sabproduct.nsf/9920C7E70022CCF98525802000702022/%24File/EPA-CASAC+2016-003+unsigned.pdf

to provide its advice on the first draft of the REAs before receiving the first draft of the PA. The schedule in the draft IRP allowed for two drafts of each of the ISA, REA, and PA.

The final IRP sequencing of the first drafts of the REA documents such that they are released after receiving CASAC review of both the first draft of the ISA and of REA planning documents is appropriate. Since the REAs build upon information in the ISA, it is logical and appropriate that EPA consider CASAC's advice on the ISA before releasing a draft of the REAs.

Because the Policy Assessment is intended to integrate information from the ISA and the REAs, it is generally not appropriate for a first draft of the PA to be released at the same time as the first draft of the REAs. Simultaneous release of the first draft of the REAs and PA was done, for example, in the last review of the ozone NAAQS. As colleagues have pointed out (see November 26, 2016 letter to CASAC from former members of the 2009 to 2014 CASAC Ozone Review Panel), the first draft of the PA in that review was very preliminary and required substantial revision.[31] Transparency of the review process and clear distinction of science and policy issues is enhanced by obtaining CASAC's advice on the REAs before submitting a first draft of the PA for CASAC review.

However, in this review, there is no separate REA. The content of the REA has been incorporated into the draft PA. This is not appropriate since there are important scientific issues pertaining to the REA that should be reviewed and vetted prior to use in the PA.

Chapter 1 should clearly explain the difference between the sequence of draft documents indicated in the IRP versus the actual sequence of draft documents in this review. Rather than multiple drafts of the ISA, REA, and PA, staggered so that science issues are vetted and settled before proceeding to policy issues, this review cycle has devolved into one draft of the ISA and one draft of the PA.

The draft of the PA is being reviewed before the ISA has been finalized. Whether or how issues raised by CASAC and the public regarding the draft ISA will be resolved, if at all, are unknown. What changes, if any, are in progress for the draft ISA, and which of these changes affect content of the draft PA? For example, the draft PA argues that focus should be given to health effects causal determinations that are "causal" or "likely to be causal" in assessing the adequacy of the current primary standards with regard to protection of public health and in assessing possible revised or new standards. The draft ISA posits a determination of "likely to be causal" for long-term exposure to UFP and central nervous system effects. Yet, it seems that this finding is not adequately addressed in the draft PA. Is this because the finding may be revised downward in the final ISA? Or, is the finding in the final ISA to later be revised downward to match a pre-determined policy outcome from the PA? The commingling of science and policy by having so much overlap in the timing between the draft PA and draft ISA, at a minimum, creates the perception that the final ISA may be tailored to match policy outcomes in the final PA that were determined before the ISA was completed.

As noted on page 1-1, line 25, the role of the PA is to "bridge the gap" between the scientific assessments, which include not just the ISA but also REAs, and judgments required of the

[31] Frey, H.C., J.M. Samet, A.V. Diez Roux, G. Allen, E.L. Avol, J. Brain, D.P. Chock, D.A. Grantz, J.R. Harkema, D.J. Jacob, D.M. Kenski, S.R. Kleeberger, F.J. Miller, H.S. Neufeld, A.G. Russell, H.H. Suh, J.S. Ultman, P.B. Woodbury, and R. Wyzga, "CASAC Advice on the EPA's Integrated Review Plan for the Ozone National Ambient Air Quality Standards (External Review Draft)," 24 page letter with 42 pages of attachments, submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA–HQ–OAR–2018–0279, November 26, 2018, https://yosemite.epa.gov/sab/sabproduct.nsf/0AC9E8672B0CA54985258351005BE54F/$File/Ozone+Letter+181126+Submitted-rev2.pdf

Administrator. The fact that the science has not been appropriately vetted prior to the release of the draft PA is problematic, as noted above.

Page 1-2, lines 9-11. Should also acknowledge that CASAC is to advise on background levels and research needs.

Page 1-2, lines 12-13: There is not a separate Risk and Exposure Assessment (REA) document in this review. To be consistent with the final IRP for this review, the text should state that EPA intended to make available to CASAC and the public two drafts of the REA. The most appropriate sequence of documents is to have the first draft of the ISA reviewed and revised prior to a first draft of the REA. The first draft of an REA should be made available and reviewed before a first draft of the PA is released. This was the situation in the most recent prior review of the PM NAAQS, for which there was a separate health risk and exposure assessment (HREA) and a welfare risk and exposure assessment (WREA).[3233] The latter was focused on visibility. In a few cases, the REA (HREA, WREA, or both) has been combined into the PA, such as for the most recent lead NAAQS review.[34] However, in such cases, this is because there were no substantial updates to the REA compared to the prior review cycle. In the case of the current PM NAAQS review, there are clearly substantial updates that have led to an entirely new REA in this review. This draft PA is not based on a reinterpretation of the REA from the prior review cycle. Instead, a new REA for health effects is included in the draft PA appendices. However, the REA should have been provided separately from the draft PA. The draft REA should have been provided for review after considering CASAC and public comments on the draft ISA and before releasing a draft PA.

Page 1-3, lines 9-11: Given that CASAC has been populated with members appointed based on geographic location and government affiliation, and that CASAC has been deprived of a duly appointed CASAC PM Review Panel, CASAC is not qualified to advise the EPA in a manner that accurately reflects that latest scientific knowledge of the kind and extent of salient issues that must be considered.

Page 1-3, lines 23-24. The text should also cite the recent Murray Energy v. EPA decision of the Court of Appeals for the District of Columbia Circuit.[35] As stated in the court's decision, "[i]ndustry Petitioners also point to section 109(d)(2)(C) of the Act, which requires CASAC to advise EPA "of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance" of revised NAAQS. 42 U.S.C. § 7409(d)(2)(C). According to Petitioners, the fact that CASAC is required to supply information to EPA about the "social, economic, or energy effects" of the revised NAAQS implies that EPA is obliged to consider that information in setting the NAAQS." However,

[32] Samet, J.M., CASAC Review of Quantitative Health Risk Assessment for Particulate Matter – Second External Review Draft (February 2010), EPA-CASAC-10-008, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, April 15, 2010. https://yosemite.epa.gov/sab/sabproduct.nsf/BC4F6E77B6385155852577070002F09F/$File/EPA-CASAC-10-008-unsigned.pdf

[33] Samet, J.M., CASAC Review of Particulate Matter Urban-Focused Visibility Assessment – Second External Review Draft (January 2010), EPA-CASAC-10-009, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, April 20, 2010. https://yosemite.epa.gov/sab/sabproduct.nsf/0D5CB76AFE7FA77C8525770D004EED55/$File/EPA-CASAC-10-009-unsigned.pdf

[34] Frey, H.C., CASAC Review of the EPA's Policy Assessment for the Review of the Lead National Ambient Air Quality Standards (External Review Draft – January 2013), EPA-CASAC-13-005, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, June 4, 2013, https://yosemite.epa.gov/sab/sabproduct.nsf/E2554E264EEF8CCB85257B80006B3014/$File/EPA-CASAC-13-005+unsigned.pdf

[35] https://law.justia.com/cases/federal/appellate-courts/cadc/15-1385/15-1385-2019-08-23.html

contrary to the petition, this decision reaffirms that "this provision was intended to "enable the [EPA] to assist the States in carrying out their statutory role as primary implementers of the NAAQS," but had "no bearing upon whether cost considerations are to be taken into account in formulating the [NAAQS].""

Page 1-4, lines 17-18: Per Murray Energy v. EPA (2019), background is simply irrelevant in setting the level of the NAAQS. The level of the NAAQS must be set based on health effects. Proximity to background may be an issue for implementation.

Page 1-4, lines 28-29: Given that CASAC lacks the breadth, depth, and diversity of expertise necessary for this review, which was embodied in the disbanded CASAC PM Review Panel, CASAC is poorly positioned to offer advice on "recent advanced in scientific knowledge on the effects of the pollutant on public health and welfare."

Page 1-5, lines 1-17. See also CASAC's charter with the U.S. Congress, which should be cited.

Page 1-10, lines 8-10: the text here regarding the establishment of a Federal Reference Method for measurement of ambient coarse PM sets an important precedent. EPA should establish a FRM for measurement of UFP.

Page 1-11, line 6. The NAAQS review process was revised in 2006 and then again in 2008 and again in 2009. The 2006 revision was the major revision. The revisions in 2008 and 2009 were incremental changes of the process established as a result of the 2006 revision. The text should be rewritten to more accurately convey this sequence of events, with citations.

Page 1-12, lines 15-19. Although the IRP has been followed in part, there have been substantial deviations from the IRP. The deviations from the IRP should be specifically enumerated and discussed. See my comments above on this point.

Page 1-12, lines 20-22. This memorandum contradicted EPA's own IRP for this review. See comments above.

Page 1-12, line 23. Should note that on October 10, 2018, the CASAC PM Review Panel was disbanded by Acting Administrator Wheeler. The draft ISA was released on October 15, 2018.

Page 1-12, lines 24-25. Please give the dates of the meetings.

Page 1-12, line 33. What changes are being made to the draft ISA in response to comments from CASAC and the public. How will changes in the ISA be incorporated into the draft PA? What is the rationale for depriving CASAC and the public of the opportunity to see a revised draft ISA before the PA is finalized? Related to this issue, is EPA under a court order or a consent decree to complete the PM NAAQS review by 2020?

EPA-2. Chapter 2 – PM Air Quality: To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for the review?

Specific comments on Chapter 2:

Page 2-3, line 17: text should be more clear if this is specifically about primary PM emissions. Aside from stationary and mobile sources, should mention area sources and fugitive emissions. At an appropriate place, should more systematically also address sources of secondary PM precursors.

Page 2-3, line 23, should add NO_x and NH_3 to the parenthetical note about SO_2).

Page 2-7: the definitions of and distinctions between elemental carbon and black carbon should be discussed. Given that this is a topic that probably has no end, EPA could acknowledge that there are differences of opinion about the use of these terms and offer an operational definition for use here. Also related to this page, a figure that apportions $PM_{2.5}$ to the components of

section 2.1.1.3 would be useful, such as based on a typical average for a selected year. This would help put into context information in Figure 2.5 and elsewhere… e.g., how much do EC and OC each contribute to $PM_{2.5}$ mass on average, and what is the variability in this contribution (e.g., inter-city? Inter-monitor? Inter-annual?) Inter-daily?).

Page 2-9, lines 9-11. To be more clear, what is meant by "or can form new particles"? Is this via condensation?

Page 2-9, lines 16-17: This text appears to be correct but may give a misleading impression. EGUs appear to be responsible for 69% of national SO2 emissions in 2014, not 80%. The reader might interpret that "nearly all" of the 80% is from EGUs, which appears not to be the case. 69% is not "nearly all" of 80%.

Page 2-9, line 19: According to the emissions trend data reported by EPA,[36] the total NO_x emitted in 2014 was 12.589 million tons, not 14.4 million tons. Please check the number and correct as appropriate.

Page 2-9, line 24: it would help to give some quantitative idea of what "significantly" means… i.e more than X%? Between Y% and Z%?

Page 2-9: related to the content here, it would be useful to either have similar content regarding components of UFP, PM_{10}, and $PM_{10-2.5}$ or some explanation of the lack of such data. This could be a paragraph on each.

Page 2-11, line 12: What is a "robust" national network? How is "robust" defined, quantified, and assessed?

Related to Page 2-11: A statement should be made that there is not a Federal Reference Method for Ultrafine Particles. Such a statement is important because a future research need is to obtain more ambient monitoring data over space and time for UFPs to support epidemiology based on UFP. Given that EPA has in the past established FRMs in anticipation of possible new indicators, it will be appropriate to provide a rationale for establishing a FRM for UFP.

Page 2-12, Figure 2-6. What are the values on the vertical axis? Are these the number of stations? Axes should be explicitly defined with axes labels.

Page 2-5, top of the page. Please add a paragraph regarding the precision and accuracy of FRM and FEM monitors for $PM_{2.5}$, particularly for annual averages down to 8 ug/m^3 and perhaps as low as 5 ug/m^3.

Page 2-18, top of page. This example of the development of an FRM for $PM_{10-2.5}$ is a good. An FRM should similarly be developed for UFP.

Page 2-19, line 7: I think this probably is supposed to be "country" rather than "county".

Page 2-19: monitoring methods related to ultrafines should also be briefly summarized.

Page 2-20, top of page. What are the demonstrated uses of sensor technologies for improved spatial resolution of ambient concentration or exposure concentrations, if any, for UFP, $PM_{2.5}$, PM_{10}?

Page 2-24, 4th line from the bottom (there are no line numbers): I could not find the "design value ratio line" in Figure 2-11.

Page 2-28, bottom paragraph, continued to next page – this is very useful information. Agree that there are decreasing trends in near road $PM_{2.5}$ increments related to fleet turnover of heavy

[36] https://www.epa.gov/air-emissions-inventories/air-pollutant-emissions-trends-data

duty diesel trucks that is leading to increased diffusion of diesel particle filters into the onroad fleet.

Page 2-38: the text refers to the accuracy and precision of publicly available data without any quantification. It would help to say something more on this topic, earlier (see comment above about the precision and accuracy for annual average concentrations down to 5-8 ug/m^3.)

Page 2-41: the discussion and treatment of this material regarding the performance of alternative hybrid modeling methods seems appropriate. The text points out that the hybrid model performance tends to be worse in parts of the western U.S and attributes this, in part to "low concentrations." Yet, earlier text indicated that concentrations in the eastern U.S. tend to be lower than in the western U.S. Thus, the observation of low concentrations is not limited to a particular region. The term "low" is undefined. For purposes of this document, "low" might be below, say, 5 ug/m^3. As indicated later, values of 8 ug/m^3 to 12 ug/m^3 are highly policy relevant and thus would not be considered to be "low.". Annual average concentrations as low as 5 ug/m^3 may also be highly policy relevant, depending on interpretations of available evidence and studies. Thus, it would be informative to assess hybrid modeling performance for various ranges of annual average concentrations, such as 5-8 ug/m^3, 8-12 ug/m^3, and 12 ug/m^3 and above.

Page 2-42, line 30: The text here seems a bit superficial and could be supported with more specifics.

Page 2-43, line 8: What is the interpretation/implication/significance of information given in Table 2-3? Or, if the text immediately above is in reference to this table, then the table should be cited earlier in this paragraph.

Page 2-44, line 8. What is meant by spatial "texture"? Avoid metaphors in formal technical writing. Perhaps this is referring to a spatial 'distribution'?

Page 2-44, lines 11-14: This is a good summary of comparisons, but what is the assessment based on this information? Which of these results are more plausible?

Page 2-45, line 7: Coefficient of variation of what? And for what averaging time? In general, always indicate averaging time when reporting concentrations or concentration-derived metrics.

Page 2-49: It appears that the assessment of background PM is largely based on results from the prior review. Is there anything new that can be learned from the hybrid modeling work that could inform some of this discussion?

Page 2-49, lines 33-35: it would be useful to mention some of the dynamics of UFP that are mentioned in the draft ISA – e.g., that they are more dynamic and have spatial gradients near sources, in part because they agglomerate to larger size ranges and thus are transformed out of the UFP size range. This has implications for the characterization of UFP background, which could be discussed.

Also, the background discussion should differentiate based on averaging times, notably daily average and annual average.

Page 2-52: what about transboundary PM precursors, such as SO_2, NO_x, NH_3, and VOCs? Although there is some mention of a few of these, these could be treated more systematically in the text.

Minor comment: change "like" to "such as" – e.g., page 2-2, line 8.

EPA-6. Chapters 3 to 5: What are the CASAC views regarding the areas for additional research identified in Chapters 3, 4 and 5? Are there additional areas that should be highlighted?

This charge question should have also included reference to Chapter 2. EPA should develop a Federal Reference Method for Ultrafine Particles. There is need for ongoing comprehensive characterization of the performance of modeled ambient concentration fields estimated using hybrid modeling methods.

Dr. Terry Gordon
October 6, 2019

SCQ-3.2 What are the panel's views on the relative weight that the draft Policy Assessment gives to the evidence-based (i.e. draft PA, section 3.2) and risk-based (i.e. draft PA, section 3.3) approaches in reaching conclusions and recommendations regarding current and alternative $PM_{2.5}$ standards?

The draft PA appropriately gives the evidence-based approach the deserving amount of weight to using those studies that "demonstrate a causal or a likely to be causal relationship with PM exposures" in the risk estimates. The choice and presentation of health outcomes was logical and well written. Similarly, the risk-based approach was clearly written and well-balanced, thus permitting the logic and presentation of the conclusions and recommendations in a fair and balanced setting. In particular, the weight of the different categories of evidence was well delineated between the studies with new evidence to suggest adverse health outcomes at levels below the current standards.

SCQ 3.3 What are the panel's views on the evidence-based approach, including:

a) The emphasis on health outcomes for which the draft ISA causality determinations are "causal" or "likely causal"?

The emphasis on causal and likely causal health outcomes was very appropriate. The designation of nervous system effects to a likely causal level was well described. The designation of birth outcomes/reproduction as "suggestive", however, is puzzling given the large amount of epidemiologic studies that show associations between these outcomes and ambient PM. Admittedly, this field is rapidly expanding and perhaps the ISA needs updating.

b) The identification of potential at-risk populations?

The at-risk populations are appropriate as indentified.

c) Reliance on key multicity epidemiology studies conducted in the US and Canada for assessing the $PM_{2.5}$ levels associated with health effects?

This reviewer agrees that the reliance on US and Canadian epidemiology studies is the correct approach given the potential for different PM composition and sources among continents/countries.

d) Characterizing air quality in these key studies using two approaches: the overall mean and $25^{th}/75^{th}$ percentiles of the distribution and the "pseudo design value" reflecting a monitor with the highest levels in an area?

These approaches seemed appropriate and balanced.

e) The preference for continuing the use of an annual $PM_{2.5}$ standard as the principle means of providing public health protection against the bulk of the distribution of short- and long-term $PM_{2.5}$ exposures?

This preference was presented in a logical fashion and is correct.

f) The draft PA conclusions on the extent to which the current scientific information strengthens or alters conclusions reached in the last review on the health effects of $PM_{2.5}$?

This reviewer agrees that the current scientific evidence strengthens the conclusions of the last review and, in particular, provides new epidemiological evidence of adverse health outcomes at or below the current standards.

g) Whether the discussions of these and other issues in Chapter 3 accurately reflect and clearly communicate the currently available health effects evidence, including important uncertainties, as characterized in the ISA?

These issues were appropriately discussed and communicate.

SCQ-4.1 To what extent does the panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the PM_{10} NAAQS review? Are there additional policy-relevant questions that should be addressed?

This chapter did an excellent job of presenting the important policy-relevant issues. This reviewer can think of no other policy-relevant questions.

SCQ-4.2 What are the panel's views of the draft PA assessment of the currently available scientific evidence regarding the health effects associated with exposures to thoracic course particles, $PM_{10-2.5}$?

Based upon the currently available evidence, as stated in the draft ISA, the draft PA presents a reasonable assessment.

SCQ-4.3 What are the panel's views on the draft PA preliminary conclusion that the available evidence does not call into question the adequacy of the public health protection afforded by the current primary PM_{10} standard and that evidence supports consideration of retaining the current standard?

This reviewer agrees that based upon the available evidence, there is not need to question the adequacy and the evidence does support that the Administer consider retaining the current $PM_{10-2.5}$ standard.

EPA-6 Chapters 3 to 5: What are the CASAC views regarding the areas for additional research identified in Chapters 3, 4 and 5? Are there additional areas that should be highlighted?

The designated areas are excellent although, even as an inhalation toxicologist, to be honest, it is unclear how much mechanistic studies will impact this or future PM NAAQS. It would be more impactful to emphasize research on associations of individual sources with adverse health outcomes, so states/regions could perhaps focus on the 'worst' polluters. In particular, more research is needed on traffic (i.e., pollution vs. noise/stress; environmental justice), coal emissions, and wildfire contributions to adverse health effects.

Dr. Jack R. Harkema
October 6, 2019

General Comments

Overall, Chapters 3 and 4 are well written and address the charge questions mandated for this PA. In general, the authors have provided the needed policy-related assessments that are based on the key findings provided by studies identified in the ISA.

SCQ-3.3. In general, I agree with the EPA's evidence-based approach including the emphasis on health outcomes deemed *causal* or *likely to be causal*.

SCQ-3.5. In general, I agree with the draft PA preliminary conclusion that, *taken together, the available scientific evidence, air quality analyses, and the risk assessment can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the current primary PM2.5 standards.*

SQ-3.6. In general, I agree with EPA's assessment of developing potential PM2.5 alternative standards.

A few specific comments and suggestions are listed below that are intended to strengthen the document for the administrator.

Specific Comments.

Chapter 3.2

Table 3-1 (p 3-18). The footnote for this table is quite unusual and raises questions and concerns. I suggest deleting this footnote in the final PA. As currently written, it implies that CASAC did not provide comments and suggestions to the EPA authors in a timely manner so that they could fully refine this part of the PA. Since there will be no additional review of the ISA document there will be adequate time for the authors to thoroughly evaluate and respond to the CASAC's additional comments/suggestions on the causality determinations stated in this table. I suggest the authors continue to base their causality determinations on the weight of the scientific evidence. To this reader, all the causality determinations are appropriately defended in the text but could be better summarized in the table (see below).

Table 3-1. This table would be improved with a column for key determinates (rationale points) for each causality. This would nicely reiterate and summarize the discussion in the text.

Chapter 3.3 Risk Based Considerations

The initial subsections (e.g., approach) of this part of Chapter 3 contain technical risk assessment jargon that could be eliminated or carefully defined for the lay person (non-risk assessor).

A summary table for the suggested changes or no changes to the PM2.5 standards (including indicator, averaging time, form, and level) this section would complement the text and help the reader understand the authors' conclusions and rationales.

Chapter 3.5

I would suggest adding the following future areas of research

- More state-of-the-art comparative toxicological studies (in vivo and in vitro) that are designed to determine 1) the similarities and differences in human and animal sensitivity to comparable concentrations/doses of PM exposure (species-dependent responses, the animal may have a greater or lesser response to the same dose of inhaled PM) and 2) the cellular and molecular mechanisms underlying the adverse health effect. This will enhance our ability to translate animal toxicology findings to human health concerns and provide plausible and advanced biologic mechanisms for epidemiological associations.

- Studies to better understand PM exposure-related associations with neurological, metabolic and autoimmune diseases (e.g., autism, depression, diabetes, pre-diabetic disorders, systemic lupus erythematosus).

Chapter 4.1-4.3

No additional comments.

Dr. Barbara J. Turpin
October 6, 2019

Chapter 2 –PM Air Quality:
To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for the review?

1. Text emphasizes the "natural" sources of SOA from biogenic VOCs while failing to acknowledge that SOA formed from biogenic VOCs is substantially influenced by anthropogenic emissions, e.g. NOx, sulfate. SOA from biogenic hydrocarbons like isoprene is to some degree controllable by managing anthropogenic emissions (see more later in this document). See the following text:

*Page 2-3 "Natural sources of PM include…*oxidation of biogenic hydrocarbons such as isoprene and terpenes to produce secondary organic aerosol (SOA),"

2. Water-soluble gases also contribute via multiphase reactions in clouds and aerosols. Not reflected in the following text:

Page 2-9 "In addition, atmospheric oxidation of VOCs, both anthropogenic and biogenic, is an important source of organic aerosols, particularly in summer. The semi-volatile and non-volatile products of VOC oxidation reactions can condense onto existing particles or can form new particles (U.S. EPA, 2009, section 3.3.2; U.S. EPA, 2018, section 2.3.2)."

What are the panel's views regarding whether the draft PA accurately reflects and communicates the air quality related information most relevant to its subsequent evidence-based assessment of the health and welfare effects studies, including uncertainties, as well as the development of the risk assessment for current and alternative standards?

In particular, do the following sections accurately reflect and communicate current scientific understanding, including uncertainties, for:

(a) relationships between annual and daily distributions of PM;

1. **Daily and sub-daily (2-hr) exposures and the relationship between annual and daily PM2.5.** – The document notes that, in the Northwestern US, daily and sub-daily (2-hr) exposures (and the relationship between annual and daily) are heavily influenced by wildfire emissions in the summer/fall and stagnation in the winter: ***Not reflected adequately here are the impacts of controllable episodic emissions on these features.*** The text acknowledges the natural factors influencing these concentrations/exposures (wildfires, stagnation) but does not acknowledge: 1) impact of episodic residential wood combustion emissions (in addition to stagnation) on these concentrations in the winter and 2) that anthropogenic impacts on climate are likely contributors to trends in drought and fire in the west. Wildfires are associated with the extreme high-end sub-daily concentrations of PM2.5.

   The text in question is here:

   Page 2-26 "Northwest U.S. has very high daily design values relative to the annual design values. This is due to episodically high PM2.5 concentrations that affect the region, both from wintertime stagnation events and summer/fall wildfire smoke events"

2-30 Wildfires are having an important and substantial impact on Apr-Sept exposure in the western US. Only says "Most of the sites measuring these very high concentrations are in the northwestern U.S. and California, where wildfires have been relatively common in recent years"

(b) the review of hybrid modelling approaches used to estimate exposure in some studies and the risk assessment; and

2.3.3.1.2 Performance of the Methods -- The most important points that should be made in this section do not come through clearly. Impressively, some of the more sophisticated methods have n-fold cross validation R^2 better than 80% and root-mean-square error (RMSE) of 2-3 ug/m^3 for daily PM2.5 predictions. These methods clearly lead to improved exposure estimates in locations without samplers. The second paragraph tells where performance is worse but not where it is better. Approaches including land-use features, rather than straight Bayesian downscaling, are better at capturing concentration gradients particularly close to sources. The consistency of the regional concentration estimates across methods is remarkably good (Table 2-3).

In some cases, variations are discussed with no explanation given as to why they make sense. For example:

"Predictions span a wider range of concentrations for the western regions centered on California and Arizona (Figure 2-25, panels a and c) than the eastern region centered on New Jersey (Figure 2-25, panel b)."

This makes sense – in the eastern US, a larger fraction of PM2.5 is secondary, formed regionally, and thus concentrations can be expected to be more spatially homogeneous. This is not explained.

"Despite general agreement among predictions for the California and the eastern U.S. areas, the spatial texture of the concentration fields differs among methods. For instance, the 12-km Bayesian downscaler produces the smoothest PM2.5 concentration field, and the 1-km neural network (DI2016) produces the field with the greatest variance."

This also makes sense, since the Bayesian downscaler does not incorporate information pertaining to the locations of primary PM2.5 sources, whereas the neural network does. Thus, both are designed to predict broad spatial PM2.5 features, but the neural network will do a better job of capturing spatial gradients near sources. This is not explained, and may leave the reader without this important context.

"In Figure 2-26, the coefficient of variation (CV; i.e., the standard deviation divided by the mean) among methods is shown in percentage units based on predictions that were averaged to a common 12-km grid. The largest values occur in the western U.S. (Figure 2-26, panel a), where terrain is complex, wildfire is prevalent, monitoring is relatively sparse, and PM2.5 concentrations tend to be low. The distance from the grid-cell center to the nearest monitor is greater than 100 km for broad areas of the west (Figure 2-27)."

Yes, distance to monitors is large in many parts of the West, but the reason the simpler methods do not perform as well in the west is because of the larger concentration gradients, not the low concentrations. Concentrations are particularly high in some places and low in many others (concentration gradients are larger in the west). This is

why it is more difficult for the simpler Bayesian downscaler to capture the spatial gradients. The methods that make use of land use variables (e.g. neural network) have an advantage in situation. The spatial gradients are more extreme in the west, whereas in the east regional secondary formation leads to more spatially uniform concentrations. The differences between methods make sense.

(c) information on background levels of various PM indicators?

1. ***Biogenic SOA is not necessarily natural***: There is substantial evidence that anthropogenic emissions impact the formation of SOA from biogenic VOCs. This was raised in my comments regarding the Integrated Science Assessment. One important example is isoprene. Oxidation of isoprene leads to several gas phase products. A major SOA precursor is isoprene epoxydiol (IEPOX). IEPOX SOA forms when IEPOX is taken up into wet aerosol. Organosulfates, major products, are formed when IEPOX reacts with acidic sulfate. These IEPOX organosulfates are formed as a result of anthropogenic SO2 reactions, and thus are controllable. Field studies measuring tracers for IEPOX SOA suggest that it is a major source of aerosol (roughly one-third of organic PM2.5) in the southeastern US in both rural and urban locations.

   SOA formed by acid-catalyzed reactions of isoprene epoxydiol, enabled by acidic sulfate (the IEPOX-SOA factor), accounted for one-third of organic aerosol measured in both urban and rural locations in the Southeastern US. (references below, and in ISA):

Budisulistiorini, S., Li, X., Bairai, S.T., Renfro, J., Liu, Y., Liu, Y.J., McKinney, K.A., Martin, S.T., McNeill, V.F., Pye, H.O.T. and Nenes, A., 2015. Examining the effects of anthropogenic emissions on isoprene-derived secondary organic aerosol formation during the 2013 Southern Oxidant and Aerosol Study (SOAS) at the Look Rock, Tennessee ground site. *Atmospheric Chemistry and Physics*, *15*(15), pp.8871-8888.

Budisulistiorini, S.H., Canagaratna, M.R., Croteau, P.L., Marth, W.J., Baumann, K., Edgerton, E.S., Shaw, S.L., Knipping, E.M., Worsnop, D.R., Jayne, J.T. and Gold, A., 2013. Real-time continuous characterization of secondary organic aerosol derived from isoprene epoxydiols in downtown Atlanta, Georgia, using the Aerodyne Aerosol Chemical Speciation Monitor. *Environmental science & technology*, *47*(11), pp.5686-5694.

Also: Model predictions suggest that more than 50% of biogenic SOA in the Eastern U.S. could be controlled by reducing anthropogenic NOX emissions.

Carlton, A.G., Pinder, R.W., Bhave, P.V. and Pouliot, G.A., 2010. To what extent can biogenic SOA be controlled?. *Environmental Science & Technology*, *44*(9), pp.3376-3380.

The following text in the "background PM section" does not recognize that SOA from biogenic VOCs is, in part, controllable:

Page 2-50: "sources that contribute to natural background PM…. oxidation of biogenic hydrocarbons such as isoprene and terpenes to produce SOA"

Page 2-55: "As a region, the Southeast has the highest levels of biogenic aerosol production in the country, so the organic matter contribution at these three sites likely represents an upper bound for the country of what natural biogenic organic aerosol production could be under present atmospheric conditions."

Chapter 3:

Table 3-2 should provide the number of subjects in each study.

What are the panel's views on the quantitative risk assessment for PM2.5, including:

a) The choice of health outcomes and studies selected for developing concentration-response functions for long and short-term effects?

1. Page 3-47 and 3-48: **short term (2-hour) exposures and effects**

   "Impaired vascular function, the effect identified in the draft ISA as the most consistent across studies (section 6.1.13.2), is shown following 2-hour exposures to PM2.5 concentrations at and above 149 μg/m3."

   Figure 2-14 shows that the 99.9th percentile 2-hour concentration is greater than 149 ug/m^3 between April and September (photochemical smog season) on days that do not meet the current NAAQS. This observation is discounted because these measurements are mostly in the west in the summer. Photochemistry and wildfires are both factors in the west in the summer. While wildfires are a likely cause, removing consideration for exposures that occur in April – September in the west on the basis that "wildfires have been relatively common in recent years" does not seem to be justified. How many hours of exposure above 149 ug/m3 are represented in Figure 2-14?

   Having said that, the observation that "PM2.5 exposure concentrations evaluated in most of these studies are well-above the ambient concentrations typically measured in locations ***meeting the current primary standards***" is a substantive and important point.

   "The extreme upper end of the distribution of 2-hour PM2.5 concentrations is shifted higher during the warmer months (April to September, denoted by red bars in Figure 2-14),…. Most of the sites measuring these very high concentrations are in the northwestern U.S. and California (see Appendix A, Figure A-1), where wildfires have been relatively common in recent years."

b) The selection criteria for the 47 urban areas and PM2.5 air quality scenarios analyzed?

c) The hybrid modeling approach used for quantifying exposure surrogates across an area and adjusting air quality for alternative standard levels, as supplemented by interpolation/extrapolation?

Generally appropriate – see also comments above for Chapter 3.

d) The characterization of variability and uncertainty in the risk assessment?

1. Page 3-70: As stated above (comments on Chapter 3) the performance of the hybrid models (most particularly the Bayesian downscaling) is not hampered by low concentrations. It is hampered by strong spatial concentration gradients. Hybrid methods that include land use factors related to primary sources are better able to address this. Regional secondary formation in the east means that spatial gradients are much smaller and the models perform better. It makes sense that the neural network hybrid model would perform better than the Bayesian downscaling in the west for this reason. Thus, I disagree with this statement. Uncertainty is larger for Bayesian downscaling models specifically, in locations with large concentration gradients. In the west, more weight should be placed on the other hybrid models.

"factors likely contributing to poorer model performance often coincide with relatively low ambient PM2.5 concentrations, potentially accounting for the observations that model performance for hybrid models weaken by some metrics with decreasing PM2.5 concentration and that the normalized variability between predictions based on different hybrid modeling approaches increases with decreasing concentrations. Thus, uncertainty in hybrid model predictions becomes an increasingly important consideration as lower predicted concentrations are considered."