

9 December 2018

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

Docket Numbers: EPA-HQ-OAR-2015-0072; EPA-HQ-ORD-2014-0859

Written Comments of John Bachmann on behalf of the Environmental Protection Network.

To: EPA Acting Administrator Andrew Wheeler and the Clean Air Scientific Advisory Committee (CASAC):

Thank you to CASAC and EPA for the opportunity to provide these written comments at this point in the review of the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM). I am representing the Environmental Protection Network (EPN), a volunteer organization of former EPA employees and others concerned about continuing protection of public health and the environment. I worked for EPA's Air Office for 33 years, many of them as Associate Director for Science/Policy and New Programs. I was heavily involved in all reviews of the PM NAAQS through 2006.

I am commenting mainly because EPN is concerned that the preemptive changes EPA has made to the NAAQS review process will undermine the quality and credibility of the NAAQS review process, and could lead ultimately to ill informed decisions that might adversely affect the public health and environmental protections that have been the hallmark of science-based air quality standards. The contribution of CASAC to the NAAQS review process is too important to short change, yet the unilateral changes made by EPA do so by eliminating the critical expertise and perspectives of the PM panel, as well as by imposing other unreasonable shortcuts to accelerate the review schedule. EPN also supports EPA's continued use of the core elements of the formal causal framework, which was developed with strong support of past CASAC panels over the last decade.

EPN's main points include:

1. *EPN strongly supports the recommendations of former CASAC and PM panel members, as well as concerns expressed by several current CASAC members, that the committee should recommend the reinstatement of a PM panel for this review.* No seven-member panel, including the current one, has the expertise or the breadth of perspectives of a CASAC supplemented by a panel of experts. All prior CASAC PM reviews, indeed every NAAQS review for which we have data, were supplemented by additional qualified scientific experts. Yet three CASAC members have been tasked with peer reviewing nine chapters covering a multiplicity of health-related scientific disciplines and totaling over 1200 pages of text, all in less than two months.

2. *EPN continues to strongly support its earlier recommendations that EPA should provide the time - as well as the expertise - needed to complete the PM and ozone reviews.* EPA's rush to complete both reviews is not driven by deadline suits or a concern about the five-year schedule.¹ The end goal of late 2020 first appeared in a May 2018 Pruitt memo on the NAAQS process, which was issued without first consulting with CASAC. As noted by former CASAC chair Chris Frey, based on past reviews, it would be very difficult even for a CASAC supplemented by a full expert panel to complete the needed reviews in that time.² Meeting the current accelerated schedule necessitates a less than rigorous peer review of all three major documents. It would provide no chance for CASAC to review second drafts, again contrary to CASAC's past practice in its review of the PM and other NAAQS.³ The requirement that the Policy Assessment (PA) must be combined with and reviewed at the same time as the Risk and Exposure Assessment (REA) puts the cart before the horse, because the PA relies in part on the REA. In addition, the new open ended charge for CASAC to advise EPA on the health effects of implementing standards risks an impermissible inclusion of economic considerations by a group charged with making recommendations on standards. Moreover, EPA has no plans for providing a staff assessment on the topic for the committee to review.
3. *EPN supports EPAs continued use of core elements of the formal Framework for Causal Determinations contained in the separate Preamble to the ISA, and its application in the draft PM ISA.* This approach has been updated and improved over the last decade, in each case with the advice and support of multiple CASAC panels involving all criteria pollutants. This framework is a fundamental basis for the integration of multiple scientific disciplines in assessing the likelihood that PM "causes or contributes" to "adverse effects." The framework is not limited to a single discipline or branch of epidemiology. EPN supports air-related "accountability" studies and causal inference research as a component to be considered in the existing causal framework. However, the draft ISA search has found a very limited number of such studies for PM, some of which support a causal relationship and at least one that does not. As detailed below, investigators who have used causal inference and other experts on the issue recognize it as a useful approach for air pollution epidemiology, but one that has not yet delivered on its potential. It simply is not consistent with the judgement of the most recent CASAC reviews or the current state of the science to suggest that the core approach in the Framework for Causal Determinations and doing risk assessments that include reliance on past epidemiology studies should no longer be used in regulatory decision making.

¹ If EPA's main concern was to meet the requirement for a five-year cycle for NAAQS reviews, it would have put the carbon monoxide review first, as it is the most out of date.

² H.C. Frey; Public Comment on the Integrated Review Plan for the Ozone NAAQS. Public written statement to CASAC, November 26, 2018.

³ One of the casualties of a single ISA review is the ability to add any significant new studies relevant to standard setting in a second draft. This is particularly problematic for this review, because it appears the draft ISA has no studies published since 2017, and important new studies of interest have appeared since or are expected soon.

The following sections provide additional details on issues with the dissolution of the CASAC PM Panel, the compromises in the NAAQS review process and comments on causality. They are consistent with the EPN recommendations, but reflect my personal assessment of the information.

The need to reinstate the PM Panel.

CASAC has had a central role in the review of the NAAQS since 1978.⁴ The committee is charged with 1) ensuring the quality of EPA's assessment of the scientific criteria, including how PM and other criteria pollutants may cause or contribute to adverse effects on public health, 2) peer reviewing the agency's staff risk and policy assessments, and 3) based on these assessments, recommending whether the existing standards should be revised, and if so, recommending a range of standards (indicator, level, averaging time, form) that the Administrator should consider in deciding on standards that are requisite to protect public health. The importance of CASAC recommendations in the process is illustrated in the judicial review of the 2006 PM_{2.5} annual standard. In that case, the court ordered that the standard be remanded to EPA because the Administrator had not adequately explained his reasoning for deviating from CASAC's recommendations to increase the protection of public health afforded by the annual standard.⁵

From the very beginning of CASAC reviews in 1978, the committee and EPA recognized that seven members would not be enough to conduct the peer review of scientific criteria and staff policy documents (originally called staff papers). They supplemented the main committee with consultants, and eventually it was termed a CASAC panel. The original group reviewing the PM and Sulfur Oxides criteria document, for which there were many fewer studies than exist today, totaled between 17 and 18, including 6 CASAC members. Dr. Frey's compilation from the CASAC web site (www.epa.gov/casac) shows the number of PM panel members grew to address the continuing expansion in of PM related research that began in the early 1990s, from 21 in the 1994-1996 review to the now disbanded 2016-2018 panel, which had 26 members.

As noted above, the last 40 years has made it clear that no seven-member panel, including the current one, has the depth of expertise or the breadth of perspectives of a CASAC supplemented by a panel of experts. The current CASAC has experts in toxicology, controlled human exposures, and statistics/risk assessment, but no epidemiologists, a discipline that has always been central to the review of PM standards. The disbanded CASAC PM panel has *more experts with experience in epidemiology research than the total number of current CASAC members*. Clearly, each of the current CASAC members has the qualifications to serve on CASAC. Yet as a group, their capabilities, expertise and perspectives are greatly limited

⁴Bachmann, J.D. 2007. Critical Review: Will the circle be unbroken: A history of the U.S. national ambient air quality standards. *J. Air Waste Manag. Assoc.* 57(6):652–697. doi:10.3155/1047-3289.57.6.650

⁵ *American Farm Bureau Federation v. EPA*, 559 F. 3d 512, 521 (D.C. Cir. 2009)

compared to what would have been the case with the PM panel. While the Clean Air Act requires that the perspective of state agencies be part of the process by requiring one state member, having over half of the panel reflecting that regulatory perspective lacks balance. Most notably, it limits the inclusion of scientists actively working on relevant peer reviewed research. Again, reinstating the PM panel would increase the range of perspectives and broaden the discussion and debate over interpreting the science to provide sound, well vetted science/policy advice to the Administrator.

It stretches the imagination to understand what moved EPA to cripple the capabilities of the CASAC and the NAAQS review in such a dramatic way. I first learned of this possibility in a meeting last June with air Assistant Administrator Bill Wehrum, who graciously invited me to a session to hear my concerns with the “Back to Basics” NAAQS process outlined in a May 9th Pruitt memo.⁶ There, he noted that the law only requires seven members.⁷ I was surprised this was even a consideration given the overriding requirements of the Clean Air Act with respect to assessing the scientific information and reviewing the standards. This requires a “thorough” and “accurate” review, as required by sections 108 (a) (2) and 109 (d) of the Act. I pointed out why every NAAQS review since CASAC came into being, particularly those for PM and ozone, required larger numbers of expert consultants and why it would seriously degrade the quality of the review to exclude them. As outlined more fully in an attachment discussed below, I had already recommended that he meet with the chartered CASAC to discuss the changes in the NAAQS process, and I understood that the air office planned to discuss these process issues with CASAC. It is now clear there was no EPA consultation with the chartered CASAC Committee last summer before implementing these dramatic shifts, including eliminating the PM and ozone panels.

The failure to consult with CASAC members experienced with the process and the decision to eliminate the panels are unfair to the current CASAC members, who now are burdened with reviewing thousands of pages of ISA materials, while lacking both numbers to spread the burden as well as expertise in epidemiology, effects on visibility and climate, economics, and some other relevant disciplines. At least three current CASAC members expressed a desire to add more expertise to the review at the November meeting on ozone. It is also unfair to EPA staff, who are expected to deliver an ISA of such quality that it could achieve closure by CASAC after only a single review. This has rarely, if ever, been possible. EPA management is establishing unreasonable goals with inadequate resources, and it is both the quality of the review and the credibility of the process that will suffer.

⁶ “Back-to-Basics Process for Reviewing National Ambient Air Quality Standards.” Memorandum from E. Scott Pruitt, EPA Administrator, to EPA Assistant Administrators, May 9, 2018. <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf>.

⁷ While seven members is the minimum required by the Act, neither the law nor the CASAC charter precludes the use of additional consultants to fill gaps in expertise needed to review criteria and standards for particular NAAQS pollutants. Moreover, using only seven members risks violating provisions in the law for a thorough review of the scientific evidence.

The need to provide sufficient time for a quality review

I am attaching a copy of a letter sent to Bill Wehrum last June together with my detailed comments on the problems I found with the streamlined process for NAAQS review in the memorandum from Administrator Pruitt. I copied the members of the chartered CASAC on that letter. I certainly support steps to shorten the process, while maintaining the quality of the review, and made some suggestions in that regard. I commend these attachments to your attention. It is unfortunate that the agency never provided CASAC or the public a forum for discussing these issues over the last six months, as some of the issues might have been more favorably resolved before now. Indeed, consulting with CASAC was the first step in the process for shortening and improving the NAAQS review that began in 2006, which ultimately resulted in a more structured integrated assessment in the ISA, as well as adding separate REA and PAs that focused on science/policy issues.

CASAC is now in the process of reviewing the draft PM ISA. It is certain that the committee, though short-handed, is taking its job seriously, and will have many substantive comments. Yet the committee should take the time to consider seriously the issue raised by many commenters, including some current and many past CASAC members, that the dissolution of the PM panel was a mistake and that the current CASAC review should be supplemented by reviews from additional experts. Further, the committee may also find some revisions to the document are substantial enough that a second review should be required for those sections. Moreover, the ISA appears to be missing potentially important new studies published since 2017 or expected to appear soon.⁸ Given these issues, the committee should not feel constrained by EPA's arbitrary deadlines that assume only a single review by a committee of seven. Unfortunately, this is CASAC's first and possibly only chance to weigh in on the recent changes to the process of this review that depart significantly from the original schedules and plans in the PM IRP that was reviewed and approved by CASAC in August 2016.⁹

⁸ Examples include a meta-analysis of 53 cohort studies (Vodanis A, Awad YA, Schwartz J. The concentration-response between long-term PM exposure and mortality: a meta-regression approach. *Environ Res* 2018;166:677-689) and the Phase I HEI studies of low levels of exposure to PM that HEI indicated in their Dec 5, 2018 comments would be available by April.

⁹ 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)*. CASAC Report EPA-CASAC-16-003. [https://yosemite.epa.gov/sab/sabproduct.nsf/368203f97a15308a852574ba005bbd01/9920C7E70022CCF98525802000702022/\\$File/EPA-CASAC+2016-003+unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/368203f97a15308a852574ba005bbd01/9920C7E70022CCF98525802000702022/$File/EPA-CASAC+2016-003+unsigned.pdf)

I wish to highlight two structural issues in the process noted above and discussed in some detail in the attachment. In the case of PM, EPA has permitted a separate review of the ISA, which is possible because the process was begun earlier. But now EPA is combining the REA and PA into a single document. Significantly, it no longer provides a chance for CASAC and the public to review even the planned approach for the REA; CASAC review of the approach as well as a subsequent review of the REA was promised in the Final IRP well before the PA. I continue to believe this combination is a mistake, because the REA is a key element in considering whether to revise the standards, and plays a role in determining what any revisions should be. For these reasons, it is unwise to issue a combined PA/REA without at least providing the promised CASAC and public review of EPA's detailed plans for conducting the risk and exposure analyses. As noted in the attachment, it would be more appropriate to produce an early draft of the PA, but not submit it for review until after the REA, or at least the plans for the REA, are reviewed. If the REA or plans receive a good review, the combined PA could be submitted for review in short order. If not, revisions could be made to the analyses so CASAC would receive a combined document based on a revised analytical approach adopted in response to CASAC comments. As noted by other commenters, reviewing a combination of two documents at a single meeting not only adds burdens to CASAC and EPA staff, but also limits the ability for public comment on the science and policy considerations, depriving both CASAC and EPA of important perspectives that should be considered in the process of conducting the analyses.

The second issue relates to EPA's decision to ask CASAC to provide advice on the adverse effects of implementing air quality standards. In addition to the obvious concerns of mixing the science and policy issues in the NAAQS review with economic considerations, this requirement presents a significant additional workload for CASAC. This committee has never been constituted with the full range of expertise needed to evaluate these issues. In the past, EPA and Congress have looked to the National Academy of Sciences (NAS) for scientific guidance and insights on implementation issues.¹⁰ Unlike the NAS, CASAC does not evaluate the scientific literature and produce assessments, which can be costly and take substantial time. Instead, CASAC and other SAB groups have been of significant value in reviewing EPA science, risk, and policy assessments, providing insights and recommendations relevant to the topics at hand.

In this case, it appears EPA is not preparing any document on the adverse effects of implementing NAAQS for CASAC to review, so it is unclear how the committee will have the time and expertise to develop useful advice for the Administrator on this topic. At the same time, it adds another task to an already overburdened committee. While the Clean Air Act calls

¹⁰ Notable examples of such NAS reports include *Acid Deposition: Atmospheric processes in Eastern North America* (1983), *Rethinking the Ozone Problem in Urban and Regional Air Pollution* (1993), *Estimating the Public Health benefits of Proposed Air Pollution Regulations* (2002), *New Source Review for Stationary Sources of Air Pollution* (2006), and the landmark *Air Quality Management in the United States* (2004).

for such a review, EPA has never charged the committee with this requirement.¹¹ The Act does not require this review to occur simultaneously with review of the standard, and there are strong reasons not to do so — even the Pruitt memorandum acknowledges that this information is not relevant to the standard-setting process.

If EPA still wants such advice, it should consider establishing an ad hoc SAB or CASAC panel consisting of experts needed for this kind of review, consistent with a recommendation made by CASAC in a 2014 letter cited in the attachment. This group could examine these issues for multiple pollutants. Because it would largely consist of experts who did not provide advice on the standards, it would also better separate the science and standards review from economic and related effects of implementation that cannot be considered in decisions on the standards. Given EPA's new aversion to supplementing CASAC with needed expert panels, it appears they have rejected this recommendation. CASAC should therefore now consider the additional burden on its time and expertise, and request that EPA drop its request or provide a document on the topic for the committee to review as well as additional experts who would only participate in this topic to facilitate meeting this unprecedented charge to the committee.

Support for Maintaining the Core Elements of EPA's Framework for Causal Determination.

As summarized in the Preamble to all ISAs:

*The U.S. EPA assesses the body of relevant literature, building upon evidence available during previous NAAQS reviews, to draw conclusions on the causal relationships between relevant pollutant exposures and health or environmental effects. ISAs use a five-level hierarchy that classifies the weight of evidence for causation. This weight-of-evidence evaluation is based on the integration of findings from various lines of evidence from across health and environmental effect disciplines that are integrated into a qualitative statement about the overall weight of the evidence and causality.*¹²

The approach is one of many adaptations of the 1965 Bradford Hill framework for assessing causality in epidemiology and public health. As EPA and others have noted, the agency has used and CASAC has reviewed EPA's systematic framework since 2008, and over the years it has been improved in response to CASAC and public comments. In 2011, CASAC, augmented with additional experts to form the Ozone review panel, reviewed the first draft of the Ozone ISA and stated:

The CASAC continues to support the use of the EPA's framework for causal determination that was first used in the ISA for particulate matter. This framework provides a comprehensive and

¹¹ The Clean Air Act also requires issuing of Control Techniques documents for NAAQS pollutants, but EPA stopped issuing them decades ago.

¹² EPA, 2015, Preamble to the Integrated Science Assessments, Research Triangle Park, NC: U.S. Environmental Protection Agency, 2015; Report No.: EPA/600/R-15/067.

transparent approach for evaluating causality. Based on long-standing approaches in public health, as brought together in a recent National Academy of Sciences (NAS) Institute of Medicine (IOM) report, the framework employs a two-step approach that first determines the weight of evidence in support of causation and then characterizes its strength in a standard scheme for causal classification. The second step further evaluates the available quantitative evidence regarding concentration-response relationships and the duration, level and types of exposures at which effects are documented. The EPA's adoption of this framework has greatly improved the consistency and transparency of its assessment as compared to the approach seen in past reviews.¹³

The 2011 committee went on to make additional recommendations for further improvements in terminology and other aspects in the approach. The recent CASAC review of the PM IRP in August 2016⁴ had no comments on the substance of the framework, but expressed concerns that the PM IRP should be clearer about how to ensure transparency and consistency in applying the framework.

According to an analysis of the record prepared by former CASAC chair Chris Frey, over the last decade the Framework for Causal Determination and its application in specific ISA's have been evaluated by 74 experts over multiple panels and review cycles.

Given the nature of comments and discussion regarding the potential importance of recent applications of epidemiology studies using causal inference methods in the ozone IRP review, it is necessary to consider the appropriate role of causal inference studies in the application of the causal framework in this PM review and to provide some additional perspectives from those familiar with the issues.

Full disclosure: In my former role in Science/Policy at EPA I advocated strongly for what we termed "accountability" research. More recently, I not only also supported applications of causal inference methods but also had the privilege of working with Harvard investigators on their HEI study, which used causal inference to examine the health effects of air quality regulations. The results were of interest in showing how the methodology can be applied as well as the importance of real world considerations to ensure appropriate study design and interpretation. The HEI commentary on this work noted:

The HEI Review Committee concluded that these accountability methods are an important addition to the "toolkit" and should continue to be further explored, but cannot wholly

¹³ Samet, J., 2011, CASAC Review of the EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants (Second External Review Draft – September 2011) Washington, DC: EPA Clean Air Scientific Advisory Committee, 2009; Report No.: EPA-CASAC-12-004.

*substitute for accountability assessments that rely on evidence from other scientific methods, including more traditional epidemiology analyses.*¹⁴

Two of the principal authors of that study recently published their own thoughts on “best practices” for examining causality in air pollution, including the appropriate role of causal inference work:

*More specifically, increased emphasis on methods for causal inference and their application to the field of air pollution epidemiology is creating a dangerous misconception. Statistical methods for causal inference have played a prominent role in advancing several areas of scientific inquiry (15); see Zigler et al. (9) and Zigler and Dominici (16) for a discussion specific to air pollution epidemiology. However, a false dichotomy is emerging that classifies studies as either causal or associational based solely on the statistical methods used for estimation. Studies that estimate exposure-response relationships with regression models typically do not use causal inference terminology and are consequently coined associational and considered less rigorous. Conversely, studies that use explicit causal inference terminology are labeled causal, which automatically endows them as a fail-safe solution for identifying the scientific truth. This misconception is dangerous in the context of environmental regulations and spreads a false message that studies using causal inference methods should always be considered more credible than studies using more traditional statistical approaches.*¹⁵

The authors go on to recommend that ISA consider using a critical assessment of the design decisions used in studies and provide some examples and criteria that EPA and CASAC should consider.

The situation with respect to the role of causal inference studies at this point calls to mind a parallel situation for PM epidemiology in the early 1990s. As detailed more fully in a case study,¹⁶ at that time Joel Schwartz was publishing multiple PM studies using statistical approaches more widely used in economics; these studies found associations between daily PM and serious effects at levels lower than the PM₁₀ standards. Over a period of several years there were multiple reanalyses, stress testing examining confounders, exposures and methodologies, as well as replications. Based on the results of this vetting process, these approaches became more widely accepted in air pollution epidemiology.

¹⁴ Zigler, C.M.; Kim, C.; Choirat, C.; Hansen, J.B.; Wang, Y.; Hund, L.; Samet, J.; King, G.; Dominici, F. Causal Inference Methods for Estimating Long-Term Health Effects of Air Quality Regulations; Research Report 187; Health Effects Institute: Boston, MA, 2016.

¹⁵ Dominici F, Zigler C. Best practices for gauging evidence of causality in air pollution epidemiology. *Am J Epidemiol.* 2017; 186(12):1303–1309. See also response by L.A. Cox. *Am J Epidemiol.* 2018;187(6):1338–1339.

¹⁶ D.S. Greenbaum, Bachmann, J.D., Krewski, D., Samet, J.M., White, R. and R.E. Wyzga, Particulate Air Pollution Standards and Morbidity and Mortality: Case Study. *American Journal of Epidemiology*, Volume 154, Issue 12, 15 December 2001, Pages S78–S90, <https://doi.org/10.1093/aje/154.12.S78>.

Today, some investigators are adapting causal inference methods, which are more widely used in other fields, to air pollution epidemiology. At the 2018 HEI annual meeting former CASAC panel member Lianne Sheppard suggested that “causal methods in air pollution epidemiology are in their infancy.”¹⁷ Indeed, whatever the future may bring, today there are very few studies included in the draft PM ISA that use causal inference, with results both supportive and non-supportive of a causal effect.

I believe the perspective of HEI’s Dan Greenbaum and Rashid Shaikh published this month is consistent with the current state of the science:

*In recent years, formal, statistical tests for determining causality have been developed. Although these may be valuable, it is difficult to foresee how a single statistical test could readily supplant EPA’s comprehensive approach to evaluate the overall strength and weight of evidence. Refinements to the current ISA framework, including possibly more formal methods for causality determination, may serve to enhance the current process; such changes are topics of discussion and debate.*¹⁸

Attachment: June 2018 Letter to Bill Wehrum transmitting comments on the “Back to Basics” NAAQS memorandum.

¹⁷ L. Sheppard and M. Carone. Causal Inference in Air Pollution Epidemiology: Has its time come? Health Effects Institute Annual Meeting. Chicago, April 29, 2018.

¹⁸ D.S.Greenbaum and R. Shaikh. The Role of Science in Setting National Ambient Air Quality Standards. *EM*. December 2018.

June 18, 2018

William Wehrum
Assistant Administrator
U.S. Environmental Protection Agency Office of Air and Radiation (6103A)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Bill,

Eleven years after we worked on improving the NAAQS process, I was distressed to see the May 9th "Back to Basics" memorandum, which appears inconsistent with what we learned during that earlier process review, as well the practical realities of reviewing both the scientific criteria and the National Ambient Air Quality Standards (NAAQS). I expressed some of my specific concerns in written and oral submissions to the May 31 meeting of the Science Advisory Board. I am attaching the portion of my comments relevant to the process below. Although these comments are critical, my intent here is to make constructive suggestions that will give you the best results with respect to conducting a soundly based and timely review for the NAAQS themselves, as well as addressing how best to assess advances in science that have implications for important NAAQS implementation issues raised in the memorandum.

Now that EPA staff are working on schedules, I hope you are planning to meet soon with the chartered Clean Air Scientific Advisory Committee (CASAC) panel to discuss both the principles, schedules, and additional responsibility and workload placed on CASAC and EPA staff. I want to highlight two major areas of concern, both of which have implications for the important principle of separating scientific and policy judgements, as well as imposing unreasonable workloads on EPA staff and CASAC.

The first is the memorandum's requirement that EPA "consider combining its integrated science, risk and exposure, and policy assessment into a single review" for ozone. From a science/policy perspective, this is wholly inconsistent with EPA staff or CASAC comments on the matter during our work on development of the current process over a decade ago. As discussed in the attachment, EPA and CASAC should discuss both the science/policy and practical workload issues inherent in a concurrent review. You should consider an alternative aimed at the goal of producing staggered sequential documents that might pass the first CASAC review, and ultimately may have a better chance of meeting your deadlines.

The second major problem is asking CASAC to provide advice on background concentrations and the adverse effects of implementing standards, as well as to review implementation guidance documents. In addition to the obvious concerns of separating science and policy issues, this presents a significant additional workload for CASAC panels, which have not been constituted with sufficient expertise to evaluate these issues.

It is important to recognize that in the past, EPA and Congress have looked to the National Academy of Sciences for scientific guidance and insights on implementation issues. Unlike the NAS, CASAC does not evaluate the scientific literature and produce assessments, which can be costly and take substantial time. Instead, CASAC and other SAB groups have been of substantial value in reviewing EPA science, risk, and policy assessments, providing insights and recommendations relevant to the topics at hand.

If EPA intends to provide relevant documents such as a regulatory impact assessment or implementation guidance documents, then CASAC and EPA should consider establishing an *ad hoc* panel staffed with the range of experts needed for such reviews. This is consistent with CASAC advice on this matter in a 2014 letter. Such experts could examine these issues for all criteria pollutants, consistent with our scientific understanding of the multipollutant and multisource nature of implementation issues. Because EPA's science assessments traditionally address background levels for ozone and particles, and a major new assessment of the issue for ozone is near publication, this issue could be one of the first addressed by such a group.

An *ad hoc* panel would create an appropriate division between those recommending standards and those addressing issues that cannot be considered by the Administrator in setting standards, and would also better spread the significant additional workload for CASAC.

I hope you and CASAC will consider these suggestions and comments as you move forward together on the NAAQS reviews.

Sincerely,

John Bachmann,
Principal, Vision Air Consulting, LLC
Former Associate Director for Science/Policy and New Programs
Office of Air Quality Planning and Standards.

cc. Peter Tsirigotis
Aaron Yeow, CASAC DFO
Tony Cox, CASAC Chair
James Boylan
Judy Chow
Ivan Fernandez
Lianne Sheppard
Larry Wolk

Attachment: Written Comments on the NAAQS Process Submitted to the Chartered SAB in May.

The New Back to Basic NAAQS Process should go back to the drawing board

Both the process of developing the NAAQS process memorandum and some of its poorly considered prescriptions provide further evidence that the Agency is in a hurry to get results, regardless of the untoward consequences of mixing science and policy, as well as placing unreasonable burdens - some of which have nothing to do with establishing standards - on CASAC as well as EPA staff. In this case, the Administrator has set specific dates that may provide a clue to the reason for moving quickly on the transparency rule and the NAAQS. The memo targets the completion of reviews of the ozone and particulate matter (PM) standards as October and December of 2020, respectively.¹

The approach followed to make such substantial changes to the NAAQS Process mirrors that followed in the transparency proposal, and accordingly is also in stark contrast to the far more transparent and inclusive process that led to most recent, and largely successful NAAQS Review process we have today.⁶ The changes imposed or recommended in the Pruitt memo were developed without meaningful involvement by those EPA staff experienced in developing integrated scientific assessments, risk and exposure analyses, and policy assessment documents. This is evidenced both in the major recommendations, and in details in drafting specific portions. The memo announces that the entire process will be managed by the Office of Air, including the science assessment formerly managed by the Office of Research and Development. No draft of the approach was presented to the full CASAC committee for review. While it is good that the drafters did search for and cite selected pieces from past CASAC communications, this is no substitute for showing the revised process to the committee itself, before it was made final. In fact some of the points cited from these past letters were written regarding the 2006 -2009 process, and concerned issues that were addressed by the current process.²

¹ The memo's first principle for these reviews is meeting the statutory deadlines (every 5 years). While EPA has completed some reviews in 5 years, it has never met this requirement for all six criteria pollutants. That said, execution of this principle would require work to begin on the current carbon monoxide (2011) standard before ozone (2015), and lead (2016) after, as CO was last revised in 2011. Reviews for all other pollutants (PM, NOx, SOx) were either completed more recently, or are already in progress. Moving ozone and PM ahead of CO is an appropriate policy decision, but also an admission that the first principle cannot be met for all pollutants, even with the ill-advised streamlining procedures suggested in the memo.

² An example is the quote from Dr. Henderson's May 12, 2006 letter to the administrator [https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CASAC-05-12-06/\\$File/CASAC-05-12-06.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CASAC-05-12-06/$File/CASAC-05-12-06.pdf) (footnote 30 in the memo) regarding the need to exclude certain older studies that are not relevant to standard setting. In fact this issue was directly addressed in developing the 2006-2009 revised process that transformed the "compendium" approach used for criteria document to an Integrated Science Assessment that placed greatest focus on reviewing studies that had been published since the end of the previous review. Most importantly, beyond the novel approach used in developing a multipollutant ISA that combines Nitrogen and Sulfur Oxide welfare effects, the memo provides no evidence that supports its claim that, under the 2006-2009 process, "CASAC

The two most problematic aspects of the revised process both present issues with respect to 1) the Administrator's fourth principle, separating science and policy considerations in the review and 2) creating unreasonable expectations for EPA staff and relevant CASAC panels. The first of these flows from the major departures from the current process that are intended to streamline the production and review of key documents (Figure 1 in the memo). The statements specifying the need to sharpen the focus of the Integrated Science Assessment (ISA), Risk and Exposure Assessments (REA), and Policy Assessments (PA) are not different in scope and tone from the intent of the 2006 process review and recommendations. The major problems with streamlining the process flows from the specific prescriptions regarding the steps in producing and reviewing these documents.

The memo requires EPA to "consider combining its integrated science, risk and exposure, and policy assessment into a single review" (page 3). From a science and policy perspective, this is an astonishingly bad idea, one that is inconsistent with EPA staff or strongly CASAC comments on the matter³ made during the 2006 process. These documents are intended to be logically sequential, each building on the one before. Producing them concurrently risks conflict with principle four, the separation of science and policy. It also would require an unreasonable effort by EPA staff produce these three documents simultaneously, and somehow create initial drafts independently of each other, coordinate them quickly, and be of such quality that they would require only a signal CASAC review for each. The CASAC panelists and interested members of the public would be required to review all three at the same time. This would place a significant burden on all panel members both before as well as during an extended public meeting. A concurrent preparation and review process for these documents would jeopardize the memo's goal of having only a single CASAC and public review for each document (page 9). For example, if CASAC found problems with the science or risk and exposure assessment, this might well require redrafting and review of the policy assessment, which depends upon both.

Without the kind of detailed timeline provided in figure 5 (see attachment A) of the 2006 EPA staff workgroup report,⁴ it is difficult to assess the time the process illustrated in

has frequently identified reducing the length and complexity of the ISA as a key process improvement for streamlining NAAQS reviews." In fact, such concerns were often raised about the older Criteria Documents.

³ The May 12 Henderson letter above states "the 'doubling-up' of the scientific subject matter to be covered at certain CASAC meetings (e.g., reviews of the draft Science Assessment and Risk Assessment documents at the same meeting and, at a subsequent meeting, the Risk Assessment and Policy Assessment documents) may even increase the number of CASAC meetings." The letter from former CASAC chair Roger McClellan on the process (cited in footnote 38 of the memo as Attachment 3B) is even stronger, stating "A draft Staff Paper should never be released to CASAC and the public prior to the Criteria Document being finalized" and later, "draft Staff Papers should not be released until after the Criteria Document is finalized and the risk assessment is available." NAAQS Process Report, Attachment 3-B (March 2006) available at: https://www3.epa.gov/ttn/naaqs/pdfs/naaqs_process_report_march2006_attachments.pdf

⁴ EPA, 2006. Review of the Process for Setting National Ambient Air Quality Standards. https://www3.epa.gov/ttn/naaqs/pdfs/naaqs_report_march2006.pdf

Figure 1 of the memo would provide for developing the three documents, as well as the time allotted for review. To insure higher quality for a single review, authors would need additional time, staff and contract resources, especially because the schedule planned for PM and ozone will contain significant overlaps, and in the early stages, the process to complete the ongoing reviews for other pollutants will continue. Is EPA budgeting for that time and resources?

EPA staff should now be developing schedules for following the new requirements. Before it goes too far down the path towards concurrent production of documents, EPA and CASAC should consider the kind of sequential process illustrated in Attachment A. As the Integrated Science Assessment is developed, staff could prepare a draft plan for conducting the Risk and Exposure Assessment, and if the first document is reviewed favorably, staff would be prepared to produce the first draft of the Risk assessment. A similar staggered approach would apply to the Policy Assessment Document, which depends on both. This would ensure each document could be produced with the certainty that the preceding one had undergone at least one peer review by CASAC. This would be more likely to provide better quality and appropriate separation of science and policy statements. The chance of meeting the five year NAAQS schedule and obtaining CASAC conditional approval after a single review varies by pollutant. The growth of relevant research for ozone and PM over the past decade has been significant, as compared to that for some other pollutants. This increases the difficulty in identifying and assessing the recent literature for these two pollutants, as compared to pollutants such as sulfur dioxide, with fewer new health effects studies. A one size fits all process is unlikely to produce similar results in terms of the time required for each review.

Accordingly, CASAC should request that EPA provide detailed schedules for the process it intends to follow for ozone and PM, and the committee should review them as well as the process recommended in the memo, consider the inherent structural and workload issues, and provide the Administrator with more up-to-date comments and advice before the revised process is put into practice.

The second major problem area, requiring CASAC to provide to advice on background concentrations and the effects of implementing standards also raises issues of the appropriate separation of science and policy and placing additional burdens on staff and CASAC. Advice on natural and anthropogenic background is more straightforward, because the ISA needs to assess the relevant new science in this area, to support the risk and exposure assessment. This at least gives CASAC a summary of the scientific information needed to make statements regarding background. In fact, one of the CASAC letters cited by the memo has already provided unsolicited science and policy advice on ozone background ⁵ that EPA might well

⁵ The letter states: "Zhang et al. [2011] estimated that during spring-summer 2006-2008 the mean enhancement from intercontinental pollution and anthropogenic methane is 9 ppb at low-altitude sites and 13 ppb at high-altitude sites (>1,500 m elevation), both roughly one third of the North American background ozone in the respective areas." (CASAC Review of EPA's Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards, EPA-CASAC-14-004 (June 2014). The letter goes on: "Given the significant portion of ozone coming from anthropogenic sources outside North America, the CASAC recommends that EPA seek opportunities for international cooperation to reduce long-range transport of ozone."

consider in deciding on regulation of methane emissions from the oil and gas industry, as well as continuing discussions with international partners in addressing long-range transport of air pollution.

Asking CASAC to respond to Section 109(d)(2)(C) requirements to evaluate adverse effects on health, welfare, social, economic, or energy effects of implementing standards is a more challenging undertaking. Doing a good job of evaluating the scientific information on these topics and their implications for improving implementation would require far more effort than has been traditionally required of either CASAC or the SAB. EPA has always believed scientific assessments of these issues is important, but EPA and Congress have traditionally looked to the National Academy of Sciences and interagency groups such as NARSTO to produce assessments that are relevant for improving air quality management. Some examples of such NAS reports include *Acid Deposition: Atmospheric processes in Eastern North America* (1983), *Rethinking the Ozone Problem in Urban and Regional Air Pollution* (1993), *Estimating the Public Health benefits of Proposed Air Pollution Regulations* (2002), *New Source Review for Stationary Sources of Air Pollution* (2006), and the landmark *Air Quality Management in the United States* (2004). These and other documents have provided important benchmarks for policies that range from new provisions in the 1990 Clean Air Act Amendments to EPA and states adoption of science-based multistate regional NO_x and SO_x programs, which have produced marked reductions in both ozone and fine particles, enabling more cost-effective implementation of these standards.

Producing this level of detailed assessment and analysis is beyond the capacity of traditional CASAC and SAB actions, which provide important guidance and insights through the process of reviewing documents provided by EPA, but do not provide extensive original assessments. Unless EPA intends to provide more comprehensive assessments than have been produced for past NAAQS Regulatory Impact Analysis (RIA), CASAC or SAB could not comply with all of the requirements regarding advice on such adverse impacts. EPA and CASAC should carefully consider the costs and benefits of the effort it would take to meet these requirements fully.

Even assuming that evaluating RIAs and/or implementation guidance documents would begin to meet some of these requirements, EPA needs to consider how better to structure any such reviews. The first issue is again separating CASAC review and recommendations on the NAAQS from reviews of RIAs and guidance that present information that should not be considered in deciding upon the standards. The memo takes a first step in this direction by requiring these reviews take place only after the NAAQS review and recommendations are completed. This is not enough. The Agency should have considered the recommendation in the June 2014 letter from CASAC cited in footnote 13, which stated: “In response to such a

request, the SAB Staff Office would form an *ad hoc* CASAC panel to obtain the full expertise necessary to conduct such a review.”

An *ad hoc* panel, whether housed in CASAC or the SAB, such as the former Advisory Council on Clean Air Compliance Analysis, which reviewed EPA cost benefit assessments of the Clean Air Act, would appropriately separate the individuals selected for their ability to review the relevant science and policy assessments and making recommendations the NAAQS from those with the expertise to assess either RIAs or EPA guidance documents for implementing standards. CASAC members who make recommendations on the standards should not play a role in the implementation review. Such an approach would also spread the burden for the additional steps involved in completing the review of the NAAQS and those subsequent reviews of analyses and guidance that cannot be used in setting the NAAQS.

A standing panel of experts that could serve needed reviews for implementation and related effects issues for all NAAQS reviews would provide an opportunity to broaden the use of available scientific insights. Over the past two decades, improved scientific information has made more-cost effective strategies possible. Policy makers at all levels now recognize the multipollutant nature of the criteria pollutants, with significant overlaps in terms of sources affected by sequential requirements for ozone, PM, CO, NO₂, and SO₂ as well as many hazardous pollutants. The memo cites an example of this recognition in footnote 22. This group could help guide policies that take better advantage of the multi-pollutant opportunities and tradeoffs. EPA might also consider a requesting a follow up to the NAS report on air quality management focused on these specific concerns.

EPA, CASAC, and SAB must go well beyond the level of detail provided in the NAAQS process memo in terms of how best to produce necessary documents and structure the SAB/CASAC to review them. Again, it is critical that CASAC take a strong role in reviewing the memo requirements, and how best to respond.

Beyond these two major issues, the idea of “one size fits all” charge questions seems at odds with the CASAC recommendations for focused charge questions referred to in footnote 24. While it is possible to start with some fundamental questions, CASAC is suggesting a greater focus, which almost certainly would require questions that pertain to issues that may be unique to a particular pollutant. An example of curious wording that staff might have corrected is the first question/bullet on page 6, regarding what new evidence suggests as to whether “NAAQS need to be revised or if an alternative level or form of these standards is needed...” This is not an either/or question, as both alternatives are revisions. As an example, a more focused question might apply more for a single criteria pollutant than for all. For example, does the recent scientific information suggest the need for a new indicator and standard for ultrafine particles? This of course would depend on the first look at the available evidence. The more generic question provided in the list with respect to naming all of the key NAAQS values, including indicators, would cover that, but again, this does not provide the kind of focus that would help guide CASAC’s review. Beyond that, whether the last ‘generic’ question regarding adverse effects is asked at the same time and to the same group as the

others bears some consideration in terms of separating the NAAQS review from the parts of the adverse effects related issues noted above.

Finally, EPA should carefully consider the practical difficulties in issuing implementation regulations and guidance simultaneously with promulgating revised NAAQS, given that the first step requires designations of nonattainment areas, a process that includes interactions with the states. The level of effort for and number of areas needing new designations can vary significantly for a range of standards under consideration, and EPA recently has shown difficulties in meeting the current statutory timelines for the 2015 ozone standards. This could present a significant problem for simultaneous release of designations and guidance, especially if EPA decides to develop such materials and enlist a CASAC panel to review them before the revisions are promulgated.

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Attachment A – Figure 5 from 2006 NAAQS Process Review Report – see next page.

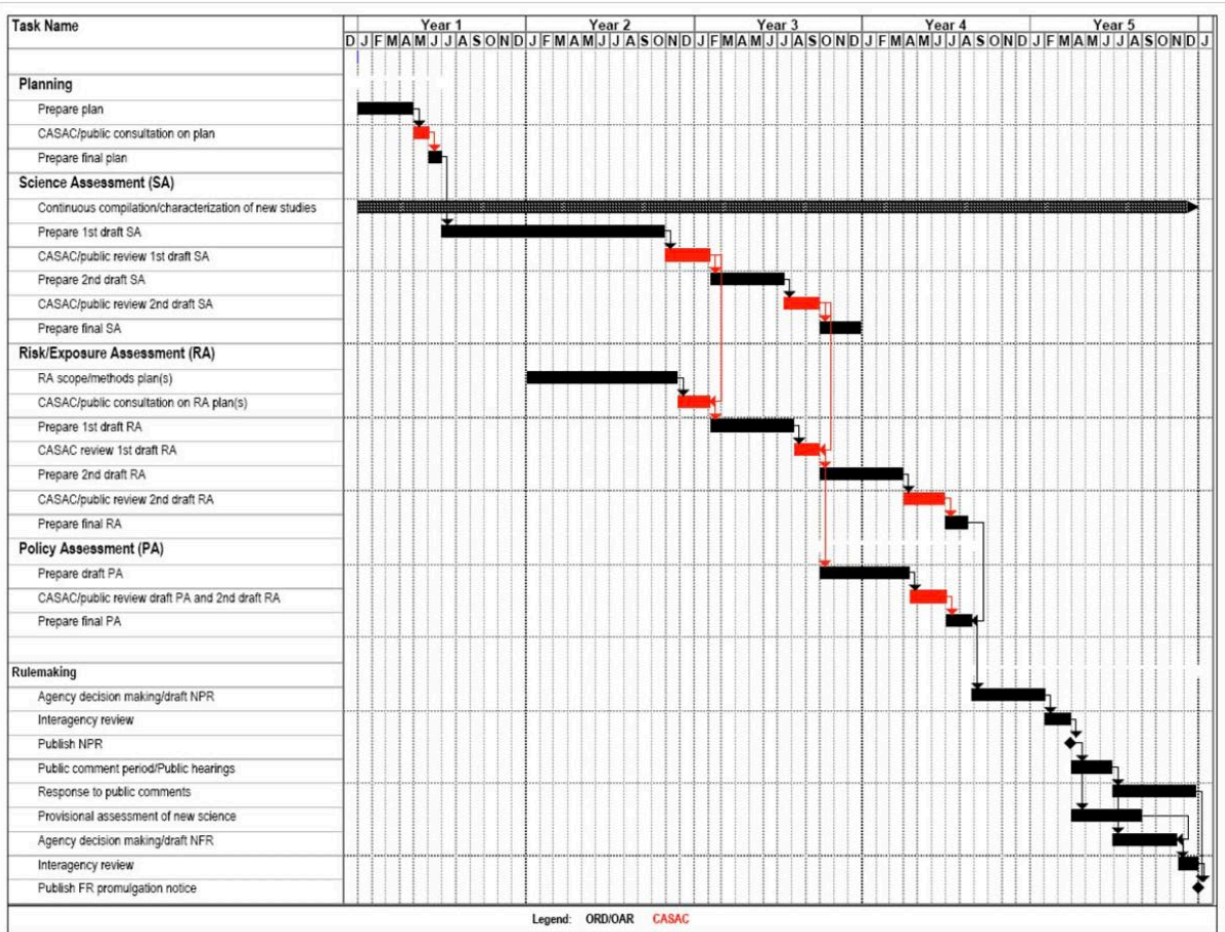


Figure 5. Timeline for Alternative NAAQS Review Framework