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November 25, 2019

Aaron Yeow
Designated Federal Officer
Clean Air Scientific Advisory Committee (CASAC)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Via e-mail: yeow.aaron@epa.gov

Re: Notification of a Public Meeting of the Chartered Clean Air Scientific Advisory Committee (CASAC) [FRL-10001-58-OA]

Dear Mr. Yeow:

The Northeast States for Coordinated Air Use Management (NESCAUM) offer the following comments for consideration in the CASAC peer review of EPA's "Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft— September 2019)" (ISA) and "Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft)" (PA). As noticed in 84 FR 58713 (November 1, 2019), CASAC will conduct a peer review of those documents at a public meeting on December 3-5, 2019. Some of these comments are also relevant to CASAC's "Draft Report on EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards (NAAQS) for Particulate Matter (External Review Draft— September 2019)," which will also be discussed at that meeting.

NESCAUM is the regional association of air pollution control agencies representing Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont. Our member state agencies have the primary responsibility in their states for implementing clean air programs that achieve the public health and environmental protection goals of the federal Clean Air Act.

NESCAUM is concerned that EPA's efforts to "streamline" the National Ambient Air Quality Standard (NAAQS) review process have severely hampered the Agency's duty to develop primary NAAQS, which protect public health with an "adequate margin of safety," and secondary NAAQS, which "protect public welfare from any known or anticipated adverse effects," as required by the Clean Air Act (42 U.S.C. §7409(b)). State clean air programs rely on strong, evidence-based NAAQS to protect the health and welfare of their residents.

The comments below address the following issues:

1. EPA's compressed NAAQS review schedule is detrimental to the development of evidence-based NAAQS.
2. CASAC should include panels similar to those in previous NAAQS reviews to ensure that a wide range of scientific expertise and perspective is represented.
3. CASAC should consider a more stringent primary NAAQS for ozone.
4. CASAC should recommend a secondary ozone NAAQS that protects against cumulative vegetation damage over a single season.
5. CASAC should make recommendations on the PM2.5 NAAQS only after conducting a review that includes a wide range of experts, similar to past CASAC review processes.

1. EPA's compressed NAAQS review schedule is detrimental to the development of evidence-based NAAQS.

The NAAQS review process involves the development of a series of documents. First, an Integrated Review Plan (IRP) identifies policy-relevant science issues and presents the schedule and process of the review. EPA then prepares an Integrated Science Assessment (ISA) to be used as the scientific foundation for the EPA Administrator's assessment of whether the NAAQS sufficiently protect public health and welfare. The ISA informs the preparation of the Risk and Exposure Assessment (REA), which presents quantitative estimates of exposures and health risks under defined air quality scenarios. Subsequently, EPA prepares a Policy Assessment (PA), which summarizes information from the ISA and REA and provides the Administrator with options regarding the indicator, averaging time, statistical form, and numerical level (concentration) of the NAAQS.

Because these documents are sequential, EPA has historically provided opportunity for CASAC peer review, as well as public comment, on drafts of each document. EPA then revised the document to address issues raised in the comments, and, if appropriate, submitted a second draft to CASAC for further review prior to finalization. In some cases, a third review of ISA documents has been necessary. Resolving issues identified in each document allowed for a solid foundation for drafting the following document in the sequence.

In May 2018, then EPA Administrator Scott Pruitt issued the "Back-to-Basics" memorandum, which outlines a framework for "streamlining" NAAQS reviews. In keeping with the directives in that memorandum, the review schedule in EPA's draft IRP for the Ozone NAAQS, which was issued in October 2018, was dramatically accelerated, as compared to previous NAAQS reviews. That schedule allowed for only one draft of the ISA, with a projected release date of spring 2019, which would be followed by a draft combined REA and PA document in fall 2019.

NESCAUM comments on the draft IRP expressed concern that the compressed schedule did not allow time for EPA to prepare a second draft of the ISA to address CASAC recommendations and public comments prior to drafting the PA. Further, NESCAUM commented that it may be

appropriate to combine the REA and PA when there is a relatively limited amount of new research related to the NAAQS under consideration and no change to the standard is anticipated; however, this is not the case for the current reviews of the particulate matter and ozone NAAQS.

The draft IRP acknowledged the importance of receiving comments on the ISA before proceeding with the development of the PA, stating the following:

> The current [draft IRP] timeline projects release of a draft ISA for CASAC review and public comment in Spring 2019. In addition to informing any revisions to the ISA, that review step and the associated comments and advice from the CASAC and the public will also inform development of the draft PA. Comments and recommendations from the CASAC, and public comment, on the draft PA later in the Fall will then inform completion of the final PA, including its presentation of options appropriate for the Administrator to consider in this review of the O_3 NAAQS. [Emphasis added]

However, the schedule in the final IRP, which was issued in August 2019, did not allow for the consideration of even one set of CASAC/public comments on the ISA prior to preparation of the PA. The review schedule in that document was compressed even further, with an anticipated release of the ISA in September 2019, the PA (including the REA analysis) in October 2019, and a concurrent CASAC peer review of both documents in November/December 2019. Federal Register notices announcing the release of the draft ISA and PA documents were published on September 26, 2019 and November 1, 2019, respectively, with the concurrent CASAC review of both documents scheduled for the first week in December.

While the schedule in the draft IRP precluded iterative drafts of the ISA, the current timeline is even more egregious, because it does not allow even one set of comments on the ISA, which is the scientific foundation of the review, prior to policy development. By scheduling concurrent CASAC/public reviews of the draft ISA and the draft PA, the EPA has further eliminated essential opportunities for input concerning the very complex scientific issues involved in the review of the NAAQS.

NESCAUM urges CASAC to ask EPA to withdraw the draft PA document from consideration until after all issues with the ISA have been resolved. The review schedule must allow time for the CASAC to request a revised draft of the ISA, and the review documents must be appropriately sequenced so that the policy alternatives presented in the draft PA are based on a strong scientific foundation in a revised ISA. The ISA document should be thoroughly reviewed and redrafted prior to consideration of the PA and the Agency should not assume that combining the REA with the PA into one document is appropriate in this review cycle.

2. CASAC should include panels similar to those in previous NAAQS reviews to ensure that a wide range of scientific expertise and perspective is represented.

NESCAUM is concerned with recent EPA decisions that limit the composition of CASAC as it performs the ozone and particulate matter NAAQS reviews. Clean Air Act §108(a)(2) specifies that decisions about whether to revise a NAAQS must "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." Fulfilling that requirement requires scientific expertise that spans a wide range of study data and human health and environmental endpoints. With the large body of science relevant to a NAAQS review, no small group of individuals, including the seven charter members of CASAC, can realistically have all the required expertise to competently perform NAAQS reviews. For the current reviews, NESCAUM is particularly concerned about the limited expertise in the current CASAC in the fields of epidemiology, statistics, and the effects of ozone and particulate matter on vegetation.

Historically, a panel of approximately 20 additional scientists has been appointed to augment the expertise of the CASAC charter members. This allowed CASAC to conduct a comprehensive assessment of all aspects of the NAAQS development, and to benefit from discussions among scientists with differing perspectives. However, in October 2018, EPA disbanded the review panel for the particulate matter NAAQS and ceased formation of a panel for the ozone NAAQS review. This is perplexing in light of the demonstrated historical success in using such expertise and the clear need for it.

A July 2019 letter from Administrator Andrew Wheeler to CASAC Chair Louis Anthony Cox, Jr., stated that to address limitations in the CASAC, EPA will:

> Create a pool of subject matter expert consultants that the seven-person chartered CASAC, through the chair, will draw from as needed to support its PM and ozone reviews. The consultants will make themselves available as requested to provide feedback on the scientific and technical aspects of science and policy assessments and related documents.[1]

While consultation with subject area experts may be valuable, such consultations do not substitute for the careful deliberative process that has allowed past panels to jointly and expertly consider all aspects of NAAQS reviews. Such panels are particularly essential for pollutants, like ozone and PM, which are associated with a wide range of complex health and welfare effects.

NESCAUM requests that EPA reconstitute the disbanded particulate matter NAAQS panel and form a panel for evaluating the ozone NAAQS review. Without such panels, the EPA risks

[1] Letter from Andrew J. Wheeler, EPA Administrator, to Louis Anthony Cox, Jr., CASAC Chair, dated July 25, 2019, https://yosemite.epa.gov/sab/sabproduct.nsf/0/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002_Response.pdf.

undermining the scientific integrity of NAAQS decisions, and threatening the credibility of CASAC as an informed venue capable of performing its tasks under the Clean Air Act.

3. CASAC should consider a more stringent primary NAAQS for ozone.

In its review of EPA's 2014 "Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards," CASAC concurred with the recommendations in that PA document that the current indicator (ozone), averaging time (maximum daily 8-hour average) and form (annual 4th highest maximum daily 8-hour average, averaged over three years) for the primary standard should be retained. However, CASAC concluded that "there is adequate scientific evidence to recommend a range of levels for a revised primary ozone standard from 70 ppb to 60 ppb," stating that:

> The CASAC advises that, based on the scientific evidence, a level of 70 ppb provides little margin of safety for the protection of public health, particularly for sensitive subpopulations. In this regard, our advice differs from that offered by EPA staff in the Second Draft PA. At 70 ppb, there is substantial scientific evidence of adverse effects as detailed in the charge question responses, including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation. Although a level of 70 ppb is more protective of public health than the current standard, it may not meet the statutory requirement to protect public health with an adequate margin of safety.[2]

Despite that CASAC opinion, EPA set the 2015 ozone NAAQS at the 70 ppb level. The current draft ISA provides further support for significant health effects at levels below 70 ppb, stating that:

> Recent studies support and expand upon the strong body of evidence, which has been accumulating over the last few decades, that short-term ozone exposure causes respiratory effects. The strongest evidence comes from controlled human exposure studies demonstrating ozone-induced decreases in lung function and inflammation in healthy, exercising adults at concentrations as low as 60 ppb after 6.6 hours of exposure. In addition, epidemiologic studies continue to provide strong evidence that ozone is associated with respiratory effects, including asthma and COPD exacerbations, as well as hospital admissions and emergency department visits for respiratory diseases. The results from toxicological studies further characterize potential mechanistic pathways and provide continued support for the biological plausibility of ozone-induced respiratory effects.[3]

The current draft ozone PA recommends retention of the 70 ppb primary ozone NAAQS. However, CASAC should carefully consider the evidence that led the previous CASAC to

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[2] Letter from H. Christopher Frey, CASAC Chair, to Gina McCarthy, EPA Administrator, dated June 26, 2014, p. ii, https://yosemite.epa.gov/sab/sabproduct.nsf/5EFA320CCAD326E885257D030071531C/%24File/EPA-CASAC-14-004+unsigned.pdf.

[3] EPA, *Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft—September 2019)*, page IS-1, https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=344670.

conclude that the now current 70 ppb primary NAAQS "may not meet the statutory requirement to protect public health with an adequate margin of safety," as discussed above. CASAC should also carefully consider any comments received from members of that panel and from scientists with expertise in all relevant areas, including epidemiology and statistics, when evaluating whether a more stringent primary standard is appropriate.

4. CASAC should recommend a secondary ozone NAAQS that protects against cumulative vegetation damage over a single season.

The June 2014 CASAC letter stated the following regarding the secondary ozone NAAQS:

> We recommend retaining the current indicator (ozone) but establishing a revised form of the secondary standard to be the biologically-relevant W126 index accumulated over a 12-hour period (8 a.m. – 8 p.m.) over the 3-month summation period of a single year resulting in the maximum value of W126 (henceforth W126). The CASAC recommends that the level associated with this form be within the range of 7 ppm-hrs to 15 ppm-hrs to protect against current and anticipated welfare effects of ozone. […]
>
> The CASAC does not recommend the use of a three-year averaging period for the secondary standard. We favor a single-year period for determining the highest three-month summation which will provide more protection for annual crops and for the anticipated cumulative effects on perennial species. The scientific analyses considered in this review, and the evidence upon which they are based, are from single-year results. If, as a policy matter, the Administrator prefers to base the secondary standard on a three-year averaging period for the purpose of program stability, then the level of the standard should be revised downward such that the level for the highest three-month summation in any given year of the three-year period would not exceed the scientifically recommended range of 7 ppm-hrs to 15 ppm-hrs.[4]

EPA did not follow the CASAC's recommendation, instead setting the 2015 secondary ozone NAAQS at the same level and form as the primary standard. In August 2019, the DC Circuit Court remanded that secondary ozone NAAQS to EPA (*Murray Energy v. EPA*, 936 F.3d 597 [D.C. Cir. 2019]). The remand instructed the EPA to:

> "[E]ither lower the standard to protect against unusually damaging cumulative seasonal exposures that will be obscured in its three-year average, or explain its conclusion that the unadjusted average is an appropriate benchmark notwithstanding CASAC's contrary advice. Alternatively, EPA could adopt the single-year W126 exposure index as the form and averaging time, which would presumably moot any problems with the way it translated that index to use as a benchmark.

[4] Letter from H. Christopher Frey, CASAC Chair, to Gina McCarthy, EPA Administrator, dated June 26, 2014, p. iii, https://yosemite.epa.gov/sab/sabproduct.nsf/5EFA320CCAD326E885257D030071531C/%24File/EPA-CASAC-14-004+unsigned.pdf.

The current draft ozone PA references but does not explicitly respond to the August 2019 remand. That document discusses ozone-related vegetation injury, including "growth, reproduction, and related larger-scale effects, as well as, visible foliar injury" and states that "we preliminarily conclude that the currently available evidence and quantitative exposure/risk information does not call into question the adequacy of the current standard such that it is appropriate to consider retaining the current standard without revision." The ISA should be revised to specifically address the issues raised in the recent remand of the secondary ozone NAAQS by the D.C. Circuit.

NESCAUM strongly recommends that if EPA does not form a comprehensive review panel, CASAC should actively engage with scientists with significant expertise in the ecological effects of ozone and vegetation damage, as well as statisticians, atmospheric scientists, and experts in other relevant fields. With the advice of those experts, CASAC should carefully review the information related to the secondary standard in the ISA and PA, along with the analyses performed by the earlier CASAC panel, in order to recommend a NAAQS that will be protective of vegetation damage and other welfare effects associated with cumulative seasonal exposures.

5. CASAC should make recommendations on the PM2.5 NAAQS only after conducting a review that includes a wide range of experts, similar to past CASAC review processes.

As discussed above, in the past, a panel of approximately 20 additional scientists had been appointed to augment the expertise of the CASAC charter members. This allowed CASAC to conduct a comprehensive assessment of all aspects of the NAAQS development, and to benefit from discussions among scientists with differing perspectives. However, in October 2018, EPA disbanded the panel that had been appointed to review the PM2.5 NAAQS.

NESCAUM strongly urges CASAC to withhold recommendations on the PM2.5 NAAQS until a review panel similar to the one that was disbanded in October 2018 is re-formed. Note that, on October 10-11 and 18, 2019, 20 scientists who were formerly members of the CASAC Particulate Matter Panel met to peer review EPA's "PA for the Review of the NAAQS for Particulate Matter (External Review Draft – September 2019)." That Independent Particulate Matter Review Panel (IPMRP) is comprised of experts in a wide range of scientific disciplines, including multiple experts who provide diversity of perspectives in many key areas, such as epidemiology, toxicology, and human clinical studies, among others. The IPRMP meeting was conducted according to the same procedures as a CASAC meeting.

Based on the scientific evidence, the IPMRP found that:

> [T]he current suite of primary fine particle (PM2.5) annual and 24-hour standards are not protective of public health. Both of these standards should be revised to new levels, while retaining their current indicators, averaging times, and forms. The annual standard should be revised to a range of 10 $\mu g/m^3$ to 8 $\mu g/m^3$. The 24-hour standard should be revised to a range of 30 $\mu g/m^3$ to 25 $\mu g/m^3$. These scientific findings are based on consistent epidemiological evidence

> from multiple multi-city studies, augmented with evidence from single-city studies, at policy-relevant ambient concentrations in areas with design values at and below the levels of the current standards, and are supported by research from experimental models in animals and humans and by accountability studies.[5]

The IPMRP further stated that "the use of calendar-day 24-hour averages for the short-term standard may not be protective of public health, unless the level is set low enough to prevent potentially harmful peak exposures" and recommended that "EPA conduct a comparative analysis of an hourly 24-hour rolling average versus the current 24-hour calendar-day average to assess the potential health protective benefits of a change in form."[6] NESCAUM supports this recommendation.

NESCAUM strongly urges CASAC to conduct a comprehensive review process similar to those used to evaluate previous NAAQS prior to recommending a PM2.5 NAAQS. Alternatively, CASAC could incorporate the findings from the IPMRP review, which was conducted according to such a process, in its recommendations.

Summary

The "streamlined" process currently in use at EPA to review NAAQS severely limits the opportunities for scientific input from CASAC and the public and may result in standards that are not adequately protective of public health and the environment. The highly compressed review schedule does not allow for redrafting documents in response to comments and, in the ozone review, the concurrent release of the ISA and PA did not allow for even one review of a draft ISA prior to issuance of the draft PA document. Further, EPA disbanded the highly qualified CASAC panel for PM and failed to form a review panel for ozone which would have provided CASAC with the breadth and depth of expertise needed to fully evaluate the diverse studies and endpoints relevant to reviewing those standards.

NESCAUM strongly recommends that EPA convene an ozone review panel and alter the current schedule to allow for a comprehensive review of the draft ISA by that panel. Review of the ozone PA document should be suspended until an ISA that satisfies comments from CASAC and the public has been prepared. All evidence, including the recommendations of 2014 CASAC panel, should be carefully considered in CASAC's recommendations for the primary and

[5] Letter to Andrew R. Wheeler, EPA Administrator, from H. Christopher Frey, IPMRP Chair, Subject: Advice from the Independent Particulate Matter Review Panel (formerly EPA CASAC Particulate Matter Review Panel) on EPA's Policy Assessment for the Review of the National Ambie0nt Air Quality Standards for Particulate Matter (External Review Draft – September 2019), dated October 22, 2019, pp. 1-2, https://yosemite.epa.gov/sab/sabproduct.nsf/81DF85B5460CC14F8525849B0043144B/$File/Independent+Particulate+Matter+Review+Panel+Letter+on+Draft+PA.pdf.

[6] Ibid, p. B-30.

secondary ozone NAAQS. The revised ISA and PA should also specifically address the issues raised in the recent remand of the secondary ozone NAAQS by the D.C. Circuit. Finally, CASAC should conduct a comprehensive review process similar to those used to evaluate previous NAAQS prior to recommending a PM2.5 NAAQS.

Sincerely,

/s/Paul J. Miller
Executive Director

cc: NESCAUM directors
Lynne Hamjian, EPA R1
Richard Ruvo, EPA R2