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To Whom It May Concern:

The National Association of Clean Air Agencies (NACAA) offers the following comments on the U.S. Environmental Protection Agency's (EPA's) proposed action, "Review of the Ozone National Ambient Air Quality Standards," which was published in the *Federal Register* on August 14, 2020 (85 Fed. Reg. 49,830).¹ NACAA is the national, nonpartisan, non-profit association of air pollution control agencies in 41 states, including 115 local air agencies, the District of Columbia and four territories. The air quality professionals in our member agencies have vast experience dedicated to improving air quality in the U.S. These comments are based upon that experience. The views expressed in these comments do not represent the positions of every state and local air pollution control agency in the country.

Based on EPA's recent review of the air quality criteria and National Ambient Air Quality Standards (NAAQS) for ozone, EPA Administrator Andrew Wheeler has proposed his decision to retain the current primary ozone NAAQS (to protect public health) and secondary ozone NAAQS (to protect public welfare) without revision. As we explain below, after closely tracking EPA's ozone NAAQS review since it was initiated in mid-2018, NACAA concludes that this review process was seriously flawed; that these flaws degraded the ozone NAAQS review process to the point where it is not possible to tell whether the proposed decision will protect public health with an adequate margin of safety, as required by the Clean Air Act; and that because the NAAQS are the foundation of much of the most critical work state and local air agencies do, it is imperative that the process by which they are reviewed does not prioritize efficiency over the protection of public health. NACAA urges EPA to return to a thorough, credible NAAQS review process.

I. The Ozone NAAQS Review Process Was Seriously Flawed.

In 2018, EPA leadership took several decisive steps that undermined the ozone NAAQS review process before it even got off the ground: Then-Administrator Scott Pruitt issued a memorandum setting out principles for future NAAQS reviews and Administrator Wheeler announced the appointment of five new members of the seven-member Clean Air Scientific Advisory Committee (CASAC) and also decided against forming an Ozone NAAQS Review Panel.

¹ 85 Fed. Reg. 49,830 (August 14, 2020) – <https://www.govinfo.gov/content/pkg/FR-2020-08-14/pdf/2020-15453.pdf>

A. EPA Used Then-Administrator Pruitt's "Back-to-Basics Process for Reviewing NAAQS" Memorandum to Severely Curtail and Degrade the Ozone Review Process.

Then-Administrator Pruitt's May 9, 2018 "Back-to-Basics Process for Reviewing National Ambient Air Quality Standards" memorandum² set out principles for EPA to follow in future NAAQS reviews, including meeting all statutory deadlines and streamlining and standardizing the process for developing and reviewing key policy-relevant information. With respect to meeting statutory deadlines, Pruitt stated that "EPA and CASAC shall look for efficiencies and opportunities to streamline the NAAQS review process to ensure that they finish within a five-year interval" as required by the Clean Air Act (CAA). Administrator Pruitt focused this statement particularly on the then-forthcoming review of the ozone NAAQS, stating that he was "directing Agency staff to begin the next review of the ozone NAAQS so EPA will be ready to finalize any necessary revisions by the statutorily required five-year deadline (October 2020)."

In its February 19, 2020 review of the EPA staff's "Integrated Science Assessment [ISA] for Ozone and Related Photochemical Oxidants (External Review Draft – February 19, 2020)"³ CASAC reported, among other things, that "[o]verall, the CASAC finds that the Draft Ozone ISA, while providing useful reviews of many aspects of ozone exposures and human health effects in selected studies, does not provide a comprehensive, systematic assessment of the available science relevant to understanding the public health impacts of changes in ambient concentrations of ozone." CASAC goes on to recommend a series of key points to be addressed in the final ISA. Administrator Wheeler responded on April 1, 2020,⁴ acknowledging CASAC's concerns and recommendations and advising the Committee as follows: "The process outlined in EPA's May 9, 2018, 'Back-to-Basics' memo directs the agency to ensure that NAAQS reviews are completed in a timely, efficient and transparent manner, consistent with the *Clean Air Act*. The five-year review cycle for each NAAQS is challenging in light of the continuous development of new and relevant science, challenges compounded by the EPA practice of facilitating CASAC and public engagement throughout the process." The Administrator went on to advise CASAC that, "with this in mind," he had directed his staff to complete the review of the ozone NAAQS by the end of 2020; to the extent possible, incorporate CASAC's comments and recommendations into the final ISA; and "for those comments and recommendations that are more substantial or cross-cutting and which cannot be fully addressed in this timeframe, develop a plan to incorporate these changes in future Ozone ISAs as well as ISAs for other criteria pollutant reviews."

In its review of the EPA staff's "Policy Assessment [PA] for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019),"⁵ also issued on February 19, 2020, CASAC explained that the problems it had outlined regarding the draft ISA adversely affected the draft PA. CASAC also reported a disagreement among Committee members on the adequacy of the primary ozone NAAQS to protect public health with an adequate margin of safety. CASAC wrote that due to the draft ISA's "limitations in the underlying science basis for policy recommendations, some CASAC members concluded that the Draft

² *Back-to-Basics Process for Reviewing National Ambient Air Quality Standards*, Memorandum from E. Scott Pruitt, U.S. Environmental Protection Agency (May 9, 2018) – <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf>

³ *CASAC Review of the EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft – (September 2019)*, Clean Air Scientific Advisory Committee (February 19, 2020) – [https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/F228E5D4D848BBED85258515006354D0/\\$File/EPA-CASAC-20-002.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/F228E5D4D848BBED85258515006354D0/$File/EPA-CASAC-20-002.pdf)

⁴ Letter from EPA Administrator Andrew R. Wheeler to CASAC Chair Louis Anthony Cox, Jr., Ph.D. (April 1, 2020) – [https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/F228E5D4D848BBED85258515006354D0/\\$File/EPA-CASAC-20-002_Response.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/F228E5D4D848BBED85258515006354D0/$File/EPA-CASAC-20-002_Response.pdf)

⁵ *CASAC Review of the EPA's Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019)* – [https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/4713D217BC07103485258515006359BA/\\$File/EPA-CASAC-20-003.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/4713D217BC07103485258515006359BA/$File/EPA-CASAC-20-003.pdf)

Ozone PA does not establish that new scientific evidence and data reasonably call into question the public health protection afforded by the current primary ozone standard.” However, “[o]ther members of the CASAC agree with the previous CASAC’s findings and recommendations in their review of the 2014 Second Draft Ozone PA. In that review, the previous CASAC opined that a primary standard set at 70 ppb may not be protective of public health with an adequate margin of safety.”

Accordingly, the Committee wrote in its February 2019 review that it “recommends that it be given an opportunity to review a second draft of the Ozone PA (with an updated Risk and Exposure Assessment) after the final ISA for ozone is released.” (CASAC agreed with EPA “that the available evidence does not reasonably call into question the adequacy of the current secondary ozone standard and concurs that it should be retained.”) But this opportunity was not provided. On May 4, 2020, Administrator Wheeler transmitted an eight-line response to CASAC’s review⁶ saying, perfunctorily, “I want to convey my appreciation to you and the CASAC members for your time and efforts. The CASAC’s thorough review and comments will be very helpful in preparing the final policy assessment. Your comments will also be helpful as the agency moves into the rulemaking portion of the review.”

By strapping itself to the “Back-to-Basics” memo EPA forced a severely truncated ozone review process of less than two years that sacrificed thoroughness, deliberation and scientific integrity for the sake of expediency. In pursuit of “efficiency,” the ozone NAAQS review process followed a compressed schedule that eliminated the preparation of key documents and precluded proper review of those that were produced. The key documents typically prepared during a NAAQS review include an Integrated Review Plan (IRP), ISA, Risk and Exposure Assessment (REA) and PA, usually with two external review drafts each of the latter three documents. Moreover, these sequential documents are intended to build on one another to inform NAAQS reviews, culminating in a proposed decision and a final decision. However, this complete, orderly and typical plan was discarded and replaced with a deficient offering that consisted of only one review draft each of the ISA and PA and no REA at all (with a risk assessment folded into the PA). This approach also comingled development and review of science, risk and policy, with the single draft of the ISA and the single draft of the PA issued by EPA barely one month apart in fall 2019. As a result, EPA introduced policy issues for consideration before issues related to science and risk were resolved and CASAC was forced to review them concurrently rather than in sequence, responding to both on February 19, 2020.

Further, this unnecessarily accelerated timeframe precluded adequate time for in-depth discussions, public input and transparency. Not only were fewer meetings of CASAC held, opportunities for public review and comment were limited.

B. CASAC Lacked the Expertise Needed to Conduct the Ozone NAAQS Review and the Administrator’s Failure to Follow Through with Appointment of an Ozone Review Panel Seriously Exacerbated this Deficit.

In October 2018, Administrator Wheeler appointed five new members to the chartered seven-member CASAC;⁷ the remaining two members had been appointed within the previous year. These appointments were based on the principles established by then-Administrator Pruitt in an October 31, 2017

⁶ Letter from EPA Administrator Andrew R. Wheeler to CASAC Chair Louis Anthony Cox, Jr., Ph.D. (May 4, 2020) – [https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/4713D217BC07103485258515006359BA/\\$File/EPA-CASAC-20-003.Respose.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/4713D217BC07103485258515006359BA/$File/EPA-CASAC-20-003.Respose.pdf)

⁷ *Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee*, Press Release, U.S. Environmental Protection Agency (October 10, 2018) – <https://archive.epa.gov/epa/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee.html>

memorandum, “Strengthening and Improving Membership on EPA Federal Advisory Committees”⁸: 1) strengthen member independence, 2) increase state, tribal and local government participation, 3) enhance geographic diversity and 4) promote fresh perspectives.

In July 2018, EPA published in the *Federal Register* a notice seeking subject matter experts to form the next Ozone Review Panel, the function of which was “to provide advice through the chartered CASAC on the scientific and technical aspects of air quality criteria and the National Ambient Air Quality Standards (NAAQS) for ozone.”⁹ However, in October 2018, the Administrator did an about-face and announced he would not appoint an Ozone Review Panel.

These actions damaged the scientific rigor and integrity of the review.

First, then-Administrator Pruitt’s principles for establishing federal advisory committees focused on appointing more state, tribal and local government members, increasing geographic diversity and bringing new faces to the table. While these are certainly laudable goals, they should not supersede criteria that consider breadth and depth of expertise and experience, a balance of scientific perspectives and continuity of knowledge and an understanding of EPA’s mission and environmental programs. In addition, excluding from eligibility any non-governmental researcher in receipt of an EPA grant eliminated from consideration many extremely qualified experts.

Second, CASAC is a seven-member body. No matter who sits on CASAC, the small Committee simply cannot provide the variety of expertise necessary to conduct a credible review of any NAAQS: disciplines such as epidemiology, toxicology, medical specialties, risk assessment, atmospheric sciences and exposure assessment from both the modeling and measurement sides, controlled human studies and more. Moreover, several experts are needed in each area of expertise to provide diverse perspectives. Since the mid-1980s, CASAC has been assisted by pollutant-specific review panels of approximately 15 to 20 subject matter experts to provide that breadth and depth of expertise and perspectives. Without the Ozone Review Panel, a virtually brand new CASAC was left lacking in crucial expertise and without the expert review and analysis of EPA staff drafts by panel members, without additional colleagues with whom to freely deliberate and without additional points of view to enrich and inform the discussions and recommendations.

CASAC understood the gravity of this loss and in its separate February 2019 reviews of the draft ISA and draft PA “strongly recommend[ed] that the EPA consider restoring a traditional interactive discussion process in which the CASAC can interact directly with external expert panels.” Unfortunately, the Administrator responded to neither of these appeals. Five months later, in his July 25, 2019 response to CASAC’s review of the draft Particulate Matter ISA, the Administrator told Committee Chair Anthony Cox that he had directed his staff to “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. ... Requests for feedback from these consultants should be submitted in writing through you, the CASAC’s chair, and the CASAC’s designated federal

⁸ *Strengthening and Improving Membership on EPA Federal Advisory Committees*, Memorandum from E. Scott Pruitt, U.S. Environmental Protection Agency (October 31, 2017) – http://www.4cleanair.org/sites/default/files/Documents/FAC_Directive-10-31-2017.pdf

⁹ Request for Nominations of Experts for the Clean Air Scientific Advisory Committee Ozone Review Panel – 85 Fed. Reg. 35,635 (July 17, 2018) – <https://www.govinfo.gov/content/pkg/FR-2018-07-27/pdf/2018-16116.pdf>

official.”¹⁰ This no-direct-contact arrangement offering only responses to questions posed is quite a departure from the highly synergistic relationship CASAC enjoyed with the Ozone Review Panel, which benefitted the review process as well as the ultimate outcome.

II. These Flaws Degraded the Ozone NAAQS Review Process to the Point Where It Is Not Possible to Tell Whether the Proposed Decision Will Protect Public Health with an Adequate Margin of Safety, as Required by the Clean Air Act.

The flawed process led to a questionable proposed decision by the EPA Administrator to retain the current primary ozone NAAQS without revision.

EPA itself acknowledges in the proposal that there is significant uncertainty. A more thorough process, and the inclusion of an Ozone Review Panel of experts, could have addressed such uncertainties and limitations.

In addition, the Administrator’s proposed decision fails to address environmental justice issues faced by at-risk populations. According to the American Lung Association, of the 20 million people living in U.S. counties with elevated levels of ozone and particulate matter pollution, 14 million are people of color; 74 million people of color live in a county with elevated levels of at least one of the two pollutants.¹¹ In a study published in the *New England Journal of Medicine* in 2017 – “Air pollution and mortality in the Medicare population”¹² – researchers concluded, “In the entire Medicare population, there was significant evidence of adverse effects related to exposure to PM_{2.5} and ozone at concentrations below current national standards. This effect was most pronounced among self-identified racial minorities and people with low income.” A thorough and complete NAAQS review should include a full evaluation of the proposal’s impacts on at-risk populations and those disproportionately affected.

III. EPA Must Return to a NAAQS Review Process that Does Not Prioritize Efficiency over the Protection of Public Health.

NACAA’s mission is to protect clean air and public health and improve the capability and effectiveness of state and local air agencies as we work to fulfill our responsibility under the Clean Air Act to mitigate and control air pollution so that our constituents can breathe clean, healthful air. We cannot succeed unless EPA – our federal regulatory partner – makes well-informed, thoughtfully considered policy decisions. In the case of the NAAQS – which are the foundation of much of the most critical work state and local air agencies do – these policy decisions must be guided by a thorough review of the latest available science by, and sound advice from, highly qualified experts from a wide array of disciplines and with a diversity of perspectives.

As the stewards of the health of our constituents it is imperative that state and local air agencies have high confidence in EPA’s NAAQS decision-making process. Unfortunately, with the recent, flawed particulate matter and ozone NAAQS reviews – under which longstanding protocols were eliminated, condensed or rushed and the consideration of science and health-based data for these important decisions is called into question – that confidence has been shaken. Further, notwithstanding EPA’s claim that its goal

¹⁰ Letter from EPA Administrator Andrew R. Wheeler to CASAC Chair Louis Anthony Cox, Jr., Ph.D. (July 25, 2019) – [https://yosemite.epa.gov/sab/sabproduct.nsf/6CBCBCC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002_Response.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/6CBCBCC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002_Response.pdf)

¹¹ *State of the Air 2020, Key Findings*, American Lung Association (April 2020) – <http://www.stateoftheair.org/key-findings/people-at-risk.html>

¹² *Air Pollution and Mortality in the Medicare Population*, *New England Journal of Medicine* (June 29, 2017) – <https://www.nejm.org/doi/full/10.1056/NEJMoa1702747>

is to “streamline” the process, the time “saved” by rushing the review will be lost to lengthy litigation because scientific integrity was sacrificed. NACAA urges EPA to return to a thorough, credible NAAQS review process that does not prioritize efficiency over the protection of public health.

On behalf of NACAA, we thank you for this opportunity to comment on this extremely important issue. If you have questions or would like further information, please contact either of us or Nancy Kruger, Deputy Director of NACAA.

Sincerely,



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