UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL CENTER FOR ENVIRONMENTAL ASSESSMENT
RESEARCH TRIANGLE PARK, NC 27711

OFFICE OF
RESEARCH AND DEVELOPMENT

September 26, 2019

MEMORANDUM

SUBJECT: Clean Air Scientific Advisory Committee Review of the External Review Draft Integrated Science Assessment for Ozone and Related Photochemical Oxidants

FROM: John Vandenberg, Ph.D. /s/
Director
National Center for Environmental Assessment
Research Triangle Park Division (B243-01)

TO: Aaron Yeow, M.P.H.
Designated Federal Officer
Clean Air Scientific Advisory Committee
EPA Science Advisory Board Staff Office (1400R)

The External Review Draft *Integrated Science Assessment for Ozone and Related Photochemical Oxidants* (hereafter referred to as draft ISA) prepared by the U.S. Environmental Protection Agency's (U.S. EPA) National Center for Environmental Assessment – Research Triangle Park Division (NCEA-RTP) as part of EPA's ongoing review of the primary (health-based) and secondary (welfare-based) National Ambient Air Quality Standards (NAAQS) for Ozone was released on September 26, 2019. Electronic copies of the draft ISA and other documents referenced below are available for download at https://www.epa.gov/isa (attached to a separate memorandum is the HERONet version of the draft ISA). I am requesting that you provide this memo to the Clean Air Scientific Advisory Committee (CASAC) for peer review of this document.

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In a July 25, 2019 letter to the CASAC, EPA Administrator Andrew Wheeler directed that the EPA staff should "Continue progress on the review of the NAAQS for ground-level ozone through production of the draft ozone ISA and accelerating the development of a draft ozone [Policy Assessment] so that both documents can be delivered for CASAC and public review by October 2019. This simultaneous review by the CASAC and the public should conclude by the end of the calendar year."

This document outlines the charge questions specific to the review of the draft ISA as part of EPA's ongoing review of the primary (health-based) and secondary (welfare-based) NAAQS for Ozone.

OVERARCHING REVIEW CONTEXT

On May 9, 2018, then EPA Administrator, Mr. Scott Pruitt, provided principles and guidance for NAAQS reviews in a memorandum titled, Back to Basics Process for Review of the National Ambient Air Quality Standards. This memorandum set out five principles for EPA to observe in future NAAQS reviews:

(1) Meet statutory deadlines;
(2) Address all CAA provisions for NAAQS reviews;
(3) Streamline and standardize the process for development and review of key policy-relevant information;
(4) Differentiate science and policy judgments in the NAAQS review process; and
(5) Issue timely implementation regulations and guidance

In the context of **Principle 2**, the memorandum poses a standardized set of charge questions to CASAC to frame the entirety of the NAAQS review. These questions are provided here as a backdrop to this review:

- What scientific evidence has been developed since the last review to indicate if the current primary and/or secondary NAAQS need to be revised or if an alternative level or form of these standards is needed to protect public health and/or public welfare? Please recommend to the Administrator any new NAAQS or revisions of existing criteria and standards as may be appropriate. In providing advice, please consider a range of options for standard setting, in terms of indicators, averaging times, form, and levels for any alternative standards, along with a description of the alternative underlying interpretations of the scientific evidence and risk/exposure information that might support such alternative standards and that could be considered by the Administrator in making NAAQS decisions.
- Are there areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised NAAQS? Please describe the research efforts necessary to provide the required information.
- What is the relative contribution to air pollution concentrations of natural as well as anthropogenic activity? In providing advice on any recommended NAAQS levels, please discuss relative proximity to peak background levels.
- Please advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such NAAQS.
- Do key studies, analyses, and assessments which may inform the Administrator's decision to revise the NAAQS properly address or characterize uncertainty and causality? Are there appropriate criteria to ensure transparency in the evaluation, assessment, and characterization of key scientific evidence for this review?

Supplemental charge questions specific to the review of the ISA are provided later in this document.

ISA CONTEXT:

Purpose: The purpose of this draft ISA is to identify, evaluate, and summarize scientific information on the health and welfare effects associated with ozone. The overall process for ISA development, including criteria used to identify relevant studies, aspects considered in judging the overall weight of evidence, and the framework for causality determinations, are described in the Preamble to the Integrated Science Assessments, which is attached and available to the public at NCEA's website (https://www.epa.gov/isa) and in the Health and Environmental Research Online (HERO) database. The Preamble to the ISA is a companion document to the draft Ozone ISA, and it reflects development and refinements based on peer review and public comment for prior ISAs. In addition, details on process specific to the draft Ozone ISA are described in Appendix 10 to the draft ISA which was developed, in part, in response to CASAC and public comments on the draft PM ISA (2018) regarding the methods for literature review, study quality evaluation, and quality assurance and quality control.

Organization: The ***Preface*** within the draft Ozone ISA outlines the legislative requirements and history of the reviews of the primary and secondary Ozone NAAQS, describes the purpose and presents an overview of the ISA, and an overview of the process for developing the ISA. The ***Executive Summary*** is intended to provide a concise synopsis of the key findings and conclusions for a broad range of audiences.

The ***Integrated Synthesis*** summarizes the overall conclusions of the draft ISA and characterizes available scientific information on policy-relevant issues. Taken together, the Executive Summary and Integrated Synthesis provide a comprehensive synthesis of key findings.

The information presented in the Integrated Synthesis is supported by detailed appendices on the relevant evidence spanning scientific disciplines that directly informs the causality determinations: atmospheric sources and emissions, ambient concentrations, and measurement and modeling of ambient concentrations of ozone (including background ozone) (***Appendix 1***); exposure to ozone (***Appendix 2***); health effects of short-term and long-term ozone exposures (***Appendices 3-7***); welfare effects (***Appendices 8-9***); and a detailed account of the process used in assessment development (***Appendix 10***).

Development Timeline: The U.S. EPA initiated this review on June 26, 2018 (83 FR 29785). Relevant science and policy issues were incorporated in EPA's *Draft Integrated Review Plan for the National Ambient Air Quality Standards for Ozone and related Photochemical Oxidants* which was available for public comment (83 FR 29785) and discussion by the CASAC via publicly accessible teleconference consultation (83 FR 55163). The *Final Integrated Review Plan for the National Ambient Air Quality Standards for Ozone and related Photochemical Oxidants* was released August 27, 2019 and is available at https://www.epa.gov/naaqs/ozone-o3-air-quality-standards (84 FR 87933).

SUPPLEMENTAL CHARGE QUESTIONS FOR SCIENTIFIC REVIEW OF THE ISA

To supplement the standardized charge questions, and guide the scientific review of this ISA, the EPA has identified these additional areas for CASAC review and comment:

- The ***Executive Summary*** is intended to provide a concise synopsis of the key findings and conclusions of the Ozone ISA for a broad range of audiences. Please comment on the clarity with which the Executive Summary communicates the key information from the draft ISA. Please provide recommendations on information that should be added or information that should be left for discussion in the Integrated Synthesis and accompanying appendices of the draft ISA.
- The ***Integrated Synthesis*** presents and synthesizes the overall conclusions from the subsequent detailed appendices of the draft ISA and characterizes available scientific information on policy-relevant issues. Please comment on the usefulness and effectiveness of the summary presentation. Please provide recommendations on approaches that may improve the communication of key findings to varied audiences and the synthesis of available information across subject areas. What information should be added or is more appropriate to leave for discussion in the subsequent detailed appendices?
- To what extent is the information presented in ***Appendix 1*** regarding sources, precursor emissions, and measurement and modeling of ambient concentrations, as well as modeled estimates of background concentrations of ozone, clearly and accurately conveyed and appropriately characterized? Please comment on the extent to which available information on the spatial and temporal trends of ozone concentrations at various scales has been adequately and accurately described.
- ***Appendix 2*** describes scientific information on exposure to ozone and implications for epidemiologic studies. To what extent is the discussion on methodological considerations for

exposure measurement and modeling clearly and accurately conveyed and appropriately characterized? Please comment on the extent to which the discussion regarding exposure assessment and the influence of exposure error on effect estimates in epidemiologic studies of the health effects of ozone has been adequately and accurately described.

- Please comment on the identification, evaluation and characterization of the available scientific evidence from epidemiologic, controlled human exposure, toxicological and associated human exposure and atmospheric sciences studies and the application of information from these studies to inform causality determinations for human health outcomes.
    - ***Appendices 3 - 7*** present assessments of the health effects associated with short-term and long-term exposure to ozone. The discussion is organized by exposure duration, broad health effects (e.g., asthma, ischemic heart disease, etc.), and scientific discipline. Please comment on the characterization of the evidence within these chapters.
    - Please comment on the portrayal and discussion of the biological plausibility evidence presented in Appendices 3-7 and the extent to which: (1) the organization adequately captures the current state of the science with respect to potential pathways by which ozone could impart health effects, and (2) as currently constructed, inform causality determinations.
- Please comment on the identification, evaluation and characterization of the available scientific evidence from studies of ecological effects of ozone, and the application of information from these studies, as presented in ***Appendix 8***, to inform causality determinations for these welfare outcomes.
- Please comment on the identification, evaluation and characterization of the available scientific evidence from studies of ozone effects on climate, and the application of information from these studies, as presented in ***Appendix 9***, to inform causality determinations for these welfare outcomes.
- ***Appendix 10*** provides details on the process by which the draft ISA was developed. Please comment on the usefulness and effectiveness of this appendix. Please provide recommendations on approaches that may improve the communication of the process used to develop the ISA.

We look forward to discussing these issues with the CASAC at our upcoming meeting. Should you have any questions regarding the draft Ozone ISA, please feel free to contact Dr. Tom Luben (919-541-5762, luben.tom@epa.gov) or Dr. Meredith Lassiter (919-541-3200).

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