



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Center for Public Health and Environmental Assessment
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OFFICE OF
RESEARCH AND DEVELOPMENT

October 7, 2021

MEMORANDUM

SUBJECT: Clean Air Scientific Advisory Committee Review of the External Review Draft of the Supplement to the 2019 Integrated Science Assessment for Particulate Matter

FROM: Steven Dutton, Ph.D. /s/
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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 of the Supplement to the 2019 Integrated Science Assessment for Particulate Matter (hereafter referred to as the draft PM Supplement) prepared by the U.S. Environmental Protection Agency's (U.S. EPA) Center for Public Health and Environmental Assessment (CPHEA) as part of U.S. EPA's ongoing reconsideration of the primary (health-based) and secondary (welfare-based) National Ambient Air Quality Standards (NAAQS) for particulate matter (PM) was released on September 30, 2021. Electronic copies of the draft PM Supplement, 2019 Particulate Matter Integrated Science Assessment (PM ISA), and other documents referenced below are available for download at <https://www.epa.gov/isa>. I am requesting that you provide this memo to the Clean Air Scientific Advisory Committee (CASAC) for peer review of the draft PM Supplement.

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OVERARCHING REVIEW CONTEXT

On June 10, 2021, U.S. EPA Administrator, Mr. Michael Regan, announced his decision to reconsider the December 2020 decision to retain the NAAQS for PM. As part of the reconsideration process, the U.S. EPA indicated that it would develop a Supplement to the 2019 PM ISA to thoroughly evaluate the most up-to-date science that became available after the literature cutoff date of the 2019 PM ISA that could either further inform the adequacy of the current PM NAAQS or address key scientific topics that have evolved since the 2020 PM NAAQS review was completed. The draft PM Supplement in combination with the 2019 PM ISA forms the complete scientific record being used in the process of reconsidering the 2020 PM NAAQS decision.

ISA CONTEXT:

Purpose of the draft PM Supplement: The combination of the 2019 PM ISA and this draft PM Supplement is intended to “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 [a] pollutant in the ambient air” [Clean Air Act, Section 108; 42 U.S.C. 7408(b)]. The 2019 PM ISA evaluated the scientific evidence for review of the primary (health-based) and secondary (welfare-based) NAAQS for PM, and provided findings, conclusions, and judgments on the strength, coherence, and plausibility of the evidence. The overall process for ISA development—which was relied upon in completing the 2019 PM ISA—including criteria used to identify relevant studies, aspects considered in judging the overall weight of evidence, and the framework for causality determinations, is described in the Preamble to the Integrated Science Assessments, which is available to the public on U.S. EPA’s ISA website (<https://www.epa.gov/isa>) and in the Health and Environmental Research Online (HERO) database (<https://hero.epa.gov/hero>).

This draft PM Supplement builds on the scientific evidence and causality determinations presented in the 2019 PM ISA. This draft PM Supplement is not intended to update the full multidisciplinary evidence base that resulted in the range of causality determinations in the 2019 PM ISA, but instead is a targeted assessment that puts the results of recent studies in the context of the scientific conclusions presented within the 2019 PM ISA. To accomplish this, the scope of this draft PM Supplement is based on evaluating and detailing the scientific information most relevant to informing the reconsideration of the 2020 PM NAAQS, and presenting it within the context of the scientific evidence and conclusions of the 2019 PM ISA.

It is important to note the welfare effects evaluated in the 2019 PM ISA and this draft PM Supplement do not include ecological effects because those are being considered as part of a separate NAAQS review focusing on the ecological effects of oxides of nitrogen, oxides of sulfur, and particulate matter.

Organization of the draft PM Supplement: The Executive Summary provides a concise synopsis of the key findings and conclusions for a broad range of audiences. Section 1 describes the rationale and scope of the draft PM Supplement with a focus on the types of studies considered for evaluation. Section 2 consists of a copy of the Integrated Synthesis Chapter (i.e., Chapter 1) of the 2019 PM ISA, which represents a comprehensive synthesis of key findings, and functions to orient the audience to the substantial scientific evidence base that already exists for the reconsideration of the PM NAAQS. Section 3 consists of an evaluation of recent health effects evidence and Section 4 of recent welfare effects evidence that falls within the scope of this draft PM Supplement as outlined in Section 1. Lastly, Section 5, represents a summary and conveys overall conclusions regarding the health and welfare effects evaluated in the draft PM Supplement. The final PM Supplement and the 2019 PM ISA, in conjunction with additional technical assessments, will provide the scientific basis for U.S. EPA’s reconsideration of the adequacy of the current primary and secondary standards for PM.

CHARGE FOR THE SCIENTIFIC REVIEW OF THE DRAFT SUPPLEMENT

The U.S. EPA has aimed to succinctly present and integrate recent policy-relevant scientific evidence with the extensive evidence-base detailed in the 2019 PM ISA. To guide the scientific review of the draft PM Supplement, U.S. EPA has identified the following areas for CASAC review and comment:

1. The Executive Summary is intended to provide a concise synopsis of the key findings and conclusions of the draft PM Supplement for a broad range of audiences.
 - a. Please comment on the clarity with which the Executive Summary communicates the key information from the draft PM Supplement.
 - b. Please provide recommendations on whether additional information should be added to the Executive Summary or information that should be left for discussion in the subsequent sections of the draft PM Supplement.
2. Section 1 consists of an introduction detailing why the draft PM Supplement is being developed along with the rationale and scope for the topics and studies considered.
 - a. Please comment on the clarity of the section, whether the scope is appropriate for the purpose of the draft PM Supplement, and whether additional information is needed to convey the purpose of the draft PM Supplement and the basis for the targeted evaluation conducted.
3. To ensure that recent studies are put in the context of the conclusions of the 2019 PM ISA the draft PM Supplement pulls in information verbatim from the 2019 PM ISA to orient the audience. Two ways this was done in the draft PM Supplement is through Section 2 which is the Integrated Synthesis Chapter (i.e., Chapter 1) of the 2019 PM ISA and leading off each health and welfare effects discussion in Section 3 and 4 with the Summary and Causality Determination from the 2019 PM ISA.
 - a. Please comment on this approach and whether any additional modifications to the structure of the document can be made to better integrate evidence evaluated in the draft PM Supplement with conclusions from the 2019 PM ISA.
4. Section 3 characterizes the recent health effects evidence that falls within the scope of the draft PM Supplement.
 - a. Please comment on the identification, evaluation, and characterization of the available scientific evidence in Section 3.
 - b. Please comment on whether the summary sections in Section 3 appropriately characterize recent evidence in the context of the conclusions of the 2019 PM ISA.
 - c. Please comment on whether there are any topics or studies that fall within the scope of the draft PM Supplement that should be added or receive additional discussion in Section 3 or any topics for which discussion should be shortened or removed from Section 3.
5. Section 4 characterizes the recent welfare effects evidence that falls within the scope of the draft PM Supplement.
 - a. Please comment on the identification, evaluation, and characterization of the available scientific evidence in Section 4.
 - b. Please comment on whether the summary section in Section 4 appropriately characterizes recent evidence in the context of the conclusions of the 2019 PM ISA.
 - c. Please comment on whether there are any topics or studies that fall within the scope of the draft PM Supplement that should be added or receive additional discussion in Section 4 or any topics for which discussion should be shortened or removed from Section 4.
6. The Summary and Conclusions section (Section 5) provides an overview of the evidence evaluated in the draft PM Supplement.
 - a. Please comment on the level of detail provided within this section and whether revisions should be made to further summarize recent evidence.

We look forward to discussing these issues with the CASAC Particulate Matter Review Panel at our upcoming meeting. Should you have any questions regarding the draft PM Supplement, please feel free to contact Mr. Jason Sacks (919-541-9729, sacks.jason@epa.gov).

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