

Current Health Effects Evidence Supports the 2020 Decision to Retain the PM NAAQS

Julie E. Goodman, Ph.D., DABT, FACE, ATS
September 14, 2022

The United States Environmental Protection Agency (US EPA) published the Supplement to the 2019 Integrated Science Assessment for Particulate Matter (US EPA, 2022) to evaluate science published after the literature cutoff date of the 2019 Particulate Matter (PM) Integrated Science Assessment (ISA) "that could either inform the adequacy of the current PM National Ambient Air Quality Standards (NAAQS) or address key scientific topics that evolved since the 2020 PM NAAQS review was completed" (US EPA, 2022). The 2019 ISA itself built on the conclusions from the 2009 ISA, incorporating new studies published between January 2009 and January 2018 (US EPA, 2019a).

Current Health Effects Evidence Supports the 2020 PM NAAQS. The health effects literature evaluated in the ISA and the ISA Supplement does not provide compelling evidence to support altering the existing PM NAAQS.

Uncertainties have not been meaningfully reduced, as studies reviewed in the Supplement use similar methods as those reviewed in the 2009 and 2019 ISA. With respect to the more traditional studies, new studies reviewed in the Supplement have similar methodological limitations as the studies reviewed in the 2009 and 2019 ISAs, and, thus, do not meaningfully reduce the uncertainty of evidence with respect to short- and long-term PM_{2.5} exposure and both mortality and cardiovascular effects. These limitations include exposure measurement error, confounding, reliance on irrelevant exposure windows, and unaccounted for indoor exposures.

US EPA has made efforts to consider accountability and causal inference studies to understand the impact of past regulations on air quality and health outcomes, but uncertainties remain. While accountability and causal inference studies can inform the relationship between PM_{2.5} exposure and health effects, they can also be subject to crucial methodological limitations that undermine the study findings, including several unique to these study designs and statistical approaches, and some common to most traditional PM epidemiology studies (*e.g.*, exposure measurement error). It is notable that US EPA focused more on accountability studies in the Supplement. While this line of evidence has not yet yielded definitive results, we and others continue to develop and apply these methods, and they will hopefully address some uncertainties inherent in more traditional epidemiology studies in the near future.

The ISA Supplement did not evaluate and integrate the evidence in a transparent, systematic, and unbiased manner. While the reasons for generating the 2021 draft ISA Supplement are clear, it is not evident why the studies were not fully incorporated with studies evaluated in the ISA, or reviewed according to the Preamble to the Integrated Science Assessments (US EPA, 2015). US EPA did not provide any information regarding the literature search strategy, the approach for reviewing individual studies, or an evaluation of study quality. As with the ISA itself, the process was not transparent, and there was insufficient detail to demonstrate that studies were identified and reviewed in a systematic and consistent manner, or integrated in a way that considered study quality and the coherence of results across studies within and across disciplines. These limitations of the Supplement also undermined the ability of the Clean Air Scientific Advisory Committee (CASAC) to provide a meaningful review of the 2021 draft ISA Supplement, do not allow for US EPA's evaluation to be reproduced by others, and may have led to biased conclusions.

Neither US EPA nor the current CASAC has sufficiently addressed the issues raised in the CASAC review of the 2019 ISA. CASAC conducted an extremely thorough evaluation of the 2019 draft ISA (US EPA, 2019b). Totalling 205 pages of committee and individual member comments, the review included overarching themes as well as specific critiques of studies and US EPA's evaluation of them in great detail. US EPA has not, to my knowledge, addressed each point raised by CASAC. The more recent CASAC review of the ISA Supplement also did not include a discussion of all of the important points raised by earlier CASAC committee.

Funding. These comments were prepared with funding from the American Petroleum Institute, but the conclusions are based on Gradient's independent review and evaluation.

References

US EPA. 2015. "Preamble to the Integrated Science Assessments." EPA/600/R-15/067, November. Accessed on December 1, 2015 at <http://www.epa.gov/isa>.

US EPA. 2019a. "Integrated Science Assessment for Particulate Matter (Final)." EPA/600/R-19/188. 1967p., December. Accessed on March 17, 2020 at <https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=347534>.

US EPA. 2019b. Letter Report to A. Wheeler (US EPA) re: CASAC Review of the EPA's Integrated Science Assessment for Particulate Matter (External Review Draft - October 2018). Clean Air Scientific Advisory Committee (CASAC). EPA-CASAC-19-002. 205p., April 11.

US EPA. 2022. "Supplement to the 2019 Integrated Science Assessment for Particulate Matter (Final)." Office of Research and Development, Center for Public Health and Environmental Assessment. EPA/600/R-22/028. 328p., May. Accessed on September 9, 2022 at <https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=354490>.