

**BEFORE THE HONORABLE JANE NISHIDA, ACTING ADMINISTRATOR UNITED
STATES ENVIRONMENTAL PROTECTION AGENCY**

IN RE PETITION FOR
RECONSIDERATION OF REVIEW
OF THE NATIONAL AMBIENT
AIR QUALITY STANDARDS
FOR OZONE, 85 FED. REG.
87,256 (Dec. 31, 2020)

Submitted by:

The States of New York, California, Connecticut, Illinois,
Maryland, Minnesota, New Jersey, Oregon, Rhode Island,
Vermont, Washington, and Wisconsin; the Commonwealths of
Massachusetts, Pennsylvania, and Virginia; the District of
Columbia; and the City of New York

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INTRODUCTION

Pursuant to Clean Air Act Section 307(d), and for the reasons set forth below, the States of New York, California, Connecticut, Illinois, Maryland, Minnesota, New Jersey, Oregon, Rhode Island, Vermont, Washington, and Wisconsin; the Commonwealths of Massachusetts, Pennsylvania, and Virginia; the District of Columbia; and the City of New York (collectively, “State Petitioners”) hereby petition the U.S. Environmental Protection Agency (EPA) for reconsideration of its final action not to strengthen the primary and secondary National Ambient Air Quality Standards (NAAQS) for ozone. This final action, titled “Review of the Ozone National Ambient Air Quality Standards,” is published in the Federal Register at 85 Fed. Reg. 87,256 (Dec. 31, 2020) (“Final Rule”). In the Final Rule, EPA decided that: (1) the current primary standard should be retained without revision because it is sufficient to protect public health with an adequate margin of safety; and (2) the current secondary standard should be retained without revision because it is sufficient to protect the public welfare. EPA’s decision not to strengthen the ozone NAAQS fails to protect the public health and welfare from harm as required under the Clean Air Act. Accordingly, State Petitioners filed a petition for review of EPA’s Final Rule on January 19, 2021,¹ seeking a determination that this final action is unlawful, arbitrary and capricious, and therefore must be vacated.

Reconsideration of the Final Rule is also warranted. As discussed below, State Petitioners have raised objections that arose after the end of the comment period and that concern issues of central relevance to the adoption of the Final Rule. 42 U.S.C. § 7607(d)(7)(B). In addition, State

¹ *State of New York, et al. v. EPA, et al.*, Case No. 21-1028 (D.C. Cir.).

Petitioners request that EPA grant discretionary reconsideration of the Final Rule to engage in a reasoned review of all of the evidence now before the agency.

First, EPA must grant reconsideration in light of new evidence from a recent study on the association between long-term exposure to ozone pollution and hospital admissions among Medicare participants.² *See* Attachment A. The study demonstrates that ozone poses significant risks to the cardiovascular and respiratory health of elderly people within the United States—a population that is already considered at-risk.³ Because the grounds for these objections arose after the close of the public comment period and are of central relevance to EPA’s decision to retain the existing standards for ozone, EPA must reopen public comment and reconsider the Final Rule. 42 U.S.C. § 7607(d)(7)(B). EPA must impart all of the procedural rights that “would have been afforded had the information been available at the time the rule was proposed.” *Id.*

Second, EPA should grant reconsideration to conduct a complete and meaningful review of information in certain epidemiologic studies about respiratory effects, cardiovascular effects, and mortality associated with ozone exposure. After the close of public comments, EPA “provisionally considered” an unspecified number of the many studies cited by State Petitioners in their comment letter dated October 1, 2020. *See* 85 Fed. Reg. at 87,262. Based on this cursory, “provisional consideration,” EPA determined that information contained in the studies did not warrant reopening the review of the air quality criteria to enable EPA, the Clean Air Scientific Advisory Committee (CASAC), and the public to consider the studies further. *Id.*

² Yazdi, Mahdiah D., et al. *Long-Term Association of Air Pollution and Hospital Admissions Among Medicare Participants Using a Doubly Robust Additive Model*, *Circulation*. 2021;143:00–00. DOI: 10.1161/CIRCULATIONAHA.120.050252.

³ *Id.*

EPA’s determination—first announced in the Final Rule—ignored important new evidence demonstrating a need for more stringent ozone standards to protect public health and welfare.

Third, EPA should grant reconsideration to consider recommendations from the Government Accountability Office (GAO) in its recent report titled, *AIR POLLUTION Opportunities to Better Sustain and Modernize the National Air Quality Monitoring System* (November 2020).⁴ See Attachment B. The report, which potentially casts doubt on the sufficiency of state ozone data used by EPA in its exposure and risk analysis, further calls into question EPA’s decision that the existing primary standard of 70 ppb protects public health with an adequate margin of safety.

STANDARD FOR RECONSIDERATION

EPA must convene a reconsideration proceeding if a person raising an objection shows: (1) it was “impracticable” to raise the objection during the public comment period, or grounds for the objection arose after the public comment period; and (2) the objection “is of central relevance to the outcome of the rule.” 42 U.S.C. § 7607(d)(7)(B). An objection is “of central relevance” if it provides “substantial support for the argument that the regulation should be revised.” *Coal. for Responsible Regulation, Inc. v. EPA*, 684 F.3d 102, 125 (D.C. Cir. 2012). The petitioner must show “the errors identified were so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made.” *Union Oil Co. of Calif. v. EPA*, 821 F.2d 678, 683 (D.C. Cir. 1987). “If an objection fits within this exception, the consequences are

⁴ See GAO Report to Congressional Requesters, *AIR POLLUTION Opportunities to Better Sustain and Modernize the National Air Quality Monitoring System* (Nov. 2020), available at <https://www.gao.gov/products/GAO-21-38> (hereinafter “GAO Report”).

weighty: EPA must grant reconsideration and conduct a new, full-dress, notice-and-comment rulemaking.” *Alon Ref. Krotz Springs, Inc. v. EPA*, 936 F.3d 628, 647 (D.C. Cir. 2019). Where the standards for mandatory reconsideration are not met, EPA may still reconsider agency actions at its discretion.

ARGUMENT

I. EPA MUST RECONSIDER THE FINAL RULE IN LIGHT OF A NEW STUDY DEMONSTRATING SIGNIFICANT HEALTH RISKS TO ELDERLY PEOPLE IN THE UNITED STATES FROM LONG-TERM EXPOSURE TO OZONE.

The NAAQS must be based on air quality criteria that “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.” 42 U.S.C. 7408(a)(2). Furthermore, the primary standard must be set at a level that “allowing an adequate margin of safety, [is] requisite to protect the public health.” 42 U.S.C. § 7409(b)(1). The primary standard must protect not only average healthy persons, but also sensitive or at-risk populations and groups, and must be designed to provide these groups with an adequate margin of safety “from the pollutant’s adverse effects – not just known adverse effects, but those of scientific uncertainty or that research has not yet uncovered.” *Am. Lung Ass’n*, 134 F.3d 388, 389 (D.C. Cir. 1998). Thus, the purpose of the “adequate margin of safety” is to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement.

A new study by Yazdi, et al., titled *Long-Term Association of Air Pollution and Hospital Admissions Among Medicare Participants Using a Doubly Robust Additive Model*, demonstrates that the existing primary ozone level of 70 ppb is not sufficiently protective of the elderly population within the United States—a group that is already considered sensitive or at-risk—

with an adequate margin of safety.⁵ Furthermore, the study suggests that additional standards for *long-term* exposure to ozone, which are not currently in place, may be necessary to protect public health within the elderly population.⁶ The existence of this new evidence necessitates reconsideration of EPA's decision not to strengthen the existing NAAQS for ozone.

A. Petitioners Were Unable to Raise These Objections During the Public Comment Period Because This Study Had Not Yet Been Published.

The study by Yazdi, et al., was published on February 22, 2021 in the American Heart Association journal *Circulation*, after the close of the public comment period. State Petitioners were unable to raise these concerns during the public comment period because the study had not yet been released to the public. Thus, the grounds for State Petitioners' objections arose after the close of the public comment period.

B. The Identification of Significant New Threats to an At-Risk Population is of Central Relevance to EPA's Unlawful Decision to Retain the Existing NAAQS.

Given the new evidence revealed in this study about the significant negative impacts of long-term ozone exposure on the cardiovascular and respiratory health of elderly people in the United States, EPA must reconsider its decision to retain the existing NAAQS for ozone.

In addition to its overall conclusion that ozone is associated with an increased risk for four different cardiovascular and respiratory outcomes, the study found an association between tropospheric ozone exposure and hospital admissions for pneumonia among Medicare participants.⁷ These adverse effects were based on exposure to levels below the current standard

⁵ Yazdi, et al., *supra* note 2.

⁶ *Id.*

⁷ *Id.* at 7.

of 70 ppb.⁸ Thus, this finding is of central relevance to EPA's contention in the final rule that the current level of 70 ppb protects public health with an adequate margin of safety.

The study also concluded that a standard that protects public health from long-term ozone exposure may be necessary given the effect of long-term ozone on respiratory outcomes.⁹ Attainment with the current standard is determined based on the 3-year average of the fourth-highest daily maximum 8-hour average ozone concentration. This fails to account for or protect against the effects of long-term exposure to sustained levels that are below the 8-hour threshold of 70 ppb. By calling into question whether an 8-hour standard protects public health with an adequate margin of safety over the long term, the study is of central relevance to EPA's determination that the current primary standard adequately protects public health under the Clean Air Act.

II. EPA SHOULD RECONSIDER ITS DECISION IN THE FINAL RULE NOT TO REOPEN THE AIR QUALITY REVIEW TO ENABLE THE AGENCY, CASAC, AND THE PUBLIC TO FULLY CONSIDER RECENT EPIDEMIOLOGIC STUDIES LINKING OZONE EXPOSURE TO NEGATIVE HEALTH EFFECTS.

Health effects literature that either became available after the arbitrarily truncated Integrated Science Assessment cut-off date, or that was available but not reviewed in the Science Assessment and Policy Assessment, demonstrates the need for a primary ozone standard below 70 ppb to protect public health with an adequate margin of safety. State Petitioners brought this literature to EPA's attention in their comments on EPA's August 14, 2020 Notice of Proposed Rulemaking.¹⁰ Specifically, State Petitioners commented that sixteen recent epidemiologic

⁸ *Id.* at 2.

⁹ *Id.* at 11.

¹⁰ Letter from Attorneys General of New York, California, Connecticut, the District of Columbia, Illinois, Maryland, Massachusetts, New Jersey, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and Wisconsin, and the Corporation Counsel of the City of New York to EPA Docket Center (Oct. 2, 2020); posted Oct. 2, 2020 at:

studies examining respiratory, cardiovascular, and mortality endpoints that have considered co-pollutants have reported significant results for ozone impacts.¹¹

Rather than fully considering these additional studies in adopting the Final Rule or “reopening the review of the air quality criteria to enable the EPA, the CASAC, and the public to consider them further,” 85 Fed. Reg. at 87,262, EPA decided to give the studies “provisional consideration” in this review. In the agency’s words, this meant it failed to accord them “in-depth critical review” on par with the studies that it considered in its Integrated Science Assessment. 85 Fed. Reg. at 87,262. Based on this abbreviated review, EPA concluded that the studies “do not materially change any of the broad scientific conclusions regarding the health and welfare effects of [ozone] in the ambient air made in the air quality criteria” and therefore that “reopening the air quality criteria review would not be warranted.” 85 Fed. Reg. 87,262-63. Properly considered, however, the epidemiologic evidence of respiratory and cardiovascular effects and mortality at exposure levels allowed by the current primary standard demonstrates that the current standard is insufficiently protective, and therefore EPA should have reopened review of the air quality criteria to allow for full, not “provisional,” consideration.¹²

For example, one study by Zu, et al., found that a 10 ppb increase in average daily 8-hour maximum ozone concentrations, starting at 40 ppb, increased the risk for asthma hospitalization by 4.7% for school aged children and 1.8% among young adults.¹³ Another recent epidemiologic

<https://www.regulations.gov/comment/EPA-HQ-OAR-2018-0279-0435>. The States’ Original Comments are hereby incorporated by reference (hereinafter, States’ Comments).

¹¹ *Id.* at 26-30.

¹² *Id.* 26-30.

¹³ Zu K, Liu X, Shi L, et al. *Concentration-response of short-term ozone exposure and hospital admissions for asthma in Texas. Environment International.* 2017;104:139-145. doi:10.1016/j.envint.2017.04.006; *See also* States’ Comments at 26.

study by Raza, et al. links short-term ozone exposure to cardiovascular and respiratory mortality, especially in individuals previously hospitalized for heart attacks.¹⁴ EPA failed to address this study's conclusion that the existing standard fails to protect individuals with a history of heart attacks—a sensitive, at-risk population—with an adequate margin of safety. As a third example, EPA failed to discuss a recent study by Lim, et al. examining the link between long-term ozone exposure and mortality.¹⁵ Despite the study's conclusions that long-term exposure to ozone is associated with increased risk for multiple causes of mortality, EPA chose not to fully consider this study in relation to the adequacy of the existing standard.¹⁶

Evidence from these studies, along with the remaining thirteen studies that State Petitioners brought to EPA's attention during the public comment period, demonstrates that the current 70 ppb primary standard will likely produce adverse health effects in a sizeable portion of the United States population.¹⁷ This in turn indicates that the existing standard fails to protect the public health—particularly that of sensitive or at-risk groups and populations—with an adequate margin of safety. Had EPA fully considered the studies submitted during the public comment period, there is a substantial likelihood that EPA would have revised the primary ozone standard to be more protective of public health. At a minimum, EPA's decision in the Final Rule not to reopen the review of the air quality criteria to enable EPA, the CASAC, and the public to

¹⁴ Raza A, Dahlquist M, Lind T, Ljungman PLS. *Susceptibility to short-term ozone exposure and cardiovascular and respiratory mortality by previous hospitalizations*. Environ Health. 2018;17(1):37. Published 2018 Apr 13. doi:10.1186/s12940-018-0384-z; *See also* States' Comments at 27-28.

¹⁵ Lim CC, Hayes RB, Ahn J, et al. *Long-Term Exposure to Ozone and Cause-Specific Mortality Risk in the United States*. Am J Respir Crit Care Med. 2019;200(8): 1022- 1031. doi:10.1164/rccm.201806-1161 OC; *See also* States' Comments at 28, 29.

¹⁶ *Id.*

¹⁷ *See* States' Comments at 26-30.

fully consider the studies was incorrect. EPA should remedy these errors now by exercising its discretion to convene reconsideration proceedings to engage in a reasoned review of these studies.

III. EPA SHOULD RECONSIDER THE FINAL RULE IN LIGHT OF A NEW REPORT FROM THE GOVERNMENT ACCOUNTABILITY OFFICE SUGGESTING THAT OZONE DATA RELIED UPON BY EPA IS INCOMPLETE.

EPA has not considered recommendations from a recent report by the Government Accountability Office, *AIR POLLUTION Opportunities to Better Sustain and Modernize the National Air Quality Monitoring System* (November 2020), addressing deficiencies in air monitoring data across the United States. The GAO Report, dated November 2020, was officially released to the public on December 7, 2020, after the comment period for the proposed rule closed.¹⁸ In light of certain findings in the report, including the existence of gaps and quality assurance issues in ozone air monitoring data, EPA should have addressed concerns about the completeness of its ozone data in its Final Rule. EPA should grant reconsideration now to address: (a) whether the regional data it relied upon in conducting its exposure and risk analysis was complete, and (b) whether problems with data quality introduced a level of uncertainty into the exposure and risk analysis that warrants a larger margin of safety for the primary standard.

The GAO Report finds, among other things, that the national ambient air quality monitoring system overseen by EPA faces numerous challenges related to aging infrastructure.¹⁹ According to EPA officials interviewed by GAO, aging air monitoring equipment creates vulnerabilities that directly affect the quality of the data.²⁰ This has led to several states

¹⁸ GAO Report, *supra* note 3.

¹⁹ *Id.* at 28.

²⁰ *Id.*

invalidating their ozone data for 2015 and 2016—two of the years EPA relied on for the exposure and risk analysis in the ozone NAAQS review. In one example, a state agency reported that inadequate air conditioning in its air monitoring equipment shelters caused a week’s worth of ozone data to be compromised.²¹ Furthermore, the report suggests that regions where GAO conducted semi-structured interviews and reported deficiencies in data collection correspond to specific regions targeted by EPA’s exposure and risk analysis.²² For example, GAO interviewed officials in EPA’s Region 6 offices in Dallas, which is also one of the eight metropolitan regions selected by EPA for inclusion in the exposure and risk analysis for ozone. In light of the fact that EPA officials in Dallas were interviewed, EPA should evaluate whether the monitoring data relied upon from that area was one of the problematic areas implicated by the GAO report.

All of these ozone-related monitoring concerns raised in the GAO Report potentially cast doubt on the accuracy of ozone data used by EPA in the exposure and risk analysis, which EPA ultimately used to “bridge the gap between the scientific assessments of the Integrated Science Assessment and the judgments required of the Administrator in his decisions on the current standard.” 85 Fed. Reg. 87,264. By EPA’s own account, the quantitative exposure and risk analyses it engages in are necessary to inform the review process. Therefore, EPA should evaluate the data gaps and monitoring issues identified in the GAO Report and, if warranted, reconsider its decision that the existing primary standard protect public health with an adequate margin of safety to satisfy the Clean Air Act’s mandate.

²¹ *Id.* at 30.

²² *Id.* at Appendix II: Objectives, Scope, and Methodology.

RELIEF REQUESTED

For the foregoing reasons, State Petitioners respectfully request that the Administrator immediately convene proceedings for reconsideration of the final action pursuant to 42 U.S.C. § 7607(d)(7)(B).

Dated: March 1, 2021

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