

IN THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

National Ambient Air Quality Standards for Ozone:)
Proposed Response to Remand) Docket # A-95-58
66 Fed. Reg. 57268 (November 14, 2001))
)

COMMENTS OF AMERICAN LUNG ASSOCIATION

American Lung Association submits these comments on EPA's proposed remand decision on the 1997 national ambient air quality standards for ozone, in which the agency addresses alleged beneficial effects of tropospheric ozone. We urge the agency to conclude this remand without further delay by deciding, based on the 1997 rulemaking record, not to weaken the 1997 NAAQS.

I. EPA MUST NOT WEAKEN THE 1997 NAAQS BASED ON ALLEGED BENEFICIAL EFFECTS OF TROPOSPHERIC OZONE.

A. This Remand Must Be Based On the 1997 Rulemaking Record.

American Lung Association supports EPA's decision¹ to base this remand on the rulemaking record that was before EPA when the agency promulgated the July 1997 ozone NAAQS. This proceeding is, after all, a remand of a decision based on that very record. Moreover, to open the proceeding to consideration of new evidence on alleged beneficial effects of tropospheric ozone would, to avoid an arbitrary and capricious approach that treats some effects differently from others,² require that the remand also be opened to consideration of new evidence on respiratory effects. The result would be to relegate the 1997 ozone NAAQS to the next review cycle, thereby effectively erasing the previous cycle that culminated in that NAAQS. That result would contravene Clean Air Act § 109(d)'s requirement that there be review cycles at five-year intervals,³ as well as the fundamental mandate of the Act's NAAQS provisions, which provide for a precautionary approach based on prevention of adverse health effects, not an indefinite wait for -- and debate about -- new studies.⁴

¹ 66 Fed. Reg. 57273, 57286-88 (Nov. 14, 2001).

² See American Trucking Assns. v. USEPA, 175 F.3d 1027, 1053 (D.C. Cir. 1999) (EPA must "us[e] the same approach" to assess both harmful and beneficial effects).

³ See, e.g., 57 Fed. Reg. 35546 (Aug. 10, 1992).

⁴ See, e.g., H.R. Rep. 294, 95th Cong., 1st Sess. 43-51 (1977) ("1977 House Report").

B. In Evaluating Data On Alleged Benefits of Tropospheric Ozone, EPA Must Use the Same Approach As For Adverse Effects.

In reviewing the 1997 record, EPA must approach evidence evenhandedly: as the D.C. Circuit held, the agency must "us[e] the same approach" to assess both harmful and beneficial effects.⁵ This principle is significant, especially because EPA has never concluded that any allegation or "evidence," regardless of its preliminary or speculative nature or degree of uncertainty, must be factored into NAAQS decisionmaking. To the contrary, EPA has in the past rejected as insufficient evidence proffered by both those seeking laxer NAAQS and those seeking more protective NAAQS -- and has been upheld by the D.C. Circuit for doing so.⁶

The need for evenhandedness, and for requiring that scientific evidence meet minimum criteria of reliability and adequacy, is especially compelling here. For the first time, EPA is considering alleged human health benefits of not reducing ambient levels of ozone. Those who allege these benefits apparently want EPA to set a NAAQS that allows the adverse respiratory effects of ozone to be more severe or widespread than allowed by the 1997 NAAQS. Longstanding D.C. Circuit precedent requires NAAQS to protect against such adverse effects.⁷ Assuming arguendo that EPA nonetheless has authority to promulgate a NAAQS that allows such effects to occur, the scientific basis applied by EPA to tropospheric ozone's alleged benefits must be just as rigorous as that applied to ozone's adverse respiratory effects. To the extent that data considered regarding alleged beneficial effects of tropospheric ozone is inadequate, reliance on such data in setting NAAQS could lead to excessively high levels of ozone and cause needless exposure and human suffering.

⁵ See n. 2, supra.

⁶ See, e.g., American Petroleum Institute v. Costle, 665 F.2d 1176, 1186 (D.C. Cir. 1981) (court upheld EPA's 1979 ozone NAAQS, even though the agency had declined one petitioner's request for weaker NAAQS; responding to a study proffered by that petitioner, EPA had cited "several grounds which undercut the reliability of [the study's] ... conclusions"); id. 1186-87 (court upheld EPA's 1979 ozone NAAQS, even though the agency had declined another petitioner's request for stronger NAAQS; court noted *inter alia* "uncertain information" concerning photochemical oxidants that EPA had declined to regulate, and "inconclusive studies indicating very low ozone damage thresholds"). See also 1977 House Report at 51 (although CAA is precautionary, it is not "a license for 'crystal ball' speculation;" "The Administrator's judgment must, of course, remain subject to restraints of reasoned decisionmaking.").

⁷ See, e.g., American Lung Assn. v. EPA, 134 F.3d 388, 389 (D.C. Cir. 1998); Lead Industries Assn. v. EPA, 647 F.2d 1130, 1153 (D.C. Cir. 1980).

C. The Record Data Purporting to Quantify Tropospheric Ozone Benefits Fails to Meet the Minimum Standards of Reliability and Adequacy Applied by EPA to Data on Adverse Respiratory Effects.

Those who allege benefits from tropospheric ozone rely on quantification efforts from the 1997 rulemaking record that fail to meet minimum standards of reliability and scientific adequacy. One tropospheric ozone benefits quantification calculation was presented orally by U.S. Department of Energy staff,⁸ and was never published or peer reviewed either internally at EPA or externally. The other quantification analysis of tropospheric ozone benefits is a draft that was never published.⁹ We submit that irrespective of the substantive limitations discussed in the Federal Register notice,¹⁰ these data do not achieve a level of scientific rigor that approaches the data relied on by EPA to assess the adverse effects of ozone. The only other quantification effort (Lutter and Wolz)¹¹ was a study by two economic analysts that relied upon the assumptions in the DOE analysis, and its results were described by the authors as "preliminary analysis." In short, these data fall below minimum standards of reliability and scientific adequacy -- including the standards met by the respiratory effects evidence EPA accepted, as well as by other respiratory effects evidence the agency rejected as too uncertain.

A large body of evidence in the record -- described in detail in the July 1997 decision, the December 1996 proposal, and the accompanying Staff Paper and Criteria Document -- supports the proposition that lowering the ambient level of ozone will reduce acute adverse health effects in humans, particularly among sensitive populations. Epidemiological studies link increases in ozone measurements to increases in hospitalization and emergency room visits. Field studies of children in summer camp demonstrate that increases in ambient levels of ozone cause reductions in lung function among some children after prolonged exposure. Chamber studies of human subjects have established that exposure to levels of ozone commonly found across the nation can cause respiratory symptoms and reduction in lung function. Moreover, other effects -- described by some as unquantified -- in reality have been demonstrated by chamber studies at quantified doses of ozone.¹² In each case -- the epidemiological, field and chamber studies -- the effects were documented at levels allowed by the 1979 ozone NAAQS. Finally, there are available a

⁸ See 66 Fed. Reg. 57286/1.

⁹ Cupitt, L.T., Draft memorandum, "Calculations of the Impact of Tropospheric Ozone Changes on UV-B Flux and Potential Skin Cancers" (1994).

¹⁰ See 66 Fed. Reg. 57284-86.

¹¹ Lutter, R. and Wolz, C., "UV-B Screening by Tropospheric Ozone: Implications for the National Ambient Air Quality Standard," 31 *Envir. Sci. Technol.* 142A-146A (1997).

¹² These effects include increases in bronchial responsiveness, decrements in alveolar macrophage function, and ozone-induced markers of inflammation and cell damage. 61 Fed. Reg. 65720-21 (Dec. 13, 1996). While EPA questioned its ability to develop quantitative risk estimates of these effects, 62 Fed. Reg. 38868/1 (July 18, 1997), the occurrence of the effects themselves is solidly documented by peer-reviewed scientific chamber studies at quantified ozone doses over quantified time periods. 61 Fed. Reg. 65720-21.

large and extensive body of ambient ozone measurements that enable investigation of various levels of ozone and various adverse health outcomes.

The data cited in support of the alleged relationship between tropospheric ozone levels and adverse health outcomes from UV-B exposure are far more limited. The hypothesized benefits of tropospheric ozone rest primarily on the reduction of long-term exposure to UV-B. However, there is a lack of credible evidence indicating that a higher or lower ozone NAAQS will have any impact on long term levels of UV-B exposure in a given geographic area. Unlike the extensive monitoring network that exists for ambient levels of ozone, there exists no routine measurements for the vertical "mixing zone" that is central to estimating the amount of UV-B protection provided by changes in ozone NAAQS. There exists no system that routinely measures the correlation between tropospheric ozone levels and UV-B levels.

There also does not currently exist a credible methodology for determining if there is a benefit from maintaining a given level of tropospheric ozone, or the magnitude of such benefit. For example, EPA identifies a substantial number of unsupportable biases in the analyses in the record that attempt to quantify the alleged benefits of tropospheric ozone -- biases that "could well be on the order of a factor of 10."¹³ In addition, more than half the benefits estimated by DOE staff and Lutter and Walz are attributed to increased incidence of melanoma and cataracts caused by a lowering of tropospheric ozone levels. According to EPA, the alleged linkages between ozone NAAQS and melanoma or cataracts are even less corroborated than the alleged linkage with nonmelanoma skin cancer.¹⁴

EPA has repeatedly (in 1979, 1993 and 1997) rejected calls for ozone NAAQS more stringent than the ones chosen by the agency, basing such rejection largely on the agency's claim that the science was too uncertain or preliminary to warrant tighter NAAQS. In particular, EPA's 1997 ozone NAAQS decision rejected requests by many commenters that the NAAQS be set at 0.07 ppm rather than 0.08 ppm, basing such rejection on alleged uncertainties in the evidence. For example, American Lung Association's 1997 ozone NAAQS rulemaking comments had supported a 0.07 ppm NAAQS, citing *inter alia* evidence of both chronic ozone respiratory effects as well as of association between ozone and mortality.¹⁵ Yet EPA, citing uncertainty in this evidence, declined this request and set the NAAQS at 0.08 ppm instead.¹⁶ Given that EPA rejected this credible respiratory effects evidence, the agency cannot lawfully or rationally accept the far more speculative "evidence" regarding the alleged beneficial effects of tropospheric ozone -- evidence that also relies on long-term exposure estimates (indeed, estimates with far

¹³ See 66 Fed. Reg. 57284-86.

¹⁴ See 66 Fed. Reg. 57286 n.53.

¹⁵ Comments of the American Lung Association to the U.S. Environmental Protection Agency Regarding "Proposed Decision: National Ambient Air Quality Standards for Ozone" (March 12, 1997), Document # IV-D-2339.

¹⁶ See 66 Fed. Reg. 57275, 57287.

greater levels of uncertainty). Such a course would violate the agency's obligation to apply the "the same approach" to treatment of beneficial and adverse ozone effects.¹⁷

In short, American Lung Association supports EPA's decision to reject weakening of the 0.08 ppm 1997 NAAQS based on alleged benefits of tropospheric ozone.

II. EPA MUST CONCLUDE THIS REMAND EXPEDITIOUSLY.

Over four and a half years after EPA promulgated a new ozone NAAQS based on compelling science showing the need for enhanced public health protection, that standard still is not being implemented. To the contrary, EPA has delayed this remand for no good reason for nearly three years, and apparently plans to further delay it a year past the end of the comment period. EPA should desist from its unlawful and unreasonable delay, and move expeditiously to finalize this remand.

Nearly three years ago, in May 1999, the D.C. Circuit issued its remand concerning the alleged beneficial effects of tropospheric ozone. EPA delayed over a year and a half -- until January 2001 -- before posting on its website a draft proposal responding to the remand. Then, inexplicably and without any possible legitimate justification, EPA delayed another ten months before publishing substantially the same document in the Federal Register as its proposed remand response. Moreover, the agency has indicated it plans to wait another year -- until 2003 -- to finalize the remand response.

This delay contravenes the Act's strong mandate that NAAQS be adequate to protect public health with an adequate margin of safety. In particular, the delay leaves millions of Americans exposed to ozone pollution that EPA itself has found causes asthma attacks, hospitalizations, and other significant adverse health effects in children, asthmatics and others. Likewise, that delay relegates these victims of excessive pollution to reliance on the 1979 NAAQS, which EPA has found fails to offer adequate protection against these effects.

EPA's delay also violates the Act's mandate that NAAQS be updated at no later than five-year intervals to ensure their continued adequacy.¹⁸ Nearly nine years after EPA's 1993 ozone NAAQS decision, it is high time for EPA to conclude the present remand, and bring this review cycle -- the first one since 1993 -- to a conclusion. Indeed, the delay proposed by EPA is so egregious that it will unlawfully push the conclusion of this remand past the deadline for the next review cycle -- i.e., past July 18, 2002, which is five years after the July 18, 1997 promulgation of the NAAQS addressed in this remand.

It also bears emphasis that the Clean Air Act allows only fifteen months for the entire process of regulating a pollutant: one year from listing to issue both criteria and proposed

¹⁷ See n.2, supra.

¹⁸ CAA § 109(d).

standards,¹⁹ and an additional three months to finalize standards.²⁰ Indefensibly, EPA has already taken double that entire period in this remand, even though the remand calls on the agency only to issue a supplemental decision on a pollutant with which it has been familiar for over thirty years, based on a record with which it has been familiar for over four years. EPA must not continue this dilatory approach. To the contrary, given Congress's intent that an entire NAAQS be finalized within three months of proposal, there can be no basis for EPA to delay its final remand response more than that amount of time past the end of the comment period. See also 62 Fed. Reg. 38858/2, 38654/3 (July 18, 1997) (four months after the March 12, 1997 close of the simultaneous comment periods for ozone and particulate matter, EPA promulgated the entire 1997 ozone NAAQS and the entire 1997 particulate matter NAAQS).

CONCLUSION

EPA itself recognizes that further delay of this rulemaking is "inappropriate" in light of the adverse health effects of ozone and the absence of credible evidence on the alleged beneficial effects of tropospheric ozone.²¹ The agency must act on that recognition and conclude this remand without further delay. It must do so by deciding, based on the record of the 1997 ozone NAAQS rulemaking, not to weaken the 1997 ozone NAAQS.

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Respectfully submitted,

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¹⁹ CAA §§ 108(a)(2) and 109(a)(2).

²⁰ CAA § 109(a)(1)(B).

²¹ 66 Fed. Reg. 57288.