



October 1, 2020

The Honorable Andrew Wheeler, Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Submitted via Regulations.gov

RE: Comments - Docket ID No. EPA-HQ-OAR-2018-0279: Review of the Ozone National Ambient Air Quality Standards

Dear Administrator Wheeler:

As national organizations representing medical societies and medical, nursing, public health, health care and patient advocacy organizations, we write to provide comments to the U.S. Environmental Protection Agency on the proposed Ozone National Ambient Air Quality Standards. Our organizations are deeply concerned by the health threats from breathing ground-level ozone pollution and have a strong interest in standards that adequately protect our members, patients and communities. Strong ozone standards that reflect the current science are critical for ensuring that everyone has equitable access to clean air. Climate change is leading to higher ozone levels in many communities. Enforcing science-based ozone standards will protect from the direct harm ozone pollution causes and further serve to be part of climate solutions.

We strongly oppose EPA's proposal to retain the primary standard for ozone. Scientific evidence gained since EPA's last ozone NAAQS review shows that ozone exposure is more dangerous than previously understood. The best available science shows that exposure to ozone causes adverse health outcomes at levels far below the current standard, meaning that the health of too many Americans is being compromised by breathing levels of ozone pollution that are currently legal. These public health impacts are wide-reaching and significant and disproportionately affect vulnerable populations.

Without question, the nation needs stronger limits on ozone pollution to protect public health. We urge you to reconsider your proposal and **set the primary standard at no higher than 60 parts per billion (ppb)**. The Clean Air Act requires the standard to protect the health of the public with an adequate margin of safety, including sensitive subpopulations.

We also oppose any weakening of the form of the standard. Any changes to the form that would allow for additional ozone exceedance days without violating the standard would allow communities to experience additional unhealthy air days without cleanup.

EPA's process for this review was inadequate.

As a preliminary, fundamental matter, the process that EPA used to arrive at its proposal to retain the current, outdated ozone standard was deeply flawed and all but assured that the proposal would fail to live up to required legal and scientific standards.

In previous reviews going back decades, the agency convened a panel of expert scientists to help review the recent research and recommend appropriate pollution limits. Such a review panel added breadth, depth and diversity of scientific expertise. For this ozone review, EPA failed to appoint such a panel, a step that cost EPA's Clean Air Scientific Advisory Committee (CASAC) and EPA essential expertise to review the complex and technical scientific literature. EPA offered flawed arguments for ending the practice: that under the Clean Air Act, only CASAC can advise EPA, and that having no expert advisory panel would expedite the review. Both arguments are specious. The review panels have always provided expert assistance only to CASAC, which CASAC then used to advise EPA. Expert review panels have worked closely with CASAC to assist in an accurate and thorough scientific review following the adopted schedule.

EPA's substitution for the expert ozone review panel was thoroughly inadequate. The agency appointed a panel that could only answer specific questions in writing rather than meet with CASAC to offer recommendations.

EPA also rushed to complete its review on an unreasonably tight timeline that did not allow for sufficient consideration of the scientific evidence. EPA chose to wait to initiate this review until only two years were left in the five-year review cycle allowed under the Clean Air Act. A process that typically takes years to complete was done in a matter of months.

Further, EPA developed and published its two critical documents for the NAAQS process, the Integrated Science Assessment and the Policy Assessment, simultaneously and did not allow adequate review from CASAC. Previous Administrations routinely recognized the necessity of having a finalized Integrated Science Assessment in hand to inform answering policy-relevant questions. The process under which the current Policy Assessment was developed did not benefit from having a fully reviewed and confirmed Science Assessment available for that work. While EPA should certainly work to meet the five-year review timeframe for the NAAQS established by law, starting the process late and then skipping steps to rush the timeframe is clearly not an adequate option to protect public health. This proposal falls short of the rigorous scientific review that the Clean Air Act requires.

Former CASAC and CASAC Ozone Review Panel members¹ raised these and other significant concerns in a letter to Administrator Wheeler, reaching conclusions that buttress our organizations' argument that this proposal was flawed from its inception, and must be reconsidered to address these serious procedural and other deficiencies:

¹ Authors of the letter include members of the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel from the 2009 to 2015 review of the primary and secondary National Ambient Air Quality Standards (NAAQS) for ozone, as well as two former chairs and ten former members of the chartered CASAC.

Changes in the NAAQS review process since 2017 have led to a situation in which standards will not reflect air quality criteria. Air quality criteria must “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 such pollutant in the ambient air” (CAA section 108(a)(2)). As a result of changes since 2017, the CASAC and the process under which it is operating is incapable of properly assessing what that science is. If EPA wishes to make changes to the NAAQS review process, EPA should do so in a systematic manner similar to that employed in 2006, when EPA staff, CASAC, and others had an opportunity to provide input regarding proposed changes.

We unanimously find that myriad unwarranted changes have been made to the NAAQS review process and to the composition of the CASAC since 2017. These changes are collectively harmful to the quality, credibility, and integrity of EPA’s scientific review process and to CASAC as an advisory body. These changes have been made without advance notice to, or input from, the CASAC, cognizant EPA staff, or the public.² (Emphasis supplied.)

Our organizations are also concerned by the lack of adequate consultation of Tribes. EPA did not offer Tribal consultation on the proposal, and then concluded that it has no Tribal implications – a conclusion strongly opposed by Tribal air experts.

EPA has set up an unprecedented, flawed process to truncate the review of the ozone NAAQS. With these changes, critical information that forms the basis of this decision is absent or unresolved. On that ground alone, the resulting proposed standard is not in accordance with the law and is arbitrary and capricious.

NAAQS must protect public health with an adequate margin of safety for sensitive groups and individuals.

In establishing the primary standard for ozone, the Clean Air Act requires, at a minimum, that EPA achieve one thing: protect public health with an adequate margin of safety. In other words, health-based air quality standards must be set at levels that protect all people, but particularly sensitive groups. Ozone and many other air pollutants tend to affect sensitive individuals more, which is why it is particularly important to build a margin of safety into air quality standards so that at-risk groups such as the elderly, children, and people with lung diseases are adequately protected.

Courts have repeatedly found that if a certain level of a pollutant “adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard.” *American Lung Ass’n v. EPA*, 134 F.3d 388, 390 (D.C. Cir. 1998) (citations omitted); see also *American Farm Bureau Fed’n*

² Frey, H.C., Diez Roux, A.V., Allen, G., et al., Advice from the former U.S. EPA Clean Air Scientific Advisory Committee Ozone Review Panel on EPA’s Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft – September 2019), and EPA’s Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019), submitted to Hon. Andrew Wheeler, Administrator, U.S. Environmental Protection Agency, and to Docket ID No. EPA–HQ–ORD–2018–0274 and Docket ID No. EPA–HQ–OAR–2018–0279, December 2, 2019. Accessed at [https://yosemite.epa.gov/sab/sabproduct.nsf//B2AF0B23ABE6A60E852584C4007312E3/\\$File/EPA+CASAC+O3+Review+ISA+PA+Letter+191202+Final.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf//B2AF0B23ABE6A60E852584C4007312E3/$File/EPA+CASAC+O3+Review+ISA+PA+Letter+191202+Final.pdf)

v. EPA, 559 F.3d 512, 524 (D.C. Cir. 2009); *Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 618 (D.C. Cir. 2010). In other words, NAAQS must “be set at a level at which there is ‘an absence of adverse effect’ on these sensitive individuals.” *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1153 (D.C. Cir. 1980).

The best available science and public health protection must prevail over any other consideration when EPA sets the final NAAQS for ozone. Under the Clean Air Act, EPA must select a standard that is based on air quality criteria reflecting “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 such pollutant in the ambient air” 42 U.S.C. § 7408(a)(2).

Simply put, standards that EPA promulgates under these provisions must be adequate to (1) protect public health and (2) provide an adequate margin of safety, in order to (3) prevent any known or anticipated health-related effects from polluted air. The Act makes clear that there are significant limitations on the discretion granted to EPA in selecting a level for the NAAQS. In exercising its judgment, EPA must err on the side of protecting public health, and may not consider cost or feasibility in connection with establishing the numerical NAAQS or other important elements of the standard (e.g., form of the standard, averaging time, etc.). The United States Court of Appeals for the D.C. Circuit summed up EPA’s mandate succinctly:

Based on these comprehensive [air quality] criteria and taking account of the ‘preventative’ and ‘precautionary’ nature of the act, the Administrator must then decide what margin of safety will protect the public health from the pollutant’s adverse effects – not just known adverse effects, but those of scientific uncertainty or that ‘research has not yet uncovered.’ Then, and without reference to cost or technological feasibility, the Administrator must promulgate national standards that limit emissions sufficiently to establish that margin of safety.

American Lung Ass’n v. EPA, 134 F.3d 388, 389 (D.C. Cir. 1998); see also *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 464–71 (2001).

EPA must err on the side of protecting public health when there is scientific uncertainty.

Courts have properly characterized the NAAQS as “preventative in nature.” *Ethyl Corp. v. EPA*, 541 F.2d 1, 15 (D.C. Cir. 1976). The Act’s mandate requires that in considering uncertainty, EPA must err on the side of caution in terms of protecting human health and welfare. As the D.C. Circuit has held, “The Act requires EPA to promulgate protective primary NAAQS even where ... the pollutant’s risks cannot be quantified or ‘precisely identified as to nature or degree.’” *Am. Trucking Ass’ns v. EPA*, 283 F.3d 355, 369 (D.C. Cir. 2002).

In keeping with the precautionary and preventative nature of NAAQS, EPA must set a standard that protects against potential health effects—not just those impacts that have been well established by science. See *Am. Trucking Ass’ns*, 283 F.3d at 369 (citing Ozone NAAQS, 62 Fed. Reg. 38857 (section 109(b)(1)’s “margin of safety requirement was intended to address uncertainties associated with inconclusive scientific and technical information ... as well as to provide a reasonable degree of protection against hazards that research has not yet identified”)); see also *API v. EPA*, 684 F.3d 1342, 1352 (D.C. Cir. 2012).

In a seminal NAAQS case, the D.C. Circuit found that Congress “specifically directed the Administrator to allow an adequate margin of safety to protect against effects which have not yet

been uncovered by research and effects whose medical significance is a matter of disagreement.” *Lead Indus. Ass’n v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980). Limited data are not an excuse for failing to establish the level at which there is an absence of adverse effect. To the contrary, “Congress’ directive to the Administrator to allow an ‘adequate margin of safety’ alone plainly refutes any suggestion that the Administrator is only authorized to set primary air quality standards which are designed to protect against health effects that are known to be clearly harmful.” *Id.* at 1154-55.

Disparities in the impact of air pollution call for greater protection.

The burden of air pollution is not evenly shared. EPA itself acknowledges that leaving current ozone standards in place disproportionately harms Black communities and low-income communities where there are higher rates of childhood asthma and other chronic diseases³. Health-based standards must be set at levels that will protect all people, but particularly these and other populations who are at greater risk.

Generally, poorer people and some racial and ethnic groups are among those who often face higher exposure to pollutants and who may experience greater responses to such pollution. Many studies have explored the differences in harm from air pollution to racial or ethnic groups and people who are in a low socioeconomic position, have less education, or live nearer to major sources of pollution,⁴ including a workshop the American Lung Association held in 2001 that focused on urban air pollution and health inequities.⁵ Other researchers have found greater risk for African Americans from hazardous air pollutants, including those pollutants that also come from traffic sources.⁶ Due to decades of residential segregation, African Americans tend to live where there is greater exposure to air pollution.⁷

Socioeconomic position also appears tied to greater harm from air pollution and multiple large studies show evidence of that link. For example, studies have identified people who live in communities with high unemployment or other markers of low socioeconomic status as having greater risk of premature death from ozone pollution.⁸ Other large studies have identified that individuals who have low socioeconomic status or who live in communities with low

³ 85 FR 49830 at p. 49850.

⁴ Institute of Medicine. *Toward Environmental Justice: Research, Education, and Health Policy Needs*. Washington, DC: National Academy Press, 1999; O’Neill MS, Jerrett M, Kawachi I, et al. Health, wealth, and air pollution: Advancing theory and methods. *Environ Health Perspect.* 2003;111:1861-1870; Finkelstein MM, Jerrett M, DeLuca P, et al. Relation between income, air pollution and mortality: A cohort study. *CMAJ.* 2003;169:397-402; Zeka A, Zanobetti A, Schwartz J. Short term effects of particulate matter on cause specific mortality: effects of lags and modification by city characteristics. *Occup Environ Med.* 2006;62:718- 725.

⁵ American Lung Association. *Urban air pollution and health inequities: A workshop report*. *Environ Health Perspect.* 2001; 109 (suppl 3): 357-374.

⁶ Apelberg BJ, Buckley TJ, White RH. Socioeconomic and racial disparities in cancer risk from air toxics in Maryland. *Environ Health Perspect.* 2005;113:693-699.

⁷ Nardone A, Casey JA, Morello-Frosch R, Mujahid M, Balmes JR, Thakur N. Associations between historical residential redlining and current age-adjusted rates of emergency department visits due to asthma across eight cities in California: an ecological study. *Lancet Planet Health.* 2020;4(1):e24-e31.

⁸ Bell ML, Dominici F. Effect modification by community characteristics on the short-term effects of ozone exposure and mortality in 98 US communities. *Am J Epidemiol.* 2008;167:986-997.

socioeconomic status face higher risk of hospital admissions and emergency department visits associated with ozone pollution.⁹

People of color also may be more likely to live in counties with higher levels of pollution. Non-Hispanic Blacks were also more likely to live in counties with worse ozone pollution. Income groups, by contrast, differed little in these exposures.¹⁰

Meeting a standard of no higher than 60 ppb would provide greater protection to groups already facing substantial challenges. Conversely, EPA's proposal to retain the outdated and inadequate primary ozone standard creates additional and unacceptable risks to these vulnerable communities, and also violates the Clean Air Act's requirement to build into the NAAQS an adequate margin of safety for sensitive and vulnerable subpopulations.

CASAC reviews show that a limit of no higher than 60 ppb is necessary.

As we explained at length in our 2015 comments to then-Administrator Gina McCarthy¹¹, clinical and epidemiological studies have consistently shown that breathing ozone can threaten life and health at concentrations far lower than the then-existing 75 ppb 8-hour average standard. EPA did not at that time heed our strong recommendation to set the standard at 60 ppb, but instead settled on an 8-hour standard of 70 ppb. A 70 ppb standard was insufficient in 2015 given the state of the scientific knowledge, and – nearly five years on – is certainly insufficient now.

During its last review in 2014, CASAC recommended that EPA set the primary ozone standard in the range of 70 ppb to 60 ppb.¹² The committee clarified, however, that a standard of 70 ppb would not ultimately guard against health effects on sensitive individuals. “[B]ased on the scientific evidence, a level of 70 ppb provides little margin of safety for the protection of public health particularly for sensitive subpopulations.”¹³

At 70 ppb, there is substantial scientific evidence of adverse effects as detailed in the charge question responses, including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation. Although a level of 70 ppb is more protective of public health than the current standard [of 75 ppb], it may not meet the statutory requirement to protect public health with an adequate margin of safety.¹⁴

⁹ Cakmak, S; Dales, RE; Judek, S. (2006b). Respiratory health effects of air pollution gases: Modification by education and income. *Arch Environ Occup Health* 61: 5-10; Burra, TA; Moineddin, R; Agha, MM; Glazier, RH. (2009). Social disadvantage, air pollution, and asthma physician visits in Toronto, Canada. *Environ Res* 109: 567-574.

¹⁰ Miranda ML, Edwards SE, Keating MH, Paul CJ. Making the environmental justice grade: The relative burden of air pollution exposure in the United States. *Int J Environ Res Public Health*. 2011;8:1755-1771.

¹¹ <https://www.lung.org/getmedia/ffc022b1-ec37-4867-b9a2-af5d8ec578b2/national-health-and-medical.pdf.pdf>

¹² Frey, H.C., et al., CASAC Review of the EPA's Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards, submitted to Hon. Gina McCarthy, Administrator, U.S. Environmental Protection Agency, EPA-CASAC-14-004, June 26, 2014. Accessed at [https://yosemite.epa.gov/sab/sabproduct.nsf/5EFA320CCAD326E885257D030071531C/\\$File/EPA-CASAC-14-004+unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/5EFA320CCAD326E885257D030071531C/$File/EPA-CASAC-14-004+unsigned.pdf)

¹³ *Id.*, at ii.

¹⁴ *Id.* (emphasis supplied.)

New evidence has emerged since CASAC's 2014 recommendation to increase the force of its warning: the margin of safety it warned was perhaps inadequate is now gone. For example, in a 2017 scientific paper, researchers found further evidence in a nationwide study that older adults faced a higher risk of premature death even when the levels of ozone pollution remained well below the current national standard¹⁵. EPA's proposal to retain the outdated standard ignores its own expert advisors, as well as the long-standing – and growing – wealth of scientific evidence pointing to the need for a more protective standard.

Current evidence shows expanded health effects of ozone exposure and further supports a standard of no higher than 60 ppb.

Since the 2015 standard, new research has added weight to the evidence showing the extensive health effects of ozone. Research not only confirms the previous conclusions about ozone's impact on human health, but adds to and clarifies the impact on multiple physiologic systems, including respiratory and cardiovascular. These studies inform our understanding of the health impacts of ozone at low concentrations.

EPA's most recent final ozone ISA, published in April 2020, summarized the most recent review of the science related to the health and welfare effects of ozone pollution. Even acknowledging our grave process concerns with the development of the document outlined above, EPA's findings still demonstrate that even low levels of ozone pollution can trigger immediate, dangerous health impacts. Breathing ozone has shown to contribute to the following¹⁶:

- Shortness of breath, wheezing, coughing;
- Asthma attacks;
- Increased risk of respiratory infections;
- Increased susceptibility to pulmonary inflammation; and
- Increased need for people with lung diseases, such as asthma or chronic obstructive pulmonary disease (COPD), to receive medical treatment and to go to the hospital.

Newer studies warn of serious effects from breathing ozone over longer periods. With more long-term data, scientists are finding that long-term exposure—that is, periods longer than eight hours, including days, months or years—may increase the risk of respiratory challenges and early death. The growing evidence of health effects associated with breathing ozone for longer periods adds to the urgency to set the most protective standard now to reduce those exposures.

¹⁵ *Id.*

¹⁶ U.S. EPA, *Integrated Science Assessment (ISA) for Ozone and Related Photochemical Oxidants* (Final Report), U.S. Environmental Protection Agency, Washington, DC, EPA/600/R20/012, 2020. Available at <https://www.epa.gov/isa/integrated-science-assessment-isa-ozone-and-related-photochemical-oxidants>.

- Examining the records from a long-term national database, researchers found a higher risk of death from respiratory diseases associated with increases in ozone.¹⁷
- New York researchers looking at hospital records for children's asthma found that the risk of admission to hospitals for asthma increased with chronic exposure to ozone. Younger children and children from low-income families were more likely than other children to need hospital admissions even during the same time periods.¹⁸
- California researchers analyzing data from their long-term Southern California Children's Health Study found that some children with certain genes were more likely to develop asthma as adolescents in response to the variations in ozone levels in their communities.¹⁹
- Studies link lower birth weight and decreased lung function in newborns to ozone levels in their community.²⁰ This research provides increasing evidence that ozone may harm newborns.

Breathing ozone can shorten your life. Strong evidence exists of the deadly impact of ozone from large studies conducted in cities across the U.S., in Europe and in Asia. Researchers repeatedly found that the risk of premature death increased with higher levels of ozone.²¹ Newer research has confirmed that ozone increased the risk of premature death even when other pollutants also are present.²²

Community health studies are pointing to less obvious, but serious effects from year-round exposure to ozone, especially for children. Scientists followed 500 Yale University students and determined that living just four years in a region with high levels of ozone and related co-pollutants was associated with diminished lung function and frequent reports of respiratory symptoms.²³ Another earlier report from the Children's Health study of 3,300 schoolchildren in Southern California found reduced lung function in girls with asthma and boys who spent more time outdoors in areas with high levels of ozone.²⁴

¹⁷ Jerrett M, Burnett RT, et al. Long-term ozone exposure and mortality. *N Engl J Med*. 2009; 1085-1095.

¹⁸ Lin S, Liu X, Le LH, and Hwang S-A. Chronic exposure to ambient ozone and asthma hospital admissions among children. *Environ Health Perspect*. 2008; 116:1725-1730.

¹⁹ Islam T, McConnell R, Gauderman WJ, Avol E, Peters JM, and Gilliland F. Ozone, oxidant defense genes, and risk of asthma during adolescence. *Am J Respir Crit Care Med*. 2009; 177(4):388-395.

²⁰ Salam MT, Millstein J, Li YF, Lurmann FW, Margolis HG, Gilliland FD. Birth outcomes and prenatal exposure to ozone, carbon monoxide, and particulate matter: Results from the Children's Health Study. *Environ Health Perspect*. 2005; 113: 1638-1644; Morello-Frosch R, Jesdale BM, Sadd JL, Pastor M. Ambient air pollution exposure and full-term birth weight in California. *Environ Health*. 2010; 9: 44.

²¹ U.S. EPA, 2020, Section 6-22.

²² Di Q, Wang Y, Zanobetti A, et al. Air Pollution and Mortality in the Medicare Population. *N Engl J Med*. 2017; 376:2513-2522.

²³ Galizia A, Kinney PL. Year-round residence in areas of high ozone: Association with respiratory health in a nationwide sample of nonsmoking young adults. *Environ Health Perspect*. 1999; 107: 675-679.

²⁴ Peters JM, Avol E, Gauderman WJ, Linn WS, Navidi W, London SJ, Margolis H, Rappaport E, Vora H, Gong H, Thomas DC. A study of twelve southern California communities with differing levels and types of air pollution. II: Effects on pulmonary function. *Am J Respir Crit Care Med*. 1999; 159: 768-775.

Breathing other pollutants in the air may make your lungs more responsive to ozone—and breathing ozone may increase your body's response to other pollutants. For example, research warns that breathing sulfur dioxide and nitrogen oxide—two pollutants common in the eastern U.S.—can make the lungs react more strongly to breathing ozone than just breathing ozone alone. Breathing ozone may also increase the response to allergens in people with allergies. A large study published in 2009 found that children were more likely to suffer from hay fever and respiratory allergies when ozone and PM2.5 levels were high.²⁵

Conclusion

EPA's proposed health-based ozone standard is at odds with the best available science, endangers public health, violates the Clean Air Act, and suffers from fatal procedural errors. Given the weight of the evidence, and in order to satisfy its legal obligation to protect against known and anticipated adverse health effects with an adequate margin of safety, **EPA must set the primary ozone standard at no higher than 60 ppb.**

Thank you for considering our comments.

Allergy & Asthma Network
Alliance of Nurses for Healthy Environments
American Academy of Pediatrics
American Lung Association
American Public Health Association
American Thoracic Society
Association of Schools and Programs for Public Health
Asthma and Allergy Foundation of America
Center for Climate Change and Health
Children's Environmental Health Network
Climate for Health
Health Care Without Harm
International Society for Environmental Epidemiology, North American Chapter
National Association of County and City Health Officials
National Association of Pediatric Nurse Practitioners
National League for Nursing
National WIC Association
Physicians for Social Responsibility
Society for Public Health Education

²⁵ Parker JD, Akinbami LJ, Woodruff TJ. Air Pollution and Childhood Respiratory Allergies in the United States. *Environ Health Perspect.* 2009; 117:140-147.