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-2015-0072: Review of the National Ambient Air Quality Standards for Particulate Matter

Dear Administrator Wheeler:

As national medical societies and public health and patient advocacy organizations, we write to provide comments on the U.S. Environmental Protection Agency’s proposed rule on the National Ambient Air Quality Standards (NAAQS) for particulate matter (Docket ID No. EPA-HQ-OAR-2015-0072). Our organizations fully understand the public health and medical threats from particle pollution and have a strong interest in standards that adequately protect our tens of thousands of members and the millions of people whose health we work to secure.

Clear and compelling scientific evidence gained since EPA’s last particulate matter NAAQS review shows that that fine particulate matter (PM 2.5) exposure is far more lethal and dangerous than previously understood. Alarming, scientific research shows that exposure to PM 2.5 causes adverse health outcomes at levels far below current standards. These public health impacts are wide-reaching and significant, and disproportionately affect vulnerable populations. **We accordingly oppose EPA’s proposal to retain current, inadequate standards for PM 2.5, and strongly urge the agency to strengthen the standards.**

Science and public health protection must prevail over any other consideration when EPA sets the final NAAQS for particulate matter. Here, based on the best available science, and pursuant to applicable legal standards, the only appropriate course of action for EPA is to strengthen the NAAQS for PM 2.5. Accordingly, our organizations strongly urge EPA to reconsider its proposal and establish primary NAAQS for fine particulate matter at levels that protect the health of the public with an adequate margin of safety, as the Clean Air Act requires:
• Annual average PM 2.5 standard of 8 micrograms per cubic meter (μg/m³)
• 24-hour average PM 2.5 standard of 25 micrograms per cubic meter (μg/m³)

NAAQS must protect public health with an adequate margin of safety

In establishing a NAAQS, the Clean Air Act requires, at a minimum, that EPA achieve one thing: protect public health with an adequate margin of safety. Here, strong scientific evidence shows that the current fine particulate matter standards are not adequate to protect public health with an adequate margin of safety.

Under the Clean Air Act, EPA must select a NAAQS 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). Primary NAAQS must be set at a level “requisite to protect the public health” with “an adequate margin of safety.” 42 U.S.C. § 7409(b)(1).

Simply put, any 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.


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 the 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.

EPA must establish NAAQS that protect vulnerable subpopulations

The NAAQS must be set at levels that are not only adequate to protect those with no enhanced vulnerability to air pollution, but that also guard against adverse effects in vulnerable subpopulations, such as children, the elderly, people with heart and lung disease, people of color, and people with low socioeconomic status. In fact, 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, 134 F.3d at 390 (citations omitted); see also American Farm Bureau Fed’n 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).

EPA must likewise build into the NAAQS an adequate margin of safety for these sensitive subpopulations. Am. Farm Bureau Fed’n, 559 F.3d at 526. 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, 647 F.2d at 1153.

New scientific research shows that PM 2.5 can cause numerous adverse health effects at levels far below the current NAAQS

Overwhelming evidence shows that PM 2.5 can kill. Particle pollution can increase the risk of heart disease, lung cancer and asthma attacks and can interfere with the growth and work of the lungs. Over 10,000 peer-reviewed scientific studies over the past two decades have shed substantial light on the serious and diverse health effects from breathing PM 2.5.

Studies published since EPA’s last review of particle pollution standards have improved our understanding of the extent and range of health effects of fine particulate matter. Alarmingly, these newer studies confirm adverse health effects at exposures much lower than current national air quality limits. The new evidence reinforces already strong existing studies and supports the conclusion that PM 2.5 can cause numerous adverse health effects in humans, at exposure levels far below the current standards.
Following its latest review of the current research on fine particle pollution, EPA concluded in written findings published in December 2019\(^1\) that breathing PM 2.5 poses serious health threats, including the following:

- Causes early death (both short-term and long-term exposure);
- Causes cardiovascular harm (e.g., heart attacks, strokes, heart disease, congestive heart failure);
- Likely to cause respiratory harm (e.g., worsened asthma, worsened COPD, inflammation);
- Likely to cause cancer;
- Likely to cause harm to the nervous system (e.g., reduced brain volume, cognitive effects);
- May cause reproductive and developmental harm


Significant for purposes of the present PM review, even at levels that meet current NAAQS, exposure to short-term PM 2.5 can be deadly. A 2016 study found that people aged 65 and older in New England faced a higher risk of premature death from particle pollution, even in places that met current standards for short-term particle pollution.\(^2\) Another study in 2017 looked more closely at Boston and found a similar higher risk of premature death from particle pollution in a city that meets current limits on short-term particle pollution.\(^3\) Looking nationwide in a 2017 study, researchers found more evidence that older adults faced a higher risk of premature death even when levels of short-term particle pollution remained well below the current national standards. This was consistent whether the older adults lived in cities, suburbs or rural areas.\(^4\) Some of the strongest research has documented that short-term exposure to particle pollution causes premature death from respiratory and cardiovascular causes.\(^5\)

It has long been known that breathing high levels of particle pollution day in and day out can be deadly, but recent research has confirmed that long-term exposure to particle pollution still kills,

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\(^4\) Di Q, Dai L, Wang Y, Zanobetti A, Choiat C, Schwartz JD, Dominici F. Association of Short-Term Exposure to Air Pollution with Mortality in Older Adults. JAMA. 2017;318:2446-2456.
even with the declining levels in the U.S. since 2000\textsuperscript{6} and even in areas, such as New England, that meet the current standard for year-round particle pollution.\textsuperscript{7}

In 2013, the International Agency for Research on Cancer (known as IARC), part of the World Health Organization, concluded that particle pollution causes lung cancer. The IARC based its decision on the review of multiple studies from the U.S., Europe, and Asia and the presence of carcinogens on the particles.\textsuperscript{8}

Studies examining the impact on the nervous system of long-term exposure to particle pollution have found links to cognitive affects in adults including reduced brain volume, cognitive decrements and dementia.\textsuperscript{9} Scientists have found evidence that particle pollution may impact pregnancy and birth outcomes, such as preterm birth, low birth weight and fetal and infant mortality.\textsuperscript{10}

It is clear from these many rigorous studies over the recent past that both the 24-hour and annual standard for PM 2.5 fail to protect public health. The newer studies validate and extend earlier research linking both acute and chronic fine particle pollution with serious morbidity and mortality. The newer research has also expanded our understanding of the range of health outcomes associated with PM, and has identified adverse respiratory and cardiovascular health effects at lower exposure levels than previously reported. Such a conclusion demands prompt action to protect human health.

**Disparities in the impact of air pollution call for more protection**

The burden of air pollution is not evenly shared. The list of populations who risk demonstrated harm from PM 2.5 has grown significantly since the previous review. Newer evidence shows that Black, Asian, and Hispanic persons, and persons who were eligible for Medicaid (i.e., those with low socioeconomic status), have a higher estimated risk of death from any cause in association with PM 2.5 exposure than the general population.\textsuperscript{11} Health-based standards must be set at levels that will protect all people, but particularly these sensitive groups.

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


\textsuperscript{9} U.S. EPA, 2019, Section 8.2.9.

\textsuperscript{10} U.S. EPA, 2019, Section 9.1.2, especially Section 9.1.2.3.1. and Section 9.1.2.6.

pollution,\textsuperscript{12} including a workshop the American Lung Association held in 2001 that focused on urban air pollution and health inequities.\textsuperscript{13} The most recent EPA review of the research on the health effects of particle pollution concluded that nonwhite populations, especially Blacks, faced higher risk from particle pollution.\textsuperscript{14}

Many studies have looked at differences in the impact of air pollution on premature death. Recent studies have looked at the mortality in the Medicaid population and found that those who live in predominantly Black or African American communities suffered greater risk of premature death from particle pollution than those who live in communities that are predominantly white.\textsuperscript{15} Another large study found that Hispanics and Asians, but especially Blacks, had a higher risk of premature death from particle pollution than whites did. This study found that income did not drive the differences. Higher-income Blacks who had higher income than many whites still faced greater risk than those whites, suggesting that the impact of other factors such as chronic stress as a result of discrimination may be playing a role.\textsuperscript{16} Other researchers have found greater risk for African Americans from hazardous air pollutants, including those pollutants that also come from traffic sources.\textsuperscript{17} Due to decades of residential segregation, African Americans tend to live where there is greater exposure to air pollution.\textsuperscript{18}

Socioeconomic position also appears tied to greater harm from air pollution, and multiple large studies show evidence of that link. Low socioeconomic status consistently increased the risk of premature death from fine particle pollution among 13.2 million Medicare recipients studied in the largest examination of particle pollution-related mortality nationwide.\textsuperscript{19} In a 2008 study that found greater risk for premature death for communities with higher African American populations, researchers also found greater risk for people living in areas with higher unemployment or higher use of public transportation.\textsuperscript{20} A 2008 study of Washington, DC, likewise found that poor air quality

\begin{itemize}
  \item \textsuperscript{14} U.S. EPA, 2019, Section 12.5.4
  \item \textsuperscript{15} Kioumourtzoglou MA, Schwartz J, James P, Dominici F, Zanobetti A. PM2.5 and mortality in 207 us cities: Modification by temperature and city characteristics. Epidemiology, 2016;27:221-227.
  \item \textsuperscript{17} 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.
  \item \textsuperscript{18} 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.
\end{itemize}


potential for links between PM 2.5 exposure and COVID-19 provides further justification for stronger standards.

**Scientific consensus for stronger standards**

Widespread consensus exists in the scientific and medical community that the current air quality standards for PM 2.5 are not protective of public health, and must be strengthened to save lives. A broad spectrum of public health and medical organizations called for stricter PM 2.5 standards during the last review than were ultimately finalized, including the American Lung Association, American Heart Association, American Public Health Association, and American Thoracic Society.\(^{27}\)

Moreover, the Independent Particulate Matter Review Panel (IPMRP)\(^{28}\) determined that the current fine particle standards are not protective of public health. Relying on studies published since 2012 that show exposure to PM 2.5 causes premature death at concentrations below current standards, the IPMRP recommended that EPA to strengthen both the annual and 24-hour standards. According to the IPMRP:

> US multicity epidemiological studies, supported by consistent results from Canadian multicity epidemiologic studies, consistent results from accountability studies, and coherent results from animal toxicological and controlled human exposure studies, provide clear and compelling scientific evidence that the current PM 2.5 standards are not adequate to protect human health. The epidemiological evidence is based on different locations, study designs, and statistical approaches, which enhances its robustness.\(^{29}\)

In addition, EPA staff scientists in the EPA Office of Air Quality Planning and Standards reviewed the adequacy of the current primary PM 2.5 standards, and concluded: “the available scientific evidence, air quality analyses, and the risk assessment ... can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the combination of the current annual and 24-hour primary PM 2.5 standards.”\(^{30}\) In reaching this conclusion, EPA staff highlighted the following:

- There is a long-standing body of strong health evidence demonstrating relationships between long- or short-term PM 2.5 exposures and a variety of outcomes, including

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\(^{28}\) The Independent Particulate Matter Review Panel consists of members of the EPA Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel that was dismissed without notice in October 2018.


mortality and serious morbidity effects. Studies published since the last review have reduced key uncertainties and broadened our understanding of the health effects that can result from exposures to PM 2.5.

- Recent U.S. and Canadian epidemiologic studies provide support for generally positive and statistically significant health effect associations across a broad range of ambient PM 2.5 concentrations, including for air quality distributions with overall mean concentrations lower than in the last review and for distributions likely to be allowed by the current primary PM 2.5 standards.
- Analyses of PM 2.5 pseudo-design values additionally support the occurrence of positive and statistically significant health effect associations based largely on air quality likely to have met the current annual and 24-hour primary standards.
- The risk assessment estimates that the current primary PM 2.5 standards could allow a substantial number of PM 2.5-associated deaths in the U.S. The large majority of these estimated deaths are associated with the annual average PM 2.5 concentrations near (and above in some cases) the average concentrations in key epidemiologic studies reporting positive and statistically significant health effect associations.


EPA's inadequate process for this review

The process that EPA used to arrive at its proposal to keep the current standards was deeply flawed. In previous reviews, 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. This time, EPA Administrator Wheeler disbanded the agency’s Particulate Matter Review Panel (PMRP), which nevertheless convened as the IPMRP and provided comments to EPA in support of strengthening the standards (see above.) EPA replaced the PMRP with an inadequate alternative that lacked equivalent expertise, could only respond to written questions, and restricted the review of scientific studies.

EPA also rushed to complete its review on an unreasonably tight timeline that did not allow for sufficient consideration of the scientific evidence. A process that typically takes years to complete was done in a matter of months. While EPA should certainly work to meet the five-year review timeframe for the NAAQS established in the Clean Air Act, starting the process late and then skipping steps to rush the timeframe is clearly not an adequate option to protect public health. In particular, we are deeply concerned that EPA departed from the past process that included the drafting of three separate, critical documents - an Integrated Scientific Assessment, a Risk and Exposure Assessment and a Policy Assessment – and completed this review without a stand-alone Risk and Exposure Assessment. Further, the Policy Assessment was drafted prior to the completion of the Integrated Science Assessment. This proposal falls short of the rigorous scientific review that the Clean Air Act requires.

Conclusion

EPA’s proposed fine particulate matter standards are at odds with the best available science, endanger public health, and violate the Clean Air Act. 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 annual PM 2.5 standard at 8 µg/m3 and the 24-hour average PM 2.5 standard at 25 µg/m3.
Thank you for considering our comments.

Allergy & Asthma Network
Alliance of Nurses for Healthy Environments
American Academy of Pediatrics
American Heart Association
American Lung Association
American Public Health Association
American Thoracic Society
Asthma and Allergy Foundation of America
Center for Climate Change and Health
Children's Environmental Health Network
Health Care Without Harm
International Society for Epidemiology -- North American Chapter
Medical Society Consortium on Climate and Health
National Association of County and City Health Officials
National Environmental Health Association
Public Health Institute
Regional Asthma Management and Prevention