

ORAL ARGUMENT NOT YET SCHEDULED

No. 24-1050 (Consolidated with 24-1051, 24-1052, and 24-1073)

**UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

COMMONWEALTH OF KENTUCKY, *et al.*,
Petitioners,

v.

ENVIRONMENTAL PROTECTION AGENCY, *et al.*,
Respondents.

**BRIEF OF AMICUS CURIAE ENVIRONMENTAL PROTECTION
NETWORK IN SUPPORT OF RESPONDENTS**

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), Environmental Protection Network provides the following:

(A) Parties, Intervenors, and Amici.

Except for Midwest Ozone Group which filed its brief after Petitioners filed their opening brief, all parties, intervenors, and amici appearing in this Court are listed in the Opening Brief for Industry and Arizona Coalition Petitioners.

(B) Rulings Under Review.

References to the rulings at issue appear in the Brief for Petitioners.

(C) Related Cases.

Aside from these consolidated petitions, there are no other related cases within the meaning of Circuit Rule 28(a)(1).

CERTIFICATE OF JUSTIFICATION FOR SEPARATE BRIEFING

Pursuant to Circuit Rule 29(d), Environmental Protection Network seeks leave to participate in this case as amicus curiae to help the Court in its understanding of the history, context, and science of the 2024 Rule at issue in this case from the unique perspective and expertise of former Environmental Protection Agency staff. Environmental Protection Network does not believe any other amici curiae provide this expertise which necessitates this separate amicus brief.

RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and Circuit Rule 26.1, Environmental Protection Network certifies that it is a 501(c)(3) nonprofit organization. It has no parent company, and no publicly held company has a 10% or greater ownership interest in it.

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EPA	Environmental Protection Agency
NAAQS	National Ambient Air Quality Standard(s)
PM _{2.5}	Fine particulate matter
RTC	Response to Comments

IDENTITY AND INTERESTS OF AMICUS CURIAE, INTERESTS IN THE CASE, AND THE SOURCE OF AUTHORITY TO FILE

Pursuant to Fed. R. App. P. 29(a)(4)(D)&(E), Environmental Protection Network states its mission is to harness the vast experience of former EPA career staff and political appointees by sharing their institutional knowledge and subject matter expertise for the benefit of the public. For example, John Hannon, an Environmental Protection Network volunteer, is a former Assistant General Counsel of the EPA Office of General Counsel. Serving as Assistant General Counsel for 19 years as part of a 29-year career, Mr. Hannon was closely involved with EPA's rulemakings to set national ambient air quality standard (NAAQS) for PM and other pollutants, supervising the group of attorneys that worked on these rulemakings. Mr. Hannon received his J.D. from Georgetown University Law Center.

Environmental Protection Network wishes to bring that expertise to bear in this litigation by providing to this Court an understanding of the historical regulatory context of the 2024 Rule. All parties consented to Environmental Protection Network's participation as amicus curiae; therefore, it submits its brief in support of Respondents in accordance with Fed. R. App. P. 29(a)(2) and Circuit Rule 29(b).

Environmental Protection Network further states that no parties' counsel authored the brief in whole or part; no party or party's counsel contributed money that was intended to fund preparing or submitting the brief; and no person, other than the amicus curiae, its members, and its counsel contributed money that was intended to fund preparing or submitting the brief.

SUMMARY OF THE ARGUMENT

Environmental Protection Network submits this brief to aid the Court in its understanding of the methodology the Environmental Protection Agency (EPA) used when it set the level of the NAAQS for fine particles (PM_{2.5}) to provide an adequate margin of safety for people exposed to this air pollutant. Reconsideration of the National Ambient Air Quality Standards for Particulate Matter, 89 Fed. Reg. 16202 (Mar. 6, 2024) (*hereinafter* 2024 Rule). The basic methodology EPA used to select the level of the annual standard in the 2024 Rule was consistent with the approaches it used in previous updates to the standards in 1997, 2006, and 2012; approaches the D.C. Circuit upheld each time they were challenged. *Am. Trucking Ass'n v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002); *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 526–27 (D.C. Cir. 2009); *Nat'l Ass'n. of Mfrs. v. EPA*, 750 F.3d 921, 924 (D.C. Cir. 2014).

To establish the new annual PM_{2.5} standard, EPA identified the group of studies most useful for selecting the level of the standard, then—consistent with decades of prior practice—chose a level “somewhat below” the lowest long-term mean concentration of the levels in these key studies. This approach was not only in accord with EPA’s past practice, but necessary given Congress’ mandate that EPA set standards that protect the people at-risk for serious health effects associated with the pollutant, including those exposed to the highest levels of PM_{2.5} in an area, with an adequate margin of safety. 42 U.S.C. § 7409(b).

EPA had fallen out of compliance with this statutory mandate in 2020 when it promulgated a new standard that allowed people, including vulnerable populations, to be exposed to concentrations higher than those found in key studies to be associated with serious adverse health effects. Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 82684 (Dec. 18, 2020) (*hereinafter* 2020 Rule); *see also* 89 Fed. Reg. at 16375; National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3086, 3162 (Jan. 15, 2013) (*hereinafter* 2012 Rule).¹ EPA’s revision to the level of the annual standard in 2024

¹ While this rule was published in the Federal Register on January 15, 2013, EPA Administrator Lisa Jackson signed and released the rule on December 14, 2012. 78 Fed. Reg. at 3276. EPA has referred to this rule as the “Review completed in 2012” in subsequent rulemakings. 85 Fed. Reg. at 82688; 89 Fed. Reg. at 16208. Amicus-Environmental Protection Network, therefore, refers to this rule as the 2012 Rule.

was necessary and proper to achieve the basic goal of NAAQS—protecting vulnerable subpopulations with an adequate margin of safety, 42 U.S.C. § 7409(b)—and should be upheld by this Court.

ARGUMENT

EPA evaluated a large body of scientific data, advice from the Clean Air Science Advisory Committee, and public comments in revising the primary annual average standard for PM_{2.5} in the 2024 Rule. This brief focuses on a core part of that decision—the methodology or approach used to select a specific level for the standard. EPA’s approach is designed to protect all people in an area with an adequate margin of safety, including the vulnerable populations exposed to the highest concentrations. With one major exception, EPA has used the same basic methodology since 1997, the first year EPA set a standard for PM_{2.5}. In 2020, EPA used a much less protective methodology, neither acknowledging nor explaining this change. In a well-reasoned decision, EPA returned to its prior lawful methodology in the 2024 Rule.

I. The D.C. Circuit Court upheld the approach EPA used in the 1997, 2006, and 2012 final rules on PM_{2.5} to set annual levels “somewhat below” the mean concentrations of key studies.

The Clean Air Act commands the EPA to establish national ambient air quality standards for air pollutants that endanger public health or welfare. 42 U.S.C. §§ 7408(a), 7409(a). Particulate matter, which includes PM_{2.5}, is one such pollutant.

The Clean Air Act requires EPA to set standards for PM_{2.5} at levels that protect the public from its serious adverse effects with an adequate margin of safety. 42 U.S.C. § 7409(b). Because EPA must set these standards using “the latest scientific knowledge” on the harms of PM_{2.5}, 42 U.S.C. § 7408(a)(2), EPA must review the standards at least every five years. 42 U.S.C. § 7409(d).

Since the EPA first adopted an annual standard for PM_{2.5} in 1997, with the exception of the 2020 Rule, it has relied upon key studies and set the level of the standard “somewhat below” the range of mean concentrations for these studies. This approach ensures an adequate margin of safety for all exposed persons, as required by the Clean Air Act. On three occasions, the D.C. Circuit Court of Appeals has upheld EPA’s use of this approach.²

A. EPA’s 1997 Rule set the annual standard for PM_{2.5} at 15.0 µg/m³, a level “somewhat below” the lowest long-term mean of key studies available at that time and permitted limited spatial averaging.

In 1997, EPA adopted the first annual average standard for PM_{2.5}, setting the level at 15.0 µg/m³. National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38652, 38711 (July 18, 1997) (*hereinafter* 1997 Rule). EPA determined the group of key studies that would be most useful for determining the level of the

² The brief focuses on this basic methodology, it does not address EPA’s decisions on what studies have or have not been considered as key studies when setting the level of the standard.

standard, focusing on “where the body of epidemiological evidence is most consistent and coherent,” and weighing most heavily “those epidemiological studies reporting associations between health effects and direct measures of fine particles.” *Id.* at 38675; *see also id.* at note 41.

In selecting a level that was “somewhat below” the lowest long-term mean of these key studies, *id.* at 38675, EPA found that:

Given the serious nature of the potential effects, the Administrator believes it is both *prudent and appropriate to select a level* for an annual standard *at or below such concentrations*. An examination of the long-term means ... finds mean concentrations ranging from about 16 to about 21 $\mu\text{g}/\text{m}^3$ Taken together, and placing greatest weight on those studies that were clearly statistically significant, this evidence suggests that an annual standard level of 15 $\mu\text{g}/\text{m}^3$ is *appropriate to reduce the risk of effects from short-term exposure to fine particles*.

Id. at 38676 (emphasis added). EPA concluded that:

Taking the epidemiological studies of both short- and long-term exposures together, the Administrator believes the concordance of evidence for PM effects and associated levels provides clear support for an annual PM_{2.5} standard level of 15 $\mu\text{g}/\text{m}^3$. *This level is below the range of annual data most strongly associated with both short- and long-term exposure effects, and because even small changes in annual means in this concentration range can make significant differences in overall risk reduction and total population exposures, the Administrator believes it will provide an adequate margin of safety against the effects* observed in these epidemiological studies.

Id. (emphasis added).

EPA also considered spatial averaging as an option, where compliance with the standard could be determined based on the level calculated by “averaging the annual arithmetic means derived from multiple monitoring sites within a monitoring planning area,” *id.* at 38671; however, EPA found this approach “may not be appropriate for all circumstances and might leave some areas without adequate protection.” *Id.* at 38672. EPA placed constraints on spatial averaging “to ensure that spatial averaging would not result in inequities in the level of protection provided by the PM standards.” *Id.* at 38672. This reflects EPA’s long-standing view that the NAAQS must protect more than the average population, for example EPA must protect groups of people vulnerable to the health risks from air pollution. 89 Fed. Reg. at 16206, note 5; *Am. Lung Ass’n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998); *Lead Indus. Ass’n, Inc. v. EPA*, 647 F.2d 1130, 1153 (D. C. Cir. 1980).

The D.C. Circuit upheld the methodology EPA used to select the level of the standard:³

Moreover, *EPA ultimately set the standard just below the range of mean annual PM_{2.5} concentrations observed in studies showing a statistically significant association between fine particulate matter and health effects.* While we cannot say those studies necessitated a standard level of 15µg/m³, neither have we any basis for concluding that EPA’s decision was unreasonable or unsupported by the record. We repeat: “That the evidence in the record may also support other conclusions, even those that are inconsistent with the Administrator’s,

³ The court did not address spatial averaging.

does not prevent us from concluding that [her] decisions were rational and supported by the record.”

*Am. Trucking Ass’n*s, 283 F.3d at 372 (cleaned up) (emphasis added).

B. EPA’s 2006 Rule retained the annual standard for PM_{2.5} at 15.0 µg/m³ and tightened the criteria for spatial averaging.

By 2006 there was a broader body of evidence on the health effects associated with PM_{2.5}, and significantly more evidence on the distribution of air quality levels across areas. Based on this larger body of evidence EPA retained the annual average of 15.0 µg/m³ and tightened the criteria for spatial averaging. National Ambient Air Quality Standards for Particulate Matter, 71 Fed. Reg. 61144, 61145 (Oct. 17, 2006) (*hereinafter* 2006 Rule). EPA summarized its 1997 approach to setting the level of the annual standard and applied the same basic approach in the 2006 Rule, but in the context of an “extensive body of new evidence based specifically on PM_{2.5}.” *Id.* at 61168. EPA retained the standard at 15.0 µg/m³ because “the level of the current annual standard is appropriate as it is appreciably below the long-term average of these key studies.” *Id.* at 61176. However, the availability of “a much larger set of PM_{2.5} air quality data than was available in the last review” raised serious questions about whether the constraints on spatial averaging were adequate to “provide appropriate public health protection,” including “the potential for disproportionate impacts on potentially vulnerable subpopulations within an area.” *Id.* at 61166.

EPA's assessment showed that the highest concentrations in an area tended to be where the population was more likely to have "lower education and income levels, and higher percentages of minority populations," groups potentially more vulnerable to the serious health effects associated with PM_{2.5}. *Id.* at 61166, note.

29. EPA found that the existing spatial averaging criteria may be inadequate "to avoid substantially greater exposures in some areas, potentially resulting in disproportionate impacts on these potentially vulnerable subpopulations." *Id.*

Based on this EPA tightened the criteria for spatial averaging. EPA explained that "current information and analyses indicate that application of *the current form has the clear potential to result in disproportionate impacts on potentially vulnerable subpopulations in some areas*" and concluded the tighter constraints were necessary "*to address possible disproportionate impacts on potentially vulnerable populations and more generally to avoid inequities across all population groups.*" *Id.* at 61167 (emphasis added).

The D.C. Circuit again upheld EPA's methodology for selecting the level of the annual standard, holding EPA:

reasonably decided to address long-term exposure with *an annual standard somewhat below the long-term mean* concentrations in the ACS and Six Cities studies. *We approved a similar approach to assuring an adequate margin of safety in ATA III and we do so again here.* See 283 F.3d at 372 (denying petition for review of standard set "just below the range of mean annual PM_{2.5} concentrations observed

in studies showing a statistically significant association between fine [PM] and health effects”).

Am. Farm Bureau Fed’n, 559 F.3d at 526–27 (D.C. Cir. 2009) (cleaned up)

(emphasis added).⁴

C. EPA’s 2012 Rule lowered the annual standard for PM_{2.5} to 12.0 µg/m³, a level “somewhat below” the lowest long-term mean of key studies and removed spatial averaging as an option.

In 2012, EPA again used the same methodology in selecting the level of the annual standard, based on an updated group of studies, and also removed spatial averaging as an option. 78 Fed. Reg. 3086. These decisions reflected EPA’s ongoing focus on protecting all of the people in an air quality area, not just the population exposed to the area’s average level of PM_{2.5}. EPA recognized that the population of people exposed to the highest levels in an area were likely to be more vulnerable and at greater risk because of factors such as minority status, age, and/or low socioeconomic status (SES). *Id.* at 3104, 3145, 3267. EPA concluded that “the Integrated Science Assessment has identified persons from lower socioeconomic strata as an at-risk population.” *Id.* at 3125. Setting the standard at a level

⁴ The Court remanded the Rule on other grounds—failure to adequately explain not considering short-term studies in selecting the level of the annual standard, a change from the 1997 Rule, and failure to adequately explain how the standard provided an adequate margin of safety from morbidity effects in children and other vulnerable populations. *Am. Farm Bureau Fed’n*, 559 F.3d at 520–26. The court did not address spatial averaging.

“somewhat below” the lowest mean in the group of key studies, combined with the removal of spatial averaging, ensured that these at-risk persons would be exposed to levels below each of the average levels found in the key studies to be associated with serious health effects. *Id.* at 3161, 3162.

There was more data on PM_{2.5} air quality and health impacts in this review, and EPA’s analysis of this data raised greater concerns about the disproportionate impact spatial averaging could have on public health protection. *Id.* at 3125. EPA recognized that there always had been concern whether spatial averaging would provide adequate protection for the vulnerable population exposed to the highest levels in an area, finding that:

[E]ven when the annual PM_{2.5} standard was first set in 1997, the spatial averaging provisions included constraints intended to ensure that inequities in the level of protection would not result. These constraints on spatial averaging were tightened in the last review, based on an analysis showing the potential for spatial averaging to allow higher PM_{2.5} concentrations in locations where subgroups within the general population were potentially disproportionately exposed and hence, at disproportionate risk (e.g., low income and minority communities). ... *[T]he current constraints on spatial averaging may be inadequate in some areas to avoid substantially greater exposures for people living near monitors recording the highest PM_{2.5} concentrations. Such exposures could result in disproportionate impacts to at-risk populations, including low-income populations as well as minority groups.*

Id. at 3126–27 (emphasis added). EPA concluded that:

[P]ublic health would not be protected with an adequate margin of safety in all locations, as required by law, if disproportionately higher

exposure concentrations in at-risk populations such as low income communities as well as minority communities were averaged together with lower concentrations measured at other sites in a large urban area.

Id. at 3127 (emphasis added). With spatial averaging removed, compliance with the annual standard would be determined by the level at the monitor with the highest average concentration in the area, the “design value” for the area. *Id.* at 3145.

On the level of the standard, EPA explained the importance of setting the level below the lowest mean concentration in the key studies, and not within the range of those studies:

[T]he Administrator recognizes that in selecting a level of the annual standard that will protect public health with an adequate margin of safety, *it is not sufficient to focus on a concentration generally somewhere within the range of long-term mean concentrations* from the key long-term and short-term exposure studies that reported lower concentrations than had been observed in earlier reviews. ... *A level somewhere within the range of long-term mean concentrations of the full set of key studies would be higher than the long-term mean of at least one of the studies being considered and therefore would not provide a sufficient degree of protection against the health effects observed in that study.* Absent some reasoned basis to place less weight on the evidence in the epidemiological study with the lowest long-term mean concentration among these key studies, *this approach would not be consistent with the requirement to set a standard that will protect public health with an adequate margin of safety.* ... *[I]t is appropriate to consider a level for an annual standard that is not just at but rather is somewhat below the long-term mean PM_{2.5} concentrations reported in each of the key long- and short-term exposure studies.*

Id. at 3158–59 (emphasis added). The key studies had mean levels ranging from 13.4 to 12.8 $\mu\text{g}/\text{m}^3$ (short-term studies) and 14.5–13.6 $\mu\text{g}/\text{m}^3$ (long-term studies).

Id. at 3159.

EPA set 12.0 $\mu\text{g}/\text{m}^3$ as the annual standard, because:

An annual standard level of 12 $\mu\text{g}/\text{m}^3$ is below the long-term mean $\text{PM}_{2.5}$ concentrations reported in *each* of the key multi-city, long- and short-term exposures studies providing evidence of an array of serious health effects (e.g., premature mortality, increased hospitalization for cardiovascular and respiratory effects). As noted above, the importance of considering a level somewhat below the lowest long-term mean concentration in the full set of studies considered is to set a standard that would provide appropriate protection against the observed effects in *all* such studies.

Id. at 3161.

Likewise, EPA considered but rejected a level of 13.0 $\mu\text{g}/\text{m}^3$ because it was above the long-term mean of two of the key studies:

[T]he appropriate focus for selecting the level of the annual $\text{PM}_{2.5}$ standard is on concentrations somewhat below the lowest long-term mean concentrations from the set of key studies ... considered by the EPA (i.e., as shown in Figure 4). Thus, a standard level set at 13 $\mu\text{g}/\text{m}^3$ or higher would clearly not provide protection for the effects observed in the full set epidemiological studies and, therefore, this standard level could not be judged to be requisite with an adequate margin of safety.

Id. at 3162 (emphasis added).

EPA's decision on the level worked hand-in-hand with the removal of spatial averaging. A level set at 12.0 $\mu\text{g}/\text{m}^3$ combined with the removal of spatial averaging

meant that all people in the area would be exposed to no higher than an average of $12.0 \mu\text{g}/\text{m}^3$, including the population exposed to the highest concentrations in the area. This protected the population exposed to the highest levels, a population most likely at greater risk based on factors such as low SES, age, and minority status.

The D.C. Circuit upheld EPA's selection of a standard of $12.0 \mu\text{g}/\text{m}^3$. *Nat'l Ass'n of Mfrs.*, 750 F.3d 921. The court found that in lowering the level of the annual standard, "EPA selected the $12.0 \mu\text{g}/\text{m}^3$ level because it was *somewhat below* the lowest long-term mean concentration shown by certain key epidemiologic studies to cause adverse health effects." *Id.* at 924. The court found that "EPA followed a similar approach in earlier particulate matter NAAQS revisions, and we upheld those EPA decisions." *Id. citing Am. Farm Bureau Fed'n*, 559 F.3d at 526–27 (EPA "reasonably decided to address long-term exposure with an annual standard somewhat below the long-term mean concentrations"); *Am. Trucking Ass'ns, Inc.*, 283 F.3d at 372 (upholding particulate matter NAAQS where "EPA ultimately set the standard just below the range of mean annual [particulate matter] concentrations observed in studies showing a statistically significant association between fine particulate matter and health effects") (internal quotations omitted).

The Court also upheld the removal of spatial averaging, finding that EPA reasonably explained its decision to move away from spatial averaging because it

would “enable some portions of a compliance area—particularly those areas where sensitive individuals are likely to live—to exceed the NAAQS for periods of time ... [and] was inconsistent with EPA's goal of ensuring that the NAAQS provide requisite protection for all individuals.” *Nat’l Ass’n of Mfrs.*, 750 F.3d at 925.

D. The 2020 Rule departed from the methodology EPA used in the 1997, 2006, and 2012 and in so doing did not provide an adequate margin of safety.

In 2020, EPA departed from its prior practice and used a less protective methodology that was inconsistent with what it used in its 1997, 2006, and 2012 rules. 85 Fed. Reg. 82684. EPA retained the 12.0 $\mu\text{g}/\text{m}^3$ standard because it was within the range of the means of the key studies, with “[t]he majority of studies (*i.e.*, 19 out of 21)” having means above 12.0 $\mu\text{g}/\text{m}^3$, it was below the “mean of the study reported means or medians equal to 13.5 $\mu\text{g}/\text{m}^3$ ”, and EPA felt it was “more appropriate to focus on the body of studies together.” *Id.* at 82717. EPA’s less protective approach relied in part on “caution” about using the means of the studies to directly set the level of the standard, where the mean of a study reflected the average level in the study, and the standard had to be met at the highest level in an area, which was typically higher than an area’s average. *Id.*

Instead of a level somewhat below the mean of the lowest key study, as EPA had done three prior times to ensure an adequate margin of safety, EPA instead chose a level within the range of means of the studies. EPA failed to acknowledge this major

change in methodology and mischaracterized the 2020 Rule's methodology as a "similar manner as previous reviews." EPA, *Responses to Significant Comments on the 2020 Proposed Rule on the National Ambient Air Quality Standards for Particulate Matter* (April 30, 2020; 85 FR 24094) (Dec. 2020) at 4. EPA failed to discuss the reasoning behind EPA's prior approach and failed to justify rejecting this reasoning and changing to a much less protective approach.

Prior to the 2020 Rule EPA had consistently set PM_{2.5} annual levels based on the protection of vulnerable populations and avoiding disparities in protection. The level of the standard needed to protect all of the people in an area, including the vulnerable populations exposed to the highest levels in an area, not just those exposed to average or lower concentrations. EPA achieved this Clean Air Act goal by setting the level "somewhat below" the lowest long-term mean in the key studies, along with tightening and eventually removing spatial averaging. The D.C. Circuit consistently upheld these approaches as lawful.

EPA's "caution" in its 2020 Rule conflicts with the core purpose of the NAAQS. Standards requisite to protect public health with an adequate margin of safety are not focused on protecting just the general or average public. The purpose of the NAAQS has always been to protect the sensitive or vulnerable subpopulations of the public, those more at risk for the serious health effects associated with the

pollutant. 89 Fed. Reg. at 16206, note 5, *Am. Lung Ass'n*, 134 F.3d at 389, *Lead Indus. Ass'n, Inc.*, 647 F.2d at 1153. While protecting the vulnerable population from serious health effects may well provide more protection than needed for those who are not vulnerable, any overprotection of the average, healthy, or less vulnerable populations cannot justify failing to protect vulnerable populations with an adequate margin of safety.

California and several other parties filed petitions for review with the D.C. Circuit challenging the 2020 Rule. *State of California v. EPA* (D.C. Cir. No. 21-1014 consolidated with Nos. 21-1027, 21-1054). The court ordered the consolidated cases held in abeyance in light of EPA's decision to reconsider the 2020 Rule so there is no decision on its lawfulness. Clerk's Order, *State of California v. EPA*, Doc. No. 1885786, Feb. 17, 2021. However, the 2020 Rule's methodology was unprecedented and its resulting impact on vulnerable populations harmful.

II. The 2024 Rule returned to the methodology used in the 1997, 2006, 2012 rules and rejected the 2020 Rule's methodology.

In 2024, EPA returned to the methodology it used, and the D.C. Circuit upheld, in the 1997, 2006, and 2012 rules, explicitly rejecting the 2020 Rule's less protective approach. 89 Fed. Reg. at 16202, 16275, 16276, 16279, 16283.

State Petitioners claim that EPA’s 2020 “decision reflected EPA’s general approach of regulating reasonably below reported means” and that “EPA purported to do the same analysis [in 2024 as in 2020].” Initial Br. for State Petr’s at 13–14, Doc. No. 2058290, 27–28. This is clearly wrong. EPA explained that it was not following the 2020 Rule approach, was returning to its prior approach, and explained why: to protect all of the people in an area, including vulnerable populations exposed to the highest levels, from the risks identified in each of the key studies.

EPA explained it was considering a larger body of key evidence in its 2024 Rule than it did in its 2020 Rule. 89 Fed. Reg. at 16275. EPA also explained it was following the methodology it had consistently used prior to the 2020 Rule for selecting the level of the annual standard. *See Id.* at 16275, 16276, 16279, 16283. In returning to the approach used prior to the 2020 Rule, EPA determined it was “most appropriate to set the level of the standard to somewhat below the lowest long-term study-reported mean PM_{2.5} concentration reported in key U.S. epidemiologic studies, which is 9.3 µg/m³.” *Id.* at 16275. EPA explained that 9.0 µg/m³ would be “a level below” the lowest long-term study level of 9.3 µg/m³ and would protect the vulnerable population exposed to the levels at the highest monitor in an area from the serious health risks associated with a long-term average of 9.3 µg/m³. *Id.* at 16283. The populations at increased health risk from PM_{2.5} included at-risk groups that were more likely *to be exposed to the higher*

levels in an area. Id. at 16204, 16236, 16375 (emphasis added); EPA, *Response to Significant Comments on the 2023 Proposed Rule for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter*, Docket Number OAR-2015-0072 (Feb. 2024) (*hereinafter* 2024 RTC), 51–52, 54–55.

EPA projected that a level of $9.0 \mu\text{g}/\text{m}^3$ would shift the entire air quality distribution such that the area's remaining population would be protected and was supported by evidence that the highest monitor was typically 10%-20% higher than the overall average in an area. 89 Fed. Reg. at 16283 (finding “a standard level of $9.0 \mu\text{g}/\text{m}^3$ is expected to provide sufficient protection not only in areas where the highest allowable concentration would be located ... but also in other parts of the area where $\text{PM}_{2.5}$ concentrations would be expected to be maintained even lower.”); *see also id.* at note 119. EPA concluded that air quality no higher than $9.0 \mu\text{g}/\text{m}^3$ at the highest monitor in an area, combined with lowering the air quality distribution across the entire area, “would provide requisite protection with adequate margin of safety, for all populations, including those most at-risk.” *Id.* at 16284; *see also id.* at 16285; 2024 RTC at 55–57.

EPA selected the level of the annual standard for the 2024 Rule using an approach that was consistent with the approach it used in the 1997, 2006, and 2012 rules. In each, EPA identified the key group of studies most useful for selecting the level of

the standard. In each, EPA selected a level “somewhat below” the lowest long-term mean of the key studies. In each, the D.C. Circuit upheld EPA’s use of the approach followed here. *Am. Trucking Ass’n*s, 283 F.3d at 372; *Am. Farm Bureau Fed’n*, 559 F.3d at 526–27 (D.C. Cir. 2009); *Nat’l Ass’n. of Mfrs.*, 750 F.3d at 924 (D.C. Cir. 2014).

By design, this approach protects all of the population in an area from the risks identified in each of the key studies. It protects the population exposed to the highest level in an area, a group likely at greater risk from exposure to PM_{2.5}, with an adequate margin of safety, as well as the remaining population in an area. The 2024 Rule is consistent with longstanding past practice, corrects the EPA’s deviation from the methodology in the 2020 Rule, and is well-reasoned and articulated throughout the 2024 Rule.

CONCLUSION

EPA properly set the level of the annual standard using the approach it used in three prior rulemakings, an approach previously upheld by the D.C. Circuit Court of Appeals. This approach ensures that all of the populations in an area, including vulnerable populations exposed to the highest concentrations, are protected with an adequate margin of safety. For the foregoing reasons, Environmental Protection Network urges this Court to consider the extensive regulatory history and EPA's documented decision-making designed to protect people from the harms of particulate matter, as Congress commanded, and respectfully requests this Court uphold the 2024 Rule.

Respectfully submitted,

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Dated: August 26, 2024

CERTIFICATE OF COMPLIANCE

Counsel hereby certifies, in accordance with Fed. R. of App. P. 28 and 32(g)(1), Circuit Rule 28, 29, and 32 that the following brief contains 4,842 words, as counted by counsel's word processing system, and thus complies with the 6,500-word limit. See Fed. R. App. P. 32 (a)(7) and 29 (a)(5). Further, this document complies with the typeface and type-style requirements of Fed. R. App. P. 32(a)(5) and (a)(6) because this document has been prepared using Microsoft Word for Microsoft 365 in proportionally spaced 14-point Times New Roman typeface.

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CERTIFICATE OF SERVICE

I hereby certify that on this 26th day of August 2024, the foregoing **AMICUS BRIEF** was served electronically on all registered counsel through the Court's CM/ECF system.

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