

In the Supreme Court of the United States

COMMONWEALTH OF KENTUCKY,
STATE OF WEST VIRGINIA, ET AL.

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, ET AL.

Respondents.

On Petition for Writ of Certiorari
to the United States Court of Appeals
for the District of Columbia Circuit

APPENDIX – Volume I of II

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued December 16, 2024 Decided June 26, 2026

No. 24-1050

COMMONWEALTH OF KENTUCKY, *et al.*,

Petitioners

v.

ENVIRONMENTAL PROTECTION AGENCY AND LEE M.
ZELDIN, IN HIS OFFICIAL CAPACITY AS ADMINISTRATOR
OF THE U.S. ENVIRONMENTAL PROTECTION AGENCY,

Respondents

ALLIANCE OF NURSES FOR
HEALTHY ENVIRONMENTS, *et al.*,

Intervenors

Consolidated with 24-1051, 24-1052,
24-1073, 24-1091

On Petitions for Review of a Final Action
of the Environmental Protection Agency

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Seth L. Johnson, *Marvin C. Brown IV*, *Shaun A. Goho*, *Hayden W. Hashimoto*, *John Walke*, and *Emily Davis* were on the brief for respondent-intervenors Health, Environmental, and Community Group.

Keri N. Powell was on the brief for *amicus curiae* WE ACT for Environmental Justice, et al. in support of respondents.

Jaclyn Lopez and *Rachel Curran* were on the brief for *amicus curiae* Environmental Protection Network in support of respondents.

Elizabeth J. Hubertz was on the brief for *amicus curiae* National Parks Conservation Association in support of respondents.

Jessica H. Arnell and *Jason A. Schwartz* were on the brief for *amicus curiae* the Institute for Policy Integrity at New York University School of Law in support of respondents.

Before: MILLETT and CHILDS, *Circuit Judges*, and GINSBURG, *Senior Circuit Judge*.

Opinion for the Court filed by *Senior Circuit Judge* GINSBURG.

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GINSBURG, *Senior Circuit Judge*: Two groups of petitioners challenge a 2024 Environmental Protection Agency rule revising the National Ambient Air Quality Standards (NAAQS) for particulate matter. Their claims specifically concern the decision of the Administrator to revise the primary annual standard for fine particulate matter (PM_{2.5}) from 12 µg/m³ to 9 µg/m³. In so doing, he expressly reconsidered a decision of the previous Administrator who in 2020 had decided to leave the 12 µg/m³ standard in place based upon the scientific evidence then available.¹

¹ In 2025, after this case had been fully briefed and argued, President Trump appointed a new Administrator of the EPA. For purposes of this opinion, “the Administrator” refers to the Administrator appointed by President Biden, who approved the

A group of industry petitioners argue that the EPA lacked statutory authority to promulgate the new rule; several states contend the EPA’s decision-making was tainted by impermissible “environmental justice” considerations; and all claim the agency action was arbitrary and capricious in violation of the Clean Air Act, 42 U.S.C. § 7607(d)(9)(A).

After initially defending the new rule, the EPA now moves to vacate the rule on the grounds that it exceeded its statutory authority and acted unreasonably by failing to consider costs. Because these arguments lack merit, we deny the petitions for review and the motion for vacatur.

I. Background

The Clean Air Act (CAA) requires that the Administrator (1) publish a list of air pollutants, (2) issue air quality criteria for those pollutants, and (3) promulgate a primary and a secondary air quality standard for each pollutant for which criteria have been issued. *See generally* 42 U.S.C. §§ 7408-09. Although this case most directly concerns a revision to the primary standard for PM_{2.5}, it necessarily implicates steps antecedent to setting the NAAQS for fine particulate matter.

A. Statutory Framework

The NAAQS-setting process begins with the statutory requirement in § 7408 that the Administrator publish and “from time to time thereafter revise” a list of air pollutants “[f]or the purpose of establishing [NAAQS].” § 7408(a)(1). Once the Administrator lists an air

2024 Final Rule. References to “the previous Administrator” are to the Administrator during President Trump’s first term, who approved the 2020 Final Rule.

pollutant, he must publish air quality criteria for that pollutant, which form the scientific basis upon which the corresponding standard relies. § 7408(a)(2). Accordingly, the 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, in varying quantities.” *Id.*²

Further, § 7408(c) provides that “[t]he Administrator shall from time to time review, and, as appropriate, modify, and reissue any criteria . . . issued pursuant to this section.” The EPA complies with the requirement by preparing an “Integrated Science Assessment,” which is a “comprehensive evaluation and synthesis of the policy-relevant science” that “serves as the scientific foundation for the review of” the NAAQS. EPA, INTEGRATED SCIENCE ASSESSMENT FOR PARTICULATE MATTER P-9 (2019).

When the Administrator issues criteria for a pollutant, he must “simultaneously” propose a corresponding standard. § 7409(a)(2). After a period for public

² As far as “practicable,” the criteria shall include the following information:

- (A) those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant;
- (B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and
- (C) any known or anticipated adverse effects on welfare.

§ 7408(a)(2).

comment, the proposed standard may be promulgated and become law. § 7409(a)(1)(B). Substantively, the Administrator must base the standard upon the scientific criteria and exercise his “judgment” to set the standard at a level “requisite to protect the public health” with “an adequate margin of safety.” § 7409(b)(1).³ A NAAQS “may be revised in the same manner as promulgated.” *Id.*

In short, pursuant to § 7408 the Administrator maintains a list of air pollutants and publishes scientific criteria for each one. Then, under § 7409(a) and (b), the Administrator promulgates a NAAQS for each listed pollutant and may later revise that standard in the manner in which it was promulgated.

That brings us to § 7409(d)(1), the interpretation of which the parties vigorously dispute. In full, the provision states:

Not later than December 31, 1980, and at five-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 7408 of this title and the national ambient air quality standards promulgated under this section and shall make such revisions in such criteria and standards and promulgate such new

³ National primary ambient air quality standards, prescribed under subsection (a) shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. Such primary standards may be revised in the same manner as promulgated.

§ 7409(b)(1).

standards as may be appropriate in accordance with section 7408 [and section 7409(b)]. The Administrator may review and revise criteria or promulgate new standards earlier or more frequently than required under this paragraph.

As this court has recognized, the first sentence requires that the Administrator “complete a ‘thorough’ review of the NAAQS every five years” and “revise the criteria and standards or promulgate new standards as appropriate.” *Murray Energy Corp. v. EPA*, 936 F.3d 597, 605 (2019).

By statutory design, an independent council of experts — the Clean Air Scientific Advisory Committee (CASAC) — “assist[s] in this process.” *Id.* At five-year intervals, the CASAC is required to “complete a review” of existing NAAQS and criteria, and “recommend to the Administrator any new [NAAQS] and revisions of existing criteria and standards as may be appropriate.” § 7409(d)(2)(B). The CASAC’s recommendations are timed to arrive approximately one year prior to the date by which the Administrator must complete his mandatory quinquennial review. *Compare* § 7409(d)(2)(B) (five-year intervals for the CASAC beginning on January 1, 1980), *with* § 7409(d)(1) (five-year intervals for the Administrator beginning on December 31, 1980). “[T]he ultimate decision to revise the NAAQS — and the determination of the new level — rests with the Administrator.” *Murray*, 936 F.3d at 605. To the extent the Administrator’s proposed or promulgated rule “differs in any important respect from any of [the CASAC’s] recommendations,” however, it must be accompanied by a statement that includes “an explanation of the reasons for such differences.” §

7607(d)(3); see § 7607(d)(6)(A); *Mississippi v. EPA*, 744 F.3d 1334, 1355 (D.C. Cir. 2013).

B. The 2020 and 2024 Final Rules

In December 2020, the previous Administrator promulgated a final rule that retained the preexisting primary annual standard for PM_{2.5} of 12.0 µg/m³. Review of the National Ambient Air Quality Standards for Particulate Matter (2020 Final Rule), 85 Fed. Reg. 82684, 82685/2-3. The Administrator’s judgment at that time was based upon the EPA’s science and policy assessments as well as comments from the CASAC and the public. *Id.* On the question whether to retain the standard of 12.0 µg/m³ for PM_{2.5}, however, the CASAC “did not reach consensus.” *Id.* at 82706/1-2. Those who supported keeping the standard at 12.0 µg/m³ “expressed the view that substantial uncertainty remains in the evidence for associations between PM_{2.5} exposures and mortality or serious morbidity effects.” *Id.* at 82706/2. Those who supported lowering the standard “emphasized recent findings of associations with PM_{2.5} in areas with average long-term PM_{2.5} concentrations below the level of the annual standard and studies that show positive associations even when estimated exposures above 12 µg/m³ are excluded from analyses.” *Id.* at 82707/1.

The previous Administrator’s approach in 2020 ultimately tracked the views of those CASAC members who supported keeping the standard at 12.0 µg/m³. He emphasized “important uncertainties and limitations” in the epidemiological studies, expressed concern “about placing too much weight” on those studies, and noted his “caution in directly comparing the reported study mean values to the standard level.” *Id.* at 82716/3-82717/1. He therefore found it “more appropriate to focus on the body of studies together” and

took note of “the mean of study-reported means” — $13.5 \mu\text{g}/\text{m}^3$ — which was “above the level of the current standard.” *Id.* at 82717/1. Several groups filed petitions challenging the 2020 Final Rule, which petitions were consolidated in this court as *California v. EPA*, No. 21-1014.

Meanwhile, President Biden assumed office in January 2021, and in February the EPA filed an unopposed motion to hold the consolidated petitions in abeyance for 90 days. In its motion, the EPA explained that the President had issued an executive order directing agency review of certain actions, including the 2020 Final Rule. *See* Exec. Order No. 13990, 86 Fed. Reg. 7037 (2021). We granted the EPA’s motion and its eight subsequent motions to extend the period of abeyance, as a result of which the case has remained in abeyance for more than five years, spanning the Biden and Trump Administrations. During that time, the Administrator initiated the review that culminated in the 2024 Final Rule before us in this case. *See* Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (2024 Final Rule), 89 Fed. Reg. 16202, 16210/2 (explaining the EPA announced its decision to reconsider the 2020 Final Rule in June 2021 “because the available scientific evidence and technical information indicate that the current standards may not be adequate to protect public health”).

As part of its review, the EPA reopened and revised the underlying air quality criteria to account for recent scientific literature. *Id.* at 16211/1-2. The result was the EPA’s Supplement to the 2019 Integrated Science Assessment for Particulate Matter and a new policy assessment. *See id.* at 16212/1-3. The CASAC also conducted a new review and this time unanimously

concluded that the 12.0 $\mu\text{g}/\text{m}^3$ primary standard should be lowered. *See id.* at 16204/2, 16256/3. A majority of the CASAC recommended a standard of 8 to 10 $\mu\text{g}/\text{m}^3$, while a minority deemed a standard of 10 to 11 $\mu\text{g}/\text{m}^3$ adequate to protect public health. *See id.* at 16204/2.

The EPA promulgated the 2024 Final Rule, titled “Reconsideration of the National Ambient Air Quality Standards for Particulate Matter,” in March of that year. *Id.* at 16202/1. The Administrator considered the various positions of the CASAC members and concluded that setting the standard at 9 $\mu\text{g}/\text{m}^3$, the middle of the range recommended by the CASAC majority, was appropriate. *Id.* at 16204/3.

C. Procedural History

Industry groups and several states thereafter filed petitions challenging the 2024 Final Rule, which this court consolidated. Other states intervened in support of the rule, as did a group of health, environmental, and community entities.

We heard oral argument on the petitions for review on December 16, 2024. Two months later, the new Administrator appointed by President Trump filed a motion to hold the case in abeyance to give the agency time to review the 2024 Final Rule. We granted that motion and three more extending the period of abeyance. In two of those motions, the EPA stated its intention to begin a new rulemaking to replace the 2024 Final Rule.

In November 2025, however, the EPA filed a motion for vacatur of the 2024 Final Rule and reversed course in two ways. First, the EPA now agreed with the Industry Petitioners that the EPA had exceeded its statutory authority in issuing the 2024 Final Rule and

had acted unreasonably by ignoring costs. Second, the EPA seemingly disavowed any intention to begin a new rulemaking to replace the 2024 Final Rule. The EPA explained that it had simply been considering next steps when it said that it would begin a new rulemaking and now called any future rulemaking “irrelevant.”

The intervenors opposed the EPA’s motion for vacatur. The Health Group Intervenors filed a cross-motion for this court to lift the abeyance and decide the merits of the petitions for review. The EPA agrees that we should lift the abeyance and asks us to reach the merits, hold the 2024 Final Rule unlawful, and vacate it. We now grant the cross-motion to lift the abeyance and proceed to the merits of the petitions for review and the motion for vacatur.

II. Analysis

We have jurisdiction under 42 U.S.C. § 7607(b)(1). We review the 2024 Final Rule under the same standard as applies to claims brought under the Administrative Procedure Act. *Heating, Air Conditioning & Refrigeration Distribs. Int’l v. EPA*, 71 F.4th 59, 63 (D.C. Cir. 2023). As relevant here, we will set aside the rule if it is “arbitrary, capricious, an abuse of discretion,” or “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.” § 7607(d)(9)(A), (C).

The standard by which we determine whether the Administrator acted within his statutory authority differs from the standard applicable when reviewing the Administrator’s judgment on the merits. With respect to the former, this court exercises its “independent judgment in deciding whether an agency has acted within its statutory authority.” *Loper Bright*

Enters. v. Raimondo, 603 U.S. 369, 412 (2024). When as here “a particular statute delegates authority to an agency consistent with constitutional limits, courts must respect the delegation, while ensuring that the agency acts within it.” *Id.* at 413; *see* § 7409(b)(1) (delegating NAAQS-setting authority to the “judgment of the Administrator” within statutorily defined limits); *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 474 (2001) (upholding the constitutionality of this delegation).

With respect to this court’s review of the Administrator’s decision on its merits, we “defer to the EPA’s scientific judgment while examining the record to ensure the Agency has considered the relevant factors and reasonably explained how it reached its conclusions.” *Am. Farm Bureau Fed’n v. EPA*, 559 F.3d 512, 519-20 (D.C. Cir. 2009). “We will give an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise.” *Ctr. for Biological Diversity v. EPA*, 749 F.3d 1079, 1087-88 (D.C. Cir. 2014) (cleaned up).

A. Statutory Authority

The Industry Petitioners, the State Petitioners, and the EPA contend the Administrator lacked statutory authority to promulgate the 2024 Final Rule. They argue first that the Administrator acted unlawfully when he reconsidered the 2020 Final Rule and issued the Final Rule only four years after the previous rulemaking; any implicit authority the EPA may have had to reconsider its rules was displaced, they say, by § 7409(d)(1), which requires the Administrator to review and revise (if appropriate) criteria and NAAQS every five years and allows him to review and revise them more frequently than required. They argue second that insofar as the 2024 Final Rule can be

characterized as a revision rather than a reconsideration, § 7409(d)(1) requires the Administrator to perform a “thorough review” of criteria and NAAQS as part of any revision — including any off-cycle revision such as this one. Because the EPA did not perform such a review, they ask us to set aside the 2024 Final Rule.

According to the State and Health Group Intervenor, § 7409(d)(1) does not displace but supplements the Administrator’s authority to revise a NAAQS under § 7409(b)(1); § 7409(d)(1) establishes a mandatory duty — that the Administrator perform a “thorough review” of NAAQS every five years — that is “distinct from EPA’s authority to otherwise reconsider or revise its NAAQS.”

1. Reconsideration or revision?

We need not delineate the precise boundaries of the Administrator’s reconsideration authority because the 2024 Final Rule is best understood as a revision to the criteria and NAAQS for particulate matter. Although titled a “reconsideration” of the 2020 Final Rule, it is in substance a revision of an individual NAAQS. Indeed, the first paragraph unambiguously states that it provides the “rationale for the Administrator’s final decisions to revise the primary annual PM_{2.5} standard.” 89 Fed. Reg. at 16203/1.

The Industry Petitioners argue the 2024 Final Rule must be a reconsideration because the Administrator “prepared only an ‘[Integrated Science Assessment] Supplement’” and “deferred consideration of a number of available scientific studies” until the next quinquennial review. They say those facts are controlling because a true revision “must build a record from scratch” while a “reconsideration would take as its

starting point the previous decision not to revise and the associated record.” Nothing in the statutory scheme, however, reflects that distinction. We see no reason the Administrator cannot revise a NAAQS and, in the process, reconsider a prior rule that left the existing NAAQS unchanged.⁴

The Industry Petitioners call upon *SEC v. Chenery Corp.*, 318 U.S. 80 (1943), to argue that the EPA cannot “recast” its reconsideration as a revision. “Under the *Chenery* doctrine, a reviewing court must confine itself to the grounds upon which the record discloses that the agency’s action was based.” *Byers v. Comm’r*, 740 F.3d 668, 680 (D.C. Cir. 2014). The *Chenery* doctrine, however, has no application here because the EPA consistently characterized its rule as a revision. It did so in its proposed and final rules, *see* 88 Fed. Reg. 5558, 5560/2 (2023); 89 Fed. Reg. at 16203/1, and it repeatedly referred to its decision to “revise” the “existing” NAAQS in its responses to comments, *see* EPA, Responses to Significant Comments on the 2023 Proposed Rule for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (Responses to Comments) at 27, 34, 46, 56, 118 (2024). This characterization is unsurprising because the principal change worked by the 2024 Final Rule was its revision of the primary annual standard for PM_{2.5}.

⁴ To the extent the Industry Petitioners argue that the Administrator lacks any reconsideration authority, they are mistaken. The CAA explicitly requires the Administrator to “convene a proceeding for reconsideration” under certain circumstances. § 7607(d)(7)(B). We need not, however, fully define the interplay between the Administrator’s reconsideration authority and his other powers. It is enough that we conclude the Administrator may revise criteria and NAAQS and, in the course of so doing, reconsider a previous rule.

2. Authority to revise NAAQS

Our conclusion that the 2024 Final Rule is best understood as a revision does not answer whether the Administrator acted within his statutory authority to revise a NAAQS. The question is particularly important here because the parties dispute the source of the Administrator’s revision authority. The Industry and State Petitioners — joined by the EPA in its motion for vacatur — argue that § 7409(d)(1) provides the sole source of the Administrator’s revision authority and authorizes him to revise NAAQS off-cycle only if he first performs a “thorough review” of the criteria and NAAQS, which the EPA concedes it did not do before promulgating the 2024 Final Rule. The intervenors respond that § 7409(b) authorizes the Administrator to revise a standard and does not require him to first perform a “thorough review.”

“Statutory interpretation, as we always say, begins with the text.” *Ross v. Blake*, 578 U.S. 632, 638 (2016). As relevant here, two provisions of § 7409 refer to the Administrator’s authority to revise a NAAQS. Section 7409(b) provides the substantive principles the Administrator is to apply when setting a primary or secondary standard and states that each “may be revised in the same manner as promulgated.” This provision was added to the CAA in 1970, Pub. L. No. 91-604, § 4(a), 84 Stat. 1676, 1679-80, and predates the addition of § 7409(d)(1) by seven years, Clean Air Act Amendments of 1977, Pub. L. No. 95-95, § 106(a), 91 Stat. 685, 691. Consequently, the Administrator indisputably had authority to revise primary and secondary NAAQS at any time. So far, so clear.

The first sentence of § 7409(d)(1) then requires the Administrator to “complete a thorough review” of the existing criteria and standards every five years and to

revise them if appropriate. The reason for that requirement is obvious: By requiring a “thorough review” the Congress ensured the Administrator would comprehensively evaluate each and every existing criterion and standard on a regular basis. In other words, it serves as an action-forcing device to ensure NAAQS do not fall too far behind the evolving scientific evidence.

Together § 7409(b) and the first sentence of § 7409(d)(1) provide that the Administrator may revise NAAQS “in the same manner as promulgated” and must revise NAAQS as appropriate every five years.⁵ The second sentence of § 7409(d)(1) then adds that “[t]he Administrator may review and revise criteria or promulgate new standards earlier or more frequently than required under this paragraph,” *i.e.*, under the first sentence. The plain objective of this sentence is to clarify that the quinquennial review required by the first sentence of § 7409(d)(1) does not limit the

⁵ When questioned about § 7409(b)(1) at oral argument, the Industry Petitioners again invoked *Chenery* to argue that the EPA could not rely upon § 7409(b)(1) as the source of its revision authority. As an initial matter, we have long held the *Chenery* doctrine inapplicable “when the question presented [was] one of statutory construction.” *Bldg. & Constr. Trades Dep’t, AFL-CIO v. U.S. Dep’t of Lab. Wage Appeals Bd.*, 829 F.2d 1186, 1189 (1987); *see also Canonsburg Gen. Hosp. v. Burwell*, 807 F.3d 295, 304 (D.C. Cir. 2015) (“We have explained that *Chenery* only limits judicial review of factual determinations or policy judgments that the agency alone is authorized to make” (cleaned up)). In any event, the *Chenery* doctrine does not apply here because the EPA raised § 7409(b) as a basis for the 2024 Final Rule in response to comments: “The EPA understands [§ 7409(b)] to authorize the Administrator to revise the NAAQS.” Responses to Comments at 120. The EPA also cited its “implicit and explicit authority to revisit earlier decisions on the NAAQS,” *id.* at 118, a matter we discuss below at 21, and its “authority under [§ 7409]” generally, *id.* at 118, 122, as authorizing its revision.

Administrator’s authority to revise a standard sooner; nothing in § 7409(d)(1) displaces the Administrator’s revision authority in § 7409(b).

The petitioners and the EPA raise several objections to this conclusion. The EPA agrees that it had revision authority before the Congress added § 7409(d)(1), but it disputes the source of that authority. The EPA claims it had “inherent authority” to revise a standard before 1977, and § 7409(b) provided only the procedure for doing so. As we have explained, however, “the term ‘inherent’ is misleading because it is axiomatic that administrative agencies may act only pursuant to authority delegated to them by Congress. Thus, the more accurate label for the power [the] EPA describes is ‘statutorily implicit.’” *Nat. Res. Def. Council v. Regan*, 67 F.4th 397, 401 (2023) (cleaned up). More to the point, § 7409(b) expressly recognizes that a NAAQS “may be revised.” The EPA offers no evidence the Congress intended to limit the Administrator’s pre-existing revision authority in 1977 when it added the periodic-review requirement. We therefore do not agree with the EPA and the petitioners that § 7409(d)(1) provides the “exclusive source of [the Administrator’s] revision authority.”

Even if § 7409(b) provides revision authority, says the EPA, we must read that provision in harmony with § 7409(d)(1). The petitioners and the EPA reason that the “thorough review” requirement applies not only to the quinquennial review mandated by the first sentence of § 7409(d)(1), but also to the off-cycle revisions referenced in the second sentence. We do not, however, understand § 7409(d)(1) to require a “thorough review” as a precondition to an off-cycle revision.

We begin again with the statutory text. The requirement that the Administrator “complete a thorough

review” of the existing criteria and standards every five years resides in the first sentence of § 7409(d)(1). The phrase “thorough review,” however, does not appear in the second sentence of § 7409(d)(1): “The Administrator may review and revise criteria or promulgate new standards earlier or more frequently than required under this paragraph.” The Industry Petitioners and the EPA argue this sentence nonetheless implicitly cross-references the first sentence through the phrases “review” and “under this paragraph.” Per this reading of § 7409(d)(1), the sole difference between the two sentences is one of timing; the process for revising a standard — whether at the required intervals or off-cycle — is the same.

We are not persuaded. Starting with “review,” the absence of the word “thorough” in the second sentence of § 7409(d)(1) is significant: “When Congress includes particular language in one section of a statute but omits it in another — let alone in the very next provision — this Court presumes that Congress intended a difference in meaning.” *Loughrin v. United States*, 573 U.S. 351, 358 (2014) (cleaned up). Omitting the word “thorough” in the second sentence of § 7409(d)(1) suggests the Congress did not intend to require the Administrator to perform such a review when making an off-cycle revision.

The phrase “under this paragraph” does refer to the first sentence of § 7409(d)(1), but we do not read that reference as importing into the second sentence all the requirements in the first sentence. As the State Intervenor explain, that reference simply clarifies that the Administrator may act sooner than required by the first sentence of § 7409(d)(1), that is, “earlier or more frequently” than every five years. Indeed, the Industry Petitioners themselves characterize that

phrase as “a cross-reference to the five-year intervals mandated in the first sentence of [§ 7409(d)(1)].” To read it as also importing the “thorough review” requirement into the second sentence, as the Industry Petitioners and the EPA ask us to do, would stretch its meaning to the point of frustrating it. That seems certain when one considers that this interpretation would undermine rather than advance the plain objective of the first sentence: Requiring a full review whenever the Administrator seeks to revise a single criterion or standard off-cycle would prevent the Administrator from responding promptly to changes in the relevant science.

When pressed on this point at oral argument, the Industry Petitioners suggested a “thorough review” outside the five-year cycle would require only that the Administrator thoroughly review the scientific criteria underlying the standard he seeks to revise. Oral Arg. Tr. 39:24-40:15. Even this more limited understanding of “thorough review” in the second sentence would undercut the Administrator’s ability to keep a NAAQS up-to-date. Requiring a comprehensive review of all the scientific inputs to the criteria for a single standard would unnecessarily delay promulgation of a new standard.

This case illustrates the problem. By 2021 the EPA became aware of certain scientific studies likely to require a change in the standard for fine particulate matter and began updating its science and policy assessments. That process resulted in the EPA’s Supplement to the 2019 Integrated Science Assessment for Particulate Matter and a new policy assessment, both published in May 2022. *See* 89 Fed. Reg. 16212/3-16213/1. Requiring the EPA to expend limited resources to review other scientific studies unlikely to

affect the final standard could delay but not improve the result.⁶ That the Congress gave the agency discretion to address the criteria most relevant to protecting public health is the only sensible reading of the statute.

The EPA says its reading of § 7409(d)(1) better consists with other provisions of the Clean Air Act, particularly the requirement that the Administrator establish air quality criteria based upon the “latest scientific knowledge.” § 7408(a)(2). To the contrary, as the Health Group Intervenors argue, importing the “thorough review” requirement into the second sentence of § 7409(d)(1) would create tension with several other parts of the statutory scheme. For example, the provision requiring the Administrator to issue criteria for newly designated air pollutants also requires that the Administrator “from time to time review, and, as appropriate, modify, and reissue any criteria . . . issued pursuant to this section.” § 7408(c). It says nothing of performing a thorough review first and instead affords the Administrator maximum flexibility to update criteria so as to reflect the prevailing science. Under the Industry Petitioners’ and the EPA’s interpretation of the second sentence of § 7409(d)(1), however, the Administrator could “revise criteria . . . more frequently than required” by the

⁶ At oral argument, the Industry Petitioners said that in order to perform a “thorough review” of a NAAQS off-cycle the EPA would not need to revisit studies that it had considered during its prior review. Oral Arg. Tr. 35:21-36:7. As for new studies, the notice-and-comment process provides an opportunity for interested parties to argue that the EPA did not consider relevant studies or that it did not provide a reasoned explanation for the studies it chose to rely upon. Indeed, the Industry Petitioners did the former in this rulemaking proceeding, but they did not raise that argument on appeal. *See* Oral Arg. Tr. 86:23-88:7.

mandatory review only if he performs the “thorough review” required by the first sentence. That effectively reads the thoroughness requirement into § 7408(c), which is inconsistent with the broad and flexible terms used in that provision. *See Loper Bright Enters.*, 603 U.S. at 395 (recognizing “appropriate” as a term that “leaves agencies with flexibility”); *cf. Waterkeeper All. v. EPA*, 140 F.4th 1193, 1215 (9th Cir. 2025) (explaining that the use of the phrase “from time to time” in the Clean Water Act “suggests that EPA has discretion about when to revise such standards”).

The Industry Petitioners and the EPA resist this conclusion by arguing that an off-cycle revision without a thorough review would undermine the periodic-review requirement. We do not see how. Acting sooner than the five-year review cycle required by § 7409(d)(1) does not excuse the Administrator from doing a thorough review every fifth year. Nor are the Industry Petitioners correct that an off-cycle revision under our interpretation of § 7409 would be “*without any limitations or requirements whatsoever*.” Any revision must satisfy the substantive standard in § 7409(b) and comply with the strictures of the CAA, including its requirement of reasoned decisionmaking. *See Heating, Air Conditioning & Refrigeration Distribs.*, 71 F.4th at 63. Those requirements are not toothless and have been applied by this court when reviewing NAAQS on many occasions.

In sum, the Administrator must “complete a thorough review” and, if appropriate, revise criteria and NAAQS every five years pursuant to the first sentence of § 7409(d)(1), but he may revise them more frequently without completing a “thorough review.” The Administrator therefore acted within his statutory authority by promulgating the 2024 Final

Rule revising the air quality standard for fine particulate matter.

B. Arbitrary and Capricious

An agency rule will be held arbitrary and capricious if, among other reasons, in formulating it the agency (1) relied upon an impermissible consideration, (2) entirely failed to consider an important aspect of a problem, (3) explained the rule in a way that runs counter to the evidence before it, or (4) adopted a rule that “is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983). The Industry and State Petitioners claim the EPA violated the CAA in each of these respects, and the EPA itself, in moving for vacatur, now joins the petitioners in asserting that the Administrator unreasonably ignored the costs associated with the mid-cycle review giving rise to the 2024 Final Rule. Each of these arguments is either foreclosed by precedent or unsupported by the record.

1. Impermissible considerations

The State Petitioners argue that the Administrator relied upon impermissible considerations — namely, promoting environmental justice and countering climate change — to justify the 2024 Final Rule. They begin by correctly observing that the Administrator’s remit under the CAA is to set primary NAAQS “requisite to protect the public health” with “an adequate margin of safety.” § 7409(b)(1). They then point to President Biden’s Executive Order No. 13990, which served as the initial catalyst for the EPA’s review, as evidence of the Administrator’s impermissible environmental goals. *See* 89 Fed. Reg. at 16210/2

(explaining the order “directed review of certain agency actions” including the 2020 Final Rule).

The EPA, for its part, did not dispute in its response brief the State Petitioners’ premise that environmental justice and climate change are impermissible reasons for setting primary NAAQS under § 7409(b)(1). Instead, the agency defended the record it made and characterized the State Petitioners’ argument as little more than an “unsubstantiated accusation that climate or environmental justice considerations improperly influenced the Agency’s course of action.” We agree with the latter point.

The EPA here is on solid ground; the administrative record simply does not support the State Petitioners’ claim. The 2024 Final Rule accurately sets out and adheres to the appropriate legal framework for setting primary NAAQS consistent with § 7409(b)(1). *See* 89 Fed. Reg. at 16206/1-16207/1. The 2024 Final Rule explained that the Administrator announced his decision to reconsider the 2020 Final Rule in June 2021 “because the available scientific evidence and technical information indicate[d] that the current standards may not be adequate to protect public health.” *Id.* at 16210/2. Indeed, in the lead-up to its review the EPA “preliminarily concluded” that certain new studies “were likely to be relevant” and “would potentially warrant a reopening of the air quality criteria.” *Id.* at 16211/1. None of these statements suggests the Administrator considered environmental justice or climate change. On the contrary, the EPA made clear in its response to public comments that it had “no intention or goal to reduce greenhouse gases through this rulemaking.” Response to Comments at 135.

Against that, the best the State Petitioners can muster are repeated references to Executive Order No.

13990, which they unilaterally christen “the Climate Order.” The references to climate change in that order, however, are not specific to NAAQS-setting and cannot overcome the evidence — or lack of it — in the administrative record.

In any event, the EPA addressed this issue head-on when responding to comments regarding the proposed rule. The agency made clear that the decision to revisit the NAAQS for particulate matter “rested with the EPA” and was grounded upon “additional available information, as well as advice from the CASAC and public comment.” *Id.* at 134. Notably, although the Administrator ultimately adopted the recommendation of the CASAC, the State Petitioners do not accuse the CASAC of improper motives. At bottom, the State Petitioners’ mixture of conjecture and strident accusations falls far short of demonstrating that the Administrator relied upon something other than public health when setting the NAAQS for particulate matter.

2. Considerations other than public health

The Industry and State Petitioners, now joined by the EPA, also argue that the 2024 Final Rule is invalid because the Administrator failed to consider matters other than public health, principally costs and attainability. Both the Supreme Court and this court have repeatedly rejected similar efforts to inject considerations unrelated to public health into the NAAQS-setting process. *See Am. Trucking*, 531 U.S. at 464 (citing D.C. Circuit cases holding that “economic considerations may play no part in the promulgation of ambient air quality standards” (cleaned up)); *Murray*, 936 F.3d at 621-22; *Am. Petroleum Inst. v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981). These cases are controlling.

The petitioners invite us to read these precedents narrowly in light of the Supreme Court’s opinion in *Michigan v. EPA*, 576 U.S. 743 (2015). In that case the Court considered whether the phrase “appropriate and necessary” in a different provision of the CAA required the EPA to consider costs. *Id.* at 752. Justice Scalia, writing for the Court, concluded that it did. *Id.* He explained that it was not “rational, never mind ‘appropriate,’ to impose billions of dollars in economic costs in return for a few dollars in health or environmental benefits.” *Id.* Yet Justice Scalia explicitly distinguished that case from *American Trucking*, an opinion he had authored a decade earlier. He explained that the provision at issue in the earlier case — § 7409(b)(1) — “expressly” directed the EPA to set NAAQS at levels requisite to protect public health and therefore should not be read “as implicitly allowing the [EPA] to consider cost anyway.” *Id.* at 755-56. Consistent with that understanding of the statutory scheme, in *Murray* this court rejected an invitation based upon *Michigan* to incorporate cost considerations into § 7409(d)(1). 936 F.3d at 622 (explaining the word “appropriate” in § 7409(d)(1) did not require consideration of economic costs and that the outcome in *Michigan* turned upon its “statutory context”). In other words, *Michigan* reinforces rather than undermines *American Trucking*.

Murray similarly forecloses the petitioners’ argument that the Administrator was required to consider attainability. In that case the petitioners argued the CAA “requires EPA to set NAAQS that are attainable.” *Id.* To the contrary, we explained that the Congress “recognized the possibility that some states could not achieve attainment,” but “rather than watering down the nationally applicable standards, [it] allowed EPA to relax enforcement on a case-by-case basis.” *Id.* at

623. The EPA, that is, may consider attainability “during enforcement, not when setting standards.” *Id.*; see also *Costle*, 665 F.2d at 1190 (“[T]he question of attainability is not relevant to the setting of ambient air quality standards under the Clean Air Act”).

The Industry and State Petitioners attempt to elude these cases by distinguishing between setting a NAAQS (to which § 7409(b) applies) and the anterior decision to revise a NAAQS. In their view, the EPA must consider costs and attainability when it initially decides “*whether* a revision ‘may be appropriate.’” They reason that the first sentence of § 7409(d)(1) provides for revisions “as may be appropriate in accordance with [§ 7408] and [§ 7409(b)],” and *Michigan* says the word “appropriate . . . requires at least some attention to cost,” 576 U.S. at 752. The Industry Petitioners attempt to bolster this conclusion by pointing to § 7409(d)(2)(C), which requires the CASAC to “advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.” It is only when the EPA formulates a standard that the Industry Petitioners concede the EPA may disregard costs and attainability. The EPA, for its part, asserts that nothing in § 7409(d)(1) prevents it from considering costs, but it tellingly fails to address *American Trucking* or *Murray*.

The Industry Petitioners’ and the EPA’s interpretation does not square with that controlling precedent: Their approach necessarily, but impermissibly, injects economic considerations and attainability into the NAAQS-setting process. See *Am. Trucking*, 531 U.S. at 464-65; *Murray*, 936 F.3d at 622-23. Whether the Administrator considers costs and attainability when

deciding whether to revise a NAAQS or when setting the NAAQS would have the same impermissible effect.

Moreover, nothing in § 7409(d)(1) suggests the Congress intended to distinguish between the Administrator considering whether to revise a standard and his setting a standard. That section requires that the Administrator revise a NAAQS “as may be appropriate in accordance with [§ 7408] and [§ 7409(b)].” In this way, the Congress tied the word “appropriate” in § 7409(d)(1) to § 7409(b), which in turn prescribes NAAQS that “are requisite to protect the public health.” *See Am. Trucking Ass’ns v. EPA*, 175 F.3d 1027, 1040 (D.C. Cir. 1999) (explaining that “the clause immediately following ‘appropriate’ . . . affirmatively precludes consideration of costs in revising NAAQS”).⁷ Indeed, this court in *Murray* explained that we had “already rejected the idea that ‘appropriate’ in [§ 7409(d)(1)] requires consideration of economic costs.” 936 F.3d at 622 (citing *Am. Trucking Ass’ns*, 175 F.3d at 1040 41, *aff’d in relevant part*, 531 U.S. at 464-65).

Nor does § 7409(d)(2)(c) support the petitioners’ two-step approach. In *Murray* we explained why § 7409(d)(2)(C) did not imply that economic costs were permissible considerations in the NAAQS-setting process: “[T]his provision was intended to ‘enable the [EPA] to assist the States in carrying out their

⁷ The petitioners briefly argue that this conclusion results in an interpretation of the statutory scheme that violates the non-delegation doctrine. That argument is foreclosed by *American Trucking*, in which the Supreme Court held that the “scope of discretion [§ 7409(b)(1)] allows is in fact well within the outer limits of our nondelegation precedents.” 531 U.S. at 474. The petitioners have preserved the issue whether that case was correctly decided expressly for further review before the Supreme Court.

statutory role as primary *implementers* of the NAAQS,’ but had ‘no bearing upon whether cost considerations are to be taken into account in *formulating* the [NAAQS].” *Id.* (quoting *Am. Trucking*, 531 U.S. at 470-71). Although *Murray* spoke of “*formulating* the NAAQS,” and not the anterior decision whether to revise a standard, we do not see how its reasoning would permit the Administrator to consider costs at either stage.⁸

The State Petitioners take a slightly different tack and, without quite saying so, challenge the holding of *American Trucking* directly. They point to the Supreme Court’s statement that “ozone and particulate matter are ‘nonthreshold’ pollutants that inflict a continuum of adverse health effects at any airborne concentration greater than zero, and hence require the EPA to make judgments of degree.” 531 U.S. at 475. Consequently, when setting NAAQS for these pollutants the Administrator must exercise “discretion” guided by the requirements of § 7409(b)(1). *Id.* at 475-76. Then, quoting Justice Breyer’s concurrence, the State Petitioners attempt to read consideration of costs into the exercise of the Administrator’s discretion. *See id.*

⁸ The Industry Petitioners also argue, based upon their two-step interpretation of § 7409(d)(1), that the Administrator was required to consider current air quality when deciding whether to revise the NAAQS. They claim the Administrator “overstated the benefits of a NAAQS revision by assuming a fictional world in which no area of the country had better air quality than the NAAQS standard of 12 µg/m³,” when in fact “the current air quality in most areas significantly out-performs that standard.” As we have explained, however, it was “not unreasonable for the EPA to measure expected benefits from the new NAAQS in part upon the assumption that, if the new NAAQS were not adopted, then each area would in the future just meet the existing standard.” *Am. Petroleum Inst. v. EPA*, 684 F.3d 1342, 1352 (2012).

at 494 (Breyer, J., concurring in part and concurring in the judgment) (The CAA “does not require the EPA to eliminate every health risk, however slight, at any economic cost, however great, to the point of hurtling industry over the brink of ruin, or even forcing deindustrialization” (cleaned up)).

The opinion of the Court to the contrary, however, was clear: § 7409(b)(1) “unambiguously bars cost considerations from the NAAQS-setting process.” 531 U.S. at 471. As we explained in *Murray* in response to the petitioners’ reliance on the same passage from Justice Breyer’s concurrence, “the concurrence does not govern our decision, and in any event, Justice Breyer agreed with the majority that economic costs could not be considered in setting NAAQS.” 936 F.3d at 622 (citing *Am. Trucking*, 531 U.S. at 490).

In short, “when Congress directs an agency to consider only certain factors in reaching an administrative decision, the agency is not free to trespass beyond the bounds of its statutory authority by taking other factors into account.” *Lead Indus. Ass’n v. EPA*, 647 F.2d 1130, 1150 (D.C. Cir. 1980). Here the EPA properly followed the Congress’s direction and declined to consider non-public health factors throughout the NAAQSsetting process.

3. Other objections

The petitioners also contend the Administrator’s decision was inadequately explained and insufficiently supported by the evidence. Their arguments are of three types. First, the Administrator did not sufficiently justify performing an off-cycle review. Second, the Administrator failed adequately to explain his reasons for departing from the conclusions of the 2020

Final Rule. Third, the scientific evidence does not justify a standard of 9 $\mu\text{g}/\text{m}^3$.

Off-Cycle Revision. The petitioners' first argument requires little additional discussion. Their charge is that the Administrator's decision to perform an off-cycle revision was unprecedented and without regard for the reliance interests of those affected by the revised standard. As already explained, however, the Congress authorized the Administrator to revise criteria and NAAQS outside the five-year cycle in the interests of public health.

Changed Course. The petitioners' second argument merits more attention but is equally unavailing. From our review of the 2024 Final Rule, we hold that the Administrator satisfactorily explained his basis for revising the standard his predecessor had decided not to revise in the 2020 Final Rule. Far from ignoring the earlier rule, the Administrator acknowledged that his analysis differed from that of "the prior Administrator," 89 Fed. Reg. at 16276/2, and he explained the bases for his decision at length, *id.* at 16273/3-16277/1. His reasons included newly available scientific evidence, the unanimous recommendation of CASAC, and a reweighing of the previously available evidence. *Id.*

With respect to new evidence, the Administrator explained that "a number of studies" were published after the previous literature cutoff date, and he therefore had "additional information for consideration in reaching his final conclusions." *Id.* at 16275/2. Several of these studies improved upon those that were available to the previous Administrator, *see id.* at 16276/1 (explaining the studies "employed statistical approaches that attempted to more extensively account for confounders and are more robust to model misspecification"); and at 16276/3 (identifying "several

[new] accountability studies”), including the “study that report[ed] the long-term mean PM_{2.5} concentration of 9.3 µg/m³,” *id.* at 16275/3. The last-referenced study was particularly significant because the Administrator set the standard “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.*

The Administrator also explained that the CASAC had unanimously agreed that the 2020 standard was inadequate based upon the newly available scientific evidence. *Id.* at 16204/3, 16256/3, 16275/1. Although most of the CASAC’s membership had changed since its earlier review, two members remained the same. Of those, one had previously concluded that the annual PM_{2.5} standard should remain at 12 µg/m³ only later to conclude, as the Administrator did, that this standard was inadequate to protect public health based upon the latest evidence. *See id.* at 16257 n.93.

With respect to his evaluation of the scientific evidence, the Administrator explained that he disagreed with the approach of the previous Administrator in certain respects. Recall that the previous Administrator took a mean-of-means approach to the scientific studies — *i.e.*, he “placed weight on the average of the study-reported means (or medians) across the U.S. monitor-based studies of 13.5 µg/m³.” *Id.* at 16275/3. The new Administrator, as already explained, set the revised standard “below the lowest long-term study-reported mean PM_{2.5} concentration.” *Id.* Additionally, the new Administrator gave weight to “U.S. hybrid model-based epidemiologic studies,” which he considered “an advancement in the available science.” *Id.*

Considering the deference we owe the Administrator’s scientific judgments, we readily conclude that he

adequately explained his reasons for not retaining the standard set in the 2020 Final Rule. *See Mississippi*, 744 F.3d at 1344 (explaining that the Administrator is not bound by previous NAAQS).

Appropriate Standard. The petitioners also argue that the evidence does not support a standard of 9 $\mu\text{g}/\text{m}^3$. Because § 7409(b)(1) expressly delegates the setting of NAAQS to the “judgment” of the Administrator, however, we must respect the Congress’s delegation and take care not to substitute our judgment for that of the Administrator, *see Loper Bright Enters.*, 603 U.S. at 412-13, which “necessarily requires the exercise of policy judgment,” *Mississippi*, 744 F.3d at 1358. Put another way, we must “defer to the EPA’s scientific judgment while examining the record to ensure the agency has considered the relevant factors and reasonably explained how it reached its conclusions.” *Am. Farm Bureau Fed’n*, 559 F.3d at 520.

Here the petitioners do not claim the Administrator overlooked an important scientific study or ignored a key public-health factor. Nor do they provide meaningful evidence that the Administrator misapplied the relevant scientific evidence; rather, the Administrator followed a methodology that this court has upheld on several occasions. *See Nat’l Ass’n of Mfrs. v. EPA*, 750 F.3d 921, 924 (D.C. Cir. 2014) (collecting cases in which this court has upheld a NAAQS set “somewhat below the lowest long-term mean concentration shown by certain key epidemiologic studies to cause adverse health effects”). Under these circumstances, we cannot agree that the Administrator’s decision was unreasoned or contrary to the evidence.

That is not to say the Administrator’s application of § 7409(b)(1) was the only permissible judgment on this record. *See Mississippi*, 744 F.3d at 1348 (“That

the evidence in the record may also support other conclusions . . . does not prevent us from concluding that [these] decisions were rational” (cleaned up)). Setting NAAQS for particulate matter entails the exercise of judgment in the face of scientific uncertainty. *See* 89 Fed. Reg. at 16276/2 (recognizing “uncertainties and limitations associated with the epidemiologic studies”); *Am. Trucking*, 531 U.S. at 475 (explaining that “judgments of degree” are necessary for “nonthreshold” pollutants). Unsurprisingly, then, all members of the CASAC recommended revising the NAAQS downward to levels ranging from 8-11 $\mu\text{g}/\text{m}^3$. *See* 89 Fed. Reg. at 16280/1 (explaining that “the majority and minority of the CASAC . . . weighed the studies in different ways”). The Administrator ultimately set the standard near the middle of the range recommended by the CASAC majority.

The Industry Petitioners fault the Administrator for not sufficiently explaining why he did not select 10 $\mu\text{g}/\text{m}^3$, which also would have fallen within the range staked out by the majority and minority members of the CASAC. The Industry Petitioners contend that the Administrator’s “own evidence and reasoning pointed more toward 10.0 $\mu\text{g}/\text{m}^3$ than 9.0 $\mu\text{g}/\text{m}^3$.” So they say because the 2024 Final Rule recognized that “an annual standard level that is no more than 15-18% higher than the study-reported means[, or 10.7 to 11.0 $\mu\text{g}/\text{m}^3$,] would generally maintain air quality exposures to be below those . . . for which we have the strongest support for adverse health effects occurring.” 89 Fed. Reg. at 16241/3. Yet the Administrator explained that he was setting the standard “below the lowest study-reported mean” to ensure that those living where $\text{PM}_{2.5}$ concentrations are highest “will be exposed to $\text{PM}_{2.5}$ concentrations below the $\text{PM}_{2.5}$ concentrations reported in the epidemiologic studies

where there is the highest confidence of an association” with adverse health effects. *Id.* at 16263/2. The Administrator’s regard for populations in areas with the highest PM_{2.5} concentration was permissible. *See Nat’l Ass’n of Mfrs.*, 750 F.3d at 926 (finding the Administrator’s consideration of populations near heavily trafficked roads reasonable “[i]n the context of [§ 7409]”).

In short, the Administrator “offered reasoned explanations for how [he] approached and weighed the evidence, and why the scientific evidence supported [his] revision of the NAAQS.” *Id.* at 924. That is sufficient for us to uphold his decision on its merits.

III. Conclusion

For the reasons stated, the petitions for review and the EPA’s motion for vacatur are

Denied.

APPENDIX B

16202 Federal Register/Vol. 89, No. 45/Wednesday,
March 6, 2024/Rules and Regulations

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50, 53, and 58

[EPA-HQ-OAR-2015-0072; FRL-8635-02- OAR]

RIN 2060-AV52

Reconsideration of the National Ambient Air Quality
Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Based on the Environmental Protection Agency's (EPA's) reconsideration of the air quality criteria and the national ambient air quality standards (NAAQS) for particulate matter (PM), the EPA is revising the primary annual PM_{2.5} standard by lowering the level from 12.0 µg/m³ to 9.0 µg/m³. The Agency is retaining the current primary 24-hour PM_{2.5} standard and the primary 24-hour PM₁₀ standard. The Agency also is not changing the secondary 24-hour PM_{2.5} standard, secondary annual PM_{2.5} standard, and secondary 24-hour PM₁₀ standard at this time. The EPA is also finalizing revisions to other key aspects related to the PM NAAQS, including revisions to the Air Quality Index (AQI) and monitoring requirements for the PM NAAQS.

DATES: This final rule is effective May 6, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2015-0072. All documents in the docket are listed on

the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through <https://www.regulations.gov>.

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Executive Summary

This document presents the Administrator's final decisions for the reconsideration of the 2020 final decision on the primary (health-based) and secondary (welfare-based) National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM). More specifically, this document summarizes the background and rationale for the Administrator's final decisions to revise the primary annual $\text{PM}_{2.5}$ standard by lowering the level from $12.0 \mu\text{g}/\text{m}^3$ to $9.0 \mu\text{g}/\text{m}^3$; to retain the current primary 24-hour $\text{PM}_{2.5}$ standard (at a level of $35 \mu\text{g}/\text{m}^3$); to retain the primary 24-hour PM_{10} standard; and, not to change the secondary PM standards at this time. In reaching his final decisions, the Administrator considered the currently available scientific evidence in the 2019 Integrated Science Assessment (2019 ISA) and the Supplement to the 2019 ISA (ISA Supplement), quantitative and policy analyses presented in the 2022 Policy

Assessment (2022 PA), advice from the Clean Air Scientific Advisory Committee (CASAC), and public comments on the proposal. The EPA has established primary and secondary standards for PM_{2.5}, which includes particles with diameters generally less than or equal to 2.5 mm, and PM₁₀, which includes particles with diameters generally less than or equal to 10 mm. The standards include two primary PM_{2.5} standards: an annual average standard, averaged over three years, with a level of 12.0 µg/m³, and a 24-hour standard with a 98th percentile form, averaged over three years, and a level of 35 µg/m³. It also includes a primary PM₁₀ standard with a 24-hour averaging time, and a level of 150 µg/m³, not to be exceeded more than once per year on average over three years. Secondary PM standards are set equal to the primary standards, except that the level of the secondary annual PM_{2.5} standard is 15.0 µg/m³.

The most recent of the PM NAAQS was completed in December 2020. In that review, the EPA retained the primary and secondary NAAQS, without revision (85 FR 82684, December 18, 2020). Following publication of the 2020 final action, several parties filed petitions for review and petitions for reconsideration of the EPA's final decision.

In June 2021, the Agency announced its decision to reconsider the 2020 PM NAAQS final action.¹ The EPA decided to reconsider the December 2020 decision because the available scientific evidence and technical information indicated that the current standards may not be adequate to protect public

¹ The press release for this announcement is available at: <https://www.epa.gov/newsreleases/epa-reexamine-health-standards-harmful-soot-previous-administration-left-unchanged>.

health and welfare, as required by the Clean Air Act. The EPA noted that the 2020 PA concluded that the scientific evidence and information called into question the adequacy of the primary PM_{2.5} standards and supported consideration of revising the level of the primary annual PM_{2.5} standard to below the current level of 12.0 µg/m³ while retaining the primary 24-hour PM_{2.5} standard (U.S. EPA, 2020b). The EPA also noted that the 2020 PA concluded that the available scientific evidence and information did not call into question the adequacy of the primary PM₁₀ or secondary PM standards and supported consideration of retaining the primary PM₁₀ standard and secondary PM standards without revision (U.S. EPA, 2020b).

The final decisions presented in this document on the primary PM_{2.5} standards have been informed by key aspects of the available health effects evidence and conclusions contained in the 2019 ISA and ISA Supplement, quantitative exposure/risk analyses and policy evaluations presented in the 2022 PA, advice from the CASAC² and public comment received as part of this reconsideration.³ The health effects

² In 2021, the Administrator announced his decision to reestablish the membership of the CASAC. The Administrator selected seven members to serve on the chartered CASAC, and appointed a PM CASAC panel to support the chartered CASAC's review of the draft ISA Supplement and the draft PA as a part of this reconsideration (see section I.C.6.b below for more information).

³ More information regarding the CASAC review of the draft ISA Supplement and the draft PA, including opportunities for public comment, can be found in the following Federal Register notices: 86 FR 54186, September 30, 2021; 86 FR 52673, September 22, 2021; 86 FR 56263, October 8, 2021; 87 FR 958, January 7, 2022.

evidence newly available in this reconsideration, in conjunction with the full body of evidence critically evaluated in the 2019 ISA, supports a causal relationship between long- and short-term exposures and mortality and cardiovascular effects, and the evidence supports a likely to be a causal relationship between long-term exposures and respiratory effects, nervous system effects, and cancer. The longstanding evidence base, including animal toxicological studies, controlled human exposure studies, and epidemiologic studies, reaffirms, and in some cases strengthens, the conclusions from past reviews regarding the health effects of PM_{2.5} exposures. Epidemiologic studies available in this reconsideration demonstrate generally positive, and often statistically significant, PM_{2.5} health effect associations. Such studies report associations between estimated PM_{2.5} exposures and non-accidental, cardiovascular, or respiratory mortality; cardiovascular or respiratory hospitalizations or emergency room visits; and other mortality/morbidity outcomes (*e.g.*, lung cancer mortality or incidence, asthma development). The scientific evidence available in this reconsideration, as evaluated in the 2019 ISA and ISA Supplement, includes a number of epidemiologic studies that use various methods to characterize exposure to PM_{2.5} (*e.g.*, ground-based monitors and hybrid modeling approaches) and to evaluate associations between health effects and lower ambient PM_{2.5} concentrations. There are a number of recent epidemiologic studies that use varying study designs that reduce uncertainties related to confounding and exposure measurement error. The results of these analyses provide further support for the robustness of associations between PM_{2.5} exposures and mortality and morbidity. Moreover, the Administrator notes that recent epidemiologic studies strengthen support

for health effect associations at lower PM_{2.5} concentrations, with these new studies finding positive and significant associations when assessing exposure in locations and time periods with lower annual mean and 25th percentile concentrations than those evaluated in epidemiologic studies available at the time of previous reviews. Additionally, the experimental evidence (*i.e.*, animal toxicological and controlled human exposure studies) strengthens the coherence of effects across scientific disciplines and provides additional support for potential biological pathways through which PM_{2.5} exposures could lead to the overt population-level outcomes reported in epidemiologic studies for the health effect categories for which a causal relationship (*i.e.*, short- and long-term PM_{2.5} exposure and mortality and cardiovascular effects) or likely to be causal relationship (*i.e.*, short- and long-term PM_{2.5} exposure and respiratory effects; and long-term PM_{2.5} exposure and nervous system effects and cancer) was concluded.

The available evidence in the 2019 ISA continues to provide support for factors that may contribute to increased risk of PM_{2.5}-related health effects including lifestage (children and older adults), pre-existing diseases (cardiovascular disease and respiratory disease), race/ethnicity, and socioeconomic status. For example, the 2019 ISA and ISA Supplement conclude that there is strong evidence that Black and Hispanic populations, on average, experience higher PM_{2.5} exposures and PM_{2.5}-related health risks than non-Hispanic White populations. In addition, studies evaluated in the 2019 ISA and ISA Supplement also provide evidence indicating that communities with lower socioeconomic status (SES), as assessed in epidemiologic studies using indicators of SES including income and educational attainment are, on

average, exposed to higher concentrations of PM_{2.5} compared to higher SES communities.

The quantitative risk assessment, as well as policy considerations in the 2022 PA, also inform the final decisions on the primary PM_{2.5} standards. The risk assessment in this reconsideration focuses on all-cause or nonaccidental mortality associated with long- and short-term PM_{2.5} exposures. The primary analyses focus on exposure and risk associated with air quality that might occur in an area under air quality conditions that just meet the current and potential alternative standards. The risk assessment estimates that the current primary PM_{2.5} standards could allow a substantial number of PM_{2.5}-associated premature deaths in the United States, and that public health improvements would be associated with just meeting all of the alternative (more stringent) annual and 24-hour standard levels modeled. Additionally, the results of the risk assessment suggest that for most of the U.S., the annual standard is the controlling standard and that revision to that standard has the most potential to reduce PM_{2.5} exposure-related risk. The analyses are summarized in this document and in the proposal and are described in detail in the 2022 PA.

In its advice to the Administrator, in its review of the 2021 draft PA, the CASAC concurred that the currently available health effects evidence calls into question the adequacy of the primary annual PM_{2.5} standard. With regard to the primary annual PM_{2.5} standard, the majority of the CASAC concluded that the level of the standard should be revised within the range of 8.0 to 10.0 µg/m³, while the minority of the CASAC concluded that the primary annual PM_{2.5} standard should be revised to a level of 10.0 to 11.0

$\mu\text{g}/\text{m}^3$. With regard to the primary 24-hour $\text{PM}_{2.5}$ standard, the CASAC did not reach consensus on the adequacy of the current standard. The majority of the CASAC concluded that the primary 24-hour $\text{PM}_{2.5}$ was not adequate and that the level of the standard should be revised to within the range of 25 to 30 $\mu\text{g}/\text{m}^3$, while the minority of the CASAC concluded that the standard was adequate and should be retained, without revision. Additionally, in their review of the 2019 draft PA, the CASAC did not reach consensus on the adequacy of the primary annual $\text{PM}_{2.5}$ standard, with the minority recommending revision and the majority recommending the standard be retained. In their review of the 2019 draft PA, the CASAC reached consensus regarding the adequacy of the primary 24-hour $\text{PM}_{2.5}$ standard, concluding that the standard should be retained.

In considering how to revise the suite of primary $\text{PM}_{2.5}$ standards to provide the requisite degree of protection, the Administrator recognizes that the current annual standard and 24-hour standard, together, are intended to provide public health protection against the full distribution of short- and long-term $\text{PM}_{2.5}$ exposures. Further, he recognizes that changes in $\text{PM}_{2.5}$ air quality designed to meet either the annual or the 24-hour standard would likely result in changes to both long-term average and short-term peak $\text{PM}_{2.5}$ concentrations.

As in 2012, the Administrator concludes that the most effective way to reduce total population risk associated with both long- and short-term $\text{PM}_{2.5}$ exposures is to set a generally controlling annual standard, and to provide supplemental protection against the occurrence of peak 24-hour $\text{PM}_{2.5}$ concentrations by means of a 24-hour standard set at

the appropriate level. Based on the current evidence and quantitative information, as well as consideration of CASAC advice and public comments, the Administrator concludes that the current primary annual $\text{PM}_{2.5}$ standard is not adequate to protect public health with an adequate margin of safety. The Administrator notes that the CASAC was unanimous in its advice on the 2021 draft PA regarding the need to revise the annual standard. In considering the appropriate level for a revised annual standard, the Administrator concludes that a standard set at a level of $9.0 \mu\text{g}/\text{m}^3$ reflects his judgment about placing the most weight on the strongest available evidence while appropriately weighing the uncertainties.

With regard to the primary 24-hour $\text{PM}_{2.5}$ standard, the Administrator finds the available scientific evidence and quantitative information to be insufficient to call into question the adequacy of the public health protection afforded by the current 24-hour standard. He further notes that a more stringent annual standard set at a level of $9.0 \mu\text{g}/\text{m}^3$ is expected to reduce both average (annual) concentrations and peak (daily) concentrations. The Administrator also notes that, in their review of the 2021 draft PA, the CASAC did not reach consensus on whether revisions to the primary 24-hour $\text{PM}_{2.5}$ standard are warranted at this time. He also notes that, in their review of the 2019 draft PA, the CASAC did reach consensus that the primary 24-hour $\text{PM}_{2.5}$ standard should be retained. The Administrator concludes that the 24-hour standard should be retained to continue to provide requisite protection against short-term peak $\text{PM}_{2.5}$ concentrations, particularly when considered in conjunction with the protection provided by the suite of standards and the decision to revise the annual standard to a level of $9.0 \mu\text{g}/\text{m}^3$.

The primary PM₁₀ standard is intended to provide public health protection against health effects related to exposures to PM_{10-2.5}, which are particles with a diameter between 10 μm and 2.5 μm. The final decision to retain the current 24-hour PM₁₀ standard has been informed by key aspects of the available health effects evidence and conclusions contained in the 2019 ISA, the policy evaluations presented in the 2022 PA, advice from the CASAC and public comments. Specifically, the health effects evidence for PM_{10-2.5} exposures is somewhat strengthened since past reviews, although the strongest evidence still only provides support for a suggestive of, but not sufficient to infer, causal relationship with long- and short-term exposures and mortality and cardiovascular effects, short-term exposures and respiratory effects, and long-term exposures and cancer, nervous system effects, and metabolic effects. In reaching his final decision on the primary PM₁₀ standard, the Administrator recognizes that, while the available health effects evidence has expanded, recent studies are subject to the same types of uncertainties that were judged to be important in previous reviews. He also recognizes that, in their review of the 2019 draft PA and the 2021 draft PA, the CASAC generally agreed that it was reasonable to retain the primary 24-hour PM₁₀ standard given the available scientific evidence, including retaining PM₁₀ as the indicator. He concludes that the newly available evidence does not call into question the adequacy of the current primary PM₁₀ standard, and retains that standard, without revision.

With respect to the secondary PM standards, this reconsideration focuses on visibility, climate, and

materials effects.⁴ The Administrator's final decision to not change the current secondary standards at this time has been informed by key aspects of the currently available welfare effects evidence as well as the conclusions contained in the 2019 ISA and ISA Supplement; quantitative analyses of visibility impairment; policy evaluations presented in the 2022 PA; advice from the CASAC; and public comments. Specifically, the welfare effects evidence available in this reconsideration is consistent with the evidence available in previous reviews and supports a causal relationship between PM and visibility, climate, and materials effects. With regard to visibility effects, the Administrator notes that he judges that the evidence supports a target level of protection of 27 dv. He further notes that the results of quantitative analyses of visibility impairment suggest that in areas that meet the current secondary 24-hour PM_{2.5} standard that estimated light extinction in terms of a 3-year visibility metric would be at or well below the target level of protection. With regard to climate and materials effects, while the evidence has expanded since previous reviews, significant limitations and

⁴ Consistent with the 2016 Integrated Review Plan (U.S. EPA, 2016), other welfare effects of PM, such as ecological effects, are being considered in the separate, on-going review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM. Accordingly, the public welfare protection provided by the secondary PM standards against ecological effects such as those related to deposition of nitrogen- and sulfur-containing compounds in vulnerable ecosystems is being considered in that separate review. Thus, the Administrator's conclusion in this reconsideration of the 2020 final decision is focused only and specifically on the adequacy of public welfare protection provided by the secondary PM standards from effects related to visibility, climate, and materials and hereafter "welfare effects" refers to those welfare effects.

uncertainties remain in the evidence. While the evidence has expanded since previous reviews, the available scientific evidence remains insufficient to allow the Administrator to make a reasoned judgment about what specific standard(s) would be requisite to protect against known or anticipated adverse effects to public welfare from PM's effects on materials damage or climate.- In their review of the 2019 draft PA and the 2021 draft PA, the CASAC did not recommend revising the secondary PM standards. In considering the available evidence and quantitative information, with its inherent uncertainties and limitations, the Administrator judges that it is appropriate not to change the secondary PM standards at this time.

The final revisions to the primary annual PM_{2.5} NAAQS trigger a process under which States (and Tribes, if they choose) make recommendations to the Administrator regarding designations, identifying areas of the country that either meet or do not meet the new or revised PM NAAQS. Those areas that do not meet the revised PM NAAQS will need to develop plans that demonstrate how they will meet the standards. As part of these plans, states have the opportunity to advance environmental justice, in this case for overburdened communities in areas with high PM concentrations above the NAAQS, by using the tools described in the current PM NAAQS implementation guidance (80 FR 58010, 58136, August 25, 2016). The EPA is not making changes to any of the current PM NAAQS implementation programs in this final rulemaking.

On other topics, the EPA is finalizing two sets of changes to the PM_{2.5} sub-index of the Air Quality Index (AQI). First, the EPA is continuing to use the

approach used in the revisions to the AQI in 2012 (77 FR 38890, June 29, 2012) of setting the lower breakpoints (50, 100 and 150) based on the levels of the primary annual and 24-hour PM_{2.5} standards. In so doing, the EPA is revising the AQI value of 50 to 9.0 µg/m³ and is retaining the AQI values of 100 and 150 at 35.4 µg/m³ and 55.4 µg/m³, respectively. Second, the EPA is revising the upper AQI breakpoints (200 and above), and replacing the linear-relationship approach used in 1999 (64 FR 42530, August 4, 1999) to set these breakpoints, with an approach that more fully considers the PM_{2.5} health effects evidence from controlled human exposure and epidemiologic studies that has become available in the last 20 years. The EPA is also revising the AQI values of 200, 300 and 500 to 125.4 µg/m³, 225.4 µg/m³, and 325.4 µg/m³, respectively. In addition, this final rule revises the daily reporting requirement from 5 days per week to 7 days per week, while also reformatting appendix G and providing clarifications.

With regard to monitoring-related activities, the EPA finalizes revisions to data calculations and ambient air monitoring requirements for PM to improve the usefulness and appropriateness of data used in regulatory decision making and to better characterize air quality in communities that are at increased risk of PM_{2.5} exposure and health risk. These changes are found in 40 CFR part 50 (appendices K, L, and N), part 53, and part 58 with associated appendices (A, B, C, D, and E). These changes include addressing updates in data calculations, approval of reference and equivalent methods, updates in quality assurance statistical calculations to account for lower concentration measurements, updates to support improvements in PM methods, a

revision to the PM_{2.5} network design to account for at-risk populations, and updates to the Probe and Monitoring Path Siting Criteria for NAAQS pollutants.

In setting the NAAQS, the EPA may not consider the costs of implementing the standards. This was confirmed by the Supreme Court in *Whitman v. American Trucking Associations*, 531 U.S. 457, 465–472, 475–76 (2001), as discussed in section II.A of this document. As has traditionally been done in NAAQS rulemaking, the EPA prepared a Regulatory Impact Analysis (RIA) to provide the public with information on the potential costs and benefits of attaining several alternative PM_{2.5} standard levels. In NAAQS rulemaking, the RIA is done for informational purposes only, and the final decisions on the NAAQS in this rulemaking are not based on consideration of the information or analyses in the RIA. The RIA fulfills the requirements of Executive Orders 14094, 13563, and 12866. The RIA estimates the costs and monetized human health benefits of attaining the revised and two alternative annual PM_{2.5} standard levels and one alternative 24-hour PM_{2.5} standard level. Specifically, the RIA examines the revised annual standard level of 9.0 µg/m³ in combination with the current 24-hour standard of 35 µg/m³ (*i.e.*, 9.0/35 µg/m³), as well as the following less and more stringent alternative standard levels: (1) An alternative annual standard level of 10.0 µg/m³ in combination with the current 24-hour standard (*i.e.*, 10.0/35 µg/m³), (2) an alternative annual standard level of 8.0 µg/m³ in combination with the current 24-hour standard (*i.e.*, 8.0/35 µg/m³), and (3) an alternative 24-hour standard level of 30 µg/m³ in combination with an alternative annual standard level of 10 µg/m³ (*i.e.*, 10.0/30 µg/m³). The RIA presents estimates of the costs and benefits of

applying illustrative national control strategies in 2032 after implementing existing and expected regulations and assessing emissions reductions to meet the current annual and 24-hour particulate matter NAAQS (12.0/35 $\mu\text{g}/\text{m}^3$).

I. Background

A. *Legislative Requirements*

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. The Administrator is to list those pollutants “emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare”; “the presence of which in the ambient air results from numerous or diverse mobile or stationary sources”; and for which he “plans to issue air quality criteria. . . .” (42 U.S.C. 7408(a)(1)). Air quality criteria are intended to “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air. . . .” (42 U.S.C. 7408(a)(2)).

Section 109 [42 U.S.C. 7409] directs the Administrator to propose and promulgate “primary” and “secondary” NAAQS for pollutants for which air quality criteria are issued [42 U.S.C. 7409(a)]. Section 109(b)(1) defines primary standards as ones “the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are

requisite to protect the public health.”⁵ Under section 109(b)(2), a secondary standard must “specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.”⁶

In setting primary and secondary standards that are “requisite” to protect public health and welfare, respectively, as provided in section 109(b), the EPA’s task is to establish standards that are neither more nor less stringent than necessary. In so doing, the EPA may not consider the costs of implementing the standards. See generally *Whitman v. American Trucking Associations*, 531 U.S. 457, 465–472, 475–76 (2001). Likewise, “[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards.” *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981); accord *Murray*

⁵ The legislative history of section 109 indicates that a primary standard is to be set at “the maximum permissible ambient air level ... which will protect the health of any [sensitive] group of the population,” and that for this purpose “reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.” S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970).

⁶ Under CAA section 302(h) (42 U.S.C. 7602(h)), effects on welfare include, but are not limited to, “effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well- being.”

Energy Corporation v. EPA, 936 F.3d 597, 623–24 (D.C. Cir. 2019).

The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. See *Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980); *American Petroleum Institute v. Costle*, 665 F.2d at 1186; *Coalition of Battery Recyclers Ass’n v. EPA*, 604 F.3d 613, 617–18 (D.C. Cir. 2010); *Mississippi v. EPA*, 744 F.3d 1334, 1353 (D.C. Cir. 2013). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels, see *Lead Industries Ass’n v. EPA*, 647 F.2d at 1156 n.51, *Mississippi v. EPA*, 744 F.3d at 1351, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved,

the size of the sensitive population(s), and the kind and degree of uncertainties. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. See *Lead Industries Ass'n v. EPA*, 647 F.2d at 1161–62; *Mississippi v. EPA*, 744 F.3d at 1353.

Section 109(d)(1) of the Act requires the review every five years of existing air quality criteria and, if appropriate, the revision of those criteria to reflect advances in scientific knowledge on the effects of the pollutant on public health and welfare. Under the same provision, the EPA is also to review every five years and, if appropriate, revise the NAAQS, based on the revised air quality criteria. Section 109(d)(1) also provides that the Administrator may review and revise criteria or promulgate new standards earlier or more frequently.

Section 109(d)(2) addresses the appointment and advisory functions of an independent scientific review committee. Section 109(d)(2)(A) requires the Administrator to appoint this committee, which is to be composed of “seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.” Section 109(d)(2)(B) provides that the independent scientific review committee “shall complete a review of the criteria . . . and the national primary and secondary ambient air quality standards . . . and shall recommend to the Administrator any new . . . standards and revisions of existing criteria and standards as may be appropriate. . . .” Since the early 1980s, this independent review function has been performed by the Clean Air

Scientific Advisory Committee (CASAC) of the EPA's Science Advisory Board.

As previously noted, the Supreme Court has held that section 109(b) “unambiguously bars cost considerations from the NAAQS-setting process.” *Whitman v. Am. Trucking Associations*, 531 U.S. 457, 471 (2001). Accordingly, while some of these issues regarding which Congress has directed the CASAC to advise the Administrator are ones that are relevant to the standard setting process, others are not. Issues that are not relevant to standard setting may be relevant to implementation of the NAAQS once they are established.

B. Related PM Control Programs

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once the EPA has established them. Under section 110, Part C, and Part D, Subparts 1 and 4 of the CAA, and related provisions and regulations, States are to submit, for the EPA's approval, State implementation plans (SIPs) that provide for the attainment and maintenance of the NAAQS for PM through control programs directed to sources of the pollutants involved. The States, in conjunction with the EPA, also administer the prevention of significant deterioration of air quality program that covers these pollutants (see 42 U.S.C. 7470–7479). In addition, Federal programs provide for or result in nationwide reductions in emissions of PM and its precursors under Title II of the Act, 42 U.S.C. 7521–7574, which involves controls for motor vehicles and nonroad engines and equipment; the new source performance standards under section 111 of the Act, 42 U.S.C. 7411; and the national emissions standards

for hazardous pollutants under section 112 of the Act, 42 U.S.C. 7412.

C. Review of the Air Quality Criteria and Standards for Particulate Matter

1. Reviews Completed in 1971 and 1987

The EPA first established NAAQS for PM in 1971 (36 FR 8186, April 30, 1971), based on the original Air Quality Criteria Document (AQCD) (DHEW, 1969).⁷ The Federal reference method (FRM) specified for determining attainment of the original standards was the high-volume sampler, which collects PM up to a nominal size of 25 to 45 μm (referred to as total suspended particulates or TSP). The primary standards were set at 260 $\mu\text{g}/\text{m}^3$, 24-hour average, not to be exceeded more than once per year, and 75 $\mu\text{g}/\text{m}^3$, annual geometric mean. The secondary standards were set at 150 $\mu\text{g}/\text{m}^3$, 24-hour average, not to be exceeded more than once per year, and 60 $\mu\text{g}/\text{m}^3$, annual geometric mean.

In October 1979 (44 FR 56730, October 2, 1979), the EPA announced the first periodic review of the air quality criteria and NAAQS for PM. Revised primary and secondary standards were promulgated in 1987 (52 FR 24634, July 1, 1987). In the 1987 decision, the EPA changed the indicator for particles from TSP to PM_{10} , in order to focus on the subset of inhalable particles small enough to penetrate to the thoracic region of the respiratory tract (including the tracheobronchial and alveolar regions), referred to as

⁷ Prior to the review initiated in 2007 (see below), the AQCD provided the scientific foundation (*i.e.*, the air quality criteria) for the NAAQS. Beginning in that review, the Integrated Science Assessment (ISA) has replaced the AQCD.

thoracic particles.⁸ The level of the 24-hour standards (primary and secondary) was set at 150 $\mu\text{g}/\text{m}^3$, and the form was one expected exceedance per year, on average over three years. The level of the annual standards (primary and secondary) was set at 50 $\mu\text{g}/\text{m}^3$, and the form was the annual arithmetic mean, averaged over three years.

2. Review Completed in 1997

In April 1994, the EPA announced its plans for the second periodic review of the air quality criteria and NAAQS for PM, and in 1997 the EPA promulgated revisions to the NAAQS (62 FR 38652, July 18, 1997). In the 1997 decision, the EPA determined that the fine and coarse fractions of PM₁₀ should be considered separately. This determination was based on evidence that serious health effects were associated with short- and long-term exposures to fine particles in areas that met the existing PM₁₀ standards. The EPA added new standards, using PM_{2.5} as the indicator for fine particles (with PM_{2.5} referring to particles with a nominal mean aerodynamic diameter less than or equal to 2.5 μm). The new primary standards were as follows: (1) An annual standard with a level of 15.0 $\mu\text{g}/\text{m}^3$, based on the 3-year average of annual arithmetic mean PM_{2.5} concentrations from single or multiple community-oriented monitors;⁹ and (2) a 24-

⁸ PM₁₀ refers to particles with a nominal mean aerodynamic diameter less than or equal to 10 μm . More specifically, 10 μm is the aerodynamic diameter for which the efficiency of particle collection is 50 percent.

⁹ The 1997 annual PM_{2.5} standard was compared with measurements made at the community-oriented monitoring site recording the highest concentration or, if specific constraints were met, measurements from multiple community-oriented monitoring sites could be averaged (*i.e.*, “spatial averaging”). In

hour standard with a level of 65 $\mu\text{g}/\text{m}^3$, based on the 3-year average of the 98th percentile of 24-hour $\text{PM}_{2.5}$ concentrations at each monitor within an area. Also, the EPA established a new reference method for the measurement of $\text{PM}_{2.5}$ in the ambient air and adopted rules for determining attainment of the new standards. To continue to address the health effects of the coarse fraction of PM_{10} (referred to as thoracic coarse particles or $\text{PM}_{10-2.5}$, generally including particles with a nominal mean aerodynamic diameter greater than 2.5 μm and less than or equal to 10 μm), the EPA retained the primary annual PM_{10} standard and revised the form of the primary 24-hour PM_{10} standard to be based on the 99th percentile of 24-hour PM_{10} concentrations at each monitor in an area. The EPA revised the secondary standards by setting them equal in all respects to the primary standards.

Following promulgation of the 1997 PM NAAQS, petitions for review were filed by several parties, addressing a broad range of issues. In May 1999, the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) upheld the EPA's decision to establish fine particle standards and to regulate coarse particle pollution, but vacated the 1997 PM_{10} standards, concluding that the EPA had not provided a reasonable explanation justifying use of PM_{10} as an indicator for coarse particles. *American Trucking*

the last review (completed in 2012) the EPA replaced the term "community-oriented" monitor with the term "area-wide" monitor. Area-wide monitors are those sited at the neighborhood scale or larger, as well as those monitors sited at micro- or middle-scales that are representative of many such locations in the same core-based statistical area (CBSA) (78 FR 3236, January 15, 2013).

Associations, Inc. v. EPA, 175 F. 3d 1027 (D.C. Cir. 1999). Pursuant to the D.C. Circuit's decision, the EPA removed the vacated 1997 PM₁₀ standards, and the pre-existing 1987 PM₁₀ standards remained in place (65 FR 80776, December 22, 2000). The D.C. Circuit also upheld the EPA's determination not to establish more stringent secondary standards for fine particles to address effects on visibility. *American Trucking Associations v. EPA*, 175 F. 3d at 1027.

The D.C. Circuit also addressed more general issues related to the NAAQS, including issues related to the consideration of costs in setting NAAQS and the EPA's approach to establishing the levels of NAAQS. Regarding the cost issue, the court reaffirmed prior rulings holding that in setting NAAQS the EPA is "not permitted to consider the cost of implementing those standards." *American Trucking Associations v. EPA*, 175 F. 3d at 1040–41. Regarding the levels of NAAQS, the court held that the EPA's approach to establishing the level of the standards in 1997 (*i.e.*, both for PM and for the ozone NAAQS promulgated on the same day) effected "an unconstitutional delegation of legislative authority." *American Trucking Associations v. EPA*, 175 F. 3d at 1034–40. Although the court stated that "the factors EPA uses in determining the degree of public health concern associated with different levels of ozone and PM are reasonable," it remanded the rule to the EPA, stating that when the EPA considers these factors for potential non-threshold pollutants "what EPA lacks is any determinate criterion for drawing lines" to determine where the standards should be set.

The D.C. Circuit's holding on the cost and constitutional issues were appealed to the United States Supreme Court. In February 2001, the Supreme

Court issued a unanimous decision upholding the EPA's position on both the cost and constitutional issues. *Whitman v. American Trucking Associations*, 531 U.S. 457, 464, 475–76. On the constitutional issue, the Court held that the statutory requirement that NAAQS be “requisite” to protect public health with an adequate margin of safety sufficiently guided the EPA's discretion, affirming the EPA's approach of setting standards that are neither more nor less stringent than necessary.

The Supreme Court remanded the case to the D.C. Circuit for resolution of any remaining issues that had not been addressed in that court's earlier rulings. *Id.* at 475–76. In a March 2002 decision, the D.C. Circuit rejected all remaining challenges to the standards, holding that the EPA's PM_{2.5} standards were reasonably supported by the administrative record and were not “arbitrary and capricious.” *American Trucking Associations v. EPA*, 283 F. 3d 355, 369–72 (D.C. Cir. 2002).

3. Review Completed in 2006

In October 1997, the EPA published its plans for the third periodic review of the air quality criteria and NAAQS for PM (62 FR 55201, October 23, 1997). After the CASAC and public review of several drafts, the EPA's National Center for Environmental Assessment (NCEA) finalized the AQCD in October 2004 (U.S. EPA, 2004a). The EPA's Office of Air Quality Planning and Standards (OAQPS) finalized a Risk Assessment and Staff Paper in December 2005 (Abt Associates, 2005; U.S. EPA, 2005).¹⁰ On

¹⁰ Prior to the review initiated in 2007, the Staff Paper presented the EPA staff's considerations and conclusions regarding the adequacy of existing NAAQS and, when

December 20, 2005, the EPA announced its proposed decision to revise the NAAQS for PM and solicited public comment on a broad range of options (71 FR 2620, January 17, 2006). On September 21, 2006, the EPA announced its final decisions to revise the primary and secondary NAAQS for PM to provide increased protection of public health and welfare, respectively (71 FR 61144, October 17, 2006). With regard to the primary and secondary standards for fine particles, the EPA revised the level of the 24-hour PM_{2.5} standards to 35 µg/m³, retained the level of the annual PM_{2.5} standards at 15.0 µg/m³, and revised the form of the annual PM_{2.5} standards by narrowing the constraints on the optional use of spatial averaging. With regard to the primary and secondary standards for PM₁₀, the EPA retained the 24-hour standards, with levels at 150 µg/m³, and revoked the annual standards. The then- Administrator judged that the available evidence generally did not suggest a link between long-term exposure to existing ambient levels of coarse particles and health or welfare effects. In addition, a new reference method was added for the measurement of PM_{10-2.5} in the ambient air in order to provide a basis for approving Federal Equivalent Methods (FEMs) and to promote the gathering of scientific data to support future reviews of the PM NAAQS.

Several parties filed petitions for review following promulgation of the revised PM NAAQS in 2006. On February 24, 2009, the D.C. Circuit issued its opinion in the case *American Farm Bureau Federation v. EPA*, 559 F. 3d 512 (D.C. Cir. 2009). The court

appropriate, the potential alternative standards that could be supported by the evidence and information. More recent reviews present this information in the Policy Assessment.

remanded the primary annual PM_{2.5} NAAQS to the EPA because the Agency had failed to adequately explain why the standards provided the requisite protection from both short- and long-term exposures to fine particles, including protection for at-risk populations. *Id.* at 520–27. With regard to the standards for PM₁₀, the court upheld the EPA’s decisions to retain the 24-hour PM₁₀ standard to provide protection from thoracic coarse particle exposures and to revoke the annual PM₁₀ standard. *Id.* at 533–38. With regard to the secondary PM_{2.5} standards, the court remanded the standards to the EPA because the Agency failed to adequately explain why setting the secondary PM standards identical to the primary standards provided the required protection for public welfare, including protection from visibility impairment. *Id.* at 528–32. The EPA responded to the court’s remands as part of the next review of the PM NAAQS, which was initiated in 2007 (discussed below).

4. Review Completed in 2012

In June 2007, the EPA initiated the fourth periodic review of the air quality criteria and the PM NAAQS by issuing a call for information (72 FR 35462, June 28, 2007). Based on the NAAQS review process, as revised in 2008 and again in 2009,¹¹ the EPA held science/policy issue workshops on the primary and secondary PM NAAQS (72 FR 34003, June 20, 2007; 72 FR 34005, June 20, 2007), and prepared and released the planning and assessment documents that comprise the review process (*i.e.*, Integrated

¹¹ The history of the NAAQS review process, including revisions to the process, is discussed at <https://www.epa.gov/naaqs/historical-information-naaqs-review-process>.

Review Plan, (IRP; U.S. EPA, 2008), Integrated Science Assessment (ISA; U.S. EPA, 2009a), Risk and Exposure Assessment (REA) planning documents for health and welfare (U.S. EPA, 2009b, U.S. EPA, 2009c), a quantitative health risk assessment (U.S. EPA, 2010a) and an urban-focused visibility assessment (U.S. EPA, 2010b), and a Policy Assessment (PA; U.S. EPA, 2011). In June 2012, the EPA announced its proposed decision to revise the NAAQS for PM (77 FR 38890, June 29, 2012).

In December 2012, the EPA announced its final decisions to revise the primary NAAQS for PM to provide increased protection of public health (78 FR 3086, January 15, 2013). With regard to primary standards for PM_{2.5}, the EPA revised the level of the annual PM_{2.5} standard¹² to 12.0 µg/m³ and retained the 24-hour PM_{2.5} standard, with its level of 35 µg/m³. For the primary PM₁₀ standard, the EPA retained the 24-hour standard to continue to provide protection against effects associated with short-term exposure to thoracic coarse particles (*i.e.*, PM_{10-2.5}). With regard to the secondary PM standards, the EPA generally retained the 24-hour and annual PM_{2.5} standards¹³ and the 24-hour PM₁₀ standard to address visibility and non-visibility welfare effects.

As with previous reviews, petitioners challenged the EPA's final rule. Petitioners argued that the EPA acted unreasonably in revising the level and form of the annual standard and in amending the monitoring network provisions. On judicial review, the revised standards and monitoring requirements were upheld

¹² The EPA also eliminated the option for spatial averaging.

¹³ Consistent with the primary standard, the EPA eliminated the option for spatial averaging with the annual standard.

in all respects. *NAM v. EPA*, 750 F.3d 921 (D.C. Cir. 2014).

5. Review Initiated in 2014

In December 2014, the EPA announced the initiation of the current periodic review of the air quality criteria for PM and of the PM_{2.5} and PM₁₀ NAAQS and issued a call for information (79 FR 71764, December 3, 2014). On February 9 to 11, 2015, the EPA's NCEA and OAQPS held a public workshop to inform the planning for the review of the PM NAAQS (announced in 79 FR 71764, December 3, 2014). Workshop participants, including a wide range of external experts as well as the EPA staff representing a variety of areas of expertise (*e.g.*, epidemiology, human and animal toxicology, risk/exposure analysis, atmospheric science, visibility impairment, climate effects), were asked to highlight significant new and emerging PM research, and to make recommendations to the Agency regarding the design and scope of the review. This workshop provided for a public discussion of the key science and policy-relevant issues around which the EPA structured the review of the PM NAAQS and of the most meaningful new scientific information that would be available in the review to inform understanding of these issues.

The input received at the workshop guided the EPA staff in developing a draft IRP, which was reviewed by the CASAC Particulate Matter Panel and discussed on public teleconferences held in May 2016 (81 FR 13362, March 14, 2016) and August 2016 (81 FR 39043, June 15, 2016). Advice from the CASAC, supplemented by the Particulate Matter Panel, and input from the public were considered in developing the final IRP (U.S. EPA, 2016). The final

IRP discusses the approaches to be taken in developing key scientific, technical, and policy documents in the review and the key policy-relevant issues that frame the EPA's consideration of whether the primary and/or secondary NAAQS for PM should be retained or revised.

In May 2018, the then-Administrator issued a memorandum announcing the Agency's intention to conduct the review of the PM NAAQS in such a manner as to ensure that any necessary revisions were finalized by December 2020 (Pruitt, 2018). Following this memo, on October 10, 2018, the then-Administrator additionally announced that the role of reviewing the key assessments developed as part of the ongoing review of the PM NAAQS (*i.e.*, drafts of the ISA and PA) would be performed by the seven-member chartered CASAC (*i.e.*, rather than the CASAC Particulate Matter Panel that reviewed the draft IRP).¹⁴

The EPA released the draft ISA in October 2018 (83 FR 53471, October 23, 2018). The draft ISA was reviewed by the chartered CASAC at a public meeting held in Arlington, VA in December 2018 (83 FR 55529, November 6, 2018) and was discussed on a public teleconference in March 2019 (84 FR 8523, March 8, 2019). The CASAC provided its advice on the draft ISA in a letter to the then-Administrator dated April 11, 2019 (Cox, 2019a). The EPA addressed these comments in the final ISA, which was released in December 2019 (U.S. EPA, 2019a).

The EPA released the draft PA in September 2019 (84 FR 47944, September 11, 2019). The draft PA was

¹⁴ Announcement available at: <https://www.regulations.gov/document/EPA-HQ-OAR-2015-0072-0223>.

reviewed by the chartered CASAC and discussed in October 2019 at a public meeting held in Cary, NC. Public comments were received via a separate public teleconference (84 FR 51555, September 30, 2019). A public meeting to discuss the chartered CASAC letter and response to charge questions on the draft PA was held in Cary, NC, in October 2019 (84 FR 51555, September 30, 2019), and the CASAC provided its advice on the draft PA, including its advice on the current primary and secondary PM standards, in a letter to the then-Administrator dated December 16, 2019 (Cox, 2019b). With regard to the primary standards, the CASAC recommended retaining the current 24-hour PM_{2.5} and PM₁₀ standards but did not reach consensus on the adequacy of the current annual PM_{2.5} standard. Some CASAC members expressed support for retaining the current primary annual PM_{2.5} standard while other members expressed support for revising that standard in order to increase public health protection (Cox, 2019b, p. 1 of letter). These views are described in greater detail in the letter to the then-Administrator (Cox, 2019b) and in the notice of final rulemaking (85 FR 82706–82707, December 18, 2020), as well as below. With regard to the secondary standards, the CASAC recommended retaining the current standards. In response to the CASAC's comments, the 2020 final PA incorporated a number of changes (Cox, 2019b, U.S. EPA, 2020b), as described in detail in section I.C.5 of the 2020 proposal document (85 FR 24100, April 30, 2020).

a. 2020 Proposed and Final Actions

On April 14, 2020, the EPA proposed to retain all of the primary and secondary PM standards, without revision. These proposed decisions were published in the Federal Register on April 30, 2020 (85 FR 24094,

April 30, 2020). The EPA's final decision on the PM NAAQS was published in the Federal Register on December 18, 2020 (85 FR 82684, December 18, 2020). In the 2020 rulemaking, the EPA retained the primary and secondary PM_{2.5} and PM₁₀ standards, without revision. The then-Administrator's rationale for his decisions is described in more detail in section II, III, and V below, and is briefly summarized here.

In reaching his final decision to retain the primary annual and 24-hour PM_{2.5} standards, the then-Administrator considered the available scientific evidence, quantitative information, CASAC advice, and public comments in his supporting rationale in the 2020 final action (85 FR 82714, December 18, 2020). In so doing, he concluded that the available controlled human exposure studies did not provide support for additional public health protection against exposures to peak PM_{2.5} concentrations, beyond the protection provided by the combination of the current primary annual and 24-hour PM_{2.5} standards. He also noted that the available epidemiologic studies did not indicate that associations in those studies are strongly influenced by exposures to peak concentrations in the air quality distribution and thus did not indicate the need for additional protection against short-term exposures to peak PM_{2.5} concentrations. Accordingly, and taking into account consensus CASAC advice to retain the current primary 24-hour PM_{2.5} standard, the then-Administrator concluded the primary 24-hour PM_{2.5} standard should be retained.

With respect to the annual PM_{2.5} standard, the then-Administrator recognized that important uncertainties and limitations that were present in epidemiologic studies in previous reviews remained in the evidence assessed in the 2019 ISA. In

considering the epidemiologic evidence, the then-Administrator noted that: (1) The reported mean concentration in the majority of the key U.S. epidemiologic studies using ground-based monitoring data are above the level of the current annual standard; (2) the mean of the reported study means (or medians) (*i.e.*, 13.5 $\mu\text{g}/\text{m}^3$) is above the level of the current primary annual $\text{PM}_{2.5}$ standard of 12 $\mu\text{g}/\text{m}^3$; (3) air quality analyses show the study means to be lower than their corresponding design by 10–20%; and (4) that these analyses must be considered in light of uncertainties inherent in the epidemiologic evidence. The then-Administrator further considered other available information, including the risk assessment, accountability studies, and controlled human exposure studies, and found that, in considering all of the evidence together along with advice from the CASAC, the suite of primary $\text{PM}_{2.5}$ standards were requisite to protect public health with an adequate margin of safety, and should be retained, without revision.

With regard to the primary PM_{10} standard, the then-Administrator noted that the expanded body of evidence has broadened the range of effects that have been linked with $\text{PM}_{10-2.5}$ exposures. In light of that information, as well as continued uncertainties in the evidence and advice from the CASAC to retain the standard, the then-Administrator judged it appropriate to retain the primary PM_{10} standard to provide the requisite degree of public health protection against $\text{PM}_{10-2.5}$ exposures, regardless of location, source of origin, or particle composition (85 FR 82725, December 18, 2020).

With regard to the secondary PM standards, the then-Administrator concluded that there was insuffi-

cient information available to establish any distinct secondary PM standards to address climate and materials effects of PM. For visibility effects, he found that in the absence of a monitoring network for direct measurement of light extinction, a calculated light extinction indicator that utilizes the IMPROVE algorithms continued to provide a reasonable basis for defining a target level of protection against PM-related visibility impairment. He further found that a visibility index with a 24-hour averaging time was reasonable based on its stability and suitability for representing subdaily periods, and a form based on the 3-year average of annual 90th percentile values was reasonable based on its stability and that it represents the median of the 20 percent worst visibility days which are targeted under the Regional Haze program. With regard to the level of a visibility index, the then-Administrator judged it appropriate to establish a target level of protection of 30 dv, reflecting the upper end of the range of visibility impairment judged to be acceptable by at least 50% of study participants in the available public preference studies, taking into consideration the variability, limitations and uncertainties of the public preference studies. The then-Administrator judged that the secondary 24-hour PM_{2.5} standard with its level of 35 µg/m³ would provide at least the target level of protection for visual air quality of 30 dv which he judged appropriate. Accordingly, taking into consideration the advice of the CASAC to retain the current secondary PM standards, the then-Administrator found the current secondary standards provide the requisite degree of protection and that they should be retained (85 FR 82742, December 18, 2020).

Following publication of the 2020 final action, several parties filed petitions for review and petitions

for reconsideration of the EPA's final decision. The petitions for review were filed in the D.C. Circuit and the Court consolidated the cases.¹⁵ Following EPA's decision to reconsider the 2020 final decision, the Court ordered the consolidated cases to be held in abeyance.

b. Reconsideration of the 2020 PM NAAQS
Final Action

Executive Order 13990 directed review of certain agency actions (86 FR 7037, January 25, 2021).¹⁶ An accompanying fact sheet provided a non-exclusive list of agency actions that agency heads should review in accordance with that order, including the 2020 Particulate Matter NAAQS Decision.¹⁷

On June 10, 2021, the Agency announced its decision to reconsider the 2020 PM NAAQS final action because the available scientific evidence and technical information indicate that the current standards may not be adequate to protect public health and welfare, as required by the Clean Air Act.¹⁸ The Administrator reached this decision in part based on the fact that the EPA noted that the 2020 PA concluded that the scientific evidence and

¹⁵ See *California v. EPA*, (D.C. Cir., No. 21–2014 consolidated with Nos. 21–1027, 21–1054).

¹⁶ See <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-protecting-public-health-and-environment-and-restoring-science-to-tackle-climate-crisis/>.

¹⁷ See <https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/20/fact-sheet-list-of-agency-actions-for-review/>.

¹⁸ The press release for this announcement is available at: <https://www.epa.gov/newsreleases/epa-reexamine-health-standards-harmful-soot-previous-administration-left-unchanged>.

information called into question the adequacy of the primary annual $\text{PM}_{2.5}$ standard and supported revising the level to below the current level of $12.0 \mu\text{g}/\text{m}^3$ while retaining the primary 24-hour $\text{PM}_{2.5}$ standard (U.S. EPA, 2020b). The EPA also noted that the 2020 PA concluded that the available scientific evidence and information supported retaining the primary PM_{10} standard and secondary PM standards without revision (U.S. EPA, 2020b).

The EPA staff conclusions detailed in the 2020 PA in combination with the CASAC advice that informed the Administrator's decisions regarding the 2020 final action, studies highlighted by public comments on the 2020 proposal, and the numerous studies published since the literature cutoff date of the 2019 ISA all informed the scope of the reconsideration.

In its review of the 2019 draft PA, some members of the CASAC had recommended that greater attention should be given to accountability studies and epidemiologic studies that employ alternative methods for confounder control (also referred to as causal inference or causal modeling studies) in order to “more fully account for effects of confounding, measurement and estimation errors, model uncertainty, and heterogeneity” in epidemiologic studies (Cox, 2019b, p. 8 of consensus responses). In addition, public commenters submitted a number of recent studies published after the literature cutoff date for the 2019 ISA that would have been considered within the scope of the 2019 ISA. While the EPA provisionally considered these studies in responding to public comments,¹⁹ it was determined that, at the

¹⁹ The list of provisionally considered studies is included in Appendix A to the 2020 Response to Comments document (U.S. EPA, 2020a).

time of the 2020 final action, these studies were generally consistent with the evidence assessed in the 2019 ISA (85 FR 82690, December 18, 2020; U.S. EPA, 2020a). As such, and consistent with previous NAAQS reviews, the EPA concluded that the new studies did not materially change any of the broad scientific conclusions regarding the health and welfare effects of PM in ambient air made in the air quality criteria, and therefore, reopening of the air quality criteria was not warranted (85 FR 82691, December 18, 2020). However, at that time, the EPA recognized that its “provisional consideration of these studies did not and could not provide the kind of in-depth critical review” (85 FR 82690, December 18, 2020) that studies undergo in the development of an ISA.

In preparing to reconsider the 2020 final decision for the PM NAAQS, the Agency revisited the need to reopen the air quality criteria, given the amount of time that had passed since the literature cutoff date of the 2019 ISA (*i.e.*, approximately January 2018) and the volume of literature that had become available, including those studies provisionally considered in responding to comments in 2020. In so doing, the EPA preliminarily concluded that at least some of these studies were likely to be relevant to its reconsideration of the air quality criteria and the PM NAAQS and that, in considering public comments on any proposed decisions for the reconsideration, these studies were likely to be raised by public commenters and would potentially warrant a reopening of the air quality criteria. For example, on February 16, 2021, the EPA received two petitions to reconsider the PM NAAQS. One petition objected to the EPA’s provisional consideration of studies submitted in public comments on the 2020 proposal and suggested that

the provisional consideration was inadequate because the studies could be important in determining whether the existing standards are adequately protective. See, Petition for Reconsideration of National Ambient Air Quality Standards for Particulate Matter, submitted by American Lung Association, et al, dated Feb. 16, 2020. The other petition identified a number of new studies, including one epidemiologic study that was published after the provisional consideration was completed that could further inform the concern expressed by the CASAC that associations reported in epidemiologic studies do not adequately account for “uncontrolled confounding and other potential sources of error and bias.” See Petition for Reconsideration of “Review of the National Ambient Air Quality Standards for Particulate Matter,” submitted by the State of California, dated Feb. 16, 2020. This was also an uncertainty noted by the then-Administrator in the 2020 decision, who also recognized “that methodological study designs to address confounding, such as causal inference methods, are an emerging field of study.” Thus, the Agency concluded it was appropriate to reconsider not only the standards but also the air quality criteria, in light of public comments during the 2020 PM NAAQS proposal and recent studies published since the cutoff date of the 2019 ISA, as reflected in petitions. In deciding to reopen the air quality criteria, the Agency concluded it was reasonable to focus on studies that were most likely to inform decisions on the appropriate standard, but not to reassess areas which, based on the assessment of available science published since the cutoff date of the 2019 ISA and through 2021, were judged unlikely to have new information that would be useful for the Administrator’s decision making. The Agency accord-

ingly announced that, in support of the reconsideration, it would develop a supplement to the 2019 ISA and a revised PA.

The EPA also explained that the draft ISA Supplement and draft PA would be reviewed at a public meeting by the CASAC, and the public would have opportunities to comment on these documents during the CASAC review process, as well as to provide input during the rulemaking through the public comment process and public hearings on the proposed rulemaking.

On March 31, 2021, the Administrator announced his decision to reestablish the membership of the CASAC to “ensure the agency received the best possible scientific insight to support our work to protect human health and the environment.”²⁰ Consistent with this memorandum, a call for nominations of candidates to the EPA’s chartered CASAC was published in the Federal Register (86 FR 17146, April 1, 2021). On June 17, 2021, the Administrator announced his selection of the seven members to serve on the chartered CASAC.^{21 22} Additionally, a call for nominations of candidates to a PM- specific panel was published in the Federal Register (86 FR 33703, June 25, 2021). The members

²⁰ The press release for this announcement is available at: <https://www.epa.gov/newsreleases/administrator-regan-directs-epa-reset-critical-science-focused-federal-advisory>

²¹ The press release for this announcement is available at: <https://www.epa.gov/newsreleases/epa-announces-selections-charter-members-clean-air-scientific-advisory-committee>.

²² The list of members of the chartered CASAC and their biosketches are available at: https://casac.epa.gov/ords/sab/r/sab_apex/casac/mems?p14_committeon=2021%20CASAC%20PM%20Panel &session=17433386035954.

of the PM CASAC panel were announced on August 30, 2021.²³

The draft ISA Supplement was released in September 2021 (U.S. EPA, 2021a; 86 FR 54186, September 30, 2021), and included a discussion of the rationale and scope of the Supplement. As explained therein, the ISA Supplement focuses on a thorough evaluation of some studies that became available after the literature cutoff date of the 2019 ISA that could either further inform the adequacy of the current PM NAAQS or address key scientific topics that have evolved since the literature cutoff date for the 2019 ISA. In selecting the health effects to evaluate within the ISA Supplement, the EPA focused on health effects for which the evidence supported a “causal relationship” because those were the health effects that were most useful in informing conclusions in the 2020 PA (U.S. EPA, 2022a, section 1.2.1).²⁴ Consistent with the rationale for the focus on

²³ The list of members of the PM CASAC panel and their biosketches are available at: https://casac.epa.gov/ords/sab/f?p=105:14:9979229564047:::14:P14_COMMITTEON:2021%20CASAC%20PM%20Panel.

²⁴ As described in section 1.2.1 of the ISA Supplement: “In considering the public health protection provided by the current primary PM_{2.5} standards, and the protection that could be provided by alternatives, [the U.S. EPA, within the 2020 PM PA] emphasized health outcomes for which the ISA determined that the evidence supports either a ‘causal’ or a ‘likely to be causal’ relationship with PM_{2.5} exposures” (U.S. EPA, 2020b). Although the 2020 PA initially focused on this broader set of evidence, the basis of the discussion on potential alternative standards primarily focused on health effect categories where the 2019 PM ISA concluded a ‘causal relationship’ (i.e., short- and long-term PM_{2.5} exposure and cardiovascular effects and mortality) as reflected in Figures 3–7 and 3–8 of the 2020 PA (U.S. EPA, 2020b).”

certain health effects, in selecting the non- ecological welfare effects to evaluate within the ISA Supplement, the EPA focused on the non-ecological welfare effects for which the evidence supported a “causal relationship” and for which quantitative analyses could be supported by the evidence because those were the welfare effects that were most useful in informing conclusions in the 2020 PA.²⁵ Specifically, for non- ecological welfare effects, the focus within the ISA Supplement is on visibility effects. The ISA Supplement also considers recent health effects evidence that addresses key scientific topics where the literature has evolved since the 2020 review was completed, specifically since the literature cutoff date for the 2019 ISA.²⁶

²⁵ As described in section 1.2.1 of the ISA Supplement: “The 2019 PM ISA concluded a ‘*causal relationship*’ for each of the welfare effects categories evaluated (*i.e.*, visibility, climate effects and materials effects). While the 2020 PA considered the broader set of evidence for these effects, for climate effects and material effects, it concluded that there remained ‘substantial uncertainties with regard to the quantitative relationships with PM concentrations and concentration patterns that limit[ed] [the] ability to quantitatively assess the public welfare protection provided by the standards from these effects’ (U.S. EPA, 2020b).”

²⁶ These key scientific topics include experimental studies conducted at near-ambient concentrations, epidemiologic studies that employed alternative methods for confounder control or conducted accountability analyses, studies that assess the relationship between PM_{2.5} exposure and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and coronavirus disease 2019 (COVID-19) death; and in accordance with recent EPA goals on addressing environmental justice, studies that examine disparities in PM_{2.5} exposure and the risk of health effects by race/ethnicity or socioeconomic status (SES) (U.S. EPA, 2022a, section 1.2.1).

Building on the rationale presented in section 1.2.1, the ISA Supplement considers peer-reviewed studies published from approximately January 2018 through March 2021 that meet the following criteria:

- Health Effects

- U.S. and Canadian epidemiologic studies for health effect categories where the 2019 ISA concluded a “*causal relationship*” (*i.e.*, short- and long-term PM_{2.5} exposure and cardiovascular effects and mortality).

- U.S. and Canadian epidemiologic studies that employed alternative methods for confounder control or conducted accountability analyses (*i.e.*, examined the effect of a policy on reducing PM_{2.5} concentrations).

- Welfare Effects

- U.S. and Canadian studies that provide new information on public preferences for visibility impairment and/or developed methodologies or conducted quantitative analyses of light extinction.

- Key Scientific Topics

- Experimental studies (*i.e.*, controlled human exposure and animal toxicological) conducted at near-ambient PM_{2.5} concentrations experienced in the U.S.

- U.S.- and Canadian-based epidemiologic studies that examined the relationship between PM_{2.5} exposures and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and coronavirus disease 2019 (COVID-19) death.

- At-Risk Populations.

■ U.S.- and Canadian-based epidemiologic or exposure studies examining potential disparities in either PM_{2.5} exposures or the risk of health effects by race/ethnicity or socioeconomic status (SES).

Given the narrow scope of the ISA Supplement, it is important to recognize that the evaluation does not encompass the full multidisciplinary evaluation presented within the 2019 ISA that would result in weight-of-evidence conclusions on causality (*i.e.*, causality determinations). The ISA Supplement critically evaluates and provides key study-specific information for those recent studies deemed to be of greatest significance for informing preliminary conclusions on the PM NAAQS in the context of the body of evidence and scientific conclusions presented in the 2019 ISA.

In developing a revised PA to support the reconsideration, the EPA considered the available scientific evidence, including the evidence presented in the 2019 ISA and ISA Supplement. The 2022 PA considered the quantitative and technical information presented in the 2020 PA, in addition to new and updated analyses conducted since the 2020 final decision. For those health and welfare effects for which the ISA Supplement evaluated recently available studies (*i.e.*, PM_{2.5}-related health effects and visibility effects), new updated quantitative analyses were conducted as a part of the development of the 2022 PA. The newly available scientific and technical information presented in the 2022 PA were considered in reaching conclusions regarding the adequacy of the current standards and any potential alternative standards. For those health and welfare effects for which newly available scientific and technical information were not evaluated (*i.e.*, PM₁₀-

^{2.5}-related health effects and non-visibility welfare effects), the conclusions presented in the 2022 PA rely heavily on the information that supported the conclusions in the 2020 PA.

The CASAC PM panel met at a virtual public meeting in November 2021 to review the draft ISA Supplement (86 FR 52673, September 22, 2021). A virtual public meeting was then held in February 2022, and during this meeting the chartered CASAC considered the CASAC PM panel's draft letter to the Administrator on the draft ISA Supplement (87 FR 958, January 7, 2022).

The chartered CASAC provided its advice on the draft ISA Supplement in a letter to the EPA Administrator dated March 18, 2022 (Sheppard, 2022b). In its review of the draft ISA Supplement, the CASAC noted that they found "the Draft ISA Supplement to be a well-written, comprehensive evaluation of the new scientific information published since the 2019 PM ISA" (Sheppard, 2022b, p. 2 of letter). Furthermore, the CASAC stated that "the final Integrated Science Assessment (ISA) Supplement . . . deserve[s] the Administrator's full consideration and [is] adequate for rulemaking" (Sheppard, 2022b, p. 2 of letter). The CASAC generally endorsed EPA's decisions regarding the limited scope of the draft ISA Supplement, stating that "this limitation [on scope] is appropriate for the targeted purpose of the Draft ISA Supplement" although the CASAC noted it would not be appropriate for ISAs generally, and recommended that the EPA provide additional acknowledgment and explanation for the limited scope (Sheppard, 2022b, p. 2 of letter; see also pp. 2–3 of consensus responses). The EPA specifically noted in the final ISA Supplement, which was released in May 2022

(U.S. EPA, 2022a; hereafter referred to as the ISA Supplement throughout this document) that the “targeted approach to developing the Supplement to the 2019 PM ISA for the purpose of reconsidering the 2020 PM NAAQS decision does not reflect a change to EPA’s approach for developing ISAs for NAAQS reviews.” Thus, the evidence presented within the 2019 ISA, along with the targeted identification and evaluation of new scientific information in the ISA Supplement, provides the scientific basis for the reconsideration of the 2020 PM NAAQS final decision.

The draft PA was released in October 2021 (86 FR 56263, October 8, 2021). The CASAC PM panel met at a virtual public meeting in December 2021 to review the draft PA (86 FR 52673, September 22, 2021). A virtual public meeting was then held in February 2022 and March 2022, and during this meeting the chartered CASAC considered the CASAC PM panel’s draft letter to the Administrator on the draft PA (87 FR 958, January 7, 2022). The chartered CASAC provided its advice on the draft PA in a letter to the EPA Administrator dated March 18, 2022 (Sheppard, 2022a). The EPA took steps to address these comments in revising and finalizing the PA. The 2022 PA considers the scientific evidence presented in the 2019 ISA and ISA Supplement and considers the quantitative and technical information presented in the 2020 PA, along with updated and newly available analyses since the completion of the 2020 review. For those health and welfare effects for which the ISA Supplement evaluated recently available evidence and for which updated quantitative analyses were supported (*i.e.*, PM_{2.5}-related health effects and visibility effects), the 2022 PA includes consideration of this newly available scientific and

technical information in reaching preliminary conclusions. For those health and welfare effects for which newly available scientific and technical information were not evaluated (*i.e.*, PM_{10-2.5}-related health effects and non-visibility effects), the conclusions presented in the 2022 PA rely heavily on the information that supported the conclusions in the 2020 PA. The final PA was released in May 2022 (U.S. EPA, 2022b; hereafter referred to as the 2022 PA throughout this document).

Drawing from his consideration of the scientific evidence assessed in the 2019 ISA and ISA Supplement and the analyses in the 2022 PA, including the uncertainties in the evidence and analyses, and from his consideration of advice from the CASAC, on January 5, 2023, the Administrator proposed to revise the level of the primary annual PM_{2.5} standard and to retain the primary 24-hour PM_{2.5} standard, the primary 24-hour PM₁₀ standard, and the secondary PM standards. These proposed decisions were published in the Federal Register on January 27, 2023 (88 FR 5558, January 27, 2023). The EPA held a multi-day virtual public hearing on February 21–23, 2023 (88 FR 6215, January 31, 2023). In total, the EPA received nearly 700,000 comments on the proposal from members of the public by the close of the public comment period on March 28, 2023. Major issues raised in the public comments are discussed throughout the preamble of this final action. A more detailed summary of all significant comments, along with the EPA’s responses (henceforth “Response to Comments” document), can be found in the docket for this rulemaking (Docket No. EPA–HQ–OAR–2015–0072).

As in prior reviews, the EPA is basing its decision in this reconsideration on studies and related information in the air quality criteria, which have undergone CASAC and public review. These studies assessed in the 2019 ISA²⁷ and ISA Supplement²⁸ and the 2022 PA, and the integration of the scientific evidence presented in them, have undergone extensive critical review by the EPA, the CASAC, and the public. Decisions on the NAAQS should be based on studies that have been rigorously assessed in an integrative manner not only by the EPA but also by the statutorily mandated independent scientific advisory committee, as well as the public review that accompanies this process. It is for this reason that the EPA preliminarily concluded that the scientific evidence available since the completion of the 2019 ISA, including those raised in public comments on the proposal in 2020, warranted a partial reopening of the air quality criteria and prepared an ISA Supplement to enable the EPA, the CASAC, and the public to consider them further. Some commenters have referred to and discussed additional individual scientific studies on the health effects of PM that

²⁷ In addition to the 2020 review's opening "call for information" (79 FR 71764, December 3, 2014), the 2019 ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009, through approximately January 2018 (U.S. EPA, 2019a, p. ES-2). References that are cited in the 2019 ISA, the references that were considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: <https://hero.epa.gov/hero/particulate-matter>.

²⁸ As described above, the ISA Supplement represents an evaluation of recent studies that are of greatest policy relevance and utility to the reconsideration of the 2020 final decision on the PM NAAQS (U.S. EPA, 2022a).

were not included in the 2019 ISA or ISA Supplement (“new studies”) and that have not gone through this comprehensive review process. In considering and responding to comments for which such “new” studies were cited in support, the EPA has provisionally considered the cited studies in the context of the findings of the 2019 ISA and ISA Supplement. The EPA’s provisional consideration of these studies did not and could not provide the kind of in-depth critical review described above, but rather was focused on determining whether they warranted further reopening the review of the air quality criteria to enable the EPA, the CASAC, and the public to consider them further.

This approach, and the decision to rely on the studies and related information in the air quality criteria, which have undergone CASAC and public review, is consistent with the EPA’s practice in prior NAAQS reviews and its interpretation of the requirements of the CAA. Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria, and the EPA has consistently followed this approach. This longstanding interpretation was strengthened by new legislative requirements enacted in 1977, which added section 109(d)(2) of the Act concerning CASAC review of air quality criteria. See 71 FR 6114, 61148 (October 17, 2006, final decision on review of NAAQS for particulate matter) for a detailed discussion of this issue and the EPA’s past practice.

As discussed in the EPA’s 1993 decision not to review the O₃ NAAQS, “new” studies may sometimes be of such significance that it is appropriate to delay

a decision in a NAAQS review and to supplement the pertinent air quality criteria so the studies can be taken into account (58 FR 13013–13014, March 9, 1993). In the present case, the EPA decided to partially reopen the air quality criteria and prepared an ISA Supplement as a part of the reconsideration to facilitate evaluation of these studies by the EPA, the CASAC, and the public. The narrow scope of the ISA Supplement is supported by EPA’s provisional consideration of “new” studies submitted in response to public comments on the 2020 proposal which concluded that, taken in context, the “new” information and findings do not materially change any of the broad scientific conclusions regarding the health and welfare effects of PM in ambient air made in the air quality criteria. Therefore, a full reopening of the air quality criteria was not warranted to assess the health and welfare effects of PM for purposes of the review.

Accordingly, the EPA is basing the final decisions in this reconsideration on the studies and related information included in the PM air quality criteria (including the 2019 PM ISA and ISA Supplement) that have undergone rigorous review by the EPA, the CASAC, and the public. The EPA will consider these “new” studies for inclusion in the air quality criteria for the next PM NAAQS review, which the EPA expects to begin soon after the conclusion of this reconsideration and which will provide the opportunity to fully assess these studies through a more rigorous review process involving the EPA, the CASAC, and the public.

D. Air Quality Information

This section provides a summary of basic information related to PM ambient air quality. It summarizes

information on the distribution of particle size in ambient air (section I.D.1), sources and emissions contributing to PM in the ambient air (section I.D.2), monitoring ambient PM in the U.S. (section I.D.3), ambient PM concentrations and trends in the U.S. (I.D.4), characterizing ambient PM_{2.5} concentrations for exposure (section I.D.5), and background PM (section I.D.6). Additional detail on PM air quality can be found in Chapter 2 of the 2022 PA (U.S. EPA, 2022b).

1. Distribution of Particle Size in Ambient Air

In ambient air, PM is a mixture of substances suspended as small liquid and/or solid particles (U.S. EPA, 2019a, section 2.2) and distinct health and welfare effects have been linked with exposures to particles of different sizes. Particles in the atmosphere range in size from less than 0.01 to more than 10 μm in diameter (U.S. EPA, 2019a, section 2.2). The EPA defines PM_{2.5}, also referred to as fine particles, as particles with aerodynamic diameters generally less than or equal to 2.5 μm . The size range for PM_{10-2.5}, also called coarse or thoracic coarse particles, includes those particles with aerodynamic diameters generally greater than 2.5 μm and less than or equal to 10 μm . PM₁₀, which is comprised of both fine and coarse fractions, includes those particles with aerodynamic diameters generally less than or equal to 10 μm . In addition, ultrafine particles (UFP) are often defined as particles with a diameter of less than 0.1 μm based on physical size, thermal diffusivity or electrical mobility (U.S. EPA, 2019a, section 2.2). Atmospheric lifetimes are generally longest for PM_{2.5}, which often remains in the atmosphere for days to weeks (U.S. EPA, 2019a, Table 2–1) before being removed by wet or dry deposition, while atmospheric

lifetimes for UFP and PM_{10-2.5} are shorter and are generally removed from the atmosphere within hours, through wet or dry deposition (U.S. EPA, 2019a, Table 2–1; U.S. EPA, 2022b, section 2.1).

2. Sources and Emissions Contributing to PM in the Ambient Air

PM is composed of both primary (directly emitted particles) and secondary particles. Primary PM is derived from direct particle emissions from specific PM sources while secondary PM originates from gas-phase precursor chemical compounds present in the atmosphere that have participated in new particle formation or condensed onto existing particles (U.S. EPA, 2019a, section 2.3). As discussed further in the 2019 ISA (U.S. EPA, 2019a, section 2.3.2.1), secondary PM is formed in the atmosphere by photochemical oxidation reactions of both inorganic and organic gas-phase precursors. Precursor gases include sulfur dioxide (SO₂), nitrogen oxides (NO_x), and volatile organic compounds (VOC) (U.S. EPA, 2019a, section 2.3.2.1). Ammonia also plays an important role in the formation of nitrate PM by neutralizing sulfuric acid and nitric acid. Sources and emissions of PM are discussed in more detail the 2022 PA (U.S. EPA, 2022b, section 2.1.1). Briefly, anthropogenic sources of PM include both stationary (*e.g.*, fuel combustion for electricity production and other purposes, industrial processes, agricultural activities) and mobile (*e.g.*, diesel- and gasoline-powered highway vehicles and other engine-driven sources) sources. Natural sources of PM include dust from the wind erosion of natural surfaces, sea salt, wildfires, primary biological aerosol particles (PBAP) such as bacteria and pollen, oxidation of biogenic hydrocarbons, such as isoprene and terpenes to produce secondary organic aerosol

(SOA), and geogenic sources, such as sulfate formed from volcanic production of SO₂. Wildland fire, which encompass both wildfire and prescribed fire, accounts for 44% of emissions of primary PM_{2.5} emissions (U.S. EPA, 2021b). Emissions from wildfire comprises 29% of primary PM_{2.5} emissions.

In recent years, the frequency and magnitude of wildfires have increased (U.S. EPA, 2019a). The magnitude of the public health impact of wildfires is substantial both because of the increase in PM_{2.5} concentrations as well as the duration of the wildfire smoke season, which is considered to range from May to November. Wildfire can make a large contribution to air pollution (including PM_{2.5}), and wildfire events can threaten public safety and life. The impacts of wildfire events can be mitigated through management of wildland vegetation, including through prescribed fire. Prescribed fire (and some wildfires) can mimic the natural processes necessary to maintain fire-dependent ecosystems, minimizing catastrophic wildfires and the risks they pose to safety, property and air quality (see, *e.g.*, 81 FR 58010, 58038, August 24, 2016). The EPA views the strategic use of prescribed fire as an important tool for reducing wildfire risk and the severity of wildfires and wildfire smoke (88 FR, 54118, 54126, August 9, 2023).²⁹ As noted in the PM NAAQS proposal, agencies have efforts in place to reduce the frequency and severity of human-caused wildfires (88 FR 5570, January 27, 2023).

Wildfire events produce high PM emissions that may impact the PM concentrations in ambient air to

²⁹ See also: <https://www.usda.gov/sites/default/files/documents/usda-epa-doi-cdc-mou.pdf>.

the extent that the concentrations result in an exceedance or violation which may affect the design value in a given area. The EPA's Exceptional Events Rule (81 FR 68216, October 3, 2016) describes the process by which air agencies may request to exclude 'event-influenced' data caused by exceptional events, which can include wildfires and prescribed fires on wildland. The EPA has issued guidance specifically addressing exceptional events demonstrations for both wildfires and prescribed fires on wildland. These documents are available on EPA's Exceptional Events Program website.³⁰ The EPA will develop fire-related exceptional events implementation tools, including updates as needed to existing guidance to facilitate more efficient processing of PM_{2.5}-related exceptional events demonstrations for both the 24-hour and annual standards.

3. Monitoring of Ambient PM

To promote uniform application of the air quality standards set forth under the CAA and to achieve the degree of public health and welfare protection intended for the NAAQS, the EPA establishes PM Federal Reference Methods (FRMs) for both PM₁₀ and PM_{2.5} in appendices J and L to 40 CFR part 50, both of which were amended following the 2006 and 2012 PM NAAQS reviews. The current PM monitoring network relies on FRMs and automated continuous Federal Equivalent Methods (FEMs) approved pursuant to 40 CFR part 53, in part to support changes necessary for implementation of the revised PM standards. Additionally, 40 CFR part 58,

³⁰ See: <https://www.epa.gov/air-quality-analysis/final-2016-exceptional-events-rule-supporting-guidance-documents-updated-faqs>.

appendices A through E, detail the requirements to measure ambient air quality and report ambient air quality data and related information. More information on PM ambient monitoring networks is available in section 2.2 of the 2022 PA (U.S. EPA, 2022b).

The PM_{2.5} monitoring program is one of the major ambient air monitoring programs with a robust, nationally consistent network of ambient air monitoring sites providing mass and/or chemical speciation measurements. 40 CFR part 58, appendix D, section 4.7 provides the applicable PM_{2.5} network design criteria. For most urban locations, PM_{2.5} monitors are sited at the neighborhood scale,³¹ where PM_{2.5} concentrations are reasonably homogeneous throughout an entire urban sub-region. In each CBSA with a monitoring requirement, at least one PM_{2.5} monitoring station representing area-wide air quality is sited in an area of expected maximum

³¹ For PM_{2.5}, neighborhood scale is defined at 40 CFR part 58, appendix D, 4.7.1(c)(3) as follows: Measurements in this category would represent conditions throughout some reasonably homogeneous urban sub-region with dimensions of a few kilometers and of generally more regular shape than the middle scale. Homogeneity refers to the particulate matter concentrations, as well as the land use and land surface characteristics. Much of the PM_{2.5} exposures are expected to be associated with this scale of measurement. In some cases, a location carefully chosen to provide neighborhood scale data would represent the immediate neighborhood as well as neighborhoods of the same type in other parts of the city. PM_{2.5} sites of this kind provide good information about trends and compliance with standards because they often represent conditions in areas where people commonly live and work for periods comparable to those specified in the NAAQS. In general, most PM_{2.5} monitoring in urban areas should have this scale.

concentration.³² By ensuring the area of expected maximum concentration in a CBSA has a site compared to both the annual and 24-hour NAAQS, all other similar locations are thus protected. Sites that represent relatively unique microscale, localized hot-spot, or unique middle scale impact sites are only eligible for comparison to the 24-hour PM_{2.5} NAAQS.

Under 40 CFR part 50, appendix L, and 40 CFR part 53, and 40 CFR part 58 appendix D there are three main methods components of the PM_{2.5} monitoring program: filter-based FRMs measuring PM_{2.5} mass, FEMs measuring PM_{2.5} mass, and other samplers used to collect the aerosol used in subsequent laboratory analysis for measuring PM_{2.5} chemical speciation. The FRMs are primarily used for comparison to the NAAQS, but also serve other important purposes, such as developing trends and evaluating the performance of FEMs. PM_{2.5} FEMs are typically continuous methods used to support forecasting and reporting of the Air Quality Index (AQI) but are also used for comparison to the NAAQS. Samplers that are part of the Chemical Speciation Network (CSN) and Interagency Monitoring of Protected Visual Environments (IMPROVE) network are used to provide chemical composition of the aerosol and serve a variety of objectives. More detail on each of these components of the PM_{2.5} monitoring program and of recent changes to PM_{2.5} monitoring requirements are described in detail in the 2022 PA (U.S. EPA, 2022b, section 2.2.3).

4. Ambient Concentrations and Trends

This section summarizes available information on recent ambient PM concentrations in the U.S. and on

³² 40 CFR part 58, app. D, 4.7.1(b)(2).

trends in PM air quality. Sections I.D.4.a and I.D.4.b summarize information on PM_{2.5} mass and components, respectively. Section I.D.4.c summarizes information on PM₁₀. Sections I.D.4.d and I.D.4.e summarize the more limited information on PM_{10-2.5} and UFP, respectively. Additional detail on PM air quality and trends can be found in the 2022 PA (U.S. EPA, 2022b, section 2.3).

a. PM_{2.5} mass

At monitoring sites in the U.S., annual PM_{2.5} concentrations from 2017 to 2019 averaged 8.0 µg/m³ (with the 10th and 90th percentiles at 5.9 and 10.0 µg/m³, respectively) and the 98th percentiles of 24-hour concentrations averaged 21.3 µg/m³ (with the 10th and 90th percentiles at 14.0 and 29.7 µg/m³, respectively) (U.S. EPA, 2022b, section 2.3.2.1). The highest ambient PM_{2.5} concentrations occur in the western U.S., particularly in California and the Pacific Northwest (U.S. EPA, 2022b, Figure 2–15). Much of the eastern U.S. has lower ambient concentrations, with annual average concentrations generally at or below 12.0 µg/m³ and 98th percentiles of 24-hour concentrations generally at or below 30 µg/m³ (U.S. EPA, 2022b, section 2.3.2.1).

Recent ambient PM_{2.5} concentrations reflect the substantial reductions that have occurred across much of the U.S. (U.S. EPA, 2022b, section 2.3.2.1). From 2000 to 2019, national annual average PM_{2.5} concentrations declined from 13.5 µg/m³ to 7.6 µg/m³, a 43% decrease (U.S. EPA, 2022b, section 2.3.2.1).³³ These declines have occurred at urban and rural monitoring sites, although urban PM_{2.5}

³³ See <https://www.epa.gov/air-trends/particulate-matter-pm25-trends> for up-to-date PM_{2.5} trends information.

concentrations remain consistently higher than those in rural areas (Chan et al., 2018) due to the impact of local sources in urban areas. Analyses at individual monitoring sites indicate that declines in ambient $\text{PM}_{2.5}$ concentrations have been most consistent across the eastern U.S. and in parts of coastal California, where both annual average and 98th percentiles of 24-hour concentrations declined significantly (U.S. EPA, 2022b, section 2.3.2.1). In contrast, trends in ambient $\text{PM}_{2.5}$ concentrations have been less consistent over much of the western U.S., with no significant changes since 2000 observed at some sites in the Pacific Northwest, the northern Rockies and plains, and the Southwest, particularly for 98th percentiles of 24-hour concentrations (U.S. EPA, 2022b, section 2.3.2.1). As noted below, some sites in the northwestern U.S. and California, where wildfire have been relatively common in recent years, have experienced high concentrations over shorter periods (*i.e.*, 2-hour averages).

The recent deployment of $\text{PM}_{2.5}$ monitors near major roads in large urban areas provides information on $\text{PM}_{2.5}$ concentrations near an important emissions source. For 2016–2018, Gantt et al. (2021) reported that 52% and 24% of the time near-road sites reported the highest annual and 24-hour $\text{PM}_{2.5}$ design value³⁴ in the CBSA, respectively. Of the CBSAs with the highest annual design values at near-road sites reported by Gantt et al. (2021), those design values were, on average, $0.8 \mu\text{g}/\text{m}^3$ higher than at the highest measuring non-near-road sites (range is 0.1 to $2.1 \mu\text{g}/\text{m}^3$ higher at near-road sites). Although most near-road monitoring sites do not

³⁴ A design value is considered valid if it meets the data handling requirements given in appendix N to 40 CFR part 50.

have sufficient data to evaluate long-term trends in near-road $\text{PM}_{2.5}$ concentrations, analyses of the data at one near-road-like site in Elizabeth, NJ,³⁵ show that the annual average near-road increment has generally decreased between 1999 and 2017 from about $2.0 \mu\text{g}/\text{m}^3$ to about $1.3 \mu\text{g}/\text{m}^3$ (U.S. EPA, 2022b, section 2.3.2.1).

Ambient $\text{PM}_{2.5}$ concentrations can exhibit a diurnal cycle that varies due to impacts from intermittent emission sources, meteorology, and atmospheric chemistry. The $\text{PM}_{2.5}$ monitoring network in the U.S. has an increasing number of continuous FEM monitors reporting hourly $\text{PM}_{2.5}$ mass concentrations that reflect this diurnal variation. The 2019 ISA describes a two-peaked diurnal pattern in urban areas, with morning peaks attributed to rush-hour traffic and afternoon peaks attributed to a combination of rush hour traffic, decreasing atmospheric dilution, and nucleation (U.S. EPA, 2019a, section 2.5.2.3, Figure 2–32). Because a focus on annual average and 24-hour average $\text{PM}_{2.5}$ concentrations could mask subdaily patterns, and because some health studies examine PM exposure durations shorter than 24- hours, it is useful to understand the broader distribution of subdaily $\text{PM}_{2.5}$ concentrations across the U.S. The 2022 PA presents information on the frequency distribution of 2-hour average $\text{PM}_{2.5}$ mass concentrations from all FEM $\text{PM}_{2.5}$ monitors in the U.S. for 2017–2019. At sites meeting the current primary $\text{PM}_{2.5}$ standards, these 2-hour concentrations generally remain below $10 \mu\text{g}/\text{m}^3$, and rarely exceed

³⁵ The Elizabeth Lab site in Elizabeth, NJ, is situated approximately 30 meters from travel lanes of the Interchange 13 toll plaza of the New Jersey Turnpike and within 200 meters of travel lanes for Interstate 278 and the New Jersey Turnpike.

30 $\mu\text{g}/\text{m}^3$. Two-hour concentrations are higher at sites violating the current standards, generally remaining below 16 $\mu\text{g}/\text{m}^3$ and rarely exceeding 80 $\mu\text{g}/\text{m}^3$ (U.S. EPA, 2022b, section 2.3.2.2.3). The extreme upper end of the distribution of 2-hour $\text{PM}_{2.5}$ concentrations is shifted higher during the warmer months, generally corresponding to the period of peak wildfire frequency (April to September) in the U.S. At sites meeting the current primary standards, the highest 2-hour concentrations measured rarely occur outside of the period of peak wildfire frequency. Most of the sites measuring these very high concentrations are in the northwestern U.S. and California, where wildfires have been relatively common in recent years (see U.S. EPA, 2022b, Appendix A, Figure A–1). When the period of peak wildfire frequency is excluded from the analysis, the extreme upper end of the distribution is reduced (U.S. EPA, 2022b, section 2.3.2.2.3).

b. $\text{PM}_{2.5}$ Components

Based on recent air quality data, the major chemical components of $\text{PM}_{2.5}$ have distinct spatial distributions. Sulfate concentrations tend to be highest in the eastern U.S., while in the Ohio Valley, Salt Lake Valley, and California nitrate concentrations are highest, and relatively high concentrations of organic carbon are widespread across most of the continental U.S. (U.S. EPA, 2022b, section 2.3.2.3). Elemental carbon, crustal material, and sea salt are found to have the highest concentrations in the northeast U.S., southwest U.S., and coastal areas, respectively.

An examination of $\text{PM}_{2.5}$ composition trends can provide insight into the factors contributing to overall reductions in ambient $\text{PM}_{2.5}$ concentrations. The biggest change in $\text{PM}_{2.5}$ composition that has occurred

in recent years is the reduction in sulfate concentrations due to reductions in SO₂ emissions. Between 2000 and 2015, the nationwide annual average sulfate concentration decreased by 17% at urban sites and 20% at rural sites. This change in sulfate concentrations is most evident in the eastern U.S. and has resulted in organic matter or nitrate now being the greatest contributor to PM_{2.5} mass in many locations (U.S. EPA, 2019a, Figure 2–19). The overall reduction in sulfate concentrations has contributed substantially to the decrease in national average PM_{2.5} concentrations as well as the decline in the fraction of PM₁₀ mass accounted for by PM_{2.5} (U.S. EPA, 2019a, section 2.5.1.1.6; U.S. EPA, 2022b, section 2.3.1).

c. PM₁₀

At long-term monitoring sites in the U.S., the 2017–2019 average of 2nd highest 24-hour PM₁₀ concentration was 68 µg/m³ (with 10th and 90th percentiles at 28 and 124 µg/m³, respectively) (U.S. EPA, 2022b, section 2.3.2.4).³⁶ The highest PM₁₀ concentrations tend to occur in the western U.S. Seasonal analyses indicate that ambient PM₁₀ concentrations are generally higher in the summer months than at other times of year, though the most extreme high concentration events are more likely in the spring (U.S. EPA, 2019a, Table 2–5). This is due to fact that the major PM₁₀ emission sources, dust and agriculture, are more active during the warmer and drier periods of the year.

Recent ambient PM₁₀ concentrations reflect reductions that have occurred across much of the U.S. (U.S.

³⁶ The form of the current 24-hour PM₁₀ standard is one-expected-exceedance, averaged over three years.

EPA, 2022b, section 2.3.2.4). From 2000 to 2019, 2nd highest 24-hour PM_{10} concentrations have declined by about 46% (U.S. EPA, 2022b, section 2.3.2.4).³⁷ Analyses at individual monitoring sites indicate that annual average PM_{10} concentrations have generally declined at most sites across the U.S., with much of the decrease in the eastern U.S. associated with reductions in $\text{PM}_{2.5}$ concentrations (U.S. EPA, 2022b, section 2.3.2.4). Annual 2nd highest 24-hour PM_{10} concentrations have generally declined in the eastern U.S., while concentrations in much of the midwest and western U.S. have remained unchanged or increased since 2000 (U.S. EPA, 2022b, section 2.3.2.4).

Compared to previous reviews, data available from the NCore monitoring network in the current reconsideration allows a more comprehensive analysis of the relative contributions of $\text{PM}_{2.5}$ and $\text{PM}_{10-2.5}$ to PM_{10} mass. $\text{PM}_{2.5}$ generally contributes more to annual average PM_{10} mass in the eastern U.S. than the western U.S. (U.S. EPA, 2022b, Figure 2–23). At most sites in the eastern U.S., the majority of PM_{10} mass is comprised of $\text{PM}_{2.5}$. As ambient $\text{PM}_{2.5}$ concentrations have declined in the eastern U.S. (U.S. EPA, 2022b, section 2.3.2.2), the ratios of $\text{PM}_{2.5}$ to PM_{10} have also declined. For sites with days having concurrently very high $\text{PM}_{2.5}$ and PM_{10} concentrations (U.S. EPA, 2022b, Figure 2–24), the $\text{PM}_{2.5}/\text{PM}_{10}$ ratios are typically higher than the annual average ratios. This is particularly true in the northwestern U.S. where the high PM_{10} concentrations can occur during wildfires with high $\text{PM}_{2.5}$ (U.S. EPA, 2022b, section 2.3.2.4).

³⁷ For more information, see <https://www.epa.gov/air-trends/particulate-matter-pm10-trends#pmnat>.

d. $\text{PM}_{10-2.5}$

Since the 2012 review, the availability of $\text{PM}_{10-2.5}$ ambient concentration data has greatly increased because of additions to the $\text{PM}_{10-2.5}$ monitoring capabilities to the national monitoring network. As illustrated in the 2022 PA (U.S. EPA, 2022b, section 2.3.2.5), annual average and 98th percentile $\text{PM}_{10-2.5}$ concentrations exhibit less distinct differences between the eastern and western U.S. than for either $\text{PM}_{2.5}$ or PM_{10} .

Due to the short atmospheric lifetime of $\text{PM}_{10-2.5}$ relative to $\text{PM}_{2.5}$, many of the high concentration sites are isolated and likely near emission sources associated with wind-blown and fugitive dust. The spatial distributions of annual average and 98th percentile concentrations of $\text{PM}_{10-2.5}$ are more similar than that of $\text{PM}_{2.5}$, suggesting that the same dust-related emission sources are affecting both long-term and episodic concentrations (U.S. EPA, 2022b, Figure 2–25). The highest concentrations of $\text{PM}_{10-2.5}$ are in the southwest U.S. where widespread dry and windy conditions contribute to wind-blown dust emissions. Additionally, compared to $\text{PM}_{2.5}$ and PM_{10} , changes in $\text{PM}_{10-2.5}$ concentrations have been small in magnitude and inconsistent in direction (U.S. EPA, 2022b, Figure 2–25). The majority of $\text{PM}_{10-2.5}$ sites in the U.S. do not have a concentration trend from 2000–2019, reflecting the relatively consistent level of dust emissions across the U.S. during the same time period (U.S. EPA, 2022b, section 2.3.2.5).³⁸

³⁸ PM from dust emissions in the National Emissions Inventory (NEI) remain fairly consistent from year-to-year, except when there are severe weather incursions or there is a dust event that transports or causes major local dust storms to occur (particularly in the western U.S.). These dust events and

e. UFP

Compared to $\text{PM}_{2.5}$ mass, there is relatively little data on U.S. particle number concentrations, which are dominated by UFP. In the published literature, annual average particle number concentrations reaching about 20,000 to 30,000 cm^3 have been reported in U.S. cities (U.S. EPA, 2019a). In addition, based on UFP measurements in two urban areas (New York City, Buffalo) and at a background site (Steuben County) in New York, there is a pronounced difference in particle number concentration between different types of locations (U.S. EPA, 2022b, Figure 2–26; U.S. EPA, 2019a, Figure 2–18). Urban particle number counts were several times higher than at the background site, and the highest particle number counts in an urban area with multiple sites (Buffalo) were observed at a near-road location (U.S. EPA, 2022b, section 2.3.2.6).

Long-term trends in UFP are not routinely available at U.S. monitoring sites. At one background site in Illinois with long-term data available, the annual average particle number concentration declined between 2000 and 2019, closely matching the reductions in annual $\text{PM}_{2.5}$ mass over that same period (U.S. EPA, 2022b, section 2.3.2.6). In addition, a small number of published studies have examined UFP trends over time. While limited, these studies also suggest that UFP number concentrations have declined over time along with decreases in $\text{PM}_{2.5}$ (U.S. EPA, 2022b, section 2.3.2.6). However, the relation-

weather incursions needed to effect dust emissions on a national level are not common and only seldomly occur. In the emissions trends analysis presented in the 2022 PA (U.S. EPA, 2022b, section 2.1.1), dust is included in the NEI sector labeled “miscellaneous.”

ship between changes in ambient PM_{2.5} and UFPs cannot be comprehensively characterized due to the high variability and limited monitoring of UFPs (U.S. EPA, 2022b, section 2.3.2.6).

5. Characterizing Ambient PM_{2.5} Concentrations for Exposure

Epidemiologic studies use various methods to characterize exposure to ambient PM_{2.5}. The methods used to estimate PM_{2.5} concentrations can vary from traditional methods using monitoring data from ground-based monitors to newer methods using more complex hybrid modeling approaches. Studies using hybrid modeling approaches aim to broaden the spatial coverage, as well as estimate more spatially-resolved ambient PM_{2.5} concentrations, by expanding beyond just those areas with monitors and providing estimates in areas that do not have ground-based monitors (*i.e.*, areas that are generally less densely populated and tend to have lower PM_{2.5} concentrations) and at finer spatial resolutions (*e.g.*, 1 km x 1 km grid cells). Ground-based PM_{2.5} monitors are generally sited in areas of expected maximum concentration. As such, the hybrid modeling approaches tend to broaden the areas captured in the exposure assessment, and in doing so, the studies that utilize these methods tend to report lower mean PM_{2.5} concentrations than monitor-based approaches. Further, other aspects of the approaches applied in the various epidemiologic studies to estimate PM_{2.5} exposure and/or to calculate the related study-reported mean concentration (*i.e.*, population weighting, trim mean approaches) can affect those data values. More detail related to hybrid modeling methods, performance of the methods, and how the reported mean concentrations compare across approaches is

provided in section 2.3.3.2 of the 2022 PA (U.S. EPA, 2022b). The subsections below discuss the characterization of PM_{2.5} concentrations based on monitoring data (I.D.5.a) and using hybrid modeling approaches (I.D.5.b).

a. Predicted Ambient PM_{2.5} and Exposure Based on Monitored Data

Ambient concentrations of PM_{2.5} are often characterized using measurements from national monitoring networks due to the accuracy and precision of the measurements and the public availability of data. For applications requiring PM_{2.5} characterizations across large areas or provide complete coverage from the site measurements, data interpolation and averaging techniques (such as Average Nearest Neighbor tools, and area-wide or population-weighted averaging of monitors) are sometimes used (U.S. EPA, 2019a, chapter 3).

For an area to meet the NAAQS, all valid design values³⁹ in that area, including the highest annual and 24-hour design values, must be at or below the levels of the standards. Because the monitoring network siting requirements are specified to capture the high PM_{2.5} concentrations (U.S. EPA, 2022b, section 2.2.3), areas meeting an annual PM_{2.5} standard with a particular level would be expected to have long-term average monitored PM_{2.5} concentrations (*i.e.*, averaged across space and over time in the

³⁹ For the annual PM_{2.5} standard, design values are calculated as the annual arithmetic mean PM_{2.5} concentration, averaged over 3 years. For the 24-hour standard, design values are calculated as the 98th percentile of the annual distribution of 24-hour PM_{2.5} concentrations, averaged over three years (appendix N of 40 CFR part 50).

area) somewhat below that standard level. This means that the $\text{PM}_{2.5}$ design value in an area is associated with a distribution of $\text{PM}_{2.5}$ concentrations in that area, and, based on monitoring siting requirements, should represent the highest concentration location applicable to be monitored under the $\text{PM}_{2.5}$ NAAQS. Analyses in the 2022 PA indicate that, based on recent air quality in U.S. CBSAs, maximum annual $\text{PM}_{2.5}$ design values are often 10% to 20% higher than annual average concentrations (*i.e.*, averaged across multiple monitors in the same CBSA) (U.S. EPA, 2022b, section 2.3.3.1, Figures 2–28 and 2–29). This difference between the maximum annual design value and the average concentration in an area can vary, depending on factors such as the number of monitors, monitor siting characteristics, and the distribution of ambient $\text{PM}_{2.5}$ concentrations. Given that higher $\text{PM}_{2.5}$ concentrations have been reported at some near-road monitoring sites relative to the surrounding area (U.S. EPA, 2022b, section 2.3.2.2.2), recent requirements for $\text{PM}_{2.5}$ monitoring at near-road locations in large urban areas (U.S. EPA, 2022b, section 2.2.3.3) may increase the ratios of maximum design values to average annual design values in some areas. Such ratios may also depend on how the averages are calculated (*i.e.*, averaged across monitors versus across modeled grid cells, as described below in section I.5.b). Compared to annual design values, the analysis in the 2022 PA indicates a more variable relationship between maximum 24-hour $\text{PM}_{2.5}$ design values and annual average concentrations (U.S. EPA, 2022b, section 2.3.3.1, Figure 2–29).

b. Comparison of PM_{2.5} Hybrid Modeling Approaches in Estimating Exposure and Relative to Design Values

Two types of hybrid approaches that have been utilized in several key PM_{2.5} epidemiologic studies in the 2019 ISA and ISA Supplement include neural network approaches and a satellite-based method with regression of residual PM_{2.5} with land-use and other variables to improve estimates of PM_{2.5} concentration in the U.S. As such, the 2022 PA further compares these two types of approaches across various scales (*e.g.*, CBSA versus nationwide), taking into account population weighting approaches utilized in epidemiologic studies when estimating PM_{2.5} exposure (U.S. EPA, 2022b, section 2.3.3.2.4). Additionally, the 2022 PA assesses how average PM_{2.5} concentrations computed in epidemiologic studies using these hybrid surfaces compare to the maximum design values measured at ground-based monitors. For this assessment, the 2022 PA evaluates the DI2019⁴⁰ and HA2020⁴¹ hybrid surfaces, surfaces that

⁴⁰ This analysis includes an updated version of the surface used in Di et al. (2016). Predictions in Di et al. (2016) were for 2000 to 2012 using a neural network model. The Di et al. (2019) study improved on that effort in several ways. First, a generalized additive model was used that accounted for geographic variations in performance to combine predictions from three models (neural network, random forest, and gradient boosting) to make the final optimal PM_{2.5} predictions. Second, the datasets were updated that were used in model training and included additional variables such as 12-km CMAQ modeling as predictors. Finally, more recent years were included in the Di et al. (2019) study.

⁴¹ The HA2020 field is based on the V4.NA.03 product available at: <https://sites.wustl.edu/acag/datasets/surface-pm-2-5/>. The name “HA2020” comes from the references for this product (Hammer et al., 2020; van Donkelaar et al., 2019).

are used in several of the key epidemiologic studies in the 2022 PA. This analysis is intended to help inform how the magnitude of the overall study-reported mean $\text{PM}_{2.5}$ concentrations in epidemiologic studies may be influenced by the approach used to compute that mean and how that value might compare to monitor reported concentrations. The $\text{PM}_{2.5}$ standards are expected to achieve a pattern of air quality through the attainment of a specific design value at each monitor in the monitoring network. As a result, it is important to be able to assess the relationship between monitor concentrations and patterns of air quality evaluated in the epidemiologic studies.

In estimating exposure, some studies focus on estimating concentrations in urban areas, while others examine the entire U.S. or large portions of the country. In general, the areas that are not included in the CBSA-only analysis tend to be more rural or less densely populated areas, tend to have lower $\text{PM}_{2.5}$ concentrations, and likely correspond to those locations where monitoring data availability is limited or nonexistent (U.S. EPA, 2022b, section 2.3.3.2.4, Figure 2–37). To evaluate the differences in mean $\text{PM}_{2.5}$ concentrations across different spatial scales, the 2022 PA analysis compares the DI2019 and HA2020 surfaces. At the national scale, the two surfaces generally produce similar average annual $\text{PM}_{2.5}$ concentrations, with the DI2019 surface being slightly higher compared to the HA2020 surface. The average annual $\text{PM}_{2.5}$ concentrations are also slightly higher using the DI2019 surface compared to the HA2020 surface when the analyses are conducted for CBSAs. Also, regardless of which surface is used, the average annual and 3-year average of the average annual $\text{PM}_{2.5}$ concentrations for the CBSA-only analyses are somewhat higher than for the

nationwide analyses (4–8% higher) (U.S. EPA, 2022b, section 2.3.3.2.4, Table 2–5).⁴² Overall, these analyses suggest that there are only slight differences in the average $\text{PM}_{2.5}$ concentrations depending on the hybrid modeling method employed, though including other hybrid modeling methods in this comparison could result in larger differences.

The 2022 PA next evaluates how the averages of the hybrid model surfaces compare to regulatory design values using both the DI2019 and HA2020 surfaces and how population weighting influences the mean $\text{PM}_{2.5}$ concentration.⁴³ As presented in the 2022 PA, the results using the DI2019 and HA2020 surfaces are similar for the average annual $\text{PM}_{2.5}$ concentrations, for each 3-year period. When population weighting is not applied, the average annual $\text{PM}_{2.5}$ concentrations generally range from 7.0 to 8.6 $\mu\text{g}/\text{m}^3$. When population weighting is applied, the average annual $\text{PM}_{2.5}$ concentrations are slightly higher, ranging from 8.2 to 10.2 $\mu\text{g}/\text{m}^3$. As with CBSAs versus the national comparison above, popu-

⁴² For the national scale, 3-year averages of the average annual $\text{PM}_{2.5}$ concentrations generally range from about 5.3 $\mu\text{g}/\text{m}^3$ to 8.1 $\mu\text{g}/\text{m}^3$, compared to the CBSA scale, which ranges from 5.7 $\mu\text{g}/\text{m}^3$ to 8.7 $\mu\text{g}/\text{m}^3$. (U.S. EPA, 2022b, section 2.3.3.2.4, Table 2–6).

⁴³ For this analysis, the 2022 PA includes CBSAs with three or more valid design values for the 3-year period. The regulatory design values for the CBSAs were calculated for each 3-year period for the CBSAs with 3 or more design values in each of the 3-year periods. Using the maximum design value for each CBSA and by each 3-year period, the ratio of maximum design values to modeled average annual $\text{PM}_{2.5}$ concentrations were calculated, for each 3-year period. More details about the analytical methods used for this analysis are described in section A.6 of Appendix A in the 2022 PA (U.S. EPA, 2022b).

lation weighting results in a higher average $\text{PM}_{2.5}$ concentration than when population weighting is not applied (U.S. EPA, 2022b, section 2.3.3.2.4, Table 2–7). For the CBSAs included in the population weighted analyses, the average maximum annual design values generally range from 9.5 to 11.7 $\mu\text{g}/\text{m}^3$. The results are similar for both the DI2019 and HA2020 surfaces and the maximum annual $\text{PM}_{2.5}$ design values measured at the monitors are often 40% to 50% higher than average annual $\text{PM}_{2.5}$ concentrations predicted by hybrid modeling methods when population weighting is not applied. However, when population weighting is applied, the ratio of the maximum annual $\text{PM}_{2.5}$ design values to the predicted average annual $\text{PM}_{2.5}$ concentrations are lower than when population weighting is not applied, with monitored design values generally 15% to 18% higher than population-weighted hybrid modeling average annual $\text{PM}_{2.5}$ concentrations (U.S. EPA, 2022b, section 2.3.3.2.4, Table 2–7).

6. Background PM

In this reconsideration, background PM is defined as all particles that are formed by sources or processes that cannot be influenced by actions within the jurisdiction of concern. U.S. background PM is defined as any PM formed from emissions other than U.S. anthropogenic (*i.e.*, manmade) emissions. Potential sources of U.S. background PM include both natural sources (*i.e.*, PM that would exist in the absence of any anthropogenic emissions of PM or PM precursors) and transboundary sources originating outside U.S. borders. Background PM is discussed in more detail in the 2022 PA (U.S. EPA, 2022b, section 2.4). At annual and national scales, estimated background PM concentrations in the U.S. are small compared to

contributions from domestic anthropogenic sources.⁴⁴ For example, based on zero-out modeling in the last review of the PM NAAQS, annual background PM_{2.5} concentrations were estimated to range from 0.5–3 µg/m³ across the sites examined. In addition, speciated monitoring data from IMPROVE sites can provide some insights into how contributions from different sources, including sources of background PM, may have changed over time. Such data suggests the estimates of background concentrations using speciated monitoring data from IMPROVE monitors are around 1–3 µg/m³ and have not changed significantly since the 2012 review. Contributions to background PM in the U.S. result mainly from sources within North America. Contributions from intercontinental events have also been documented (*e.g.*, transport from dust storms occurring in deserts in North Africa and Asia), but these events are less frequent and represent a relatively small fraction of background PM in most of the U.S. (U.S. EPA, 2022b, section 2.4).

⁴⁴ Sources that contribute to natural background PM include dust from the wind erosion of natural surfaces, sea salt, wildland fires, primary biological aerosol particles such as bacteria and pollen, oxidation of biogenic hydrocarbons such as isoprene and terpenes to produce secondary organic aerosols (SOA), and geogenic sources such as sulfate formed from volcanic production of SO₂ and oceanic production of dimethylsulfide (U.S. EPA, 2022b, section 2.4). While most of these sources release or contribute predominantly to fine aerosol, some sources including windblown dust, and sea salt also produce particles in the coarse size range (U.S. EPA, 2019a, section 2.3.3).

II. Rationale for Decisions on the Primary PM_{2.5} Standards

This section presents the rationale for the Administrator's decision to revise the primary annual PM_{2.5} standard down to a level of 9 µg/m³ and retain the primary 24-hour PM_{2.5} standard. This rationale is based on a thorough review of the scientific evidence generally published through January 2018,⁴⁵ as evaluated in the 2019 ISA (U.S. EPA, 2019a), on the human health effects of PM_{2.5} associated with long- and short-term exposures⁴⁶ to PM_{2.5} in the ambient air. Additionally, this rationale is based on a thorough evaluation of some studies that became available after the literature cutoff date of the 2019 ISA, as evaluated in the ISA Supplement, that could either further inform the adequacy of the current PM NAAQS or address key scientific topics that have evolved since the literature cutoff date for the 2019 ISA, generally through March 2021 (U.S. EPA, 2022a).⁴⁷ The Administrator's rationale also takes

⁴⁵ In addition to the 2020 review's opening "call for information" (79 FR 71764, December 3, 2014), the 2019 ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009, through approximately January 2018 (U.S. EPA, 2019a, p. ES-2). References that are cited in the 2019 ISA, the references that were considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: <https://hero.epa.gov/hero/particulate-matter>.

⁴⁶ Short-term exposures are defined as those exposures occurring over hours up to 1 month, whereas long-term exposures are defined as those exposures occurring over 1 month to years (U.S. EPA, 2019a, section P.3.1).

⁴⁷ The ISA Supplement represents an evaluation of recent studies that are of greatest policy relevance to the

into account: (1) The 2022 PA evaluation of the policy-relevant information in the 2019 ISA and ISA Supplement and presentation of quantitative analyses of air quality and health risks; (2) CASAC advice and recommendations; and (3) public comments received during the development of these documents.

In presenting the rationale for the Administrator's decisions and its foundations, section II.A provides background on the general approach for this reconsideration and the basis for the existing standard, and also presents brief summaries of key aspects of the currently available health effects and risk information. Section II.B summarizes the CASAC advice and the basis for the proposed conclusions, addresses public comments received on the proposal and presents the Administrator's conclusions on the adequacy of the current standards, drawing on consideration of the scientific evidence and quantitative risk information, advice from the CASAC, and comments from the public. Section II.C summarizes the Administrator's decision on the primary PM_{2.5} standards.

A. Introduction

The general approach for this reconsideration of the 2020 final decision on the primary PM_{2.5} standards is fundamentally based on using the EPA's

reconsideration of the 2020 final decision on the PM NAAQS. Specifically, the ISA Supplement focuses on studies of health effects for which the evidence in the 2019 ISA supported a "causal relationship" (*i.e.*, short- and long-term PM_{2.5} exposure and mortality and cardiovascular effects) because those were the health effects that were most useful in informing conclusions in the 2020 PA. The ISA Supplement does not include an evaluation of studies for other PM_{2.5}-related health effects (U.S. EPA, 2022a).

assessment of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgment regarding primary PM_{2.5} standards that protect public health with an adequate margin of safety. The EPA's assessments are primarily documented in the 2019 ISA, ISA Supplement, and 2022 PA, all of which have received CASAC review and public comment (83 FR 53471, October 23, 2018; 83 FR 55529, November 6, 2018; 85 FR 4655, January 27, 2020; 86 FR 52673, September 22, 2021; 86 FR 54186, September 30, 2021; 86 FR 56263, October 8, 2021; 87 FR 958, January 7, 2022; 87 FR 22207, April 14, 2022; 87 FR 31965, May 26, 2022). In bridging the gap between the scientific assessments of the 2019 ISA and ISA Supplement and the judgments required of the Administrator in determining whether the current standards provide the requisite public health protection, the 2022 PA evaluates policy implications of the evaluation of the current evidence in the 2019 ISA and ISA Supplement, and the risk information documented in the 2022 PA. In evaluating the public health protection afforded by the current standards, the four basic elements of the NAAQS (*i.e.*, indicator, averaging time, level, and form) are considered collectively.

The final decision on the adequacy of the current primary PM_{2.5} standards is a public health policy judgment to be made by the Administrator. In reaching conclusions with regard to the standards, the decision will draw on the scientific information and analyses about health effects and population risks, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and analyses. This approach is based on the recognition that the available health effects evidence generally reflects a

continuum, consisting of levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. This approach is consistent with the requirements of the NAAQS provisions of the Clean Air Act and with how the EPA and the courts have historically interpreted the Act (summarized in section I.A above). These provisions require the Administrator to establish primary standards that, in the judgment of the Administrator, are requisite to protect public health with an adequate margin of safety. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that primary standards be set at a zero-risk level, but rather at a level that avoids unacceptable risks to public health, including the health of sensitive (also referred to as “at-risk”) groups.⁴⁸

1. Background on the Current Standards

The current primary PM_{2.5} standards were retained in 2020 based on the scientific evidence and quantitative risk information available at that time, as well as the then-Administrator’s judgments regarding the available health effects evidence and the appropriate degree of public health protection afforded by the existing standards (85 FR 82718, December 18, 2020). With the 2020 decision, the then-Administrator retained the primary annual PM_{2.5} standard with its

⁴⁸ As noted in section I.A above, the legislative history describes such protection for the sensitive group of individuals and not for a single person in the sensitive group (see S. Rep. No. 91–1196, 91st Cong, 2d Sess. 10 [1970]); see also *Am. Lung Ass’n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998).

level of 12.0 $\mu\text{g}/\text{m}^3$ and retained the primary 24-hour $\text{PM}_{2.5}$ standard with its level of 35 $\mu\text{g}/\text{m}^3$. The key considerations and the then-Administrator's conclusions regarding the primary $\text{PM}_{2.5}$ standards in the 2020 review are summarized below.

The health effects evidence base available in the 2020 review included extensive evidence from previous reviews as well as the evidence that had emerged since the prior review had been completed in 2012. This evidence base, spanning several decades, documents the relationship between short- and long-term $\text{PM}_{2.5}$ exposure and mortality or serious morbidity effects. The evidence available in the 2019 ISA reaffirmed, and in some cases strengthened, the conclusions from the 2009 ISA regarding the health effects of $\text{PM}_{2.5}$ exposures (U.S. EPA, 2019a). Much of the evidence came from epidemiologic studies conducted in North America, Europe, or Asia examining short-term and long-term exposures that demonstrated generally positive, and often statistically significant, $\text{PM}_{2.5}$ health effect associations with a range of outcomes including non-accidental, cardiovascular, or respiratory mortality; cardiovascular- or respiratory-related hospitalizations or emergency department visits; and other mortality/ morbidity outcomes (*e.g.*, lung cancer mortality or incidence, asthma development). Experimental evidence, as well as evidence from panel studies, strengthened support for potential biological pathways through which $\text{PM}_{2.5}$ exposures could lead to health effects reported in many population-based epidemiologic studies, including support for pathways that could lead to cardiovascular, respiratory, nervous system, and cancer-related effects. Based on this evidence, the 2019 ISA concluded there to be a causal relationship between long- and short-term $\text{PM}_{2.5}$ exposure and mortality

and cardiovascular effects, as well as likely to be causal relationships between long- and short-term PM_{2.5} exposure and respiratory effects, and between long-term PM_{2.5} exposure and cancer and nervous system effects (U.S. EPA, 2019a, section 1.7).

Epidemiologic studies reported PM_{2.5} health effect associations with mortality and/or morbidity across multiple U.S. cities and in diverse populations, including in studies examining populations and lifestages that may be at increased risk of experiencing a PM_{2.5}-related health effect (*e.g.*, older adults, children). The 2019 ISA cited extensive evidence indicating that “both the general population as well as specific populations and lifestages are at risk for PM_{2.5}-related health effects” (U.S. EPA, 2019a, p. 12–1), including children and older adults, people with pre-existing respiratory or cardiovascular disease, minority populations, and low socioeconomic status (SES) populations.

The risk information available in the 2020 review included risk estimates for air quality conditions just meeting the existing primary PM_{2.5} standards, and also for air quality conditions just meeting potential alternative standards. The general approach to estimating PM_{2.5}-associated health risks combined concentration-response (C–R) functions from epidemiologic studies with model-based PM_{2.5} air quality surfaces, baseline health incidence data, and population demographics for 47 urban areas (U.S. EPA, 2020b, section 3.3, Figure 3–10, Appendix C). The risk assessment estimated that the existing primary PM_{2.5} standards could allow a substantial number of PM_{2.5}-associated deaths in the U.S. Uncertainty in risk estimates (*e.g.*, in the size of risk estimates) can result from a number of factors, including assumptions

about the shape of the C–R relationship with mortality at low ambient PM_{2.5} concentrations, the potential for confounding and/or exposure measurement error, and the methods used to adjust PM_{2.5} air quality.

Consistent with the general approach routinely employed in NAAQS reviews, the initial consideration in the 2020 review of the primary PM_{2.5} standards was with regard to the adequacy of the protection provided by the existing standards.

As an initial matter, the then-Administrator considered the range of scientific evidence evaluating these effects, including studies of at-risk populations, to inform his review of the primary PM_{2.5} standards, placing the greatest weight on evidence of effects for which the 2019 ISA determined there to be a causal or likely to be causal relationship with long- and short-term PM_{2.5} exposures (85 FR 82714–82715, December 18, 2020).

With regard to indicator, the then-Administrator recognized that, consistent with the evidence available in prior reviews, the scientific evidence continued to provide strong support for health effects following short- and long- term PM_{2.5} exposures. He noted the 2020 PA conclusions that the information continued to support the PM_{2.5} mass-based indicator and remained too limited to support a distinct standard for any specific PM_{2.5} component or group of components, and too limited to support a distinct standard for the ultrafine fraction. Thus, the then-Administrator concluded that it was appropriate to retain PM_{2.5} as the indicator for the primary standards for fine particles (85 FR 82715, December 18, 2020).

With respect to averaging time and form, the then-Administrator noted that the scientific evidence continued to provide strong support for health effects associations with both long-term (*e.g.*, annual or multi-year) and short-term (*e.g.*, mostly 24-hour) exposures to PM_{2.5}, consistent with the conclusions in the 2020 PA. In the 2019 ISA, epidemiologic and controlled human exposure studies examined a variety of PM_{2.5} exposure durations. Epidemiologic studies continued to provide strong support for health effects associated with short-term PM_{2.5} exposures based on 24-hour PM_{2.5} averaging periods, and the EPA noted that associations with subdaily estimates are less consistent and, in some cases, smaller in magnitude (U.S. EPA, 2019a, section 1.5.2.1; U.S. EPA, 2020b, section 3.5.2.2). In addition, controlled human exposure and panel- based studies of subdaily exposures typically examined subclinical effects, rather than the more serious population- level effects that have been reported to be associated with 24-hour exposures (*e.g.*, mortality, hospitalizations). Taken together, the 2019 ISA concluded that epidemiologic studies did not indicate that subdaily averaging periods were more closely associated with health effects than the 24-hour average exposure metric (U.S. EPA, 2019a, section 1.5.2.1). Additionally, while controlled human exposure studies provided consistent evidence for cardiovascular effects following PM_{2.5} exposures for less than 24 hours (*i.e.*, <30 minutes to 5 hours), exposure concentrations in the studies were well- above the ambient concentrations typically measured in locations meeting the existing standards (U.S. EPA, 2020b, section 3.2.3.1). Thus, these studies also did not suggest the need for additional protection against subdaily PM_{2.5} exposures (U.S. EPA, 2020b, section 3.5.2.2). Therefore, the

then-Administrator judged that the 24-hour averaging time remained appropriate (85 FR 82715, December 18, 2020).

With regard to the form of the 24-hour standard (98th percentile, averaged over three years), the then-Administrator noted that epidemiologic studies continued to provide strong support for health effect associations with short-term (*e.g.*, mostly 24-hour) PM_{2.5} exposures (U.S. EPA, 2020b, section 3.5.2.3) and that controlled human exposure studies provided evidence for health effects following single short-term “peak” PM_{2.5} exposures. Thus, the evidence supported retaining a standard focused on providing supplemental protection against short-term peak exposures and supported a 98th percentile form for a 24-hour standard. The then-Administrator further noted that this form also provided an appropriate balance between limiting the occurrence of peak 24-hour PM_{2.5} concentrations and identifying a stable target for risk management programs (U.S. EPA, 2020b, section 3.5.2.3). As such, the then-Administrator concluded that the available information supported retaining the form and averaging time of the current 24-hour standard (98th percentile, averaged over three years) and annual standard (annual average, averaged over three years) (85 FR 82715, December 18, 2020).

With regard to the level of the standards, in reaching his final decision, the then-Administrator considered the large body of evidence presented and assessed in the 2019 ISA (U.S. EPA, 2019a), the policy-relevant and risk-based conclusions and rationales as presented in the 2020 PA (U.S. EPA, 2020b), advice from the CASAC, and public comments. In particular, in considering the 2019 ISA and 2020 PA, he

considered key epidemiologic studies that evaluated associations between PM_{2.5} air quality distributions and mortality and morbidity, including key accountability studies; the availability of experimental studies to support biological plausibility; controlled human exposure studies examining effects following short-term PM_{2.5} exposures; air quality analyses; and the important uncertainties and limitations associated with the information (85 FR 82715, December 18, 2020).

As an initial matter, the then-Administrator considered the protection afforded by both the annual and 24-hour standards together against long- and short-term PM_{2.5} exposures and health effects. The Administrator recognized that the annual standard was most effective in controlling “typical” PM_{2.5} concentrations near the middle of the air quality distribution (*i.e.*, around the mean of the distribution), but also provided some control over short-term peak PM_{2.5} concentrations. On the other hand, the 24-hour standard, with its 98th percentile form, was most effective at limiting peak 24-hour PM_{2.5} concentrations, but in doing so also had an effect on annual average PM_{2.5} concentrations. Thus, while either standard could be viewed as providing some measure of protection against both average exposures and peak exposures, the 24-hour and annual standards were not expected to be equally effective at limiting both types of exposures. Thus, consistent with previous reviews, the then-Administrator’s consideration of the public health protection provided by the existing primary PM_{2.5} standards was based on his consideration of the combination of the annual and 24-hour standards. Specifically, he recognized that the annual standard was more likely to appropriately limit the “typical” daily and annual

exposures that are most strongly associated with the health effects observed in epidemiologic studies. The then-Administrator concluded that an annual standard (as the arithmetic mean, averaged over three years) remained appropriate for targeting protection against the annual and daily PM_{2.5} exposures around the middle portion of the PM_{2.5} air quality distribution. Further, recognizing that the 24-hour standard (with its 98th percentile form) was more directly tied to short-term peak PM_{2.5} concentrations, and more likely to appropriately limit exposures to such concentrations, the then-Administrator concluded that the current 24-hour standard (with its 98th percentile form, averaged over three years) remained appropriate to provide a balance between limiting the occurrence of peak 24-hour PM_{2.5} concentrations and identifying a stable target for risk management programs. However, the then-Administrator recognized that changes in PM_{2.5} air quality to meet an annual standard would likely result not only in lower short- and long-term PM_{2.5} concentrations near the middle of the air quality distribution, but also in fewer and lower short-term peak PM_{2.5} concentrations. The then-Administrator further recognized that changes in air quality to meet a 24-hour standard, with a 98th percentile form, would result not only in fewer and lower peak 24-hour PM_{2.5} concentrations, but also in lower annual average PM_{2.5} concentrations (85 FR 82715–82716, December 18, 2020).

Thus, in considering the adequacy of the 24-hour standard, the then-Administrator noted the importance of considering whether additional protection was needed against short-term exposures to peak PM_{2.5} concentrations. In examining the scientific evidence, he noted the limited utility of the animal toxicological

studies in directly informing conclusions on the appropriate level of the standard given the uncertainty in extrapolating from effects in animals to those in human populations. The then-Administrator noted that controlled human exposure studies provided evidence for health effects following single, short-term $\text{PM}_{2.5}$ exposures that corresponded best to exposures that might be experienced in the upper end of the $\text{PM}_{2.5}$ air quality distribution in the U.S. (*i.e.*, “peak” concentrations). However, most of these studies examined exposure concentrations considerably higher than are typically measured in areas meeting the standards (U.S. EPA, 2020b, section 3.2.3.1). In particular, controlled human exposure studies often reported statistically significant effects on one or more indicators of cardiovascular function following 2-hour exposures to $\text{PM}_{2.5}$ concentrations at and above $120 \mu\text{g}/\text{m}^3$ (at and above $149 \mu\text{g}/\text{m}^3$ for vascular impairment, the effect shown to be most consistent across studies). To provide insight into what these studies may indicate regarding the primary $\text{PM}_{2.5}$ standards, the 2020 PA (U.S. EPA, 2020b, p. 3–49) noted that 2-hour ambient concentrations of $\text{PM}_{2.5}$ at monitoring sites meeting the current standards almost never exceeded $32 \mu\text{g}/\text{m}^3$. In fact, even the extreme upper end of the distribution of 2-hour $\text{PM}_{2.5}$ concentrations at sites meeting the primary $\text{PM}_{2.5}$ standards remained well-below the $\text{PM}_{2.5}$ exposure concentrations consistently shown in controlled human exposure studies to elicit effects (*i.e.*, 99.9th percentile of 2-hour concentrations at these sites is $68 \mu\text{g}/\text{m}^3$ during the warm season). Thus, the experimental evidence did not indicate the need for additional protection against exposures to peak $\text{PM}_{2.5}$ concentrations, beyond the protection provided by the combination of the 24-hour and the

annual standards (U.S. EPA, 2020b, section 3.2.3.1; 85 FR 82716, December 18, 2020).

With respect to the epidemiologic evidence, the then-Administrator noted that the studies did not indicate that associations in those studies were strongly influenced by exposures to peak concentrations in the air quality distribution and thus did not indicate the need for additional protection against short-term exposures to peak PM_{2.5} concentrations (U.S. EPA, 2020b, section 3.5.1). The then-Administrator noted that this was consistent with CASAC consensus support for retaining the current 24-hour standard. Thus, the then-Administrator concluded that the 24-hour standard with its level of 35 µg/m³ was adequate to provide supplemental protection (*i.e.*, beyond that provided by the annual standard alone) against short-term exposures to peak PM_{2.5} concentrations (85 FR 82716, December 18, 2020).

With regard to the level of the annual standard, the then-Administrator recognized that the annual standard, with its form based on the arithmetic mean concentration, was most appropriately meant to limit the “typical” daily and annual exposures that were most strongly associated with the health effects observed in epidemiologic studies. However, the then-Administrator also noted that while epidemiologic studies examined associations between distributions of PM_{2.5} air quality and health outcomes, they did not identify particular PM_{2.5} exposures that cause effects and thus, they could not alone identify a specific level at which the standard should be set, as such a determination necessarily required the then-Administrator’s judgment. Thus, consistent with the approaches in previous NAAQS reviews, the then-

Administrator recognized that any approach that used epidemiologic information in reaching decisions on what standards are appropriate necessarily required judgments about how to translate the information from the epidemiologic studies into a basis for appropriate standards. This approach included consideration of the uncertainties in the reported associations between daily or annual average PM_{2.5} exposures and mortality or morbidity in the epidemiologic studies. Such an approach is consistent with setting standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the Clean Air Act (CAA) (85 FR 82716, December 18, 2020).

The then-Administrator emphasized uncertainties and limitations that were present in epidemiologic studies in previous reviews and persisted in the 2020 review. These uncertainties included exposure measurement error, potential confounding by copollutants, increasing uncertainty of associations at lower PM_{2.5} concentrations, and heterogeneity of effects across different cities or regions (85 FR 82716, December 18, 2020). The then-Administrator also noted the advice given by the CASAC on this matter. As described in section I.C.5 above, the CASAC did not reach consensus on the adequacy of the primary annual PM_{2.5} standard. “Some CASAC members” expressed support for retaining the primary annual PM_{2.5} standard while “other members” expressed support for revising that standard in order to increase public health protection (Cox, 2019b, p. 1 of consensus letter). The CASAC members who supported retaining the annual standard expressed their concerns with the epidemiologic studies, asserting that these studies did not provide a sufficient basis for revising the existing standards. They also identified several

key concerns regarding the associations reported in epidemiologic studies and concluded that “while the data on associations should certainly be carefully considered, this data should not be interpreted more strongly than warranted based on its methodological limitations” (Cox, 2019b, p. 8 consensus responses).

Taking into consideration the views expressed by the CASAC members who supported retaining the annual standard, the then-Administrator recognized that epidemiologic studies examined associations between distributions of PM_{2.5} air quality and health outcomes, and they did not identify particular PM_{2.5} exposures that cause effects (U.S. EPA, 2020b, section 3.1.2). While the Administrator remained concerned about placing too much weight on epidemiologic studies to inform conclusions on the adequacy of the primary standards, he noted the approach to considering such studies in the 2012 review. In the 2012 review, it was noted that the evidence of an association in any epidemiologic study was “strongest at and around the long-term average where the data in the study are most concentrated” (78 FR 3140, January 15, 2013). In considering the characterization of epidemiologic studies, the then-Administrator viewed that when assessing the mean concentrations of the key short-term and long-term epidemiologic studies in the U.S. that used ground-based monitoring (*i.e.*, those studies where the mean is most directly comparable to the current annual standard), the majority of studies had mean concentrations at or above the level of the existing annual standard, with the mean of the study-reported means or medians equal to 13.5 µg/m³, a concentration level above the existing level of the primary annual standard of 12 µg/m³. The then-Administrator further noted his caution in directly

comparing the reported study mean values to the standard level given that study-reported mean concentrations, by design, are generally lower than the design value of the highest monitor in an area, which determines compliance. In the 2020 PA, analyses of recent air quality in U.S. CBSAs indicated that maximum annual PM_{2.5} design values for a given three-year period were often 10% to 20% higher than average monitored concentrations (*i.e.*, averaged across multiple monitors in the same CBSA) (U.S. EPA, 2020b, Appendix B, section B.7). He further noted his concern in placing too much weight on any one epidemiologic study but instead judged that it was more appropriate to focus on the body of studies together and therefore noted the calculation of the mean of study-reported means (or medians). Thus, while the then- Administrator was cautious in placing too much weight on the epidemiologic evidence alone, he noted that: (1) The reported mean concentration in the majority of the key U.S. epidemiologic studies using ground-based monitoring data were above the level of the existing annual standard; (2) the mean of the reported study means (or medians) (*i.e.*, 13.5 µg/m³) was above the level of the current standard;⁴⁹ (3) air quality analyses showed the study means to be lower than their corresponding design values by 10–20%; and (4) these analyses must be considered in light of uncertainties inherent in the epidemiologic evidence. When taken together, the then-Administrator judged that, even if it were appropriate to place more weight on the epidemiologic evidence, this information did

⁴⁹ The median of the study-reported mean (or median) PM_{2.5} concentrations is 13.3 µg/m³, which was also above the level of the existing standard.

not call into question the adequacy of the current standards (85 FR 82716–17, December 18, 2020).

In addition to the evidence, the then-Administrator also considered the potential implications of the risk assessment. He noted that all risk assessments have limitations and that he remained concerned about the uncertainties in the underlying epidemiologic data used in the risk assessment. The then-Administrator also noted that in previous reviews, these uncertainties and limitations have often resulted in less weight being placed on quantitative estimates of risk than on the underlying scientific evidence itself (*e.g.*, 78 FR 3086, 3098–99, January 15, 2013). These uncertainties and limitations included uncertainty in the shapes of C–R functions, particularly at low concentrations; uncertainties in the methods used to adjust air quality; and uncertainty in estimating risks for populations, locations and air quality distributions different from those examined in the underlying epidemiologic study (U.S. EPA, 2020b, section 3.3.2.4). Additionally, the then-Administrator noted similar concern expressed by some members of the CASAC who support retaining the existing standards; they highlighted similar uncertainties and limitations in the risk assessment (Cox, 2019b). In light of all of this, the then-Administrator judged it appropriate to place little weight on quantitative estimates of PM_{2.5}-associated mortality risk in reaching conclusions about the level of the primary PM_{2.5} standards (85 FR 82717, December 18, 2020).

The then-Administrator additionally considered an emerging body of evidence from accountability studies that examined past reductions in ambient PM_{2.5} and the degree to which those reductions

resulted in public health improvements. While the then-Administrator agreed with public commenters that well-designed and conducted accountability studies can be informative, he viewed the interpretation of such studies in the context of the primary PM_{2.5} standards as complicated by the fact that some of the available studies had not evaluated PM_{2.5} specifically (*e.g.*, as opposed to PM₁₀ or total suspended particulates), did not show changes in PM_{2.5} air quality, or had not been able to disentangle health impacts of the interventions from background trends in health (U.S. EPA, 2020b, section 3.5.1). He further recognized that the small number of available studies that did report public health improvements following past declines in ambient PM_{2.5} had not examined air quality meeting the existing standards (U.S. EPA, 2020b, Table 3–3). This included U.S. studies that reported increased life expectancy, decreased mortality, and decreased respiratory effects following past declines in ambient PM_{2.5} concentrations. Such studies examined “starting” annual average PM_{2.5} concentrations (*i.e.*, prior to the reductions being evaluated) ranging from about 13.2 to >20µg/m³ (*i.e.*, U.S. EPA, 2020b, Table 3–3). Given the lack of available accountability studies reporting public health improvements attributable to reductions in ambient PM_{2.5} in locations meeting the existing standards, together with his broader concerns regarding the lack of experimental studies examining PM_{2.5} exposures typical of areas meeting the existing standards, the then-Administrator judged that there was considerable uncertainty in the potential for increased public health protection from further reductions in ambient PM_{2.5} concentrations beyond those achieved under the existing primary PM_{2.5} standards (85 FR 82717, December 18, 2020).

When the above considerations were taken together, the then-Administrator concluded that the scientific evidence assessed in the 2019 ISA, together with the analyses in the 2020 PA based on that evidence and consideration of CASAC advice and public comments, did not call into question the adequacy of the public health protection provided by the existing annual and 24-hour PM_{2.5} standards. In particular, the then-Administrator judged that there was considerable uncertainty in the potential for additional public health improvements from reducing ambient PM_{2.5} concentrations below the concentrations achieved under the existing primary standards and that, therefore, standards more stringent than the existing standards (*e.g.*, with lower levels) were not supported. That is, he judged that more stringent standards would be more than requisite to protect the public health with an adequate margin of safety. This judgment reflected the Administrator's consideration of the uncertainties in the potential implications of the lower end of the air quality distributions from the epidemiologic studies due in part to the lack of supporting evidence from experimental studies and retrospective accountability studies conducted at PM_{2.5} concentrations meeting the existing standards (85 FR 82717, December 18, 2020).

In reaching this conclusion in the 2020 review, the then-Administrator judged that the existing standards provided an adequate margin of safety. With respect to the annual standard, the level of 12 µg/m³ was below the lowest "starting" concentration (*i.e.*, 13.2 µg/ m³) in the available accountability studies that showed public health improvements attributable to reductions in ambient PM_{2.5}. In addition, while the then-Administrator placed less weight on the epidemiologic evidence for selecting a standard, he noted

that the level of the annual standard was below the reported mean (and median) concentrations in the majority of the key U.S. epidemiologic studies using ground-based monitoring data (noting that these means tend to be 10–20% lower than their corresponding area design values which is the more relevant metric when considering the level of the standard) and below the mean of the reported means (or medians) of these studies (*i.e.*, 13.5 $\mu\text{g}/\text{m}^3$). In addition, the then-Administrator recognized that concentrations in areas meeting the existing 24-hour and annual standards remained well-below the $\text{PM}_{2.5}$ exposure concentrations consistently shown to elicit effects in human exposure studies (85 FR 82717–82718, December 18, 2020).

In addition, based on the then- Administrator’s review of the science in the 2020 review, including controlled human exposure studies examining effects following short-term $\text{PM}_{2.5}$ exposures, the epidemiologic studies, and accountability studies conducted at levels just above the existing annual standard, he judged that the degree of public health protection provided by the existing annual standard is not greater than warranted. This judgment, together with the fact that no CASAC member expressed support for a less stringent standard, led the then-Administrator to conclude that standards less stringent than the existing standards (*e.g.*, with higher levels) were also not supported (85 FR 82718, December 18, 2020).

In reaching his final decision in the 2020 review, the then-Administrator concluded that the scientific evidence and technical information continued to support the existing annual and 24-hour $\text{PM}_{2.5}$ standards. This conclusion reflected the then-Administrator’s

view that there were important limitations and uncertainties that remained in the evidence. The then-Administrator concluded that these limitations contributed to considerable uncertainty regarding the potential public health implications of revising the existing primary PM_{2.5} standards. Given this uncertainty, and noting the advice from some CASAC members, he concluded that the primary PM_{2.5} standards, including the indicators (PM_{2.5}), averaging times (annual and 24-hour), forms (arithmetic mean and 98th percentile, averaged over three years) and levels (12.0 µg/m³, 35 µg/m³), when taken together, remained requisite to protect the public health. Therefore, in the 2020 review, the Administrator reached the conclusion that the primary 24-hour and annual PM_{2.5} standards, together, were requisite to protect public health from fine particles with an adequate margin of safety, including the health of at-risk populations, and retained the standards, without revision (85 FR 82718, December 18, 2020).

2. Overview of the Health Effects Evidence

The information summarized here and further detailed in section II.B of the proposal (88 FR 5580, January 27, 2023), is an overview of the policy-relevant aspects of the health effects evidence available in this reconsideration; the assessment of this evidence is documented in the 2019 ISA (U.S. EPA, 2019a) and ISA Supplement (U.S. EPA, 2022a) and its policy implications are further discussed in the 2022 PA (U.S. EPA, 2022b). While the 2019 ISA provides the broad scientific foundation for this reconsideration, additional literature has become available since the cutoff date of the 2019 ISA that expands the body of evidence related to mortality and cardiovascular effects for both short- and long-term

PM_{2.5} exposure, which can inform the Administrator's judgment on the adequacy of the current primary PM_{2.5} standards. As such, the ISA Supplement builds on the information presented within the 2019 ISA with a targeted identification and evaluation of new scientific information (U.S. EPA, 2022a, section 1.2). The ISA Supplement focuses on PM_{2.5} health effects evidence where the 2019 ISA concludes a "causal relationship," because such health effects are given the most weight in an Administrator's decisions in a NAAQS review. As such, in selecting the health effects to evaluate within the ISA Supplement (*i.e.*, newly available evidence related to short- and long-term PM_{2.5} exposure and mortality and cardiovascular effects), the primary rationale is based on the causality determinations for health effect categories presented in the 2019 PM ISA, and the subsequent use of the health effects evidence in the 2020 PM PA. Specifically, U.S. and Canadian epidemiologic studies for mortality and cardiovascular effects, along with controlled human exposure studies associated with cardiovascular effects at near ambient concentrations, were considered to be of greatest utility in informing the Administrator's conclusions on the adequacy of the current primary PM_{2.5} standards. Additionally, studies examining associations outside the U.S. or Canada reflect air quality and exposure patterns that may be less typical of the U.S., and thus less likely to be informative for purposes of reviewing the NAAQS (U.S. EPA, 2022b, p.1–3). While the ISA Supplement does not include information for health effects other than mortality and cardiovascular effects, the scientific evidence for other health effect categories is evaluated in the 2019 ISA, which in combination with the ISA Supplement represents the complete

scientific record for the reconsideration of the 2020 final decision.

The ISA Supplement also assessed accountability studies because these types of epidemiologic studies were part of the body of evidence that was a focus of the 2020 review. Accountability studies inform our understanding of the potential for public health improvements as ambient PM_{2.5} concentrations have declined over time. Further, the ISA Supplement considered studies that employed statistical approaches that attempt to more extensively account for confounders and are more robust to model misspecification (*i.e.*, used alternative methods for confounder control),⁵⁰ given that such studies were highlighted by the CASAC and identified in public comments in the 2020 review. Since the literature cutoff date for the 2019 ISA, multiple accountability studies and studies that employ alternative methods for confounder control have become available for consideration in the ISA Supplement and, subsequently, in this reconsideration.

The ISA Supplement also considered recent health effects evidence that addresses key scientific issues where the literature has expanded since the

⁵⁰ As noted in the ISA Supplement (U.S. EPA, 2022a, p. 1–3): “In the peer-reviewed literature, these epidemiologic studies are often referred to as causal inference studies or studies that used causal modeling methods. For the purposes of this Supplement, this terminology is not used to prevent confusion with the main scientific conclusions (*i.e.*, the causality determinations) presented within an ISA. In addition, as is consistent with the weight- of-evidence framework used within ISAs and discussed in the Preamble to the Integrated Science Assessments, an individual study on its own cannot inform causality, but instead represents a piece of the overall body of evidence.”

completion of the 2019 ISA.⁵¹ The 2019 ISA evaluated a couple of controlled human exposure studies that investigated the effect of exposure to near-ambient concentrations of PM_{2.5} (U.S. EPA, 2019a, section 6.1.10 and 6.1.13). The ISA Supplement adds to this limited evidence, including a recent study conducted in young healthy individuals exposed to near-ambient PM_{2.5} concentrations (U.S. EPA, 2022a, section 3.3.1). Given the importance of identifying populations at increased risk of PM_{2.5}-related effects, the ISA Supplement also included epidemiologic or exposure studies that examined whether there is evidence of exposure or risk disparities by race/ ethnicity or SES. These types of studies provide additional information related to factors that may increase risk of PM_{2.5}-related health effects and provide additional evidence for consideration by the Administrator in reaching conclusions regarding the adequacy of the current standards. In addition, the ISA Supplement evaluated studies that examined the relationship between short- and long-term PM_{2.5} exposures and SARS-CoV-2 infection and/or COVID-19 death, as these studies are a new area of research and were raised by a number of public commenters in the 2020 review.

The evidence presented within the 2019 ISA, along with the targeted identification and evaluation of new scientific information in the ISA Supplement, provides the scientific basis for the reconsideration of the 2020 final decision on the primary PM_{2.5}

⁵¹ As with the epidemiologic studies for long- and short-term PM_{2.5} exposure and mortality and cardiovascular effects, epidemiologic studies of exposure or risk disparities and SARS-CoV-2 infection and/or COVID-19 death were limited to those conducted in the U.S. and Canada.

standards. The subsections below briefly summarize the nature of PM_{2.5}-related health effects (II.A.2.a), with a focus on those health effects for which the 2019 ISA concluded a “causal” or “likely to be causal” relationship, the potential public health implications and populations at risk (II.A.2.b), and PM_{2.5} concentrations in key studies reporting health effects (II.A.2.c).

a. Nature of Effects

The evidence base available in the reconsideration includes decades of research on PM_{2.5}-related health effects (U.S. EPA, 2004b; U.S. EPA, 2009a; U.S. EPA, 2019a), including the full body of evidence evaluated in the 2019 ISA (U.S. EPA, 2019a), along with the targeted evaluation of recent evidence in the ISA Supplement (U.S. EPA, 2022a). In considering the available scientific evidence, the sections below, and in more detail in section II.B.1 of the proposal (88 FR 5580, January 27, 2023), summarize the relationships between long-and short-term PM_{2.5} exposures and mortality (II.A.2.a.i), cardiovascular effects (II.A.2.a.ii), respiratory effects (II.A.2.a.iii), cancer (II.A.2.a.iv), nervous system effects (II.A.2.a.v) and other effects (II.A.2.a.vi). For these outcomes, the 2019 ISA concluded that the evidence supports either a “causal” or a “likely to be causal” relationship.⁵²

⁵² In this reconsideration of the PM NAAQS, the EPA considers the full body of health evidence, placing the greatest emphasis on the health effects for which the evidence has been judged in the 2019 ISA to demonstrate a “causal” or “likely to be causal” relationship with PM_{2.5} exposures.

i. Mortality

Long-Term PM_{2.5} Exposures

In the 2012 review, the 2009 ISA reported that the evidence was “sufficient to conclude that the relationship between long-term PM_{2.5} exposures and mortality is causal” (U.S. EPA, 2009a, p. 7–96). The strongest evidence supporting this conclusion was provided by epidemiologic studies, particularly those examining two seminal cohorts, the American Cancer Society (ACS) cohort and the Harvard Six Cities cohort. Analyses of the Harvard Six Cities cohort included evidence indicating that reductions in ambient PM_{2.5} concentrations are associated with reduced mortality risk (Laden et al., 2006) and increases in life expectancy (Pope et al., 2009). Further support was provided by other cohort studies conducted in North America and Europe that reported positive associations between long-term PM_{2.5} exposure and mortality (U.S. EPA, 2019a).

Cohort studies, which have become available since the completion of the 2009 ISA and evaluated in the 2019 ISA, continue to provide consistent evidence of positive associations between long-term PM_{2.5} exposures and mortality. These studies add support for associations with all-cause and total (non-accidental) mortality,⁵³ as well as with specific causes of mortality, including cardiovascular disease and respiratory disease (U.S. EPA, 2019a, section 11.2.2). Several of these studies conducted analyses over longer study durations and periods of follow-up than examined in the original ACS and Harvard Six Cities cohort

⁵³ The majority of these studies examined non-accidental mortality outcomes, though some Medicare studies lack cause-specific death information and, therefore, examine total mortality.

studies and continue to report positive associations between long-term exposure to PM_{2.5} and mortality (U.S. EPA, 2019a, section 11.2.2.1; Figures 11–18 and 11–19). In addition to studies focusing on the ACS and Harvard Six Cities cohorts, additional studies examining other cohorts also provide evidence of consistent, positive associations between long-term PM_{2.5} exposure and mortality across a wide range of demographic groups (*e.g.*, age, sex, occupation), spatial and temporal extents, exposure assessment metrics, and statistical techniques (U.S. EPA, 2019a, sections 11.2.2.1, 11.2.5; U.S. EPA, 2022a, Table 11–8). This includes some of the largest cohort studies conducted to date, such as analyses of the U.S. Medicare cohort that includes nearly 61 million enrollees and studies that control for a range of individual and ecological covariates, including race, age, SES, smoking status, body mass index, and annual weather variables (*e.g.*, temperature, humidity) (U.S. EPA, 2019a).

In addition to those cohort studies evaluated in the 2019 ISA, recent North American cohort studies evaluated in the ISA Supplement continue to examine the relationship between long-term PM_{2.5} exposure and mortality and report consistent, positive, and statistically significant associations. These recent studies also utilize large and demographically diverse cohorts that are generally representative of the national populations in both the U.S. and Canada. These “studies published since the 2019 ISA support and extend the evidence base that contributed to the conclusion of a *causal relationship* between long-term PM_{2.5} exposure and mortality” (U.S. EPA, 2022a, section 3.2.2.2.1, Figure 3–19, Figure 3–20).

Furthermore, studies evaluated in the 2019 ISA and the ISA Supplement that examined cause-specific mortality expand upon previous research that found consistent, positive associations between PM_{2.5} exposure and specific mortality outcomes, which include cardiovascular and respiratory mortality, as well as other mortality outcomes. For cardiovascular-related mortality, the evidence evaluated in the ISA Supplement is consistent with the evidence evaluated in the 2019 ISA with recent studies reporting positive associations with long-term PM_{2.5} exposure. When evaluating cause-specific cardiovascular mortality, recent studies reported positive associations for a number of outcomes, such as ischemic heart disease (IHD) and stroke mortality (U.S. EPA, 2022a, Figure 3–23). Moreover, recent studies also provide some initial evidence that individuals with pre-existing health conditions, such as heart failure and diabetes, are at an increased risk of PM_{2.5}-related health effects (U.S. EPA, 2022a, section 3.2.2.4) and that these individuals have a higher risk of mortality overall, which was previously only examined in studies that used stratified analyses rather than a cohort of people with an underlying health condition (U.S. EPA, 2022a, section 3.2.2.4). With regard to respiratory mortality, epidemiologic studies evaluated in the 2019 ISA and ISA Supplement continue to provide support for associations between long-term PM_{2.5} exposure and respiratory mortality (U.S. EPA, 2019a, section 5.2.10; U.S. EPA, 2022a, Table 3–2).

A series of epidemiologic studies evaluated in the 2019 ISA tested the hypothesis that past reductions in ambient PM_{2.5} concentrations are associated with increased life expectancy or a decreased mortality rate and report that reductions in ambient PM_{2.5} are associated with improvements in longevity (U.S.

EPA, 2022a, section 11.2.2.5). Pope et al. (2009) conducted a cross-sectional analysis using air quality data from 51 metropolitan areas across the U.S., beginning in the 1970s through the early 2000s, and found that a 10 $\mu\text{g}/\text{m}^3$ decrease in long-term $\text{PM}_{2.5}$ concentration was associated with a 0.61-year increase in life expectancy. In a subsequent analysis, the authors extended the period of analysis to include 2000 to 2007, a time period with lower ambient $\text{PM}_{2.5}$ concentrations and found a decrease in long-term $\text{PM}_{2.5}$ concentration continued to be associated with an increase in life expectancy, though the magnitude of the increase was smaller than during the earlier time period (*i.e.*, a 10 $\mu\text{g}/\text{m}^3$ decrease in long-term $\text{PM}_{2.5}$ concentration was associated with a 0.35-year increase in life expectancy) (Correia et al., 2013). Additional studies conducted in the U.S. or Europe similarly report that reductions in ambient $\text{PM}_{2.5}$ are associated with improvements in longevity (U.S. EPA, 2022a, section 11.2.2.5).

Since the literature cutoff date for the 2019 ISA, a few epidemiologic studies were published that examined the relationship between long-term $\text{PM}_{2.5}$ exposure and life-expectancy (U.S. EPA, 2022a, section 3.2.1.3) and report results that are consistent with and expand upon the body of evidence from the 2019 ISA. For example, Bennett et al. (2019) reported that $\text{PM}_{2.5}$ concentrations above the lowest observed concentration (2.8 $\mu\text{g}/\text{m}^3$) were associated with a 0.15 year decrease in national life expectancy for women and 0.13 year decrease in national life expectancy for men (U.S. EPA, 2022a, section 3.2.2.2.4, Figure 3–25). Another study compared participants living in areas with $\text{PM}_{2.5}$ concentrations $>12 \mu\text{g}/\text{m}^3$ to participants living in areas with $\text{PM}_{2.5}$ concentrations $<12 \mu\text{g}/\text{m}^3$ and reported that the number of years of

life lost due to living in areas with higher PM_{2.5} concentrations was 0.84 years over a 5-year period (Ward-Caviness et al., 2020; U.S. EPA, 2022a, section 3.2.2.2.4).

Additionally, a number of accountability studies, which are epidemiologic studies that evaluate whether an environmental policy or air quality intervention resulted in reductions in ambient air pollution concentrations and subsequent reductions in mortality or morbidity, have emerged and were evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.2.2.3). For example, Sanders et al. (2020a) examined whether policy actions (*i.e.*, the first annual PM_{2.5} NAAQS implementation rule in 2005 for the 1997 annual PM_{2.5} standard with a 3-year annual average of 15.0 µg/m³) reduced PM_{2.5} concentrations and mortality rates in Medicare beneficiaries between 2000–2013, and found that following implementation of the annual PM_{2.5} NAAQS, annual PM_{2.5} concentrations decreased by 1.59 µg/m³ (95% CI: 1.39, 1.80) which corresponded to a 0.93% reduction in mortality rates among individuals 65 years and older ([95% CI: 0.10%, 1.77%]) in non-attainment counties relative to attainment counties.

The 2019 ISA also evaluated a small number of studies that used alternative methods for confounder control to further assess relationship between long-term PM_{2.5} exposure and mortality (U.S. EPA, 2019a, section 11.2.2.4). In addition, multiple epidemiologic studies that implemented alternative methods for confounder control and were published since the literature cutoff date of the 2019 ISA were evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.2.2.3). These studies used a variety of statistical methods including generalized propensity score (GPS),

inverse probability weighting (IPW), and difference-in-difference (DID) to reduce uncertainties related to confounding bias in the association between long-term PM_{2.5} exposure and mortality. These studies reported consistent positive associations between long-term PM_{2.5} exposure and total mortality (U.S. EPA, 2022a, section 3.2.2.3), and provided further support for the associations reported in the cohort studies referenced above.

The 2019 ISA and ISA Supplement also evaluated the degree to which recent studies examining the relationship between long-term PM_{2.5} exposure and mortality addressed key policy-relevant issues and/or previously identified data gaps in the scientific evidence, including methods to estimate exposure, methods to control for confounding (*e.g.*, co-pollutant confounding), the shape of the C–R relationship, as well as examining whether a threshold exists below which mortality effects do not occur. With respect to exposure assessment, based on its evaluation of the evidence, the 2019 ISA concludes that positive associations between long-term PM_{2.5} exposures and mortality are robust across recent analyses using various approaches to estimate PM_{2.5} exposures (*e.g.*, based on monitors, models, satellite-based methods, or hybrid methods that combine information from multiple sources) (U.S. EPA, 2019a, section 11.2.5.1). Hart et al. (2015) report that correction for bias due to exposure measurement error increases the magnitude of the hazard ratios (confidence intervals widen but the association remains statistically significant), suggesting that failure to correct for exposure measurement error could result in attenuation or underestimation of risk estimates.

The 2019 ISA additionally concludes that positive associations between long-term PM_{2.5} exposures and mortality are robust across statistical models that use different approaches to control for confounders or different sets of confounders (U.S. EPA, 2019a, sections 11.2.3 and 11.2.5), across diverse geographic regions and populations, and across a range of temporal periods including periods of declining PM concentrations (U.S. EPA, 2019a, sections 11.2.2.5 and 11.2.5.3). Additional evidence further demonstrates that associations with mortality remain robust in copollutants analyses (U.S. EPA, 2019a, section 11.2.3), and that associations persist in analyses restricted to long-term exposures (annual average PM_{2.5} concentrations) below 12 µg/m³ (Di et al., 2017b) or 10 µg/m³ (Shi et al., 2016), indicating that risks are not disproportionately driven by the upper portions of the air quality distribution. Recent studies evaluated in the ISA Supplement further assess potential copollutant confounding and indicate that while there is some evidence of potential confounding of the PM_{2.5}-mortality association by copollutants in some of the studies (*i.e.*, those studies of the Mortality Air Pollution Associations in Low Exposure Environments (MAPLE) cohort), this result is inconsistent with other recent studies evaluated in the 2019 ISA that were conducted in the U.S. and Canada that found associations in both single and copollutant models (U.S. EPA, 2019a; U.S. EPA, 2022a, section 3.2.2.4)

Additionally, a few studies use statistical techniques to reduce uncertainties related to potential confounding to further inform conclusions on causality for long-term PM_{2.5} exposure and mortality, as further detailed in section II.B.1.a.i of the proposal (88 FR 5582, January 27, 2023), studies by Greven et

al. (2011), Pun et al. (2017), and Eum et al. (2018) completed sensitivity analyses as part of their Medicare cohort study in which they decompose ambient $\text{PM}_{2.5}$ into “spatial” and “spatiotemporal” components in order to evaluate the potential for bias due to unmeasured spatial confounding. Pun et al. (2017) observed positive associations for the “temporal” variation model and approximately null associations for the “spatiotemporal” variation model for all causes of death except for COPD mortality. The difference in the results of these two models for most causes of death suggests the presence of unmeasured confounding, though the authors do not indicate anything about the direction or magnitude of this bias. It is important to note that the “temporal” and “spatiotemporal” coefficients are not directly comparable to the results of other epidemiologic studies when examined individually and can only be used in comparison with one another to evaluate the potential for unmeasured confounding bias. Eum et al. (2018) and Wu et al. (2020) also attempted to address long-term trends and meteorological variables as potential confounders and found that not adjusting for temporal trends could overestimate the association, while effect estimates in analyses that excluded meteorological variables remained unchanged compared to the main analyses. While results of these analyses suggest the presence of some unmeasured confounding, they do not indicate the direction or magnitude of the bias.⁵⁴

⁵⁴ In public comments on the 2019 draft PA, the authors of the Pun et al. (2017) study further note that “the presence of unmeasured confounding. . . was expected given that we did not control for several potential confounders that may impact $\text{PM}_{2.5}$ -mortality associations, such as smoking, socio-economic status (SES), gaseous pollutants, $\text{PM}_{2.5}$ components, and long-term

An additional important consideration in characterizing the public health impacts associated with PM_{2.5} exposure is whether C–R relationships are linear across the range of concentrations or if nonlinear relationships exist along any part of this range. Studies evaluated in the 2019 ISA and the ISA Supplement examine this issue, and continue to provide evidence of linear, no-threshold relationships between long-term PM_{2.5} exposures and all-cause and cause-specific mortality (U.S. EPA, 2019a, section 11.2.4; U.S. EPA, 2022a, section 3.2.2.2.7, Table 3–6). Across the studies evaluated in the 2019 ISA and the ISA Supplement, a variety of statistical methods have been used to assess whether there is evidence of deviations in linearity (U.S. EPA, 2019a, Table 11–7; U.S. EPA, 2022a, section 2.2.3.2). Studies have also conducted cut-point analyses that focus on examining risk at specific ambient PM_{2.5} concentrations. Generally, the evidence remains consistent in supporting a no-threshold relationship, and in supporting a linear relationship for PM_{2.5} concentrations >8 µg/m³. However, uncertainties remain about the shape of the C–R curve at PM_{2.5} concentrations <8 µg/m³, with some recent studies providing evidence for either a sublinear, linear, or supralinear relationship at these lower concentrations (U.S. EPA, 2019a, section 11.2.4; U.S. EPA, 2022a, section 2.2.3.2). There was also some limited evidence indicating that the slope of the C–R function may be steeper (supralinear) at lower concentrations for cardiovascular mortality (U.S. EPA, 2022a, section 3.1.1.2.6).

time trends in PM_{2.5} and that “spatial confounding may bias mortality risks both towards and away from the null” (Docket ID EPA–HQ–OAR–2015–0072–0065; accessible in <https://www.regulations.gov/>).

The biological plausibility of PM_{2.5}-attributable mortality is supported by the coherence of effects across scientific disciplines (*i.e.*, animal toxicological, controlled human exposure studies, and epidemiologic) when evaluating respiratory and cardiovascular morbidity effects, which are some of the largest contributors to total (nonaccidental) mortality. The 2019 ISA outlines the available evidence for biologically plausible pathways by which inhalation exposure to PM_{2.5} could progress from initial events (*e.g.*, pulmonary inflammation, autonomic nervous system activation) to endpoints relevant to population outcomes, particularly those related to cardiovascular diseases such as ischemic heart disease, stroke and atherosclerosis (U.S. EPA, 2019a, section 6.2.1), and to metabolic effects, including diabetes (U.S. EPA, 2019a, section 7.3.1). The 2019 ISA notes “more limited evidence from respiratory morbidity” (U.S. EPA, 2019a, p. 11–101) such as development of chronic obstructive pulmonary disease (COPD) (U.S. EPA, 2019a, section 5.2.1) to support the biological plausibility of mortality due to long-term PM_{2.5} exposures (U.S. EPA, 2019a, section 11.2.1).

Taken together, epidemiologic studies, including those evaluated in the 2019 ISA and more recent studies evaluated in the ISA Supplement, consistently report positive associations between long-term PM_{2.5} exposure and mortality across different geographic locations, populations, and analytic approaches (U.S. EPA, 2019a; U.S. EPA, 2022a, section 3.2.2.4). As such, these studies reduce key uncertainties identified in previous reviews, including those related to potential copollutant confounding, and provide additional information on the shape of the C–R curve. As evaluated in the 2019 ISA, experimental and epidemiologic evidence for cardiovascular effects, and

respiratory effects to a more limited degree, supports the plausibility of mortality due to long-term PM_{2.5} exposures. Overall, studies evaluated in the 2019 ISA support the conclusion of a causal relationship between long-term PM_{2.5} exposure and mortality, which is supported and extended by evidence from recent epidemiologic studies evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.2.2.4).

Short-Term PM_{2.5} Exposures

The 2009 ISA concluded that “a causal relationship exists between short-term exposure to PM_{2.5} and mortality” (U.S. EPA, 2009a). This conclusion was based on the evaluation of both multi- and single-city epidemiologic studies that consistently reported positive associations between short-term PM_{2.5} exposure and non-accidental mortality. These associations were strongest, in terms of magnitude and precision, primarily at lags of 0 to 1 days. Examination of the potential confounding effects of gaseous copollutants was limited, though evidence from single-city studies indicated that gaseous copollutants have minimal effect on the PM_{2.5}-mortality relationship (*i.e.*, associations remain robust to inclusion of other pollutants in copollutant models). The evaluation of cause-specific mortality found that effect estimates were larger in magnitude, but also had larger confidence intervals, for respiratory mortality compared to cardiovascular mortality. Although the largest mortality risk estimates were for respiratory mortality, the interpretation of the results was complicated by the limited coherence from studies of respiratory morbidity. However, the evidence from studies of cardiovascular morbidity provided both coherence and biological plausibility for the relationship between short-term PM_{2.5} exposure and cardiovascular mortality.

Multicity studies evaluated in the 2019 ISA and the ISA Supplement provide evidence of primarily positive associations between daily PM_{2.5} exposures and mortality, with percent increases in total mortality ranging from 0.19% (Lippmann et al., 2013) to 2.80% (Kloog et al., 2013)⁵⁵ at lags of 0 to 1 days in single-pollutant models. Whereas many studies assign exposures using data from ambient monitors, other studies employ hybrid modeling approaches, which estimate PM_{2.5} concentrations using data from a variety of sources (*i.e.*, from satellites, land use information, and modeling, in addition to monitors) and enable the inclusion of less urban and more rural locations in analyses (*e.g.*, Kloog et al., 2013, Lee et al., 2015, Shi et al., 2016).

Some studies have expanded the examination of potential confounders including long-term temporal trends, weather, and co-occurring pollutants. Mortality associations were found to remain positive, although in some cases were attenuated, when using different approaches to account for temporal trends or weather covariates (*e.g.*, U.S. EPA, 2019a, section 11.1.5.1). For example, Sacks et al. (2012) examined the influence of model specification using the approaches for confounder adjustment from models employed in several multicity studies within the context of a common data set (U.S. EPA, 2019a, section 11.1.5.1). These models use different approaches to control for long-term temporal trends and the potential confounding effects of weather. The authors report that associations between daily PM_{2.5} and cardiovascular mortality were similar across models, with the

⁵⁵ As detailed in the Preface to the ISA, risk estimates are for a 10 µg/m³ increase in 24-hour avg PM_{2.5} concentrations, unless otherwise noted (U.S. EPA, 2019a).

percent increase in mortality ranging from 1.5–2.0% (U.S. EPA, 2019a, Figure 11–4). Thus, alternative approaches to controlling for long-term temporal trends and for the potential confounding effects of weather may influence the magnitude of the association between PM_{2.5} exposures and mortality but have not been found to influence the direction of the observed association (U.S. EPA, 2019a, section 11.1.5.1). Taken together, the 2019 ISA and the ISA Supplement conclude that recent multicity studies conducted in the U.S., Canada, Europe, and Asia continue to provide consistent evidence of positive associations between short-term PM_{2.5} exposures and total mortality across studies that use different approaches to control for the potential confounding effects of weather (*e.g.*, temperature) (U.S. EPA, 2019a, section 1.4.1.5.1; U.S. EPA, 2022a, section 3.2.1.2).

With regard to copollutants, studies evaluated in the 2019 ISA provide additional evidence that associations between short-term PM_{2.5} exposures and mortality remain positive and relatively unchanged in copollutant models with both gaseous pollutants and PM_{10–2.5} (U.S. EPA, 2019a, section 11.1.4). Additionally, the low ($r < 0.4$) to moderate correlations ($r = 0.4–0.7$) between PM_{2.5} and gaseous pollutants and PM_{10–2.5} increase the confidence in PM_{2.5} having an independent effect on mortality (U.S. EPA, 2019a, section 11.1.4). Consistent with the studies evaluated in the 2019 ISA, studies evaluated in the ISA Supplement that used data from more recent years also indicate that associations between short-term PM_{2.5} exposure and mortality remain unchanged in copollutant models. However, the evidence indicates that the association could be larger in magnitude in the presence of some

copollutants such as oxidant gases (Lavigne et al., 2018; Shin et al., 2021).

The generally positive associations reported with mortality are supported by a small group of studies employing alternative methods for confounder control or quasi-experimental statistical approaches (U.S. EPA, 2019a, section 11.1.2.1). For example, two studies by Schwartz et al. report associations between PM_{2.5} instrumental variables and mortality (U.S. EPA, 2019a, Table 11–2), including in an analysis limited to days with 24-hour average PM_{2.5} concentrations <30 µg/m³ (Schwartz et al., 2015; Schwartz et al., 2017). In addition to the main analyses, these studies conducted Granger-like causality tests as sensitivity analyses to examine whether there was evidence of an association between mortality and PM_{2.5} after the day of death, which would support the possibility that unmeasured confounders were not accounted for in the statistical model. Neither study reports evidence of an association with PM_{2.5} after death (*i.e.*, they do not indicate unmeasured confounding). Yorifuji et al. (2016) conducted a quasi-experimental study to examine whether a specific regulatory action in Tokyo, Japan (*i.e.*, a diesel emission control ordinance) resulted in a subsequent reduction in daily mortality (Yorifuji et al., 2016). The authors reported a reduction in mortality in Tokyo due to the ordinance, compared to Osaka, which did not have a similar diesel emission control ordinance in place. In another study, Schwartz et al. (2018) utilized three statistical methods including instrumental variable analysis, a negative exposure control, and marginal structural models to estimate the association between PM_{2.5} and daily mortality (Schwartz et al., 2018). Results from this study continue to support a relationship between short-

term PM_{2.5} exposure and mortality. Additional epidemiologic studies evaluated in the ISA Supplement that employed alternative methods for confounder control to examine the association between short-term PM_{2.5} exposure and mortality also report consistent positive associations in studies that examine effects across multiple cities in the U.S. (U.S. EPA, 2022a).

The positive associations for total mortality reported across the majority of studies evaluated are further supported by cause-specific mortality analyses, which generally report consistent, positive associations with both cardiovascular and respiratory mortality (U.S. EPA, 2019a, section 11.1.3). Recent multicity studies evaluated in the ISA Supplement add to the body of evidence indicating a relationship between short-term PM_{2.5} exposure and cause-specific mortality, with more variability in the magnitude and precision of associations for respiratory mortality (U.S. EPA, 2022a; Figure 3–14). For both cardiovascular and respiratory mortality, there has been a limited assessment of potential copollutant confounding, though initial evidence indicates that associations remain positive and relatively unchanged in models with gaseous pollutants and PM_{10–2.5}, which further supports the copollutant analyses conducted for total mortality. The strong evidence for ischemic events and heart failure, as detailed in the assessment of cardiovascular morbidity (U.S. EPA, 2019a, Chapter 6), provides biological plausibility for PM_{2.5}-related cardiovascular mortality, which comprises the largest percentage of total mortality (*i.e.*, ~33%) (NHLBI, 2017). Although there is evidence for exacerbations of COPD and asthma, the collective body of respiratory morbidity evidence provides limited biological

plausibility for PM_{2.5}-related respiratory mortality (U.S. EPA, 2019a, Chapter 5).

In the 2009 ISA, one of the main uncertainties identified was the regional and city-to-city heterogeneity in PM_{2.5}-mortality associations. Studies evaluated in the 2019 ISA examine both city-specific as well as regional characteristics to identify the underlying contextual factors that could contribute to this heterogeneity (U.S. EPA, 2019a, section 11.1.6.3). Analyses focusing on effect modification of the PM_{2.5} mortality relationship by PM_{2.5} components, regional patterns in PM_{2.5} components and city specific differences in composition and sources indicate some differences in the PM_{2.5} composition and sources across cities and regions, but these differences do not fully explain the observed heterogeneity. Additional studies find that factors related to potential exposure differences, such as housing stock and commuting, as well as city specific factors (*e.g.*, land use, port volume, and traffic information), may also explain some of the observed heterogeneity (U.S. EPA, 2019a, section 11.1.6.3). Collectively, studies evaluated in the 2019 ISA and the ISA Supplement indicate that the heterogeneity in PM_{2.5} mortality risk estimates cannot be attributed to one factor, but instead a combination of factors including, but not limited to, PM composition and sources as well as community characteristics that could influence exposures (U.S. EPA, 2019a, section 11.1.12; U.S. EPA, 2022a, section 3.2.1.2.1).

A number of studies evaluated in the 2019 ISA and ISA Supplement conducted systematic evaluations of the lag structure of associations for the PM_{2.5}-mortality relationship by examining either a series of single day or multiday lags and these studies

continue to support an immediate effect (*i.e.*, lag 0 to 1 days) of short-term PM_{2.5} exposures on mortality (U.S. EPA, 2019a, section 11.1.8.1; U.S. EPA, 2022a, section 3.2.1.1). Recent studies also conducted analyses comparing the traditional 24-hour average exposure metric with a subdaily metric (*i.e.*, 1-hour max) and provide evidence of a similar pattern of associations for both the 24-hour average and 1-hour max metric, with the association larger in magnitude for the 24-hour average metric.

Multicity studies indicate that positive and statistically significant associations with mortality persist in analyses restricted to short-term (24-hour average PM_{2.5} concentrations) PM_{2.5} exposures below 35 µg/m³ (Lee et al., 2015),⁵⁶ below 30 µg/m³ (Shi et al., 2016), and below 25 µg/m³ (Di et al., 2017a), indicating that risks associated with short-term PM_{2.5} exposures are not disproportionately driven by the peaks of the air quality distribution. Additional studies examined the shape of the C–R relationship for short-term PM_{2.5} exposure and mortality and whether a threshold exists below which mortality effects do not occur (U.S. EPA, 2019a, section 11.1.10). These studies used various statistical approaches and consistently demonstrate linear C–R relationships with no evidence of a threshold.

Moreover, recent studies evaluated in the ISA Supplement provide additional support for a linear, no-threshold C–R relationship between short-term

⁵⁶ Lee et al. (2015) restrict exposures below 35 µg/m³ only in areas with annual average concentrations <12 µg/m³. Additionally, Lee et al. (2015) also report that positive and statistically significant associations between short-term PM_{2.5} exposures and mortality persist in analyses restricted to areas with long-term concentrations below 12 µg/m³.

PM_{2.5} exposure and mortality, with confidence in the shape decreasing at concentrations below 5 µg/m³ (Shi et al., 2016; Lavigne et al., 2018). Recent analyses provide initial evidence indicating that PM_{2.5}-mortality associations persist and may be stronger (*i.e.*, a steeper slope) at lower concentrations (*e.g.*, Di et al., 2017a; Figure 11–12 in U.S. EPA, 2019). However, given the limited data available at the lower end of the distribution of ambient PM_{2.5} concentrations, the shape of the C–R curve remains uncertain at these low concentrations. Although difficulties remain in assessing the shape of the short-term PM_{2.5}-mortality C–R relationship, to date, studies have not conducted systematic evaluations of alternatives to linearity and recent studies evaluated in the ISA Supplement continue to provide evidence of a no-threshold linear relationship, with less confidence at concentrations lower than 5 µg/m³.

Overall, epidemiologic studies evaluated in the 2019 ISA and the ISA Supplement build upon and extend the conclusions of the 2009 ISA for the relationship between short-term PM_{2.5} exposures and total mortality. Supporting evidence for PM_{2.5}-related cardiovascular morbidity, and more limited evidence from respiratory morbidity, provide biological plausibility for mortality due to short-term PM_{2.5} exposures. The primarily positive associations observed across studies conducted in diverse geographic locations is further supported by the results from copollutant analyses indicating robust associations, along with evidence from analyses examining the C–R relationship. Overall, studies evaluated in the 2019 ISA support the conclusion of a causal relationship between short-term PM_{2.5} exposure and mortality, which is further supported by evidence from recent epidemiologic studies evaluated in the

ISA Supplement (U.S. EPA, 2022a, section 3.2.1.4, p. 3–69).

ii. Cardiovascular Effects Long-Term
PM_{2.5} Exposures

The scientific evidence reviewed in the 2009 ISA was “sufficient to infer a causal relationship between long-term PM_{2.5} exposure and cardiovascular effects” (U.S. EPA, 2009a). The strongest line of evidence comprised findings from several large epidemiologic studies of U.S. and Canadian cohorts that reported consistent positive associations between long-term PM_{2.5} exposure and cardiovascular mortality (Pope et al., 2004; Krewski et al., 2009; Miller et al., 2007; Laden et al., 2006). Studies of long-term PM_{2.5} exposure and cardiovascular morbidity were limited in number. Biological plausibility and coherence with the epidemiologic findings were provided by studies using genetic mouse models of atherosclerosis demonstrating enhanced atherosclerotic plaque development and inflammation, as well as changes in measures of impaired heart function, following 4- to 6-month exposures to PM_{2.5} concentrated ambient particles (CAPs), and by a limited number of studies reporting CAPs-induced effects on coagulation factors, vascular reactivity, and worsening of experimentally induced hypertension in mice (U.S. EPA, 2009a).

Consistent with the evidence assessed in the 2009 ISA, the 2019 ISA concludes that recent studies, together with the evidence available in previous reviews, support a causal relationship between long-term exposure to PM_{2.5} and cardiovascular effects. Additionally, recent epidemiologic studies published since the completion of the 2019 ISA and evaluated in the ISA Supplement expands the body of evidence and further supports such a conclusion (U.S. EPA,

2022a). As discussed above (section II.A.2.a.i), results from U.S. and Canadian cohort studies evaluated in the 2019 ISA conducted at varying spatial and temporal scales and employing a variety of exposure assessment and statistical methods consistently report positive associations between long-term $\text{PM}_{2.5}$ exposure and cardiovascular mortality (U.S. EPA, 2019, Figure 6–19, section 6.2.10). Positive associations between long-term $\text{PM}_{2.5}$ exposures and cardiovascular mortality are generally robust in copollutant models adjusted for ozone, NO_2 , $\text{PM}_{10-2.5}$, or SO_2 . In addition, most of the results from analyses examining the shape of the C–R relationship between long-term $\text{PM}_{2.5}$ exposures and cardiovascular mortality support a linear relationship and do not identify a threshold below which mortality effects do not occur (U.S. EPA, 2019a, section 6.2.16, Table 6–52).

The body of literature examining the relationship between long-term $\text{PM}_{2.5}$ exposure and cardiovascular morbidity has greatly expanded since the 2009 ISA, with positive associations reported in several cohorts evaluated in the 2019 ISA (U.S. EPA, 2019a, section 6.2). Though results for cardiovascular morbidity are less consistent than those for cardiovascular mortality (U.S. EPA, 2019a, section 6.2), studies in the 2019 ISA and the ISA Supplement provide some evidence for associations between long-term $\text{PM}_{2.5}$ exposures and the progression of cardiovascular disease. Positive associations with cardiovascular morbidity (*e.g.*, coronary heart disease, stroke, arrhythmias, myocardial infarction (MI), atherosclerosis progression) are observed in several epidemiologic studies (U.S. EPA, 2019a, sections 6.2.2 to 6.2.9; U.S. EPA, 2022a, section 3.1.2.2). Additionally, studies evaluated in the ISA Supplement report positive associations among those with pre-existing conditions, among

patients followed after a cardiac event procedure, and among those with a first hospital admission for heart attacks among older adults enrolled in Medicare (U.S. EPA, 2022a, sections 3.1.1 and 3.1.2).

Recent studies published since the literature cutoff date of the 2019 ISA and evaluated in the ISA Supplement further assessed the relationship between long-term $\text{PM}_{2.5}$ exposure and cardiovascular effects by conducting accountability analyses or by using alternative methods for confounder control in evaluating the association between long-term $\text{PM}_{2.5}$ exposure and cardiovascular hospital admissions (U.S. EPA, 2022a, section 3.1.2.3). Studies that apply alternative methods for confounder control increase confidence in the relationship between long-term $\text{PM}_{2.5}$ exposure and cardiovascular effects by using methods that reduce uncertainties related to potential confounding through statistical and/or study design approaches. For example, to control for potential confounding Wei et al. (2021) used a doubly robust additive model (DRAM) and found an association between long-term exposure to $\text{PM}_{2.5}$ and cardiovascular effects, including MI, stroke, and atrial fibrillation, among the Medicare population. For example, an accountability study by Henneman et al. (2019) utilized a difference-in-difference (DID) approach to determine the relationship between coal-fueled power plant emissions and cardiovascular effects and found that reductions in $\text{PM}_{2.5}$ concentrations resulted in reductions of cardiovascular-related hospital admissions. Furthermore, several recent epidemiologic studies evaluated in the ISA Supplement reported that the association between long-term $\text{PM}_{2.5}$ exposure with stroke persisted after adjustment for NO_2 but was attenuated in the model with O_3 and oxidant gases represented by the redox

weighted average of NO₂ and O₃ (U.S. EPA, 2022a, section 3.1.2.2.8). Overall, these studies report consistent findings that long-term PM_{2.5} exposure is related to increased hospital admissions for a variety of cardiovascular disease outcomes among large nationally representative cohorts and provide additional support for a relationship between long-term PM_{2.5} exposure and cardiovascular effects.

Positive associations reported in epidemiologic studies are supported by toxicological evidence evaluated in the 2019 ISA. The positive associations reported in epidemiologic studies are supported by toxicological evidence for increased plaque progression in mice following long-term exposure to PM_{2.5} collected from multiple locations across the U.S. (U.S. EPA, 2019a, section 6.2.4.2). A small number of epidemiologic studies also report positive associations between long-term PM_{2.5} exposure and heart failure, changes in blood pressure, and hypertension (U.S. EPA, 2019a, sections 6.2.5 and 6.2.7). Associations with heart failure are supported by animal toxicological studies demonstrating decreased cardiac contractility and function, and increased coronary artery wall thickness following long-term PM_{2.5} exposure (U.S. EPA, 2019a, section 6.2.5.2). Similarly, a limited number of animal toxicological studies demonstrating a relationship between long-term PM_{2.5} exposure and consistent increases in blood pressure in rats and mice are coherent with epidemiologic studies reporting positive associations between long-term exposure to PM_{2.5} and hypertension.

Additionally, a number of studies evaluated in the ISA Supplement focusing on morbidity outcomes, including those that focused on incidence of MI, atrial fibrillation (AF), stroke, and congestive heart failure

(CHF), expand the evidence pertaining to the shape of the C–R relationship between long-term PM_{2.5} exposure and cardiovascular effects. These studies use statistical techniques that allow for departures from linearity (U.S. EPA, 2022a, Table 3–3), and generally support the evidence characterized in the 2019 ISA showing linear, no-threshold C–R relationship for most cardiovascular disease (CVD) outcomes. However, there is evidence for a sublinear or supralinear C–R relationship for some outcomes (U.S. EPA, 2022a, section 3.1.2.2.9).⁵⁷

Longitudinal epidemiologic analyses also report positive associations with markers of systemic inflammation (U.S. EPA, 2019a, section 6.2.11), coagulation (U.S. EPA, 2019a, section 6.2.12), and endothelial dysfunction (U.S. EPA, 2019a, section 6.2.13). These results are coherent with animal toxicological studies generally reporting increased markers of systemic inflammation, oxidative stress, and endothelial dysfunction (U.S. EPA, 2019a, section 6.2.12.2 and 6.2.14).

In summary, the 2019 ISA concludes that there is consistent evidence from multiple epidemiologic studies illustrating that long-term exposure to PM_{2.5} is associated with mortality from cardiovascular causes. Epidemiologic studies evaluated in the ISA Supplement provide additional evidence of positive associations between long-term PM_{2.5} exposure and cardiovascular morbidity (U.S. EPA, 2022a, section 3.1.2.2). Associations with coronary heart disease (CHD), stroke and atherosclerosis progression were

⁵⁷ As noted above for mortality, uncertainty in the shape of the C–R relationship increases near the upper and lower ends of the distribution due to limited data.

observed in several additional epidemiologic studies, providing coherence with the mortality findings. Results from copollutant models generally support an independent effect of PM_{2.5} exposure on mortality. Additional evidence of the independent effect of PM_{2.5} on the cardiovascular system is provided by experimental studies in animals, which support the biological plausibility of pathways by which long-term exposure to PM_{2.5} could potentially result in outcomes such as CHD, stroke, CHF, and cardiovascular mortality. Overall, studies evaluated in the 2019 ISA support the conclusion of a causal relationship between long-term PM_{2.5} exposure and cardiovascular effects, which is supported and extended by evidence from recent epidemiologic studies evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.1.2.2).

Short-Term PM_{2.5} Exposures

The 2009 ISA concluded that “a causal relationship exists between short-term exposure to PM_{2.5} and cardiovascular effects” (U.S. EPA, 2009a). The strongest evidence in the 2009 ISA was from epidemiologic studies of emergency department (ED) visits and hospital admissions for IHD and heart failure (HF), with supporting evidence from epidemiologic studies of cardiovascular mortality (U.S. EPA, 2009a). Animal toxicological studies provided coherence and biological plausibility for the positive associations reported with MI, ED visits, and hospital admissions. These included studies reporting reduced myocardial blood flow during ischemia and studies indicating altered vascular reactivity. In addition, effects of PM_{2.5} exposure on a potential indicator of ischemia (*i.e.*, ST segment depression on an electrocardiogram) were reported in both animal

toxicological and epidemiologic panel studies.⁵⁸ Key uncertainties from the last review resulted from inconsistent results across disciplines with respect to the relationship between short-term exposure to PM_{2.5} and changes in blood pressure, blood coagulation markers, and markers of systemic inflammation. In addition, while the 2009 ISA identified a growing body of evidence from controlled human exposure and animal toxicological studies, uncertainties remained with respect to biological plausibility.

Studies evaluated in the 2019 ISA provide additional support for a causal relationship between short-term PM_{2.5} exposure and cardiovascular effects. This includes generally positive associations observed in multicity epidemiologic studies of emergency department visits and hospital admissions for IHD, heart failure (HF), and combined cardiovascular-related endpoints. In particular, nationwide studies of older adults (65 years and older) using Medicare records report positive associations between PM_{2.5} exposures and hospital admissions for HF (U.S. EPA, 2019a, section 6.1.3.1). Moreover, recent multicity studies, published after the literature cutoff date of the 2019 ISA and evaluated in the ISA Supplement, are consistent with studies evaluated in the 2019 ISA that report positive association between short-term PM_{2.5} exposure and ED visits and hospital admission for IHD, heart attacks, and HF (U.S. EPA, 2022a, section 3.1). Epidemiologic studies conducted in single cities contribute some support to the causality

⁵⁸ Some animal studies included in the 2009 ISA examined exposures to mixtures, such as motor vehicle exhaust or woodsmoke. In these studies, it was unclear if the resulting cardiovascular effects could be attributed specifically to the fine particle component of the mixture.

determination, though associations reported in single-city studies are less consistently positive than in multicity studies, and include a number of studies reporting null associations (U.S. EPA, 2019a, sections 6.1.2 and 6.1.3). As a whole, though, the recent body of IHD and HF epidemiologic evidence supports the evidence from previous ISAs reporting mainly positive associations between short-term $\text{PM}_{2.5}$ concentrations and emergency department visits and hospital admissions.

Consistent with the evidence assessed in the 2019 ISA, some studies evaluated in the ISA Supplement report no evidence of an association with stroke, regardless of stroke subtype. Additionally, as in the 2019 ISA, evidence evaluated in the ISA Supplement continues to indicate an immediate effect of $\text{PM}_{2.5}$ on cardiovascular-related outcomes primarily within the first few days after exposure, and that associations generally persisted in models adjusted for copollutants (U.S. EPA, 2022a, section 3.1.1.2).

The ISA Supplement includes additional epidemiologic studies, published since the literature cutoff date for the 2019 ISA, including accountability analyses and epidemiologic studies that employ alternative methods for confounder control to evaluate the association between short-term $\text{PM}_{2.5}$ exposure and cardiovascular-related effects (U.S. EPA, 2022a, section 3.1.1.3). These studies employ a number of statistical approaches and report positive associations, providing additional support for a relationship between short-term $\text{PM}_{2.5}$ exposure and cardiovascular effects, while also reducing uncertainties related to potential confounder bias.

A number of controlled human exposure, animal toxicological, and epidemiologic panel studies provide evidence that $\text{PM}_{2.5}$ exposure could plausibly result in

IHD or HF through pathways that include endothelial dysfunction, arterial thrombosis, and arrhythmia (U.S. EPA, 2019a, section 6.1.1). The most consistent evidence from recent controlled human exposure studies is for endothelial dysfunction, as measured by changes in brachial artery diameter or flow mediated dilation. Multiple controlled human exposure studies that examined the potential for endothelial dysfunction report an effect of PM_{2.5} exposure on measures of blood flow (U.S. EPA, 2019a, section 6.1.13.2). However, these studies report variable results regarding the timing of the effect and the mechanism by which reduced blood flow occurs (*i.e.*, availability vs sensitivity to nitric oxide). In addition, some controlled human exposure studies using CAPs report evidence for small increases in blood pressure (U.S. EPA, 2019a, section 6.1.6.3). Although not entirely consistent, there is also some evidence across controlled human exposure studies for conduction abnormalities/arrhythmia (U.S. EPA, 2019a, section 6.1.4.3), changes in heart rate variability (HRV) (U.S. EPA, 2019a, section 6.1.10.2), changes in hemostasis that could promote clot formation (U.S. EPA, 2019a, section 6.1.12.2), and increases in inflammatory cells and markers (U.S. EPA, 2019a, section 6.1.11.2). A recent study by Wyatt et al. (2020), evaluated in the ISA Supplement, adds to the limited evidence base of controlled human exposure studies conducted at near ambient PM_{2.5} concentrations. The study, completed in healthy young adults subject to intermittent exercise, found some significant cardiovascular effects (*e.g.*, systematic inflammation markers, including C-reactive protein (CRP), and cardiac repolarization). Thus, when taken as a whole, controlled human exposure studies are coherent with epidemiologic studies in that they demonstrate that short-term exposures to

PM_{2.5} may result in the types of cardiovascular endpoints that could lead to emergency department visits and hospital admissions for IHD or HF, as well as mortality in some people.

Animal toxicological studies published since the 2009 ISA and evaluated in the 2019 ISA also support a relationship between short-term PM_{2.5} exposure and cardiovascular effects. A study demonstrating decreased cardiac contractility and left ventricular pressure in mice is coherent with the results of epidemiologic studies that report associations between short-term PM_{2.5} exposure and heart failure (U.S. EPA, 2019a, section 6.1.3.3). In addition, and as with controlled human exposure studies, there is generally consistent evidence in animal toxicological studies for indicators of endothelial dysfunction (U.S. EPA, 2019a, section 6.1.13.3). Some studies in animals also provide evidence for changes in a number of other cardiovascular endpoints following short-term PM_{2.5} exposure including conduction abnormalities and arrhythmia (U.S. EPA, 2019a, section 6.1.4.4), changes in HRV (U.S. EPA, 2019a, section 6.1.10.3), changes in blood pressure (U.S. EPA, 2019a, section 6.1.6.4), and evidence for systemic inflammation and oxidative stress (U.S. EPA, 2019a, section 6.1.11.3).

In summary, evidence evaluated in the 2019 ISA extends the consistency and coherence of the evidence base evaluated in the 2009 ISA and prior assessments. Epidemiologic studies reporting robust associations in copollutant models are supported by direct evidence from controlled human exposure and animal toxicologic studies reporting independent effects of PM_{2.5} exposures on endothelial dysfunction as well as endpoints indicating impaired cardiac function, increased risk of arrhythmia, changes in

HRV, increases in BP, and increases in indicators of systemic inflammation, oxidative stress, and coagulation (U.S. EPA, 2019, section 6.1.16). For some cardiovascular effects, there are inconsistencies in results across some animal toxicological, controlled human exposure, and epidemiologic panel studies, though this may be due to substantial differences in study design and/or study populations. Overall, the results from epidemiologic panel, controlled human exposure, and animal toxicological studies, in particular those related to endothelial dysfunction, impaired cardiac function, ST segment depression, thrombosis, conduction abnormalities, and changes in blood pressure provide coherence and biological plausibility for the consistent results from epidemiologic studies observing positive associations between short-term PM_{2.5} exposures and IHD and HF, and ultimately cardiovascular mortality. Overall, studies evaluated in the 2019 ISA support the conclusion of a causal relationship between short-term PM_{2.5} exposure and cardiovascular effects, which is supported and extended by evidence from recent epidemiologic studies evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.1.1.4).

iii. Respiratory Effects Long-Term PM_{2.5} Exposures

The 2009 ISA concluded that “a causal relationship is likely to exist between long-term PM_{2.5} exposure and respiratory effects” (U.S. EPA, 2009a). This conclusion was based mainly on epidemiologic evidence demonstrating associations between long-term PM_{2.5} exposure and changes in lung function or lung function growth in children. Biological plausibility was provided by a single animal toxicological study examining pre- and post-natal exposure to PM_{2.5}

CAPs, which found impaired lung development. Epidemiologic evidence for associations between long-term PM_{2.5} exposure and other respiratory outcomes, such as the development of asthma, allergic disease, and COPD; respiratory infection; and the severity of disease was limited, both in the number of studies available and the consistency of the results. Experimental evidence for other outcomes was also limited, with one animal toxicological study reporting that long-term exposure to PM_{2.5} CAPs results in morphological changes in nasal airways of healthy animals. Other animal studies examined exposure to mixtures, such as motor vehicle exhaust and woodsmoke, and effects were not attributed specifically to the particulate components of the mixture.

Cohort studies evaluated in the 2019 ISA provided additional support for the relationship between long-term PM_{2.5} exposure and decrements in lung function growth (as a measure of lung development), indicating a robust and consistent association across study locations, exposure assessment methods, and time periods (U.S. EPA, 2019a, section 5.2.13). This relationship was further supported by a retrospective study that reports an association between declining PM_{2.5} concentrations and improvements in lung function growth in children (U.S. EPA, 2019a, section 5.2.11). Epidemiologic studies also examine asthma development in children (U.S. EPA, 2019a, section 5.2.3), with prospective cohort studies reporting generally positive associations, though several are imprecise (*i.e.*, they report wide confidence intervals). Supporting evidence is provided by studies reporting associations with asthma prevalence in children, with childhood wheeze, and with exhaled nitric oxide, a marker of pulmonary inflammation (U.S. EPA, 2019a, section 5.2.13). Additionally, the 2019 ISA

includes an animal toxicological study showing the development of an allergic phenotype and an increase in a marker of airway responsiveness supports the biological plausibility of the development of allergic asthma (U.S. EPA, 2019a, section 5.2.13). Other epidemiologic studies report a PM_{2.5}-related acceleration of lung function decline in adults, while improvement in lung function was observed with declining PM_{2.5} concentrations (U.S. EPA, 2019a, section 5.2.11). A longitudinal study found declining PM_{2.5} concentrations are also associated with an improvement in chronic bronchitis symptoms in children, strengthening evidence reported in the 2009 ISA for a relationship between increased chronic bronchitis symptoms and long-term PM_{2.5} exposure (U.S. EPA, 2019a, section 5.2.11). A common uncertainty across the epidemiologic evidence is the lack of examination of copollutants to assess the potential for confounding. While there is some evidence that associations remain robust in models with gaseous pollutants, a number of these studies examining copollutant confounding were conducted in Asia, and thus have limited generalizability due to high annual pollutant concentrations.

When taken together, the 2019 ISA concludes that the epidemiologic evidence strongly supports a relationship with decrements in lung function growth asthma development in children, as well as increased bronchitis symptoms in children with asthma. Additionally, the epidemiologic evidence strongly supports a relationship with an acceleration of lung function decline in adults, and with respiratory mortality and cause-specific respiratory mortality for COPD and respiratory infection (U.S. EPA, 2019a, p. 1–34). In support of the biological plausibility of associations reported in epidemiologic studies associ-

ated with respiratory health effects, animal toxicological studies evaluated in the 2019 ISA continue to provide direct evidence that long-term exposure to PM_{2.5} results in a variety of respiratory effects, including pulmonary oxidative stress, inflammation, and morphologic changes in the upper (nasal) and lower airways. Other results show that changes are consistent with the development of allergy and asthma, and with impaired lung development. Overall, the 2019 ISA concludes that “the collective evidence is sufficient to conclude that a causal relationship is likely to exist between long-term PM_{2.5} exposure and respiratory effects” (U.S. EPA, 2019a, section 5.2.13).

Short-Term PM_{2.5} Exposures

The 2009 ISA (U.S. EPA, 2009a) concluded that a “causal relationship is likely to exist” between short-term PM_{2.5} exposure and respiratory effects. This conclusion was based mainly on the epidemiologic evidence demonstrating positive associations with various respiratory effects. Specifically, the 2009 ISA described epidemiologic evidence as consistently showing PM_{2.5}-associated increases in hospital admissions and ED visits for COPD and respiratory infection among adults or people of all ages, as well as increases in respiratory mortality. These results were supported by studies reporting associations with increased respiratory symptoms and decreases in lung function in children with asthma, though the epidemiologic evidence was inconsistent for hospital admissions or emergency department visits for asthma. Studies examining copollutant models showed that PM_{2.5} associations with respiratory effects were robust to inclusion of CO or SO₂ in the model, but often were attenuated (though still positive) with

inclusion of O₃ or NO₂. In addition to the copollutant models, evidence supporting an independent effect of PM_{2.5} exposure on the respiratory system was provided by animal toxicological studies of PM_{2.5} CAPs demonstrating changes in some pulmonary function parameters, as well as inflammation, oxidative stress, injury, enhanced allergic responses, and reduced host defenses. Many of these effects have been implicated in the pathophysiology for asthma exacerbation, COPD exacerbation, or respiratory infection. In the few controlled human exposure studies conducted in individuals with asthma or COPD, PM_{2.5} exposure mostly had no effect on respiratory symptoms, lung function, or pulmonary inflammation. Available studies in healthy people also did not clearly demonstrate respiratory effects following short-term PM_{2.5} exposures.

Epidemiologic studies evaluated in the 2019 ISA continue to provide strong evidence for a relationship between short-term PM_{2.5} exposure and several respiratory-related endpoints, including asthma exacerbation (U.S. EPA, 2019a, section 5.1.2.1), COPD exacerbation (U.S. EPA, 2019a, section 5.1.4.1), and combined respiratory-related diseases (U.S. EPA, 2019a, section 5.1.6), particularly from studies examining ED visits and hospital admissions. The generally positive associations between short-term PM_{2.5} exposure and asthma and COPD as well as ED visits and hospital admissions are supported by epidemiologic studies demonstrating associations with other respiratory-related effects such as symptoms and medication use that are indicative of asthma and COPD exacerbations (U.S. EPA, 2019a, sections 5.1.2.2 and 5.4.1.2). The collective body of epidemiologic evidence for asthma exacerbation is more consistent in children than in adults.

Additionally, epidemiologic studies examining the relationship between short-term PM_{2.5} exposure and respiratory mortality provide evidence of consistent positive associations, demonstrating a continuum of effects (U.S. EPA, 2019a, section 5.1.9).

Epidemiologic studies evaluated in the 2019 ISA expand the assessment of potential copollutant confounding evaluated in the 2009 ISA. There is some evidence that PM_{2.5} associations with asthma exacerbation, combined respiratory-related diseases, and respiratory mortality remain relatively unchanged in copollutant models with gaseous pollutants including O₃, NO₂, SO₂, and with more limited evidence for CO, as well as other particle sizes (*i.e.*, PM_{10-2.5}) (U.S. EPA, 2019a, section 5.1.10.1).

Insight into whether there is an independent effect of PM_{2.5} on respiratory health is also partially addressed by findings from animal toxicological studies evaluated in the 2019 ISA. Specifically, short-term exposure to PM_{2.5} enhanced asthma-related responses in an animal model of allergic airways disease and enhanced lung injury and inflammation in an animal model of COPD (U.S. EPA, 2019a, sections 5.1.2.4.4 and 5.1.4.4.3). The experimental evidence provides biological plausibility for some respiratory-related endpoints, including limited evidence of altered host defense and greater susceptibility to bacterial infection as well as consistent evidence of respiratory irritant effects. However, animal toxicological evidence for other respiratory effects is inconsistent. A recent study evaluated in the ISA supplement by Wyatt et al. (2020) and conducted at near ambient PM_{2.5} concentrations, adds to the limited evidence base of controlled human exposure studies. The study, completed in healthy

young adults subject to intermittent exercise, found some significant respiratory effects (including decrease in lung function), however these findings were inconsistent with the controlled human exposure studies evaluated in the 2019 ISA (U.S. EPA, 2019a, section 5.1.7.2, 5.1.2.3, and 6.1.11.2.1).

The 2019 ISA concludes that “[t]he strongest evidence of an effect of short-term PM_{2.5} exposure on respiratory effects is provided by epidemiologic studies of asthma and COPD exacerbation. While animal toxicological studies provide biological plausibility for these findings, some uncertainty remains with respect to the independence of PM_{2.5} effects” (U.S. EPA, 2019a, p. 5–155). When taken together, the 2019 ISA concludes that this evidence “is sufficient to conclude that a causal relationship is likely to exist between short-term PM_{2.5} exposure and respiratory effects” (U.S. EPA, 2019a, p. 5–155).

iv. Cancer

The 2009 ISA concluded that the overall body of evidence was “suggestive of a causal relationship between relevant PM_{2.5} exposures and cancer” (U.S. EPA, 2009a). This conclusion was based primarily on positive associations observed in a limited number of epidemiologic studies of lung cancer mortality. The few epidemiologic studies that had evaluated PM_{2.5} exposure and lung cancer incidence or cancers of other organs and systems generally did not show evidence of an association. Toxicological studies did not focus on exposures to specific PM size fractions, but rather investigated the effects of exposures to total ambient PM, or other source-based PM such as wood smoke. Collectively, results of in vitro studies were consistent with the larger body of evidence demonstrating that ambient PM and PM from

specific combustion sources are mutagenic and genotoxic. However, animal inhalation studies found little evidence of tumor formation in response to chronic exposures. A small number of studies provided preliminary evidence that PM exposure can lead to changes in methylation of DNA, which may contribute to biological events related to cancer.

Since the completion of the 2009 ISA, additional cohort studies provide evidence that long-term PM_{2.5} exposure is positively associated with lung cancer mortality and with lung cancer incidence, and provide initial evidence for an association with reduced cancer survival (U.S. EPA, 2019a, section 10.2.5). Re-analyses of the ACS cohort using different years of PM_{2.5} data and follow up, along with various exposure assignment approaches, provide consistent evidence of positive associations between long-term PM_{2.5} exposure and lung cancer mortality (U.S. EPA, 2019a, Figure 10–3). Additional support for positive associations with lung cancer mortality is provided by recent epidemiologic studies using individual level data to control for smoking status, as well as by studies of people who have never smoked (though such studies generally report wide confidence intervals due to the small number of lung cancer mortality cases within this population), and in additional analyses of cohorts that relied upon proxy measures to account for smoking status (U.S. EPA, 2019a, section 10.2.5.1.1). Although studies that evaluate lung cancer incidence, including studies of people who have never smoked, are limited in number, studies in the 2019 ISA generally report positive associations with long-term PM_{2.5} exposures (U.S. EPA, 2019a, section 10.2.5.1.2). A subset of the studies focusing on lung cancer incidence also examined histological subtype, providing some

evidence of positive associations for adenocarcinomas, the predominate subtype of lung cancer observed in people who have never smoked (U.S. EPA, 2019a, section 10.2.5.1.2). Associations between long-term PM_{2.5} exposure and lung cancer incidence were found to remain relatively unchanged, though in some cases confidence intervals widened, in analyses that attempted to reduce exposure measurement error by accounting for length of time at residential address or by examining different exposure assignment approaches (U.S. EPA, 2019a, section 10.2.5.1.2).

To date, relatively few studies have evaluated the potential for copollutant confounding of the relationship between long-term PM_{2.5} exposure and lung cancer mortality or incidence. A small number of such studies have generally focused on O₃ and report that PM_{2.5} associations remain relatively unchanged in copollutant models (U.S. EPA, 2019a, section 10.2.5.1.3). However, available studies have not systematically evaluated the potential for copollutant confounding by other gaseous pollutants or by other particle size fractions (U.S. EPA, 2019a, section 10.2.5.1.3).

Compared to total (non-accidental) mortality (U.S. EPA, 2019a, section 10.2.4.1.4), fewer studies have examined the shape of the C–R curve for cause-specific mortality outcomes, including lung cancer. Several studies of lung cancer mortality and incidence have reported no evidence of deviations from linearity in the shape of the C–R relationship (Lepeule et al., 2012; Raaschou-Nielsen et al., 2013; Puett et al., 2014), though authors provided only limited discussions of results (U.S. EPA, 2019a, section 10.2.5.1.4).

In support of the biological plausibility of an independent effect of PM_{2.5} on lung cancer, the 2019 ISA notes evidence from experimental and epidemiologic studies demonstrating that PM_{2.5} exposure can lead to a range of effects indicative of mutagenicity, genotoxicity, and carcinogenicity, as well as epigenetic effects (U.S. EPA, 2019a, section 10.2.7). For example, both in vitro and in vivo toxicological studies have shown that PM_{2.5} exposure can result in DNA damage (U.S. EPA, 2019a, section 10.2.2). Although such effects do not necessarily equate to carcinogenicity, the evidence that PM exposure can damage DNA, and elicit mutations, provides support for the plausibility of epidemiologic associations exhibited with lung cancer mortality and incidence. Additional supporting studies indicate the occurrence of micronuclei formation and chromosomal abnormalities (U.S. EPA, 2019a, section 10.2.2.3), and differential expression of genes that may be relevant to cancer pathogenesis, following PM_{2.5} exposures. Experimental and epidemiologic studies that examine epigenetic effects indicate changes in DNA methylation, providing some support that PM_{2.5} exposure contributes to genomic instability (U.S. EPA, 2019a, section 10.2.3). Overall, there is limited evidence that long-term PM_{2.5} exposure is associated with cancers in other organ systems, though there is some evidence that PM_{2.5} exposure may reduce survival in individuals with cancer (U.S. EPA, 2019a, section 10.2.7; U.S. EPA, 2022a, section 2.1.1.4.1).

Epidemiologic evidence for associations between PM_{2.5} and lung cancer mortality and incidence, together with evidence supporting the biological plausibility of such associations, contributes to the 2019 ISA's conclusion that the evidence "is sufficient to conclude that a causal relationship is likely to exist

between long-term PM_{2.5} exposure and cancer” (U.S. EPA, 2019, section 10.2.7).

v. Nervous System Effects

Reflecting the very limited evidence available in the 2012 review, the 2009 ISA did not make a causality determination for long-term PM_{2.5} exposures and nervous system effects (U.S. EPA, 2009c). Since the 2012 review, this body of evidence has grown substantially (U.S. EPA, 2019, section 8.2). Animal toxicological studies assessed in the 2019 ISA report that long-term PM_{2.5} exposures can lead to morphologic changes in the hippocampus and to impaired learning and memory. This evidence is consistent with epidemiologic studies reporting that long-term PM_{2.5} exposure is associated with reduced cognitive function (U.S. EPA, 2019a, section 8.2.5). Further, while the evidence is limited, the presence of early markers of Alzheimer’s disease pathology has been demonstrated in rodents following long-term exposure to PM_{2.5} CAPs. These findings support reported associations with neurodegenerative changes in the brain (*i.e.*, decreased brain volume), all-cause dementia, or hospitalization for Alzheimer’s disease in a small number of epidemiologic studies (U.S. EPA, 2019a, section 8.2.6). Additionally, loss of dopaminergic neurons in the substantia nigra, a hallmark of Parkinson disease, has been reported in mice (U.S. EPA, 2019a, section 8.2.4), though epidemiologic studies provide only limited support for associations with Parkinson’s disease (U.S. EPA, 2019a, section 8.2.6). Overall, the lack of consideration of copollutant confounding introduces some uncertainty in the interpretation of epidemiologic studies of nervous system effects, but this uncertainty is partly addressed by the evidence for an independent effect

of PM_{2.5} exposures provided by experimental animal studies.

While the findings described above are most relevant to older adults, several studies of neurodevelopmental effects in children have also been conducted. Epidemiologic studies provided limited evidence of an association between PM_{2.5} exposure during pregnancy and childhood on cognitive and motor development (U.S. EPA, 2019, section 8.2.5.2). While some studies report positive associations between long-term exposure to PM_{2.5} during the prenatal period and autism spectrum disorder (ASD) (U.S. EPA, 2019, section 8.2.7.2), the interpretation of these epidemiologic studies is limited due to the small number of studies, their lack of control for potential confounding by copollutants, and uncertainty related to the critical exposure windows. Biological plausibility is provided for the ASD findings by a study in mice that found inflammatory and morphologic changes in the corpus collosum and hippocampus, as well as ventriculomegaly (*i.e.*, enlarged lateral ventricles) in young mice following prenatal exposure to PM_{2.5} CAPs.

Taken together, the 2019 ISA concludes that studies indicate long-term PM_{2.5} exposures can lead to effects on the brain associated with neurodegeneration (*i.e.*, neuroinflammation and reductions in brain volume), as well as cognitive effects in older adults (U.S. EPA, 2019a, Table 1–2). Animal toxicological studies provide evidence for a range of nervous system effects in adult animals, including neuroinflammation and oxidative stress, neurodegeneration, cognitive effects, and effects on neurodevelopment in young animals. The epidemiologic evidence is more limited, but studies generally

support associations between long-term PM_{2.5} exposure and changes in brain morphology, cognitive decrements and dementia. There is also initial, and limited, evidence for neurodevelopmental effects, particularly ASD. The consistency and coherence of the evidence supports the 2019 ISA's conclusion that "the collective evidence is sufficient to conclude that a causal relationship is likely to exist between long-term PM_{2.5} exposure and nervous system effects" (U.S. EPA, 2019a, section 8.2.9).

vi. Other Effects

For other health effect categories that were evaluated for their relationship with PM_{2.5} exposures (*i.e.*, short-term PM_{2.5} exposure and nervous system effects and short- and long-term PM_{2.5} exposure and metabolic effects, reproduction and fertility, and pregnancy and birth outcomes (U.S. EPA, 2022a, Table ES-1), the currently available evidence is "suggestive of, but not sufficient to infer, a causal relationship," mainly due to inconsistent evidence across specific outcomes and uncertainties regarding exposure measurement error, the potential for confounding, and potential modes of action (U.S. EPA, 2019a, sections 7.14, 7.2.10, 8.1.6, and 9.1.5). The causality determination for short-term PM_{2.5} exposure and nervous system effects in the 2019 ISA reflects a revision to the causality determination in the 2009 ISA from "inadequate to infer a causal relationship," while this is the first-time assessments of causality were conducted for long-term PM_{2.5} exposure and nervous system effects, as well as short- and long-term PM_{2.5} exposure and metabolic effects reflect.

Recent studies evaluated in the 2019 ISA also further explored the relationship between short-and

long- term UFP exposure and health effects. (*i.e.*, cardiovascular effects and short- term UFP exposures; respiratory effects and short-term UFP exposures; and nervous system effects and long- and short-term exposures (U.S. EPA, 2022a, Table ES–1). The currently available evidence is “suggestive of, but not sufficient to infer, a causal relationship” for short-term UFP exposure and cardiovascular and respiratory effects and for short- and long-term UFP exposure and nervous system effects, primarily due to uncertainties and limitations in the evidence, specifically, variability across studies in the definition of UFPs and the exposure metric used (U.S. EPA, 2019a, P.3.1; U.S. EPA, 2022a, section 3.3.1.6.3). The causality determinations for the other health effect categories evaluated in the 2019 ISA are “inadequate to infer a causal relationship.” Additionally, this is the first time assessments of causality were conducted for short- and long-term UFP exposure and metabolic effects and long-term UFP exposure and nervous system effects (U.S. EPA, 2022a, Table ES–1).

With the advent of the global COVID–19 pandemic, a number of recent studies evaluated in the ISA Supplement examined the relationship between ambient air pollution, specifically PM_{2.5}, and SARS–CoV–2 infections and COVID–19 deaths, including a few studies within the U.S. and Canada (U.S. EPA, 2022a, section 3.3.2).⁵⁹ Some studies examined

⁵⁹ While there is no exact corollary within the 2019 ISA for these types of studies, the 2019 ISA presented evidence that evaluates the potential relationship between short- and long-term PM_{2.5} exposure and respiratory infection (U.S. EPA, 2022a, section 5.1.5 and 5.2.6). Studies assessed in the 2019 ISA report some evidence of positive associations between short-term PM_{2.5} and hospital admissions and ED visits for respiratory infections,

whether daily changes in $\text{PM}_{2.5}$ can influence SARS-CoV-2 infection and COVID-19 death (U.S. EPA, 2022a, section 3.3.2.1). Additionally, several studies evaluated whether long-term $\text{PM}_{2.5}$ exposure increases the risk of SARS-CoV-2 infection and COVID-19 death in North America (U.S. EPA, 2022a, section 3.3.2.2). While there is initial evidence of positive associations with SARS-CoV-2 infection and COVID-19 death, uncertainties remain due to methodological issues that may influence the results, including: (1) The use of ecological study design; (2) studies were conducted during the ongoing pandemic when the etiology of COVID-19 was still not well understood (*e.g.*, specifically, there are important differences in COVID-19-related outcomes by a variety of factors such as race and SES); and (3) studies did not account for crucial factors that could influence results (*e.g.*, stay-at-home orders, social distancing, use of masks, and testing capacity) (U.S. EPA, 2022a, chapter 5). Taken together, while there is initial evidence of positive associations with SARS-CoV-2 infection and COVID-19 death, uncertainties remain due to methodological issues.

however the interpretation of these studies is complicated by the variability in the type of respiratory infection outcome examined (U.S. EPA, 2022a, Figure 5–7). In the 2019 ISA, studies of long-term $\text{PM}_{2.5}$ exposure were limited and while there were some positive associations reported, there was minimal overlap in respiratory infection outcomes examined across studies. Exposure to $\text{PM}_{2.5}$ has been shown to impair host defense, specifically altering macrophage function, providing a biological pathway by which $\text{PM}_{2.5}$ exposure could lead to respiratory infection (U.S. EPA, 2022a, sections 5.1.1 and 5.1.5.) There is some additional evidence that $\text{PM}_{2.5}$ exposure can lead to decreases in an individual's immune response, which can subsequently facilitate replication of respiratory viruses (Bourdrel et al., 2021).

b. Public Health Implications and At-Risk Populations

The public health implications of the evidence regarding PM_{2.5}-related health effects, as for other effects, are dependent on the type and severity of the effects, as well as the size of the population affected. Such factors are discussed below in the context of our consideration of the health effects evidence related to PM_{2.5} in ambient air. This section also summarizes the current information on population groups at increased risk of the effects of PM_{2.5} in ambient air.

The information available in this reconsideration has not altered our understanding of human populations at risk of health effects from PM_{2.5} exposures. As recognized in the 2020 review, the 2019 ISA cites extensive evidence indicating that “both the general population as well as specific populations and lifestages are at risk for PM_{2.5}-related health effects” (U.S. EPA, 2019a, p. 12–1). Factors that may contribute to increased risk of PM_{2.5}-related health effects include lifestage (children and older adults), pre-existing diseases (cardiovascular disease and respiratory disease), race/ethnicity, and SES.⁶⁰

Children make up a substantial fraction of the U.S. population, and often have unique factors that contribute to their increased risk of experiencing a health effect due to exposures to ambient air pollutants because of their continuous growth and

⁶⁰ As described in the 2019 ISA, other factors that have the potential to contribute to increased risk include obesity, diabetes, genetic factors, smoking status, sex, diet, and residential location (U.S. EPA, 2019, chapter 12).

development.⁶¹ Children may be particularly at risk for health effects related to ambient PM_{2.5} exposures compared with adults because they have (1) a developing respiratory system, (2) increased ventilation rates relative to body mass compared with adults, and (3) an increased proportion of oral breathing, particularly in boys, relative to adults (U.S. EPA, 2019a, section 12.5.1.1). There is strong evidence that demonstrates PM_{2.5} associated health effects in children, particularly from epidemiologic studies of long-term PM_{2.5} exposure and impaired lung function growth, decrements in lung function, and asthma development. However, there is limited evidence from stratified analyses that children are at increased risk of PM_{2.5}-related health effects compared to adults. Additionally, there is some evidence that indicates that children receive higher PM_{2.5} exposures than adults, and dosimetric differences in children compared to adults can contribute to higher doses (U.S. EPA, 2019a, section 12.5.1.1).

In the U.S., older adults, often defined as adults 65 years of age and older, represent an increasing portion of the population and often have pre-existing diseases or conditions that may compromise biological function. While there is limited evidence to indicate that older adults have higher exposures than younger adults, older adults may receive higher doses of PM_{2.5} due to dosimetric differences. There is consistent evidence from studies of older adults demonstrating generally consistent positive associations in studies examining health effects from short- and long-term PM_{2.5} exposure and cardiovascular or respiratory hospital admissions, emergency

⁶¹ Children, as used throughout this document, generally refers to those younger than 18 years old.

department visits, or mortality (U.S. EPA, 2019a, sections 6.1, 6.2, 11.1, 11.2, 12.5.1.2). Additionally, several animal toxicological, controlled human exposure, and epidemiologic studies did not stratify results by lifestage, but instead focused the analyses on older individuals, and can provide coherence and biological plausibility for the occurrence among this lifestage (U.S. EPA, 2019a, section 12.5.1.2).

Individuals with pre-existing disease may be considered at greater risk of an air pollution-related health effect than those without disease because they are likely in a compromised biological state that can vary depending on the disease and severity. With regard to cardiovascular disease, we first note that cardiovascular disease is the leading cause of death in the U.S., accounting for one in four deaths, and approximately 12% of the adult population in the U.S. has a cardiovascular disease (U.S. EPA, 2019a, section 12.3.1). Strong evidence demonstrates that there is a causal relationship between cardiovascular effects and long- and short-term exposures to PM_{2.5}. Some of the evidence supporting this conclusion is from studies of panels or cohorts with pre-existing cardiovascular disease, which provide supporting evidence but do not directly demonstrate an increased risk (U.S. EPA, 2019a, section 12.3.1). Epidemiologic evidence indicates that individuals with pre-existing cardiovascular disease may be at increased risk for PM_{2.5}-associated health effects compared to those without pre-existing cardiovascular disease. While the evidence does not consistently support increased risk for all pre-existing cardiovascular diseases, there is evidence that certain pre-existing cardiovascular diseases (*e.g.*, hypertension) may be a factor that increases PM_{2.5}-related risk. Furthermore, there is strong evidence supporting a

causal relationship for long- and short-term PM_{2.5} exposure and cardiovascular effects, particularly for IHD (U.S. EPA, 2019a, chapter 6, section 12.3.1).

With regard to respiratory disease, we first note that the most chronic respiratory diseases in the U.S. are asthma and COPD. Asthma affects a substantial fraction of the U.S. population and is the leading chronic disease among children. COPD primarily affects older adults and contributes to compromised respiratory function and underlying pulmonary inflammation. The body of evidence indicates that individuals with pre-existing respiratory diseases, particularly asthma and COPD, may be at increased risk for PM_{2.5}-related health effects compared to those without pre-existing respiratory diseases (U.S. EPA, 2019a, section 12.3.5). There is strong evidence indicating PM_{2.5}-associated respiratory effects among those with asthma, which forms the primary evidence base for the likely to be causal relationship between short-term exposures to PM_{2.5} and respiratory health effects (U.S. EPA, 2019a, section 12.3.5). For asthma, epidemiologic evidence demonstrates associations between short-term PM_{2.5} exposures and respiratory effects, particularly evidence for asthma exacerbation, and controlled human exposure and animal toxicological studies demonstrate support for the biological plausibility for asthma exacerbation with PM_{2.5} exposures (U.S. EPA, 2019a, section 12.3.5.1). For COPD, epidemiologic studies report positive associations between short-term PM_{2.5} exposures and hospital admissions and emergency department visits for COPD, with supporting evidence from panel studies demonstrating COPD exacerbation. Epidemiologic evidence is supported by some experimental evidence of COPD-related effects, which provides support for the biological plausibility for COPD in

response to PM_{2.5} exposures (U.S. EPA, 2019a, section 12.3.5.2).

There is strong evidence for racial and ethnic disparities in PM_{2.5} exposures and PM_{2.5}-related health risk, as assessed in the 2019 ISA and with even more evidence available since the literature cutoff date for the 2019 ISA and evaluated in the ISA Supplement. There is strong evidence demonstrating that Black and Hispanic populations, in particular, have higher PM_{2.5} exposures than non-Hispanic White populations (U.S. EPA, 2019a, Figure 12–2; U.S. EPA, 2022a, Figure 3–38). Black populations or individuals that live in predominantly Black neighborhoods experience higher PM_{2.5} exposures, in comparison to non-Hispanic White populations. There is also consistent evidence across multiple studies that demonstrate increased risk of PM_{2.5}-related health effects, with the strongest evidence for health risk disparities for mortality (U.S. EPA, 2019a, section 12.5.4). There is also evidence of health risk disparities for both Hispanic and non-Hispanic Black populations compared to non-Hispanic White populations for cause-specific mortality and incident hypertension (U.S. EPA, 2022a, section 3.3.3.2).

Socioeconomic status (SES) is a composite measure that includes metrics such as income, occupation, or education, and can play a role in access to healthy environments as well as access to healthcare. SES may be a factor that contributes to differential risk from PM_{2.5}-related health effects. Studies assessed in the 2019 ISA and ISA Supplement provide evidence that lower SES communities are exposed to higher concentrations of PM_{2.5} compared to higher SES communities (U.S. EPA, 2019a, section 12.5.3; U.S.

EPA, 2022a, section 3.3.3.1.1). Studies using composite measures of neighborhood SES consistently demonstrated a disparity in both PM_{2.5} exposure and the risk of PM_{2.5}-related health outcomes. There is some evidence that supports associations larger in magnitude between mortality and long-term PM_{2.5} exposures for those with low income or living in lower income areas compared to those with higher income or living in higher income neighborhoods (U.S. EPA, 2019a, section 12.5.3; U.S. EPA, 2022a, section 3.3.3.1.1). Additionally, evidence supports conclusions that lower SES is associated with cause-specific mortality and certain health endpoints (*i.e.*, HI and CHF), but less so for all-cause or total (non-accidental) mortality (U.S. EPA, 2022a, section 3.3.3.1).

The magnitude and characterization of a public health impact is dependent upon the size and characteristics of the populations affected, as well as the type or severity of the effects. As summarized above, lifestage (children and older adults), race/ethnicity and SES are factors that increase the risk of PM_{2.5}-related health effects. The American Community Survey (ACS) for 2019 estimates that approximately 22% and 16% of the U.S. population are children (age<18) and older adults (age 65+), respectively. For all ages, non-Hispanic Black and Hispanic populations comprise approximately 12% and 18% of the overall U.S. population in 2019. Currently available information that helps to characterize key features of these population is included in the 2022 PA (U.S. EPA, 2022b, Table 3–2).

As noted above, individuals with pre-existing cardiovascular disease and pre-existing respiratory disease may also be at increased risk of PM_{2.5}-related health effects. Currently available information that

helps to characterize key features of populations with cardiovascular or respiratory diseases or conditions is included in the 2022 PA (U.S. EPA, 2022b, Table 3–3). The National Center for Health Statistics data for 2018 indicate that, for adult populations, older adults (*e.g.*, those 65 years and older) have a higher prevalence of cardiovascular diseases compared to younger adults (*e.g.*, those 64 years and younger). For respiratory diseases, older adults also have a higher prevalence of emphysema than younger adults, and adults 44 years or older have a higher prevalence of chronic bronchitis. However, the prevalence for asthma is generally similar across all adult age groups.

With respect to race, American Indians or Alaskan Native populations have the highest prevalence of all heart disease and coronary heart disease, while Black populations have the highest prevalence of hypertension and stroke. Hypertension has the highest prevalence across all racial groups compared to other cardiovascular diseases or conditions, ranging from approximately 22% to 32% of each racial group. Overall, the prevalence of cardiovascular diseases or conditions is lowest for Asians compared to Whites, Blacks, and American Indians or Alaskan Natives. Asthma prevalence is highest among Black and American Indian or Alaska Native populations, while the prevalence of chronic bronchitis and emphysema is generally similar across racial groups. Overall, the prevalence of respiratory diseases is lowest for Asians compared to Whites, Blacks, and American Indians or Alaskan Natives. With regard to ethnicity, cardiovascular and respiratory disease prevalence across all diseases or conditions is generally similar between Hispanic and non-Hispanic populations, although non-Hispanics have a slightly higher prevalence compared to Hispanics.

Taken together, this information indicates that the groups at increased risk of PM_{2.5}-related health effects represent a substantial portion of the total U.S. population. In evaluating the primary PM_{2.5} standards, an important consideration is the potential PM_{2.5}-related public health impacts in these populations.

c. PM_{2.5} Concentrations in Key Studies Reporting Health Effects

To inform conclusions on the adequacy of the public health protection provided by the current primary PM_{2.5} standards, the sections below summarize the 2022 PA's evaluation of the PM_{2.5} exposures, specifically the concentrations that have been examined in controlled human exposure studies, animal toxicological studies, and epidemiologic studies. The 2022 PA places the greatest emphasis on the health outcomes for which the 2019 ISA concludes that the evidence supports a "causal" or a "likely to be causal" relationship with short- or long-term PM_{2.5} exposures (U.S. EPA, 2022b, section 3.3.3). As described in greater detail in section II.A.2 above, this includes short- or long-term PM_{2.5} exposures and mortality, cardiovascular effects, and respiratory effects and long-term PM_{2.5} exposures and cancer and nervous system effects. While the causality determinations in the 2019 ISA are informed by studies evaluating a wide range of PM_{2.5} concentrations,⁶² the sections

⁶² As described in more detail in section 5 of the Preamble to the ISAs, judgments regarding causality take into consideration a number of aspects when evaluating the available scientific evidence (U.S. EPA, 2015, Table I). In reaching conclusions regarding causality, "evidence is evaluated for major outcome categories or groups of related endpoints (*e.g.*, respiratory effects, vegetation growth), integrating evidence from across

below summarize the considerations in the 2022 PA regarding the degree to which the evidence assessed in the 2019 ISA and ISA Supplement supports the occurrence of PM-related health effects at concentrations relevant to informing conclusions on the primary PM_{2.5} standards. In so doing, the 2022 PA focuses on the available studies that are most directly informative to reaching conclusions regarding the adequacy of the current primary PM_{2.5} standards (*e.g.*, epidemiologic studies with annual mean PM_{2.5} concentrations near or below the level of the standard; and controlled human exposure studies at PM_{2.5} exposures that elicit consistent effects, as well

disciplines, and evaluating the coherence of evidence across a spectrum of related endpoints” (U.S. EPA, 2015, p. 24). Furthermore, “[i]n drawing judgments regarding causality for the criteria air pollutants, the ISA focuses on evidence of effects in the range of relevant pollutant exposures or doses and not on determination of causality at any dose. Emphasis is placed on evidence of effects at doses (*e.g.*, blood Pb concentration) or exposures (*e.g.*, air concentrations) that are relevant to, or somewhat above, those currently experienced by the population. The extent to which studies of higher concentrations are considered varies by pollutant and major outcome category, but generally includes those with doses or exposures in the range of one to two orders of magnitude above current or ambient conditions to account for intra-species variability and toxicokinetic or toxicodynamic differences between experimental animals and humans. Studies that use higher doses or exposures may also be considered to the extent that they provide useful information to inform understanding of mode of action, inter-species differences, or factors that may increase risk of effects for a population and if biological mechanisms have not been demonstrated to differ based on exposure concentration. Thus, a causality determination is based on weight-of-evidence evaluation for health or welfare effects, focusing on the evidence from exposures or doses generally ranging from recent ambient concentrations to one or two orders of magnitude above recent ambient concentrations” (U.S. EPA, 2015, p. 24).

as examining PM_{2.5} exposures at concentrations that are at or near the level of the standard).

i. PM_{2.5} Exposure Concentrations
Evaluated in Experimental Studies

Evidence for a particular PM_{2.5}-related health outcome is strengthened when results from experimental studies demonstrate biologically plausible mechanisms through which adverse human health outcomes could occur (U.S. EPA, 2015, p. 20). Two types of experimental studies are of particular importance in understanding the effects of PM exposures: controlled human exposure and animal toxicological studies. In such studies, investigators expose human volunteers or laboratory animals, respectively, to known concentrations of air pollutants under carefully regulated environmental conditions and activity levels. Thus, controlled human exposure and animal toxicological studies can provide information on the health effects of experimentally administered pollutant exposures under highly controlled laboratory conditions (U.S. EPA, 2015, p. 11).

Controlled human exposure studies have reported that PM_{2.5} exposures lasting from less than one hour up to five hours can impact cardiovascular function,⁶³ and the most consistent evidence from these studies is for impaired vascular function (U.S. EPA, 2019a, section 6.1.13.2). In addition, although less consistent, the 2019 ISA notes that studies examining PM_{2.5}

⁶³ In contrast, controlled human exposure studies provide little evidence for respiratory effects following short-term PM_{2.5} exposures (U.S. EPA, 2019a, section 5.1, Table 5–18). Therefore, this section focuses on cardiovascular effects evaluated in controlled human exposure studies of PM_{2.5} exposure.

exposures also provide evidence for increased blood pressure (U.S. EPA, 2019a, section 6.1.6.3), conduction abnormalities/arrhythmia (U.S. EPA, 2019a, section 6.1.4.3), changes in heart rate variability (U.S. EPA, 2019a, section 6.1.10.2), changes in hemostasis that could promote clot formation (U.S. EPA, 2019a, section 6.1.12.2), and increases in inflammatory cells and markers (U.S. EPA, 2019a, section 6.1.11.2). The 2019 ISA concludes that, when taken as a whole, controlled human exposure studies demonstrate that short-term exposure to PM_{2.5} may impact cardiovascular function in ways that could lead to more serious outcomes (U.S. EPA, 2019a, section 6.1.16). Thus, such studies can provide insight into the potential for specific PM_{2.5} exposures to result in physiological changes that could increase the risk of more serious effects. Table 3–4 in the 2022 PA summarizes information from the 2019 ISA and 2022 ISA supplement on available controlled human exposure studies that evaluate effects on markers of cardiovascular function following exposure to PM_{2.5} (U.S. EPA, 2022b). Most of the controlled human exposure studies in Table 3–4 of the 2022 PA have evaluated average PM_{2.5} concentrations at or above about 100 µg/m³, with exposure durations typically up to about two hours. Statistically significant effects on one or more indicators of cardiovascular function are often, though not always, reported following 2-hour exposures to average PM_{2.5} concentrations at and above about 120 µg/m³, with less consistent evidence for effects following exposures to concentrations lower than 120 µg/m³. Impaired vascular function, the effect identified in the 2019 ISA as the most consistent across studies (U.S. EPA, 2019a, section 6.1.13.2) is shown following 2-hour exposures to PM_{2.5} concentrations at and above 149 µg/m³.

Mixed results are reported in the studies that evaluated longer exposure durations (*i.e.*, longer than 2 hours) and lower (*i.e.*, near-ambient) PM_{2.5} concentrations (U.S. EPA, 2022b, section 3.3.3.1). For example, significant effects for some outcomes were reported following 5-hour exposures to 24 µg/m³ in Hemmingsen et al. (2015b), but not for other outcomes following 5-hour exposures to 24 µg/m³ in Hemmingsen et al. (2015a) and not following 24-hour exposures to 10.5 µg/m³ in Bräuner et al. (2008). Additionally, Wyatt et al. (2020) found significant effects for some cardiovascular (*e.g.*, systematic inflammation markers, cardiac repolarization, and decreased pulmonary function) effects following 4-hour exposures to 37.8 µg/m³ in healthy young participants (18–35 years, n=21) who were subject to intermittent moderate exercise. The higher ventilation rate and longer exposure duration in this study compared to most controlled human exposure studies is roughly equivalent to a 2-hour exposure of 75–100 µg/m³ of PM_{2.5}. Therefore, dosimetric considerations may explain the observed changes in inflammation in young healthy individuals. Though this study provides evidence of some effects at lower PM_{2.5} concentrations, overall, there is inconsistent evidence for inflammation in other controlled human exposure studies evaluated in the 2019 ISA (U.S. EPA, 2019a, sections 5.1.7., 5.1.2.3.3, and 6.1.11.2.1; U.S. EPA, 2022a, section 3.3.1).

While controlled human exposure studies are important in establishing biological plausibility, it is unclear how the results from these studies alone and the importance of the effects observed in these studies, should be interpreted with respect to adversity to public health. More specifically, impaired vascular function can signal an intermediate effect along the potential biological pathways for cardiovas-

cular effects following short-term exposure to PM_{2.5} and show a role for exposure to PM_{2.5} leading to potential worsening of IHD and heart failure followed potentially by ED visits, hospital admissions, or mortality (U.S. EPA, 2019a, section 6.1 and Figure 6–1). However, just observing the occurrence of impaired vascular function alone does not clearly suggest an adverse health outcome. Additionally, associated judgments regarding adversity or health significance of measurable physiological responses to air pollutants have been informed by guidance, criteria or interpretative statements developed within the public health community, including the American Thoracic Society (ATS) and the European Respiratory Society (ERS), which cooperatively updated the ATS 2000 statement *What Constitutes an Adverse Health Effect of Air Pollution* (ATS, 2000) with new scientific findings, including the evidence related to air pollution and the cardiovascular system (Thurston et al., 2017).⁶⁴ With regard to vascular function, the

⁶⁴ The ATS/ERS described its 2017 statement as one “intended to provide guidance to policymakers, clinicians and public health professionals, as well as others who interpret the scientific evidence on the health effects of air pollution for risk management purposes” and further notes that “considerations as to what constitutes an adverse health effect, in order to provide guidance to researchers and policymakers when new health effects markers or health outcome associations might be reported in future.” The most recent policy statement by the ATS, which once again broadens its discussion of effects, responses and biomarkers to reflect the expansion of scientific research in these areas, reiterates that concept, conveying that it does not offer “strict rules or numerical criteria, but rather proposes considerations to be weighed in setting boundaries between adverse and nonadverse health effects,” providing a general framework for interpreting evidence that proposes a “set of considerations that can be applied in forming judgments” for this context (Thurston et al., 2017).

ATS/ ERS statement considers the adversity of both chronic and acute reductions in endothelial function. While the ATS/ ERS statement concluded that chronic endothelial and vascular dysfunction can be judged to be a biomarker of an adverse health effect from air pollution, they also conclude that “the health relevance of acute reductions in endothelial function induced by air pollution is less certain” (Thurston et al., 2017). This is particularly informative to our consideration of the controlled human exposure studies which are short-term in nature (*i.e.*, generally ranging from 2- to 5-hours), including those studies that are conducted at near-ambient PM_{2.5} concentrations.

The 2022 PA also notes that it is important to recognize that controlled human exposure studies include a small number of individuals compared to epidemiologic studies. Additionally, these studies tend to include generally healthy adult individuals, who are at a lower risk of experiencing health effects. These studies, therefore, often do not include children, older adults, or individuals with pre-existing conditions. As such, these studies are somewhat limited in their ability to inform at what concentrations effects may be elicited in at-risk populations.

Nonetheless, to provide some insight into what these controlled human exposure studies may indicate regarding short-term exposure to peak PM_{2.5} concentrations and how concentrations relate to ambient PM_{2.5} concentrations, analyses in the 2022 PA (U.S. EPA, 2022b, Figure 2–19) examine monitored 2-hour PM_{2.5} concentrations (the exposure window most often utilized in the controlled human exposure studies) at sites meeting the current primary PM_{2.5} standards to evaluate the degree to which 2-hour ambient PM_{2.5} concentrations at such locations are

likely to exceed the 2-hour exposure concentrations in the controlled human exposure studies at which statistically significant effects are reported in multiple studies for one or more indicators of cardiovascular function. At sites meeting the current primary PM_{2.5} standards, most 2-hour concentrations are below 10 µg/m³, and almost never exceed 30 µg/m³. The extreme upper end of the distribution of 2-hour PM_{2.5} concentrations is shifted higher during the warmer months (April to September), generally corresponding to the period of peak wildfire frequency in the U.S. At sites meeting the current primary PM_{2.5} standards, the highest 2-hour concentrations measured tend to occur during the period of peak wildfire frequency (*i.e.*, 99.9th percentile of 2-hour concentrations is 62 µg/m³ during the warm season considered as a whole). Most of the sites measuring these very high concentrations are in the northwestern U.S. and California (U.S. EPA, 2022b, Appendix A, Figure A-1), where wildfires have been relatively common in recent years. When the typical fire season is excluded from the analysis, the extreme upper end of the distribution is reduced (*i.e.*, 99.9th percentile of 2-hour concentrations is 55 µg/m³).⁶⁵ Given these results, the 2022 PA concludes that PM_{2.5} exposure concentrations evaluated in most of these controlled human exposure studies are well-above the 2-hour ambient PM_{2.5} concentrations typically measured in locations meeting the current primary standards.

With respect to animal toxicological studies, the 2019 ISA relies on animal toxicological studies to support the plausibility of a wide range of PM_{2.5}-

⁶⁵ Similar analyses of 4-hour and 5-hour PM_{2.5} concentrations are presented in Appendix A, Figure A-2 and Figure A-3, respectively of the 2022 PA (U.S. EPA, 2022b).

related health effects. While animal toxicological studies often examine more severe health outcomes and longer exposure durations than controlled human exposure studies, there is uncertainty in extrapolating the effects seen in animals, and the PM_{2.5} exposures and doses that cause those effects, to human populations. The 2022 PA considers these uncertainties when evaluating what the available animal toxicological studies may indicate with regard to the current primary PM_{2.5} standards.

As with controlled human exposure studies, most animal toxicological studies evaluated in the 2019 ISA have examined effects following exposure to PM_{2.5} well above the concentrations likely to be allowed by the current PM_{2.5} standards. Such studies have generally examined short-term exposures to PM_{2.5} concentrations ranging from 100 to >1,000 µg/m³ and long-term exposures to concentrations from 66 to >400 µg/m³ (*e.g.*, see U.S. EPA, 2019a, Table 1–2). Two exceptions are animal toxicological studies reporting impaired lung development following long-term exposures (*i.e.*, 24 hours per day for several months prenatally and postnatally) to an average PM_{2.5} concentration of 16.8 µg/m³ (Mauad et al., 2008) and increased carcinogenic potential following long-term exposures (*i.e.*, 2 months) to an average PM_{2.5} concentration of 17.7 µg/m³ (Cangerana Pereira et al., 2011). These two studies report serious effects following long-term exposures to PM_{2.5} concentrations similar to the ambient concentrations reported in some PM_{2.5} epidemiologic studies (U.S. EPA, 2019a, Table 1–2), though still above the ambient concentrations likely to occur in areas meeting the current primary PM_{2.5} standards. However, noting uncertainty in extrapolating the effects seen in animals, and the PM_{2.5} exposures and doses that cause those effects to

human populations, animal toxicological studies are of limited utility in informing decisions on the public health protection provided by the current or alternative primary $\text{PM}_{2.5}$ standards. Therefore, the animal toxicological studies are most useful in providing further evidence to support the biological mechanisms and plausibility of various adverse effects.

ii. Ambient $\text{PM}_{2.5}$ Concentrations in
Locations of Epidemiologic Studies

As summarized in section II.A.2.a above, epidemiologic studies examining associations between daily or annual average $\text{PM}_{2.5}$ exposures and mortality or morbidity represent a large part of the evidence base supporting several of the 2019 ISA's "causal" and "likely to be causal" determinations. The 2022 PA considers the ambient $\text{PM}_{2.5}$ concentrations present in areas where epidemiologic studies have evaluated associations with mortality or morbidity, and what such concentrations may indicate regarding the adequacy of the primary $\text{PM}_{2.5}$ standards. The use of information from epidemiologic studies to inform conclusions on the primary $\text{PM}_{2.5}$ standards is complicated by the fact that such studies evaluate associations between distributions of ambient $\text{PM}_{2.5}$ and health outcomes, and do not identify the specific exposures that can lead to the reported effects. Rather, health effects can occur over the entire distribution of ambient $\text{PM}_{2.5}$ concentrations evaluated, and epidemiologic studies conducted to date do not identify a population-level threshold below which it can be concluded with confidence that $\text{PM}_{2.5}$ -associated health effects do not occur. Therefore, the 2022 PA evaluates the $\text{PM}_{2.5}$ air quality distributions over which epidemiologic studies support health effect associations (U.S. EPA, 2022b, section 3.3.3.2).

In the absence of discernible thresholds, the 2022 PA considers the study-reported ambient PM_{2.5} concentrations reflecting estimated exposure with a focus around the middle portion of the PM_{2.5} air quality distribution, where the bulk of the observed data reside and which provides the strongest support for reported health effect associations. The section below, as well as in more detail in section II.B.3.b.i of the proposal (88 FR 5594, January 27, 2023), describes the consideration of the key epidemiologic studies and observations from these studies, as evaluated in the 2022 PA (U.S. EPA, 2022b, section 3.3.3.2).

As an initial matter, in considering the PM_{2.5} air quality distributions associated with mortality or morbidity in the key epidemiologic studies, the 2022 PA recognizes that in previous reviews, the decision framework used to judge adequacy of the existing PM_{2.5} standards, and what levels of any potential alternative standards should be considered, placed significant weight on epidemiologic studies that assessed associations between PM_{2.5} exposure and health outcomes that were most strongly supported by the body of scientific evidence. In doing so, the decision framework recognized that while there is no specific point in the air quality distribution of any epidemiologic study that represents a “bright line” at and above which effects have been observed and below which effects have not been observed, there is significantly greater confidence in the magnitude and significance of observed associations for the part of the air quality distribution corresponding to where the bulk of the health events in each study have been observed, generally at or around the mean concentration. This is the case both for studies of daily PM_{2.5} exposures and for studies of annual average PM_{2.5} exposures (U.S. EPA, 2022b, section 3.3.3.2.1).

As discussed further in the 2022 PA, studies of daily PM_{2.5} exposures examine associations between day-to-day variation in PM_{2.5} concentrations and health outcomes, often over several years (U.S. EPA, 2022b, section 3.3.3.2.1). While there can be considerable variability in daily exposures over a multi-year study period, most of the estimated exposures reflect days with ambient PM_{2.5} concentrations around the middle of the air quality distributions examined (*i.e.*, “typical” days rather than days with extremely high or extremely low concentrations). Similarly, for studies of annual PM_{2.5} exposures, most of the health events occur at estimated exposures that reflect annual average PM_{2.5} concentrations around the middle of the air quality distributions examined. In both cases, epidemiologic studies provide the strongest support for reported health effect associations for this middle portion of the PM_{2.5} air quality distribution, which corresponds to the bulk of the underlying data, rather than the extreme upper or lower ends of the distribution. Consistent with this, as noted in the 2022 PA (U.S. EPA, 2022b, section 3.3.1.1), several epidemiologic studies report that associations persist in analyses that exclude the upper portions of the distributions of estimated PM_{2.5} exposures, indicating that “peak” PM_{2.5} exposures are not disproportionately responsible for reported health effect associations.

Thus, in considering PM_{2.5} air quality data from epidemiologic studies, consistent with approaches in the 2012 and 2020 reviews (78 FR 3161, January 15, 2013; U.S. EPA, 2011, sections 2.1.3 and 2.3.4.1; 85 FR 82716–82717, December 18, 2020; U.S. EPA, 2020b, sections 3.1.2 and 3.2.3), the 2022 PA evaluates study-reported means (or medians) of daily and annual average PM_{2.5} concentrations as indicators for the middle portions of the air quality distribu-

tions, over which studies generally provide strong support for reported associations and for which confidence in the magnitude and significance of associations observed in the epidemiologic studies is greatest (78 FR 3101, January 15, 2013). In addition to the overall study means, the 2022 PA also focuses on concentrations somewhat below the means (*e.g.*, 25th and 10th percentiles), when such information is available from the epidemiologic studies, which again is consistent with approaches used in previous reviews. In so doing, the 2022 PA notes, as in previous reviews, that a relatively small portion of the health events are observed in the lower part of the air quality distribution and confidence in the magnitude and significance of the associations begins to decrease in the lower part of the air quality distribution. Furthermore, consistent with past reviews, there is no single percentile value within a given air quality distribution that is most appropriate or “correct” to use to characterize where our confidence in associations becomes appreciably lower. However, and as detailed further in the 2022 PA, the range from the 25th to 10th percentiles is a reasonable range to consider as a region where there is appreciably less confidence in the associations observed in epidemiologic studies compared to the means (U.S. EPA, 2022b, p. 3–69).⁶⁶

In evaluating the overall study-reported means, and concentrations somewhat below the means from

⁶⁶ As detailed in the 2011 PA, we note the interrelatedness of the distributional statistics and a range of one standard deviation around the mean which represents approximately 68% of normally distributed data, and in that one standard deviation below the mean falls between the 25th and 10th percentiles (U.S. EPA, 2011, p. 2–71; U.S. EPA, 2005, p. 5–22).

epidemiologic studies, the 2022 PA focuses on the form, averaging time and level of the current primary annual $\text{PM}_{2.5}$ standard. Consistent with the approaches used in the 2012 and 2020 reviews (78 FR 3161–3162, January 15, 2013; 85 FR 82716–82717, December 18, 2020), the annual standard has been utilized as the primary means of providing public health protection against the bulk of the distribution of short- and long-term $\text{PM}_{2.5}$ exposures. Thus, the evaluation of the study-reported mean concentrations from key epidemiologic studies lends itself best to evaluating the adequacy of the annual $\text{PM}_{2.5}$ standard (rather than the 24-hour standard with its 98th percentile form). This is true for the study-reported means from both long-term and short-term exposure epidemiologic studies, recognizing that the overall mean $\text{PM}_{2.5}$ concentrations reported in studies of short-term (24-hour) exposures reflect averages across the study population and over the years of the study. Thus, mean concentrations from short-term exposure studies reflect long-term averages of 24-hour $\text{PM}_{2.5}$ exposure estimates. In this manner, the examination of study-reported means in key epidemiologic studies in the 2022 PA aims to evaluate the protection provided by the annual $\text{PM}_{2.5}$ standard against the exposures where confidence is greatest for associations with mortality and morbidity. In addition, the protection provided by the annual standard is evaluated in conjunction with that provided by the 24-hour standard, with its 98th percentile form, which aims to provide supplemental protection against the short-term exposures to peak $\text{PM}_{2.5}$ concentrations that can occur in areas with strong contributions from local or seasonal sources, even when overall ambient mean $\text{PM}_{2.5}$ concentrations in an area remain relatively low.

In focusing on the annual standard, and in evaluating the range of study-reported exposure concentrations for which the strongest support for adverse health effects exists, the 2022 PA examines exposure concentrations in key epidemiologic studies to determine whether the current primary annual PM_{2.5} standard provides adequate protection against these exposure concentrations. This means, as in past reviews, application of a decision framework based on assessing means reported in key epidemiologic studies must also consider how the study means were computed and how these values compare to the annual standard metric (including the level, averaging time and form) and the use of the monitor with the highest PM_{2.5} design value in an area for compliance. In the 2012 review, it was recognized that the key epidemiologic studies computed the study mean using an average across monitor-based PM_{2.5} concentrations. As such, the Agency noted that this decision framework applied an approach of using maximum monitor concentrations to determine compliance with the standard, while selecting the standard level based on consideration of composite monitor concentrations. Further, the Agency included analyses (Hassett-Sipple et al., 2010; Frank, 2012) that examined the differences in these two metrics (*i.e.*, maximum monitor concentrations and composite monitor concentrations) across the U.S. and in areas included in the key epidemiologic studies and found that the maximum design value in an area was generally higher than the monitor average across that area, with the difference varying based on location and concentration. This information was taken into account in the Administrator's final decision in selecting a level for the primary annual PM_{2.5} standard the 2012 review and discussed more

specifically in her considerations on adequate margin of safety.

Consistent with the approach taken in 2012, in assessing how the overall mean (or median) $\text{PM}_{2.5}$ concentrations reported in key epidemiologic studies can inform conclusions on the primary annual $\text{PM}_{2.5}$ standard, the 2022 PA notes that the relationship between mean $\text{PM}_{2.5}$ concentrations and the area design value continues to be an important consideration in evaluating the adequacy of the current or potential alternative annual $\text{PM}_{2.5}$ standard levels in this reconsideration. In a given area, the area design value is based on the monitor in an area with the highest $\text{PM}_{2.5}$ concentrations and is used to determine compliance with the standard. The highest $\text{PM}_{2.5}$ concentrations spatially distributed in the area would generally occur at or near the area design value monitor and the distribution of $\text{PM}_{2.5}$ concentrations would generally be lower in other locations and at monitors in that area. As such, when an area is meeting a specific annual standard level, the annual average exposures in that area are expected to be at concentrations lower than that level and the average of the annual average exposures across that area are expected (*i.e.*, a metric similar to the study-reported mean values) to be lower than that level.⁶⁷

⁶⁷ In setting a standard level that would require the design value monitor to meet a level equal to the study-reported mean $\text{PM}_{2.5}$ concentrations would generally result in lower concentrations of $\text{PM}_{2.5}$ across the entire area, such that even those people living near an area design value monitor (where PM concentrations are generally highest) will be exposed to $\text{PM}_{2.5}$ concentrations below the air quality conditions reported in the epidemiologic studies.

Another important consideration is that there are a substantial number of different types of epidemiologic studies available since the 2012 review, included in both the 2019 ISA and the ISA Supplement, that make understanding the relationship between the mean $\text{PM}_{2.5}$ concentrations and the area design value even more important (U.S. EPA, 2019a; U.S. EPA, 2022a). While the key epidemiologic studies in the 2012 review were all monitor-based studies, the newer studies include hybrid modeling approaches, which have emerged in the epidemiologic literature as an alternative to approaches that only use ground-based monitors to estimate exposure. As assessed in the 2019 ISA and ISA Supplement, a substantial number of epidemiologic studies used hybrid model-based methods in evaluating associations between $\text{PM}_{2.5}$ exposure and health effects (U.S. EPA, 2019a; U.S. EPA, 2022a). Hybrid model-based studies employ various fusion techniques that combine ground-based monitored data with air quality modeled estimates and/ or information from satellites to estimate $\text{PM}_{2.5}$ exposures.⁶⁸ Additionally, hybrid modeling approaches tend to broaden the areas captured in the exposure assessment, and in so doing, tend to report lower mean $\text{PM}_{2.5}$ concentrations than monitor-based approaches because they include more suburban and rural areas where concentrations are lower. While these studies provide a broader estimation of $\text{PM}_{2.5}$ exposures compared to monitor-based studies (*i.e.*, $\text{PM}_{2.5}$ concentrations are estimated in areas without monitors), the hybrid modeling approaches result in study-reported means that are more difficult

⁶⁸ More detailed information about hybrid model methods and performance is described in section 2.3.3.2 of the 2022 PA (U.S. EPA, 2022b).

to relate to the annual standard metric and to the use of maximum monitor design values to assess compliance. In addition, and to further complicate the comparison, when looking across these studies, variations exist in how exposure is estimated between such studies, which in turn affects how the study means are calculated. Two important variations across studies include: (1) Variability in spatial scale used (*i.e.*, averages computed across the nation (or large portions of the country) versus a focus on only CBSAs) and (2) variability in exposure assignment methods (*i.e.*, averaging across all grid cells [non-population weighting], averaging across a scaled-up area like a ZIP code [aspects of population weighting applied], and/or applying population weighting). To elaborate further on the variability in exposure assignment methods, studies that use hybrid modeling approaches can estimate $PM_{2.5}$ concentrations at different spatial resolutions, including at 1 km x 1 km grid cells, at 12 km x 12 km grid cells, or at the census tract level. Mean reported $PM_{2.5}$ concentrations can then be estimated either by averaging up to a larger spatial resolution that corresponds to the spatial resolution for which health data exists (*e.g.*, ZIP code level) and therefore apply aspects of population weighting. These values are then averaged across all study locations at the larger spatial resolution (*e.g.*, averaged across all ZIP codes in the study) over the study period, resulting in the study-reported mean 24-hour average or average annual $PM_{2.5}$ concentration. Other studies that use hybrid modeling methods to estimate $PM_{2.5}$ concentrations may use each grid cell to calculate the study-reported mean 24-hour average or average annual $PM_{2.5}$ concentration. As such, these types of studies do not apply population weighting in their mean

concentrations. In studies that use each grid cell to report a mean $\text{PM}_{2.5}$ concentration and do not apply aspects of population weighting, the study mean may not reflect the exposure concentrations used in the epidemiologic study to assess the reported association. The impact of the differences in methods is an important consideration when comparing mean concentrations across studies (U.S. EPA, 2022b, section 3.3.3.2.1). Thus, the 2022 PA also considers the methods used to estimate $\text{PM}_{2.5}$ concentrations, which vary from traditional methods using monitoring data from ground-based monitors⁶⁹ to those using more complex hybrid modeling approaches and how these methods calculate the study-reported mean $\text{PM}_{2.5}$ concentration.⁷⁰

Given the emergence of the hybrid model-based epidemiologic studies since the 2012 review, the 2022 PA explores the relationship between the approaches used in these studies to estimate $\text{PM}_{2.5}$ concentrations and the impact that the different methods have on the study-reported mean $\text{PM}_{2.5}$ concentrations. The 2022 PA further seeks to understand how the

⁶⁹ In those studies that use ground-based monitors alone to estimate long- or short-term $\text{PM}_{2.5}$ concentrations, approaches include: (1) $\text{PM}_{2.5}$ concentrations from a single monitor within a city/ county; (2) average of $\text{PM}_{2.5}$ concentrations across all monitors within a city/county or other defined study area (*e.g.*, CBSA); or (3) population-weighted averages of exposures. Once the study location average $\text{PM}_{2.5}$ concentration is calculated, the study-reported long-term average is derived by averaging daily/annual $\text{PM}_{2.5}$ concentrations across all study locations over the entire study period.

⁷⁰ Detailed information on the methods by which mean $\text{PM}_{2.5}$ concentrations are calculated in key monitor- and hybrid model-based U.S. and Canadian epidemiologic studies are presented in Tables 3–6 through 3–9 in the 2022 PA (U.S. EPA, 2022b).

approaches and resulting mean concentrations compare across studies, as well as what the resulting mean values represent relative to the annual standard. In so doing, the 2022 PA presents analyses that compare the area annual design values, composite monitor $\text{PM}_{2.5}$ concentrations, and mean concentrations from two hybrid modeling approaches, including evaluation of the means when population weighting is applied and when population weighting is not applied (U.S. EPA, 2022b, section 2.3.3.1).

In the air quality analyses comparing composite monitored $\text{PM}_{2.5}$ concentrations with annual $\text{PM}_{2.5}$ design values in U.S. CBSAs, maximum annual $\text{PM}_{2.5}$ design values were approximately 10% to 20% higher than annual average composite monitor concentrations (*i.e.*, averaged across multiple monitors in the same CBSA) (sections I.D.5.a above and U.S. EPA, 2022b, section 2.3.3.1, Figure 2–28 and Table 2–3). The difference between the maximum annual design value and average concentration in an area can be smaller or larger than this range (10–20%), depending on a variety of factors such as the number of monitors, monitor siting characteristics, the distribution of ambient $\text{PM}_{2.5}$ concentrations, and how the average concentrations are calculated (*i.e.*, averaged across monitors versus across modeled grid cells). Results of this analysis suggest that there will be a distribution of concentrations across an area and the maximum annual average monitored concentration in an area (at the design value monitor, used for compliance with the standard), will generally be 10–20% higher than the average $\text{PM}_{2.5}$ concentration across the other monitors in the area. Thus, in considering how the annual standard levels would relate to the study-reported means from key monitor-based epidemiologic studies, the 2022 PA generally

concludes that an annual standard level that is no more than 10–20% higher than monitor-based study-reported mean $\text{PM}_{2.5}$ concentrations would generally maintain air quality exposures to be below those associated with the study-reported mean $\text{PM}_{2.5}$ concentrations, exposures for which the strongest support for adverse health effects occurring is available.

The 2022 PA also evaluates data from two hybrid modeling approaches (DI2019 and HA2020) that have been used in several recent epidemiologic studies (U.S. EPA, 2022b, section 2.3.3.2.4).⁷¹ The analysis shows that the means differ when $\text{PM}_{2.5}$ concentrations are estimated in urban areas only (CBSAs) versus when the averages were calculated with all or most grid cells nationwide, likely because areas included outside of CBSAs tend to be more rural and have lower estimated $\text{PM}_{2.5}$ concentrations. The 2022 PA recognizes the importance of this variability in the means since the study areas included in the calculation of the mean, and more specifically whether a study is focused on nationwide, regional, or urban areas, will affect the calculation of the study mean based on how many rural areas, with lower estimated $\text{PM}_{2.5}$ concentrations, are included in the study area. While the determination of what spatial scale to use to estimate $\text{PM}_{2.5}$ concentrations does not inherently affect the quality of the epidemiologic study, the spatial scale can influence the calculated reported long-term mean concentration across the study area and period. The results of the analysis show that, regardless of the hybrid modeling approach assessed, the annual average $\text{PM}_{2.5}$ concentrations in

⁷¹ More details on the evaluation of the two hybrid modeling approaches is provided in section 2.3.3.2.4 of the 2022 PA (U.S. EPA, 2022b).

CBSA-only analyses are 4–8% higher than for nationwide analyses, likely as a result of higher PM_{2.5} concentrations in more densely populated areas, and exclusion of more rural areas (U.S. EPA, 2022b, Table 2–4). When evaluating comparisons between surfaces that estimate exposure using aspects of population weighting versus surfaces that do not calculate means using population weighting, surfaces that calculate long-term mean PM_{2.5} concentrations with population-weighted averages have higher average annual PM_{2.5} concentrations, compared to annual PM_{2.5} concentrations in analyses that do not apply population weighting.⁷² Analyses show that average maximum annual design values are 40 to 50% higher when compared to annual average PM_{2.5} concentrations estimated without population weighting versus 15% to 18% higher when compared to average annual PM_{2.5} concentrations estimated with population weighting applied (similar to the differences observed for the composite monitor comparison values for the monitor-based epidemiologic studies) (U.S. EPA, 2022b, section 2.3.3.2.4). Given these results, it is worth noting that for the studies using the hybrid modeling approaches, the choice of methodology employed in calculating the study-reported means (*i.e.*, using population weighting or not), and not a difference in estimates of exposure in the study itself, can produce substantially different study-reported mean values, where approaches that do not apply population weighting leading to much lower estimated mean PM_{2.5} concentrations.

⁷² The annual PM_{2.5} concentrations for the population-weighted averages ranged from 8.2–10.2 µg/m³, while those that do not apply population weighting ranged from 7.0–8.6 µg/m³. Average maximum annual design values ranged from 9.5 to 11.7 µg/m³.

Based on these results, and similar to conclusions for the monitor-based studies, the 2022 PA generally concludes that study-reported mean concentrations in the studies that employ hybrid modeling approaches and calculate a population-weighted mean are associated with air quality conditions that would be achieved by meeting annual standard levels that are 15–18% higher than study-reported means. Therefore, an annual standard level that is no more than 15–18% higher than the study-reported means would generally maintain air quality exposures to be below those associated with the study-reported mean PM_{2.5} concentrations, exposures for which we have the strongest support for adverse health effects occurring. For the studies that utilize hybrid modeling approaches but do not incorporate population weighting in calculating the mean, the annual design values associated with these air quality conditions are expected to be much higher (*i.e.*, 40–50% higher) and this larger difference makes it more difficult to consider how these studies can be used to determine the adequacy of the protection afforded by the current or potential alternative annual standards. Additionally, as noted above in studies that utilize hybrid modeling approaches and that do not incorporate population weighting in calculating the mean (*e.g.*, use each grid cell to calculate a mean PM_{2.5} concentration), the study mean does not reflect the exposure concentrations used in the epidemiologic study to assess the reported association.

The 2022 PA notes that while these analyses can be useful to informing the understanding of the relationship between study-reported mean concentrations and the level of the annual standard, some limitations of this analysis must be recognized (U.S. EPA, 2022a, section 3.3.3.2.1). First, the comparisons

used only two hybrid modeling approaches. Although these two hybrid modeling surfaces have been used in a number of recent epidemiologic studies, they represent just two of the many hybrid modeling approaches that have been used in epidemiologic studies to estimate $\text{PM}_{2.5}$ concentrations. These methods continue to evolve, with further development and improvement to prediction models that estimate $\text{PM}_{2.5}$ concentrations in epidemiologic studies. In addition to differences in hybrid modeling approaches, epidemiologic studies also use different methods to assign a population weighted average $\text{PM}_{2.5}$ concentration to their study population, and the assessment presented in the 2022 PA does not evaluate all of the potential methods that could be used.

Additionally, while some of these epidemiologic studies also provide information on the broader distributions of exposure estimates and/or health events and the $\text{PM}_{2.5}$ concentrations corresponding to the lower percentiles of those data (*e.g.*, 25th and/or 10th), the air quality analysis in the 2022 PA focuses on mean $\text{PM}_{2.5}$ concentrations and a similar comparison for lower percentiles of data was not assessed. Therefore, any direct comparison of study-reported $\text{PM}_{2.5}$ concentrations corresponding to lower percentiles and annual design values is more uncertain than such comparisons with the mean. Finally, air quality analysis presented in the 2022 PA and detailed above in section I.D.5 included two hybrid modeling-based approaches that used U.S.-based air quality information for estimating $\text{PM}_{2.5}$ concentrations. As such, the analyses are most relevant to interpreting the study-reported mean concentrations from U.S. epidemiologic studies and do not provide additional information about how the mean exposures

concentrations reported in epidemiologic studies in other countries would compare to annual design values observed in the U.S. In addition, while information from Canadian studies can be useful in assessing the adequacy of the annual standard, differences in the exposure environments and population characteristics between the U.S. and other countries can affect the study-reported mean value and its relationship with the annual standard level. Sources and pollutant mixtures, as well as PM_{2.5} concentration gradients, may be different between countries, and the exposure environments in other countries may differ from those observed in the U.S. Furthermore, differences in population characteristics and population densities can also make it challenging to directly compare studies from countries outside of the U.S. to a design value in the U.S.

As with the experimental studies discussed above, the 2022 PA focuses on epidemiologic studies assessed in the 2019 ISA and ISA Supplement that have the potential to be most informative in reaching decisions on the adequacy of the primary PM_{2.5} standards. The 2022 PA focuses on epidemiologic studies that provide strong support for “causal” or “likely to be causal” relationships with PM_{2.5} exposures in the 2019 ISA. Further, the 2022 PA also focuses on the health effect associations that are determined in the 2019 ISA and ISA Supplement to be consistent across studies, coherent with the broader body of evidence (*e.g.*, including animal and controlled human exposure studies), and robust to potential confounding by co-occurring pollutants and other factors.⁷³ In particular the 2022 PA considers

⁷³ As described in the Preamble to the ISAs (U.S. EPA, 2015), “the U.S. EPA emphasizes the importance of examining the

the U.S. and Canadian epidemiologic studies to be more useful for reaching conclusions on the current standards than studies conducted in other countries, given that the results of the U.S. and Canadian studies are more directly applicable for quantitative considerations, whereas studies conducted in other countries reflect different populations, exposure characteristics, and air pollution mixtures. Additionally, epidemiologic studies outside of the U.S. and Canada generally reflect higher PM_{2.5} concentrations in ambient air than are currently found in the U.S., and are less relevant to informing questions about adequacy of the current standards.⁷⁴ However, and as

pattern of results across various studies and does not focus solely on statistical significance or the magnitude of the direction of the association as criteria of study reliability. Statistical significance is influenced by a variety of factors including, but not limited to, the size of the study, exposure and outcome measurement error, and statistical model specifications. Statistical significance may be informative; however, it is just one of the means of evaluating confidence in the observed relationship and assessing the probability of chance as an explanation. Other indicators of reliability such as the consistency and coherence of a body of studies as well as other confirming data may be used to justify reliance on the results of a body of epidemiologic studies, even if results in individual studies lack statistical significance. Traditionally, statistical significance is used to a larger extent to evaluate the findings of controlled human exposure and animal toxicological studies. Understanding that statistical inferences may result in both false positives and false negatives, consideration is given to both trends in data and reproducibility of results. Thus, in drawing judgments regarding causality, the U.S. EPA emphasizes statistically significant findings from experimental studies, but does not limit its focus or consideration to statistically significant results in epidemiologic studies.”

⁷⁴ This emphasis on studies conducted in the U.S. or Canada is consistent with the approach in the 2012 and 2020 reviews of the PM NAAQS (U.S. EPA, 2011, section 2.1.3; U.S. EPA,

noted above, the 2022 PA also recognizes that while information from Canadian studies can be useful in assessing the adequacy of the annual standard, there are still important differences between the exposure environments in the U.S. and Canada and interpreting the data (*e.g.*, mean concentrations) from the Canadian studies in the context of a U.S.-based standard may present challenges in directly and quantitatively informing questions regarding the adequacy of then current or potential alternative the levels of the annual standard. Lastly, the 2022 PA emphasizes multicity/multistate studies that examine health effect associations, as such studies are more encompassing of the diverse atmospheric conditions and population demographics in the U.S. than studies that focus on a single city or State. Figures 3–4 through 3–7 in the 2022 PA summarize the study details for the key U.S. and Canadian epidemiologic studies (U.S. EPA, 2022b, section 3.3.3.2.1).⁷⁵

The key epidemiologic studies identified in the 2022 PA indicate generally positive and statistically significant associations between estimated PM_{2.5} exposures (short- or long-term) and mortality or morbidity across a range of ambient PM_{2.5} concentrations (U.S. EPA, 2022b, section 3.3.3.2.1),

2020b, section 3.2.3.2.1) and with approaches taken in other NAAQS reviews. However, the importance of studies in the U.S., Canada, and other countries in informing an ISA's considerations of the weight of the evidence that informs causality determinations is recognized.

⁷⁵ The cohorts examined in the studies included in Figure 3–4 to Figure 3–7 of the 2022 PA include large numbers of individuals in the general population, and often also include those populations identified as at-risk (*i.e.*, children, older adults, minority populations, and individuals with pre-existing cardiovascular and respiratory disease).

report overall mean (or median) PM_{2.5} concentrations, and include those for which the years of PM_{2.5} air quality data used to estimate exposures overlap entirely with the years during which health events are reported.⁷⁶ Additionally, for studies that estimate PM_{2.5} exposure using hybrid modeling approaches, the 2022 PA also considers the approach used to estimate PM_{2.5} concentrations and the approach used to validate hybrid model predictions when evaluating those studies as key epidemiologic studies⁷⁷ and focuses on those studies that use recent methods based on surfaces that are with fused with monitored PM_{2.5} concentration data (U.S. EPA, 2022b, section 3.3.3.2.1).

⁷⁶ For some studies of long-term PM_{2.5} exposures, exposure is estimated from air quality data corresponding to only part of the study period, often including only the later years of the health data, and are not likely to reflect the full ranges of ambient PM_{2.5} concentrations that contributed to reported associations. While this approach can be reasonable in the context of an epidemiologic study that is evaluating health effect associations with long-term PM_{2.5} exposures, under the assumption that spatial patterns in PM_{2.5} concentrations are not appreciably different during time periods for which air quality information is not available (*e.g.*, Chen et al., 2016), the 2022 PA focuses on the distribution of ambient PM_{2.5} concentrations that could have contributed to reported health outcomes. Therefore, the 2022 PA identifies studies as key epidemiologic studies when the years of air quality data and health data overlap in their entirety.

⁷⁷ Such studies are identified as those that use hybrid modeling approaches for which recent methods and models were used (*e.g.*, recent versions and configurations of the air quality models); studies that are fused with PM_{2.5} data from national monitoring networks (*i.e.*, FRM/FEM data); and studies that reported a thorough model performance evaluation for core years of the study.

Figure 1 below (U.S. EPA, 2022b, Figure 3–8) highlights the overall mean (or median) PM_{2.5} concentrations reported in key U.S. studies that use ground-based monitors alone to estimate long- or short-term PM_{2.5} exposure.⁷⁸ For the small subset of studies with available information on the broader distributions of underlying data, Figure 1 below also identifies the study-period PM_{2.5} concentrations corresponding to the 25th and 10th percentiles of health events⁷⁹ (see Appendix B, Section B.2 of the 2022 PA for more information). Figure 2 (U.S. EPA, 2022a, Figure 3–14) presents overall means of predicted PM_{2.5} concentrations for key U.S. model-based epidemiologic studies that apply aspects of population-weighting, and the concentrations corresponding to the 25th and 10th percentiles of estimated exposures or health events⁸⁰ when

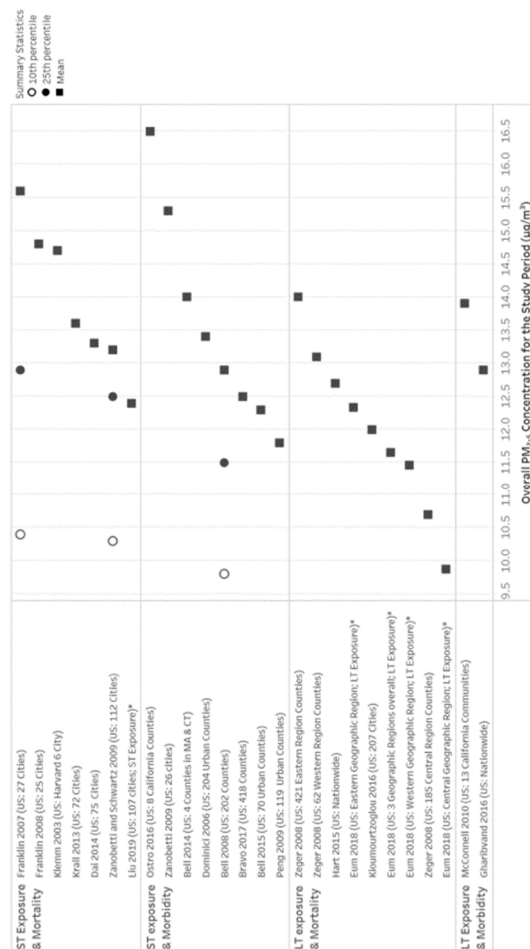
⁷⁸ Canadian studies that use ground-based monitors estimate long- or short-term PM_{2.5} exposures are found in Figure 3–9 of the 2022 PA, including concentrations corresponding to the 25th and 10th percentiles of estimated exposures or health events, when available (U.S. EPA, 2022b).

⁷⁹ That is, 25% of the total health events occurred in study locations with mean PM_{2.5} concentrations (*i.e.*, averaged over the study period) below the 25th percentiles identified in Figure 3–8 of the 2022 PA and 10% of the total health events occurred in study locations with mean PM_{2.5} concentrations below the 10th percentiles identified.

⁸⁰ For most studies in Figure 2 below (Figure 3–14 in the 2022 PA), 25th percentiles of exposure estimates are presented. The exception is Di et al. (2017b), for which Figure 2 (U.S. EPA, 2022b, Figure 3–14) presents the short-term PM_{2.5} exposure estimates corresponding to the 25th and 10th percentiles of deaths in the study population (*i.e.*, 25% and 10% of deaths occurred at concentrations below these concentrations). In addition, the authors of Di et al. (2017b) provided population-weighted exposure values. The 10th and 25th percentiles of

available (see Appendix B, section B.3 for additional information).⁸¹

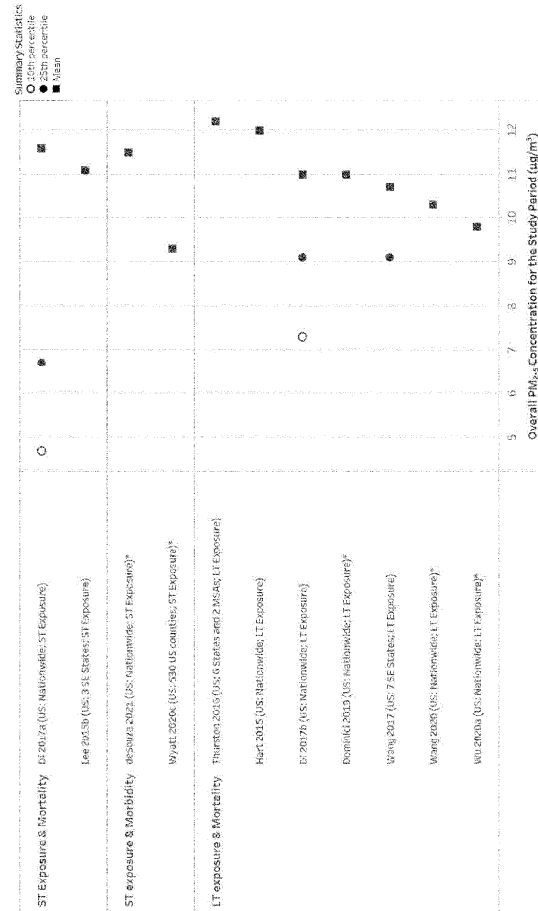
Figure 1. Monitor-based PM_{2.5} Concentrations in Key U.S. Epidemiologic Studies. (Asterisks denote studies included in the ISA Supplement)



these population-weighted exposure estimates are 7.9 and 9.5 µg/m³, respectively.

⁸¹ Overall mean (or median) PM_{2.5} concentrations reported in key Canadian studies that use model-based approaches to estimate long- or short-term PM_{2.5} concentrations and the concentrations corresponding to the 25th and 10th percentiles of estimated exposures or health events, when available are found in Figure 3–9 of the 2022 PA (U.S. EPA, 2022b).

Figure 2. Hybrid Model-Predicted PM_{2.5} Concentrations in Key U.S. Epidemiologic Studies that Apply Aspects of Population-Weighting. (Asterisks denote studies included in the ISA Supplement)



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Based on its evaluation of study-reported mean concentrations, the 2022 PA notes that key epidemiologic studies conducted in the U.S. or Canada report generally positive and statistically significant associations between estimated PM_{2.5} exposures (short- or long-term) and mortality or morbidity across a wide range of ambient PM_{2.5} concentrations (U.S. EPA, 2022b, section 3.3.3.2.1). The 2022 PA makes a number of observations with regard to the study-

reported PM_{2.5} concentrations in the key U.S. and Canadian epidemiologic studies.

The 2022 PA first considers the PM_{2.5} concentrations from the key U.S. epidemiologic studies. For studies that use monitors to estimate PM_{2.5} exposures, overall mean PM_{2.5} concentrations range between 9.9 µg/ m³⁸² to 16.5 µg/m³ (Figure 1 above and U.S. EPA, 2022b, Figure 3–8). For key U.S. epidemiologic studies that use hybrid model-predicted exposures and apply aspects of population-weighting, mean PM_{2.5} concentrations range from 9.3 µg/m³ to just above 12.2 µg/m³ (Figure 2 above and U.S. EPA, 2022b, Figure 3–14). In studies that average up from the grid cell level to the ZIP code, postal code, or census tract level, mean PM_{2.5} concentrations range from 9.8 µg/m³ to 12.2 µg/m³. The one study that population-weighted the grid cell prior to averaging up to the ZIP code or census tract level reported mean PM_{2.5} concentrations of 9.3 µg/m³. Based on air quality analyses noted above, these hybrid modelled epidemiologic studies are expected to report means similar to those from monitor-based studies.

Other key U.S. epidemiologic studies that use hybrid modeling approaches estimate mean PM_{2.5} exposure by averaging each grid cell across the entire study area, whether that be the nation or a region of the country. These studies do not weight the estimated exposure concentrations based on population density or location of health events. As such, the study mean reported in these studies may not reflect

⁸² This is generally consistent with, but slightly below, the lowest study-reported mean PM_{2.5} concentration from monitor-based studies available in the 2020 PA, which was 10.7 µg/m³ (U.S. EPA, 2020a, Figure 3–7).

the exposure concentrations used in the epidemiologic study to assess the reported association. As a result, these reported mean concentrations are the most different (and much lower) than the means reported in monitor-based studies. Due to the methodology employed in calculating the study-reported means and not necessarily a difference in estimates of exposure, these epidemiologic studies are expected to report some of the lowest mean values. For these studies, the reported mean $\text{PM}_{2.5}$ concentrations range from $8.1 \mu\text{g}/\text{m}^3$ to $11.9 \mu\text{g}/\text{m}^3$ (U.S. EPA, 2022b, Figure 3–14). As noted above, for studies that utilize hybrid modeling approaches but do not incorporate population weighting into the reported mean calculation, the associated annual design values would be expected to be much higher (*i.e.*, 40–50% higher) than the study-reported means. This larger difference between design values and study-reported mean concentrations makes it more difficult to consider how these studies can be used to determine the adequacy of the protection afforded by the current or potential alternative annual standards (U.S. EPA, 2022b, section 3.3.3.2.1).

In addition to the mean $\text{PM}_{2.5}$ concentrations, a subset of the key U.S. epidemiologic studies report $\text{PM}_{2.5}$ concentrations corresponding to the 25th and 10th percentiles of health data or exposure estimates to provide insight into the concentrations that comprise the lower quartile of the air quality distributions. In studies that use monitors to estimate $\text{PM}_{2.5}$ exposures, 25th percentiles of health events correspond to $\text{PM}_{2.5}$ concentrations (*i.e.*, averaged over the study period for each study city) at or above $11.5 \mu\text{g}/\text{m}^3$ and 10th percentiles of health events correspond to $\text{PM}_{2.5}$ concentrations at or above $9.8 \mu\text{g}/\text{m}^3$ (*i.e.*, 25% and 10% of health events,

respectively, occur in study locations with PM_{2.5} concentrations below these values) (Figure 1 above and U.S. EPA, 2022b, Figure 3–8). Of the key U.S. epidemiologic studies that use hybrid modeling approaches and apply population-weighting to estimate long-term PM_{2.5} exposures, the ambient PM_{2.5} concentrations corresponding to 25th percentiles of estimated exposures are 9.1 µg/m³ (Figure 2 and U.S. EPA, 2022b, Figure 3–14). In key U.S. epidemiologic studies that use hybrid modeling approaches and apply population-weighting to estimate short-term PM_{2.5} exposures, the ambient concentrations corresponding to 25th percentiles of estimated exposures, or health events, are 6.7 µg/m³ (Figure 2 and U.S. EPA, 2022b, Figure 3–14). In key U.S. epidemiologic studies that use hybrid modeling approaches and do not apply population-weighting to estimate PM_{2.5} exposures, the ambient concentrations corresponding to 25th percentiles of estimated exposures, or health events, range from 4.6 to 9.2 µg/m³ (U.S. EPA, 2022b, Figure 3–14).⁸³ In the key epidemiologic studies that apply hybrid modeling approaches with population-weighting and with information available on the 10th percentile of health events, the ambient PM_{2.5} concentration corresponding to that 10th percentile range from 4.7 µg/m³ to 7.3 µg/m³ (Figure 2 and U.S. EPA, 2022b, Figure 3–14).

The 2022 PA next considers the PM_{2.5} concentrations from the key Canadian epidemiologic studies.

⁸³ In the one study that reports 25th percentile exposure estimates of 4.6 µg/m³ (Shi et al., 2016), the authors report that most deaths occurred at or above the 75th percentile of annual exposure estimates (*i.e.*, 10 µg/m³). The short-term exposure estimates accounting for most deaths are not presented in the published study.

Generally, the study-reported mean concentrations in Canadian studies are lower than those reported in the U.S. studies for both monitor-based and hybrid model methods. For the majority of key Canadian epidemiologic studies that use monitor-based exposure, mean PM_{2.5} concentrations generally ranged from 7.0 µg/m³ to 9.0 µg/m³ (U.S. EPA, 2022b, Figure 3–9). For these studies, 25th percentiles of health events correspond to PM_{2.5} concentrations at or above 6.5 µg/m³ and 10th percentiles of health events correspond to PM_{2.5} concentrations at or above 6.4 µg/m³ (U.S. EPA, 2022b, Figure 3–9). For the key Canadian epidemiologic studies that use hybrid model-predicted exposure, the mean PM_{2.5} concentrations are generally lower than in U.S. model-based studies (U.S. EPA, 2022b, Figure 3–10), ranging from approximately 6.0 µg/m³ to just below 10.0 µg/m³ (U.S. EPA, 2022b, Figure 3–11). The majority of the key Canadian epidemiologic studies that used hybrid modeling were completed at the nationwide scale, while four studies were completed at the regional geographic spatial scale. In addition, all the key Canadian epidemiologic studies apply aspects of population weighting, where all grid cells within a postal code are averaged, individuals are assigned exposure at the postal code resolution, and study mean PM_{2.5} concentrations are based on the average of individual exposures. The majority of studies estimating exposure nationwide range between just below 6.0 µg/m³ to 8.0 µg/m³ (U.S. EPA, 2022b, Figure 3–11). One study by Erickson et al. (2020) presents an analysis related immigrant status and length of residence in Canada versus non-immigrant populations, which accounts for the four highest mean PM_{2.5} concentrations which range between 9.0 µg/m³ and 10.0 µg/m³ (U.S. EPA, 2022b, Figure 3–11).

The four studies that estimate exposure at the regional scale report mean PM_{2.5} concentrations that range from 7.8 µg/m³ to 9.8 µg/m³ (U.S. EPA, 2022b, Figure 3–11). Three key Canadian epidemiologic studies report information on the 25th percentile of health events. In these studies, the ambient PM_{2.5} concentration corresponding to the 25th percentile is approximately 8.0 µg/m³ in two studies, and 4.3 µg/m³ in a third study (U.S. EPA, 2022b, Figure 3–11).

In addition to the expanded body of evidence from the key U.S. epidemiologic studies discussed above, there are also a subset of epidemiologic studies that have emerged that further inform an understanding of the relationship between PM_{2.5} exposure and health effects, including studies with the highest exposures excluded (restricted analyses), epidemiologic studies that employed statistical approaches that attempt to more extensively account for confounders and are more robust to model misspecification (*i.e.*, used alternative methods for confounder control),⁸⁴ and accountability studies (U.S. EPA, 2019a, U.S. EPA, 2021a, U.S. EPA, 2022a).

Restricted analyses are studies that examine health effect associations in analyses with the

⁸⁴ As noted in the ISA Supplement (U.S. EPA, 2022a, p. 1–3): “In the peer-reviewed literature, these epidemiologic studies are often referred to as alternative methods for confounder control. For the purposes of this Supplement, this terminology is not used to prevent confusion with the main scientific conclusions (*i.e.*, the causality determinations) presented within an ISA. In addition, as is consistent with the weight-of-evidence framework used within ISAs and discussed in the Preamble to the Integrated Science Assessments, an individual study on its own cannot inform causality, but instead represents a piece of the overall body of evidence.”

highest exposures excluded, restricting analyses to daily exposures less than the 24-hour primary PM_{2.5} standard and annual exposures less than the annual PM_{2.5} standard. The 2022 PA presents a summary of restricted analyses evaluated in the 2019 ISA and ISA Supplement (U.S. EPA, 2022b, Table 3–10). The restricted analyses can be informative in assessing the nature of the association between long-term exposures (*e.g.*, annual average concentrations <12.0 µg/m³) or short-term exposures (*e.g.*, daily concentrations <35 µg/m³) when looking only at exposures to lower concentrations, including whether the association persists in such restricted analyses compared to the same analyses for all exposures, as well as whether the association is stronger, in terms of magnitude and precision, than when completing the same analysis for all exposures. While these studies are useful in supporting the confidence and strength of associations at lower concentrations, these studies also have inherent uncertainties and limitations, including uncertainty in how studies exclude concentrations (*e.g.*, are they excluded at the modeled grid cell level, the ZIP code level) and in how concentrations in studies that restrict air quality data relate to design values for the annual and 24-hour standards. Further, these studies often do not report descriptive statistics (*e.g.*, mean PM_{2.5} concentrations, or concentrations at other percentiles) that allow for additional consideration of this information. As such, while these studies can provide additional supporting evidence for associations at lower concentrations, the 2022 PA notes that there are also limitations in how to interpret these studies when evaluating the adequacy of the current or potential alternative standards.

Restricted analyses provide additional information on the nature of the association between long- or short-term exposures when analyses are restricted to lower PM_{2.5} concentrations and indicate that effect estimates are generally greater in magnitude in the restricted analyses for long- and short-term PM_{2.5} exposure compared to the main analyses. In two U.S. studies that report mean PM_{2.5} concentrations in restricted analyses and that estimate effects associated with long-term exposure to PM_{2.5}, the effect estimates are greater in the restricted analyses than in the main analyses. Di et al. (2017a) and Dominici et al. (2019) report positive and statistically significant associations in analyses restricted to concentrations less than 12.0 µg/m³ for all-cause mortality and effect estimates are greater in the restricted analyses than effect estimates reported in main analyses. In addition, both studies report mean PM_{2.5} concentrations of 9.6 µg/m³. While none of the U.S. studies of short-term exposure present mean PM_{2.5} concentrations for the restricted analyses, these studies generally have mean 24-hour average PM_{2.5} concentrations in the main analyses below 12.0 µg/m³, and report increases in the effect estimates in the restricted analyses compared to the main analyses. Additionally, in the one Canadian study of long-term PM_{2.5} exposure, Zhang et al. (2021) conducted analyses where annual PM_{2.5} concentrations were restricted to concentrations below 10.0 µg/m³ and 8.8 µg/m³, which presumably have lower mean concentrations than the mean of 7.8 µg/m³ reported in the main analyses, though restricted analysis mean PM_{2.5} concentrations are not reported. Effect estimates for non-accidental mortality are greater in analyses restricted to PM_{2.5} concentrations less than 10.0 µg/m³, but less in analyses restricted to <8.8 µg/m³.

The second type of studies that have recently emerged and further inform the consideration of the relationship between $\text{PM}_{2.5}$ exposure and health effects in the 2022 PA are those that employ alternative methods for confounder control. Alternative methods for confounder control seek to mimic randomized experiments through the use of study design and statistical methods to more extensively account for confounders and are more robust to model misspecification. The 2022 PA presents a summary of the studies that employ alternative methods for confounder control, and employ a variety of statistical methods, which are evaluated in the 2019 ISA and ISA Supplement (U.S. EPA, 2022b, Table 3–11). These studies reported consistent results among large study populations across the U.S. and can further inform the relationship between long- and short-term $\text{PM}_{2.5}$ exposure and total mortality. Studies that employ alternative methods for confounder control to assess the association between long-term exposure to $\text{PM}_{2.5}$ and mortality reduce uncertainties related to confounding and provide additional support for the associations reported in the broader body of cohort studies that examined long-term $\text{PM}_{2.5}$ exposure and mortality.

Lastly, there is a subset of epidemiologic studies that assess whether long-term reductions in ambient $\text{PM}_{2.5}$ concentrations result in corresponding reductions in health outcomes. These include studies that evaluate the potential for improvements in public health, including reductions in mortality rates, increases in life expectancy, and reductions in respiratory disease as ambient $\text{PM}_{2.5}$ concentrations have declined over time. Some of these studies, accountability studies, provide insight on whether the implementation of environmental policies or air

quality interventions result in changes/reductions in air pollution concentrations and the corresponding effect on health outcomes.⁸⁵ The 2022 PA presents a summary of these studies, which are assessed in the 2019 ISA and ISA Supplement (U.S. EPA, 2022b, Table 3–12). These studies lend support for the conclusion that improvements in air quality are associated with improvements in public health.

More specifically, of the accountability studies that account for changes in PM_{2.5} concentrations due to a policy or the implementation of an intervention and whether there was evidence of changes in associations with mortality or cardiovascular effects as a result of changes in annual PM_{2.5} concentrations, Corrigan et al. (2018), Henneman et al. (2019) and Sanders et al. (2020a) present analyses with starting PM_{2.5} concentrations (or concentrations prior to the policy or intervention) below 12.0 µg/m³. Henneman et al. (2019) explored changes in modeled PM_{2.5} concentrations following the retirement of coal fired power plants in the U.S., and found that reductions from mean annual PM_{2.5} concentrations of 10.0 µg/m³ in 2005 to mean annual PM_{2.5} concentrations of 7.2 µg/m³ in 2012 from coal-fueled power plants resulted in corresponding reductions in the number of cardiovascular-related hospital admissions, including for all cardiovascular disease, acute MI, stroke, heart failure, and ischemic heart disease in those aged 65 and older. Corrigan et al. (2018) examined whether there was a change in the cardiovascular mortality rate before (2000–2004) and after (2005–2010)

⁸⁵ Given the nature of these studies, the majority tend to focus on time periods in the past during which ambient PM_{2.5} concentrations were substantially higher than those measured more recently (*e.g.*, see U.S. EPA, 2022b, Figure 2–16).

implementation of the first annual $\text{PM}_{2.5}$ NAAQS implementation based on mortality data from the National Center for Health Statistics and reported 1.10 (95% confidence interval (CI): 0.37, 1.82) fewer cardiovascular deaths per year per 100,000 people for each $1 \mu\text{g}/\text{m}^3$ reduction in annual $\text{PM}_{2.5}$ concentrations. When comparing whether counties met the annual $\text{PM}_{2.5}$ standard (attainment counties), there were 1.96 (95% CI: 0.77, 3.15) fewer cardiovascular deaths for each $1 \mu\text{g}/\text{m}^3$ reduction in annual $\text{PM}_{2.5}$ concentrations between the two periods for attainment counties, whereas in non-attainment counties (*e.g.*, counties that did not meet the annual $\text{PM}_{2.5}$ standard), there were 0.59 (95% CI: -0.54 , 1.71) fewer cardiovascular deaths between the two periods. And lastly, Sanders et al. (2020a) examined whether policy actions (*i.e.*, the first annual $\text{PM}_{2.5}$ NAAQS implementation rule in 2005 for the 1997 annual $\text{PM}_{2.5}$ standard with a 3-year annual average of $15 \mu\text{g}/\text{m}^3$) reduced $\text{PM}_{2.5}$ concentrations and mortality rates in Medicare beneficiaries between 2000–2013. They report evidence of changes in associations with mortality (a decreased mortality rate of ~ 0.5 per 1,000 in attainment and non-attainment areas) due to changes in annual $\text{PM}_{2.5}$ concentrations in both attainment and non-attainment areas. Additionally, attainment areas had starting concentrations below $12.0 \mu\text{g}/\text{m}^3$ prior to implementation of the annual $\text{PM}_{2.5}$ NAAQS in 2005. In addition, following implementation of the annual $\text{PM}_{2.5}$ NAAQS, annual $\text{PM}_{2.5}$ concentrations decreased by $1.59 \mu\text{g}/\text{m}^3$ (95% CI: 1.39, 1.80) which corresponded to a reduction in mortality rates among individuals 65 years and older (0.93% [95% CI: 0.10%, 1.77%]) in non-attainment counties relative to attainment counties. In a life expectancy study, Bennett et al. (2019) reports

increases in life expectancy in all but 14 counties (1325 of 1339 counties) that have exhibited reductions in PM_{2.5} concentrations from 1999 to 2015. These studies provide support for improvements in public health following the implementation of policies, including in areas with PM_{2.5} concentrations below the level of the current annual standard, as well as increases in life expectancy in areas with reductions in PM_{2.5} concentrations.

d. Uncertainties in the Health Effects Evidence

The 2022 PA recognizes that there are a number of uncertainties and limitations associated with the available health effects evidence. Although the epidemiologic studies clearly demonstrate associations between long- and short-term PM_{2.5} exposures and health outcomes, several uncertainties and limitations in the health effects evidence remain. Epidemiologic studies evaluating short-term PM_{2.5} exposure and health effects have reported heterogeneity in associations between cities and geographic regions within the U.S. Heterogeneity in the associations observed across epidemiologic studies may be due in part to exposure error related to measurement-related issues, the use of central fixed-site monitors to represent population exposure to PM_{2.5}, and a limited understanding of factors including exposure error related to measurement-related issues, variability in PM_{2.5} composition regionally, and factors that result in differential exposures (*e.g.*, topography, the built environment, housing characteristics, personal activity patterns). Heterogeneity is expected when the methods or the underlying distribution of covariates vary across studies (U.S. EPA, 2019a, p. 6–221). Studies assessed in the 2019 ISA and ISA

Supplement have advanced the state of exposure science by presenting innovative methodologies to estimate PM exposure, detailing new and existing measurement and modeling methods, and further informing our understanding of the influence of exposure measurement error due to exposure estimation methods on the associations between PM_{2.5} and health effects reported in epidemiologic studies (U.S. EPA, 2019a, section 1.2.2; U.S. EPA, 2022a). Data from PM_{2.5} monitors continue to be commonly used in health studies as a surrogate for PM_{2.5} exposure, and often provide a reasonable representation of exposures throughout a study area (U.S. EPA, 2019a, section 3.4.2.2; U.S. EPA, 2022a, section 3.2.2.2.2). However, an increasing number of studies employ hybrid modeling methods to estimate PM_{2.5} exposure using data from several sources, often including satellites and models, in addition to ground-based monitors. These hybrid models typically have good cross-validation, especially for PM_{2.5}, and have the potential to reduce exposure measurement error and uncertainty in the health effect estimates from epidemiologic models of long-term exposure (U.S. EPA, 2019a, section 3.5; U.S. EPA, 2022a, section 2.3.3).

While studies using hybrid modeling methods have reduced exposure measurement error and uncertainty in the health effect estimates, these studies use a variety of approaches to estimate PM_{2.5} concentrations and to assign exposure to assess the association between health outcomes and PM_{2.5} exposure. This variability in methodology has inherent limitations and uncertainties, as described in more detail in section 2.3.3.1.5 of the 2022 PA, and the performance of the modeling approaches depends on the availability of monitoring data which varies by location. Factors that likely contribute to poorer model

performance often coincide with relatively low ambient $\text{PM}_{2.5}$ concentrations, in areas where predicted exposures are at a greater distance to monitors, and under conditions where the reliability and availability of key datasets (*e.g.*, air quality modeling) are limited. Thus, uncertainty in hybrid model predictions becomes an increasingly important consideration as lower predicted concentrations are considered.

Regardless of whether a study uses monitoring data or a hybrid modeling approach when estimating $\text{PM}_{2.5}$ exposures, one key limitation that persists is associated with the interpretation of the study-reported mean $\text{PM}_{2.5}$ concentrations and how they compare to design values, the metric that describes the air quality status of a given area relative to the NAAQS.⁸⁶ As discussed above in section II.B.3.b, the overall mean $\text{PM}_{2.5}$ concentrations reported by key epidemiologic studies reflect averaging of short- or long-term $\text{PM}_{2.5}$ exposure estimates across location (*i.e.*, across multiple monitors or across modeled grid cells) and over time (*i.e.*, over several years). For monitor-based studies, the comparison is somewhat more straightforward than for studies that use hybrid modeling methods, as the monitors used to estimate exposure in the epidemiologic studies are generally the same monitors that are used to calculate design values for a given area. It is expected that areas meeting a $\text{PM}_{2.5}$ standard with a particular

⁸⁶ For the annual $\text{PM}_{2.5}$ standard, design values are calculated as the annual arithmetic mean $\text{PM}_{2.5}$ concentration, averaged over 3 years. For the 24-hour standard, design values are calculated as the 98th percentile of the annual distribution of 24-hour $\text{PM}_{2.5}$ concentrations, averaged over three years (Appendix N of 40 CFR part 50).

level would be expected to have average $\text{PM}_{2.5}$ concentrations (*i.e.*, averaged across space and over time in the area) somewhat below that standard level., but the difference between the maximum annual design value and average concentration in an area can be smaller or larger than analyses presented above in section I.D.5.a, likely depending on factors such as the number of monitors, monitor siting characteristics, and the distribution of ambient $\text{PM}_{2.5}$ concentrations. For studies that use hybrid modeling methods to estimate $\text{PM}_{2.5}$ concentrations, the comparison between study-reported mean $\text{PM}_{2.5}$ concentrations and design values is more complicated given the variability in the modeling methods, temporal scales (*i.e.*, daily versus annual), and spatial scales (*i.e.*, nationwide versus urban) across studies. Analyses above in section I.D.5.b and detailed more in the 2022 PA (U.S. EPA, 2022b, section 2.3.3.2.4) present a comparison between two hybrid modeling surfaces, which explored the impact of these factors on the resulting mean $\text{PM}_{2.5}$ concentrations and provided additional information about the relationship between mean concentrations from studies using hybrid modeling methods and design values. However, the results of those analyses only reflect two surfaces and two types of approaches, so uncertainty remains in understanding the relationship between estimated modeled $\text{PM}_{2.5}$ concentrations and design values more broadly across hybrid modeling studies. Moreover, this analysis was completed using two hybrid modeling methods that estimate $\text{PM}_{2.5}$ concentrations in the U.S., thus an additional uncertainty includes understanding the relationship between modeled $\text{PM}_{2.5}$ concentrations and design values reported in Canada.

In addition, where PM_{2.5} and other pollutants (*e.g.*, ozone, nitrogen dioxide, and carbon monoxide) are correlated, it can be difficult to distinguish whether attenuation of effects in some studies results from copollutant confounding or collinearity with other pollutants in the ambient mixture (U.S. EPA, 2019a, section 1.5.1; U.S. EPA, 2022a, section 2.2.1). Studies evaluated in the 2019 ISA and ISA Supplement further examined the potential confounding effects of both gaseous and particulate copollutants on the relationship between long- and short-term PM_{2.5} exposure and health effects. As noted in the Appendix to the 2019 ISA (U.S. EPA, 2019a, Table A-1), copollutant models are not without their limitations, such as instances for which correlations are high between pollutants resulting in greater copollutant confounding bias in results. However, the studies continue to provide evidence indicating that associations with PM_{2.5} are relatively unchanged in copollutants models (U.S. EPA, 2019a, section 1.5.1; U.S. EPA, 2022a, section 2.2.1).

Another area of uncertainty is associated with other potential confounders, beyond copollutants. Some studies have expanded the examination of potential confounders to not only include copollutants, but also systematic evaluations of the potential impact of inadequate control from long- term temporal trends and weather (U.S. EPA, 2019a, section 11.1.5.1). Analyses examining these covariates further confirm that the relationship between PM_{2.5} exposure and mortality is unlikely to be biased by these factors. Other studies have explored the use of alternative methods for confounder control to more extensively account for confounders and are more robust to model misspecification that can further inform the causality determination for long-term and short-term PM_{2.5}

and mortality and cardiovascular effects (U.S. EPA, 2019a, section 11.2.2.4; U.S. EPA, 2022a, sections 3.1.1.3, 3.1.2.3, 3.2.1.2, and 3.2.2.3). These studies indicate that bias from unmeasured confounders can occur in either direction, although controlling for these confounders did not result in the elimination of the association, but instead provided additional support for associations between long-term PM_{2.5} exposure and mortality when accounting for additional confounders (U.S. EPA, 2022a, section 3.2.2.2.6).

Another important limitation associated with the evidence is that, while epidemiologic studies indicate associations between PM_{2.5} and health effects, the currently available evidence does not identify particular PM_{2.5} concentrations that do not elicit health effects. Rather, health effects can occur over the entire distribution of ambient PM_{2.5} concentrations evaluated, and epidemiologic studies conducted to date do not identify a population-level threshold below which it can be concluded with confidence that PM_{2.5}-related effects do not occur.

Overall, evidence assessed in the 2019 ISA and ISA Supplement continues to indicate a linear, no-threshold C–R relationship for PM_{2.5} concentrations >8 µg/m³. However, uncertainties remain about the shape of the C–R curve at PM_{2.5} concentrations <8 µg/m³, with some recent studies providing evidence for either a sublinear, linear, or supralinear relationship at these lower concentrations (U.S. EPA, 2019a, section 11.2.4; U.S. EPA, 2022a, section 2.2.3.2).

There are also a number of uncertainties and limitations associated with the experimental evidence (*i.e.*, controlled human exposure studies and animal toxicological studies). With respect to controlled

human exposure studies, the PA recognizes that these studies include a small number of individuals compared to epidemiologic studies. Additionally, these studies tend to include generally healthy adult individuals, who are at a lower risk of experiencing health effects. These studies, therefore, often do not include populations that are at increased risk of PM_{2.5}-related health effects, including children, older adults, or individuals with pre-existing conditions. As such, these studies are somewhat limited in their ability to inform at what concentrations effects may be elicited in at-risk populations. With respect to animal toxicological studies, while these studies often examine more severe health outcomes and longer exposure durations and higher exposure concentrations than controlled human exposure studies, there is uncertainty in extrapolating the effects seen in animals, and the PM_{2.5} exposures and doses that cause those effects, to human populations.

Consideration of health effects are informed by the epidemiologic, controlled human exposure, and animal toxicological studies. The evaluation and integration of the scientific evidence in the ISA focuses on evaluating the findings from the body of evidence across disciplines, including evaluating the strengths and weaknesses in the overall collection of studies across disciplines. Integrating evidence across disciplines can strengthen causal inference, such that a weak inference from one line of evidence can be addressed by other lines of evidence, and coherence of these lines of evidence can add support to a cause-effect interpretation of the association. Evaluation and integration of the evidence also includes consideration of uncertainties that are inherent in the scientific findings (U.S. EPA, 2015, pp. 13–15), some of which are described above.

3. Summary of Exposure and Risk Estimates

Beyond the consideration of the scientific evidence, discussed above in section II.B, the EPA also considers the extent to which new or updated quantitative analyses of PM_{2.5} air quality, exposure, or health risks could inform conclusions on the adequacy of the public health protection provided by the current primary PM_{2.5} standards. Additionally, the 2022 PA includes an at-risk analysis that assesses PM_{2.5}-attributable risk associated with PM_{2.5} air quality that has been adjusted to simulate air quality scenarios of policy interest (*e.g.*, “just meeting” the current or potential alternative standards). Drawing on the summary in section II.C of the proposal, the sections below provide a brief overview of key aspects of the assessment design (II.A.3.a), key limitations and uncertainties (II.A.3.b), and exposure/risk estimates (II.A.3.c).

a. Key Design Aspects

Risk assessments combine data from multiple sources and involve various assumptions and uncertainties. Input data for these analyses includes C–R functions from epidemiologic studies for each health outcome and ambient annual or 24-hour PM_{2.5} concentrations for the study areas utilized in the risk assessment (U.S. EPA, 2022b, section 3.4.1). Additionally, quantitative and qualitative methods were used to characterize variability and uncertainty in the risk estimates (U.S. EPA, 2022b, section 3.4.1.7).

Concentration-response functions used in the risk assessment are from large, multicity U.S. epidemiologic studies that evaluate the relationship between PM_{2.5} exposures and mortality. Epidemiologic studies and concentration-response studies that were used in

the risk assessment to estimate risk were identified using criteria that take into account factors such as study design, geographic coverage, demographic populations, and health endpoints (U.S. EPA, 2022b, section 3.4.1.1).⁸⁷ The risk assessment focuses on all-cause or nonaccidental mortality associated with long-term and short-term PM_{2.5} exposures, for which the 2019 ISA concluded that the evidence provides support for a “causal relationship” (U.S. EPA, 2022b, section 3.4.1.2).⁸⁸

As described in more detail in the 2022 PA, the risk assessment first estimated health risks associated with air quality for 2015 adjusted to simulate “just meeting” the current primary PM_{2.5} standards (*i.e.*, the annual standard with its level of 12.0 µg/m³ and the 24-hour standard with its level of 35 µg/m³). Air quality modeling was then used to simulate air quality just meeting an alternative standard with a level of 10.0 µg/m³ (annual) and 30 µg/m³ (24-hour). In addition to the model-based approach, for the subset of 30 areas controlled by the annual standard linear interpolation and extrapolation were employed to simulate just meeting alternative annual standards with levels of 11.0 (interpolated between 12.0 and 10.0 µg/m³), 9.0 µg/m³, and 8.0 µg/m³ (both extrapolated from 12.0 and 10.0 µg/m³) (U.S. EPA, 2022b, section 3.4.1.3). The 2022 PA notes that there is

⁸⁷ Additional detail regarding the selection of epidemiologic studies and specification of C–R functions is provided in the 2022 PA (U.S. EPA, 2022b, Appendix C, section C.1.1).

⁸⁸ While the 2019 ISA also found that evidence supports the determination of a “causal relationship” between long- and short-term PM_{2.5} exposures and cardiovascular effects, cardiovascular mortality was not included as a health outcome as it will be captured in the estimates of all-cause mortality.

greater uncertainty regarding whether a revised 24-hour standard (*i.e.*, with a lower level) is needed to further limit “peak” PM_{2.5} concentration exposure and whether a lower 24-hour standard level would most effectively reduce PM_{2.5}-associated health risks associated with “typical” daily exposures. The risk assessment estimates health risks associated with air quality adjusted to meet a revised 24-hour standard with a level of 30 µg/m³, in conjunction with estimating the health risks associated with meeting a revised annual standard with a level of 10.0 µg/m³ (U.S. EPA, 2022b, section 3.4.1.3). More details on the air quality adjustment approaches used in the risk assessment are described in section 3.4.1.4 and Appendix C of the 2022 PA (U.S. EPA, 2022b).

When selecting U.S. study areas for inclusion in the risk assessment, the available ambient monitors, geographic diversity, and ambient PM_{2.5} air quality concentrations were taken into consideration (U.S. EPA, 2022b, section 3.4.1.4). When these factors were applied, 47 urban study areas were identified, which include nearly 60 million people aged 30–99, or approximately 30% of the U.S population in this age range (U.S. EPA, 2022b, section 3.4.1.5, Appendix C, section C.1.3). Of the 47 study areas, there were 30 study areas where just meeting the current standards is controlled by the annual standard,⁸⁹ 11 study areas where just meeting the current standards is

⁸⁹ For these areas, the annual standard is the “controlling standard” because when air quality is adjusted to simulate just meeting the current or potential alternative annual standards, that air quality also would meet the 24-hour standard being evaluated.

controlled by the daily standard,⁹⁰ and 6 study areas where the controlling standard differed depending on the air quality adjustment approach (U.S. EPA, 2022b, section 3.4.1.5).⁹¹

In addition to the overall risk assessment, the 2022 PA also includes an at-risk analysis and estimates exposures and health risks of specific populations identified as at-risk that would be allowed under the current and potential alternative standards to further inform the Administrator's conclusions regarding the adequacy of the public health protection provided by the current primary PM_{2.5} standards. In so doing, the 2022 PA evaluates exposure and PM_{2.5} mortality risk for older adults (*e.g.*, 65 years and older), stratified for White, Black, Asian, Native American, Non-Hispanic, and Hispanic individuals residing in the same study areas included in the overall risk assessment. This analysis utilizes a recent epidemiologic study that provides race- and ethnicity-specific risk coefficients (Di et al., 2017b).

b. Key Limitations and Uncertainties

Uncertainty in risk estimates (*e.g.*, in the size of risk estimates) can result from a number of factors, including the assumptions about the shape of the C-R function with mortality at low ambient PM concentrations, the potential for confounding and/or

⁹⁰ For these areas, the 24-hour standard is the controlling standard because when air quality is adjusted to simulate just meeting the current or potential alternative 24-hour standards, that air quality also would meet the annual standard being evaluated. Some areas classified as being controlled by the 24-hour standard also violate the annual standard.

⁹¹ In these 6 areas, the controlling standard depended on the air quality adjustment method used and/or the standard scenarios evaluated.

exposure measurement error in the underlying epidemiologic studies, and the methods used to adjust PM_{2.5} air quality. More specifically, the use of air quality modeling to adjust PM_{2.5} concentrations are limited as they rely on model predictions, are based on emission changes scaled by fixed percentages, and use only two of the full set of possible emission scenarios and linear interpolation/extrapolation to adjust air quality that may not fully capture potential non-linearities associated with real-world changes in air quality. Additionally, the selection of case study areas is limited to urban areas predominantly located CA and in the Eastern U.S. that are controlled by the annual standard. While the risk assessment does not report quantitative uncertainty in the risk estimates as exposure concentrations are reduced, it does provide information on the distribution of concentrations associated with the risk estimates when evaluating progressively lower alternative annual standards. Based on these data, as lower alternative annual standards are evaluated, larger proportions of the distributions in risk occur at or below 10 µg/m³ (at concentrations below or near most of the study-reported means from the key U.S. epidemiologic studies) and at or below 8 µg/m³ (the concentration at which the ISA reports increasing uncertainty in the shape of the C–R curve based on the body of epidemiologic evidence).

Similarly, the at-risk analysis is also subject to many of these same uncertainties noted above. Additionally, the at-risk analysis included C–R functions from only one study (Di et al., 2017b), which reported associations between long-term PM_{2.5} exposures and mortality, stratified by race/ethnicity, in populations age 65 and older, as opposed to the multiple studies used in the overall risk assessment

to convey risk estimate variability. These and other sources of uncertainty in the overall risk assessment and the at-risk analyses are characterized in more depth in the 2022 PA (U.S. EPA, 2022b, section 3.4.1.7, section 3.4.1.8, Appendix C, section C.3).

c. Summary of Risk Estimates

Although limitations in the underlying data and approaches lead to some uncertainty regarding estimates of PM_{2.5}-associated risk, 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. For example, when air quality in the 47 study areas is adjusted to simulate just meeting the current standards, the risk assessment estimates up to 45,100 deaths in 2015 are attributable to long-term PM_{2.5} exposures associated with just meeting the current annual and 24-hour PM_{2.5} standards (U.S. EPA, 2022b, section 3.4.2.1). Additionally, as described in more detail in the 2022 PA, the at-risk analysis suggests that a lower annual standard level (*i.e.*, below 12 µg/m³ and down as low as 8 µg/m³) will help to reduce PM_{2.5} exposure and may also help to mitigate exposure and risk disparities in populations identified as particularly at-risk for adverse effects from PM exposures (*i.e.*, minority populations).

Compared to the current annual standard, meeting a revised annual standard with a lower level is estimated to reduce PM_{2.5}-associated health risks in the 30 study areas controlled by the annual standard by about 7–9% for a level of 11.0 µg/m³, 15–19% for a level of 10.0 µg/m³, 22–28% for a level of 9.0 µg/m³, and 30–37% for a level of 8.0 µg/m³) (U.S. EPA, 2022b, Table 3–17). Meeting a revised annual standard with a lower level may also help to mitigate exposure

and risk disparities in populations identified as particularly at-risk for adverse effects from PM exposures (*i.e.*, minority populations) in simulated scenarios just meeting alternative annual standards. However, though reduced, disparities by race and ethnicity persist even at an alternative annual standard level of 8 $\mu\text{g}/\text{m}^3$, the lowest alternative annual standard included in the risk assessment (U.S. EPA, 2022b, section 3.4.2.4).

Revising the level of the 24-hour standard to 30 $\mu\text{g}/\text{m}^3$ is estimated to lower $\text{PM}_{2.5}$ -associated risks across a more limited population and number of areas than revising the annual standard (U.S. EPA, 2022, section 3.4.2.4). Risk reduction predictions are largely confined to areas located in the western U.S., several of which are also likely to experience risk reductions upon meeting a revised annual standard. In the 11 areas controlled by the 24-hour standard, when air quality is simulated to just meet the current 24-hour standard, $\text{PM}_{2.5}$ exposures are estimated to be associated with as many as 2,570 deaths annual. Compared to just meeting the current standard, air quality just meeting an alternative 24-hour standard level of 30 $\mu\text{g}/\text{m}^3$ is associated with reductions in estimated risk of 9–13% (U.S. EPA, 2022b, section 3.4.2.3).

B. Conclusions on the Primary $\text{PM}_{2.5}$ Standards

In drawing conclusions on the adequacy of the current primary $\text{PM}_{2.5}$ standards, in view of the advances in scientific knowledge and additional information now available, the Administrator has considered the evidence base, information, and policy judgments that were the foundation of the 2012 and 2020 reviews and reflects upon the body of evidence and information newly available in this reconsidera-

tion. In so doing, the Administrator has taken into account both evidence-based and risk-based considerations, as well as advice from the CASAC and public comments. Evidence-based considerations draw upon the EPA's integrated assessment of the scientific evidence of health effects related to PM_{2.5} exposure presented in the 2019 ISA and ISA Supplement (summarized in the proposal in sections II.B (88 FR 5580, January 27, 2023) and II.D.2.a (88 FR 5609, January 27, 2023), and also in section II.A.2 above) to address key policy-relevant questions in the reconsideration. Similarly, the risk-based considerations draw upon the assessment of population exposure and risk (summarized in the proposal in sections II.C (88 FR 5605, January 27, 2023) and II.D.2.b (88 FR 5614, January 27, 2023), and also in section II.A.3 above) in addressing policy-relevant questions focused on the potential for PM_{2.5} exposures associated with mortality under air quality conditions just meeting the current and potential alternative standards.

The approach to reviewing the primary standards is consistent with requirements of the provisions of the CAA related to the review of the NAAQS and with how the EPA and the courts have historically interpreted the CAA. As discussed in section I.A above, these provisions require the Administrator to establish primary standards that, in the Administrator's judgment, are requisite (*i.e.*, neither more nor less stringent than necessary) to protect public health with an adequate margin of safety. Consistent with the Agency's approach across all NAAQS reviews, the EPA's approach to informing these judgments is based on a recognition that the available health effects evidence generally reflects a continuum that includes ambient air exposures for which scientists

generally agree that health effects are likely to occur through lower levels at which the likelihood and magnitude of response become increasingly uncertain. The CAA does not require the Administrator to establish a primary standard at a zero- risk level or at background concentration levels, but rather at a level that reduces risk sufficiently so as to protect public health, including the health of sensitive groups, with an adequate margin of safety.

The decisions on the adequacy of the current primary PM_{2.5} standards described below is a public health policy judgment by the Administrator that draws on the scientific evidence for health effects, quantitative analyses of population exposures and/or health risks, and judgments about how to consider the uncertainties and limitations that are inherent in the scientific evidence and quantitative analyses. The four basic elements of the NAAQS (*i.e.*, indicator, averaging time, form, and level) have been considered collectively in evaluating the public health protection afforded by the current standards.

Section II.B.2 below briefly summarizes the basis for the Administrator's proposed decision, drawing from section II.D.3 of the proposal (88 FR 5617, January 27, 2023). The advice and recommendations of the CASAC and public comments on the proposed decision are addressed below in sections II.B.1 and II.B.3, respectively. The Administrator's final conclusions in this reconsideration regarding the adequacy of the current primary PM_{2.5} standards and whether any revisions are appropriate are described in section II.B.4.

1. CASAC Advice

As part of its review of the 2019 draft PA, the CASAC provided advice on the adequacy of the public health protection afforded by the current primary PM_{2.5} standards. Its advice is documented in a letter sent to the EPA Administrator (Cox, 2019b). In this letter, the committee recommended retaining the current 24-hour PM_{2.5} standard but did not reach consensus on whether the scientific and technical information support retaining or revising the current annual standard. In particular, though the CASAC agreed that there is a long-standing body of health evidence supporting relationships between PM_{2.5} exposures and various health outcomes, including mortality and serious morbidity effects, individual CASAC members “differ[ed] in their assessments of the causal and policy significance of these associations” (Cox, 2019b, p. 8 of consensus responses). Drawing from this evidence, “some CASAC members” expressed support for retaining the current annual standard while “other members” expressed support for revising that standard in order to increase public health protection (Cox, 2019b, p.1 of letter). These views are summarized below.

The CASAC members who supported retaining the current annual standard expressed the view that substantial uncertainty remains in the evidence for associations between PM_{2.5} exposures and mortality or serious morbidity effects. These committee members asserted that “such associations can reasonably be explained in light of uncontrolled confounding and other potential sources of error and bias” (Cox, 2019b, p. 8 of consensus responses). They noted that associations do not necessarily reflect causal effects, and they contended that recent

epidemiologic studies assessed in the 2019 ISA that report positive associations at lower estimated exposure concentrations mainly confirm what was anticipated or already assumed in setting the 2012 NAAQS. In particular, they concluded that such studies have some of the same limitations as prior studies and do not provide new information calling into question the existing standard. They further asserted that “accountability studies provide potentially crucial information about whether and how much decreasing PM_{2.5} causes decreases in future health effects” (Cox, 2019b, p. 10 of consensus responses), and they cited recent reviews (*i.e.*, Henneman et al., 2017; Burns et al., 2019) to support their position that in such studies, “reductions of PM_{2.5} concentrations have not clearly reduced mortality risks” (Cox, 2019b, p. 8 of consensus responses). Thus, the committee members who supported retaining the current annual standard advise that, “while the data on associations should certainly be carefully considered, this data should not be interpreted more strongly than warranted based on its methodological limitations” (Cox, 2019b, p. 8 of consensus responses).

These members of the CASAC further concluded that the quantitative risk assessment included in the 2019 draft PA does not provide a valid basis for revising the current standards. This conclusion was based on concerns that (1) “the risk assessment treats regression coefficients as causal coefficients with no justification or validation provided for this decision;” (2) the estimated regression concentration-response functions “have not been adequately adjusted to correct for confounding, errors in exposure estimates and other covariates, model uncertainty, and heterogeneity in individual biological (causal)

[concentration-response] functions;” (3) the estimated concentration-response functions “do not contain quantitative uncertainty bands that reflect model uncertainty or effects of exposure and covariate estimation errors;” and (4) “no regression diagnostics are provided justifying the use of proportional hazards . . . and other modeling assumptions” (Cox, 2019b, p. 9 of consensus responses). These committee members also contended that details regarding the derivation of concentration-response functions, including specification of the beta values and functional forms, were not well-documented, hampering the ability of readers to evaluate these design details. Thus, these members “think that the risk characterization does not provide useful information about whether the current standard is protective” (Cox, 2019b, p. 11 of consensus responses).

Drawing from their evaluation of the evidence and the risk assessment in the 2019 draft PA, these committee members concluded that “the Draft PM PA does not establish that new scientific evidence and data reasonably call into question the public health protection afforded by the . . . 2012 PM_{2.5} annual standard” (Cox, 2019b, p.1 of letter).

In contrast, “[o]ther members of CASAC conclude[d] that the weight of the evidence, particularly reflecting recent epidemiology studies showing positive associations between PM_{2.5} and health effects at estimated annual average PM_{2.5} concentrations below the current standard, does reasonably call into question the adequacy of the 2012 annual PM_{2.5} [standard] to protect public health with an adequate margin of safety” (Cox, 2019b, p.1 of letter). The committee members who supported this conclusion noted that the body of health evidence for PM_{2.5} not only

includes the repeated demonstration of associations in epidemiologic studies, but also includes support for biological plausibility established by controlled human exposure and animal toxicology studies. They pointed to recent studies demonstrating that the associations between PM_{2.5} and health effects occur in a diversity of locations, in different time periods, with different populations, and using different exposure estimation and statistical methods. They concluded that “the entire body of evidence for PM health effects justifies the causality determinations made in the Draft PM ISA” (Cox, 2019b, p. 8 of consensus responses).

The members of the CASAC who supported revising the current annual standard particularly emphasized recent findings of associations with PM_{2.5} in areas with average long-term PM_{2.5} concentrations below the level of the annual standard and studies that show positive associations even when estimated exposures above 12 µg/m³ are excluded from analyses. They found it “highly unlikely” that the extensive body of evidence indicating positive associations at low estimated exposures could be fully explained by confounding or by other non-causal explanations (Cox, 2019b, p. 8 of consensus responses). They additionally concluded that “the risk characterization does provide a useful attempt to understand the potential impacts of alternate standards on public health risks” (Cox, 2019b, p. 11 of consensus responses). These CASAC members concluded that the available evidence reasonably calls into question the protection provided by the current primary PM_{2.5} standards and supports revising the annual standard to increase that protection (Cox, 2019b).

As a part of this reconsideration, the CASAC reviewed the 2021 draft PA (developed to support the reconsideration as described in section I.C.5 above). As a part of their review of the 2021 draft PA, the CASAC provided advice on the adequacy of the current primary PM_{2.5} standards. The range of views summarized here generally reflects differing judgments as to the relative weight to place on various types of evidence, the risk-based information, and the associated uncertainties, as well as differing judgments about the importance of various PM_{2.5}-related health effects from a public health perspective.

In its comments on the 2021 draft PA, the CASAC stated that: “[o]verall the CASAC finds the Draft PA to be well-written and appropriate for helping to ‘bridge the gap’ between the agency’s scientific assessments and quantitative technical analyses, and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the National Ambient Air Quality Standards (NAAQS)” (Sheppard, 2022a, p. 1 of consensus letter). The CASAC also stated that the “[d]raft PA adequately captures and appropriately characterizes the key aspects of the evidence assessed and integrated in the 2019 ISA and Draft ISA Supplement of PM_{2.5}-related health effects” (Sheppard, 2022b, p. 2 of consensus letter). The CASAC also stated that “[t]he interpretation of the risk assessment for the purpose of evaluating the adequacy of the current primary PM_{2.5} annual standard is appropriate given the scientific findings presented” (Sheppard, 2022a, p. 2 of consensus letter).

With regard to the adequacy of the current primary annual PM_{2.5} standard, “all CASAC members agree

that the current level of the annual standard is not sufficiently protective of public health and should be lowered” (Sheppard, 2022a, p. 2 of consensus letter). Additionally, “the CASAC reached consensus that the indicator, form, and averaging time should be retained, without revision” (Sheppard, 2022a, p. 2 of consensus letter). With regard to the level of the primary annual $\text{PM}_{2.5}$ standard, the CASAC had differing recommendations for the appropriate range for an alternative level. The majority of the CASAC “judge[d] that an annual average in the range of 8–10 $\mu\text{g}/\text{m}^3$ ” was most appropriate, while the minority of the CASAC members stated that “the range of the alternative standard of 10–11 $\mu\text{g}/\text{m}^3$ is more appropriate” (Sheppard, 2022a, p. 16 of consensus responses). The CASAC did highlight, however, that “the alternative standard level of 10 $\mu\text{g}/\text{m}^3$ is within the range of acceptable alternative standards recommended by all CASAC members, and that an annual standard below 12 $\mu\text{g}/\text{m}^3$ is supported by a larger and coherent body of evidence” (Sheppard, 2022a, p. 16 of consensus responses).

In reaching conclusions on a recommended range of 8–10 $\mu\text{g}/\text{m}^3$ for the primary annual $\text{PM}_{2.5}$ standard, the majority of the CASAC placed weight on various aspects of the available scientific evidence and quantitative risk assessment information discussed in the 2021 draft PA (Sheppard, 2022a, p. 16 of consensus responses). In particular, these members cited recent U.S.- and Canadian-based epidemiologic studies that show positive associations between $\text{PM}_{2.5}$ exposure and mortality with study-reported mean concentrations below 10 $\mu\text{g}/\text{m}^3$. Further, these members also noted that the lower portions of the air quality distribution (*i.e.*, concentrations below the mean) provide additional information to support associa-

tions between health effects and PM_{2.5} concentrations lower than the reported long-term mean concentration. In addition, the CASAC members recognized that the available evidence has not identified a threshold concentration, below which an association no longer remains, pointing to the conclusion in the draft ISA Supplement that the “evidence remains clear and consistent in supporting a no- threshold relationship, and in supporting a linear relationship for PM_{2.5} concentrations >8 µg/m³” (Sheppard, 2022a, p. 16 of consensus responses). Finally, these CASAC members placed weight on the at-risk analysis as providing support for protection of at-risk demographic groups, including minority populations.

In recommending a range of 10–11 µg/m³ for the primary annual PM_{2.5} standard, the minority of the CASAC emphasized that there were few key epidemiologic studies that reported positive and statistically significant health effects associations for PM_{2.5} air quality distributions with overall mean concentrations below 9.6 µg/m³ (Sheppard, 2022a, p. 17 of consensus responses). In so doing, the minority of the CASAC specifically noted the variability in the relationship between study-reported means and area annual design values based on the methods utilized in the studies, noting that design values are generally higher than area average exposure levels. Further, the minority of the CASAC stated that “uncertainties related to copollutants and confounders make it difficult to justify a recommendation below 10–11 µg/m³” (Sheppard, 2022a, p. 17 of consensus responses). Finally, the minority of the CASAC placed less weight on the risk assessment results, noting large uncertainties, including the approaches used for adjusting air quality to simulate just meeting the current and alternative standards.

With regard to the current primary 24-hour PM_{2.5} standard, in their review of the 2021 draft PA, the CASAC did not reach consensus regarding the adequacy of the public health protection provided by the current standard. As described further below, the majority of the CASAC members concluded “that the available evidence calls into question the adequacy of the current 24-hour standard” (Sheppard, 2022a, p. 3 of consensus letter), while the minority of the CASAC members agreed with “the EPA’s preliminary conclusion [in the draft PA] to retain the current 24-hour PM_{2.5} standard without revision” (Sheppard, 2022a, p. 4 of consensus letter). The CASAC recommended that in future reviews, the EPA should also consider alternative forms for the primary 24-hour PM_{2.5} standard. Specifically, the CASAC “suggests considering a rolling 24-hour average and examining alternatives to the 98th percentile of the 3-year average,” pointing to concerns that computing 24-hour average PM_{2.5} concentrations using the current midnight-to-midnight timeframe could potentially underestimate the effects of high 24-hour exposures, especially in areas with wood-burning stoves and wintertime stagnation (Sheppard, 2022a, p. 18 of consensus responses).

As noted above, the majority of the CASAC favored revising the level of the primary 24-hour PM_{2.5} standard, suggesting that a range of 25–30 µg/m³ would be adequately protective. In so doing, the majority of the CASAC placed weight on the available epidemiologic evidence, including epidemiologic studies that restricted analyses to 24-hour PM_{2.5} concentrations below 25 µg/m³. These members also placed weight on results of controlled human exposure studies with exposures close to the current standard, which they note provide support for the

epidemiologic evidence to lower the standard. These members noted the limitations in using controlled human exposure studies alone in considering the adequacy of the 24-hour standard, recognizing that controlled human exposure studies preferentially recruit less susceptible individuals and have a typical exposure duration shorter than 24 hours. These members also placed “greater weight on the scientific evidence than on the values estimated by the risk assessment,” citing their concerns that the risk assessment “may not adequately capture areas with wintertime stagnation and residential wood-burning where the annual standard is less likely to be protective” (Sheppard, 2022a, p. 17 of consensus responses). Furthermore, these CASAC members “also are less confident that the annual standard could adequately protect against health effects of short-term exposures” (Sheppard, 2022a, p. 17 of consensus responses).

The minority of the CASAC agreed with the EPA’s preliminary conclusion in the 2021 draft PA to retain the current primary 24-hour PM_{2.5} standard. In so doing, the minority of the CASAC placed greater weight on the risk assessment, noting that the risk assessment accounts for both the level and the form of the current standard and the manner by which attainment with the standard is determined. Further, the minority of the CASAC stated that the “risk assessment indicates that the annual standard is the controlling standard across most of the urban study areas evaluated and revising the level of the 24-hour standard is estimated to have minimal impact on the PM_{2.5}-associated risks” and therefore, “the annual standard can be used to limit both long- and short-term PM_{2.5} concentrations” (Sheppard, 2022a, p. 18 of consensus responses). Further, the

minority of the CASAC placed more weight on the controlled human exposure studies, which show “effects at PM_{2.5} concentrations well above those typically measured in areas meeting the current standards” and which suggest that “the current standards are providing adequate protection against these exposures” (Sheppard, 2022a, p. 18 of consensus responses).

While the CASAC members expressed differing opinions on the appropriate revisions to the current standards, they did “find that both primary standards, 24-hour and annual, are critical to protect public health given the evidence on detrimental health outcomes at both short-term and long-term exposures including peak events” (Sheppard, 2022a, p. 13 of consensus responses). The comments from the CASAC also took note of uncertainties that remain in this reconsideration of the primary PM_{2.5} standards and they identified a number of additional areas for future research and data gathering and dissemination that would inform future reviews of the primary PM_{2.5} NAAQS (Sheppard, 2022a, pp. 14–15 of consensus responses).

2. Basis for the Proposed Decision

In reaching his proposed decisions to revise the level of the primary annual PM_{2.5} standard from its current level of 12.0 µg/m³ to within the range of 9.0 to 10.0 µg/m³, and to retain the current primary 24-hour PM_{2.5} standard (88 FR 5558, January 27, 2023), the Administrator carefully considered the assessment of the current evidence and conclusions reached in the 2019 ISA and ISA Supplement; the currently available exposure and risk information, including associated limitations and uncertainties, described in detail in the 2022 PA; the considerations

and staff conclusions and associated rationales presented in the 2022 PA; the advice and recommendations from the CASAC; and public comments that had been offered up to that point (88 FR 5558, January 27, 2023).

In reaching his proposed conclusions on whether the currently available scientific evidence and quantitative risk-based information support or call into question the adequacy of the public health protection afforded by the current primary PM_{2.5} standards, and as is the case with NAAQS reviews in general, the extent to which the current primary PM_{2.5} standards are judged to be adequate will depend on a variety of factors, including science policy and public health policy judgments to be made by the Administrator on the strength and uncertainties of the scientific evidence. The factors relevant to judging the adequacy of the standards also include the interpretation of, and decisions as to the weight to place on, different aspects of the results of the risk assessment for the study areas included and the associated uncertainties. Thus, in reaching proposed conclusions of the current standards, the Administrator recognized that such a determination depends in part on judgments regarding aspects of the evidence and risk estimates, and judgments about the degree of protection that is requisite to protect public health with an adequate margin of safety.

The Administrator's full rationale for his proposed conclusions is presented in section II.D.3 of proposal (88 FR 5658, January 27, 2023), but is also briefly summarized here. In reaching the proposed decision to revise the annual standard level to 9–10 µg/m³, the Administrator placed weight on the full body of scientific information. He noted that the 2019 ISA

finds that exposure to PM_{2.5} causes mortality and cardiovascular effects and is likely to cause respiratory effects, cancer, and nervous system effects as detailed further in section II.B.1 of the proposal. As detailed further in section II.B.4 of the proposal, he additionally noted that the 2019 ISA identifies at-risk populations at greater risk of health effects from exposure to PM_{2.5}, including children, older adults, people with pre-existing respiratory or cardiovascular disease, minority populations, and low socioeconomic status (SES) populations.

The Administrator also recognized that epidemiologic studies provide the strongest scientific evidence when evaluating the adequacy of the level of the annual standard. He noted that there is no specific point in the air quality distribution of any epidemiologic study that represents a 'bright line' at and above which effects have been observed and below which effects have not been observed. In his proposed decision, he noted previous decision-making frameworks, which placed weight on values at or near the study-reported mean PM_{2.5} concentrations, which is where the most confidence in the reported association of the epidemiologic study exists. He further noted that there are a number of epidemiologic studies available in this reconsideration that use new PM_{2.5} exposure estimation techniques (*e.g.*, hybrid modeling) that were not used in epidemiologic studies that were available in previous reviews. These recent epidemiologic studies that use new exposure estimation techniques report long-term mean PM_{2.5} concentrations that are well below corresponding design values, which is an important consideration in reaching decisions on the level of the annual PM_{2.5} standard.

In reaching his proposed decision, the Administrator noted that a level of 9–10 $\mu\text{g}/\text{m}^3$ would near or below the reported 25th percentiles in key U.S. based epidemiologic studies, while also recognizing that he has less confidence in the magnitude and significance of the association at even lower percentiles (*e.g.*, 10th percentile), where even fewer health events are observed. The Administrator also noted that a proposed level of 9–10 $\mu\text{g}/\text{m}^3$ would be near the mean $\text{PM}_{2.5}$ reported in Canadian based studies, though he also recognized that there are a number of factors associated with the studies in Canada (*e.g.*, exposure environments) that make it more difficult to compare mean concentrations from Canadian studies to design values, which determine compliance with the standard in the U.S.

The Administrator took note of additional pieces of scientific evidence, which were not available in previous reviews, including restricted analyses, which support that the association seen in epidemiologic studies does not just occur from the peaks of the exposure distribution. Additionally, he notes that a level of 9–10 $\mu\text{g}/\text{m}^3$ would be below the starting concentration in newly available accountability studies, though he did note that it is more difficult to interpret these studies in the context of selecting the level of the annual $\text{PM}_{2.5}$ standard.

Further, the Administrator took into consideration the advice of the CASAC, noting that all members included 10 $\mu\text{g}/\text{m}^3$ in their recommended range, and that the proposed range of 9–10 $\mu\text{g}/\text{m}^3$ for the level of the primary annual $\text{PM}_{2.5}$ standard was within the range recommended by the majority of the CASAC.

In reaching the proposed conclusion of a range between 9–10 $\mu\text{g}/\text{m}^3$, the Administrator noted that a

level as high as $11 \mu\text{g}/\text{m}^3$ might not provide an adequate margin of safety, given that $11 \mu\text{g}/\text{m}^3$ was well above many of the epidemiologic study-reported mean $\text{PM}_{2.5}$ concentrations. Additionally, the Administrator noted the uncertainties associated with the scientific and quantitative information supporting a level as low as $8 \mu\text{g}/\text{m}^3$, which call into question the potential public health improvements of a standard below $9 \mu\text{g}/\text{m}^3$. The Administrator specifically noted the lack of key U.S. studies with mean concentrations below $9.3 \mu\text{g}/\text{m}^3$ and he further noted that the risk assessment suggests that the risk remaining under a standard of $8 \mu\text{g}/\text{m}^3$ would occur at very low concentrations (*e.g.*, mainly $7 \mu\text{g}/\text{m}^3$ and below).

As such, the Administrator's proposed decision noted that the current $\text{PM}_{2.5}$ annual standard did not adequately provide requisite protection against exposures to $\text{PM}_{2.5}$ and that a proposed range of 9–10 $\mu\text{g}/\text{m}^3$ would provide an adequate margin of safety.

In his proposed decision to retain the current primary 24-hour $\text{PM}_{2.5}$ standard with a level of 35 $\mu\text{g}/\text{m}^3$, the Administrator first considered the scientific information related to short-term exposures to $\text{PM}_{2.5}$ and health effects. He noted that the controlled human exposure studies are the strongest line of evidence for informing his conclusions regarding the adequacy of the current 24-hour standard. In so doing, the Administrator recognized that controlled human exposure studies are conducted with healthy adult volunteers and that these studies do not include individuals who may be at increased risk of $\text{PM}_{2.5}$ -related health effects (*i.e.*, children, older adults, people with pre-existing diseases). He also noted that the effects observed in the controlled

human exposure studies (*e.g.*, changes in vascular function) are not effects that are judged to be clearly adverse. He recognized the most consistent evidence of effects in these studies occurs at higher concentrations (*e.g.*, $>120 \mu\text{g}/\text{m}^3$) following 1–5 hour exposures, and that one study observed effects at concentrations as low as $38 \mu\text{g}/\text{m}^3$ following 4-hour exposures. However, the Administrator reiterated that these studies do not tell us at exactly what concentrations an adverse effect might occur, especially for at-risk populations. As noted above in section II.A.2.c, controlled human exposure studies tend to include generally healthy adult individuals who are at a lower risk of experiencing health effects, and often do not include at-risk populations (*e.g.*, children, older adults, or individuals with pre-existing conditions). As such, the Administrator recognized that these studies are somewhat limited in their ability to inform at what concentrations effects may be elicited in in at-risk populations. The Administrator also considered air quality analyses in the 2022 PA that demonstrate that there will be very few, if any, days with $\text{PM}_{2.5}$ concentrations at levels evaluated in controlled human exposure studies that are associated with effects in areas that meet the current primary 24-hour $\text{PM}_{2.5}$ standard.

The Administrator also noted that as, in previous PM NAAQS reviews, the protection provided by the suite of standards (*e.g.*, annual and 24-hour standards) is evaluated together. He noted that the annual standard is the controlling standard in most areas of the country. He also considered air quality analyses in the 2022 PA that suggest that revision of the annual standard to a level between $9\text{--}10 \mu\text{g}/\text{m}^3$ would also control 24-hour $\text{PM}_{2.5}$ concentrations in most areas to, or below, $30 \mu\text{g}/\text{m}^3$. Finally, the

Administrator noted the agreement with the advice from the minority of CASAC and additionally noted the limited rationale and evidence provided by the majority CASAC's recommendation to support revision of the 24-hour standard. As such, the Administrator proposed to retain the current 24-hour standard with its level of 35 $\mu\text{g}/\text{m}^3$.

Additionally, the Administrator proposed to conclude that it is appropriate to retain all other elements (*i.e.*, indicator, averaging time, and form) of the annual and 24-hour standards.

3. Comments on the Proposed Decision

With respect to the adequacy of the primary annual $\text{PM}_{2.5}$ standard, a number of commenters, primarily those from industry and industry groups, non-governmental organizations, and some State and local governments, disagree with the EPA's proposed decision to revise the level of the primary annual $\text{PM}_{2.5}$ standard. These commenters generally expressed the view that the current standards provide the requisite degree of public health protection and should be retained, consistent with the 2020 final decision. In supporting their view, these commenters assert that the scientific evidence available in this reconsideration is essentially unchanged since the 2020 final decision and that the additional scientific evidence and quantitative risk information available for the reconsideration does not support strengthening the primary annual $\text{PM}_{2.5}$ standard. These commenters also assert that uncertainties associated with the available scientific evidence have not changed since the 2020 final decision, and they note that these uncertainties were essential factors in the then-Administrator's decision to retain the primary annual $\text{PM}_{2.5}$ standard. These commenters argue

that, while the current Administrator acknowledges these uncertainties, he does not place enough weight on them in reaching his conclusions regarding the current standard. The commenters specifically highlight uncertainties related to exposure misclassification, confounding, and other sources of potential bias, which they claim supports retaining the current level of the annual standard. These commenters also note that these uncertainties were emphasized by the minority of the CASAC in their review of the 2021 draft PA, and the commenters further suggest that the lack of consensus from the CASAC on the appropriate level for the primary annual PM_{2.5} standard show that the research is unclear. The commenters contend that there is not support in this reconsideration for deviating from the then-Administrator's decision in 2020.

In contrast, other commenters, primarily from public health and environmental organizations, some State and local elected representatives, and some State and local government agencies agree with the EPA's proposed decision that the primary annual PM_{2.5} standard is not adequate. These commenters support revising the level of the primary annual PM_{2.5} standard and emphasize that the available scientific evidence, in particular epidemiologic studies, along with the CASAC's advice in their review for the 2021 draft PA, provide strong support for the proposed decision. In particular, these commenters agree with the EPA's conclusions about the strength of the scientific evidence, including uncertainties, and they emphasize that the CASAC reached consensus in their review of the 2021 draft PA that the current primary annual PM_{2.5} standard is not adequate. Some of these commenters also note that a revised primary annual PM_{2.5} standard would result in significant

public health benefits by reducing morbidity and mortality associated with PM_{2.5} exposure, especially for at-risk populations.

The EPA agrees with commenters that the primary annual PM_{2.5} standard is not adequate. The EPA recognizes the longstanding body of health evidence supporting relationships between PM_{2.5} exposures (short- and long-term) and both mortality and serious morbidity effects. The evidence available in this reconsideration (*i.e.*, the studies assessed in the 2019 ISA and ISA Supplement summarized above in section II.A.2.a) reaffirms, and in some cases strengthens, the conclusions from the 2009 ISA regarding the health effects of PM_{2.5} exposures. As noted above, epidemiologic studies demonstrate generally positive and often statistically significant associations between PM_{2.5} exposures and health effects. Such studies report associations between estimated PM_{2.5} exposures and non-accidental, cardiovascular, or respiratory mortality; cardiovascular or respiratory hospitalizations or emergency room visits; and other mortality/ morbidity outcomes (*e.g.*, lung cancer mortality or incidence, asthma development). Recent experimental evidence, as well as evidence from epidemiologic panel studies, strengthens support for potential biological pathways through which PM_{2.5} exposures could lead to the serious effects reported in many population-level epidemiologic studies, including support for pathways that could lead to cardiovascular, respiratory, nervous system, and cancer-related effects. Moreover, these recent epidemiologic studies strengthen support for health effect associations at PM_{2.5} concentrations lower than in those evaluated in epidemiologic studies available at the time of previous reviews.

Additionally, as discussed in more detail in section I.C.5.b above, the ISA Supplement focused on studies that were most likely to inform decisions on the appropriate standard, but not to reassess areas that, based on the assessment of available science published since the cutoff date of the 2019 ISA and through 2021, were judged unlikely to have new information that would be useful for the Administrator's decision making. The ISA Supplement included U.S. and Canadian epidemiologic studies for health effect categories where the 2019 ISA concluded a causal relationship (*i.e.*, short- and long-term PM_{2.5} exposure and cardiovascular effects and mortality), as well as U.S. and Canadian epidemiologic studies that employed alternative methods for confounder control or conducted accountability analyses (*i.e.*, studies that examined the effect of a policy on reducing PM_{2.5} concentrations). These studies, summarized in section II.A.2.a above, examine both short- and long-term PM_{2.5} exposure and cardiovascular effects and mortality. Additionally, studies that employ alternative methods for confounder control, as described in II.A.2.a above and in Table 3–11 and of the 2022 PA (U.S. EPA, 2022b), use a variety of statistical methods to control for confounding bias. These studies consistently report positive associations, which further supports the broader body of epidemiologic evidence for both cardiovascular effects and mortality.

In addition, there are epidemiologic studies that provide supplemental information for consideration in reaching conclusions that the current suite of PM_{2.5} standards is not adequate. These studies include analyses that restrict annual average PM_{2.5} concentrations to concentrations below 12 µg/m³ and provide support for positive and statistically significant asso-

ciations with mortality and cardiovascular morbidity at mean PM_{2.5} concentrations below the current level of the primary annual PM_{2.5} standard (described above in section II.A.2.c.ii and in Table 3–10 of the 2022 PA (U.S. EPA, 2022b)). Recent accountability studies that have starting annual PM_{2.5} concentrations at or below 12 µg/m³ suggest public health improvements may occur at concentrations below 12 µg/m³. These studies indicate positive and statistically significant associations with mortality and morbidity (*e.g.*, cardiovascular hospital admissions) and reductions in PM_{2.5} concentrations in ambient air (described above in section II.A.2.c.ii and in Table 3–12 of the 2022 PA (U.S. EPA, 2022b)).

Thus, in considering the available scientific evidence to inform conclusions on the adequacy of the primary PM_{2.5} standards, the Administrator recognizes that the 2019 ISA and the ISA Supplement together provides a strong scientific foundation for concluding that the current primary PM_{2.5} standards are not adequate.

In addition to the scientific evidence above, the risk assessment estimates that the current primary annual PM_{2.5} standard could allow a substantial number of deaths in the U.S. Although the Administrator recognizes that while the risk estimates can help to place the evidence for specific health effects into a broader public health context, they should be considered along with the inherent uncertainties and limitations of such analyses when informing judgments about the potential for additional public health protection associated with PM_{2.5} exposures and related health effects. The Administrator takes into consideration these uncertainties, which are described in more detail in

section II.A.3.b above, but notes that the general magnitude of risk estimates supports the potential for significant public health impacts, particularly for lower alternative annual standard levels.

In the CASAC's review of the 2019 draft PA, the CASAC did not reach consensus on whether the current annual standard is adequate, with the majority of the CASAC recommending that the annual standard be retained and the minority of the CASAC recommending that the standard be revised. In their review of the 2021 draft PA, the CASAC unanimously recommended that the current annual standard is not sufficiently protective of public health (Sheppard, 2022a, p. 2 of consensus letter).

The EPA disagrees with the commenters who state that the available scientific and quantitative information available in this reconsideration does not provide support for the current Administrator to reach a different decision than the then-Administrator reached in the 2020 final action. The EPA agrees with these commenters that there are uncertainties associated with the currently available scientific evidence. The EPA has considered these uncertainties extensively both in reaching conclusions in the 2022 PA (U.S. EPA, 2022b, sections 3.4.3, 3.6.1, and 4.6.3) and in the proposal (88 FR 5604, 5609, January 27, 2023), and the EPA addresses more detailed public comments about these uncertainties, including those related to copollutant confounding, unmeasured confounding, and temporal and spatiotemporal confounding, in the Response to Comments document. However, we disagree with the commenters that the evidence does not provide support for the Administrator's conclusion that the current primary annual PM_{2.5} standard is not adequate to protect

public health with an adequate margin of safety, and should be revised. As described above, epidemiologic studies in the 2019 ISA and the ISA Supplement support and extend the evidence evaluated in the 2009 ISA, through studies conducted in diverse populations and geographic locations, using various statistical models and approaches to control for potential confounders, and using a variety of exposure assessment methodologies. Therefore, the consistent, positive associations reported across studies (U.S. EPA, 2019a, Figures 11–1 and 11–18; U.S. EPA, 2022a) are unlikely to be the result of unmeasured confounding and other biases are unlikely to account for the consistent positive associations observed across epidemiologic studies. Additionally, this reconsideration includes epidemiologic studies that were not before the then-Administrator for consideration in reaching his final decisions at the time of the 2020 decision and that specifically evaluate confounding using alternative methods for confounder control). These recent epidemiologic studies provide support for the current Administrator’s conclusion that the suite of primary PM_{2.5} standards are not adequate. While confounding was an uncertainty noted by the then-Administrator in the 2020 decision, he recognized “that methodological study designs to address confounding, such as causal inference methods, are an emerging field of study” (85 FR 82710, December 18, 2020). The ISA Supplement considered studies that employed statistical approaches that attempt to more extensively account for confounders and are more robust to model misspecification (*i.e.*, used alternative methods for confounder control),⁹² given

⁹² As noted in the ISA Supplement: “In the peer-reviewed literature, these epidemiologic studies are often referred to as causal inference studies or studies that used causal modeling

that such studies were highlighted by the CASAC in their review of the 2019 draft PA and identified in public comments on the 2020 proposal. Since the literature cutoff date for the 2019 ISA, multiple studies that employ alternative methods for confounder control have become available for consideration in the ISA Supplement and, subsequently, in this reconsideration. For example, one study before the Administrator in this reconsideration that was not available in the 2019 ISA is Schwartz et al. (2021), which used a causal modeling approach focused on exposure changes and controls for measured confounders by design in order to evaluate the association between long-term PM_{2.5} exposure and mortality in the Medicare population. The study authors found significant associations of PM_{2.5} with increased mortality rates using a causal modeling approach robust to omitted confounding. The results of this study and other studies in the ISA Supplement that employ alternative methods to control for confounders lend support to the robustness of positive associations between PM_{2.5} exposure and multiple morbidity and mortality endpoints exhibited across epidemiologic studies, and also indicate that unmeasured confounding and other biases are unlikely to account for the consistent positive associations observed across epidemiologic studies (U.S. EPA, 2022b, sections 3.1.1.3, 3.1.2.3, 3.2.1.3, and 3.2.2.3).

methods. For the purposes of this Supplement, this terminology is not used to prevent confusion with the main scientific conclusions (*i.e.*, the causality determinations) presented within an ISA. In addition, as is consistent with the weight-of-evidence framework used within ISAs and discussed in the Preamble to the Integrated Science Assessments, an individual study on its own cannot inform causality, but instead represents a piece of the overall body of evidence” (U.S. EPA, 2022a, p. 1–3).

Further, the EPA disagrees with the commenters who argue that the Administrator did not appropriately consider the strengths and limitations of the health evidence in reaching his decision to revise the current primary annual PM_{2.5} standard in this reconsideration. In reaching his proposed decision, the Administrator considered the entire body of evidence and how to appropriately weigh the uncertainties associated with the health evidence (88 FR 5617, January 27, 2023). Such an approach is consistent with setting standards that are neither more nor less stringent than necessary, recognizing that “Congress provided that the Administrator is to use his judgment in setting air quality standards precisely to permit him to act in the face of uncertainty,” the Administrator must set standards on “the frontiers of scientific and medical knowledge” and “Congress directed the Administrator to err on the side of caution in making the necessary decisions.” *Lead Indus. Ass’n, Inc. v. EPA*, 647 F.2d 1130, 1155 & n.50 (D.C. Cir. 1980) (quoting H.R. Rep. No. 95–294, at 50). As such, a determination of identifying a specific level at which the standard should be set necessarily requires the Administrator’s judgement (e.g., weighing the uncertainties and margin of safety).

Additionally, the EPA disagrees with the commenters that contend that there is no basis in this reconsideration for deviating from the previous Administrator’s decision in 2020. It is well-established that in CAA section 109 Congress specifically left the determination of the requisite NAAQS to the judgment of the Administrator and, moreover, that “decisions about the appropriate NAAQS level must ‘necessarily . . . rest largely on policy judgments.’” *Mississippi v. EPA*, 744 F.3d

1344, 1357 (D.C. Cir. 2013) (quoting *Lead Industries Ass’n v. EPA*, 647 F.2d 1130, 1147 (D.C. Cir. 1980)). As the Court of Appeals for the D.C. Circuit has noted, “Every time EPA reviews a NAAQS, it (presumably) does so against contemporary policy judgments and the existing corpus of scientific knowledge.” *Id.*, at 1343.

In this reconsideration, both the existing corpus of scientific knowledge as well as the Administrator’s policy judgments about how to interpret and weigh that evidence to protect public health with an adequate margin of safety have changed. The expansion of the air quality criteria to encompass additional studies, information and analyses in the ISA Supplement and 2022 PA, as well as the additional consideration of the scientific record by the CASAC and the public provided the Administrator with significant additional information on which to base his decision.⁹³ In addition, in this reconsideration, the Administrator is reaching different judgments about how to weigh the epidemiologic evidence, including the uncertainties in the scientific evidence, and how to ensure an adequate margin of safety to protect against uncertain harms, compared to the approach in the 2020 final decision. For example, as discussed in greater detail above in section II.A.1 and in the 2020 notice of final rulemaking (85 FR 82717, December 18, 2020), in considering the epidemiologic

⁹³ The EPA notes that, in considering the additional scientific evidence available in this reconsideration, one member of the CASAC who reviewed both the 2019 draft PA and the 2021 draft PA found that the available scientific and quantitative information available in this reconsideration supported revising the level of the primary annual PM_{2.5} standard, whereas he recommended retaining the standard during the review of the 2019 draft PA.

evidence as part of his decision to retain the current primary annual PM_{2.5} standard in the 2020 decision, the then-Administrator placed weight on the mean of the study-reported means (or medians) (*i.e.*, 13.5 µg/m³) from key U.S. epidemiologic studies that are monitor-based being above the level of the current primary annual PM_{2.5} standard of 12.0 µg/m³. By contrast, in this reconsideration, the current Administrator has taken an approach more similar to how the EPA has considered study-reported mean PM_{2.5} concentrations relative to the level of the primary annual PM_{2.5} standard in other recent PM NAAQS reviews. In so doing, in reaching his decision to revise the level of the primary annual PM_{2.5} standard to 9.0 µg/m³, he is using an approach that places weight on selecting a level for the standard that is below the study-reported mean PM_{2.5} concentrations reported in key U.S. epidemiologic studies, including recent epidemiologic studies that use hybrid model-based methods, as well as being near or below the 25th percentile PM_{2.5} concentrations in those key U.S. epidemiologic studies that report these concentrations.

As such and further detailed in section II.B.4 below, in considering the adequacy of the current primary PM standards in this reconsideration, the Administrator has carefully considered the: (1) Policy-relevant evidence and conclusions contained in the 2019 ISA and 2022 ISA Supplement; (2) the quantitative information presented and assessed in the 2022 PA; (3) the evaluation of this evidence, the quantitative information, and the rationale and conclusions presented in the 2022 PA; (4) the advice and recommendations from the CASAC; and (5) public comments. The Administrator concludes that the current suite of primary PM_{2.5}

standards are not adequate to protect public health with an adequate margin of safety.

The four basic elements of the NAAQS (indicator, averaging time, form, and level) are considered collectively in evaluating the health protection afforded by a standard. The EPA received relatively few comments on the averaging time and form for the primary PM_{2.5} standards, but those who did provide comments on these elements were primarily from public health and environmental organizations, State and local elected representatives, and State and local government agencies. Some commenters assert that the current 24-hour averaging time for the primary 24-hour PM_{2.5} standard does not adequately protect against short-term peaks. These commenters further state that the 24-hour averaging time protects against chronic exposures but does not adequately protect against serious acute risks from certain sources such as prescribed burning. Also, a few commenters explicitly recommend that a subdaily averaging time would be more appropriate, although none of the commenters recommended a specific averaging time for consideration. Additionally, some commenters cite to the CASAC's advice in their review of the 2021 draft PA that future reviews of the PM NAAQS should include evaluation of alternative forms and averaging times of the current primary 24-hour PM_{2.5} standard.

The EPA disagrees with commenters that the current primary 24-hour PM_{2.5} standard, with its 24-hour averaging time, does not adequately protect against short-term peaks and disagrees that there is sufficient information to conclude that a subdaily averaging time would be more appropriate than a 24-hour averaging time. The EPA has

reviewed the currently available scientific evidence and finds that it does not indicate that alternative averaging times would be more appropriate for the primary PM_{2.5} standards. Accordingly, the EPA concludes that it is appropriate to retain both the annual and 24-hour averaging times for standards meant to protect against long- and short-term PM_{2.5}.

As noted in the proposal, the 2019 ISA and ISA Supplement found that the scientific evidence continues to provide strong support for health effect associations with both long-term (*e.g.*, annual or multi-year) and short-term (*e.g.*, mostly 24-hour) exposures to PM_{2.5}. Epidemiologic studies continue to provide strong support for health effects associated with short-term PM_{2.5} exposures based on 24-hour PM_{2.5} averaging periods, and we note that subdaily effect estimates are less consistent and, in some cases, smaller in magnitude (88 FR 5618, January 27, 2023). Controlled human exposure and panel-based studies of subdaily exposures typically examine subclinical effects rather than the more serious population-level effects that have been reported to be associated with 24-hour exposures (*e.g.*, mortality, hospitalizations). Collectively, the 2019 ISA concludes that epidemiologic studies do not indicate that subdaily averaging periods are more closely associated with health effects than the 24-hour average exposure metric (U.S. EPA, 2019a, section 1.5.2.1). Additionally, the EPA notes that while recent controlled human exposure studies provide consistent evidence for cardiovascular effects following PM_{2.5} exposures for less than 24 hours (*i.e.*, <30 minutes to 5 hours), exposure concentrations in these studies are well-above the ambient concentrations typically measured in locations meeting the current standards (U.S. EPA, 2022a, section 3.3.3.1).

Therefore, this information does not indicate that a revision to the averaging time is needed to provide additional protection against subdaily PM_{2.5} exposures, beyond that provided by the current primary standards. This conclusion is also supported by the advice given to EPA by the CASAC in their review of the 2021 draft PA, which reached consensus that averaging times for the standards should be retained, without revision (Sheppard 2022a, p. 2 of consensus letter).⁹⁴ For all of these reasons, the Administrator concludes that the currently available evidence does not support considering alternatives to the annual and 24-hour averaging times for standards meant to protect against long- and short-term PM_{2.5} exposures.

Multiple commenters, primarily from public health and environmental organizations, recommend revising the form of the primary 24-hour PM_{2.5} standard to a 99th percentile to provide increased public health protection against peak PM_{2.5} exposures, particularly for at-risk populations. These commenters express concern that the current 98th percentile form allows 7 exceedances per year and contend that a 99th percentile form that would allow half that number is more appropriate. Commenters also cite to the CASAC's advice in their review of the 2021 draft PA, which recommended that the EPA consider alternative percentiles for the form of the primary 24-hour PM_{2.5} standard in the future.

The EPA disagrees that the current 98th percentile form does not provide the requisite public health

⁹⁴ In providing advice on the 2019 draft PA, the CASAC did not weigh in specifically on the averaging time of the primary 24-hour PM_{2.5} standard but did recommend that the standard be retained because the available evidence does not call into question its adequacy (Cox, 2019b, p. 3 of consensus letter).

protection against peak PM_{2.5} exposures and concludes that the 98th percentile, averaged over three years, remains appropriate for the primary 24-hour PM_{2.5} standard. As noted in previous reviews and in the proposal, the EPA has set both an annual standard and a 24-hour standard to provide protection from health effects associated with both long- and short-term exposures to PM_{2.5} (62 FR 38667, July 18, 1997; 88 FR 5620, January 27, 2023). With respect to the form of the 24-hour standard, as described just above, the epidemiologic studies continue to provide strong support for health effect associations with short-term (*e.g.*, mostly 24-hour) PM_{2.5} exposures and controlled human exposure studies provide evidence for health effects following single short-term “peak” PM_{2.5} exposures (88 FR 5619, January 27, 2023). Both the 98th and the 99th percentile form provide a very high degree of control of peak concentrations. As the commenters point out, a 99th percentile would reduce the number of allowable exceedances to four days per year. The EPA anticipates, however, that such a revision to the form would make the attainment status of an area more subject to change from unpredictable nonanthropogenic factors, such as meteorological events. The EPA has often noted that frequent shifts in attainment status that are unrelated to long-term air quality trends is inconsistent with providing a stable target for air quality planning and risk management programs, which in turn provides for the most effective public health protection in the long run (78 FR 3127, January 15, 2013; 80 FR 65351, October 26, 2015). Thus, the EPA’s interest in an appropriate degree of stability is to ensure that the State air quality programs are effective in controlling pollution and that the public health protections of the standard are

achieved. As discussed above, while recent controlled human exposure studies provide consistent evidence for cardiovascular effects following PM_{2.5} exposures for less than 24 hours (*i.e.*, < 30 minutes to 5 hours), exposure concentrations in these studies are well-above the ambient concentrations typically measured in locations meeting the current standards (U.S. EPA, 2022a, section 3.3.3.1), and the 98th percentile form is very effective at limiting occurrences of exposures of concern. Taking into consideration the available scientific information and quantitative information, the EPA therefore concludes that the 98th percentile form provides an appropriate balance between limiting the occurrence of peak 24-hour PM_{2.5} concentrations and identifying a stable target for risk management programs. This conclusion is also supported by the advice given to the EPA by the CASAC in their review of the 2021 draft PA, where they reached consensus that the form for the standards should be retained, without revision (Sheppard, 2022a, p. 2 of consensus letter).⁹⁵

Additionally, the EPA recognizes the CASAC's advice in their review of the 2021 draft PA, where they recommended "that in future reviews, the EPA provide a more comprehensive assessment of the 24-hour standard that includes the form as well as the level" (Sheppard, 2022a, p. 4 of consensus letter). This advice is reflected in the proposal by the EPA, which noted "that it would be appropriate to gather additional air quality and scientific information and further consider these issues in future reviews" (88 FR 5619, January 27, 2023). The EPA will consider

⁹⁵ The CASAC did not provide advice or recommendations regarding the forms of the primary PM_{2.5} standards in their review of the 2019 draft PA (Cox, 2019b).

the information provided by the commenters regarding the form of the 24-hour PM_{2.5} standard in the next review of the PM NAAQS.

A number of commenters who support revising the level of the primary annual PM_{2.5} standard, particularly those who support a revised level of 8 µg/m³, disagree with how the EPA has emphasized the mean PM_{2.5} concentrations reported in key epidemiologic studies to inform conclusions on the level of the primary PM_{2.5} standard. These commenters argue that, in this reconsideration, the EPA is arbitrarily emphasizing uncertainties in key epidemiologic studies in the focus on mean concentrations. Many of these commenters recommend that the EPA consider the full distribution of PM_{2.5} concentrations from the key epidemiologic studies in reaching conclusions on the appropriate level for the primary annual PM_{2.5} standards, in particular concentrations below the mean, such as the 25th percentile. In supporting this view, commenters point to the CASAC's advice in their review of the 2021 draft PA, where the majority of the CASAC stated that the "use of the mean to define where the data provide the most evidence is conservative since robust data clearly indicate effects below the mean in concentration- response functions" (Sheppard, 2022a, p. 16 of consensus responses), and that "[e]pidemiologic studies require consideration of distribution around the mean of exposure to identify effects and thus lower levels than the mean must be considered as part of the range where the data provide higher confidence" (Sheppard, 2022a, p. 13 of consensus responses).

As an initial matter, consistent with some previous approaches and as detailed by the Administrator in reaching conclusions on the level of the primary

annual $\text{PM}_{2.5}$ standard in section II.B.4 below, the EPA considers the long-term study-reported mean $\text{PM}_{2.5}$ concentrations from key epidemiologic studies and sets the level of the standard to somewhat below the lowest long-term mean $\text{PM}_{2.5}$ concentration. Additionally, as discussed further below, the EPA also considers the available information from a subset of epidemiologic studies that report exposure estimates or health events at the 25th and 10th percentiles of $\text{PM}_{2.5}$ concentrations. The Administrator gives some weight to the 25th percentile data, although he recognizes that his confidence in the magnitude and significance in the reported concentrations, and their ability to inform decisions on the appropriate level of the annual standard, decreases with reduced data (below the mean) and diminishes further at percentiles that are even further below the mean and the 25th percentile. Therefore, the Administrator places weight on the reported 25th percentiles concentrations, rather than the reported 10th percentile concentrations, for the subset of studies that report lower percentile $\text{PM}_{2.5}$ concentrations in reaching his conclusions regarding the appropriate level for the primary annual $\text{PM}_{2.5}$ standard.

In considering the available scientific evidence to reach decisions on the adequacy of the suite of primary $\text{PM}_{2.5}$ standards, the EPA notes that in previous PM NAAQS reviews (including the 1997, 2006 and 2012 reviews), evidence-based approaches were used that focused on identifying standard levels near or somewhat below long-term mean concentrations reported in key epidemiologic studies. These approaches were supported by the CASAC in previous reviews

and were supported in this reconsideration by the CASAC in their review of the 2021 draft PA.⁹⁶

In considering the available scientific evidence, the EPA notes the strength of the epidemiologic evidence which includes multiple studies that consistently report positive associations for short- and long-term PM_{2.5} exposures and mortality and cardiovascular effects. Some available studies also use a variety of statistical methods to control for confounding bias and report similar associations, which further supports the broader body of epidemiologic evidence for both mortality and cardiovascular effects. Additionally, the EPA notes that recent epidemiologic studies strengthen support for health effect associations at PM_{2.5} concentrations lower than in those evaluated in epidemiologic studies available at the time of previous reviews.

⁹⁶ The Administrator notes that, in their review of the 2021 draft PA, a majority of members of the CASAC noted that there are some limitations for this approach “for the purpose of informing the adequacy of the standards” (Sheppard, 2022a, p. 8 of consensus responses) and advised that future reviews should include evaluation of other metrics, including the distribution of concentrations reported in epidemiologic studies and in analyses restricting concentrations to below the current standard level. The Administrator also notes that, in their review of the 2019 draft PA, the CASAC lacked consensus on the inferences to be drawn from the epidemiologic evidence, with a majority of CASAC having concerns about confounding, error and bias and concluding that newer studies did not provide a basis for revising the current standards, while a minority concluded that the evidence, including more recent studies showing associations in areas with average long-term PM_{2.5} concentrations below the current annual standard, supported their conclusion that the current standards are inadequate (Cox, 2019b, pp. 8–9 of consensus responses).

While these epidemiologic studies evaluate associations between distributions of ambient $\text{PM}_{2.5}$ concentrations and health outcomes, they do not identify the specific exposures that led to the reported effects. As such, there is no specific point in the air quality distribution of any epidemiologic study that represents a “bright line” at and above which effects have been observed and below which effects have not been observed.

Studies of daily $\text{PM}_{2.5}$ exposures examine associations between day-to-day variation in $\text{PM}_{2.5}$ concentrations and health outcomes, often over several years. While there can be considerable variability in daily exposures over a multi-year study period, most of the estimated exposures reflect days with ambient $\text{PM}_{2.5}$ concentrations around the middle of the air quality distributions examined (*i.e.*, “typical” days rather than days with extremely high or extremely low concentrations). Similarly, for studies of annual $\text{PM}_{2.5}$ exposures, most of the health events occur at estimated exposures that reflect annual average $\text{PM}_{2.5}$ concentrations around the middle of the air quality distributions examined. In both cases, epidemiologic studies provide the strongest support for reported health effect associations for this middle portion of the $\text{PM}_{2.5}$ air quality distribution, which corresponds to the bulk of the underlying data, rather than the extreme upper or lower ends of the distribution. Therefore, in the absence of discernible thresholds, long-term study-reported means—that is, the study-reported ambient $\text{PM}_{2.5}$ concentrations in the epidemiologic studies that reflect estimated exposures with a focus around the middle portion of the $\text{PM}_{2.5}$ air quality distribution where the bulk of the observed data reside—provide the strongest

support for reported health effect associations in epidemiologic studies.

Based on the air quality criteria for this reconsideration, as described in the 2019 ISA, ISA Supplement, 2022 PA and the proposal, the EPA believes it is appropriate to continue to use the mean PM_{2.5} concentrations from the key epidemiologic studies to inform conclusions regarding the appropriate level for the primary annual PM_{2.5} standard.

There are a large number of key epidemiologic studies available in this reconsideration to inform conclusions regarding the level of the primary annual PM_{2.5} standard. For the key U.S. epidemiologic studies, the study-reported mean PM_{2.5} concentrations range from 9.9–16.5 µg/m³ for monitor-based studies (Figure 1 above) and range from 9.3–12.2 µg/m³ for hybrid modeling-based studies (Figure 2 above).

In addition to the study-reported mean PM_{2.5} concentrations, the EPA agrees with the CASAC's advice in their review of the 2021 draft PA and public comments that information on other percentiles below the mean can also be informative, and the EPA notes that the CASAC advised that for the purpose of informing the adequacy of the standards, future reviews should include an evaluation of other metrics, including the distribution of concentrations reported in epidemiologic studies (Sheppard, 2022a, p. 9 of consensus responses). As such, in reaching conclusions in this reconsideration, the EPA takes note of the additional study-reported PM_{2.5} concentrations below the means (*e.g.*, 25th and 10th percentiles) that are available from a limited subset of key U.S. epidemiologic studies. As shown in Figures 1 and 2 above, six key U.S. epidemiologic studies report information on other percentiles (*e.g.*, 10th and 25th percentiles of

PM_{2.5} concentrations or 10th and 25th percentiles of PM_{2.5} concentrations associated with health events) that are below the mean.⁹⁷ Three of the studies are monitor-based and three are hybrid model-based.

The key U.S. epidemiologic studies that report percentiles below the mean that are monitor based are older studies. These studies included smaller numbers of people than the newer hybrid model-based studies. For the three older, monitor-based studies, because the cohorts were smaller in size, a relatively smaller portion of the health events were observed in the lower part of the air quality distribution. As such, our confidence in the magnitude and significance of the associations begins to decrease in the lower part of the air quality distribution of those older, monitor-based studies.

The three newer, hybrid model-based studies have larger cohort sizes than the older, monitor-based studies and, as noted by commenters, have more health events in the lower part of the air quality distribution. For these reasons, the EPA notes that we have more confidence in the reported association at concentrations lower than the reported mean in these more recent hybrid model-based studies, particularly at the 25th percentile compared to the 10th percentile. While the cohort sizes in the more recent, hybrid model-based studies are larger than the older, monitor-based studies, the EPA notes that the 10th percentiles are well below the middle portion of the air quality distribution for which we have the greatest confidence, and as noted above, our

⁹⁷ The Wang et al. (2017) study only reports the 25th percentile of the estimated PM_{2.5} concentrations, not the 10th percentile.

confidence in the magnitude and significance of associations in the lower parts of the air quality distribution begins to decrease. While we have more confidence in the lower percentiles because of the larger cohort sizes in the more recent hybrid model-based studies, we also have more confidence in the 25th percentiles than in the 10th percentiles, which are further from the means and closer to the lower end of the air quality distribution.

In considering how the six studies that report percentiles lower than the mean can be used to inform conclusions regarding the level of the primary annual $\text{PM}_{2.5}$ standard, the EPA first notes that the three monitor-based epidemiologic studies (Bell et al., 2008; Franklin et al., 2007; Zanobetti and Schwartz, 2009) report 25th percentile concentrations that are at or above $11.5 \mu\text{g}/\text{m}^3$. For two of the more recent hybrid model-based studies (Di et al., 2017b; Wang et al., 2017), the 25th percentile of estimated $\text{PM}_{2.5}$ concentrations are just above $9 \mu\text{g}/\text{m}^3$, while one study (Di et al., 2017a) reports a $\text{PM}_{2.5}$ concentrations corresponding to 25th percentiles of health events of just below $7 \mu\text{g}/\text{m}^3$. For the Di et al. (2017a) study, the 25th percentile $\text{PM}_{2.5}$ concentration ($6.7 \mu\text{g}/\text{m}^3$) is based on the $\text{PM}_{2.5}$ concentration at which the 25th percentile of deaths occur in the study, while the reported mean ($11.6 \mu\text{g}/\text{m}^3$) is based on estimated $\text{PM}_{2.5}$ exposure concentrations. Additionally, the 25th percentiles of the other two recently available hybrid model-based studies (Di et al., 2017b; Wang et al., 2017) are based on estimated $\text{PM}_{2.5}$ concentrations. As such, the $\text{PM}_{2.5}$ concentration at which the 25th percentile of health events occur may be different from the estimated 25th percentile $\text{PM}_{2.5}$ concentration in this study (Di et al., 2017a), creating an uncertain basis for comparison with the studies by

Di et al. (2017b) and Wang et al. (2017). The 25th percentiles from these studies, in particular those that are more recently available, help to inform the Administrator's judgments regarding the appropriate level for the primary annual PM_{2.5} standard.

Some commenters disagree with the EPA's consideration of the relationship between mean PM_{2.5} concentrations reported in the key epidemiologic studies and design values to inform conclusions on the appropriate level for the primary annual PM_{2.5} standards. Commenters contend that setting the level of the primary annual standard below the design values in the epidemiologic studies, rather than below the study-reported mean concentrations, might keep overall mean PM_{2.5} concentrations throughout an area below the study-reported means but allow PM_{2.5} concentrations in some parts of the area, including near the "design value monitor" to remain above the study-reported mean PM_{2.5} concentrations, which are the concentrations where the evidence of health effects is strongest. Commenters contend that such a decision framework would not result in a standard that would provide requisite protection with an adequate margin of safety, particularly for at-risk populations. These commenters further support this view by citing the CASAC's advice in their review of the 2021 draft PA, where the majority of CASAC stated that "even if a design value is somewhat higher than the area average, it reflects actual exposure levels and thus any portion of the population living near the design value monitor does experience exposures at that level and consequent health effects of exposure to that higher concentration" (Sheppard, 2022a, p. 14 of consensus responses). Additionally, these commenters suggest that the EPA should not deviate from the approach taken in the

2012 review, which was to set the standard at a level “somewhat below” the lowest mean $\text{PM}_{2.5}$ concentration in the key epidemiologic studies.

To the extent that commenters are suggesting that the EPA is setting the level of the primary annual $\text{PM}_{2.5}$ standard below the design values in the epidemiologic studies, rather than below the study-reported mean $\text{PM}_{2.5}$ concentrations, we disagree with the commenters. In reaching conclusions on the level of the primary annual $\text{PM}_{2.5}$ standard, the EPA considers the long-term study-reported mean $\text{PM}_{2.5}$ concentrations from key epidemiologic studies and sets the level of the standard to somewhat below the lowest long-term mean $\text{PM}_{2.5}$ concentration, not below the design values in the epidemiologic studies. Additionally, the EPA also considers the available information from a subset of epidemiologic studies that report exposure estimates or health events at the 25th and 10th percentiles of $\text{PM}_{2.5}$ concentrations. The EPA particularly considers the 25th percentile data, while recognizing that our confidence in the magnitude and significance in the reported concentrations, and the ability of the lower percentile $\text{PM}_{2.5}$ concentrations to inform decisions on the appropriate level of the annual standard, decreases with reduced data (below the mean) and diminishes further at percentiles that are even further below the mean and the 25th percentile.

However, the EPA notes that it is important to understand, and to not ignore, the relationship between the study-reported mean $\text{PM}_{2.5}$ concentrations reported in key epidemiologic studies and the area design value. As an initial matter, the NAAQS consists of all four elements of the standard (indicator, averaging time, form, and level) and

setting a standard that is requisite to protect public health includes consideration of all four elements together. Following implementation of the NAAQS, the design value is the metric used to determine compliance with the standard and is the statistic that describes the air quality status of a given location relative to the level of the primary annual $\text{PM}_{2.5}$ NAAQS. The design value is different from the study-reported mean $\text{PM}_{2.5}$ concentrations. This is because the study-reported mean $\text{PM}_{2.5}$ concentrations are an annual average $\text{PM}_{2.5}$ concentration, similar to the level of the standard, but the epidemiologic studies do not report statistics that take into account the other elements of the standard (*i.e.*, averaging time and form). Therefore, when considering the appropriate revisions to the annual $\text{PM}_{2.5}$ standard, the EPA must consider the protection provided by a revised standard taking into account all of the elements of the standard, not just the annual average $\text{PM}_{2.5}$ concentration alone.

In considering the annual standard, and in assessing the range of study-reported exposure concentrations for which we have the strongest support for adverse health effects observed in epidemiologic studies, the EPA focuses on whether the current primary annual $\text{PM}_{2.5}$ standard provides adequate protection against these exposure concentrations or if the level of the standard should be revised to provide the appropriate public health protection. This means that, as in some previous reviews, it is important to consider how the study means were computed and how these concentrations compare to the annual standard metric (including the level, averaging time and form) which must be met at the monitor with the highest $\text{PM}_{2.5}$ design value in an area for compliance with the NAAQS. This approach is based on the application of

a decision framework based on assessing means (as well as the lower distribution of reported PM_{2.5} concentration, as noted above) reported in key epidemiologic studies. In the 2012 review, the available key epidemiologic studies computed the mean PM_{2.5} concentrations using an average across monitor-based PM_{2.5} concentrations. As such, at that time, the decision framework used an approach based on maximum monitor concentrations to determine compliance with the standard, while selecting the standard level based on consideration of composite monitor concentrations (*i.e.*, selecting the standard level of 12.0 µg/m³ was just below the long-term study- reported mean PM_{2.5} concentrations in key epidemiologic studies). Further, the EPA conducted analyses that examined the differences in these two metrics (*i.e.*, maximum monitor concentrations, which is how compliance with the standard is assessed and composite monitor concentrations, which is how key epidemiologic studies report their mean concentrations) across the U.S. and in areas included in the key epidemiologic studies and found that the maximum design value in an area was generally higher than the monitor average across that area, with the amount of difference between the two metrics varying based on location and concentration (Hassett-Sipple et al., 2010; Frank, 2012). This information was taken into account by the then-Administrator's final decision in selecting a level of 12.0 µg/m³ for the primary annual PM_{2.5} standard in the 2012 review and discussed more specifically in her considerations on adequate margin of safety.

The relationship between the mean PM_{2.5} concentrations and the area design value continues to be an important consideration in evaluating the adequacy of the current or potential alternative

annual standard levels in this reconsideration. Again, in a given area, the area design value is based on the monitor in an area with the highest $\text{PM}_{2.5}$ concentrations and is used to determine compliance with the standard, including the averaging time and form of the standard (*i.e.*, an annual average over 3-years must not exceed the level of the annual $\text{PM}_{2.5}$ standard). The highest $\text{PM}_{2.5}$ concentrations spatially distributed in the area would generally occur at or near the area design value monitor and the distribution of $\text{PM}_{2.5}$ concentrations would generally be lower in other locations and at monitors in that area. As such, when an area is meeting a specific annual standard level (*e.g.*, $9.0 \mu\text{g}/\text{m}^3$), we would expect the annual average exposures (*i.e.*, a metric similar to the study-reported mean values) in that area to be at concentrations lower than that level (*e.g.*, lower than $9.0 \mu\text{g}/\text{m}^3$).

However, as described in section II.A.2.c.ii, we note that there are a substantial number of different types of epidemiologic studies available since the 2012 review, as assessed in both the 2019 ISA and the ISA Supplement, that make understanding the relationship between the mean $\text{PM}_{2.5}$ concentrations and the area design value an even more important consideration in this reconsideration (U.S. EPA, 2019a; U.S. EPA, 2022a). While the key epidemiologic studies in the 2012 review were all monitor-based studies, the recent epidemiologic studies in this reconsideration include hybrid modeling approaches that have emerged in the epidemiologic literature as an alternative to approaches that only use ground-based monitors to estimate $\text{PM}_{2.5}$ exposure. As assessed in the 2019 ISA and ISA Supplement, a substantial number of epidemiologic studies used hybrid model-based methods in evaluating associations between

PM_{2.5} exposure and health effects. Hybrid model-based studies employ various fusion techniques that combine ground-based monitored data with air quality modeled estimates and/or information from satellites to estimate PM_{2.5} exposures. While these studies provide a broader estimation of PM_{2.5} exposures compared to monitor-based studies (*i.e.*, PM_{2.5} concentrations are estimated in areas without monitors), the hybrid modeling approaches result in study-reported means that are more difficult to relate to the annual standard metric and to the maximum monitor design values used to assess compliance. In addition, to further complicate the comparison, when looking across these studies, we find variations in how exposure is estimated between such studies, and thus, how the study means are calculated. Two important variations across studies include: (1) Variability in spatial scale used (*i.e.*, averages computed across the national (or large portions of the country) versus a focus on only CBSAs); and (2) variability in exposure assignment methods (*i.e.*, averaging across all grid cells, averaging across a scaled-up area like a ZIP code, and population weighting). The differences in these approaches can result in studies reporting different study means, even though the association between PM_{2.5} exposure and health effects outcomes are similar.

To emphasize the importance of the differences between the studies, we revisit the simplified example in the State of Georgia from the 2022 PA that evaluates monitors and hybrid modeling approaches, noting that this example is useful to exhibit how the differences in the methods used to estimate exposure can lead to differences in the reported mean concentrations (U.S. EPA, 2022b, p. 3–71). In this example, for all monitors within the

Atlanta-Sandy Springs-Roswell CBSA, the average $\text{PM}_{2.5}$ concentration is $9.3 \mu\text{g}/\text{m}^3$, while the area design value (based on the highest monitored $\text{PM}_{2.5}$ concentration in the area) is $10.4 \mu\text{g}/\text{m}^3$. This comparison helps to illustrate the fact that composite monitor values tend to be somewhat lower than the highest area monitor values, consistent with the key points made in the 2012 review. This example also illustrates how monitors are sited to represent the higher concentrations within the area and that the area's annual design value, which is used for compliance with the standard, is calculated based on the highest monitor in the area. Next, in this example, mean $\text{PM}_{2.5}$ concentrations were calculated using similar approaches to those used in hybrid modeling-based epidemiologic studies to compute study-reported means, including (1) the average concentration across the entire State of Georgia; (2) the population-weighted average across the entire State; (3) the average concentration across the Atlanta-Sandy Springs-Roswell CBSA; and (4) the population-weighted average across the Atlanta-Sandy Springs-Roswell CBSA. At the urban level (*e.g.*, Atlanta-Sandy Springs-Roswell CBSA), the average $\text{PM}_{2.5}$ concentration when taking the mean of all grid cells is $9.2 \mu\text{g}/\text{m}^3$, whereas the population-weighted mean is $9.6 \mu\text{g}/\text{m}^3$. Across Georgia, the average $\text{PM}_{2.5}$ concentration using the hybrid approach and averaged across each grid cell is $8.3 \mu\text{g}/\text{m}^3$, which is lower than the population-weighted statewide average of $9.1 \mu\text{g}/\text{m}^3$. While this is a simple example completed in one State and one CBSA, it suggests that the lowest mean values tend to result from the approaches that use concentrations from all or most grid cells (*e.g.*, did not apply population weighting), both urban and rural, across the study

area to compute the mean. Higher mean values are observed when the approach focuses on the urban areas alone or when the approach incorporates population weighting. Overall, this example suggests that the means from studies using hybrid modeling approaches are generally lower than the means from monitor-based approaches, and means from both approaches are lower than the annual design values for the same area. Population weighting tends to increase the calculated mean concentration, likely because more densely populated areas also tend to have higher $\text{PM}_{2.5}$ concentrations. In other words, this simplified example exhibits how not all reported mean $\text{PM}_{2.5}$ concentrations from key epidemiologic studies are the same; some reported means are from monitored studies and some reported means are from hybrid modeling studies, while some reported means include only urban areas, and other reported means include both urban and rural areas, and some reported means include aspects of population weighting while others do not.

As detailed above in section I.D.5, in the air quality analyses comparing composite monitored $\text{PM}_{2.5}$ concentrations with annual $\text{PM}_{2.5}$ design values in U.S. CBSAs, maximum annual $\text{PM}_{2.5}$ design values were approximately 10% to 20% higher than annual average composite monitor concentrations (*i.e.*, averaged across multiple monitors in the same CBSA). Based on these results, this analysis suggests that there will be a distribution of concentrations and the maximum annual average monitored concentration in an area (at the design value monitor, used for compliance with the standard), will generally be 10–20% higher than the average across the other monitors in the area. Thus, in considering how the annual standard levels would relate to the study-

reported means from monitor-based studies, we can generally conclude that an annual standard level that is no more than 10–20% higher than monitor-based study-reported mean $\text{PM}_{2.5}$ concentrations would generally maintain air quality exposures to be below those associated with the study-reported mean $\text{PM}_{2.5}$ concentrations, exposures for which we have the strongest support for adverse health effects occurring.

Air quality analyses described in section I.D.5 above also consider information from the epidemiologic studies that utilized the hybrid modeling approaches. Analyses show that average maximum annual design values are 40–50% higher when compared to annual average $\text{PM}_{2.5}$ concentrations estimated without population weighting and are 15–18% higher when compared to average annual $\text{PM}_{2.5}$ concentrations with population weighting applied. Given these results, it is worth noting that for the studies using the hybrid modeling approaches, the choice of methodology employed in calculating the study-reported means (*i.e.*, using population weighting versus not applying aspects of population weighting), and not a difference in estimates of exposure in the study itself, can produce substantially different study-reported mean values, with the approach that does not employ population weighting producing a much lower reported mean $\text{PM}_{2.5}$ concentration. Therefore, the impact of the differences in methods is an important consideration when comparing mean concentrations across studies.

Because of the differences in the methods employed by the key epidemiologic studies, and as demonstrated by the example and air quality analyses above, the application of any decision framework that

considers the study-reported mean PM_{2.5} concentrations, and evaluates whether the current annual standard provides adequate protection against these reported exposure concentrations, is more complicated than the approaches used in past reviews. As such, the EPA disagrees with commenters who argue that the EPA's consideration of the relationship between mean PM_{2.5} concentrations reported in key epidemiologic studies and design values is not appropriate and should be ignored.

In considering the information from the epidemiologic studies, while the EPA does not dispute the reported associations of epidemiologic studies in hybrid modeling studies that report long-term mean concentrations and do not apply aspects of population weighting, using the reported long-term mean concentration from these studies in informing an appropriate level of the annual PM_{2.5} standard is more uncertain. Given this, hybrid modeling studies that do not apply aspects of population weighting provide less information on conclusions regarding the appropriate level of the primary annual PM_{2.5} standard. In support of this, some commenters also noted this consideration and suggested that the Administrator place lower weight on U.S. studies that did not use population weighting.

In considering the relationship between study-reported mean PM_{2.5} concentrations and the design values, the EPA agrees with commenters that setting the level of the primary annual standard below the design values, rather than below the study-reported mean concentrations, might allow PM_{2.5} concentrations in some part of the area near the design value monitor to remain above the study-reported mean PM_{2.5} concentration, where evidence of health effects

is strongest. As discussed in the proposal and in section II.B.4 below, the Administrator specifically notes that the highest $\text{PM}_{2.5}$ concentrations spatially distributed in the area would generally occur at or near the area design value monitor and that $\text{PM}_{2.5}$ concentrations will be equal to or lower at other monitors in the area. Furthermore, since monitoring strategies aim to site monitors in areas with higher $\text{PM}_{2.5}$ concentrations, monitored areas will generally have higher concentrations compared to areas without monitors. Therefore, by setting the level of the standard to $9.0 \mu\text{g}/\text{m}^3$ and just below the lowest study-reported mean $\text{PM}_{2.5}$ concentration (e.g., $9.3 \mu\text{g}/\text{m}^3$), the highest possible design value in a given area would be just below the study-reported mean $\text{PM}_{2.5}$ concentration, the concentration where we have the most confidence in the reported health effect association, and we anticipate that, based on our assessment of air quality data, the distribution of $\text{PM}_{2.5}$ concentrations would decrease even further with distance from the highest monitor (*i.e.*, the “design value monitor”) (see, for example, U.S. EPA, 2022a, section 2.3.3.2.4 and pp. 3–71 to 3–77). The Administrator further notes that when an epidemiologic study reports a mean $\text{PM}_{2.5}$ concentration that reflects the average of annual average monitor-based concentrations across an area, the area design value will generally be higher than the study-reported mean.

Similarly, he observes that when a study reports a mean that reflects the average of annual average concentrations estimated at across an area using a hybrid modeling approach, the area design value will generally be higher. As such, by evaluating the difference between the study-reported mean $\text{PM}_{2.5}$ concentrations and design values, the Administrator seeks to set the level of the standard below the lowest

study-reported mean, while ensuring that the primary annual $\text{PM}_{2.5}$ standard, including its averaging time and form, provides protection against the exposures associated with health effects observed in the key epidemiologic studies.

Additionally, the EPA disagrees with commenters who contend that the approach taken may allow $\text{PM}_{2.5}$ near the design value monitor to remain above the study-reported mean $\text{PM}_{2.5}$ concentrations. In following this approach of setting the annual standard level somewhat below the lowest reported mean $\text{PM}_{2.5}$ concentration, setting a standard level that requires the design value monitor (which is the highest monitor in an area) to be just below the lowest study-reported mean across key studies will generally result in distributions of even lower concentrations of $\text{PM}_{2.5}$ across the entire area, such that even those people living near an area design value monitor (where $\text{PM}_{2.5}$ concentrations are generally highest) will be exposed to $\text{PM}_{2.5}$ concentrations below the $\text{PM}_{2.5}$ concentrations reported in the epidemiologic studies where there is the highest confidence of an association. In their review of the 2021 draft PA, the majority of the CASAC had some concerns about the approach for comparing study means and design values, questioning whether such an approach would provide adequate protection for people who live in areas with higher concentrations, such as those living in areas with higher concentrations (*e.g.*, near the design value monitor) (Sheppard, 2022a, p. 8 of consensus responses). The minority of the CASAC, in considering the relationship between the study-reported mean $\text{PM}_{2.5}$ concentration and design values, stated that “the form of the standard and the way attainment with the standard is determined (*i.e.*,

highest design value in the CBSA) are important factors when determining the appropriate level for the standard” and noted that that design values are generally higher than area average exposure levels (Sheppard, 2022a, p. 17 of consensus responses). For all of the reasons discussed above, and consistent with the minority of the CASAC’s advice in their review of the 2021 draft PA, we disagree with the commenters that areas near the design value monitors would be expected to experience PM_{2.5} concentrations above the study-reported mean concentrations.

Several commenters assert that epidemiologic studies that restrict PM_{2.5} concentration to below 12 µg/m³ provide additional support for revising the level of the primary annual PM_{2.5} standard to 8 µg/m³. Some commenters disagree with the EPA’s assertion that the studies that employ restricted analyses do not provide enough information to understand how the studies were restricted to certain PM_{2.5} concentrations, with commenters providing additional information on the methods for restricted analyses. The commenters state that for the long-term studies at issue here, the study authors simply examined their database that linked subjects to long-term PM_{2.5} concentrations above 12 µg/m³, removed those data from the analysis, and reran the analysis. Additionally, one commenter provided an explanation of how the restricted analyses were conducted in studies for which he was an author. The commenter notes that for each year a subject was in the study, annual PM_{2.5} concentrations were assigned at the ZIP code level. If they moved, they were assigned the ZIP code level PM_{2.5} concentration for the new ZIP code. The commenter notes that these restricted analyses only included subjects whose annual PM_{2.5} exposure

never exceeded that restricted concentration for any year of follow-up in the study. The commenter suggested that the EPA may be concerned as to how PM_{2.5} concentrations in restricted analyses related to a design value since these are exposures for individuals who may have relocated during the study but argue that that is not the point. The commenters assert that while the analyses were restricted to people never exposed above certain concentrations over longer periods of time, the actual PM_{2.5} exposure was one year of exposure in most of these studies. Commenters also suggest that, since the EPA has deviated from its approach from the 2012 review for considering study-reported mean PM_{2.5} concentrations, the EPA should dismiss its concerns regarding being able to relate the mean PM_{2.5} concentrations from these studies to design values.

First, the EPA agrees with commenters that studies that employ restricted analyses can be used for informing conclusions regarding the appropriate level of the primary annual PM_{2.5} standard. However, the EPA disagrees that the information provided by the commenters provides a sufficient basis for an annual standard level of 8 µg/m³. Restricted analyses provide additional support for effects at lower concentrations, exhibiting associations for mean concentrations presumably below the mean concentrations for the main analyses. However, even though commenters note that any individual with exposures over the restricted analyses is excluded from restricted analyses, uncertainties remain with regard to how the mean PM_{2.5} concentrations in restricted analyses compare to design values, particularly in light of the removal of entire ZIP codes from analyses. Design values are calculated based on all measured PM_{2.5} concentrations. When an analysis is restricted below

a certain level, some parts of the air quality distribution are removed, but comparing the restricted mean to a design value is not possible because these are two different metrics. For example, in a study that restricts concentrations below $12 \mu\text{g}/\text{m}^3$, that represents only part of the air quality distribution, whereas a design value for that study area would include all $\text{PM}_{2.5}$ concentrations, not just the ones below $12 \mu\text{g}/\text{m}^3$. Therefore, in contrast to means from the main (unrestricted) analysis, it is not possible to compare mean concentrations from restricted analyses to design values. Further, it is unclear how one could evaluate such a relationship between design values and mean $\text{PM}_{2.5}$ concentrations from studies that use restricted analyses because the standard is set based on all of its elements (indicator, averaging time, form, and level) and removing $\text{PM}_{2.5}$ concentrations from the calculation of the design value for such a comparison would result in a metric that is no longer a design value that would provide the intended protection of the standard. This leads to greater uncertainty in how to use the mean $\text{PM}_{2.5}$ concentrations from these studies that use restricted analyses in a similar decision framework as the epidemiologic studies that report long-term mean $\text{PM}_{2.5}$ concentrations for health effect associations for the full distribution of $\text{PM}_{2.5}$ concentrations.

As described in reaching his conclusions in the section below, the Administrator judges that, despite these uncertainties and limitations, studies that use restricted analyses can provide supplemental information for consideration in reaching conclusions regarding both the adequacy and level of the standard. He notes two studies (Di et al., 2017b and Dominici et al., 2019) are available in this reconsideration that report means in their restricted

analyses (restricting annual average PM_{2.5} exposure below 12 µg/m³) and used population-weighted approaches to estimate PM_{2.5} exposures and these studies report mean PM_{2.5} concentrations of 9.6 µg/m³. He recognizes that these studies are just one line of evidence for consideration and that along with the broader evidence base, including the key epidemiologic studies, these studies provide support that the level of the primary annual PM_{2.5} standard should be set below 10 µg/m³.

We disagree with the commenters that concerns about relating the mean PM_{2.5} concentrations from restricted analyses to design values are not valid. As an initial matter, restricted analyses were not available and did not inform the 2012 decision to revise the annual PM_{2.5} standard level to 12.0 µg/m³. The approach in 2012 in revising the annual standard was to set the level to somewhat below the mean of key epidemiologic studies. As noted above, while the EPA believes that restricted analyses can help inform conclusions regarding the adequacy and the level of the primary annual PM_{2.5} standard, in the context of placing the studies in a decision framework to inform the appropriate level of the annual PM_{2.5} standard, the EPA has not deviated from its approach from the 2012 review. Given that restricted analyses are new since the 2012 review, the EPA disagrees with commenters that uncertainties associated with these studies should not be considered, and that these studies should be used in a similar manner to their main analyses in taking an approach to set a level of the standard somewhat below the lowest long-term reported mean PM_{2.5} concentration. Specifically, as detailed above there are uncertainties and limitations associated with relating the mean PM_{2.5} concentrations from these studies to design

values for studies that use restricted analyses, and many of these studies did not expressly report a mean PM_{2.5} concentration for the restricted analysis which makes it impossible to make such a comparison.

Several commenters contend that in considering the accountability studies, the EPA inappropriately reached conclusions regarding the level of the primary annual PM_{2.5} standard based on the starting PM_{2.5} concentrations of these studies, rather than the ending concentrations (*i.e.*, concentrations after a policy was implemented). The commenters assert that these studies provide support for revising the level of the primary annual PM_{2.5} standard to below the proposed range of 9–10 µg/m³ to protect public health with an adequate margin of safety.

Accountability studies examine the effect of a policy on reducing PM_{2.5} concentrations in ambient air and evaluate whether such reductions were observed to also lead to reductions in PM_{2.5}-associated health outcomes (*e.g.*, mortality). Additionally, accountability studies can reduce uncertainties related to residual confounding of temporal and spatial factors (U.S. EPA, 2022a, p. 3–25). Prior to implementation of the policies, three accountability studies newly available in this reconsideration and assessed in the ISA Supplement, report mean PM_{2.5} concentrations below the level of the current annual standard level (12.0 µg/m³) and ranged from 10.0 µg/m³ to 11.1 µg/m³ (Sanders et al., 2020b; Corrigan et al., 2018; and Henneman et al., 2019). These studies suggest that public health improvements may occur following the implementation of a policy that reduces annual average PM_{2.5} concentrations below the level of the current standard of 12.0 µg/m³, and

potentially below the lowest “starting” concentrations in these studies of $10.0 \mu\text{g}/\text{m}^3$. However, while the small number of studies may provide limited information related to informing the adequacy and level of the annual $\text{PM}_{2.5}$ standard, we note that accountability studies are only one line of evidence, and that these studies provide supplemental information for consideration in addition to the full body of evidence. Further, the EPA does not believe it would be appropriate to determine the level of the standard by reference to ending concentrations in accountability studies. Accountability studies are most informative in demonstrating that public health improvements may occur following the implementation of a policy that reduces annual average $\text{PM}_{2.5}$ concentrations below the level of the current standard of $12.0 \mu\text{g}/\text{m}^3$, and potentially below the lowest “starting” concentrations in these studies of $10.0 \mu\text{g}/\text{m}^3$. However, the EPA finds the available information from accountability studies is too limited to support a conclusion that the appropriate level at which to set the primary annual $\text{PM}_{2.5}$ standard would be equal to the ending concentrations of those studies, as the commenters suggest. These studies demonstrate that there are reductions in health outcomes when $\text{PM}_{2.5}$ concentrations are reduced in these studies from the starting concentration to the ending concentration, but do not provide support for health effect associations at or below the ending concentrations that would warrant a more stringent standard.

Commenters disagree with the Administrator placing less weight on the epidemiologic studies conducted in Canada when reaching conclusions regarding the level of the primary annual $\text{PM}_{2.5}$ standard. These commenters argue that the Canadian epidemiologic

studies provide support for setting the level at the lowest end of the proposed range (*i.e.*, 8 $\mu\text{g}/\text{m}^3$) because they report mean $\text{PM}_{2.5}$ concentrations, in some cases, below 8 $\mu\text{g}/\text{m}^3$. Commenters disagree with the EPA's reasoning for placing less weight on the Canadian epidemiologic studies, suggesting it conflicts with the approaches in previous PM NAAQS reviews and arguing that the findings of the Canadian epidemiologic studies can be directly translated into a primary annual $\text{PM}_{2.5}$ standard. Additionally, while the commenters disagree with the EPA's approach for considering the study-reported mean $\text{PM}_{2.5}$ concentrations and design values in general, they note that the CASAC, in their review of the 2021 PA, noted that "while there may be no design value in Canada, there are data that indicate what a U.S. design value would be if an area average like that found in the Canadian studies were to occur in the U.S." (Sheppard, 2022a, p. 13 of consensus responses). The commenters contend that the EPA failed to acknowledge this advice from the CASAC, specifically noting that the majority of the CASAC highlighted Canadian epidemiologic studies as a part of their rationale for revising the level of the primary annual $\text{PM}_{2.5}$ standard to within the range of 8–10 $\mu\text{g}/\text{m}^3$.

In considering the information from the epidemiologic studies in reaching his conclusions, the Administrator considered the full body of evidence, including studies conducted in the U.S. and Canada. However, as described in the proposal and in section II.B.4 below, the Administrator also recognizes that the exposure environments in the U.S. are different from those in Canada. In particular, the U.S. population density is approximately 43 people per square kilometer in the

contiguous U.S.⁹⁸ compared to Canada, which has one of the lowest population densities on the Earth with 4.2 people per square kilometer (Statistics Canada, 2023). This difference in population density between the U.S. and Canada was not as apparent, and did not need to be highlighted, in the 2012 review given that the available Canadian epidemiologic studies used population-weighting and focused on urban areas where monitors were available and population densities were more comparable with those in the U.S. Given this, the study-reported mean concentrations from U.S. and Canadian studies in the 2012 review were very similar. The recent epidemiologic evidence available in this reconsideration, however, includes studies that utilize approaches that highlight the importance of considering the differences between the two exposure environments in the U.S. versus Canada. When focusing on the recently available Canadian monitor-based epidemiologic studies in this reconsideration, the information indicates that these studies, unlike the studies available in the 2012 review, do not apply population weighting (*e.g.*, Lavigne et al., 2018; Liu et al., 2019). As noted in responding to other public comments above, the absence of population weighting is an important consideration that limits the utility of these studies in informing the appropriate level of the primary annual PM_{2.5} standard. In addition, there are recently available studies in the 2019 ISA and ISA Supplement that expand the geographical extent of the epidemiologic study areas by estimating exposure concentrations in areas where there are no monitors.

⁹⁸ All of the key U.S. epidemiologic studies considered in this reconsideration focus on all or subsections of the continental U.S.

To do this, these studies use either a statistical extrapolation of monitored values or use air quality modeling and other forms of data (*e.g.*, hybrid model-based approaches). For these Canadian studies, the EPA notes two important considerations in using the information to directly translate to policy decisions regarding the level of the annual standard in the U.S. The first is that in incorporating a larger portion of Canada into these recent studies, more rural areas are included, and as such, the population densities and exposure environment differences become more important. The second is that in analyses that evaluate and validate hybrid models, there is less certainty in PM_{2.5} exposure estimates in more rural areas, which are further from air quality monitors and where PM_{2.5} concentrations in the ambient air tend to be lower (U.S. EPA, 2022b, pp. 2–51 and 2–63). Additionally, it is unclear what portion of the PM_{2.5} concentrations from rural areas are contributing to the study reported mean. Given this, studies that incorporate more rural areas into the epidemiologic studies highlight the importance of considering the differences between the population exposures in the studies themselves and in the U.S. versus Canadian study areas, as well as the influence these differences have on the interpretation of the epidemiologic study results. For these reasons, while the Canadian epidemiologic studies provide additional support for associations between PM_{2.5} concentrations and health effects, the long-term means from Canadian epidemiologic studies are a less certain basis for informing the EPA’s selection of the annual standard level, given that it is a U.S.-based standard.

With respect to the CASAC’s advice in their review of the 2021 draft PA, the EPA recognizes that the majority of the CASAC pointed to the Canadian

studies as supporting their recommendation to revise the annual standard level to within the range of 8–10 $\mu\text{g}/\text{m}^3$. However, the EPA also notes that the CASAC did not advise the EPA to revise the annual standard to a level that was below the study-reported means in the key Canadian epidemiologic studies. Indeed, the CASAC noted that some of the Canadian studies showed associations below 8 $\mu\text{g}/\text{m}^3$, but did not recommend that the Administrator consider levels below 8 $\mu\text{g}/\text{m}^3$ for the annual standard. Further, based on the CASAC's advice, the Administrator is not excluding Canadian studies from his consideration in this reconsideration, but he is considering them in light of the limitations and challenges presented and in the context of the full body of available scientific evidence.

Lastly, the EPA disagrees with commenters that the findings of the Canadian epidemiologic studies can be directly translated into a primary annual $\text{PM}_{2.5}$ standard based on the evaluation of the relationship between U.S. study-reported mean $\text{PM}_{2.5}$ concentrations and U.S. design values. It is unclear whether the relationship between U.S. study-reported mean $\text{PM}_{2.5}$ concentrations and U.S. design values (which, in the case of U.S. hybrid model-based studies, indicates that design values are 15–18% greater than area mean $\text{PM}_{2.5}$ concentrations) would apply to the Canadian epidemiologic studies and their reported mean $\text{PM}_{2.5}$ concentrations, given that these studies generally report lower $\text{PM}_{2.5}$ concentrations than the U.S.-based studies. As such, interpreting the study-reported mean concentrations from the Canadian studies in the context of a U.S.-based standard may present challenges in directly and quantitatively informing decisions regarding potential alternative levels of the annual standard,

particularly noting the different in exposure relationships in the U.S. versus Canada given the large difference in population densities between the two countries. Further, as mentioned above, while the CASAC advised the EPA to consider the Canadian studies as relevant evidence and found that placing weight on the Canadian studies supported their recommendation to revise the annual standard level to within the range of 8–10 $\mu\text{g}/\text{m}^3$, the lower end of their recommended range for the level of the annual standard did not extend below the lower study-reported means from those studies.

Commenters who supported retaining and revising the primary annual $\text{PM}_{2.5}$ standard both raised concerns regarding how the EPA used the scientific evidence and quantitative risk assessment related to disparities in $\text{PM}_{2.5}$ exposure and risk in informing conclusions on the standard. Commenters who supported retaining the standard assert that the available scientific evidence that demonstrates disparities for minority populations do not support revising the standard, noting that these studies are in areas that tend to have large minority populations and more sources of PM. These commenters contend that because the studies conclude that minority populations experience more effects than others living in the same area that something other than $\text{PM}_{2.5}$ concentrations in ambient air is causing the disproportionate impact on minority populations, providing proximity to a source as an example. The commenters note that it is unclear how a national standard will reduce exposure disparities for population groups living in the same area, and further assert that studies of exposure disparities among minority populations were considered in reaching the 2020 final decision to retain the standards.

Conversely, commenters who support revising the standard assert that the at-risk analyses conducted in the 2022 PA provide support for revising the primary annual PM_{2.5} standard to a level of 8 µg/m³. In particular, these commenters state that the at-risk analysis demonstrated that while disparities in mortality risk remain at a standard level of 9.0 µg/m³, disparities in exposure are significantly reduced for an alternative standard level of 8.0 µg/m³ (U.S. EPA, 2022b, p. 3–162).

As discussed in section I above, the primary (health-based) NAAQS are established at a level that is requisite to protect public health, including the health of sensitive or at-risk groups, with an adequate margin of safety.⁹⁹ In so doing, decisions on the NAAQS are based on an explicit and comprehensive assessment of the current scientific evidence and associated risk analyses. More specifically, the EPA expressly considers the available information regarding health effects among at-risk populations in decisions on the primary NAAQS. Where populations with disparities in exposure and risk are among the at-risk populations, the decision on the standards is based on providing requisite protection for these and other at-risk populations and lifestages.

⁹⁹ The legislative history of section 109 indicates that a primary standard is to be set at “the maximum permissible ambient air level ... which will protect the health of any [sensitive] group of the population,” and that for this purpose “reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.” S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970); see also, *e.g.*, *Am. Lung Ass’n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998) (“If a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard”).

The Administrator expressly considered the available information regarding health effects among at-risk populations in reaching the proposed decisions that the current primary annual PM_{2.5} standard is not requisite to protect public health with an adequate margin of safety, and should be revised. The 2019 ISA and ISA Supplement identified children, older adults, people with pre-existing diseases (cardiovascular disease and respiratory disease), minority populations, and low SES populations as at-risk populations. The Administrator is thus, in his final decision, establishing primary PM_{2.5} standards which, in his judgment, will provide protection for these at-risk populations, including minority populations, with an adequate margin of safety.

With respect to the risk assessment, while the EPA notes that the analyses support the conclusion that the primary PM_{2.5} standards are not adequate, as detailed further in the proposal and above in section II.A.3, the EPA also cautions against an over-interpretation of the absolute results. The quantitative risk assessment provides estimates of PM_{2.5}-attributable mortality based on input data that include C-R functions from epidemiologic studies that do not quantitatively account for uncertainties in associations between PM_{2.5} exposure and health effects at lower concentrations and are based on an air quality adjustment approach that incorporates proportional decreases in PM_{2.5} concentrations to meet lower alternative standard levels. As a result, simulated air quality improvements used in the risk assessment will always lead to proportional decreases in risk (*i.e.*, each additional µg/m³ reduction produces additional benefits with no clear stopping point), without considering the substantially greater uncertainties associated with the relationship between

PM_{2.5} exposures and health effects at lower concentrations.

The same is true for the new at-risk analysis in the risk assessment presented in the 2022 PA that is based on a recent epidemiologic study that is available in this reconsideration that provides mortality risk coefficients for older adults (*i.e.*, 65 years and older) based on PM_{2.5} exposure and stratified by racial and ethnic demographics. Generally, the results of at-risk analyses can vary greatly depending on the inputs to the analyses, including the representativeness of the populations and demographics captured by the study areas that are a part of the analyses, as well as the available C–R functions from epidemiologic studies that stratify by race and ethnicity and the air quality adjustment approaches that are used to simulate air quality at different standard levels. In fact, for this at-risk analysis, the results are even more uncertain than similar estimates from the overall risk assessment due to additional sources of uncertainty specific to the at-risk analysis, such as using C–R functions derived from smaller epidemiologic sample sizes along with the sources of uncertainty that apply to the overall risk assessment (U.S. EPA, 2022b, section 3.4.1.8). Additionally, in characterizing at-risk populations, the at-risk analysis only used one of the air quality adjustment approaches used in the overall risk assessment, which decreases the potential representativeness of the PM_{2.5} concentrations across the study areas (U.S. EPA, 2022b, section 3.4.1.8). Lastly, this at-risk analysis relies on the stratified risk coefficients from only one epidemiologic study.¹⁰⁰

¹⁰⁰ Additional information on all available at-risk epidemiologic studies in this reconsideration are available in

For these reasons, the Administrator places little weight on the absolute results of the risk assessment, including the at-risk analysis, for purposes of selecting the level of the annual standard that is requisite.

While there are substantial uncertainties in the absolute results of the quantitative risk assessment, the EPA also notes that recent scientific evidence evaluated in the ISA Supplement, which built upon the 2019 PM ISA conclusions, found that the evidence “[c]ontinue[s] to support disparities in PM_{2.5} exposure and health risks by race and ethnicity” while studies of SES “provide additional support indicating there may be disparities in PM_{2.5} exposure and health risk by SES” (U.S. EPA, 2022a, p. 5–4). Thus, in light of the statutory requirement to provide protection for at-risk populations, it is not surprising that the stratified population results of the risk assessment suggest that meeting a revised standard would result in higher risk reductions for minority and low SES populations.

In conclusion, the EPA recognizes that the at-risk analysis was based on one epidemiologic study that stratified by race/ethnicity for older adults (*e.g.*, 65+ years old) and that there is increasing uncertainty in quantitative estimates of stratified risk estimates at the lower end of the range of standard levels assessed. Moreover, the EPA finds that the goal of the NAAQS is to provide the requisite protection to at-risk groups, and where minority populations are included among the at-risk groups, providing requisite protection to minority populations will also

section 3.4 and Appendix C of the 2022 PA (U.S. EPA, 2022b, section 3.4, Figure 3–17, and Appendix C, section C.3.2).

result in protecting the public health of other populations. Thus, in setting the NAAQS to protect the health of at-risk groups with an adequate margin of safety, the Administrator is selecting the standard that will provide requisite protection, including for minority populations and other at-risk populations, which also generally results in protecting the public health of other populations and reducing risk disparities.

A number of commenters, primarily from industries and industry groups and some States, support the EPA's proposed decision to retain the primary 24-hour $\text{PM}_{2.5}$ standard. Many of these commenters contend that the available scientific evidence and quantitative information has not significantly changed since the 2020 final decision and note that important uncertainties remain. The commenters agree with the EPA's conclusions regarding the controlled human exposure studies and their relationship to short-term peak $\text{PM}_{2.5}$ concentrations in ambient air. These commenters also noted the primary annual and 24-hour $\text{PM}_{2.5}$ standards work together to provide public health protection, with the 98th percentile form of the 24-hour standard effectively limiting peak daily concentrations. The commenters agree with the EPA that the current suite of standards maintain subdaily concentrations below the higher concentrations in controlled human exposure studies where more consistent health effects are observed. Commenters also agree with the EPA's conclusions that the epidemiologic studies are not useful for informing decisions on the level of the primary 24-hour $\text{PM}_{2.5}$ standard because the standard focuses on reducing peak exposures with its 98th percentile form, while the epidemiologic studies often focus on the mean or median as the percentile

for which associations with short-term exposures are observed. These commenters also agree with the EPA's focus on U.S.-based studies because of differences compared to Canadian studies. The commenters also generally agree with the Administrator's judgment that it was appropriate to place less weight on the risk assessment, noting that the annual standard is controlling in most areas of the country and revising the annual standard would have the most potential to reduce risk related to PM_{2.5} exposures and would reduce both average (annual) and peak (daily) PM_{2.5} concentrations. Finally, these commenters note that the CASAC did not reach consensus on whether the current primary 24-hour PM_{2.5} standard should be revised, and they agree with the minority of the CASAC's recommendation in their review of the 2021 draft PA that the primary 24-hour primary PM_{2.5} standard should be retained. These commenters also note the CASAC's support in their review of the 2019 draft PA for retaining the primary 24-hour PM_{2.5} standard.

A number of commenters, primarily from public health and environmental organizations and some States, oppose the EPA's proposed decision to retain the primary 24-hour PM_{2.5} standard. These commenters support revising the level of the primary 24-hour PM_{2.5} standard, contending that a more stringent standard is necessary to provide requisite public health protection with an adequate margin of safety, particularly for at-risk groups. In so doing, these commenters place weight on the same aspects of the available scientific evidence as the majority of the CASAC in their review of the 2021 draft PA, and generally advocate for revising the level of the standard to within the range of 25–30 µg/m³ as recommended by the majority of the CASAC. Some of

these commenters support a level no higher than 25 $\mu\text{g}/\text{m}^3$ and others support a level of 20 $\mu\text{g}/\text{m}^3$. These commenters generally cite to the available scientific evidence, including evidence of disproportionate exposures and risks for certain at-risk groups, and the CASAC's advice in support for their recommendation. Some of these commenters also suggest that decisions regarding the primary 24-hour $\text{PM}_{2.5}$ standard should not be related to decisions on the primary annual $\text{PM}_{2.5}$ standard.

As an initial matter, the EPA disagree with commenters who suggest that decisions regarding the primary 24-hour $\text{PM}_{2.5}$ standard should not be related to decisions on the primary annual $\text{PM}_{2.5}$ standard. In reviewing the adequacy of the public health protection afforded by the primary $\text{PM}_{2.5}$ standards, the Administrator's consistent past practice has been to evaluate the combination of the annual and 24-hour standards together. In 2012, the then-Administrator concluded that the most effective and efficient way to reduce total population risk associated with both long- and short-term $\text{PM}_{2.5}$ exposures was to set a generally controlling annual standard, and to provide supplemental protection by means of a 24-hour standard set at the appropriate level. In so doing, the then-Administrator explicitly recognized that potential air quality changes associated with meeting a revised annual standard (with a level of 12 $\mu\text{g}/\text{m}^3$) would result in lowering risks associated with both long- and short-term $\text{PM}_{2.5}$ exposures by lowering the overall distribution of air quality concentrations, and that retaining a 24-hour standard at the appropriate level would ensure an adequate margin of safety against short-term effects in areas with high peak-to-mean ratios (78 FR 3163, January 15, 2013). In this reconsideration, also, the Administrator

considers it appropriate to rely on the annual standard (arithmetic mean, averaged over three years) for targeting protection against both long- and short-term PM_{2.5} exposures, noting that the annual standard is typically controlling, while the 24-hour standard (98th percentile, averaged over three years) can provide supplemental protection against the occurrence of peak 24-hour PM_{2.5} concentrations (U.S. EPA, 2022b, section 3.6.3). Further, the Administrator notes that, as in the 2012 review, changes in PM_{2.5} air quality to meet a revised annual standard would affect the entire distribution of long- and short-term concentrations, thus likely resulting not only in lower short- and long-term PM_{2.5} concentrations near the middle of the air quality distribution, but also in fewer and lower short-term peak PM_{2.5} concentrations.¹⁰¹ Thus, the Administrator continues to conclude it is appropriate to consider whether the annual and 24-hour standards together provide requisite protection of public health, rather than considering each standard in isolation.

Regarding the appropriate basis for determining the level of the 24-hour standard, a number of commenters who support revising the primary 24-hour PM_{2.5} standard to a lower level contend that the EPA should not rely on the controlled human

¹⁰¹ Similarly, the Administrator recognizes that changes in air quality to meet a 24-hour standard, would result not only in fewer and lower peak 24-hour PM_{2.5} concentrations, but also in lower annual average PM_{2.5} concentrations. However, as noted in 2012, an approach that relied on setting the level of the 24-hour standard such that the 24-hour standard was generally controlling would be less effective and result in less uniform protection across the U.S. than an approach that focuses on setting a generally controlling annual standard (78 FR 3163, January 15, 2013).

exposure studies in evaluating the adequacy of the public health protection afforded by the primary 24-hour PM_{2.5} standard. These commenters support this view by citing the CASAC comments in their review of the 2019 draft PA which advised that controlled human exposure studies have limitations that may impact their ability to inform conclusions on the adequacy of the public health protection afforded by the primary 24-hour PM_{2.5} standard. Commenters noted that these studies do not include the most vulnerable populations and often involve exposure to only one pollutant to elicit a response, and therefore are not representative of real-world exposures.

Other commenters support the EPA's use of the controlled human exposure studies to inform the adequacy of the public health protection and note that the 24-hour standard must at least provide protection against the health effects observed in controlled human exposure studies. Some of the commenters cite the Wyatt et al. (2020) study that demonstrated cardiovascular effects following 2-hour exposures to 120 µg/m³ and 4-hour exposures to 37.8 µg/m³. Some of these commenters contend that the current primary 24-hour PM_{2.5} standard allows PM_{2.5} exposures comparable to those observed to elicit effects in the controlled human exposure studies, and therefore, the EPA must revise the level of the current standard to protect public health. To support this view, some commenters submitted an analysis of monitoring data from 2017–2020, which compares the number of days per year where maximum daily PM_{2.5} concentrations exceed 120 µg/m³ and 37.8 µg/m³.

Additionally, other commenters assert that the EPA should focus less on peak PM_{2.5} concentrations “typically measured” in areas meeting the current

primary PM_{2.5} standards even if they do not exceed the concentrations in the controlled human exposure studies because, in their view, the standard needs to protect against atypical exposures to atypical peak PM_{2.5} concentrations. These commenters conclude that, when considered together, the controlled human exposure studies and the epidemiologic studies warrant strengthening the level of the primary 24-hour PM_{2.5} standard.

The EPA generally disagrees with commenters who contend that it is inappropriate to rely on the controlled human exposures studies in evaluating the adequacy of the public health protection afforded by the primary 24-hour PM_{2.5} standard. The Agency considers these studies informative both for establishing biological plausibility and for determining an appropriate level for the 24-hour standard. When looking to the experimental studies, the EPA finds that the 2019 ISA and ISA Supplement included controlled human exposure studies that report statistically significant effects on one or more indicators of cardiovascular function following 2-hour exposures to PM_{2.5} concentrations at and above 120 µg/m³ (and at and above 149 µg/m³ for vascular impairment, the effect shown to be most consistent across studies). As noted in the 2019 ISA, these studies are important in establishing biological plausibility for PM_{2.5} exposures causing more serious health effects, such as those seen in short-term exposure epidemiologic studies, and they provide support that more adverse effects may be experienced following longer exposure durations and/or exposure to higher concentrations. Additionally, one controlled human exposure study assessed in the ISA Supplement reports evidence of some effects for cardiovascular markers at lower PM_{2.5} concentrations, 4-hour exposures to 37.8 µg/m³

(Wyatt et al., 2020). However, there is inconsistent evidence for inflammation in other controlled human exposure studies evaluated in the 2019 ISA. The EPA notes that although the controlled human exposure studies do not provide a threshold below which no effects occur, the observed effects in these controlled human exposures studies are ones that signal an intermediate effect in the body, likely due to short-term exposure to PM_{2.5}, and typically would not, by themselves, be judged as adverse (88 FR 5620, January 27, 2023)^{102 103}

¹⁰² Judgments regarding adversity or health significance of measurable physiological responses to air pollutants have been informed by guidance, criteria or interpretative statements developed within the public health community, including the American Thoracic Society (ATS) and the European Respiratory Society (ERS), which cooperatively updated the ATS 2000 statement *What Constitutes an Adverse Health Effect of Air Pollution* (ATS, 2000) with new scientific findings, including the evidence related to air pollution and the cardiovascular system (Thurston et al., 2017).

¹⁰³ The ATS/ERS described its 2017 statement as one “intended to provide guidance to policymakers, clinicians and public health professionals, as well as others who interpret the scientific evidence on the health effects of air pollution for risk management purposes” and further notes that “considerations as to what constitutes an adverse health effect, in order to provide guidance to researchers and policymakers when new health effects markers or health outcome associations might be reported in future.” The most recent policy statement by the ATS, which once again broadens its discussion of effects, responses and biomarkers to reflect the expansion of scientific research in these areas, reiterates that concept, conveying that it does not offer “strict rules or numerical criteria, but rather proposes considerations to be weighed in setting boundaries between adverse and nonadverse health effects,” providing a general framework for interpreting evidence that proposes a “set

The EPA notes that the majority of the CASAC, in their review of the 2021 draft PA, commented that these controlled human exposure studies generally do not include populations with substantially increased risk from exposure to PM_{2.5}, such as children, older adults, or those with more severe underlying illness, and often involve exposure to only one pollutant to elicit a response. However, both the majority and the minority of the CASAC explained that, even taking into consideration their limitations, the controlled human exposure studies provide some support for assessing the adequacy of the 24-hour standard.¹⁰⁴

The EPA agrees with the CASAC that the controlled human exposure studies generally do not include populations with substantially increased risk from exposure to PM_{2.5}, like children, older adults, or those with pre-existing severe illness, like cardiovascular effects. As such, and as an initial note, these studies are therefore somewhat limited in their ability to inform at what concentrations effects may be elicited in at-risk populations. In spite of this limitation, the EPA also agrees with the CASAC, that even taking into consideration the limitations of the

of considerations that can be applied in forming judgments” for this context (Thurston et al., 2017).

¹⁰⁴ In their review of the 2021 draft PA, the majority of the CASAC advised that “evidence of effects from controlled human exposure studies with exposures close to the current standard support epidemiologic evidence for lowering the standard” (Sheppard, 2022a, p. 4 of consensus letter). The minority of the CASAC also advised that it was appropriate to place “more emphasis on the controlled human exposure studies, showing effects at PM_{2.5} concentrations well above those typically measured in areas meeting the current standards” (Sheppard, 2022a, p. 4 of consensus letter), in evaluating adequacy of the 24-hour standard.

controlled human exposure studies, these studies can provide some support for evaluating the adequacy of the 24-hour standard. However, the EPA further notes that while the controlled human exposure studies are important in establishing biological plausibility, the health outcomes observed in these controlled human exposure studies are often “intermediate” outcomes (*i.e.*, not always clearly adverse) and therefore it is unclear how the importance of the effects observed in the studies should be interpreted with respect to adversity to public health. The EPA finds that it is appropriate to consider these study limitations in assessing the information provided by controlled human exposure studies in evaluating the adequacy of the primary 24-hour PM_{2.5} standard.

The EPA agrees with commenters that the primary 24-hour PM_{2.5} standard must at least provide protection against the health effects consistently observed in controlled human exposure studies. As discussed in the proposal, the EPA looks at whether the exposures that elicit a response following exposure to PM_{2.5} in the controlled human exposure studies occur under recent air quality conditions in areas meeting the current standards. Based on these air quality analyses, the EPA concludes that these types of exposures very rarely occur when the current standards are being met.

The EPA did receive multiple comments questioning these results and the approach in the EPA’s analyses. For example, some commenters submitted an analysis of monitoring data from 2017–2020, which compares the number of days per year where maximum daily PM_{2.5} concentrations exceed 120 µg/m³ and 37.8 µg/m³ and evaluate the number of

days subset by groups of monitors with 4-year average PM_{2.5} concentrations close to the levels of combinations of current and proposed annual (+/- 0.2 µg/m³) and 24-hour (+/- 2 µg/m³) PM_{2.5} standards. To support their view that the primary PM_{2.5} standards should be revised, the commenters describe decreases in days per monitor per year with 2-hour maximum concentrations greater than 120 µg/m³ and 4-hour maximum concentrations greater than 37.8 µg/m³ when comparing monitors that achieve close to 10 and 30 µg/m³ versus monitors that meet close to 8 µg/m³ and 25 µg/m³. The commenters noted decreases in the number of days per monitor per year with 2-hour maximum concentrations over 120 µg/m³ and 4-hour max concentration over 37.8 µg/m³ were also seen when comparing monitors close to achieving 24-hour standards with levels of 35 µg/m³ versus 25 µg/m³.

First, the EPA notes that this analysis submitted by commenters was limited to a very small number of monitors and did not include a national perspective. Second, the EPA notes that this analysis focused on number of days (rather than the number of times) where there was a 2-hour maximum concentration over 120 µg/m³ or a 4-hour max concentration over 37.8 µg/m³. In order to evaluate the protection provided by the current 24-hour standard against peak exposures, including exposures with 2-hour concentrations greater than 120 µg/m³ and 4-hour concentrations greater than 37.8 µg/m³, the EPA considers it more informative and appropriate from a public health perspective to assess the number of times a subdaily exposure of concern occurs in a year, rather than the number of days on which they occur because the former identifies more potential exposures of concern and provides more information about the

scale and scope of the occurrences of those exposures. Lastly, the analyses allowed monitors somewhat above the standards to be included. Therefore, it is unclear whether the exceedances of the 2-hour or 4-hour benchmarks would still have occurred if the area had actually been meeting the current primary PM_{2.5} standards. However, in considering the analyses submitted by the commenters, the EPA conducted new analyses¹⁰⁵ that looked at all individual monitors across the U.S. and evaluated the percentage of times the monitors experienced a 2-hour maximum concentration over 120 µg/m³ or a 4-hour max concentration over 37.8 µg/m³ when that monitor was meeting the current standards. Further, given that the Administrator concludes that the level of the current primary annual PM_{2.5} is not adequate and that it should be revised to 9.0 µg/m³, the new analysis evaluates the percentage of times during a recent 3-year period (*i.e.* 2019–2021) that individual monitors experienced a 2-hour maximum concentration over 120 µg/m³ or a 4-hour max concentration over 37.8 µg/m³ when that monitor was meeting the current primary 24-hour PM_{2.5} standard with its level of 35 µg/m³ and a revised primary annual PM_{2.5} standard of 9.0 µg/m³.

In evaluating the results from the new analyses, it is important to keep in mind that the 2019 ISA and ISA Supplement concluded that the most consistent evidence from the controlled human exposures

¹⁰⁵ Jones et al. (2023). Comparison of Occurrence of Scientifically Relevant Air Quality Observations Between Design Value Groups. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: <https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072>.

studies is for impaired vascular function following 2-hour exposures to average $\text{PM}_{2.5}$ concentrations at and above about $120 \mu\text{g}/\text{m}^3$, with less consistent evidence for effects following exposures to concentrations lower than $120 \mu\text{g}/\text{m}^3$. The new analyses show that across all monitors, on average, only 0.029 percent of 2-hour observations reach $\text{PM}_{2.5}$ concentrations higher than $120 \mu\text{g}/\text{m}^3$ in areas meeting the current 24-hour standard and a revised annual standard of $9.0 \mu\text{g}/\text{m}^3$. Further, recognizing that one purpose of the 24-hour standard is to protect against exposure in areas with high peak-to-mean ratios, when assessing the monitors individually across the U.S. under these same conditions, the monitors reporting the highest $\text{PM}_{2.5}$ concentrations have only 0.47 percent of 2-hour observations reach $\text{PM}_{2.5}$ concentrations higher than $120 \mu\text{g}/\text{m}^3$.

Additionally, the analyses also evaluated the frequency of reporting a 4-hour maximum concentration over $37.8 \mu\text{g}/\text{m}^3$ when monitors were meeting the current 24-hour standard and a revised annual standard of $9.0 \mu\text{g}/\text{m}^3$. For this part of the analysis, the EPA finds that across all monitors, on average, only 0.41 percent of 4-hour observations reach $\text{PM}_{2.5}$ concentrations higher than $37.8 \mu\text{g}/\text{m}^3$ in areas meeting the current 24-hour standard and a revised annual standard of $9.0 \mu\text{g}/\text{m}^3$. Further, when assessing the monitors individually across the U.S. under these same conditions, the monitors reporting the highest $\text{PM}_{2.5}$ concentrations have only 2.6 percent of 4-hour observations reach $\text{PM}_{2.5}$ concentrations higher than $37.8 \mu\text{g}/\text{m}^3$. Thus, the EPA disagrees with commenters that the current primary 24-hour $\text{PM}_{2.5}$ standard typically allows $\text{PM}_{2.5}$ exposures at or above those observed to cause health effects in controlled human exposure studies.

Furthermore, the EPA notes that in light of the small number of occurrences and the intermediate nature of the effects observed in Wyatt et al. (2020) at concentrations of $37.8 \mu\text{g}/\text{m}^3$ (*i.e.*, effects that typically would not, by themselves, be judged as adverse), there is substantial basis to doubt whether further improvements in public health would be achieved by further reducing these exposures. In drawing this conclusion, the EPA notes the lack of evidence of effects from controlled human exposure studies at levels below the current 24-hour standard and the fact that the results of Wyatt et al. (2020) are inconsistent with other currently available studies, and this study only observes intermediate effects.

In response to commenters that cited the majority of the CASAC's view that, in general, "[t]here is . . . less confidence that the annual standard could adequately protect against health effects of short-term exposures" (Sheppard, 2022a, p. 4 of consensus letter), the EPA disagrees with the majority of CASAC, noting that the results of the EPA's analysis suggest that high peak concentrations are extremely infrequent in areas meeting an annual standard of $9.0 \mu\text{g}/\text{m}^3$, occurring less than 0.029–0.41 percent of the time (for 2-hour concentrations $>120 \mu\text{g}/\text{m}^3$ and 4-hour concentrations $>37.8 \mu\text{g}/\text{m}^3$, respectively). This suggests that in most locations, even the upper tail of the distribution would be controlled quite well under a revised annual standard. With regard to the likelihood that the current standards would allow peak concentrations that are clearly of concern from a health perspective, therefore, the EPA concludes that such occurrences are extremely infrequent—and will be even less frequent under the improved air quality conditions associated with meeting a revised annual $\text{PM}_{2.5}$ standard of $9.0 \mu\text{g}/\text{m}^3$.

A number of commenters who support revising the primary 24-hour PM_{2.5} standard to a lower level suggest that the available epidemiologic evidence provides support for such a revision. To support their view, the commenters note that the currently available evidence, including a number of epidemiologic studies that demonstrate associations between short-term PM_{2.5} exposures and health effects, provides support for causal relationships for short-term PM_{2.5} exposures and health effects as described in the 2019 ISA and ISA Supplement. The commenters further note that the available epidemiologic studies include diverse populations that are broadly representative of the U.S. population, including at-risk populations, which they assert is an advantage over the controlled human exposure studies and the risk assessment, which are not as broadly representative.

These commenters highlight a number of specific epidemiologic studies that they suggest provide support for revising the level of the 24-hour standard. Additionally, commenters contend that there are epidemiologic studies using restricted analyses that show that positive and statistically significant associations between short-term PM_{2.5} exposure and mortality persist at daily mean concentrations below 25 µg/m³. The commenters also cite several studies that provide no evidence of a threshold. These commenters also point to the CASAC advice in their review of the 2021 draft PA, where the majority of the CASAC cited epidemiologic studies using restricted analyses as offering support for revision. The commenters argue that the EPA cannot base discretion on uncertainties related to the methods used in restricted analyses in the epidemiologic studies. In so doing, these commenters disagree with the EPA that it is important to take into

consideration that these studies do not consider the form or averaging time of the 24-hour standard. Finally, the commenters claim that while the EPA stated that the study-reported means from epidemiologic studies that use restricted analyses are more useful for identifying impacts from typical 24-hour exposures than for peak 24-hour exposures, the commenters assert that the studies also indicate that there are health risks at relatively high concentrations below the current level of the primary 24-hour PM_{2.5} standard that must be addressed.

As noted by the commenters, epidemiologic studies that show positive and statistically significant associations between short-term PM_{2.5} exposure and mortality provide support for the causal determination in the 2019 ISA. The EPA also agrees that the available epidemiologic studies include diverse populations that are broadly representative of the U.S. population, including at-risk populations. Further, the EPA agrees that studies evaluated in the 2019 ISA and the ISA Supplement continue to provide evidence of linear, no-threshold concentration-response relationships, but with less certainty in the shape of the curve at lower concentrations (*i.e.*, below about 8 µg/m³), with some recent studies providing evidence for either a sublinear, linear, or supralinear relationship at these lower concentrations (U.S. EPA, 2019a, section 11.2.4; U.S. EPA, 2022a, section 2.2.3.2).

However, findings of positive, significant associations in short-term epidemiologic studies do not directly indicate that short-term effects would occur in areas meeting the 24-hour standard and therefore, do not directly address the question of whether the current 24-hour standard is adequate. While short-term epidemiologic studies evaluate

associations between distributions of ambient PM_{2.5} and health outcomes, they do not identify the specific exposures (*i.e.*, a specific 24-hour concentration) that can lead to the reported effects. Short-term epidemiologic studies evaluate the association between day-to-day variation in daily (24-hour) PM_{2.5} exposure and health endpoints (*e.g.*, mortality) to understand how these changes in air pollution concentrations are associated with changes in health outcomes. But these studies do not report daily concentrations; rather, they report the long-term mean concentration of the 24-hour PM_{2.5} concentrations over the entire multi-year period of the study, and typically report their results as a relative risk (*e.g.*, for each 10 µg/m³ increase in PM_{2.5}, the risk of mortality or cardiovascular hospital admissions increases by a certain percentage, across the full range of the 24-hour PM_{2.5} concentrations in the study). This means that there is no specific point in the air quality distribution of any epidemiologic study that represents a “bright line” at and above which effects have been observed and below which effects have not been observed. Nor, as noted above, do these studies allow for any direct inferences about health impacts associated with the short-term “peak” exposures that the primary 24-hour standard is designed to protect against. While there can be considerable variability in daily exposures over a multi-year study period, most of the estimated exposures in these epidemiologic studies reflect days with ambient PM_{2.5} concentrations around the mean or middle of the air quality distributions examined (*i.e.*, “typical” days rather than days with extremely high or extremely low concentrations). This is true of long-term epidemiologic studies as well. The difference between epidemiologic studies examining associations

with long-term exposures and short-term exposures is comparing different levels of exposure over different exposure durations (*i.e.*, long-term studies exposures are defined as those that are annual or multi-year, while short-term exposures are defined as those that are mostly 24-hour) (U.S. EPA, 2019a, section P.3.1). Thus, in both cases, and in the absence of a discernible threshold, epidemiologic studies of short-term and long-term exposures provide the strongest support and confidence for reported health effect associations around the middle portion of the PM_{2.5} air quality distribution (*e.g.*, the study-reported mean PM_{2.5} concentration), which corresponds to the bulk of the underlying data, rather than at the extreme upper or lower ends of the distribution. However, the difference between the annual standard and the 24-hour standard, aside from averaging times, is that the form of the annual standard is a mean PM_{2.5} concentration, which is based on the bulk of the air quality data, while the form of the 24-hour standard is a 98th percentile form, which is based on peak concentrations. Both long-term and short-term epidemiologic studies are informative for determining the appropriate level of the annual PM_{2.5} standard, which is designed to control “typical” daily exposures and risks, because these studies most often report long-term mean (or median) PM_{2.5} concentrations that are representative of “typical” exposures that are associated with health effects. In contrast, while the short-term epidemiologic studies examine health effects associated with shorter exposure durations (*e.g.*, mostly 24-hour exposures), these studies are less informative for determining the appropriate level of the 24-hour PM_{2.5} standard because these

studies do not report the 98th percentile PM_{2.5} concentrations,¹⁰⁶ which is more directly comparable to the form of the 24-hour standard. Additionally, if the 98th percentile of data were reported, the EPA would consider the peak concentrations observed in these studies (which by definition rarely occur) in conjunction with other supporting evidence. However, as already noted, there is an absence of new information in this reconsideration (either from controlled human exposure studies or epidemiologic studies) suggesting that peak concentrations just below the level of the current 24-hour standard (with its level of 35 µg/m³) are associated with adverse effects. Instead, the evidence links risk to more typical daily exposures near the middle of the air quality distribution—exposures most effectively controlled through a strengthening of the annual standard. As noted in the 2012 final rule, “reducing the annual standard is the most efficient way to reduce the risks from short-term exposures . . . as the bulk of the risk comes from the large number of days across the bulk of the air quality distribution, not the relatively small number of days with peak concentrations” (78 FR 3156, January 15, 2013).

¹⁰⁶ In the 2022 PA, the EPA has identified a number of key areas for additional research and data collection for PM_{2.5}, based on the uncertainties and limitations that remain in the scientific evidence and technical information. In addition to research and data collection, the EPA specifically highlights additional information that could be reported in the epidemiologic studies that may help inform future reviews of the primary PM_{2.5} standards, including additional descriptive statistics in the upper percentiles of the air quality distribution (*i.e.*, from the 95th to the 99th percentile), as well as the number of days of concentrations and/or health events within each of these percentiles (U.S. EPA, 2022a, section 3.7).

As noted above, in evaluating the adequacy of the current standards, the EPA has consistently considered the annual standard (based on arithmetic mean concentrations) and 24-hour standard (based on 98th percentile concentrations) together in evaluating the public health protection provided by the standards against the full distribution of short- and long-term PM_{2.5} exposures. Moreover, the EPA has previously noted that the annual standard is generally controlling in most parts of the country, providing an effective and efficient way to reduce total population risk to both long- and short-term PM_{2.5} exposures, while the 24-hour standard, with its 98th percentile form, provides supplemental protection, particularly for areas with high peak-to-mean ratios of 24-hour PM_{2.5} concentrations (78 FR 3158, January 15, 2013). In such areas, annual average PM_{2.5} concentrations could be quite low, and the 24-hour standard provides a means of ensuring control of episodic peaks possibly associated with strong local or seasonal sources, or PM_{2.5}-related effects that may be associated with shorter-than daily exposure periods. The approach taken in evaluating the adequacy and alternative levels of the annual standard has been to evaluate the long-term mean PM_{2.5} concentrations of both long-term and short-term key epidemiologic studies, where we have the most confidence in the reported health effects association, while also giving some consideration to lower percentiles of the air quality distribution (*e.g.*, 25th percentiles). However, using a similar approach to evaluate the adequacy of the current and any potential alternative levels of the 24-hour standard with short-term epidemiologic studies, as the majority of CASAC and some commenters are suggesting, presents challenges.

Short-term epidemiologic studies, including those that use restricted analyses, often report metrics that include mean PM_{2.5} concentrations, with some studies also reporting lower percentiles, such as the 25th percentile. As previously noted above, for studies of daily PM_{2.5} exposure, which examine associations between day-to-day variation in PM_{2.5} concentrations and health outcomes, often over several years, most of the estimated exposures reflect days with ambient PM_{2.5} concentrations around the middle of the air quality distributions examined (*i.e.*, the mean or median). However, there is not a metric or statistic reported in short-term epidemiologic studies that allows for a direct comparison to the current 24-hour PM_{2.5} standard and its 98th percentile form. While a 98th percentile of PM_{2.5} concentrations is a metric that might be more closely compared to the 24-hour standard level, 98th percentile PM_{2.5} concentrations were not reported in key epidemiologic studies. Consistent with the Administrator's final decision in 2012, the EPA notes that even if 98th percentile values were reported, it would be inappropriate to focus on these concentrations without also considering the impact of a revised annual standard on short-term concentrations, since many areas would be expected to experience decreasing short- and long-term PM_{2.5} concentrations in response to a revised annual standard (78 FR 3156, January 15, 2013). Furthermore, in light of the scarcity of days at the very upper end of the distribution, and to avoid placing undue reliance on the peak concentrations observed in these studies (which by definition rarely occur), the EPA finds that such values would need to be considered in conjunction with other supporting evidence. In addition, as described above, the other lines of evidence available for consideration by the

EPA do not indicate that the current primary 24-hour standard requires revision to protect public health with an adequate margin of safety. The EPA notes again the lack of corroborating evidence from controlled human exposure studies. While the EPA agrees with the CASAC that the controlled human exposure studies are limited in their ability to speak to the concentrations at which effects may be elicited in at-risk populations, as discussed above the lowest concentration associated with effects is $37.8 \mu\text{g}/\text{m}^3$ and the effects observed were “intermediate” outcomes that are not by themselves considered adverse. We also note that, as detailed in section II.A.2.a above, the study that observed intermediate effects at concentrations of $37.8 \mu\text{g}/\text{m}^3$ was evaluated in the ISA Supplement and the results of this study were inconsistent with the controlled human exposure studies evaluated in the 2019 ISA. Additionally, as noted above, the EPA finds that across all monitors, on average, only 0.41 percent of 4-hour observations reach $\text{PM}_{2.5}$ concentrations higher than $38 \mu\text{g}/\text{m}^3$ in areas meeting the current 24-hour standard and a revised annual standard of $9.0 \mu\text{g}/\text{m}^3$. Given the rarity of these occurrences and the fact that the effects associated with exposures to this $\text{PM}_{2.5}$ concentration have not been found to be adverse in and of themselves, the EPA finds it reasonable to conclude that this pattern of air quality will protect at-risk populations, even though such populations were not in the study groups. The EPA concludes that further evidence would be needed at specific short-term (*i.e.*, hourly or daily) concentrations below the level of the current 24-hour standard to support any revision to the current 24-hour standard.

With regard to the data that are available from the short-term epidemiologic studies (which, as noted, do

not include 98th percentile values), the EPA considers it inappropriate to utilize the study-reported means from the short-term epidemiologic evidence to assess the adequacy of the 24-hour standard, with its 98th percentile form, considering that the study-reported mean concentrations do not provide meaningful insight regarding the frequency or health significance of peak concentrations occurring during the study period. As indicated in the 2022 PA, the study-reported means of short-term epidemiologic studies do not serve a purpose in determining a level at which we can confidently attribute effects to the impact of “peak” exposures. The 24-hour standard is intended to provide supplemental protection against short-term peak exposures and while there is a general relationship between mean concentrations and 98th percentile concentrations in individual locations, such relationships vary by location and there is not an established relationship that can be relied upon to predict 98th percentile concentrations based on mean PM_{2.5} concentrations reported in multi-city epidemiologic studies. Instead, mean concentrations from short-term epidemiologic studies are more useful in addressing questions regarding the effects of “typical” or average 24-hour exposures, which are addressed through the annual standard. For this reason, the EPA does consider the mean concentrations of short-term studies (as well as the means from the long-term studies) in evaluating the level of the annual standard, which the EPA recognizes as the generally controlling standard for both long- and short-term exposures. However, the EPA does not agree with commenters that it is appropriate to use means from short-term epidemiologic studies as the basis for a decision-making framework to determine the

adequacy of the current 24-hour standard, with its 98th percentile form.

As described in the proposal (88 FR 5613, January 27, 2023), the 2022 PA also noted the epidemiologic studies that restrict 24-hour average $\text{PM}_{2.5}$ concentrations to values of less than $35 \mu\text{g}/\text{m}^3$, and in some cases less than $25 \mu\text{g}/\text{m}^3$, and annual average $\text{PM}_{2.5}$ concentrations less than $12 \mu\text{g}/\text{m}^3$. Restricted analyses use a subset of data from their main analyses and conduct an epidemiologic study with health events that occur at concentrations below a certain concentration (*e.g.*, $25 \mu\text{g}/\text{m}^3$). While some of these studies do not report the mean $\text{PM}_{2.5}$ concentration for the restricted analysis, the mean of the restricted analysis is presumably less than the mean $\text{PM}_{2.5}$ concentration in the main analysis. Restricted analyses from long-term and short-term exposure epidemiologic studies are informative in providing support that the health effects associations are not driven by just the upper peaks of the $\text{PM}_{2.5}$ air quality distributions and provide support for revision to the level of the annual $\text{PM}_{2.5}$ standard. Short-term restricted analyses also report positive associations between short-term $\text{PM}_{2.5}$ exposure and morbidity and mortality. As an example, in a restricted analysis evaluating the association between short-term exposures and $\text{PM}_{2.5}$ concentrations less than $25 \mu\text{g}/\text{m}^3$, Di et al. (2017a) removed 6.3 percent of the data from their main analyses, (*i.e.*, all $\text{PM}_{2.5}$ concentrations greater than $25 \mu\text{g}/\text{m}^3$), and still found a positive and significant association between short-term $\text{PM}_{2.5}$ exposure and mortality. This study provides additional support that the association between short-term exposure to $\text{PM}_{2.5}$ and mortality in the main epidemiologic analysis is not driven by the upper peaks of the $\text{PM}_{2.5}$ air quality distribution, which in turn supports the

conclusion that lowering the entire distribution of air quality concentrations through a revised annual standard is an appropriate means of protecting against adverse effects from short-term exposure, as discussed further below.

In their review of the 2021 draft PA, the majority of the CASAC highlighted three U.S.-based epidemiologic studies that restricted 24-hour average $\text{PM}_{2.5}$ concentrations below $25 \mu\text{g}/\text{m}^3$ as a part of their rationale for recommending that the EPA revise the level of the primary 24-hour $\text{PM}_{2.5}$ standard. Similarly, in evaluating positive associations in restricted analyses, some commenters also suggest that because an association exists at 24-hour concentrations below $25 \mu\text{g}/\text{m}^3$, the 24-hour standard level should be set at the concentration at which the analysis was restricted (*e.g.*, $25 \mu\text{g}/\text{m}^3$). However, the EPA notes that neither the CASAC nor public commenters provided any detail regarding, how, in their view, these studies demonstrate that the level of the current 24-hour standard is not adequate, and/or how these studies demonstrate what revised level of the 24-hour standard would provide requisite public health protection with an adequate margin of safety. The EPA considers that such an approach would have several important limitations. First, the approach assumes that a specific point on the air quality distribution (*e.g.*, the point at which the analysis was restricted) is where health effects are exhibited and where we have the most confidence in the reported association. However, in addition to the limitations associated with the short-term epidemiologic studies outlined above, the EPA does not agree that it would be appropriate to identify the requisite level of the primary 24-hour $\text{PM}_{2.5}$ standard based on the specific concentration at which the analyses restrict

their studies. The choice to restrict the data at a particular concentration is in effect arbitrary, and does not establish that any particular effects are attributable to that concentration as opposed to other concentrations within the restricted analysis.

Further, these restricted analyses do not report the PM_{2.5} concentration at the 98th percentile of data or other metrics relating to the upper end of the distribution that could provide information about health risks associated with peak exposures. For example, the CASAC does not provide a discussion of what the comparable 98th percentile concentration is in the distribution of remaining 24-hour PM_{2.5} concentrations of restricted analyses (because such data is not reported by the study authors) and what degree of confidence the Administrator should place on those upper percentile values (*e.g.*, 98th percentile values). In order to identify a level of the 24-hour standard based on associations between the “upper end” of exposures, either in the unrestricted or the restricted analyses, and adverse health effects, it would be necessary to have both greater detail on the distribution of air quality in the study and greater confidence in the reported association at the peak concentrations such as the 98th percentile—in other words, a better understanding of how specific 24-hour concentrations correspond to the frequency and total number of observed health events in the study.

Further, the EPA notes that when resulting analyses based on the restricted dataset continue to find positive associations between the remaining air quality distribution and health effects, it suggests that the relationship was in fact not driven primarily by the upper tail (now removed from the dataset) but rather by lower portions of the distribution of air

quality. In other words, we have no confidence that the remaining upper end of the air quality distribution is driving the remaining associations reported in the restricted analyses, as opposed to the vast array of health events at and around the mean $PM_{2.5}$ concentration. In fact, it is reasonable to conclude that to effectively address the health effects observed in the study, it is necessary to control not just the peak concentrations but to reduce the bulk of the exposures (occurring near the mean), a task more effectively achieved, as noted above through a tightening of the annual standard, which has the effect of shifting the entire distribution of $PM_{2.5}$ concentrations downward (both peaks and means). Therefore, while the EPA agrees that both short- and long-term epidemiologic studies that completed restricted analyses and reported the resulting study means could be used to inform conclusions regarding the adequacy of the annual standard, given that the resulting study means (when reported) could be evaluated in the context of the decision framework described above for informing decisions on the level of the annual standard, the EPA considers that current short-term epidemiologic studies that restrict analyses are subject to the same limitations outlined above for current short-term epidemiologic studies in how they can be used in a decision-making framework to inform the adequacy and alternative level of the primary 24-hour $PM_{2.5}$ standard. As such, while the available short-term epidemiologic studies that restrict their analyses are useful for informing conclusions regarding the strength of the associations for health outcomes, they are not, as currently designed, as useful for informing conclusions regarding the adequacy of the current primary 24-hour $PM_{2.5}$ standard. In reaching this conclusion, the

EPA notes that the majority of the CASAC did not address the limitations of these studies outlined in the 2021 draft PA, particularly in the context of the 24-hour standard with its 98th percentile form. Among the future research needs identified by the EPA in the 2022 final PA, the Agency noted a number of gaps in the currently available information reported in the epidemiologic studies of short-term exposure, including “descriptive statistics of PM_{2.5} concentrations at individual percentiles from the 95th percentile to the 99th percentile, as well as the number of days of concentrations and/or health events within each of these percentiles” and other descriptive statistics and details regarding analytical design in studies employing restricted analyses (U.S. EPA, 2022b, pp. 3–225 to 3–226). Such information could significantly improve the EPA’s ability to draw conclusions from these studies with regard to the adequacy of the current primary 24-hour PM_{2.5} standard.

Due to the limitations and uncertainties outlined above, in reaching his decision on the primary 24-hour PM_{2.5} standard, the Administrator judges that the information from currently available short-term epidemiologic studies, including those that use restricted analyses, is inadequate to inform decisions regarding the adequacy of the current 24-hour standard. Additionally, consistent with the final decision in 2012, the EPA continues to view an approach that focuses on setting a generally controlling annual standard as the most effective and efficient way to reduce total population risk associated with both long- and short-term PM_{2.5} exposures. Potential air quality changes associated with meeting an annual standard level of 9.0 µg/m³ will result in lowering risk associated with both long-

and short-term PM_{2.5} exposure by lowering the overall air quality distribution. As discussed above, reducing the annual standard is the most efficient way to reduce the risks from short-term exposures identified in the epidemiologic studies, as the available evidence suggests the bulk of the risk comes from the large number of days across the bulk of the air quality distribution, not the relatively small number of days with peak concentrations. However, as in the 2012 review, the Administrator recognizes that an annual standard alone would not be expected to offer sufficient protection with an adequate margin of safety against the effects of short-term PM_{2.5} exposures in all parts of the country, particularly in areas with high peak-to-mean ratios, and concludes that it is appropriate to continue to provide supplemental protection by means of a 24-hour standard. In so doing, the Administrator concludes that retaining the level of the primary 24-hour PM_{2.5} standard of 35 µg/m³ will provide requisite protection against short-term peak PM_{2.5} concentrations, in conjunction with a revised annual standard level of 9.0 µg/m³.

4. Administrator's Conclusions

This section summarizes the Administrator's considerations and conclusions related to the adequacy of the current primary PM_{2.5} standards and presents his decision to revise the primary annual PM_{2.5} standard to a level of 9.0 µg/m³ and retain the primary 24-hour PM_{2.5} standard. In establishing primary standards under the Act that are "requisite" to protect public health with an adequate margin of safety, the Administrator is seeking to establish standards that are neither more nor less stringent than necessary for this purpose. He recognizes that the requirement to provide an adequate margin of safety was intended

to address uncertainties associated with inconclusive scientific and technical information and to provide a reasonable degree of protection against hazards that research has not yet identified.

However, the Act does not require that primary standards be set at a zero-risk level; rather, the NAAQS must be sufficiently protective, but not more stringent than necessary.

Given these requirements, the Administrator's final decision in this reconsideration is a public health policy judgment drawing upon scientific and technical information examining the health effects of PM_{2.5} exposures, including how to consider the range and magnitude of uncertainties inherent in that information. This public health policy judgment is based on an interpretation of the scientific and technical information that neither overstates nor understates its strengths and limitations, nor the appropriate inferences to be drawn, and is informed by the Administrator's consideration of advice from the CASAC and public comments received on the proposal.

The initial issue to be addressed in the reconsideration of the primary PM_{2.5} standards is whether, in view of the advances in scientific knowledge and other information reflected in the 2019 ISA, ISA Supplement, and 2022 PA, the current standards are requisite to protect public health with an adequate margin of safety. In considering the adequacy of the current suite of primary PM_{2.5} standards, the Administrator has considered the large body of evidence presented and assessed in the 2019 ISA and ISA Supplement, the conclusions presented in the 2022 PA, the views expressed by the CASAC, and public comments. The Administrator has taken into

account both evidence- and risk-based considerations in developing final conclusions on the adequacy of the current primary PM_{2.5} standards. The Administrator has additionally considered the associated public health policy judgments and judgments about the uncertainties inherent in the scientific evidence and quantitative analyses that are integral to the conclusions on the adequacy of the current primary PM_{2.5} standards.

In evaluating the adequacy of the current standards, the Administrator first recognizes the longstanding body of health evidence supporting relationships between PM_{2.5} exposures (short- and long-term) and mortality and serious morbidity effects. The evidence available in this reconsideration (*i.e.*, that assessed in the 2019 ISA and ISA Supplement) and summarized above in section II.A.2.a reaffirms, and in some cases strengthens, the conclusions from the 2009 ISA regarding the health effects of PM_{2.5} exposures. Recent epidemiologic studies demonstrate generally positive and often statistically significant associations between PM_{2.5} exposures and a number of health effects, including non-accidental, cardiovascular, or respiratory mortality; cardiovascular or respiratory hospitalizations or emergency room visits; and other mortality/morbidity outcomes (*e.g.*, lung cancer mortality or incidence, asthma development). Recent controlled human exposure and animal toxicological studies, as well as evidence from epidemiologic panel studies, strengthens support for potential biological pathways through which PM_{2.5} exposures could lead to the serious effects reported in many population-level epidemiologic studies, including support for pathways that could lead to cardiovascular, respiratory, nervous system, and cancer-related effects. In considering the

available scientific evidence, and consistent with approaches employed in past NAAQS reviews, the Administrator places the most weight on evidence supporting “causal” or “likely to be causal” relationship with long or short-term PM_{2.5} exposures. In addition, the Administrator also takes note of those populations identified to be at greater risk of PM_{2.5}-related health effects, as characterized in the 2019 ISA and ISA Supplement, and the potential public health implications.

In evaluating what existing or revised standards may be requisite to protect public health, as described above in section II.A.2, the Administrator’s approach recognizes that the current annual standard (based on arithmetic mean concentrations) and 24-hour standard (based on 98th percentile concentrations), together, are intended to provide public health protection against the full distribution of short- and long-term PM_{2.5} exposures. This approach recognizes that changes in PM_{2.5} air quality designed to meet either the annual or the 24-hour standard would likely result in changes to both long-term average and short-term peak PM_{2.5} concentrations.

Further, consistent with the approach adopted in 2012, the Administrator concludes that the most effective and efficient way to reduce total population risk associated with both long- and short-term PM_{2.5} exposures is to set a generally controlling annual standard, and to provide supplemental protection against the occurrence of peak 24-hour PM_{2.5} concentrations by means of a 24-hour standard set at the appropriate level. In reaching this conclusion, the Administrator explicitly recognizes that air quality changes associated with meeting a revised annual standard would result in lowering risks associated

with both long- and short-term PM_{2.5} exposures by lowering the overall distribution of air quality concentrations, leading to not only in lower short- and long-term PM_{2.5} concentrations near the middle of the air quality distribution, but also in fewer and lower short-term peak PM_{2.5} concentrations. Similarly, the Administrator recognizes that changes in air quality to meet a 24-hour standard, would result not only in fewer and lower peak 24-hour PM_{2.5} concentrations, but also in lower annual average PM_{2.5} concentrations. However, as noted in 2012, he also recognizes that an approach that relies on setting the level of the 24-hour standard such that the 24-hour standard is generally controlling would be less effective and result in less uniform protection across the U.S. than an approach that focuses on setting a generally controlling annual standard. Thus, he concludes that relying on a revised annual standard as the controlling standard will reduce aggregate risks associated with both long- and short-term exposures more consistently than a generally controlling 24-hour standard. He further concludes that retaining a 24-hour standard at the appropriate level will ensure an adequate margin of safety against short-term effects in areas with high peak-to-mean ratios.

In light of his focus on the annual standard as the generally controlling standard, in considering whether the primary PM_{2.5} standards are adequate, the Administrator first considers information available to inform his final conclusions regarding the primary annual PM_{2.5} standard. In so doing, he notes that in this reconsideration, a large number of key U.S. epidemiologic studies report positive and statistically significant associations for air quality distributions with overall mean PM_{2.5} concentrations that are well

below the current level of the annual standard of 12.0 $\mu\text{g}/\text{m}^3$. He further recognizes that there is additional scientific evidence assessed in the 2019 ISA and newly assessed in this reconsideration in the ISA Supplement that can provide supplemental information to inform his decisions. In addition to the key U.S. epidemiologic studies, the Administrator also recognizes that key Canadian epidemiologic studies also demonstrate positive and statistically significant associations at concentrations below 12 $\mu\text{g}/\text{m}^3$. He also recognizes that epidemiologic studies that restrict annual average $\text{PM}_{2.5}$ concentrations to below 12 $\mu\text{g}/\text{m}^3$ also provide support for positive and statistically significant associations at lower mean $\text{PM}_{2.5}$ concentrations, as do accountability studies that also suggest public health improvements may occur at concentrations below 12 $\mu\text{g}/\text{m}^3$.

With regard to the available scientific evidence to inform his final decisions on the adequacy of the current 24-hour standard, the Administrator finds that there is less information available to support decisions on the 24-hour standard than that summarized above for the annual standard. The Administrator first notes that controlled human exposure studies, including those newly available in this reconsideration, demonstrate effects following short-term $\text{PM}_{2.5}$ exposures at concentrations higher than the current 24-hour standard. The Administrator also considers air quality analyses conducted in the 2022 PA and in responding to public comments, as described above in section II.B.3, that evaluate $\text{PM}_{2.5}$ concentrations in ambient air for similar durations to the controlled human exposure studies. As noted above, these air quality analyses indicate that the current 24-hour standard, particularly in conjunction with the revised level of the annual standard,

provides a high degree of protection against subdaily $\text{PM}_{2.5}$ concentrations that have been shown to elicit effects in controlled human exposure studies. The Administrator considers a limited number of available epidemiologic studies that report associations with health effects when the analyses are restricted to daily $\text{PM}_{2.5}$ concentrations below $35 \mu\text{g}/\text{m}^3$. As described above, although these studies are useful in demonstrating that health effects are associated with exposure to daily $\text{PM}_{2.5}$ concentrations in the lower part of the air quality distribution, they do not provide information about health effects associated with the short-term “peak” exposures that the 24-hour standard is designed to protect against. Accordingly, these studies have limited relevance in informing a decision about the appropriate level of the 24-hour standard.

In addition to the scientific evidence, the Administrator also considers the information from the risk assessment. In so doing, he notes that the risk assessment estimates that the current primary annual $\text{PM}_{2.5}$ standard could allow a substantial number of deaths in the U.S. With respect to the 24-hour standard, the Administrator recognizes that there are only a small number of study areas where the 24-hour standard is controlling and changes in the 24-hour standard level are estimated to have a much smaller impact on public health. The Administrator recognizes that while the risk estimates can help to place the evidence for specific health effects into a broader public health context, they should be considered along with the inherent uncertainties and limitations of such analyses when informing judgments about the potential for additional public health protection associated with $\text{PM}_{2.5}$ exposure and related health effects. While the Administrator

recognizes that these uncertainties are important, he also notes that the general magnitude of the risk estimates provide support for significant public health impacts, particularly for lower alternative annual standard levels.

In reaching his final conclusions regarding the adequacy of the primary $\text{PM}_{2.5}$ standards, the Administrator also considers the CASAC's advice and recommendations, as well as public comments. With respect to the CASAC's advice, the Administrator recognizes that, in their review of the 2021 draft PA, the CASAC reached consensus that the current primary annual $\text{PM}_{2.5}$ standard is not adequate and that it is not sufficiently protective of public health. The Administrator also takes note of the CASAC's advice in their review of the 2019 draft PA, where the CASAC did not reach consensus on the adequacy of the primary annual $\text{PM}_{2.5}$ standard, with the minority recommending revision and the majority recommending the standard be retained. Furthermore, he recognizes that in reviewing the 2019 draft PA, the CASAC reached consensus regarding the adequacy of the primary 24-hour $\text{PM}_{2.5}$ standard, concluding that the standard should be retained. Conversely, in their review of the 2021 draft PA, the majority of the CASAC advised that the current primary 24-hour $\text{PM}_{2.5}$ standard is not adequate and recommended revising the level of the standard, while the minority of the CASAC concluded that the standard was adequate and should be retained. However, in considering the advice of the CASAC collectively in the context of this reconsideration, the Administrator recognizes that the 2021 draft PA included scientific evidence and quantitative risk information that was not available in the 2019 draft PA, and therefore, the advice and recommendations of the CASAC in their

review of the 2021 draft PA are based on consideration of the full body of scientific evidence available in this reconsideration, including the evidence evaluated in the 2019 ISA and the ISA Supplement.

The Administrator recognizes that much of the scientific evidence available in this reconsideration was also available in the 2019 ISA and was considered by the then-Administrator when he decided that the current primary PM_{2.5} standards are requisite to protect public health with an adequate margin of safety. However, as described in section I.C.5.b above, in reaching his decision to reconsider the 2020 final decision, the Administrator also recognized that there were a number of studies published since the literature cutoff date of the 2019 ISA that were raised by some members of the CASAC in their review of the 2019 draft PA, in public comments on the 2020 proposal, and in the petitions for reconsideration. As such, the expansion of the air quality criteria in this reconsideration to encompass both the 2019 ISA and the additional scientific evidence evaluated in the ISA Supplement, along with evidence and updated quantitative analyses in the 2022 PA also provided an expanded record for the CASAC's review and public comments as a part of this reconsideration. Taken together, the 2019 ISA, ISA Supplement, and 2022 PA, along with the CASAC's advice and recommendations and public comments, provide the Administrator with additional information for consideration in reaching his final conclusions in this reconsideration. As a result, the record before him notably expands upon and strengthens the basis for the conclusions of the 2019 ISA while reducing some uncertainties that were identified in the 2020 final action.

In considering the available information in this reconsideration, the current Administrator reached different conclusions regarding the appropriate weight to place on certain aspects of the evidence than the then-Administrator in the 2020 final decision. For example, in reaching his conclusions on the primary annual PM_{2.5} standard in 2020, the then-Administrator concluded that it was appropriate to place more weight on epidemiologic studies that used ground-based monitors and to place less weight on the studies that used hybrid model-based approaches, citing to increased uncertainties associated with this new and emerging approach to estimating exposure. In placing more weight on the key U.S. monitor-based studies, the then-Administrator noted that the majority of these studies had mean concentrations at or above the level of the annual standard (12.0 µg/m³). However, unlike the approach for considering such studies in the 2012 review, the then-Administrator concluded that it was appropriate to consider the study-reported means collectively, and in so doing, he placed weight on the average of the study-reported means (or medians) across the U.S. monitor-based studies of 13.5 µg/m³, and noted that this concentration was above the level of the standard (85 FR 82717, December 18, 2020). In contrast, in this reconsideration, the current Administrator judges that it is appropriate to consider the individual study-reported mean PM_{2.5} concentrations from not only the U.S. monitor-based epidemiologic studies, but also the U.S. hybrid model-based epidemiologic studies, which are an advancement in the available science since the completion of the 2009 ISA. The current Administrator also adopts an approach similar to some previous approaches for the PM NAAQS in which he judges it most

appropriate to set the level of the standard to somewhat below the lowest long-term study-reported mean $\text{PM}_{2.5}$ concentration reported in key U.S. epidemiologic studies, which is $9.3 \mu\text{g}/\text{m}^3$. The study that reports the long-term mean $\text{PM}_{2.5}$ concentration of $9.3 \mu\text{g}/\text{m}^3$ is newly available in this reconsideration and is evaluated in the ISA Supplement. In the 2019 ISA, the lowest long-term study-reported mean $\text{PM}_{2.5}$ concentrations for U.S.-based studies that use ground-based monitors and hybrid model-based approaches are $9.9 \mu\text{g}/\text{m}^3$ and $10.7 \mu\text{g}/\text{m}^3$, respectively. In judging that it is appropriate to consider both monitor- and hybrid model-based epidemiologic studies and that it is appropriate to adopt an approach to set the level of the standard to somewhat below the lowest long-term mean $\text{PM}_{2.5}$ concentration, the current Administrator judges that the available scientific evidence—evaluated in both the 2019 ISA and in the ISA Supplement—provide support for his conclusion that that current primary $\text{PM}_{2.5}$ standard is not adequate and should be revised.

In addition to adopting a different approach than the previous Administrator for considering the long-term mean $\text{PM}_{2.5}$ concentrations from key U.S. epidemiologic studies (one more consistent with the approach of the EPA in other prior reviews), the current Administrator both has information newly available in this reconsideration before him and is reaching different conclusions about how to weigh the evidence before him in reaching his final conclusions. For example, in reaching his final decision in 2020, the then-Administrator was concerned about placing too much weight on epidemiologic studies to inform his conclusions on the adequacy of the primary $\text{PM}_{2.5}$ standards, noting that the epidemiologic studies do not identify particular $\text{PM}_{2.5}$ concentrations that

cause effects and cannot alone identify a specific level at which to set the standard. In so doing, the then-Administrator placed greater weight on the uncertainties and limitations associated with the epidemiologic studies, including exposure measurement error, potential confounding by copollutants, increased uncertainty of associations at lower PM_{2.5} concentrations, and heterogeneity of effects across different cities or regions (85 FR 82716, December 18, 2020). The Administrator recognizes that in reaching these judgments, the then-Administrator took into consideration the views of some members of the CASAC, who, in their advice on the 2019 draft PA, expressed the view that the current PM NAAQS should be retained because reported associations between short- and long-term PM_{2.5} exposures and adverse health outcomes “can reasonably be explained in light of uncontrolled confounding and other potential sources of error and bias” (Cox, 2019b, p. 8 of consensus responses).

In this reconsideration, the current Administrator notes that the ISA Supplement evaluates additional studies that employed statistical approaches that attempted to more extensively account for confounders and are more robust to model misspecification (*i.e.*, used alternative methods for confounder control, which are sometimes referred to as causal modeling or causal inference methods) that build upon those studies available and evaluated in the 2019 ISA (U.S. EPA, 2019, sections 11.1.2.1 and 11.2.2.4). These studies report consistent positive associations between long-term and short-term PM_{2.5} exposure and total mortality and cardiovascular effects (U.S. EPA, 2022a, section 3.2.2.3). In considering the epidemiologic evidence evaluated in the 2019 ISA, along with the newly available studies evaluated in

the ISA Supplement, the current Administrator also recognizes that there are uncertainties and limitations associated with the epidemiologic studies, but judges that it is appropriate to place less weight on these uncertainties than the then-Administrator placed on them in reaching his final decision in 2020, given the strength of the longstanding large body of epidemiologic evidence, employing a variety of study designs, that demonstrates associations between long- and short-term PM_{2.5} exposures and health effects across multiple U.S. cities and in diverse populations, including in studies examining populations and lifestages that may be at comparatively higher risk of experiencing a PM_{2.5}-related health effect (*e.g.*, older adults, children).

In reaching this final decision, the Administrator recognizes he is differing not only with the prior Administrator but also with the advice some members of the CASAC provided during their review of the 2019 draft PA. Specifically, taking into consideration the strength of the evidence providing support for causality determinations, the advice of other members of the CASAC and the need to protect public health with an adequate margin of safety, the current Administrator disagrees with these members of CASAC regarding the weight to be given to epidemiologic evidence “based on its methodological limitations” (Cox, 2019b, p. 8 of consensus responses), such as the possibility “that such associations could reasonably be explained by uncontrolled confounding and other potential sources of error and bias” (Cox, 2019b, p. 8 of consensus responses).

As another example of information that was not available to the CASAC in providing advice to the Administrator in reaching his final decision in 2020,

the then-Administrator noted in his final decision that, while some members of the CASAC and public commenters highlighted a number of accountability studies that examined past reductions in ambient PM_{2.5} concentrations and the degree to which those reductions have resulted in public health improvements, the small number of available accountability studies did not examine air quality with starting concentrations meeting the primary annual PM_{2.5} standard of 12.0 µg/m³. The then- Administrator took into consideration the absence of such accountability studies, as part of his consideration of the full body of scientific evidence, in reaching his judgment that there was considerable uncertainty in the potential for increased public health protection from further reductions in ambient PM_{2.5} concentrations beyond those achieved under the existing primary PM_{2.5} NAAQS (85 FR 82717, December 18, 2020). However, there are several accountability studies available since the literature cutoff date of the 2019 ISA and evaluated in the ISA Supplement in this reconsideration that have starting concentrations (or concentrations prior to the policy or intervention) below 12.0 µg/m³ (Corrigan et al, 2018; Henneman et al., 2019; Sanders et al., 2020a). The current Administrator concludes that, while the number of available accountability studies is limited, he recognizes that these studies provide supplemental information for consideration for informing decisions on the appropriate level of the primary annual PM_{2.5} standard along with the full body of evidence.

As EPA has frequently noted throughout this document, the extent to which the current primary PM_{2.5} standards are judged to be adequate depends in part on science policy and public health policy judgments to be made by the Administrator on the

strength and uncertainties of the scientific evidence, such as how to consider epidemiologic evidence and the need for an adequate margin of safety in setting the standards. Thus, it would be pure speculation to guess whether the then-Administrator would have reached the same or different conclusions in the 2020 final decision had the record before him included the newly available information in this reconsideration.¹⁰⁷ However, the current Administrator concludes that, for the reasons explained herein that, in his judgment, based on the record before him in this reconsideration, it is necessary and appropriate to revise the primary annual PM_{2.5} NAAQS to provide requisite protection of public health with an adequate margin of safety.

Based on the available scientific evidence and quantitative information, as well as consideration of the CASAC's advice and public comments, the Administrator concludes that the current primary annual PM_{2.5} standard is not adequate to protect public health with an adequate margin of safety. In addition, he finds the available information insufficient to call into question the adequacy of the public health protection afforded by the current primary 24-hour PM_{2.5} standard.

In considering how to revise the current suite of primary PM_{2.5} standards in order to achieve the

¹⁰⁷ The EPA notes that, in considering the additional scientific evidence available in this reconsideration, one member of the CASAC who reviewed both the 2019 draft PA and the 2021 draft PA found that the available scientific and quantitative information available in this reconsideration supported revising the level of the primary annual PM_{2.5} standard to within the range of 10–11 µg/m³, whereas he recommended retaining the standard during the review of the 2019 draft PA.

requisite protection for public health, with an adequate margin of safety, against long- and short-term PM_{2.5} exposures the Administrator considers the four basic elements of the NAAQS (indicator, averaging time, form, and level) collectively. With respect to indicator, the Administrator recognizes that the scientific evidence in this reconsideration, as in previous reviews, continues to provide strong support for health effects associated with PM_{2.5} mass. He notes the 2022 PA conclusion that the available information continues to support the PM_{2.5} mass-based indicator and remains too limited to support a distinct standard for any specific PM_{2.5} component or group of components, and too limited to support a distinct standard for the ultrafine fraction of PM (U.S. EPA, 2022b, section 3.6.3.2.1). In its advice on the adequacy of the current primary PM_{2.5} standards in their review of the 2021 draft PA, the CASAC reached consensus that the PM_{2.5} mass-based indicator should be retained, without revision (Sheppard, 2022a, p. 2 of consensus letter).¹⁰⁸ Additionally, there was no information in the public comments that provided a rationale for an alternative indicator. For all of these reasons, the Administrator concludes that it is appropriate to retain PM_{2.5} mass as the indicator for the primary standards for fine particles.

Consistent with his proposed conclusions regarding averaging time, the Administrator notes that the scientific evidence continues to provide strong support for health effect associations with both long- and short-term PM_{2.5} exposures (88 FR 5618, January 27, 2023). Epidemiologic studies continue to provide

¹⁰⁸ The CASAC did not provide advice or recommendations regarding the indicator of the primary PM_{2.5} standards in their review of the 2019 draft PA (Cox, 2019b).

strong support for health effects associated with short-term PM_{2.5} exposures based on 24-hour averaging periods, and associations in epidemiologic studies with subdaily estimates are less consistent and, in some cases, smaller in magnitude (88 FR 5618, January 27, 2023). Taken together, the 2019 ISA concludes that epidemiologic studies do not indicate that subdaily averaging periods are more closely associated with health effects than the 24-hour average exposure metric (U.S. EPA, 2019a, section 1.5.2.1). In addition, controlled human exposure and panel-based studies of subdaily exposures typically examine subclinical effects rather than the more serious population-level effects that have been reported to be associated with 24-hour exposures (*e.g.*, mortality, hospitalizations). While recent controlled human exposure studies provide consistent evidence for cardiovascular effects following PM_{2.5} exposures for less than 24 hours (*i.e.*, <30 minutes to 5 hours), air quality analyses have shown that the current averaging times can effectively protect against the exposure concentrations in these studies. This information does not indicate that a revision to the averaging time is necessary to provide additional protection against subdaily PM_{2.5} exposures, beyond that provided by the current primary annual and 24-hour PM_{2.5} standards. The Administrator also notes that this conclusion is also supported by the CASAC's advice in their review of the 2021 draft PA where they reached consensus that averaging times for the primary PM_{2.5} standards should be retained, without revision (Sheppard, 2022a, p. 2 of consensus letter).¹⁰⁹

¹⁰⁹ The CASAC did not provide advice or recommendations regarding the averaging times of the primary PM_{2.5} standards in their review of the 2019 draft PA (Cox, 2019b).

The Administrator also considers the relatively few public comments received that support a subdaily averaging time, but concludes that the currently available information does not provide support for an alternate averaging time. Consistent with his proposed decision, the Administrator concludes that it is appropriate to retain the annual and 24-hour averaging times for the primary PM_{2.5} standards to protect against long- and short-term PM_{2.5} exposures.

With regard to form, the Administrator first notes that the EPA has set both an annual standard and a 24-hour standard to provide protection from health effects associated with both long- and short-term exposures to PM_{2.5} (62 FR 38667, July 18, 1997; 88 FR 5620, January 27, 2023). With regard to the form of the annual standard, the Administrator recognizes that a large majority of the recently available epidemiologic studies continue to report associations between health effects and annual average PM_{2.5} concentrations. These studies of annual average PM_{2.5} concentrations provide support for retaining the current form of the annual standard to provide protection against long- and short-term PM_{2.5} exposures. In its review of the 2021 draft PA, the CASAC reached consensus that the form of the annual standard (*i.e.*, annual mean, averaged over 3 years) should be retained, without revision (Sheppard, 2022a, p. 2 of consensus letter).¹¹⁰ The Administrator also notes that there were no public comments that recommended an alternative form for the primary annual PM_{2.5} standard.

¹¹⁰ The CASAC did not provide advice or recommendations regarding the forms of the primary PM_{2.5} standards in their review of the 2019 draft PA (Cox, 2019b).

With regard to the form of the 24-hour standard (98th percentile, averaged over three years), epidemiologic studies continue to provide strong support for health effect associations with short-term (*e.g.*, mostly 24-hour) PM_{2.5} exposures, and controlled human exposure studies provide evidence for health effects following single short-term “peak” PM_{2.5} exposures (88 FR 5618, January 27, 2023). Therefore, the Administrator concludes that the evidence supports retaining a standard focused on providing supplemental protection against short-term peak exposures and supports a 98th percentile form for a 24-hour standard, in combination with a primary annual PM_{2.5} standard with its annual mean averaged over three years form. As described in the proposal and in responding to comments in section II.B.3 above, the Administrator further notes that the 98th percentile, averaged over three years, form also provides an appropriate balance between limiting the occurrence of peak 24-hour PM_{2.5} concentrations and identifying a stable target for risk management programs (U.S. EPA, 2022b, section 3.6.3.2.3). Furthermore, the Administrator notes that the multi-year percentile form (*i.e.*, averaged over three years) offers greater stability to the air quality management process by reducing the possibility that statistically unusual indicator values will lead to transient violations of the standard. This conclusion is also supported by the CASAC’s advice in their review of the 2021 draft PA, where they reached consensus that the form for the primary PM_{2.5} standards should be retained, without revision (Sheppard, 2022a, p. 2 of consensus letter).¹¹¹ The Administrator also recog-

¹¹¹ The CASAC did not provide advice or recommendations regarding the forms of the primary PM_{2.5} standards in their review of the 2019 draft PA (Cox, 2019b).

nizes that the CASAC recommended that in future reviews, the EPA also consider alternative forms for the primary 24-hour $\text{PM}_{2.5}$ standard (Sheppard, 2022a, p. 18 of consensus responses). Based on the CASAC's advice, the proposal solicited comment on alternatives to the current form for consideration in future reviews (88 FR 5619, January 27, 2023). The Administrator recognizes that there were a limited number of public comments related to the form of the primary $\text{PM}_{2.5}$ standards as discussed in section II.D.3 above and in the Response to Comments document, and notes that, the EPA will consider the information provided by the commenters regarding the form of the 24-hour $\text{PM}_{2.5}$ standard in the next review of the PM NAAQS. Consistent with his proposed decision, in considering the information summarized above, the Administrator concludes that it is appropriate to retain the forms of the current annual and 24-hour $\text{PM}_{2.5}$ standards.

In considering how to revise the current suite of $\text{PM}_{2.5}$ standards to provide the requisite public health protection with an adequate margin of safety, the Administrator next evaluates the appropriate levels of the primary $\text{PM}_{2.5}$ standards, beginning with the annual $\text{PM}_{2.5}$ standard. In having carefully considered public comments related to the primary annual $\text{PM}_{2.5}$ standard, the Administrator believes that the fundamental conclusions regarding the scientific evidence and quantitative information that supported his proposed conclusions (as described in the 2019 ISA, ISA Supplement, 2022 PA, and the proposal) remain valid. In considering the level at which the primary annual $\text{PM}_{2.5}$ standard should be set, the Administrator considers the entire body of evidence and information, giving appropriate weight to each part of that body of evidence and information.

He continues to place the greatest weight in this reconsideration on the available scientific evidence that provides support for associations between health effects and long- and short-term PM_{2.5} exposures. In conjunction with his decisions to retain the current indicator, averaging time, and form as described above, the Administrator is revising the level of the primary annual PM_{2.5} standard to 9.0 µg/m³. In so doing, he is selecting a primary annual PM_{2.5} standard that, together with the primary 24-hour PM_{2.5} standard, provides requisite public health protection with an adequate margin of safety, based on his judgments about and interpretation of the scientific evidence and quantitative risk information.

The Administrator's decision to revise the level of the primary annual PM_{2.5} standard to 9.0 µg/m³ builds upon his conclusion that the overall body of scientific evidence and quantitative risk information calls into question the adequacy of public health protection afforded by the current standard, particularly for at-risk populations. Consistent with his consideration of the available information in reaching his proposed decisions, the Administrator's final decision on the level of the primary annual PM_{2.5} standard places the greatest emphasis on key U.S. epidemiologic studies that report associations between long- and short-term PM_{2.5} exposures and mortality and morbidity. As in the proposal, and as discussed further below, he views additional epidemiologic studies (*i.e.*, studies that employ alternative methods for confounding control, studies that employ restricted analyses, and accountability studies), the controlled human exposure studies, and the risk assessment as providing supplemental information in support of his decision to revise the current annual standard, but recognizes that some of these lines of evidence and

information provide a more limited basis for selecting a particular standard level among a range of options. See *Mississippi*, 744 F. 3d at 1351–52 (studies can legitimately support a decision to revise the standard, but not provide sufficient information to justify their use in setting the level of a revised standard).

Given his consideration of the scientific evidence, quantitative risk information, advice from the CASAC, and public comments, the Administrator judges that a primary annual PM_{2.5} standard with a level of 9.0 µg/m³ is requisite to protect public health with an adequate margin of safety. He notes that the determination of what constitutes an adequate margin of safety is expressly left to the judgment of the EPA Administrator. See *Lead Industries Association v. EPA*, 647 F.2d at 1161–62; *Mississippi*, 744 F.3d at 1353. He further notes that in evaluating how particular standards address the requirement to provide an adequate margin of safety, it is appropriate to consider such factors as the nature and severity of the health effects, the size of the at-risk populations, and the kind and degree of the uncertainties present. In considering the need for an adequate margin of safety, the Administrator notes that a primary annual PM_{2.5} standard with a level of 9.0 µg/m³ would be expected to provide substantial improvements in public health compared to the current annual standard, including for at-risk groups such as children, older adults, people with preexisting conditions, minority populations, and low SES populations.

Consistent with his conclusions on the need for revision of the current annual standard, in reaching a decision on level, the Administrator places the most weight on information from epidemiologic studies. In so doing, the Administrator notes that these studies

provide consistent evidence of positive and statistically significant associations between long- and short-term exposure to PM_{2.5} and mortality and morbidity (88 FR 5624, January 27, 2023). The Administrator recognizes that placing weight on the information from the epidemiologic studies allows for examination of the entire population, including those that may be at comparatively higher risk of experiencing a PM_{2.5}-related health effects (*e.g.*, children, older adults, minority populations) (88 FR 5624, January 27, 2023). The Administrator also recognizes that recent epidemiologic studies continue to support a no-threshold relationship, meaning that there is no “bright line” below which no effects have been found. These studies also support a linear relationship between health effects and PM_{2.5} exposures at PM_{2.5} concentrations greater than 8 µg/m³, though uncertainties remain about the shape of the C–R curve at PM_{2.5} concentrations less than 8 µg/m³, with some recent studies providing evidence for either a sublinear, linear, or supralinear relationship at these lower concentrations (U.S. EPA, 2019a, section 11.2.4; U.S. EPA, 2022a, section 2.2.3.2; 88 FR 5625, January 27, 2023).

As at the time of proposal, the Administrator notes that some recent epidemiologic studies have adopted a broad range of approaches to examine confounding and the results of those examinations support the robustness of reported associations seen in epidemiologic studies. These include studies that employ alternative methods for confounder control and studies that evaluate the uncertainty related to exposure measurement error, both of which continue to support associations between PM_{2.5} exposures and health effects while taking approaches to address uncertainties.

In considering the epidemiologic evidence, the Administrator judges that, in reaching his decision on an appropriate level for the annual standard that will protect public health with an adequate margin of safety, in the absence of any discernible population-level thresholds, and in recognizing the need to weigh uncertainties associated with the epidemiologic evidence, it is most appropriate to examine where the evidence of associations observed in the epidemiologic studies is strongest and, conversely, to place less weight where he has less confidence in the associations observed in the epidemiologic studies. As at the time of proposal, the Administrator notes that in previous reviews, evidence-based approaches noted that the evidence of an association in any epidemiologic study is “strongest at and around the long-term average where the data in the study are most concentrated” (78 FR 3140, January 15, 2013). Given this, these approaches focused on identifying standard levels near or somewhat below long-term mean concentrations reported in key epidemiologic studies. These approaches were supported by previous CASAC advice as well as the CASAC’s advice in their review of the 2021 draft PA as a part of this reconsideration.

Additionally, the Administrator acknowledges that in the 2020 final action, the then-Administrator decided to retain the standard based in part on concerns about placing reliance on the epidemiologic studies and his judgment that even if he did rely on them, the majority of the studies had means or medians, as well as the mean of all of the key study-reported means or medians, above the level of the current annual standard. However, after considering the evidence, the advice of CASAC, and public comments the Administrator judges that this

approach is insufficient to protect public health with an adequate margin of safety. The Administrator's decision to reach a different judgment about the appropriate level of the annual standard reflects the updated and expanded scientific record available to the Administrator in this reconsideration, as well as the additional advice from the CASAC and the public comments based on this newly available information. In addition, the Administrator observes the decision in this action to place weight on the epidemiologic studies, and to revise the annual primary standard to a level below the lowest long-term mean in the U.S.-based epidemiologic studies, is consistent with the EPA's past practice in PM NAAQS reviews.

In this reconsideration, the Administrator is considering the scientific record which has been expanded and updated since the 2020 final action, as well as the additional advice from the CASAC and the public comments that are based on the newly available information that expands upon the information previously available. In addition, the Administrator is exercising his judgment about how to interpret and weigh the expanded evidence in a way that is more consistent with the approaches used in prior PM NAAQS reviews. As a result, the Administrator has concluded on reconsideration that the level of the primary annual standard is not adequate and should be revised to protect public health with an adequate margin of safety.

Consistent with his proposed decisions, in reaching conclusions on the level of the primary annual PM_{2.5} standard, the Administrator considers the long-term¹¹² study-reported mean PM_{2.5} concentrations

¹¹² "Long-term" represents PM_{2.5} exposures and concentrations that are annual or multi-year.

from key long- and short-term epidemiologic studies and sets the level of the standard to somewhat below the lowest long-term mean PM_{2.5} concentration.¹¹³ He notes that in previous PM NAAQS reviews (including the 1997, 2006 and 2012 reviews), evidence-based approaches focused on identifying standard levels near or somewhat below long-term mean concentrations reported in key long- and short-term epidemiologic studies. These approaches were supported by the CASAC in previous reviews and were supported in this reconsideration by the CASAC in their review of the 2021 draft PA. In considering the available scientific evidence to inform such an approach, the Administrator notes the strength of the epidemiologic evidence which includes multiple studies that consistently report positive associations for short- and long-term PM_{2.5} exposure and mortality and cardiovascular effects. Some available studies also use a variety of statistical methods to control for confounding bias and report similar associations, which further supports the broader body of epidemiologic evidence for both mortality and cardiovascular effects. Additionally, he notes that recent epidemiologic studies available for consideration in reaching his final decision strengthen support for health effect associations at PM_{2.5} concentrations lower than in those evaluated in epidemiologic studies available at the time of previous reviews. The Administrator does recognize, however, that while these epidemiologic studies evaluate associations between distributions of ambient PM_{2.5} concentrations and health outcomes,

¹¹³ As described in section II.A.2.c above, key epidemiologic studies are those that report overall mean (or median) PM_{2.5} concentrations and for which the years of PM_{2.5} air quality data used to estimate exposures overlap entirely with the years during which health events are reported.

they do not identify the specific exposures that led to the reported effects. As such, he notes that there is no specific point in the air quality distribution of any epidemiologic study that represents a “bright line” at and above which effects have been observed and below which effects have not been observed. The Administrator further notes that the epidemiologic studies provide the strongest support for reported health effect associations for this middle portion of the PM_{2.5} air quality distribution, which corresponds to the bulk of the underlying data, rather than the extreme upper or lower ends of the distribution, and concludes that the long-term study-reported means from both long- and short-term studies provide the strongest support for reported health effect associations in epidemiologic studies. For these reasons, as described in the proposal and in responding to public comments in section II.B.3 above, the Administrator concludes that it is appropriate to continue to employ an approach that focuses on the mean PM_{2.5} concentrations from the key epidemiologic studies to inform his conclusions regarding the appropriate level for the primary annual PM_{2.5} standard.

In adopting such an approach, the Administrator considers the long-term mean concentrations reported in two types of key epidemiologic studies: (1) Monitor-based studies¹¹⁴ (epidemiologic studies that used ground-based monitors to estimate exposure,

¹¹⁴ Reported mean PM_{2.5} concentrations in monitor-based studies are averaged across monitors in each study area with multiple monitors, referred to as a composite monitor concentration, in contrast to the highest concentration monitored in the study area, referred to as a maximum monitor concentration (*i.e.*, the “design value” concentration), which is used to determine whether an area meets a given standard.

similar to approaches used in past reviews), and (2) hybrid modeling-based studies¹¹⁵ (epidemiologic studies that used hybrid modeling approaches and apply aspects of population weighting to estimate exposures). In reaching conclusions regarding the level of a standard that would provide requisite protection with an adequate margin of safety, the Administrator recognizes that he must use his judgment regarding the appropriate weight to place on the available evidence and technical information, including uncertainties. As shown in Figures 1 and 2 above, for the key U.S. monitor-based epidemiologic studies, the study-reported mean concentrations range from 9.9–16.5 $\mu\text{g}/\text{m}^3$, and for the key U.S. hybrid modeling-based epidemiologic studies, the mean concentrations range from 9.3–12.2 $\mu\text{g}/\text{m}^3$. The Administrator also recognizes that, in their review of the 2021 draft PA, both the majority and minority of the CASAC emphasized the epidemiologic studies in support of their recommendations for the level of the annual standard, but they weighed the studies in different ways (Sheppard, 2022a, p. 16–17 of consensus responses).

Based on this information, and in considering the CASAC's advice in their review of the 2021 draft PA, the Administrator judges that it is appropriate to set the level of the primary $\text{PM}_{2.5}$ standard at least as low as the lowest mean $\text{PM}_{2.5}$ concentration from

¹¹⁵ Studies that use hybrid modeling approaches employ methods to estimate ambient $\text{PM}_{2.5}$ concentrations across large geographical areas, including areas without monitors, and thus, when compared to monitor-based studies, require additional information to inform the relationship between the estimated $\text{PM}_{2.5}$ concentrations across an area and the maximum monitor design values used to assess compliance.

these key U.S.-based epidemiologic studies, which is $9.3 \mu\text{g}/\text{m}^3$. The Administrator additionally notes that setting the annual standard level at $9.0 \mu\text{g}/\text{m}^3$, which is below the lowest study-reported mean $\text{PM}_{2.5}$ concentration of $9.3 \mu\text{g}/\text{m}^3$, would be expected to shift the distribution of $\text{PM}_{2.5}$ concentrations in an area such that the area's highest monitor would generally be at or below $9.0 \mu\text{g}/\text{m}^3$ annually, when meeting the annual standard. In this situation, the resulting average or mean $\text{PM}_{2.5}$ concentration for the entire area (measured across a number of monitors) would be even further below the study-reported means,¹¹⁶ and will provide adequate protection not only in areas where the highest allowable concentrations would be expected (*i.e.*, near design value monitors) but also in other parts of the area where $\text{PM}_{2.5}$ concentrations would be expected to be maintained even lower.

As noted above, however, the Administrator must exercise his judgment regarding the appropriate weight to place on the available scientific evidence and quantitative information, including uncertainties, in determining what level of the annual standard is sufficient to protect public health with an adequate margin of safety. In so doing, he considers other information available in this reconsideration to inform his judgments, including study-reported $\text{PM}_{2.5}$ concentrations at lower percentiles in key epidemiologic studies, supplemental information from other types of epidemiologic studies, study-reported $\text{PM}_{2.5}$

¹¹⁶ Analyses in the 2022 PA suggest that the highest monitored value would be expected to be greater than the study-reported mean values by 10–20% for monitor-based studies and 15–18% for hybrid modeling studies that apply aspects of population weighting.

concentrations from key Canadian epidemiologic studies, and the results from the quantitative risk assessment.

In weighing the evidence in considering the requisite level of the annual standard, the Administrator also takes into account additional information from the key long- and short-term U.S. epidemiologic studies available that provide study-reported PM_{2.5} concentrations below the mean and, in particular, the subset of epidemiologic studies that report 25th and 10th percentile concentrations. Consistent with his proposed conclusions, as well as the CASAC's advice in their review of the 2021 draft PA and public comments, the Administrator judges that it is appropriate to place some weight on these lower percentiles in reaching his conclusions on the level of the primary annual standard. There are six key U.S. epidemiologic studies that report information on other percentiles (*e.g.*, 10th and 25th percentiles of PM_{2.5} concentrations or 10th and 25th percentiles of PM_{2.5} concentrations associated with health events) that are below the mean.¹¹⁷ In considering the information from these studies, the Administrator first notes that the three older, monitor-based studies that report lower percentiles of PM_{2.5} concentrations have smaller cohort sizes than the three hybrid model-based studies. Thus, the Administrator recognizes that the older, monitor-based studies had a relatively smaller portion of the health events that were observed in the lower part of the air quality distribution because of the generally smaller size of the cohorts. He further notes that the

¹¹⁷ The Wang et al. (2017) study only reports the 25th percentile of the estimated PM_{2.5} concentrations, not the 10th percentile.

recent hybrid model-based studies have larger cohort sizes than the older, monitor-based studies, and therefore, have more health events in the lower part of the air quality distribution. Because of the larger cohort sizes and having a larger portion of health events that are observed across the air quality distribution, the Administrator has more confidence in the magnitude and significance of the associations in the lower parts of the air quality distribution for the recent, hybrid model-based studies compared to the older, monitor-based studies. Given this, the Administrator judges that it is appropriate to place weight on the 25th percentile concentrations reported in the recently available hybrid model-based studies in reaching his conclusions regarding the appropriate level for the primary annual $\text{PM}_{2.5}$ standard. However, the Administrator also recognizes that his confidence in the magnitude and significance in the reported concentrations, and their ability to inform decisions on the appropriate level of the annual standard, starts to diminish at percentiles that are even further below the mean and the 25th percentile. For these reasons, the Administrator places weight on the reported 25th percentile concentrations in the recent hybrid model-based studies, rather than the reported 10th percentile concentrations, in reaching his conclusions regarding the appropriate level for the primary annual $\text{PM}_{2.5}$ standard.

In considering the information from these studies, as described in section II.A.2.c and in responding to public comments in section II.B.3 above, the Administrator notes that there are two hybrid model-based studies with large cohort sizes that apply population weighting and report lower percentile values. These studies are Di et al. (2017b) and Wang et al. (2017) and the reported 25th percentile

concentration is $9.1 \mu\text{g}/\text{m}^3$ for both studies.¹¹⁸ In considering these studies, the Administrator concludes that it is appropriate to place weight on the 25th percentile concentrations of these newer hybrid model-based studies (of $9.1 \mu\text{g}/\text{m}^3$) such that setting the level of the standard near these 25th percentile concentrations would provide requisite protection. The Administrator observes that an annual standard level of $9.0 \mu\text{g}/\text{m}^3$ would be near the reported 25th percentile concentrations in these studies.

As at the time of proposal, the Administrator also takes note of the study-reported long-term mean $\text{PM}_{2.5}$ concentrations in long- and short-term Canadian epidemiologic studies, which ranged from 6.9 to $13.3 \mu\text{g}/\text{m}^3$ for monitor-based studies and 5.9 to $9.8 \mu\text{g}/\text{m}^3$ for hybrid model-based studies. While the Administrator notes that these studies provide additional support for associations between $\text{PM}_{2.5}$ concentrations and health effects, he is also mindful that there are important differences between the exposure environments in the U.S. and Canada and that interpreting the data (*e.g.*, study-reported mean concentrations) from the Canadian studies in the context of a U.S.-based standard may present challenges in directly and quantitatively informing decisions regarding potential alternative levels of the annual standard. For example, in terms of people per square kilometer, the U.S. population density is

¹¹⁸ There is a third hybrid model-based study, as described in the 2022 PA and in section II.B.3 above in responding to public comments, but it is not referenced here because it reports a 25th percentile $\text{PM}_{2.5}$ concentration based on the 25th percentile of health events that occur in the study (Di et al., 2017a) rather than report the 25th percentile based on air quality concentrations.

nearly 10 times in the contiguous U.S. compared to Canada. As described in more detail in responding to public comments in section II.B.3 above, in this reconsideration, the Administrator recognizes that this difference in population density between the U.S. and Canada is more apparent than in previous reviews because the studies available in this reconsideration use different approaches than those previously available. In the 2012 review, the available Canadian epidemiologic studies used population-weighting and focused on urban areas where monitors were available and population densities were more comparable with those in the U.S., and at that time, the U.S. and Canadian studies reported similar mean PM_{2.5} concentrations. However, in this reconsideration, the Administrator takes note that for the new Canadian epidemiologic studies: (1) The Canadian monitor-based studies available in this reconsideration do not apply population weighting as the previously available studies did; and (2) some of the studies now use hybrid modeling approaches for estimating exposure. The Administrator recognizes that these differences are important to consider in reaching conclusions on how these Canadian epidemiologic studies should be interpreted regarding decisions on the requisite level of the primary annual PM_{2.5} standard. Specifically, the Administrator notes that the more recent Canadian studies that use hybrid modeling incorporate larger portions of the country, and therefore include more rural areas. The more rural areas that are included in the study using the hybrid modeling approaches, the more important it is to consider how the population densities and exposure environments differ between the U.S. and Canada. Additionally, the Administrator notes that for hybrid modeling-based studies there is less

certainty in PM_{2.5} exposure estimates in more rural areas, which are further from air quality monitors and where PM_{2.5} concentrations in the ambient air tend to be lower. For these hybrid model-based studies, the portion of the rural areas that are contributing to the study-reported mean PM_{2.5} concentrations in these studies is unclear. For these reasons, the Administrator concludes that it is important to consider the differences between the population exposures in the U.S. and Canadian study areas and how these differences influence the interpretation of the epidemiologic study results.

Thus, the Administrator considers the Canadian studies to inform his judgments on what level for the annual standard is requisite in light of the limitations and challenges presented. The Administrator also recognizes that the majority of the CASAC in their review of the 2021 draft PA, as well as a number of public commenters, place weight on the Canadian epidemiologic studies in recommending that the level of the primary annual PM_{2.5} standard be revised to 8–10 µg/m³. The Administrator further notes while the majority of the CASAC advised the EPA to consider the Canadian studies in revising the annual standard level to within the range of 8.0–10.0 µg/m³, they did not advise the EPA to set the annual standard level below the study-reported means from those studies. Given these considerations, the Administrator judges that it is appropriate to set the level of annual standard within the range of 8–10 µg/m³ to be consistent with the majority of the CASAC's advice in their consideration of these studies.

The Administrator also recognizes that information from epidemiologic studies that included analyses

that restrict annual average PM_{2.5} concentrations to concentrations below the level of the current annual standard can be useful for informing conclusions regarding the appropriate level of the primary annual PM_{2.5} standard. In so doing, he particularly notes the two key U.S. epidemiologic studies (Di et al., 2017b and Dominici et al., 2019) that restrict annual average PM_{2.5} concentrations to less than 12 µg/m³ and report positive and statistically significant associations with all-cause mortality and mean PM_{2.5} concentrations of 9.6 µg/m³. He also considers these results along with the uncertainties and limitations associated with studies that restricted analyses below certain PM_{2.5} concentrations. As described in responding to comments in section II.B.3 above, uncertainties associated with how the studies exclude PM_{2.5} concentrations from the analyses (*e.g.*, at what spatial resolution are concentrations being excluded), make it difficult to understand how to interpret the results of the restricted analyses in the context of the approach employed in this reconsideration, which takes into consideration the relationship between mean PM_{2.5} concentrations and design values.

The Administrator also recognizes that, in their review of the 2021 draft PA, the CASAC noted that epidemiologic studies that restrict analyses below certain PM_{2.5} concentrations represent one area for which the evidence has expanded in this reconsideration, stating that these studies provide support for mortality effects at concentrations below the current PM NAAQS (Sheppard, 2022a, p. 5 of consensus responses). In their recommendations on alternative levels for the primary annual PM_{2.5} standard, the majority of the CASAC cited to studies that restrict PM_{2.5} concentrations to below 12 µg/m³ as a part of their rationale for supporting a level within the range

of 8–10 $\mu\text{g}/\text{m}^3$ (Sheppard, 2022a p. 16 of consensus responses). Additionally, the Administrator notes that some members of the CASAC, in their review of the 2019 draft PA, concluded that the epidemiologic studies that restrict analyses below 12 $\mu\text{g}/\text{m}^3$ and show positive associations with health effects, along with other aspects of the scientific evidence, provide support for their conclusion that the primary annual $\text{PM}_{2.5}$ standard is not adequate (Cox, 2019b, p. 9 of consensus responses). Furthermore, the Administrator takes note of public commenters who also noted that the epidemiologic studies that restrict $\text{PM}_{2.5}$ concentrations to below the current standard provide support, along with the other available information, for lowering the level of the primary annual $\text{PM}_{2.5}$ standard. In considering the studies that include restricted analyses, along with the CASAC's advice and public comments on these types of studies, the Administrator concludes that, although there are inherent uncertainties associated with this limited body of evidence, these studies that apply restricted analyses provide support for serious effects (*e.g.*, mortality) at concentrations below 10.0 $\mu\text{g}/\text{m}^3$. Given this, the Administrator concludes that it is appropriate to place some weight on these studies, and in doing so, notes that a standard level of 9.0 $\mu\text{g}/\text{m}^3$ would be below the reported mean $\text{PM}_{2.5}$ concentrations of 9.6 $\mu\text{g}/\text{m}^3$ in these studies and would, thus, be expected to provide protection against exposures related to these reported mean concentrations.

The Administrator also takes into consideration recent U.S. accountability studies, which assess the health effects associated with actions that improve air quality (*e.g.*, air quality policies or implementation of an intervention). These types of studies can also reduce uncertainties related to residual

confounding of temporal and spatial factors (U.S. EPA, 2022a, p. 3–25). The Administrator notes that in the 2020 review, the available accountability studies had “starting” annual average PM_{2.5} concentrations (*i.e.*, mean concentration prior to reductions being evaluated) from 13.2–31.5 µg/m³, and the then-Administrator cited the lack of accountability studies in areas where the “starting” concentration met the current primary PM_{2.5} standards as part of his rationale for retaining the standards. As at the time of proposal, the current Administrator notes that in three studies newly available in this reconsideration and assessed in the ISA Supplement, prior to implementation of the policies, mean PM_{2.5} concentrations in these studies were below the level of the current annual standard level (12.0 µg/m³) and ranged from 10.0 µg/m³ to 11.1 µg/m³. These studies report positive and significant associations between mortality and cardiovascular morbidity and reductions in ambient PM_{2.5} following the implementation of a policy (Henneman et al., 2019; Corrigan et al., 2018; Sanders et al., 2020a; 88 FR 5627, January 27, 2023). These studies suggest that public health improvements may occur following the implementation of a policy that reduces annual average PM_{2.5} concentrations below the level of the current standard of 12.0 µg/m³. The Administrator recognizes that in their review of the 2021 draft PA, the CASAC noted that the availability of recent accountability studies was one area where the evidence had been strengthened and that the studies assessed in the ISA Supplement provide evidence of mortality effects at annual average PM_{2.5} concentrations below the current NAAQS (Sheppard, 2022a, p. 5 of consensus responses). The Administrator recognizes that the CASAC also concluded that, along with other lines of evidence, the

accountability studies with starting concentrations below the levels of the current standards are appropriate to consider for informing conclusions on alternative standard levels (Sheppard, 2022a, p. 13 of consensus responses). The Administrator also notes the advice of the CASAC in their review of the 2019 draft ISA, where they suggested that accountability studies be taken into account and such studies provide potentially crucial information about whether and how much decreasing $\text{PM}_{2.5}$ causes decreases in future health effects, which reflects the primary purpose of the NAAQS (Cox, 2019b, p. 8 and 10 of consensus responses). The Administrator also notes that in their review of the 2019 draft ISA, some members of the CASAC cautioned against placing more weight on the data from accountability studies based on the methodological limitations of the studies (Cox, 2019b, p. 8 of consensus responses). The Administrator notes that the CASAC did not explicitly cite to accountability studies in their reviews of the 2019 draft PA or 2021 draft PA as support for their recommendations on the adequacy of the primary annual $\text{PM}_{2.5}$ standard or potential alternative standard levels. A number of public commenters who support revising the level of the standard to $8 \mu\text{g}/\text{m}^3$ cite these accountability studies, along with the broader evidence base, as support for a more protective standard. The Administrator, in considering the evidence, the advice from the CASAC, and public comment, first recognizes that accountability studies are just one line of evidence to be considered in the broader evaluations of the information available to inform conclusions on the level of the standard. In so doing, he notes that public health improvements may occur following the implementation of a policy that reduces annual average $\text{PM}_{2.5}$ concentrations below

the level of the current standard of 12.0 $\mu\text{g}/\text{m}^3$, and potentially below the lowest “starting” concentrations in these studies of 10.0 $\mu\text{g}/\text{m}^3$. However, the Administrator concludes that the limited number of accountability studies provide limited information for informing decisions on the appropriate level of the primary annual $\text{PM}_{2.5}$ standard but recognizes that these studies provide supplemental information for consideration along with the full body of evidence. Taken together, the Administrator notes a revised annual standard level of 9.0 $\mu\text{g}/\text{m}^3$ is at or below the lowest starting concentration of these accountability studies (*i.e.*, 10.0 $\mu\text{g}/\text{m}^3$), and judges that it is appropriate to place some weight on these studies, particularly for informing his public policy judgments regarding an adequate margin of safety.

In addition to his consideration of and conclusions regarding the available scientific evidence, the Administrator also considers the results of the quantitative risk assessment to inform his conclusions regarding the appropriate level for the primary annual $\text{PM}_{2.5}$ standard. The Administrator recognizes that the risk estimates can help to place the evidence for specific health effects into a broader public health context, but should be considered along with the inherent uncertainties and limitations of such analyses when informing judgments about the potential for additional public health protection associated with $\text{PM}_{2.5}$ exposure and related health effects. The Administrator recognizes that the overall risk assessment estimates suggest that the current primary annual $\text{PM}_{2.5}$ standard could allow a substantial number of $\text{PM}_{2.5}$ -associated deaths in the U.S. The Administrator also recognizes that the CASAC concurred with the 2021 draft PA’s assessment that meaningful risk reductions will result from lowering

the annual PM_{2.5} standard (Sheppard, 2022a, p. 16 of consensus responses).

Additionally, with respect to the results of the quantitative risk assessment, the Administrator recognizes that the 2022 PA also provides information on the distribution of concentrations associated with the estimated mortality risk at each alternative standard level assessed (U.S. EPA, 2022b, sections 3.4.2.2 and 3.6.2.2, Figure 3–18 and 3–19). When meeting an annual standard of 9.0 µg/m³ at the design value monitor, the exposure concentrations within an area are estimated to be below 9 µg/m³, with the majority of those exposures being at concentrations of below 8 µg/m³. The Administrator notes that this range of concentrations is below the lowest means in the key long- and short-term epidemiologic studies (concentrations at which the evidence is the strongest in supporting an association between exposure to PM_{2.5} and adverse health effects observed in the key epidemiologic studies available in this reconsideration). Thus, the Administrator concludes that the results of the quantitative risk assessment suggest that a revised annual standard level of 9.0 µg/m³ is estimated to reduce PM_{2.5} exposures to fall within the range of concentrations in which there is the most confidence in the associations and thus, confidence that estimated risk reductions will actually occur.

The Administrator also notes the information provided by the quantitative risk assessment on the distribution of concentrations associated with the estimated mortality risk for a higher annual standard level of 10.0 µg/m³ and a lower standard level of 8.0 µg/m³ (U.S. EPA, 2022b, sections 3.4.2.2 and 3.6.2.2, Figure 3–18 and 3–19). The Administrator

finds that, for an annual standard level of $10.0 \mu\text{g}/\text{m}^3$, the quantitative risk assessment estimates that the standard would allow multiple exposures at concentrations above the lowest means in the key epidemiologic studies, and therefore, calls into question whether a standard level of $10.0 \mu\text{g}/\text{m}^3$ would provide enough public health protection. Additionally, the Administrator also finds that, for a lower annual standard level of $8.0 \mu\text{g}/\text{m}^3$, the quantitative risk assessment estimates the exposure concentrations to be below $8 \mu\text{g}/\text{m}^3$, with the majority of those exposures being at concentrations of below $7 \mu\text{g}/\text{m}^3$. The Administrator observes that the majority of exposure concentrations under this air quality scenario are estimated to fall outside of the range of concentrations in which he has the most confidence in the associations and that the additional risk reductions will actually occur.

Recognizing and building upon the above considerations and judgments, and with consideration of advice from the CASAC and public comment, the Administrator concludes that the current body of scientific evidence and quantitative risk assessment support his judgment that the level of the primary annual $\text{PM}_{2.5}$ standard should be revised to a level of $9.0 \mu\text{g}/\text{m}^3$. Revising the level of the primary annual $\text{PM}_{2.5}$ standard will, in the Administrator's judgment, provide requisite public health protection with an adequate margin of safety.

The Administrator recognizes that placing weight on the information from the epidemiologic studies allows for examination of the entire population, including those that may be at comparatively higher risk of experiencing a $\text{PM}_{2.5}$ -related health effects (*e.g.*, children, older adults, minority populations)

(88 FR 5624, January 27, 2023). In considering the epidemiologic evidence, the Administrator judges that, in reaching his decision on an appropriate level for the annual standard that will protect public health with an adequate margin of safety, in the absence of any discernible population-level thresholds, and in recognizing the need to weigh uncertainties associated with the epidemiologic evidence, it is most appropriate to examine where the evidence of associations observed in the epidemiologic studies is strongest and, conversely, to place less weight where he has less confidence in the associations observed in the epidemiologic studies. The Administrator notes that in previous reviews, evidence-based approaches noted that the evidence of an association in any epidemiologic study is “strongest at and around the long-term average where the data in the study are most concentrated” (78 FR 3140, January 15, 2013). These approaches were supported by previous CASAC advice as well as the CASAC’s advice in their review of the 2021 draft PA as a part of this reconsideration. Given this, the Administrator notes that in revising the annual PM_{2.5} standard to a level of 9.0 µg/m³, he is setting the standard at a level below the long-term mean PM_{2.5} concentrations in the key long- and short-term epidemiologic studies, including the lowest study reported mean of 9.3 µg/m³, following an approach that is consistent with previous PM NAAQS reviews. The Administrator additionally notes that air quality analyses in the 2022 PA demonstrate that areas meeting a revised annual standard of 9.0 µg/m³ would be expected to shift the distribution of PM_{2.5} exposure concentrations in an area such that the area’s highest monitor would generally be at or below 9.0 µg/m³ annually, and most of the resulting PM_{2.5} concentrations across the area

would be even further below the study-reported means.^{119 120} Thus, 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 (*i.e.*, near design value monitors) but also in other parts of the area where $\text{PM}_{2.5}$ concentrations would be expected to be maintained even lower.

Furthermore, the Administrator recognizes the CASAC's advice in their review of the 2021 draft PA, as well as public comments, that weight should be placed on study-reported $\text{PM}_{2.5}$ concentrations that are somewhat below the mean, particularly for some of the newer epidemiologic studies with larger cohort sizes. In weighing uncertainties associated with using these data to inform a revised annual standard level, as well as noting the limited studies for which this information is available, the Administrator judges that some weight should be placed on these data, but they should not receive the same weight as the study-reported mean concentrations. Thus, the Administrator concludes that it would be appropriate to set the annual standard level near the 25th percentile $\text{PM}_{2.5}$ concentrations in the two newer key epidemiologic studies for which these values were reported. In doing so, the Administrator notes that a

¹¹⁹ Analyses in the 2022 PA suggest that the highest monitored value would be expected to be greater than the study-reported mean values by 10–20% for monitor-based studies and 15–18% for hybrid modeling studies that apply aspects of population weighting (U.S. EPA, 2022b, section 2.3.3.2.4).

¹²⁰ The risk assessment in the 2022 PA used air quality adjustments to simulate just meeting the current primary $\text{PM}_{2.5}$ standards, as well as alternative standard levels (U.S. EPA, 2022b, section 3.4.1.4 and Appendix C, section C.1.4).

decision to revise the annual standard to $9.0 \mu\text{g}/\text{m}^3$ would set a level of the standard near and somewhat below the reported 25th percentile $\text{PM}_{2.5}$ concentrations of $9.1 \mu\text{g}/\text{m}^3$ in these two more recent hybrid model-based studies.

The Administrator also takes note of the study-reported long-term mean $\text{PM}_{2.5}$ concentrations in the key Canadian epidemiologic studies. While the Administrator notes that these studies provide additional support for associations between $\text{PM}_{2.5}$ concentrations and health effects, he is also mindful that there are important differences between the exposure environments in the U.S. and Canada that affect interpretation of the data in the context of informing decisions regarding potential alternative levels of the annual standard. The Administrator also recognizes that the majority of the CASAC in their review of the 2021 draft PA, as well as a number of public commenters, placed weight on the Canadian epidemiologic studies in recommending that the level of the primary annual $\text{PM}_{2.5}$ standard be revised to 8–10 $\mu\text{g}/\text{m}^3$. The Administrator notes that a decision to revise the annual standard to $9.0 \mu\text{g}/\text{m}^3$ would set the level of the standard within the range of levels recommended by the majority of CASAC in their consideration of these studies.

Additionally, the Administrator also considers the information provided by epidemiologic studies that use restricted analyses, as well as accountability studies. With respect to the restricted analyses, the Administrator, in considering the CASAC's advice in their review of the 2021 draft PA and many public comments on these types of studies, concludes that, although there are inherent uncertainties associated with this limited body of evidence, the studies that

apply restricted analyses provide support for serious effects (*e.g.*, mortality) at concentrations below 10.0 $\mu\text{g}/\text{m}^3$. Additionally, in considering accountability studies, the Administrator concludes that while the small number of these studies provide limited information for informing decisions on the appropriate level of the primary annual $\text{PM}_{2.5}$ standard, these studies provide supplemental information for consideration along with the full body of evidence. The Administrator further notes that these studies suggest that public health improvements may occur following the implementation of a policy that reduces annual average $\text{PM}_{2.5}$ concentrations below the level of the current standard of 12.0 $\mu\text{g}/\text{m}^3$, and potentially below the lowest “starting” concentrations in these studies of 10.0 $\mu\text{g}/\text{m}^3$. Taken together, the Administrator judges that it is appropriate to place some weight on these types of studies, particularly for informing his public policy judgments regarding an adequate margin of safety, and notes that a revised annual standard level of 9.0 $\mu\text{g}/\text{m}^3$ is below the lowest starting concentration of the accountability studies (*i.e.*, 10.0 $\mu\text{g}/\text{m}^3$), and below the concentration at which studies that apply restricted analyses provide support for serious effects (*i.e.*, 9.6 $\mu\text{g}/\text{m}^3$).

The Administrator also judges that the results of the quantitative risk assessment provide support for a primary annual $\text{PM}_{2.5}$ standard with a level of 9.0 $\mu\text{g}/\text{m}^3$. The results of the risk assessment suggest that when meeting an annual standard of 9.0 $\mu\text{g}/\text{m}^3$, $\text{PM}_{2.5}$ exposures are maintained below 9 $\mu\text{g}/\text{m}^3$ at the design value monitor, with the majority of those exposures being at concentrations below 8 $\mu\text{g}/\text{m}^3$. Thus, the Administrator notes that an annual standard level of 9.0 $\mu\text{g}/\text{m}^3$ would be expected to provide protection from exposures where he has the

greatest confidence in the associations between health effects and PM_{2.5} exposures (*i.e.* the long-term mean PM_{2.5} concentrations in the key U.S. epidemiologic studies, of which the lowest is 9.3 µg/m³) and would provide an adequate margin of safety by maintaining most PM_{2.5} exposures even further below 9.0 µg/m³.

When considering adequate margin of safety, the Administrator notes that in his decision to revise the annual standard level to 9.0 µg/m³, he is placing weight on the information from the epidemiologic studies which allows for examination of the entire population, including those that may be at comparatively higher risk of experiencing a PM_{2.5}-related health effects (*e.g.*, children, older adults, minority populations). Additionally, as discussed above, the Administrator also recognizes that setting the annual standard level at 9.0 µg/m³, which is below concentrations at which the evidence is the strongest in supporting an association between exposure to PM_{2.5} and adverse health effects observed in the key epidemiologic studies available in this reconsideration, would be expected to shift the distribution of PM_{2.5} exposure concentrations in an area such that the area's highest monitor would generally be at or below 9.0 µg/m³ annually, and most of the resulting PM_{2.5} concentrations across the area would be even lower. In considering these air quality relationships, the Administrator judges that a revised annual standard level of 9.0 µg/m³ would provide requisite protection with adequate margin of safety, for all populations, including those most at-risk.

In reaching this conclusion, the Administrator recognizes that in establishing primary standards under the Act that are requisite to protect public

health with an adequate margin of safety, he is seeking to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that primary standards be set at a zero-risk level or to protect the most sensitive individual, but rather at a level that avoids unacceptable risks to public health. In this context, the Administrator's conclusion is that revised primary annual standard, in conjunction with the 24-hour standard, provides the appropriate degree of protection, and that more or less stringent standards would not be requisite.

In considering the requirement for an adequate margin of safety, the Administrator notes that the determination of what constitutes an adequate margin of safety is expressly left to the judgment of the EPA Administrator. *See Lead Industries Association v. EPA*, 647 F.2d at 1161–62; *Mississippi*, 744 F.3d at 1353. He further notes that in evaluating how particular standards address the requirement to provide an adequate margin of safety, it is appropriate to consider such factors as the nature and severity of the health effects, the size of sensitive population(s) at risk, and the kind and degree of the uncertainties present. Consistent with past practice and long-standing judicial precedent, and as described in this section, the Administrator takes the need for an adequate margin of safety into account as an integral part of his decision making on a standard. *See, e.g., NRDC v. EPA*, 902 F. 2d 962, 973–74 (D.C. Cir. 1990).

Given all of the evidence and information discussed above, the Administrator judges that a standard with a level of 9.0 $\mu\text{g}/\text{m}^3$ is requisite to protect public health with an adequate margin of safety. In so doing, he first recognizes that a less stringent

standard would allow the occurrence of higher long- and short-term PM_{2.5} concentrations at a level at or above the mean PM_{2.5} concentrations in key U.S. epidemiologic studies. That is, a less stringent standard would be expected to allow more PM_{2.5} exposures at concentrations at or above which the key U.S. epidemiologic studies have reported associations between mean PM_{2.5} concentrations and serious health effects and would deviate from some past approaches for selecting the appropriate level of the annual standard. A less stringent standard would also not provide requisite protection with an adequate margin of safety against PM_{2.5} exposures in the lower percentiles of the air quality distribution (*i.e.*, 25th percentile) for which associations with health effects have been observed in a limited number of epidemiologic studies. Furthermore, the Administrator notes that the primary annual and 24-hour PM_{2.5} standards, together, are intended to provide public health protection against the full distribution of long- and short-term PM_{2.5} exposures. As noted above, the Administrator recognizes that the changes in PM_{2.5} air quality designed to meet a less stringent annual standard would likely result in higher exposures across the distribution of air quality, including both higher average (or typical) concentrations as well as higher short-term peak PM_{2.5} concentrations. Taking into consideration both the full evidence base for associations of PM_{2.5} with mortality and other adverse health effects, including the reported mean PM_{2.5} concentrations from key long- and short-term U.S. epidemiologic studies, information from epidemiologic studies that report 25th percentile PM_{2.5} concentrations, supplemental information from other epidemiologic studies (*i.e.*, epidemiologic studies that use restricted analyses, accountability studies, and

Canadian epidemiologic studies), and the results of the risk assessment, as well as the advice from the CASAC and public comments, the Administrator concludes that a less stringent standard would allow risks of mortality and other adverse health effects that are too great, and thus would not provide sufficient protection for public health as required by the CAA.

Additionally, in considering a less stringent standard, the Administrator recognizes that through its control of long- and short-term $\text{PM}_{2.5}$ concentrations, the annual standard provides a margin of safety for less well-studied exposure levels and population groups for which the evidence is limited or lacking. In so doing, he recognizes that our understanding of the relationships between the presence of a pollutant in ambient air and associated health effects is based on a broad body of information encompassing not only more established aspects of the evidence, such as the conclusion that long- and short-term exposures to $\text{PM}_{2.5}$ are causally related to mortality and cardiovascular effects and likely to be causally related to respiratory effects, but also aspects with which there may be substantial uncertainty. In particular, the Administrator notes that there are other categories of effects with causality determinations that are suggestive of, but not sufficient to infer, a causal relationship between $\text{PM}_{2.5}$ exposure and health outcomes. These include, but are not limited to, short-term exposure and nervous system effects, as well as long- and short-term exposure and pregnancy and birth outcomes, where the evidence is less certain but which represent potentially substantial additional risk to public health from exposure to $\text{PM}_{2.5}$. He recognizes the CAA requirement that requires primary standards to

provide an adequate margin of safety 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 and in his judgment, the primary NAAQS must be set at a level that is adequately protective against these and other effects which research has not yet identified. Thus, even if the Administrator had somewhat greater concerns about the possibility of confounding, error and bias in the epidemiologic studies, which reduced his confidence in finding that PM_{2.5} is causally related to mortality and cardiovascular effects, he would still find it appropriate to set the primary NAAQS below the means of key U.S. epidemiologic studies given the strength of the evidence providing support for the association, as well as additional evidence linking PM_{2.5} to other endpoints of substantial public health concern, and the need to protect public health with an adequate margin of safety. In considering the uncertainties in both the epidemiologic evidence and the controlled human exposures studies, the Administrator recognizes that collectively, the health effects evidence generally reflects a continuum, consisting of levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. In light of these uncertainties, the Administrator recognizes that the CAA requirement that primary standards provide an adequate margin of safety, as summarized in section I.A above, is 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. The Administrator has taken the need to provide for an adequate margin of safety into account as an integral part of his decision-making on the appropriate standards in setting the standard at a level below the level where available epidemiologic studies, which include diverse populations that are broadly representative of the U.S. population including at-risk populations, have provided the strongest evidence supporting effects, and in other ways as well. For example, consideration of a margin of safety is reflected in the approach of setting the level of the annual standard near and somewhat below the 25th percentile PM_{2.5} concentrations from key U.S. epidemiologic studies (*i.e.*, 9.1 µg/m³), as well as recognition that attaining a design value will generally result in significantly broader and greater improvements of air quality across an area (including but certainly not limited to areas near the design value monitor) (U.S. EPA, 2022a, sections 2.3.3.2.4 and 3.3.3.2.1, Table 3–5). Based on all of the considerations noted here, and considering the current body of evidence, including the associated limitations and uncertainties, in combination with the exposure/risk information, the Administrator concludes that a less stringent standard than the current standard would not provide the requisite protection of public health, including an adequate margin of safety.

Having concluded that a less stringent standard would not provide the requisite protection of public health, the Administrator next considers whether a more stringent standard would be appropriate. In so doing, he notes that a decision to set the level of the annual standard to below 9.0 µg/m³ would place a large amount of the emphasis on potential public health importance of further reducing the occurrence

of PM_{2.5} concentrations of concern, though the exposures about which he is most concerned are well controlled with an annual standard level of 9.0 µg/m³, as demonstrated by the quantitative risk assessment. Such a decision would also place greater weight on (1) further reducing ambient PM_{2.5} concentrations relative to those observed in long-and short-term epidemiologic studies, including those that he had judged to have significant uncertainties, including Canadian studies, studies using restricted analyses, and accountability studies; (2) shifting the air quality distribution in areas such that the highest exposure concentrations are reduced to below PM_{2.5} concentrations observed in epidemiologic studies to be in the 25th or lower percentile, for which the evidence is limited; and (3) further shifting exposure concentrations to those shown at the lower end of the distribution in the quantitative risk assessment, despite the important uncertainties in the overall risk assessment. As discussed in this section and in responses to significant comments above and in the Response to Comments document, the Administrator has concluded that placing a large emphasis on these factors and revising the standard to a level below 9.0 µg/m³ would result in a standard that is more stringent than the evidence indicates to be sufficient to protect public health with an adequate margin of safety. Compared to a primary annual PM_{2.5} standard set at a level of 9.0 µg/m³, the Administrator concludes that the extent to which lower standard levels could result in further public health improvements becomes notably less certain.

Thus, having carefully considered the scientific evidence, quantitative information, CASAC advice, and public comments relevant to his decision on the level of the primary annual PM_{2.5} standard, as

discussed above and in the Response to Comments document, the Administrator is revising the level of the primary annual $\text{PM}_{2.5}$ standard to $9.0 \mu\text{g}/\text{m}^3$. In the Administrator's judgment, based on the currently available evidence and information, an annual standard set at this level and using the specified indicator, averaging time, and form, in conjunction with the other primary PM standards, would be requisite to protect public health with an adequate margin of safety. The Administrator judges that such a standard would protect, with an adequate margin of safety, the health of at-risk populations, including children, older adults, those with pre-existing cardiovascular and respiratory diseases, minority populations, and low SES populations. The Administrator believes that a standard set at $9.0 \mu\text{g}/\text{m}^3$ would be sufficient to protect public health with a margin of safety, and believes that a lower standard would be more than what is necessary to provide this degree of protection. This judgment by the Administrator appropriately considers the degree of protection that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In reaching his conclusions on adequacy of the current suite of primary $\text{PM}_{2.5}$ standards, based on consideration of the available scientific evidence and quantitative information, the CASAC's advice and public comments, the Administrator finds that the available information is insufficient to call into question the adequacy of the public health protection afforded by the current primary 24-hour $\text{PM}_{2.5}$ standard. As described earlier in this section, the

Administrator concludes that it is appropriate to retain the current indicator ($\text{PM}_{2.5}$), averaging time (24-hour), and form (98th percentile, averaged over three years) for the primary 24-hour $\text{PM}_{2.5}$ standard and below explains the basis for his final decision that is also appropriate to retain the current level of the primary 24-hour $\text{PM}_{2.5}$ standard.

In reaching his conclusion to retain the current primary 24-hour $\text{PM}_{2.5}$ standard the Administrator does so in light of the conclusion that the epidemiologic evidence supports associations between short- and long-term $\text{PM}_{2.5}$ exposures and adverse health effects, but that the epidemiologic evidence does not identify specific concentrations at which those effects occur and the Administrator has greatest confidence in effects where the bulk of the data is reported (*i.e.*, the mean $\text{PM}_{2.5}$ concentration, with some consideration for the 25th percentile of the air quality distribution). Thus, in considering the epidemiologic evidence, the Administrator concludes it is appropriate to focus on setting a generally controlling annual standard as the most effective and efficient way to reduce total population risk associated with both long- and short-term $\text{PM}_{2.5}$ exposures, and that it is appropriate to revise the level of the annual standard level to $9.0 \mu\text{g}/\text{m}^3$. In addition to the epidemiologic evidence, the Administrator also considers the available controlled human exposure studies, which provide evidence for health effects following single, short-term $\text{PM}_{2.5}$ exposures to concentrations that typically correspond to upper end of the $\text{PM}_{2.5}$ air quality distribution in the U.S. (*i.e.*, “peak” concentrations). In so doing, the Administrator notes that these studies report statistically significant effects on one or more indicators of cardiovascular function following 2-hour exposures to

PM_{2.5} concentrations at and above 120 µg/m³ and at and above 149 µg/m³ for vascular impairment, the effect shown to be most consistent across studies. In particular, the Administrator notes that a single study is assessed in the ISA Supplement that reports effects following 4-hour exposures at 37.8 µg/m³, although the results of this study are inconsistent with the results of the controlled human exposure studies assessed in the 2019 ISA. Along with the inconsistent results from the controlled human exposure studies, the Administrator also recognizes that effects observed in these studies are intermediate effects which are not typically considered adverse and that the study participants were healthy individuals. Taking into consideration the available scientific evidence, including the uncertainties and limitations, along with the CASAC's advice, the Administrator concludes that it is appropriate to maintain a primary 24-hour PM_{2.5} standard to protect against peak exposures.

Thus, the Administrator considers what primary 24-hour PM_{2.5} standard is requisite to provide supplemental protection against peak exposures. While having confidence that the revised annual standard will result in lowering risk associated with both long- and short-term PM_{2.5} exposure by lowering the overall air quality distribution, as in the 2012 review, the Administrator recognizes that an annual standard alone would not be expected to offer sufficient protection with an adequate margin of safety against the effects of short-term PM_{2.5} exposures in all parts of the country. Therefore, he continues to conclude that it is appropriate to continue to provide supplemental protection by means of a 24-hour standard, in conjunction with a revised annual standard level of 9.0 µg/m³.

In considering the available scientific evidence assessed in the 2019 ISA and ISA Supplement, the Administrator first considers the controlled human exposure studies for informing his decisions on the primary 24-hour PM_{2.5} standard. In so doing, he notes that in their review of the 2021 draft PA, the majority of CASAC members expressed the view that controlled human exposure studies are not the best evidence to use for justifying retaining the 24-hour standard without revision, in part because these studies preferentially recruit less susceptible individuals and have a typical exposure duration much shorter than 24 hours. Thus, in the view of the majority, “the evidence of effects from controlled human exposure studies with exposures close to the current 24-hour standard supports epidemiological evidence for lowering the standard” (Sheppard, 2022a, p. 3–4 of consensus letter). In reviewing the controlled human exposure studies, the Administrator agrees with the majority of CASAC that these controlled human exposure studies generally do not include populations with substantially increased risk from exposure to PM_{2.5}, such as children, older adults, or those with more severe underlying illness. However, he disagrees with any conclusion that they should not be used to inform a decision about the adequacy of the current standard. The Administrator finds the information available from these studies to be useful, noting that the recently available controlled human exposure studies provide evidence for health effects following single, short-term exposures to PM_{2.5} concentrations that are greater than those allowed under the current standard. The results of the controlled human exposure studies are inconsistent, particularly at lower PM_{2.5} concentrations, but some studies do report statistically significant effects on

one or more indicators of cardiovascular function following 2-hour exposures to PM_{2.5} concentrations at and above 120 µg/m³ (and at and above 149 µg/m³ for vascular impairment, the effect shown to be most consistent across studies). Additionally, one controlled human exposure study assessed in the ISA Supplement reports evidence of some effects for cardiovascular markers following 4-hour exposures to 37.8 µg/m³ (Wyatt et al., 2020). However, there is inconsistent evidence for inflammation in other controlled human exposure studies evaluated in the 2019 ISA. The Administrator finds these studies are important in establishing biological plausibility for PM_{2.5} exposures causing more serious health effects, such as those seen in short-term exposure epidemiologic studies, and they provide support that more adverse effects may be experienced following longer exposure durations and/or exposure to higher concentrations. As described in more detail in responding to public comments in section II.B.3 above, he notes that although the controlled human exposure studies do not provide a threshold below which no effects occur, the observed effects in these controlled human exposures studies are ones that signal an intermediate effect in the body, likely due to short-term exposure to PM_{2.5}, and typically would not, by themselves, be judged as adverse. As noted in sections II.A.2 and II.B.3 above, associated judgments regarding adversity or health significance of measurable physiological responses to air pollutants in previous NAAQS reviews have been informed by guidance, criteria or interpretative statements developed within the public health community. This type of information on adversity of effects is particularly informative to the Administrator's judgments regarding the adversity of the effects observed in the

controlled human exposure studies which are short-term in nature (*i.e.*, generally ranging from 2- to 5-hours), including those studies that are conducted at near-ambient PM_{2.5} concentrations. Based on the observation that the effects observed in Wyatt et al. (2020) are not by themselves adverse, and the fact that the findings of this study are inconsistent with other currently available evidence regarding the level at which effects are observed, the Administrator disagrees with the view expressed by the majority of CASAC that this study supports epidemiologic evidence for lowering the 24-hour standard.

Consistent with his approach in reaching his proposed decision and taking into consideration these points as well as balancing these limitations (*i.e.*, that the health outcomes observed in these controlled human exposure studies are not clearly adverse and that the studies generally do not include those at increased risk from PM_{2.5} exposure), the Administrator still considers it appropriate to ensure that the 24-hour PM_{2.5} standard provides protection against health effects consistently observed in the controlled human exposure studies. He next examines the air quality analyses, described in more detail in section II.A.c.i above, to assess whether during recent air quality conditions, areas meeting the current standards would experience PM_{2.5} concentrations reported in these controlled human exposure studies. He observes that air quality analyses demonstrate that the PM_{2.5} exposures shown to cause consistent effects in the controlled human exposure studies are well above the ambient concentrations typically measured in locations meeting the current primary standards, and therefore suggest that the current primary PM_{2.5} standards provide protection against these “peak” concentrations. In fact, at air quality monitoring sites

meeting the current primary PM_{2.5} standards (*i.e.*, the 24-hour standard of 35 µg/m³ and the annual standard of 12 µg/m³), the 2-hour concentrations generally remain below 10 µg/m³, and rarely exceed 30 µg/m³. Though two-hour concentrations are higher at monitoring sites violating the current standards, they generally remain below 16 µg/m³ and rarely exceed 80 µg/m³, still below concentrations in CHE studies where consistent effects are observed (*e.g.*, greater than 120 µg/m³) (U.S. EPA, 2022b, section 2.3.2.2.3, Figure 2–19, and section 3.3.3.1). Additionally, and in response to public comments, the Administrator notes additional air quality analyses conducted by the EPA,¹²¹ that provide a more refined analysis of whether areas that meet the current standards experience peak concentrations reported in controlled human exposure studies. He notes that 2-hour observations greater than 120 µg/m³ and 4-hour observations greater than 38 µg/m³ rarely occur (*e.g.*, 0.025% of rolling 2-hour observations are greater than 120 µg/m³ and 0.78% of rolling 4-hour observations greater than 38 µg/m³). Based on this information, the Administrator finds that the current suite of standards maintains subdaily concentrations of PM_{2.5} in ambient air far below the exposure concentrations in controlled human exposure studies where consistent effects have been observed, and notes that while these studies generally do not include the most at-risk individuals, the exposure

¹²¹ Jones et al. (2023). Comparison of Occurrence of Scientifically Relevant Air Quality Observations Between Design Value Groups. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA–HQ–OAR–2015–0072). Available at: <https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072>.

concentrations in these studies also do not elicit adverse effects.

Further, in light of the Administrator's emphasis on the annual standard as the controlling standard, with the 24-hour standard providing supplemental protection against peak concentrations, he next considers the potential impact of a revised annual standard of $9.0 \mu\text{g}/\text{m}^3$ on the occurrence of peak sub-daily $\text{PM}_{2.5}$ concentrations. Specifically, the Administrator takes note of the new air quality analyses¹²² where he observes that lower percentages of concentrations greater than $120 \mu\text{g}/\text{m}^3$ and $38 \mu\text{g}/\text{m}^3$ occur in areas meeting an annual standard of $9.0 \mu\text{g}/\text{m}^3$ and a 24-hour standard of $35 \mu\text{g}/\text{m}^3$, versus an annual standard of $12.0 \mu\text{g}/\text{m}^3$ and a 24-hour standard of $35 \mu\text{g}/\text{m}^3$. Thus, he concludes that an annual standard that is controlling across most areas of the country will continue to effectively limit peak daily concentrations in conjunction with the existing 24-hour standard, with its level of $35 \mu\text{g}/\text{m}^3$ and 98th percentile form, which continues to provide supplemental protection against peak concentrations.

In addition, the Administrator also notes that the majority of the CASAC in their review of the 2021 draft PA, as well as a number of public commenters, support their recommendation to revise the current 24-hour standard by pointing to "substantial epidemiologic evidence from both morbidity and mortality

¹²² Jones et al. (2023). Comparison of Occurrence of Scientifically Relevant Air Quality Observations Between Design Value Groups. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA-HQ-OAR-2015-0072). Available at: <https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072>.

studies” which “includes three U.S. air pollution studies with analyses restricted to 24-hour concentrations below 25 $\mu\text{g}/\text{m}^3$ ” (Sheppard, 2022a, p. 17 consensus responses). The Administrator notes that the epidemiologic evidence available in this reconsideration, including the studies that restrict short-term $\text{PM}_{2.5}$ exposures (*i.e.*, 24-hour $\text{PM}_{2.5}$ concentrations) to levels below 25 $\mu\text{g}/\text{m}^3$, provides support for positive and statistically significant associations between short-term exposure to $\text{PM}_{2.5}$ and all-cause mortality (Di et al., 2017a) and CVD hospital admissions (deSouza et al., 2021; Di et al., 2017a). He agrees that these studies help to provide additional support for reaching conclusions on causality in the 2019 ISA. He further agrees that the available epidemiologic studies provide important information that it is appropriate to consider in this reconsideration, including information on associations between health effects and $\text{PM}_{2.5}$ exposures in diverse populations that are broadly representative of the U.S. population, and include populations identified as at-risk (*e.g.*, older adults, minority populations), as well as evidence of linear, no-threshold concentration-response relationships in those associations, although with less certainty in the shape of the curve at long-term average concentrations below about 8 $\mu\text{g}/\text{m}^3$.

However, the Administrator also notes significant limitations in the currently available epidemiologic information that limit his ability to draw conclusions from the key short-term studies, including those that employ restricted analyses, to inform his decision regarding the level of the 24-hour $\text{PM}_{2.5}$ standard. As a result of these limitations, the Administrator does not find that the short-term epidemiologic studies, or the other evidence such as the controlled human

exposure studies or the risk assessment, provide a sufficient justification for revising the 24-hour standard.

First, he notes that short-term epidemiologic studies examine associations between day-to-day variations in $\text{PM}_{2.5}$ concentrations and health outcomes, often over multi-year study periods. As such, these studies report long-term mean 24-hour $\text{PM}_{2.5}$ concentrations (*e.g.*, mean 24-hour $\text{PM}_{2.5}$ concentrations over multi-year study periods), rather than at specific points in the distribution (*i.e.*, 90th or 98th percentile 24-hour concentrations) at which effects occur. Further, he notes that while there can be considerable variability in daily exposures over a multi-year study period, the bulk of the observations reflect days with ambient $\text{PM}_{2.5}$ concentrations in the middle of the air quality distribution (*i.e.*, “typical” days rather than days with extremely low or extremely high concentrations). As a result, the results of these studies are more directly applicable to decisions regarding the annual standard (which is based on the long-term mean of both short- and long-term epidemiologic studies), and the fact that they do not report other air quality statistics, such as the 98th percentile concentrations which might be more directly compared to the level of the 24-hour standard, makes them less useful for informing decisions on the 24-hour standard. As discussed in responding to comments above, the form of the annual standard is based on the annual mean $\text{PM}_{2.5}$ concentration averaged over three years,¹²³ which makes it better suited as a basis for controlling air quality to avoid effects observed in both long-term

¹²³ The annual mean is calculated by averaging daily values in a calendar quarter and then averaging calendar quarters. See 40 CFR part 50 Appendix N, section 4.4.

and short-term epidemiologic studies. By contrast, the form of the 24-hour standard is the 98th percentile averaged over three years, which makes it appropriate for controlling short-term peak concentrations. However, based on the available air quality information, including distribution statistics of $\text{PM}_{2.5}$ concentrations and health events reported in the short-term epidemiologic studies, these studies are too limited in their ability to identify health effects attributable to specific short-term peak concentrations that are necessary to evaluate whether the 24-hour standard with its 98th percentile form should be revised (*e.g.*, restricted epidemiologic studies do not report the number or the percentile of health events or the percentile of $\text{PM}_{2.5}$ concentrations across the highest part of the restricted air quality distribution, including the 98th percentile). Thus, the Administrator does not consider it appropriate to use the reported means from short-term studies to determine the appropriate level for a 24-hour standard with a 98th percentile form.

Similarly, the Administrator does not consider the results of the restricted analyses to be well suited to informing the choice of level for a 24-hour standard. Restricted analyses use a subset of data from their main analyses to evaluate health events that occur at concentrations below a certain concentration (*e.g.*, $25 \mu\text{g}/\text{m}^3$). The Administrator notes that the associations between the health effects (*e.g.*, mortality and cardiovascular morbidity) and $\text{PM}_{2.5}$ concentrations remain even after excluding higher concentrations in the restricted analyses, and he also recognizes that the magnitude of the effect is generally greater in the restricted analyses compared to the associations reported in the main analysis. He considers such analyses to be informative in indicating that the

health effects association reported in the main (unrestricted) analysis are not driven only by the upper peaks of the PM_{2.5} air quality distribution, but rather persist at lower portions of the distribution (consistent with his emphasis on the annual standard, which is focused on exposures near the mean concentration, where the bulk of the exposure distribution is concentrated). Indeed, he notes that if peak concentrations were the principal driver of health effects associated with PM_{2.5} exposure, one might expect the associations to become weaker as the upper portion of the data is excluded in the restricted analyses, which is not what is reported by the analyses (*e.g.*, the restricted analyses generally report associations that are greater in magnitude compared to the main analyses). However, he disagrees with the assertion by the CASAC in their review of the 2021 draft PA and some public commenters that it would be appropriate to focus on the specific PM_{2.5} concentration (*e.g.*, 25 or 30 µg/ m³) at which the analysis was restricted as the basis for choosing a 24-hour standard level. The Administrator recognizes that in restricted analyses, while an association continues to persist across the full range of the air quality distribution, and that the cutpoint concentration at which the analysis was restricted (*e.g.*, 25 or 30 µg/m³) becomes the maximum PM_{2.5} concentration in the distribution, he also notes that these studies do not provide information related to the distribution of health events and PM_{2.5} concentrations, and as such, he is more uncertain where the bulk of the data are and where he has confidence in the reported association.¹²⁴ He notes that no evidence

¹²⁴ These studies do not report information about the distribution of the health events and PM_{2.5} concentrations (*e.g.*, means, medians, other percentiles) in the restricted analyses.

exists to support a conclusion that the $\text{PM}_{2.5}$ concentration chosen as the cutpoint in a restricted analysis has any bearing on the concentration at which effects are likely to occur (or not occur). He notes that, as with long-term studies, the evidence does not suggest there is a specific point in the air quality distribution of these short-term studies that represents a “bright line” at and above which effects have been observed and below which effects have not been observed. In order to identify a level of the 24-hour standard based on associations between the “upper end” of exposures, either in the unrestricted or the restricted analyses, and adverse health effects, it would be necessary to have a better understanding of how specific 24-hour concentrations correspond to the frequency and total number of observed health events in the study. Currently, such information, including 98th percentile statistics, are not reported in the key short-term epidemiologic studies (and if they were reported, the Administrator would have to carefully consider how to weigh the data). As such, in reaching his decision on the primary 24-hour $\text{PM}_{2.5}$ standard, the Administrator judges that the currently available information from short-term epidemiologic studies, including those that employ restricted analyses, does not provide a sufficient basis to revise the current 24-hour standard, given that the 24-hour standard focuses on reducing “peak” exposures (with its 98th percentile form), but rather that such information supports his judgment that it is appropriate to focus on revising the annual standard for purposes of reducing all exposures, across the entire distribution of air quality, to increase public health protection.

In reaching final decisions regarding the adequacy of the primary 24-hour $\text{PM}_{2.5}$ standard, the

Administrator continues to view an approach that focuses on setting a generally controlling annual standard as the most effective and efficient way to reduce total population risk associated with both long- and short-term PM_{2.5} exposures. Additionally, he emphasizes that improvements in air quality associated with meeting an annual standard level of 9.0 µg/m³ will result in lowering risk associated with both long- and short-term PM_{2.5} exposure by lowering the overall air quality distribution. The Administrator concludes that reducing the annual standard is the most efficient way to reduce the risks from short-term exposures identified in the epidemiologic studies, as the available evidence suggests the bulk of the risk comes from the large number of days across the bulk of the air quality distribution, not the relatively small number of days with peak concentrations. However, as in the 2012 review, the Administrator recognizes that an annual standard alone would not be expected to offer sufficient protection with an adequate margin of safety against the effects of short-term PM_{2.5} exposures in all parts of the country and concludes that, in conjunction with a revised annual standard level of 9.0 µg/m³, it is appropriate to continue to provide supplemental protection by means of a 24-hour standard, particularly for areas with high peak-to-mean ratios possibly associated with strong local or seasonal sources.

In selecting the level of a 24-hour standard designed to provide supplemental protection against peak exposures (in conjunction with a revised annual standard of 9.0 µg/m³), the Administrator considers the information from the controlled human exposure studies and the EPA's analysis of peak concentrations observed in areas meeting the current standard of 35 µg/m³ in conjunction with a revised standard of

9.0 $\mu\text{g}/\text{m}^3$ to be of particular relevance. He notes the controlled human exposure evidence includes studies reporting effects on one or more indicators of cardiovascular function following 2-hour exposures at and above 120 $\mu\text{g}/\text{m}^3$, including effects reported at and above 149 $\mu\text{g}/\text{m}^3$ for vascular impairment, the effect shown to be most consistent across studies, and less consistent effects at lower concentrations, including a single study at near ambient concentrations (Wyatt et al., 2020) reporting effects following 4-hour exposures at 37.8 $\mu\text{g}/\text{m}^3$. He recognizes that the effects observed (in those studies that observed effects) are ones that signal an intermediate effect in the body, likely due to short-term exposure to $\text{PM}_{2.5}$, and typically would not, by themselves, be judged as adverse, and the study participants were healthy individuals.

He notes in particular that, in the EPA's analysis, in areas meeting the current 24-hour standard and the revised annual standard 0.029 percent of 2-hour observations and 0.41 percent of 4-hour observations reach $\text{PM}_{2.5}$ concentrations higher than 120 $\mu\text{g}/\text{m}^3$ and 37.8 $\mu\text{g}/\text{m}^3$, respectively. He also notes the lack of evidence of effects from controlled human exposure studies at levels below the current 24-hour standard and the fact that the results of Wyatt et al. (2020) are inconsistent with other available studies, as well as the intermediate nature of effects observed in this study. In his judgment, the small number of occurrences of peak exposures indicate that, in conjunction with a revised annual standard of 9.0 $\mu\text{g}/\text{m}^3$, the current 24-hour standard of 35 $\mu\text{g}/\text{m}^3$ remains requisite to protect public health with an adequate margin of safety, and that there is substantial basis to doubt whether further improvements in public health would be achieved by further reducing these

exposures. Furthermore, the Administrator concludes that due to the limitations and uncertainties outlined above, the information from recent short-term epidemiologic studies, including those that use restricted analyses, is inadequate to inform decisions regarding the adequacy of the current 24-hour standard. Thus, in reaching his decision on the primary 24-hour PM_{2.5} standard, the Administrator concludes that currently available evidence does not call into question the adequacy of the current standard.

In addition to the scientific evidence, the Administrator also considers the risk assessment in evaluating the appropriate level of the 24-hour PM_{2.5} standard. The risk assessment indicates that the annual standard is the controlling standard across most of the urban study areas evaluated (*i.e.*, when air quality related to the annual average PM_{2.5} concentrations decrease, daily average PM_{2.5} concentrations are also expected to decrease). When air quality is adjusted to just meet an alternative 24-hour standard level of 30 µg/m³ in the areas where the 24-hour standard is controlling, the risk assessment estimates reductions in PM_{2.5}-associated risks across a more limited population and number of areas compared to when air quality is adjusted to simulate alternative levels for the annual standard (*i.e.*, where the annual standard is controlling), and these predictions are largely confined to areas located in the western U.S., several of which are also likely to experience risk reductions upon meeting a revised annual standard. With respect to the CASAC's advice in their review of the 2021 draft PA, the Administrator notes that the minority of CASAC advised that these results suggest that the annual standard can be used to limit both long- and short-term PM_{2.5} concentrations and views these risk assessment

results as supporting the conclusion that the current 24-hour standard is adequate (Sheppard, 2022a, p. 4 of consensus letter). In contrast, the majority of CASAC members in their review of the 2021 draft PA, as well as a number of public commenters that support revision of the 24-hour standard, placed greater weight on the evidence-based considerations (*e.g.* scientific evidence, like the restricted analyses) than on the values estimated by the risk assessment, noting the potential for uncertainties in how the risk assessment was able to “capture areas with wintertime stagnation and residential wood-burning where the annual standard is less likely to be protective” (Sheppard, 2022a, p. 4 of consensus letter).

In considering the application of the risk assessment to judgments about the adequacy of the current primary 24-hour PM_{2.5} standard, the Administrator again notes that the risk assessment analyses of PM_{2.5}-attributable mortality use input data that include C–R functions from epidemiologic studies that have no threshold and a linear C–R relationship down to zero, as well an air quality adjustment approach that incorporates proportional decreases in PM_{2.5} concentrations to meet lower standard levels. As such, the Administrator notes that this quantitative approach does not incorporate any elements of uncertainty in associations of health effects at lower concentrations and that simulated air quality improvements will always lead to proportional decreases in risk (*i.e.*, each additional µg/m³ reduction produces additional benefits with no clear stopping point at any PM_{2.5} concentration). Therefore, the Administrator recognizes that while the risk estimates can help to place the evidence for specific health effects into a broader public health context, the results should be considered along with the

inherent uncertainties and limitations of such analyses when informing judgments about the potential for additional public health protection associated with PM_{2.5} exposure and related health effects. Further, the Administrator notes additionally that air quality analyses have also been considered in looking at the adequacy of the 24-hour standard in controlling peak PM_{2.5} concentrations of potential concern,¹²⁵ and that those analyses included monitoring information from across the entire U.S., specifically highlighting areas with higher peak concentrations and including areas impacted by wintertime stagnation and residential wood-burning. Thus, while the risk assessment may have focused on a subset of areas across the U.S. based on the study area selection criteria, the Administrator is considering a broader set of information in reaching his conclusions regarding the appropriateness of the current 24-hour standard to control peak concentrations.

The Administrator also considers the advice from the CASAC in their reviews of the 2019 draft PA and 2021 draft PA. In their review of the 2019 draft PA, the CASAC “agrees with the EPA and finds that the available evidence does not call into question the adequacy of public health protection afforded by the current 24-hour PM_{2.5} standard and concurs that it be retained” (Cox, 2019b, p. 3 of letter). He also notes that in their review of the 2021 draft PA, the CASAC did not reach consensus on whether the current

¹²⁵ Jones et al. (2023). Comparison of Occurrence of Scientifically Relevant Air Quality Observations Between Design Value Groups. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA-HQ-OAR-2015-0072). Available at: <https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072>.

24-hour standard is adequate, with the majority of the CASAC recommending that the 24-hour standard be revised and the minority of the CASAC recommending that the standard be retained. The majority of the CASAC members further stated that “[t]here is also less confidence that the annual standard could adequately protect against health effects of short-term exposures. A range of 25–30 $\mu\text{g}/\text{m}^3$ for the 24-hour $\text{PM}_{2.5}$ standard would be adequately protective” (Sheppard, 2022a, p. 4 of consensus letter). The Administrator also acknowledges that some public commenters agreed with the majority of the CASAC in supporting a revision to the level of the 24-hour standard to a range between 25–30 $\mu\text{g}/\text{m}^3$. These commenters cite a number of reasons, including: (1) Results from controlled human exposure studies at near ambient concentrations; (2) aspects of the scientific evidence, including restricted analyses that report positive and significant associations below 35 $\mu\text{g}/\text{m}^3$; and (3) quantitative risk analyses that show decreasing risk with decreasing $\text{PM}_{2.5}$ concentrations. In responding to these comments, the Administrator recognizes that some commenters have different interpretations of the evidence, air quality information, and quantitative results from the risk assessment in this review and would make different judgments about the weight to place on the relative strength and limitations of the currently available scientific evidence and information and how such information could be used in making public health policy decisions on the 24-hour standard. However, as outlined above, the Administrator has carefully considered the information available from controlled human exposure studies and short-term epidemiologic studies, and weighed the strengths and limitations of this evidence in formulating his

decisions. Furthermore, as discussed above the Administrator has noted significant uncertainties and limitations inherent in the risk estimates, as well as noting that very few areas were included. In addition, he has given careful consideration to the majority of the CASAC's advice in their review of the 2021 draft PA, but has drawn different conclusions with respect to how currently available evidence and air quality information inform the selection of level for the 24-hour primary PM_{2.5} standard.

In considering the advice of the majority of CASAC, the Administrator notes that a decision to set the level of the 24-hour standard to below 35 µg/m³ would place a large amount of emphasis on the potential public health importance of further reducing the occurrence of peak PM_{2.5} concentrations. However, the Administrator concludes that there is insufficient basis to conclude that a more stringent standard to further reduce peak concentrations is needed or would benefit public health. As discussed above, he judges that the PM_{2.5} exposures in controlled human exposure studies that correspond to peak concentrations will already be well controlled via the combination of the revised annual standard, with a level of 9.0 µg/m³, and the 24-hour standard with its level 35 µg/m³ and its 98th percentile form. Taking into consideration the inconsistent results reported in controlled human exposure studies, the intermediate nature of the health effects observed in the controlled human exposure studies that are not typically considered adverse, the health status of the study participants, and how infrequently peak concentrations of potential concern are anticipated to occur in areas meeting the revised primary annual PM_{2.5} standard, he judges that the current 24-hour standard is requisite to protect against the effects

reported in these studies with an adequate margin of safety. Likewise, he judges that neither the epidemiologic studies (including the studies that use restricted analyses) nor the risk assessment provide a sufficient basis for revising the 24-hour standard. As discussed above, the epidemiologic studies, including short-term studies and those with restricted analyses, are not well-suited for identifying a level for a 24-hour standard to address health effects associated with peak concentrations. The restricted analyses support the conclusion that the health effects associated with $PM_{2.5}$ is not associated primarily with exposure to higher concentrations of the main analyses, but like other epidemiologic studies they typically report only long-term mean 24-hour concentrations (*e.g.*, restricted epidemiologic studies do not report the number or the percentile of health events or the percentile of $PM_{2.5}$ concentrations across the highest part of the restricted air quality distribution, including the 98th percentile) and do not identify any particular concentration within the air quality distribution above which effects have been observed and below which effects have not been observed. Similarly, the risk assessment highlights that the annual standard is controlling across much of the U.S. and is generally more effective at reducing risk than the 24-hour standard and, taking into account the limitations and assumptions of the risk assessment discussed above, does not provide a basis for revising the 24-hour standard. For the reasons discussed herein, the Administrator judges that the uncertainties as to whether there would be public health benefits from a more stringent 24-hour standard are too great to justify revising the standard.

Thus, having carefully considered the scientific evidence, quantitative information, CASAC advice, and public comments, the Administrator is retaining the current primary 24-hour $\text{PM}_{2.5}$ standard, with its level of to $35 \mu\text{g}/\text{m}^3$ and its 98th percentile form. In the Administrator's judgment, based on the currently available evidence and information, a 24-hour standard set at this level and using the specified indicator, averaging time, and form would be requisite to protect public health with an adequate margin of safety, in conjunction with the annual standard. As noted, in evaluating the adequacy of the current standards, the Administrator focuses on evaluating the public health protection afforded by the annual and 24-hour standards, taken together, against adverse health effects associated with long- or short-term $\text{PM}_{2.5}$ exposures. A 24-hour standard set at a level of $35 \mu\text{g}/\text{m}^3$, in conjunction with a revised annual standard level of $9.0 \mu\text{g}/\text{m}^3$, in the judgment of the Administrator, provides an appropriate level of public health protection, for both long- and short-term $\text{PM}_{2.5}$ exposures. The Administrator believes that a 24-hour standard set at $35 \mu\text{g}/\text{m}^3$ would continue to be sufficient to protect public health with a margin of safety, and believes that a lower standard would be more than what is necessary to provide this degree of protection when considered in conjunction with a revised annual standard. The Administrator concludes the current 24-hour standard at a level of $35 \mu\text{g}/\text{m}^3$, in conjunction with a revised annual standard level of $9.0 \mu\text{g}/\text{m}^3$, will provide appropriate protection in areas in which the long-term mean concentrations are already relatively low (*i.e.*, below $9 \mu\text{g}/\text{m}^3$) but where there may be elevated short-term peak $\text{PM}_{2.5}$ concentrations, often associated with strong local or seasonal sources. This

judgment by the Administrator appropriately considers the degree of protection that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In making this decision to retain the current level of the primary $\text{PM}_{2.5}$ 24-hour standard at $35 \mu\text{g}/\text{m}^3$ in conjunction with revising the annual standard level from $12.0 \mu\text{g}/\text{m}^3$ to $9.0 \mu\text{g}/\text{m}^3$, given all of the evidence and information discussed above, the Administrator judges that the revised suite of primary $\text{PM}_{2.5}$ standards and the rationale supporting these levels appropriately reflects consideration of the strength of the available evidence and other information and its associated uncertainties as well as the advice of CASAC and consideration of public comments. He additionally judges that this suite of primary $\text{PM}_{2.5}$ standards is requisite to protect public health, including at-risk populations, with an adequate margin of safety from effects associated with long and short-term exposures to fine particles. This judgment by the Administrator appropriately considers the requirement for standards that are requisite to protect public health but are neither more nor less stringent than necessary.

C. Decisions on the Primary $\text{PM}_{2.5}$ Standards

For the reasons discussed above, and taking into account the information and assessments presented in the 2019 ISA and ISA Supplement, the scientific and quantitative risk information in the 2022 PA, the advice and recommendations of the CASAC, and public comments, the Administrator revises the

current suite of primary PM_{2.5} standards. Specifically, the Administrator revises the level of the primary annual PM_{2.5} standard to 9.0 µg/m³ while retaining its form, indicator and averaging time. In conjunction with revising the primary annual PM_{2.5} standard level to provide protection from effects associated with long- and short-term PM_{2.5} exposures, the Administrator retains the level of 35 µg/m³ and the 98th percentile form, indicator and averaging time of the primary 24-hour PM_{2.5} standard to continue to provide supplemental protection for areas with high peak PM_{2.5} concentrations. The Administrator concludes that this suite of standards is requisite to protect public health with an adequate margin of safety against health effects potentially associated with long- and short-term PM_{2.5} exposures.

III. Rationale for Decisions on the Primary PM₁₀ Standard

This section presents the rationale for the Administrator's decision to retain the existing primary PM₁₀ standard. This decision is based on a thorough review of the latest scientific information, published through January 2018¹²⁶ and evaluated in the 2019 ISA, on human health effects associated with PM_{10-2.5} in ambient air. As described in section I above and in section 1.2 of the ISA Supplement, the

¹²⁶ In addition to the review's opening "call for information" (79 FR 71764, December 3, 2014), the 2019 ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009, through approximately January 2018 (U.S. EPA, 2019a, p. ES-2). References cited in the 2019 ISA, the references considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: <https://hero.epa.gov/hero/particulate-matter>.

scope of the updated scientific evaluation of the health effects evidence is based on those PM size fractions, exposure durations, and health effects category combinations where the 2019 ISA concluded a causal relationship exists (U.S. EPA, 2019a, U.S. EPA, 2022b).). Therefore, because the 2019 ISA did not conclude a causal relationship for PM_{10-2.5} for any exposure durations or health effect categories, the ISA Supplement does not include an evaluation of additional studies for PM_{10-2.5}. As a result, the 2019 ISA continues to serve as the scientific foundation for assessing the adequacy of the primary PM₁₀ standard in this reconsideration of the 2020 final decision (U.S. EPA, 2019a, section 1.7; U.S. EPA, 2022a). The Administrator's decision also takes into account the 2022 PA evaluation of the policy-relevant information in the 2019 ISA, CASAC advice and recommendations, and public comments.

In presenting the rationale for the Administrator's final decision and its foundations, Section III.A provides background on the 2020 final decision to retain the primary PM₁₀ and a brief summary of key aspects of the currently available health effects information. Section III.B summarizes the CASAC advice and the Administrator's proposed conclusions to retain the existing primary PM₁₀ standard, addresses public comments received on the proposal, and presents the Administrator's conclusions on the adequacy of the current standard, drawing on consideration of information in the 2019 ISA and the 2022 PA, advice from the CASAC, and comments from the public. Section III.C summarizes the Administrator's decision on the primary PM₁₀ standard.