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

CENTER FOR BIOLOGICAL DIVERSITY, Petitioner, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and JANE NISHIDA, Acting Administrator, United States Environmental Protection Agency, Respondents.	)	**PETITION FOR REVIEW** Docket No. 21-1054

Pursuant to the Clean Air Act § 307(b)(1), 42 U.S.C. §7607(b)(1), Rule 15 of the Federal Rules of Appellate Procedures and Circuit Rule 15, the Center for Biological Diversity petitions the Court for review of the final action taken by respondents United States Environmental Protection Agency and its Acting Administrator, Jane Nishida, entitled "Review of the National Ambient Air Quality Standards for Particulate Matter." EPA assigned this action Docket number EPA–HQ–OAR–2015–0072. Notice of this action was published in the Federal Register on December 18, 2020. *See* 85 Fed. Reg. 82,684 (Dec. 18, 2020) attached as Exhibit 1.

DATED: February 9, 2021

Respectfully submitted,

/s/ Robert Ukeiley

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FOR THE DISTRICT OF COLUMBIA CIRCUIT

CENTER FOR BIOLOGICAL DIVERSITY,	)	
Petitioner,	)	
v.	)	
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and	)	
	)	Docket No. 21-1054
JANE NISHIDA, Acting Administrator, United States Environmental Protection Agency,	)	
Respondents.	)	

RULE 26.1 DISCLOSURE STATEMENT

The Center for Biological Diversity has no parent companies. There are no publicly held companies that have a 10 percent or greater ownership interest in the Center for Biological Diversity.

The Center for Biological Diversity is a not-for-profit corporation whose mission is to ensure the preservation, protection, and restoration of biodiversity, native species, ecosystems, public lands and waters, and public health through science, policy, and environmental law.

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Counsel for Petitioner Center for Biological Diversity

CERTIFICATE OF SERVICE

I hereby certify that I have served the foregoing Petition for Review on respondents by sending a copy via First Class Mail to each of the following addresses on the 9th day of February, 2021.

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/s/ Robert Ukeiley

EXHIBIT 1

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[EPA–HQ–OAR–2015–0072; FRL–10018–11–OAR]

RIN 2060–AS50

Review of the National Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: Based on the Environmental Protection Agency's (EPA's) review of the air quality criteria and the national ambient air quality standards (NAAQS) for particulate matter (PM), the Administrator has reached final decisions on the primary and secondary PM NAAQS. With regard to the primary standards meant to protect against fine particle exposures (*i.e.,* annual and 24-hour $PM_{2.5}$ standards), the primary standard meant to protect against coarse particle exposures (*i.e.,* 24-hour PM_{10} standard), and the secondary $PM_{2.5}$ and PM_{10} standards, the EPA is retaining the current standards, without revision.

DATES: This final action is effective December 18, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2015–0072. Incorporated into this docket is a separate docket established for the Integrated Science Assessment (Docket ID No. EPA–HQ–ORD–2014–0859). All documents in the docket are listed in *https://www.regulations.gov/.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (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. With the exception of such material, publicly available docket materials are available electronically through *https://www.regulations.gov/.* Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Dr. Lars Perlmutt, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C539–04, Research Triangle Park, NC 27711; telephone: (919) 541–3037; fax: (919) 541–5315; email: *perlmutt.lars@epa.gov.*

SUPPLEMENTARY INFORMATION:

Basis for Immediate Effective Date

In accordance with section 307(d)(1)(V), the Administrator has designated this action as being subject to the rulemaking procedures in section 307(d) of the Clean Air Act (CAA). Section 307(d)(1) of the CAA states that: ''The provisions of section 553 through 557 * * * of Title 5 shall not, except as expressly provided in this subsection, apply to actions to which this subsection applies.'' Thus, section 553(d) of the Administrative Procedure Act (APA), which requires publication of a substantive rule to be made ''not less than 30 days before its effective date'' subject to limited exceptions, does not apply to this action. In the alternative, the EPA concludes that it is s consistent with APA section 553(d) to make this action effective December 18, 2020.

Section 553(d)(3) of the APA, 5 U.S.C. 553(d)(3), provides that final rules shall not become effective until 30 days after publication in the **Federal Register** ''except . . . as otherwise provided by the agency for good cause found and published with the rule.'' ''In determining whether good cause exists, an agency should 'balance the necessity for immediate implementation against principles of fundamental fairness which require that all affected persons be afforded a reasonable amount of time to prepare for the effective date of its ruling.'' *Omnipoint Corp.* v. *Fed. Commc'n Comm'n,* 78 F.3d 620, 630 (D.C. Cir. 1996) (quoting *United States* v. *Gavrilovic,* 551 F.2d 1099, 1105 (8th Cir. 1977)). The purpose of this provision is to ''give affected parties a reasonable time to adjust their behavior before the final rule takes effect.'' *Id.; see also Gavrilovic,* 551 F.2d at 1104 (quoting legislative history).

The EPA is determining that in light of the nature of this action, good cause exists to make this final action effective immediately because the Agency seeks to provide regulatory certainty as soon as possible and the Administrator's decision to retain the current NAAQS does not change the status quo or impose new obligations on any person or entity. As a result, there is no need to provide parties additional time to adjust their behavior, and no person will be harmed by making the action immediately effective as opposed to delaying the effective date by 30 days. Accordingly, the EPA is making this action effective immediately upon publication.

General Information

Availability of Information Related to This Action

A number of the documents that are relevant to this final decision are available through the EPA's website at *https://www.epa.gov/naaqs/particulate-matter-pm-air-quality-standards.* These documents include the Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (U.S. EPA, 2016), available at *https://www3.epa.gov/ttn/naaqs/standards/pm/data/201612-final-integrated-review-plan.pdf,* the Integrated Science Assessment for Particulate Matter (U.S. EPA, 2019), available at *https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=347534,* the Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (U.S. EPA, 2020), available at *https://www.epa.gov/naaqs/particulate-matter-pm-standards-policy-assessments-current-review-0,* and the notice of proposed rulemaking, available at *https://www.epa.gov/naaqs/particulate-matter-pm-standards-federal-register-notices-current-review.* These and other related documents are also available for inspection and copying in the EPA docket identified above.

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The following topics are discussed in this preamble:

Executive Summary

This notice presents the Administrator's final decisions to retain the current primary (health-based) and secondary (welfare-based) National Ambient Air Quality Standards (NAAQS) for particulate matter (PM), without revision.

In ambient air, PM is a mixture of substances suspended as small liquid and/or solid particles. Particles in the atmosphere range in size from less than 0.01 to more than 10 micrometers (μm) in diameter. Particulate matter and its precursors are emitted from both anthropogenic sources (*e.g.,* electricity generating units, cars and trucks, agricultural operations) and natural sources (*e.g.,* sea salt, wildland fires, biological aerosols). When describing PM, subscripts are used to denote particle size. For example, $PM_{2.5}$ includes particles with diameters generally less than or equal to 2.5 μm and PM_{10} includes particles with diameters generally less than or equal to 10 μm.

The EPA has established primary (health-based) and secondary (welfare-based) NAAQS for $PM_{2.5}$ and PM_{10}. This includes two primary $PM_{2.5}$ standards, an annual average standard with a level of 12.0 $\mu g/m^3$ and a 24-hour standard with a 98th percentile form and a level of 35 $\mu g/m^3$. It also includes a primary PM_{10} standard with a 24-hour averaging time, a 1-expected exceedance form, and a level of 150 $\mu g/m^3$. 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 $\mu g/m^3$. In reaching decisions on these PM standards in the current review, the Administrator has considered the available scientific evidence assessed in the Integrated Science Assessment (ISA), analyses in the Policy Assessment (PA), advice from the Clean Air Scientific Advisory Committee (CASAC), and public comments on the proposal.

For the primary $PM_{2.5}$ standards, the Administrator concludes that there are important uncertainties in the evidence for adverse health effects below the current standards and in the potential for additional public health improvements from reducing ambient $PM_{2.5}$ concentrations below those standards. Based on the available evidence, the Administrator has concluded that the current primary $PM_{2.5}$ standards are requisite to protect public health, with an adequate margin of safety, from effects of $PM_{2.5}$ in ambient air and should be retained, without revision. Therefore, the EPA is retaining those standards (*i.e.,* both the annual and 24-hour standards), without revision.

For the primary PM_{10} standard, the Administrator observes that, while the available health effects evidence has expanded, recent studies are subject to the same types of uncertainties that were judged important in the last review. He concludes that, based on the newly available evidence with its inherent uncertainties, the current primary PM_{10} standard is requisite to protect public health, with an adequate margin of safety, from effects of PM_{10} in ambient air, and should be retained, without revision. Therefore, the EPA is retaining that standard, without revision.

For the secondary standards, the Administrator observes that the expanded evidence for non-ecological welfare effects is consistent with the last review [1] and that updated quantitative analyses show results similar to those in the last review. Based on his consideration of the available evidence and quantitative information, he concludes that the current secondary PM standards are requisite to protect public welfare, against visibility effects and that there is insufficient information to establish distinct

[1] The welfare effects considered in this review include visibility impairment, climate effects, and materials effects. Ecological effects associated with PM, and the adequacy of protection provided by the secondary PM standards for those effects, are being addressed in the separate review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM (U.S. EPA, 2016, section 5.2; U.S. EPA, 2020, section 5.1.1) in recognition of the linkages between oxides of nitrogen, oxides of sulfur, and PM with respect to atmospheric deposition and ecological effects. Addressing the pollutants together enables the EPA to take a comprehensive approach to considering the nature and interactions of the pollutants, which is important for ensuring that all scientific information relevant to ecological effects is thoroughly evaluated. Information on the current review of these secondary NAAQS can be found at *https://www.epa.gov/naaqs/nitrogen-dioxide-no2-and-sulfur-dioxide-so2-secondary-air-quality-standards.*

secondary PM standards to address materials and climate effects. Therefore, the EPA is retaining those standards, without revision.

These decisions are consistent with the CASAC's consensus advice on the primary 24-hour $PM_{2.5}$ standard, the primary PM_{10} standard, and the secondary standards. The CASAC provided differing views on the primary annual $PM_{2.5}$ standard, with some committee members recommending that the EPA retain the current standard and other members recommending revision of that standard.

I. Background

A. Legislative Requirements

Two sections of the 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.'' [2] 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.'' [3]

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 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 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)(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. A number of other advisory functions are also identified for the committee by section 109(d)(2)(C), which reads:

> Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) 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.

[2] 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).

[3] 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.''

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.[4]

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 sections 110 and 171–190 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 such standards through control programs directed to sources of the pollutants involved. The states, in conjunction with the EPA, also administer the Prevention of Significant Deterioration (PSD) program (CAA sections 160 to 169). In addition, Federal programs provide for nationwide reductions in emissions of PM and other air pollutants through the Federal motor vehicle and motor vehicle fuel control program under title II of the Act (CAA sections 202 to 250), which involves controls for emissions from mobile sources and controls for the fuels used by these sources, and new source performance standards for stationary sources under section 111 of the CAA.

C. History of the PM Air Quality Criteria and Standards

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).[5] 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 µg/m^3, 24-hour average, not to be exceeded more than once per year, and 75 µg/m^3, annual geometric mean. The secondary standards were set at 150 µg/m^3, 24-hour average, not to be exceeded more than once per year, and 60 µg/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},[6] 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 thoracic particles. The level of the 24-hour standards (primary and secondary) was set at 150 µg/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 µg/m^3, and the form was 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 PM_{10} 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 PM_{10} 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 µg/m^3, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple community-oriented monitors;[7] and (2) a 24-hour standard with a level of 65 µg/m^3, based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each monitor within an area. Also, the EPA established a new reference method for the measurement of $PM_{2.5}$ 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 $PM_{10-2.5}$; 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 p.m. 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, holding that ''the growing empirical evidence demonstrating a relationship between fine particle pollution and adverse health effects amply justifies establishment of new fine particle standards.'' *American Trucking Associations, Inc.* v. *EPA,* 175 F. 3d 1027, 1055–56 (D.C. Cir. 1999). The D.C. Circuit also found ''ample support'' for the EPA's decision to regulate coarse particle pollution, but vacated the 1997 PM_{10} standards, concluding that the

[4] Some aspects of the CASAC's advice may not be relevant to the EPA's process of setting primary and secondary standards that are requisite to protect public health and welfare. Indeed, were the EPA to consider costs of implementation when reviewing and revising the standards ''it would be grounds for vacating the NAAQS.'' *Whitman,* 531 U.S. at 471 n.4. At the same time, the CAA directs the CASAC to provide advice on ''any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance'' of the NAAQS to the Administrator under section 109(d)(2)(C)(iv). In *Whitman,* the Court clarified that most of that advice would be relevant to implementation but not standard setting, as it ''enable[s] the Administrator to assist the States in carrying out their statutory role as primary *implementers* of the NAAQS.'' *Id.* at 470 (emphasis in original). However, the Court also noted that the CASAC's ''advice concerning certain aspects of 'adverse public health . . . effects' from various attainment strategies is unquestionably pertinent'' to the NAAQS rulemaking record and relevant to the standard setting process. *Id.* at 470 n.2.

[5] Prior to the review initiated in 2007 (see section I.C.4), 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.

[6] PM_{10} 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.

[7] 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 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).

EPA had not provided a reasonable explanation justifying use of PM_{10} as an indicator for coarse particles. *American Trucking Associations* v. *EPA,* 175 F. 3d at 1054–55. Pursuant to the D.C. Circuit's decision, the EPA removed the vacated 1997 PM_{10} standards, and the pre-existing 1987 PM_{10} 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 holdings on the cost and constitutional issues were appealed to the U.S. 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, 2004). 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).[8] On 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/m^3, retained the level of the annual $PM_{2.5}$ standards at 15.0 µg/m^3, 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 PM_{10}, the EPA retained the 24-hour standards, with levels at 150 µg/m^3, and revoked the annual standards.[9] The 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. These petitions addressed the following issues: (1) Selecting the level of the primary annual $PM_{2.5}$ standard; (2) retaining PM_{10} as the indicator of a standard for thoracic coarse particles, retaining the level and form of the 24-hour PM_{10} standard, and revoking the PM_{10} annual standard; and (3) setting the secondary $PM_{2.5}$ standards identical to the primary standards. 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 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 PM_{10}, the court upheld the EPA's decisions to retain the 24-hour PM_{10} standard to provide protection from thoracic coarse particle exposures and to revoke the annual PM_{10} 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.

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,[10] the EPA held science/policy

[8] 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 appropriate, the potential alternative standards that could be supported by the evidence and information. More recent reviews present this information in the Policy Assessment (PA).

[9] In the 2006 proposal, the EPA proposed to revise the 24-hour PM_{10} standard in part by establishing a new $PM_{10-2.5}$ indicator for thoracic coarse particles (*i.e.,* particles generally between 2.5 and 10 µm in diameter). The EPA proposed to include any ambient mix of $PM_{10-2.5}$ that was dominated by resuspended dust from high density traffic on paved roads and by PM from industrial sources and construction sources. The EPA proposed to exclude any ambient mix of $PM_{10-2.5}$ that was dominated by rural windblown dust and soils and by PM generated from agricultural and mining sources. In the final decision, the existing PM_{10} standard was retained, in part due to an ''inability . . . to effectively and precisely identify which ambient mixes are included in the [$PM_{10-2.5}$] indicator and which are not'' (71 FR 61197, October 17, 2006).

[10] 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.*

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.,* IRP (U.S. EPA, 2008), ISA (U.S. EPA, 2009c), REA planning documents for health and welfare (U.S. EPA, 2009b, U.S. EPA, 2009a), a quantitative health risk assessment (U.S. EPA, 2010a) and an urban-focused visibility assessment (U.S. EPA, 2010b), and 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 $PM_{2.5}$ standard [11] to 12.0 μg/m³ and retained the 24-hour $PM_{2.5}$ standard, with its level of 35 μg/m³. For the primary PM_{10} 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 $PM_{2.5}$ standards [12] and the 24-hour PM_{10} 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 in all respects. *NAM* v. *EPA,* 750 F.3d 921 (D.C. Cir. 2014).

D. Current Review of the Air Quality Criteria and Standards

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 PM_{10} NAAQS and issued a call for information (79 FR 71764, December 3, 2014). From February 9 to February 11, 2015, the EPA's NCEA and OAQPS held a public workshop to inform the planning for the current 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 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 this review. This workshop provided for a public discussion of the key science and policy-relevant issues around which the EPA has structured the current review of the PM NAAQS and of the most meaningful new scientific information that would be available in this review to inform understanding of these issues.

The input received at the workshop guided EPA staff in developing a draft IRP, which was reviewed by the CASAC Particulate Matter Review 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 chartered CASAC, supplemented by the Particulate Matter Review 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 this review and the key policy-relevant issues.

In May 2018, the Administrator issued a memorandum describing a ''back-to-basics'' process for reviewing the NAAQS (Pruitt, 2018). This memo announced the Agency's intention to conduct the current review of the PM NAAQS in such a manner as to ensure that any necessary revisions are finalized by December 2020. Following this memo, on October 10, 2018 the 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).[13]

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 EPA Administrator dated April 11, 2019 (Cox, 2019b). In that letter, the CASAC's recommendations address both the draft ISA's assessment of the science for PM-related effects and the process under which this review of the PM NAAQS is being conducted.

Regarding the assessment of the evidence, the CASAC letter states that ''the Draft ISA does not provide a sufficiently comprehensive, systematic assessment of the available science relevant to understanding the health impacts of exposure to particulate matter (PM)'' (Cox, 2019b, p. 1 of letter). The CASAC recommended that this and other limitations (*i.e.,* ''[i]nadequate evidence for altered causal determinations'' and the need for a ''[c]learer discussion of causality and causal biological mechanisms and pathways'') be remedied in a revised ISA (Cox, 2019b, p. 1 of letter).

Given the Administrator's timeline for this review, as noted above (Pruitt, 2018), the EPA did not prepare a second draft ISA (Wheeler, 2019). Rather, the EPA has taken steps to address the CASAC's comments in the final ISA (U.S. EPA, 2019). In particular, the final ISA includes additional text and a new appendix to clarify the comprehensive and systematic process employed by the EPA to develop the ISA. In addition, several causality determinations were re-examined and, consistent with the CASAC advice, the final ISA reflects a revised causality determination for long-term ultrafine particle (UFP) exposures and nervous system effects (*i.e.,* from ''likely to be causal'' to ''suggestive of, but not sufficient to infer, a causal relationship'').[14] The final ISA also contains additional text to clarify the evidence for biological pathways of particular PM-related effects and the role of that evidence in causality determinations.

Among its comments on the process, the chartered CASAC recommended ''that the EPA reappoint the previous CASAC PM panel (or appoint a panel with similar expertise)'' (Cox, 2019b). The Agency's response to this advice was provided in a letter from the Administrator to the CASAC chair dated

[11] The EPA also eliminated the option for spatial averaging.

[12] Consistent with the primary standard, the EPA eliminated the option for spatial averaging with the annual standard.

[13] The CASAC charter is available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf.* The Administrator's announcement is available at: *https://archive.epa.gov/epa/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee.html.*

[14] Based on the CASAC's comments, the EPA also re-examined the causality determinations for cancer and for nervous system effects following long-term $PM_{2.5}$ exposures. The EPA's consideration of these comments in the final ISA is described in detail in the proposal in sections II.B.1.d (85 FR 24111, April 30, 2020) and II.B.1.e (85 FR 24113, April 30, 2020).

July 25, 2019.[15] In that letter, the Administrator announced his intention to identify a pool of non-member subject matter expert consultants to support the CASAC's review activities for the PM and ozone NAAQS. A **Federal Register** notice requesting the nomination of scientists from a broad range of disciplines ''with demonstrated expertise and research in the field of air pollution related to PM and ozone'' was published in August 2019 (84 FR 38625, August 7, 2019). The Administrator selected consultants from among those nominated, and input from members of this pool of consultants informed the CASAC's review of the draft PA.

The EPA released the draft PA in September 2019 (84 FR 47944, September 11, 2019). The draft PA drew from the assessment of the evidence in the draft ISA. It was 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 December 2019 (84 FR 58713, November 1, 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 EPA Administrator dated December 16, 2019 (Cox, 2019a).

With regard to the primary standards, the CASAC recommended retaining the current 24-hour $PM_{2.5}$ and PM_{10} standards but did not reach consensus on the adequacy of the current annual $PM_{2.5}$ standard. With regard to the secondary standards, the CASAC recommended retaining the current standards. The CASAC's advice on the primary and secondary PM standards, and the Administrator's consideration of that advice in reaching proposed decisions, is discussed in detail in sections II.C.2 and II.C.3 (primary $PM_{2.5}$ standards), III.C.2 and III.C.3 (primary PM_{10} standards), and IV.D.2 and IV.D.3 (secondary standards) of the proposal notice (85 FR 24094, April 30, 2020).

The CASAC additionally made a number of recommendations regarding the information and analyses presented in the draft PA. Specifically, the CASAC recommended that a revised PA include: (1) Additional discussion of the current CASAC and NAAQS review process; (2) additional characterization of PM-related emissions, monitoring and air quality information, including uncertainties in that information; (3) additional discussion and examination of uncertainties in the $PM_{2.5}$ health evidence and the risk assessment; (4) updates to reflect changes in the ISA's causality determinations; and (5) additional discussion of the evidence for PM-related welfare effects, including uncertainties (Cox, 2019a, pp. 2–3 in letter). In response to the CASAC's comments, the final PA[16] incorporated a number of changes, as described in detail in section I.C.5 of the proposal (85 FR 24100, April 2020).

Drawing from his consideration of the scientific evidence assessed in the ISA and the analyses in the PA, including uncertainties in the evidence and analyses, and from his consideration of advice from the CASAC, on April 14, 2020 the Administrator 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 held virtual public hearings on the proposal on May 20–22, 2020 and May 27, 2020 (85 FR 26634, May 5, 2020). In total, the EPA received more than 66,000 comments on the proposal from members of the public and various stakeholder groups by the close of the public comment period on June 29, 2020. 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''), can be found in the docket for this rulemaking (Docket No. EPA–HQ–OAR–2015–0072).

As in prior NAAQS reviews, the EPA is basing its decision in this review on studies and related information included in the air quality criteria, which have undergone CASAC and public review. The studies assessed in the ISA[17] and PA, and the integration of the scientific evidence presented in them, have undergone extensive critical review by the EPA, the CASAC, and the public. The rigor of that review makes these studies, and their integrative assessment, the most reliable source of scientific information on which to base decisions on the NAAQS, decisions that all parties recognize as of great import. Decisions on the NAAQS can have profound impacts on public health and welfare, and NAAQS decisions 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. Some commenters have referred to and discussed individual scientific studies on the health effects of PM that were not included in the ISA ('''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 ISA. 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 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 studies and related information included 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 61144, 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 revise the O_3 NAAQS, ''new'' studies may sometimes be of

[15] Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/0/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002_Response.pdf.*

[16] Given the Administrator's timeline for this review, as noted above (Pruitt, 2018), the EPA did not prepare a second draft PA. Rather, the CASAC's advice was considered in developing the final PA (U.S. EPA, 2020).

[17] Studies identified for the ISA were based on the review's opening ''call for information'' (79 FR 71764, December 3, 2014), as well as literature searches conducted routinely to identify and evaluate ''studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009 and March 31, 2017. A limited literature update identified some additional studies that were published before December 31, 2017'' (U.S. EPA, 2019, Appendix, p. A–3). References that are cited in the 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.*

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 at 13013–13014, March 9, 1993). In the present case, the EPA's provisional consideration of ''new'' studies concludes 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. For this reason, reopening the air quality criteria review would not be warranted.

Accordingly, the EPA is basing the final decisions in this review on the studies and related information included in the PM air quality criteria that have undergone rigorous review by the EPA, 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 review and which will provide the opportunity to fully assess these studies through a more rigorous review process involving the EPA, CASAC, and the public.

E. 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 (I.E.1), sources and emissions contributing to PM in the ambient air (I.E.2), ambient PM concentrations and trends in the U.S. (I.E.3), and background PM (I.E.4). Additional detail on PM air quality can be found in Chapter 2 of the Policy Assessment (U.S. EPA, 2020; PA) and section I.D of the proposal (85 FR 24100, April 30, 2020).

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, 2019, 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, 2019, 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. PM_{10}, 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, 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, 2019, 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, 2019, 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, 2019, Table 2–1; 85 FR 24100, April 30, 2020).

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 chemical compounds present in the atmosphere that have participated in new particle formation or condensed onto existing particles (U.S. EPA, 2019, section 2.3). As discussed further in the ISA (U.S. EPA, 2019, section 2.3.2.1), secondary PM is formed in the atmosphere by photochemical oxidation reactions of both inorganic and organic gas-phase precursors. Sources and emissions of PM are discussed in more detail the PA (U.S. EPA, 2020, section 2.1.1) and in the proposal (85 FR 24101, April 30, 2020).

3. Ambient Concentrations and Trends

This section summarizes available information on recent ambient PM concentrations in the U.S. and on trends in PM air quality. Sections I.E.3.a and I.E.3.b summarize information on $PM_{2.5}$ mass and components, respectively. Section I.E.3.c summarizes information on PM_{10}. Sections I.E.3.d and I.E.3.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 PA (U.S. EPA, 2020, section 2.3) and in the proposal (85 FR 24100, April 30, 2020).

a. $PM_{2.5}$ Mass

At monitoring sites in the U.S., annual $PM_{2.5}$ concentrations from 2015 to 2017 averaged 8.0 µg/m³ (and ranged from 3.0 to 18.2 µg/m³) and the 98th percentiles of 24-hour concentrations averaged 20.9 µg/m³ (and ranged from 9.2 to 111 µg/m³) (U.S. EPA, 2020, section 2.3.2.1). The highest ambient $PM_{2.5}$ concentrations occur in the west, particularly in California and the Pacific northwest (U.S. EPA, 2020, Figure 2–8). 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, 2020, section 2.3.2).

Recent ambient $PM_{2.5}$ concentrations reflect the substantial reductions that have occurred across much of the U.S. (U.S. EPA, 2020, section 2.3.2.1). From 2000 to 2017, national annual average $PM_{2.5}$ concentrations have declined from 13.5 µg/m³ to 8.0 µg/m³, a 41% decrease (U.S. EPA, 2020, section 2.3.2.1).[18] These declines have occurred at urban and rural monitoring sites, although urban $PM_{2.5}$ 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 $PM_{2.5}$ 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 have declined significantly (U.S. EPA, 2020, section 2.3.2.1). In contrast, trends in ambient $PM_{2.5}$ 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, 2020, section 2.3.2.1).

The recent deployment of $PM_{2.5}$ monitors near major roads in large urban areas provides information on $PM_{2.5}$ concentrations near an important emissions source. Of the 25 CBSAs with valid design values at near-road monitoring sites,[19] 52% measured the highest annual design value at the near-road site while 24% measured the highest 24-hour design value at the near-road site (U.S. EPA, 2020, section 2.3.2.2). Of the CBSAs with highest annual design values at near-road sites, those design values were, on average, 0.7 µg/m³ higher than at the highest measuring non-near-road sites (range is 0.1 to 2.0 µg/m³ higher at near-road sites). Although most near-road monitoring sites do not have sufficient data to evaluate long-term trends in

[18] See *https://www.epa.gov/air-trends/particulate-matter-pm25-trends* and *https://www.epa.gov/air-trends/particulate-matter-pm25-trends#pmnat* for more information.

[19] A design value is considered valid if it meets the data handling requirements given in 40 CFR Appendix N to part 50.

near-road $PM_{2.5}$ concentrations, analyses of the data at one near-road-like site in Elizabeth, NJ,[20] show that the annual average near-road increment has generally decreased between 1999 and 2017 from about 2.0 µg/m³ to about 1.3 µg/m³ (U.S. EPA, 2020, section 2.3.2.2).

b. $PM_{2.5}$ Components

Based on recent air quality data, the major chemical components of $PM_{2.5}$ 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, 2020, 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 $PM_{2.5}$ composition trends can provide insight into the factors contributing to overall reductions in ambient $PM_{2.5}$ concentrations. The biggest change in $PM_{2.5}$ composition that has occurred in recent years is the reduction in sulfate concentrations due to reductions in SO_2 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, 2019, 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 PM_{10} mass accounted for by $PM_{2.5}$ (U.S. EPA, 2019, section 2.5.1.1.6; U.S. EPA, 2020, section 2.3.1).

c. PM_{10}

At monitoring sites in the U.S., the 2015–2017 average of 2nd highest 24-hour PM_{10} concentration was 56 µg/m³ (ranging from 18 to 173 µg/m³) (U.S. EPA, 2020, section 2.3.2.4).[21] The highest PM_{10} concentrations tend to occur in the western U.S. Seasonal analyses indicate that ambient PM_{10} 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, 2019, Table 2–5). This is due to fact that the major PM_{10} emission sources, dust and agriculture, are more active during the warmer and drier periods of the year.

Recent ambient PM_{10} concentrations reflect reductions that have occurred across much of the U.S. (U.S. EPA, 2020, section 2.3.2.4). From 2000 to 2017, annual second highest 24-hour PM_{10} concentrations have declined by about 30% (U.S. EPA, 2020, section 2.3.2.4).[22] These 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, 2020, section 2.3.2.4). Analyses at individual monitoring sites indicate that annual average PM_{10} concentrations have also declined at most sites across the U.S., with much of the decrease in the eastern U.S. associated with reductions in $PM_{2.5}$ concentrations.

d. $PM_{10-2.5}$

Since the last review, the availability of $PM_{10-2.5}$ ambient concentration data has greatly increased because of additions to the $PM_{10-2.5}$ monitoring capabilities to the national monitoring network. As illustrated in the PA (U.S. EPA, 2020, section 2.3.2.5), annual average and 98th percentile $PM_{10-2.5}$ concentrations exhibit less distinct differences between the eastern and western U.S. than for either $PM_{2.5}$ or PM_{10}. Additionally, compared to $PM_{2.5}$ and PM_{10}, changes in $PM_{10-2.5}$ concentrations have been small in magnitude and inconsistent in direction (U.S. EPA, 2020, section 2.3.2.5).

e. UFP

Compared to $PM_{2.5}$ mass, there is relatively little data on U.S. particle number concentrations, which are dominated by UFP. Based on measurements in two urban areas (New York City, Buffalo) and at a background site (Steuben County) in New York, urban particle number counts were several times higher than at the background site (U.S. EPA, 2020, section 2.3.2.6; U.S. EPA, 2019, Figure 2–18). The highest particle number counts in an urban area with multiple sites (Buffalo) were observed at a near-road location.

Long-term trends in UFP are not routinely available at U.S. monitoring sites. At one site in Illinois with long-term data available, the annual average particle number concentration declined between 2000 and 2017, closely matching the reductions in annual $PM_{2.5}$ mass over that same period (U.S. EPA, 2020, 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 $PM_{2.5}$ (U.S. EPA, 2020, section 2.3.2.6).

4. Background PM

In this review, 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 PA (U.S. EPA, 2020, section 2.4) and in the proposal (85 FR 24102, April 30, 2020). At annual and national scales, estimated background PM concentrations in the U.S. are small compared to contributions from domestic anthropogenic emissions.[23] 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 last review. Contributions to background PM in the U.S. result

[20] 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.

[21] The form of the current 24-hour PM_{10} standard is one-expected-exceedance, averaged over three years.

[22] For more information, see *https://www.epa.gov/air-trends/particulate-matter-pm10-trends#pmnat.*

[23] 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 SO_2 and oceanic production of dimethyl-sulfide (U.S. EPA, 2020, 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, 2019, section 2.3.3).

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 places.

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

This section presents the rationale for the Administrator's decision to retain the current primary $PM_{2.5}$ standards. This decision is based on a thorough review in the ISA of the latest scientific information, published through December 2017,[24] on human health effects associated with long-and short-term exposures to $PM_{2.5}$ in the ambient air. This decision also takes into account analyses in the PA of policy-relevant information from the ISA, as well as information on air quality; the analyses of human health risks in the PA; CASAC advice; and consideration of public comments received on the proposal.

Section II.A provides background on the general approach for this review 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 proposed conclusions and CASAC advice, addresses public comments received on the proposal and presents the Administrator's conclusions on the adequacy of the current standard, 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

As in prior reviews, the general approach to reviewing the current primary $PM_{2.5}$ standards is based, most fundamentally, on using the EPA's assessment of current scientific evidence and associated quantitative analyses to inform the Administrator's judgment regarding primary $PM_{2.5}$ standards that protects public health with an adequate margin of safety. In drawing conclusions with regard to the primary $PM_{2.5}$ standards, the final decision on the adequacy of the standard is largely a public health policy judgment to be made by the Administrator. The Administrator's final decision draws upon scientific information and analyses about health effects, population risks, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and risk analyses. The approach to informing these judgments, discussed more fully below, 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 CAA and with how the EPA and the courts have historically interpreted the Act. These provisions require the Administrator to establish primary standards that, in his judgment, 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 groups.[25] 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.

In evaluating the appropriateness of retaining or revising the current primary $PM_{2.5}$ standards, the EPA has adopted an approach that builds upon the general approach used in the last review and reflects the body of evidence of information now available. As summarized in section II.A.1 below, the Administrator's decisions in the prior review were based on an integration of information on health effects associated with exposure to $PM_{2.5}$ with information on the public health significance of key health effects, as well as on policy judgments as to when the standard is requisite to protect public health with an adequate margin of safety and on consideration of advice from the CASAC and public comments. These decisions were also informed by air quality and related analyses and quantitative risk information.

Similarly, in this review, as described in the PA, the proposal, and elsewhere in this document, we draw on the current evidence and quantitative assessments of public health risk of $PM_{2.5}$ in ambient air. The past and current approaches are both based, most fundamentally, on the EPA's assessments of the current scientific information and associated quantitative analyses. The EPA's assessments are primarily documented in the ISA and PA, which have received CASAC review and public comment (83 FR 53471, October 23, 2018; 83 FR 55529, November 6, 2018; 84 FR 8523, March 8, 2019; 84 FR 47944, September 11, 2019; 84 FR 51555, September 30, 2019; 84 FR 58713, September 30, 2019). To bridge the gap between the scientific assessments of the ISA and quantitative assessments of the PA and the judgments required of the Administrator in determining whether the current standard remains requisite to protect public health with an adequate margin of safety, the PA evaluates the policy implications of the current evidence in the ISA and of the quantitative analyses in the PA.

In considering the scientific and technical information, we consider both the information available at the time of the last review and information newly available since the last review, including most particularly that which has been critically analyzed and characterized in the current ISA. We additionally consider the quantitative risk information described in the PA that estimated population-level health risks associated with ambient $PM_{2.5}$ concentrations that have been adjusted to simulate air quality scenarios of policy interest (*e.g.,* ''just meeting'' the current standards) in multiple study areas. The evidence-based discussions presented below (and summarized more fully in the proposal) draw upon evidence from studies evaluating health effects related to exposures to $PM_{2.5}$, as discussed in the ISA. The risk-based discussions also presented below (and summarized more fully in the proposal) have been drawn from the quantitative analyses for $PM_{2.5}$, as discussed in the PA. Sections II.A.2 and II.A.3 below provide an overview for the current health effects evidence related to short- and long-term exposures to $PM_{2.5}$ and quantitative risk information with a focus on specific policy-relevant questions identified for these categories of information in the PA.

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[24] In addition to the review's opening ''call for information'' (79 FR 71764, December 3, 2014), ''the current ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009 and March 31, 2017. A limited literature update identified some additional studies that were published before December 31, 2017'' (U.S. EPA, 2019, Appendix, p. A–3). References that are cited in the 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.*

[25] As noted in section I.A above, such protection is specified for the sensitive group of individuals and not to a single person in the sensitive group (see S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 [1970]).

1. Background on the Current Standards

The last review of the primary PM NAAQS was completed in 2012 (78 FR 3086, January 15, 2013). As noted above (section I.C.4), in the last review the EPA lowered the level of the primary annual $PM_{2.5}$ standard from 15.0 to 12.0 µg/m^3,[26] and retained the existing 24-hour $PM_{2.5}$ standard with its level of 35 µg/m^3. The 2012 decision to strengthen the suite of primary $PM_{2.5}$ standards was based on the prior Administrator's consideration of the extensive body of scientific evidence assessed in the 2009 ISA (U.S. EPA, 2009c); the quantitative risk analyses presented in the 2010 health risk assessment (U.S. EPA, 2010a); the advice and recommendations of the CASAC (Samet, 2009; Samet, 2010c; Samet, 2010b); and public comments on the proposed rule (78 FR 3086, January 15, 2013; U.S. EPA, 2012). In particular, she noted the ''strong and generally robust body of evidence of serious health effect associated with both long- and short-term exposures to $PM_{2.5}$'' (78 FR 3120, January 15, 2013). This included epidemiological studies reporting health effect associations based on long-term average $PM_{2.5}$ concentrations ranging from about 15.0 µg/m^3 or above (*i.e.,* at or above the level of the then-existing annual standard) to concentrations ''significantly below the level of the annual standard'' (78 FR 3120, January 15, 2013). Based on her ''confidence in the association between exposure to $PM_{2.5}$ and serious public health effects, combined with evidence of such an association in areas that would meet the current standards'' (78 FR 3120, January 15, 2013), the prior Administrator concluded that revision of the suite of primary $PM_{2.5}$ standards was necessary in order to provide increased public health protection.

The prior Administrator next considered what specific revisions to the existing primary $PM_{2.5}$ standards were appropriate, given the available evidence and quantitative risk information. She considered both the annual and 24-hour $PM_{2.5}$ standards, focusing on the basic elements of those standards (*i.e.,* indicator, averaging time, form, and level). With regard to the indicator, the EPA recognized that the health studies available during the last review continued to link adverse health outcomes (*e.g.,* premature mortality, hospital admissions, emergency department visits) with long- and short-term exposures to $PM_{2.5}$ (78 FR 3121, January 15, 2013). In assessing the appropriateness of $PM_{2.5}$ mass as the indicator, the EPA also considered the available scientific evidence and information available related to ultrafine particles[27][28] and PM components,[29] noting the significant uncertainties and limitations associated with the evidence, as well as the availability of monitoring data. Consistent with the considerations and conclusions in the 2011 PA, the CASAC advised that it was appropriate to consider retaining $PM_{2.5}$ as the indicator for fine particles. In light of the evidence and the CASAC's advice, the prior Administrator concluded that it was ''appropriate to retain $PM_{2.5}$ as the indicator for fine particles'' (78 FR 3123, January 15, 2013).

With regard to averaging time, in the last review, the EPA considered issues related to the appropriate averaging time for $PM_{2.5}$ standards, with a focus on evaluating support for the existing annual and 24-hour averaging times and for potential alternative averaging times based on sub-daily or seasonal metrics. Based on the evidence assessed in the 2009 ISA, the 2011 PA noted that the overwhelming majority of studies utilized annual (or multi-year) or 24-hour PM averaging periods (U.S. EPA, 2011, section 2.3.2). Given this evidence-base, and limitations in the data for alternatives, the 2011 PA reached the overall conclusions that the available information provided strong support for considering retaining the existing annual and 24-hour averaging times (U.S. EPA, 2011, p. 2–58). The CASAC agreed that these conclusions were reasonable (Samet, 2010a, p. 2–58). The prior Administrator concurred with the CASAC's advice. Specifically, she judged that it was ''appropriate to retain the current annual and 24-hour averaging times for the primary $PM_{2.5}$ standards to protect against health effects associated with long- and short-term exposure periods'' (78 FR 3124, January 15, 2013).

With regard to form, the EPA first noted that the form of the annual $PM_{2.5}$ standard was established in 1997 as an annual arithmetic mean, averaged over 3 years, from single or multiple community-oriented monitors.[30] That is, the level of the annual standard was to be compared to measurements made at each community-oriented monitoring site, or if criteria were met, measurements from multiple community-oriented monitoring sites could be averaged together (*i.e.,* spatial averaging)[31] (62 FR 38671–38672, July 18, 1997). In the 1997 review, the EPA also established the form of the 24-hour $PM_{2.5}$ standard as the 98th percentile of 24-hour concentrations at each monitor within an area (*i.e.,* no spatial averaging), averaged over three years (62 FR 38671–38674, July 18, 1997). In the 2006 review, the EPA retained these standard forms but tightened the criteria for using spatial averaging with the annual standard (71 FR 61167, October 17, 2006).[32]

At the time of the last review, the EPA again considered the form of the standard with a focus on the issue of spatial averaging. An analysis of air quality and population demographic information indicated that the highest $PM_{2.5}$ concentrations in a given area tended to be measured at monitors in locations where the surrounding populations were more likely to live below the poverty line and to include larger percentages of racial and ethnic minorities (U.S. EPA, 2011, p. 2–60). Based on this analysis, the 2011 PA concluded that spatial averaging could result in disproportionate impacts in at-risk populations and populations with

[26] The Agency also eliminated spatial averaging provisions as part of the form of the annual standard.

[27] In the last review, the ISA defined ultrafine particles (UFP) as generally including particles with a mobility diameter less than or equal to 0.1 µm. Mobility diameter is defined as the diameter of a particle having the same diffusivity or electrical mobility in air as the particle of interest and is often used to characterize particles of 0.5 µm or smaller (U.S. EPA, 2009c, pp. 3–2 to 3–3).

[28] The 2011 PA noted the limited body of evidence assessed in the 2009 ISA (summarized in U.S. EPA, 2009c, section 2.3.5 and Table 2–6) and the limited monitoring information available to characterized ambient concentrations of UFP (U.S. EPA, 2011, section 1.3.2).

[29] The 2009 ISA concluded that ''the evidence is not yet sufficient to allow differentiation of those constituents or sources that are more closely related to specific health outcomes'' (U.S. EPA, 2009c, pp. 2–26 and 6–212; 78 FR 3123, January 15, 2013). The 2011 PA further noted that ''many different constituents of the fine particle mixture as well as groups of components associated with specific source categories of fine particles are linked to adverse health effects'' (U.S. EPA, 2011, p. 2–55; 78 FR 3123, January 15, 2013).

[30] In the last review, the EPA replaced the term ''community-oriented'' monitor with the term ''area-wide'' monitor (U.S. EPA, 2020, section 1.3). *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). CBSAs are required to have at least one area-wide monitor sited in the area of expected maximum $PM_{2.5}$ concentration.

[31] The original criteria for spatial averaging included: (1) The annual mean concentration at each site shall be within 20% of the spatially averaged annual mean, and (2) the daily values for each monitoring site pair shall yield a correlation coefficient of at least 0.6 for each calendar quarter (62 FR 38671–38672, July 18, 1997).

[32] Specifically, the Administrator revised spatial averaging criteria such that ''(1) [t]he annual mean concentration at each site shall be within 10 percent of the spatially averaged annual mean, and (2) the daily values for each monitoring site pair shall yield a correlation coefficient of at least 0.9 for each calendar quarter'' (71 FR 61167, October 17, 2006).

lower socioeconomic status (SES). Therefore, the PA concluded that it was appropriate to consider revising the form of the annual $PM_{2.5}$ standard such that it did not allow for the use of spatial averaging across monitors (U.S. EPA, 2011, p. 2–60). The CASAC agreed with the PA conclusions that it was ''reasonable'' for the EPA to eliminate the spatial averaging provisions (Samet, 2010c, p. 2).

With regard to the form of the annual $PM_{2.5}$ standard, the prior Administrator concluded that public health would not be protected with an adequate margin of safety in all locations if disproportionately higher $PM_{2.5}$ concentrations in low income and minority communities were averaged together with lower concentrations measured at other sites in a larger urban area. Therefore, she concluded that the form of the annual $PM_{2.5}$ standard should be revised to eliminate spatial averaging provisions (78 FR 3124, January 15, 2013).

With regard to the form of the 24-hour $PM_{2.5}$ standard, the EPA recognized that the existing 98th percentile form was originally selected 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.[33] Updated air quality analyses in the last review provided additional support for the increased stability of the 98th percentile $PM_{2.5}$ concentration, compared to the 99th percentile (U.S. EPA, 2011, Figure 2–2, p. 2–62). Consistent with the PA conclusions based on this analysis, the prior Administrator concluded that it was appropriate to retain the 98th percentile form for the 24-hour $PM_{2.5}$ standard (78 FR 3127, January 15, 2013).

With regard to alternative levels of the annual and 24-hour $PM_{2.5}$ standards, in the last review, the EPA considered the public health protection provided by the standards, taken together, against mortality and morbidity effects associated with long- or short-term $PM_{2.5}$ exposures. This approach recognized that it is appropriate to consider the protection provided by attaining the air quality needed to meet the suite of standards, and that there is no bright line clearly directing the choice of levels. Rather, the choice of what is appropriate is a public health policy judgment entrusted to the Administrator. See *Mississippi,* 744 F.3d at 1358, *Lead Industries Ass'n,* 647 F.2d at 1147.

In selecting the levels of the annual and 24-hour $PM_{2.5}$ standards, the prior Administrator placed the greatest emphasis on health endpoints for which the evidence was strongest, based on the assessment of the evidence in the ISA and on the ISA's causality determinations (U.S. EPA, 2009c, section 2.3.1). She particularly noted that the evidence was sufficient to conclude a causal relationship exists between $PM_{2.5}$ exposures and mortality and cardiovascular effects (*i.e.,* for both long- and short-term exposures) and that the evidence was sufficient to conclude a causal relationship is ''likely'' to exist between $PM_{2.5}$ exposures and respiratory effects (*i.e.,* for both long- and short-term exposures). She also noted additional, but more limited, evidence for a broader range of health endpoints, including evidence ''suggestive of a causal relationship'' between long-term exposures and developmental and reproductive effects as well as carcinogenic effects (78 FR 3158, January 15, 2013).

To inform her decisions on an appropriate level for the annual standard, the Administrator considered the degree to which epidemiological studies indicate confidence in the reported health effect associations over distributions of $PM_{2.5}$ concentrations in ambient air. She noted that a level of 12.0 μg/m³ was below the long-term mean $PM_{2.5}$ concentrations reported in key epidemiological studies that provided evidence of an array of serious health effects (78 FR 3161, January 15, 2013). She further noted that 12.0 μg/m³ generally corresponded to the lower portions (*i.e.,* about the 25th percentile) of distributions of health events in the limited number of epidemiological studies for which population-level information was available. A level of 12.0 μg/m³ also reflected placing some weight on studies of reproductive and developmental effects, for which the evidence was more uncertain (78 FR 3161–3162, January 15, 2013).

Given the uncertainties remaining in the scientific evidence, the Administrator judged that an annual standard level below 12.0 μg/m³ was not supported. She specifically noted uncertainties related to understanding the relative toxicity of the different components in the fine particle mixture, the role of $PM_{2.5}$ in the complex ambient mixture, exposure measurement error in epidemiological studies, and the nature and magnitude of estimated risks at relatively low ambient $PM_{2.5}$ concentrations. Furthermore, she noted that epidemiological studies had reported heterogeneity in effect estimates both within and between cities and in geographic regions of the U.S. She recognized that this heterogeneity may be attributed, in part, to difference in $PM_{2.5}$ composition in different regions and cities. With regard to evidence for reproductive and developmental effects, the prior Administrator recognized that there were a number of limitations associated with this body of evidence, including the limited number of studies evaluating such effects; uncertainties related to identifying the relevant exposure time periods of concern, and limited toxicologic evidence providing information on the mode of action(s) or biological plausibility for an association between long-term $PM_{2.5}$ exposures and adverse birth outcomes. On balance, she found that the available evidence, interpreted in light of these remaining uncertainties, did not justify an annual standard level set below 12.0 μg/m³ as being requisite to protect public health with an adequate margin of safety (*i.e.,* a standard with a lower level would have been more stringent than necessary).

In conjunction with a revised annual standard with a level of 12.0 μg/m³, the prior Administrator concluded that the evidence supported retaining the 35 μg/m³ level of the 24-hour $PM_{2.5}$ standard. She noted that the existing 24-hour standard, with its 35 μg/m³ level and 98th percentile form, would provide supplemental protection, particularly for areas with high peak-to-mean ratios possibly associated with strong seasonal sources and for areas with $PM_{2.5}$-related effects that may be associated with shorter than daily exposure periods (78 FR 3163, January 15, 2013). Thus, she concluded that the available evidence and information, considered together with its inherent uncertainties and limitations, supported an annual standard with a level of 12.0 μg/m³ combined with a 24-hour standard with a level of 35 μg/m³.

2. Overview of Health Effects Evidence

In this section, we provide an overview of the policy-relevant aspects of the health effects evidence available for consideration in this review. Section II.B of the proposal provides a detailed summary of key information contained in the ISA (U.S. EPA, 2019) and in the PA (U.S. EPA, 2020) on the health effects associated with $PM_{2.5}$ exposures, and the related public health implications, focusing particularly on the information most relevant to consideration of effects associated with the presence of $PM_{2.5}$ in ambient air. The subsections below briefly

[33] See *ATA III,* 283 F.3d at 374–76 which concludes that it is legitimate for the EPA to consider overall stability of the standard and its resulting promotion of overall effectiveness of NAAQS control programs in setting a standard that is requisite to protect the public health.

summarize the information discussed in more detail in section II.B of the proposal (85 FR 24106 to 24114, April 30, 2020).

a. Nature of Effects

Drawing from the assessment of the evidence in the ISA (U.S. EPA, 2019), and the summaries of that assessment in the PA (U.S. EPA, 2020), the sections below summarize the evidence for relationships between long- or 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 ISA concludes that the evidence supports either a ''causal'' or a ''likely to be causal'' relationship with $PM_{2.5}$ exposures.[34]

i. Mortality

Long-Term $PM_{2.5}$ Exposures

In the last 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, 2009c, p. 7–96). The strongest evidence supporting this conclusion was provided by epidemiological 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 demonstrations that reductions in ambient $PM_{2.5}$ concentrations are associated with reduced mortality risk (Laden et al., 2006) and with 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 $PM_{2.5}$ exposures and risk of mortality (U.S. EPA, 2009c).

Recent cohort studies, which have become available since the 2009 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 total and non-accidental mortality,[35] as well as with specific causes of death, including cardiovascular disease and respiratory disease (U.S. EPA, 2019, section 11.2.2). Many of these recent studies have extended the follow-up periods originally evaluated in the ACS and Harvard Six Cities cohort studies and continue to observe positive associations between long-term $PM_{2.5}$ exposures and mortality (U.S. EPA, 2019, section 11.2.2.1, Figures 11–18 and 11–19). Adding to recent evaluations of the ACS and Six Cities cohorts, studies conducted with other cohorts also show consistent, positive associations between long-term $PM_{2.5}$ exposure and mortality across various demographic groups (*e.g.,* age, sex, occupation), spatial and temporal extents, exposure assessment metrics, and statistical techniques (U.S. EPA, 2019, sections 11.2.2.1 and 11.2.5). This includes some of the largest cohort studies conducted to date, with analyses of the U.S. Medicare cohort that include nearly 61 million enrollees (Di et al., 2017b) and studies that control for a range of individual and ecological covariates.

A recent series of accountability studies has additionally tested the hypothesis that past reductions in ambient $PM_{2.5}$ concentrations have been associated with increased life expectancy or a decreased mortality rate (U.S. EPA, 2019, 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 μg/m³ decrease in long-term $PM_{2.5}$ 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 (Correia et al., 2013), a time period with lower ambient $PM_{2.5}$ concentrations. In this follow-up study, a decrease in long-term $PM_{2.5}$ concentrations 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 μg/m³ decrease in long-term $PM_{2.5}$ concentration was associated with a 0.35-year increase in life expectancy). Additional studies conducted in the U.S. or Europe similarly report that reductions in ambient $PM_{2.5}$ are associated with improvements in longevity (U.S. EPA, 2019, section 11.2.2.5).

The ISA concludes that positive associations between long-term $PM_{2.5}$ exposures and mortality are robust across analyses examining a variety of study designs (*e.g.,* U.S. EPA, 2019, section 11.2.2.4), approaches to estimating $PM_{2.5}$ exposures (U.S. EPA, 2019, section 11.2.5.1), approaches to controlling for confounders (U.S. EPA, 2019, sections 11.2.3 and 11.2.5), geographic regions and populations, and temporal periods (U.S. EPA, 2019, sections 11.2.2.5 and 11.2.5.3). Recent evidence further demonstrates that associations with mortality remain robust in copollutant analyses (U.S. EPA, 2019, section 11.2.3), and that associations persist in analyses restricted to long-term exposures below 12 μg/m³ (Di et al., 2017b) or 10 μg/m³ (Shi et al., 2016).

Another important consideration in characterizing the potential for additional public health improvements associated with changes in $PM_{2.5}$ exposure is whether concentration-response relationships are linear across the range of concentrations or if nonlinear relationships exist along any part of this range. Several recent studies 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, 2019, section 11.2.4). However, interpreting the shapes of these relationships, particularly at $PM_{2.5}$ concentrations near the lower end of the air quality distribution, can be complicated by relatively low data density in the lower concentration range, the possible influence of exposure measurement error, and variability among individuals with respect to air pollution health effects. These sources of variability and uncertainty tend to smooth and ''linearize'' population-level concentration-response functions, and thus could obscure the existence of a threshold or nonlinear relationship (85 FR 24107, April 30, 2020).

The biological plausibility of $PM_{2.5}$-attributable mortality is supported by the coherence of effects across scientific disciplines (*i.e.,* animal toxicologic, controlled human exposure studies, and epidemiologic). The ISA outlines the available evidence for plausible pathways by which inhalation exposure to $PM_{2.5}$ could progress from initial events (*e.g.,* respiratory tract inflammation, autonomic nervous system modulation) to endpoints relevant to population outcomes, particularly those related to cardiovascular diseases such as ischemic heart disease, stroke and atherosclerosis (U.S. EPA, 2019, section 6.2.1), and to metabolic disease and diabetes (U.S. EPA, 2019, section 7.2.1). The ISA notes ''more limited evidence from respiratory morbidity'' (U.S. EPA, 2019, p. 11–101) to support the biological plausibility of mortality due

[34] In this review 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 ISA to demonstrate a ''causal'' or a ''likely to be causal'' relationship with PM exposures.

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

to long-term $PM_{2.5}$ exposures (U.S. EPA, 2019, section 11.2.1).

Taken together, recent studies reaffirm and further strengthen the body of evidence from the 2009 ISA for the relationship between long-term $PM_{2.5}$ exposure and mortality. Recent epidemiological studies consistently report positive associations with mortality across different geographic locations, populations, and analytic approaches. Recent experimental and epidemiological 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. The 2019 ISA concludes that, ''collectively, this body of evidence is sufficient to conclude that a causal relationship exists between long-term $PM_{2.5}$ exposure and total mortality'' (U.S. EPA, 2019, section 11.2.7; p. 11–102).

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, 2009c). This conclusion was based on the evaluation of both multi- and single-city epidemiological studies that consistently reported positive associations between short-term $PM_{2.5}$ exposure and non-accidental mortality. 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.

Recent multicity studies evaluated since the 2009 ISA continue to 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) [36] at lags of 0 to 1 days in single-pollutant models. Whereas most studies rely on assigning exposures using data from ambient monitors, associations are also reported in recent studies that employ hybrid modeling approaches using additional $PM_{2.5}$ data (*i.e.,* from satellites, land use information, and modeling, in addition to monitors), allowing for the inclusion of more rural locations in analyses (Kloog et al., 2013, Shi et al., 2016, Lee et al., 2015).

Some recent studies have expanded the examination of potential confounders (*e.g.,* U.S. EPA, 2019, section 11.1.5.1) to include not only copollutants, but also systematic evaluations of the potential impact of inadequate control from long-term temporal trends and weather. 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, 2019, 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, 2019, section 11.1.4).

The generally positive associations reported with mortality are supported by a small group of studies employing causal inference or quasi-experimental statistical approaches (U.S. EPA, 2019, section 11.1.2.1). For example, a recent study examined 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 report 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.

Positive associations with total mortality are further supported by analyses reporting positive associations with cause-specific mortality, including cardiovascular and respiratory mortality (U.S. EPA, 2019, section 11.1.3). For cause-specific mortality, there has been only a limited assessment of potential copollutant confounding, though initial evidence indicates that associations remain positive and relatively unchanged in models with gaseous pollutants and $PM_{10-2.5}$. The evidence for ischemic events and heart failure, as detailed in the assessment of cardiovascular morbidity (U.S. EPA, 2019, chapter 6), provides biological plausibility for $PM_{2.5}$-related cardiovascular mortality, which comprises the largest percentage of total mortality (*i.e.,* ~33%) (U.S. National Institutes of Health, 2013). Although there is evidence for exacerbations of chronic obstructive pulmonary disease (COPD) and asthma, the collective body of evidence for respiratory effects, particularly from controlled human exposure studies, provides only limited support for the biological plausibility of $PM_{2.5}$-related respiratory mortality (U.S. EPA, 2019, 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. Recent studies examine both city-specific as well as regional characteristics to identify the underlying contextual factors that could contribute to this heterogeneity (U.S. EPA, 2019, section 11.1.6.3). Collectively, these studies indicate that the heterogeneity in $PM_{2.5}$-mortality risk estimates cannot be attributed to one factor, but instead to 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, 2019, section 11.1.12).

A few recent studies have conducted analyses comparing the traditional 24-hour average exposure metric with a sub-daily metric (*i.e.,* 1-hour max). These initial studies 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 (U.S. EPA, 2019, section 11.1.8.1).

Recent multicity studies indicate that positive and statistically significant associations with mortality persist in analyses restricted to short-term $PM_{2.5}$ exposures below 35 $\mu g/m^3$ (Lee et al., 2015),[37] below 30 $\mu g/m^3$ (Shi et al., 2016), and below 25 $\mu g/m^3$ (Di et al., 2017a). Additional studies examine the shape of the concentration-response relationship and whether a threshold exists specifically for $PM_{2.5}$ (U.S. EPA, 2019, section 11.1.10). These studies have used various statistical approaches and consistently found linear relationships with no evidence of a threshold. Recent analyses provide initial evidence indicating that $PM_{2.5}$-mortality associations persist and may be stronger (*i.e.,* a steeper slope) at lower

[36] As detailed in the ISA, risk estimates are for a 10 $\mu g/m^3$ increase in 24-hour average $PM_{2.5}$ concentrations, unless otherwise noted (U.S. EPA, 2019, Preface).

[37] 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 $\mu g/m^3$.

concentrations (*e.g.,* Di et al., 2017a; U.S. EPA, 2019, Figure 11–12). However, given the limited data available at the lower end of the distribution of ambient $PM_{2.5}$ concentrations, the shape of the concentration-response curve remains uncertain at these low concentrations and, to date, studies have not conducted extensive analyses exploring alternatives to linearity when examining the shape of the $PM_{2.5}$-mortality concentration-response relationship.

Overall, recent epidemiological studies 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, provides 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 of the concentration-response relationship. The 2019 ISA states that, collectively, ''this body of evidence is sufficient to conclude that a causal relationship exists between short-term $PM_{2.5}$ exposure and total mortality'' (U.S. EPA, 2019, p. 11–58).

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, 2009c). The strongest line of evidence comprised findings from several large epidemiological studies of U.S. cohorts that consistently showed 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 epidemiological 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, 2009c).

Studies conducted since the last review continue to support the relationship between long-term exposure to $PM_{2.5}$ and cardiovascular effects. As discussed above, results from recent U.S. and Canadian cohort studies consistently report positive associations between long-term $PM_{2.5}$ exposure and cardiovascular mortality (U.S. EPA, 2019, Figure 6–19) in evaluations conducted at varying spatial scales and employing a variety of exposure assessment and statistical methods (U.S. EPA, 2019, section 6.2.10). Positive associations between long-term $PM_{2.5}$ exposures and cardiovascular mortality are generally robust in copollutant models adjusted for ozone, NO_2, $PM_{10-2.5}$, or SO_2. In addition, most of the results from analyses examining the shape of the concentration-response relationship for cardiovascular mortality support a linear relationship with long-term $PM_{2.5}$ exposures and do not identify a threshold below which effects do not occur (U.S. EPA, 2019, section 6.2.16, Table 6–52).[38]

The available evidence examining the relationship between long-term $PM_{2.5}$ exposure and cardiovascular morbidity has greatly expanded since the 2009 ISA, with positive associations reported in several cohorts examining a range of cardiovascular outcomes (U.S. EPA, 2019, section 6.2). Though results for cardiovascular morbidity are less consistent than those for cardiovascular mortality (U.S. EPA, 2019, section 6.2), recent studies provide some evidence for associations between long-term $PM_{2.5}$ exposures and the progression of cardiovascular disease, including cardiovascular morbidity (*e.g.,* coronary heart disease, stroke) and atherosclerosis progression (*e.g.,* coronary artery calcification) (U.S. EPA, 2019, sections 6.2.2. to 6.2.9). Associations reported in such studies are supported by toxicologic 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, 2019, section 6.2.4.2). A small number of epidemiological studies also report positive associations between long-term $PM_{2.5}$ exposure and heart failure, changes in blood pressure, and hypertension (U.S. EPA, 2019, sections 6.2.5 and 6.2.7). Associations with heart failure are supported by animal toxicologic studies demonstrating decreased cardiac contractility and function, and increased coronary artery wall thickness following long-term $PM_{2.5}$ exposure (U.S. EPA, 2019, section 6.2.5.2). Similarly, a limited number of animal toxicologic studies demonstrating a relationship between long-term exposure to $PM_{2.5}$ and consistent increases in blood pressure in rats and mice are coherent with epidemiological studies reporting positive associations between long-term exposure to $PM_{2.5}$ and hypertension. Further, a recent animal toxicologic study also demonstrates increased plaque progression in mice following long-term exposure to $PM_{2.5}$ and provides coherent results with epidemiological evidence reporting positive associations between long-term exposure to $PM_{2.5}$ and indicators of atherosclerosis (U.S. EPA, 2019, section 6.2.4.2).

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

In summary, the 2019 ISA concludes that there is consistent evidence from multiple epidemiological studies illustrating that long-term exposure to $PM_{2.5}$ is associated with mortality from cardiovascular causes. Associations with CHD, stroke and atherosclerosis progression were observed in several additional epidemiological 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. The combination of epidemiological and experimental evidence results in the ISA conclusion that ''a causal relationship exists between long-term exposure to $PM_{2.5}$ and cardiovascular effects'' (U.S. EPA, 2019, p. 6–222).

Short-Term $PM_{2.5}$ Exposures

The 2009 ISA concluded that ''a causal relationship exists between short-

[38] As noted above for mortality, uncertainty in the shape of the concentration-response relationship increases near the upper and lower ends of the concentration distribution where the data are limited.

term exposure to $PM_{2.5}$ and cardiovascular effects'' (U.S. EPA, 2009c). The strongest evidence in the 2009 ISA was from epidemiological studies of emergency department visits and hospital admissions for ischemic heart disease (IHD) and heart failure (HF), with supporting evidence from epidemiological studies of cardiovascular mortality (U.S. EPA, 2009c). Animal toxicologic studies reported evidence of reduced myocardial blood flow during ischemia and studies indicating altered vascular reactivity (*i.e.,* vascular function), which provided coherence and biological plausibility for the effects observed in epidemiological studies. In addition, both animal toxicologic and epidemiological panel studies reported effects of $PM_{2.5}$ exposure on ST segment depression, an electrocardiogram change that potentially indicates ischemia.[39] Key uncertainties from the last review included 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 toxicologic studies, uncertainties remained with respect to biological plausibility.

A large body of recent evidence confirms and extends the evidence from the 2009 ISA supporting the relationship between short-term $PM_{2.5}$ exposure and cardiovascular effects. This includes generally positive associations observed in multicity epidemiological studies of emergency department visits and hospital admissions for IHD, HF, and combined cardiovascular-related endpoints. In particular, nationwide studies of older adults (65 years and older) report positive associations between $PM_{2.5}$ exposures and hospital admissions for HF (U.S. EPA, 2019, section 6.1.3.1). Single-city epidemiological studies contribute some support, though associations reported are less consistently positive than in multicity studies, and include a number of studies reporting null associations (U.S. EPA, 2019, sections 6.1.2 and 6.1.3).

In addition, a number of more recent controlled human exposure, animal toxicologic, and epidemiological panel studies provide evidence that $PM_{2.5}$ exposure could plausibly result in IHD or HF through pathways that include endothelial dysfunction, arterial thrombosis, and arrhythmia (U.S. EPA, 2019, 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 (U.S. EPA, 2019, section 6.1.13.2). These studies report variable results regarding the timing of the effect and the mechanism by which reduced blood flow occurs (*i.e.,* availability of vs. sensitivity to nitric oxide). Some controlled human exposure studies using $PM_{2.5}$ CAPs report evidence for small increases in blood pressure (U.S. EPA, 2019, section 6.1.6.3). In addition, although not entirely consistent, there is also some evidence across controlled human exposure studies for conduction abnormalities/arrhythmia (U.S. EPA, 2019, section 6.1.4.3), changes in heart rate variability (HRV) (U.S. EPA, 2019, section 6.1.10.2), changes in hemostasis that could promote clot formation (U.S. EPA, 2019, section 6.1.12.2), and increases in inflammatory cells and markers (U.S. EPA, 2019, section 6.1.11.2). Thus, when taken as a whole, controlled human exposure studies are coherent with epidemiological studies in that they provide evidence 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.

Animal toxicologic studies published since the 2009 ISA also support a relationship between short-term $PM_{2.5}$ exposure and cardiovascular effects. A recent study demonstrating decreased cardiac contractility and left ventricular pressure in mice is coherent with the results of epidemiological studies that report associations between short-term $PM_{2.5}$ exposure and heart failure (U.S. EPA, 2019, section 6.1.3.3). In addition, similar to results of controlled human exposure studies, there is generally consistent evidence in animal toxicologic studies for indicators of endothelial dysfunction (U.S. EPA, 2019, section 6.1.13.3). Studies in animals also provide evidence for changes in a number of other cardiovascular endpoints following short-term $PM_{2.5}$ exposure. Although not entirely consistent, these studies provide some evidence of conduction abnormalities and arrhythmia (U.S. EPA, 2019, section 6.1.4.4), changes in HRV (U.S. EPA, 2019, section 6.1.10.3), changes in blood pressure (U.S. EPA, 2019, section 6.1.6.4), and evidence for systemic inflammation and oxidative stress (U.S. EPA, 2019, section 6.1.11.3).

In summary, recent evidence supports the conclusions reported in the 2009 ISA indicating relationships between short-term $PM_{2.5}$ exposures and hospital admissions and ED visits for IHD and HF, along with cardiovascular mortality. Epidemiological 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). Epidemiological panel studies, although not entirely consistent, provide some evidence that $PM_{2.5}$ exposures are associated with cardiovascular effects, including increased risk of arrhythmia, decreases in HRV, increases in BP, and ST segment depression. Overall, the results from epidemiological panel, controlled human exposure, and animal toxicologic 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 epidemiological studies reporting positive associations between short-term $PM_{2.5}$ exposures and IHD and HF, and ultimately cardiovascular mortality. The 2019 ISA concludes that, overall, ''there continues to be sufficient evidence to conclude that a causal relationship exists between short-term $PM_{2.5}$ exposure and cardiovascular effects'' (U.S. EPA, 2019, p. 6–138).

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, 2009c). This conclusion was based mainly on epidemiological 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 toxicologic study examining pre- and post-natal exposure to $PM_{2.5}$ CAPs, which found impaired lung development. Epidemiological evidence for associations between long-term $PM_{2.5}$ exposure and other respiratory outcomes, such as the

[39] 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 particulate components of the mixture.

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 toxicologic study reporting that long-term exposure to $PM_{2.5}$ CAPs results in morphological changes in the 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.

Recent cohort studies provide 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, 2019, section 5.2.13). This relationship is further supported by a recent retrospective study that reports an association between declining $PM_{2.5}$ concentrations and improvements in lung function growth in children (U.S. EPA, 2019, section 5.2.11). Epidemiological studies also examined asthma development in children (U.S. EPA, 2019, section 5.2.3), with recent 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, 2019, section 5.2.13). A recent animal toxicologic 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, 2019, section 5.2.13). Other epidemiological 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, 2019, section 5.2.11). A recent 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, 2019, section 5.2.11). A common uncertainty across the epidemiological 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 collective evidence is sufficient to conclude a likely to be causal relationship between long-term $PM_{2.5}$ exposure and respiratory effects'' (U.S. EPA, 2019, p. 5–220).

Short-Term $PM_{2.5}$ Exposures

The 2009 ISA (U.S. EPA, 2009c) 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 epidemiological evidence demonstrating positive associations with various respiratory effects. Specifically, the 2009 ISA described epidemiological evidence as consistently showing $PM_{2.5}$-associated increases in hospital admissions and emergency department 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 available epidemiological 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 SO_2 in the model, but often were attenuated (though still positive) with inclusion of O_3 or NO_2. In addition to the copollutant models, evidence supporting an independent effect of $PM_{2.5}$ exposure on the respiratory system was provided by animal toxicologic 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 find respiratory effects following short-term $PM_{2.5}$ exposures.

Recent epidemiological studies provide evidence for a relationship between short-term $PM_{2.5}$ exposure and several respiratory-related endpoints, including asthma exacerbation (U.S. EPA, 2019, section 5.1.2.1), COPD exacerbation (U.S. EPA, 2019, section 5.1.4.1), and combined respiratory-related diseases (U.S. EPA, 2019, section 5.1.6), particularly from studies examining emergency department visits and hospital admissions. The generally positive associations between short-term $PM_{2.5}$ exposure and asthma and COPD emergency department visits and hospital admissions are supported by epidemiological 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, 2019, sections 5.1.2.2 and 5.4.1.2). The collective body of epidemiological evidence for asthma exacerbation is more consistent in children than in adults. Additionally, epidemiological 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, 2019, section 5.1.9).

Building on the studies evaluated in the 2009 ISA, recent epidemiological studies expand the assessment of potential copollutant confounding. 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 (*i.e.,* O_3, NO_2, SO_2, with more limited evidence for CO) and other particle sizes (*i.e.,* $PM_{10-2.5}$) (U.S. EPA, 2019, section 5.1.10.1).

Insight into whether there is an independent effect of $PM_{2.5}$ on respiratory health is provided by findings from animal toxicologic studies. Specifically, short-term exposure to $PM_{2.5}$ has been shown to enhance asthma-related responses in an animal model of allergic airways disease and lung injury and inflammation in an animal model of COPD (U.S. EPA, 2019, 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. Animal toxicologic evidence for other respiratory effects is inconsistent and controlled human exposure studies provide limited evidence of respiratory effects (U.S. EPA, 2019, section 5.1.12).

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 epidemiological studies of asthma and COPD exacerbation. While animal toxicologic studies provide biological plausibility for these findings, some uncertainty remains with respect to the independence of $PM_{2.5}$ effects'' (U.S. EPA, 2019, p. 5–155). When taken together, the ISA concludes that this evidence ''is sufficient to conclude a likely to be causal relationship between short-term $PM_{2.5}$ exposure and respiratory effects'' (U.S. EPA, 2019, 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, 2009c). This conclusion was based primarily on positive associations observed in a limited number of epidemiological studies of lung cancer mortality. The few epidemiological 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. Toxicologic 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 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, 2019, section 10.2.5), with limited evidence of cancer in other organ systems. Reanalyses 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, 2019, Figure 10–3). Additional support for positive associations with lung cancer mortality is provided by recent epidemiological studies using individual-level data to control for smoking status, in studies of people who have never smoked), and in analyses of cohorts that relied upon proxy measures to account for smoking status (U.S. EPA, 2019, 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, recent studies generally report positive associations with long-term $PM_{2.5}$ exposures (U.S. EPA, 2019, section 10.2.5.1.2). In addition, a subset of the studies focusing on lung cancer incidence also examined histological subtypes, providing some evidence of positive associations for adenocarcinomas, the predominate subtype of lung cancer observed in people who have never smoked (U.S. EPA, 2019, 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, 2019, 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. The small number of such studies have generally focused on O_3 and report that $PM_{2.5}$ associations remain relatively unchanged in copollutant models (U.S. EPA, 2019, 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, 2019, section 10.2.5.1.3). Compared to total (non-accidental) mortality (discussed above), fewer studies have examined the shape of the concentration-response curve for cause-specific mortality outcomes, including lung cancer. Several of these studies have reported no evidence of deviations from linearity in the shape of the concentration-response 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, 2019, section 10.2.5.1.4).

In support of the biological plausibility of an independent effect of $PM_{2.5}$ on cancer, the 2019 ISA notes evidence from recent experimental 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, 2019, section 10.2.7). For example, both in vitro and in vivo toxicologic studies have shown that $PM_{2.5}$ exposure can result in DNA damage (U.S. EPA, 2019, 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 epidemiological associations with lung cancer mortality and incidence. Additional supporting studies indicate the occurrence of micronuclei formation and chromosomal abnormalities (U.S. EPA, 2019, section 10.2.2.3), and differential expression of genes that may be relevant to cancer pathogenesis, following PM exposures. Experimental and epidemiological studies that examine epigenetic effects indicate changes in DNA methylation, providing some support for $PM_{2.5}$ exposure contributing to genomic instability (U.S. EPA, 2019, section 10.2.3).

Epidemiological evidence for associations between $PM_{2.5}$ exposure 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 there is a likely to be causal relationship between long-term $PM_{2.5}$ exposure and cancer'' (U.S. EPA, 2019, p. 10–77).

In its letter to the Administrator on the draft ISA, the CASAC states that ''the Draft ISA does not present adequate evidence to conclude that there is likely to be a causal relationship between long-term $PM_{2.5}$ exposure and . . . cancer'' (Cox, 2019a, p. 1 of letter). The CASAC specifically states that this causality determination ''relies largely on epidemiology studies that . . . do not provide exposure time frames that are appropriate for cancer causation and that there are no animal studies showing direct effects of $PM_{2.5}$ on cancer formation'' (Cox, 2019a, p. 20 of consensus responses).

With respect to the latency period, it is well recognized that ''air pollution exposures experienced over an extended historical time period are likely more relevant to the etiology of lung cancer than air pollution exposures experienced in the more recent past'' (Turner et al. 2011). However, many epidemiological studies conducted within the U.S. that examine long-term

$PM_{2.5}$ exposure and lung cancer incidence and lung cancer mortality rely on more recent air quality data because routine $PM_{2.5}$ monitoring did not start until 1999–2000. An exception to this is the ACS study that had $PM_{2.5}$ concentration data from two time periods, 1979–1983 and from 1999–2000. Turner et al. (2011), conducted a comparison of $PM_{2.5}$ concentrations between these two time periods and found that they were highly correlated (r >0.7), with the relative rank order of metropolitan statistical areas (MSAs) by $PM_{2.5}$ concentrations being ''generally retained over time.'' Therefore, areas where $PM_{2.5}$ concentrations were high remained high over decades (or were low and remained low) relative to other locations. Long-term exposure epidemiological studies rely on spatial contrasts between locations; therefore, if a location with high $PM_{2.5}$ concentrations continues to have high concentrations over decades relative to other locations a relationship between the $PM_{2.5}$ exposure and cancer should persist. This was confirmed in a sensitivity analysis conducted by Turner et al. (2011), where the authors reported a similar hazard ratio (HR) for lung cancer mortality for participants assigned exposure to $PM_{2.5}$ (1979–1983) and $PM_{2.5}$ (1999–2000) in two separate analyses.

While experimental studies showing a direct effect of $PM_{2.5}$ on cancer formation were limited to an animal model of urethane-induced tumor initiation, a large number of experimental studies report that $PM_{2.5}$ exhibits several key characteristics of carcinogens, as indicated by genotoxic effects, oxidative stress, electrophilicity, and epigenetic alterations, all of which provide biological plausibility that $PM_{2.5}$ exposure can contribute to cancer development. The experimental evidence, in combination with multiple recent and previously evaluated epidemiological studies examining the relationship between long-term $PM_{2.5}$ exposure and both lung cancer incidence and lung cancer mortality that reported generally positive associations across different cohorts, exposure assignment methods, and in analyses of never smokers further addresses uncertainties identified in the 2009 ISA. Therefore, upon re-evaluating the causality determination for cancer, when considering CASAC comments on the draft ISA and applying the causal framework as described (U.S. EPA, 2015; U.S. EPA, 2019, section A.3.2.1), the EPA continues to conclude in the 2019 ISA that the evidence for long-term $PM_{2.5}$ exposure and cancer supports a ''likely to be causal relationship'' (U.S. EPA, 2019, p. 10–77).

v. Nervous System Effects

Reflecting the very limited evidence available in the last 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 last review, this body of evidence has grown substantially (U.S. EPA, 2019, section 8.2). Recent studies in adult animals 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 epidemiological studies reporting that long-term $PM_{2.5}$ exposure is associated with reduced cognitive function (U.S. EPA, 2019, section 8.2.5). Further, while the evidence is limited, early markers of Alzheimer's disease pathology have been reported 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, and hospitalization for Alzheimer's disease in a small number of epidemiological studies (U.S. EPA, 2019, section 8.2.6). Additionally, loss of dopaminergic neurons in the substantia nigra, a hallmark of Parkinson's disease, has been reported in mice following long-term $PM_{2.5}$ exposures (U.S. EPA, 2019, section 8.2.4), though epidemiological studies provide only limited support for associations with Parkinson's disease (U.S. EPA, 2019, section 8.2.6). Overall, the lack of consideration of copollutant confounding introduces some uncertainty in the interpretation of epidemiological 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.

In addition to the findings described above, which are most relevant to older adults, several recent studies of neurodevelopmental effects in children have also been conducted. Epidemiological 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). Interpretation of these epidemiological studies is limited due to the small number of studies, their lack of control for potential confounding by copollutants, and uncertainty regarding 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 the strongest evidence of an effect of long-term exposure to $PM_{2.5}$ on the nervous system is provided by toxicologic studies that show inflammation, oxidative stress, morphologic changes, and neurodegeneration in multiple brain regions following long-term exposure of adult animals to $PM_{2.5}$ CAPs. These findings are coherent with epidemiological studies reporting consistent associations with cognitive decrements and with all-cause dementia. The ISA determines that ''[o]verall, the collective evidence is sufficient to conclude a likely to be causal relationship between long-term $PM_{2.5}$ exposure and nervous system effects'' (U.S. EPA, 2019, p. 8–61).

In its letter to the Administrator on the draft ISA, the CASAC states that ''the Draft ISA does not present adequate evidence to conclude that there is likely to be a causal relationship between long-term $PM_{2.5}$ exposure and nervous system effects'' (Cox, 2019a, p. 1 of letter). The CASAC specifically states that ''[f]or a likely causal conclusion, there would have to be evidence of health effects in studies where results are not explained by chance, confounding, and other biases, but uncertainties remain in the overall evidence'' (Cox, 2019a, p. 20 of consensus responses). These uncertainties in the eyes of CASAC reflect that animal toxicologic studies ''have largely been done by a single group,'' and for epidemiological studies that examined brain volume that ''brain volumes can vary . . . between normal people'' and the results from studies of cognitive function were ''largely non-statistically significant'' (Cox, 2019a, p. 20 of consensus responses).

With these concerns in mind, and as noted in the proposed rule (85 FR 24114, April 30, 2020), the EPA re-evaluated the evidence and note that animal toxicologic studies were conducted in ''multiple research groups [and show a range of effects including] inflammation, oxidative stress, morphologic changes, and neurodegeneration in multiple brain regions following long-term exposure of adult animals to $PM_{2.5}$ CAPs'' (U.S. EPA, 2019, p. 8–61). The results from the animal toxicologic studies ''are coherent with a number of epidemiological studies reporting consistent associations with cognitive decrements and with all-cause dementia'' (U.S. EPA, 2019, p. 8–61). Additionally, as discussed in the Preamble to the ISAs (U.S. EPA, 2015):

''. . . the U.S. EPA emphasizes the importance of examining the 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 . . . 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 . . . [Therefore, the U.S. EPA] . . . does not limit its focus or consideration to statistically significant results in epidemiologic studies.''

Therefore, upon re-evaluating the causality determination, when considering the CASAC comments on the draft ISA and applying the causal framework as described (U.S. EPA, 2015; U.S. EPA, 2019, section A.3.2.1), the EPA continues to conclude in the 2019 ISA that the evidence for long-term $PM_{2.5}$ exposure and nervous system effects supports a ''likely to be causal relationship'' (U.S. EPA, 2019, p. 8–61).

vi. Other Effects

For other categories of health effects and $PM_{2.5}$ exposures,[40] 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, 2019, sections 7.1.4, 7.2.10, 8.1.6, and 9.1.5). These causality determinations are revised from ''inadequate to infer a causal relationship'' or not evaluated in the 2009 ISA this review; however, the ''suggestive of, but not sufficient to infer, a causal relationship'' causality determinations reflect continued uncertainties in the evidence.

[40] The other categories evaluated in the ISA include nervous system effects and short-term exposures; metabolic effects; reproduction and fertility; and pregnancy and birth outcomes (U.S. EPA, 2019, Table ES–1).

b. At-Risk Populations

In this review, we use the term ''at-risk populations'' to describe populations with a quality or characteristic in common (*e.g.,* a specific pre-existing illness or specific lifestage) that contributes to them having a greater likelihood of experiencing $PM_{2.5}$-related health effects. In the current review, consistent with the last 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, 2019, p. 12–1). For example, in support of its ''causal'' and ''likely to be causal'' determinations, the ISA cites substantial evidence for: PM-related mortality and cardiovascular effects in older adults (U.S. EPA, 2019, sections 11.1, 11.2, 6.1, and 6.2); PM-related cardiovascular effects in people with pre-existing cardiovascular disease (U.S. EPA, 2019, section 6.1); PM-related respiratory effects in people with pre-existing respiratory disease, particularly asthma exacerbations in children (U.S. EPA, 2019, section 5.1); and PM-related impairments in lung function growth and asthma development in children (U.S. EPA, 2019, sections 5.1 and 5.2; 12.5.1.1).

The ISA additionally notes that stratified analyses (*i.e.,* analyses that directly compare PM-related health effects across groups) provide support for racial and ethnic differences in $PM_{2.5}$ exposures and in $PM_{2.5}$-related health risk (U.S. EPA, 2019, section 12.5.4). Drawing from such studies, the ISA concludes that ''[t]here is strong evidence demonstrating that black and Hispanic populations, in particular, have higher $PM_{2.5}$ exposures than non-Hispanic white populations'' and that ''there is consistent evidence across multiple studies demonstrating an increase in risk for nonwhite populations'' (U.S. EPA, 2019, p. 12–38). Stratified analyses focusing on other groups also suggest that populations with pre-existing cardiovascular or respiratory disease, populations that are overweight or obese, populations that have particular genetic variants, populations that are of low socioeconomic status, and current/former smokers could be at increased risk for $PM_{2.5}$-related adverse health effects (U.S. EPA, 2019, Chapter 12).

Thus, the groups at greater 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 for additional public health improvements in these populations.

c. Evidence-Based Considerations

The sections below summarize the PA's evaluation of the $PM_{2.5}$ exposure concentrations that have been examined in controlled human exposure studies, animal toxicology studies, and epidemiological studies.

i. $PM_{2.5}$ 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 toxicologic 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 toxicology studies can provide information on the health effects of experimentally administered pollutant exposures under well-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 (U.S. EPA, 2019, section 6.1). The most consistent evidence from these studies is for impaired vascular function (U.S. EPA, 2019, section 6.1.13.2). Table 3–2 in the PA (U.S. EPA, 2020) summarizes information from the ISA on available controlled human exposure studies that evaluate effects on markers of cardiovascular function following exposures to $PM_{2.5}$. Most of the controlled human exposure studies in Table 3–2 of the PA have evaluated average $PM_{2.5}$ exposure concentrations at or above about 100 $\mu g/m^3$, 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 $\mu g/m^3$, with less consistent evidence for effects following exposures to lower concentrations. Impaired vascular function, the effect identified in the ISA as the most consistent across studies (U.S. EPA, 2019, 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 few studies that evaluate longer exposure durations (*i.e.,* longer than 2 hours) and lower $PM_{2.5}$ concentrations (U.S. EPA, 2020, section 3.2.3.1).

To provide some insight into what these studies may indicate regarding the primary $PM_{2.5}$ standards, analyses in the PA examine monitored 2-hour $PM_{2.5}$ concentrations at sites meeting the current standards (U.S. EPA, 2020, section 3.2.3.1). At these sites, most 2-hour concentrations are below 11 μg/m³, and they almost never exceed 32 μg/m³. Even the highest 2-hour concentrations remain well-below the exposure concentrations consistently shown to cause effects in controlled human exposure studies (*i.e.,* 99.9th percentile of 2-hour concentrations is 68 μg/m³ during the warm season). Thus, while controlled human exposure studies support the plausibility of the serious cardiovascular effects that have been linked with ambient $PM_{2.5}$ exposures (U.S. EPA, 2019, Chapter 6), the PA notes that the $PM_{2.5}$ exposures evaluated in most of these studies are well-above the ambient concentrations typically measured in locations meeting the current primary standards (U.S. EPA, 2020, section 3.2.3.2.1).

With respect to animal toxicology studies, the ISA relies on animal toxicology studies to support the plausibility of a wide range of $PM_{2.5}$-related health effects. While animal toxicology 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.

As with controlled human exposure studies, most of the animal toxicology studies assessed in the ISA have examined effects following exposures to $PM_{2.5}$ concentrations 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 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, 2019, Table 1–2). Two exceptions are a study 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 a study reporting 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 close to the ambient concentrations reported in some $PM_{2.5}$ epidemiological studies (U.S. EPA, 2019, Table 1–2), though still above the ambient concentrations likely to occur in areas meeting the current primary standards. Thus, as is the case with controlled human exposure studies, animal toxicology studies support the plausibility of various adverse effects that have been linked to ambient $PM_{2.5}$ exposures (U.S. EPA, 2019), but have not evaluated $PM_{2.5}$ exposures likely to occur in areas meeting the current primary standards.

ii. Ambient Concentrations in Locations of Epidemiological Studies

As summarized above in section II.A.2.a, epidemiological studies examining associations between daily or annual average $PM_{2.5}$ exposures and mortality or morbidity represent a large part of the evidence base supporting several of the ISA's ''causal'' and ''likely to be causal'' determinations for cardiovascular effects, respiratory effects, cancer, and mortality. The PA considers what information from these epidemiological studies may indicate regarding primary $PM_{2.5}$ standards. The use of information from epidemiological studies to inform conclusions on the primary $PM_{2.5}$ standards is complicated by the fact that such studies evaluate associations between distributions of ambient $PM_{2.5}$ and health outcomes, but do not identify the specific exposures that cause reported effects. Rather, health effects can occur over the entire distributions of ambient $PM_{2.5}$ concentrations evaluated, and epidemiological studies do not identify a population-level threshold below which it can be concluded with confidence that PM-associated health effects do not occur (U.S. EPA, 2020, section 3.2.3.2). Therefore, the PA evaluates the $PM_{2.5}$ air quality distributions over which epidemiological studies support health effect associations. As discussed further in the PA (U.S. EPA, 2020, section 3.2.3.2.1), 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. 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 estimated exposures reflect annual average $PM_{2.5}$ concentrations around the middle of the air quality distributions examined. In both cases, epidemiological 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, and as noted in the PA (U.S. EPA, 2020, section 3.2.1.1), several epidemiological 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 epidemiological studies, the PA evaluates study-reported means (or medians) of daily and annual average $PM_{2.5}$ concentrations as proxies for the middle portions of the air quality distributions that support reported associations. In Figure 3–7, the PA highlights the overall mean (or median) $PM_{2.5}$ concentrations reported in key U.S. and Canadian epidemiological studies that use ground-based monitors alone to estimate long- or short-term $PM_{2.5}$ exposures. In Figure 3–8, the PA also considers the emerging body of studies that use hybrid modeling methods to estimate long- or short-term $PM_{2.5}$ exposures. Hybrid methods incorporate data from several sources, often including satellites and models, in addition to ground-based monitors.

Epidemiological studies using hybrid methods are generally new in this review. These modeling methods have improved the ability to estimate $PM_{2.5}$ exposure for populations throughout the conterminous U.S. compared with the earlier approaches based on monitoring data alone. Excellent performance in cross-validation tests suggests that hybrid methods are reliable for estimating $PM_{2.5}$ exposure in many applications. As discussed in Chapter 3 of the PA, good agreement in health study results between monitor- and model-based methods for urban areas (McGuinn et al., 2017) and general consistency in results for the conterminous U.S. (Jerrett et al., 2017; Di et al., 2016) also suggests that the fields are reliable for use in health studies. However, there are also important limitations associated with the modeled fields that should be kept in mind. First, performance evaluations for the methods are weighted toward densely monitored urban areas at the scales of representation of the monitoring networks. Predictions at different scales or in sparsely monitored areas are relatively untested. Second, studies have reported heterogeneity in performance with relatively weak performance in parts of the western U.S., at low concentrations, at greater distance to monitors, and under conditions where the reliability and availability of key input datasets (*e.g.,* satellite retrievals and air quality modeling) are limited. Lastly, differences in predictions among different hybrid methods have also been reported and tend to be most important under conditions with the performance issues just noted. Differences in predictions can be related to the different approaches used to create long-term $PM_{2.5}$ fields (*e.g.,* averaging daily $PM_{2.5}$ fields vs. developing long-term average fields), which can be impacted by variability in monitoring schedules, and the spatial scale at which these fields are created. Future work to further characterize the performance of modeled fields will be useful in informing our understanding of the implications of using these fields to estimate $PM_{2.5}$ exposures in health studies (U.S. EPA, 2020, section 2.3.3.1.4).

In assessing how the overall mean (or median) $PM_{2.5}$ concentrations reported in key epidemiological studies can inform conclusions on the primary $PM_{2.5}$ standards, there are some important considerations. As noted in the PA, study-reported $PM_{2.5}$ concentrations reflect the averages of daily or annual $PM_{2.5}$ air quality concentrations or exposure estimates in the study population over the years examined by the study, and are not the same as the $PM_{2.5}$ design values used by the EPA to determine whether areas meet or violate the PM NAAQS (U.S. EPA, 2020, section 3.2.3.2.1). Overall mean $PM_{2.5}$ concentrations in key studies reflect averaging of short- or long-term $PM_{2.5}$ exposure estimates across locations (*i.e.,* across multiple monitors or across modeled grid cells) and over time (*i.e.,* over several years). In contrast, to determine whether areas meet or violate the NAAQS, the EPA measures air pollution concentrations at individual monitors (*i.e.,* concentrations are not averaged across monitors) and calculates design values at monitors meeting appropriate data quality and completeness criteria. For the annual $PM_{2.5}$ standard, design values are calculated as the annual arithmetic mean $PM_{2.5}$ concentration, averaged over 3 years (described in Appendix N of 40 CFR part 50). For an area to meet the NAAQS, all valid design values in that area, including the highest monitored values, must be at or below the level of the standard.

In the context of epidemiological studies that use ground-based monitors, analyses of recent air quality in U.S. CBSAs indicate that maximum annual $PM_{2.5}$ design values for a given three-year period are often 10% to 20% higher than average monitored concentrations (*i.e.,* averaged across multiple monitors in the same CBSA) (U.S. EPA, 2020, Appendix B, section B.7). This comparison is more difficult for epidemiological studies that use hybrid methods. To try to address this issue, the PA also considered a second approach to evaluating information from epidemiological studies. In this approach, the PA calculated study area air quality metrics similar to $PM_{2.5}$ design values (*i.e.,* referred to in the PA as pseudo-design values; U.S. EPA, 2020, section 3.2.3.2.2) and considered the degree to which such metrics indicate that study area air quality would likely have met or violated the current standards during study periods. This approach was generally not well received by commenters during the review of the PA.

3. Overview of Risk and Exposure Assessment Information

Beyond the consideration of the scientific evidence, discussed above in section II.A.2, 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. Conducting such quantitative analyses, if appropriate, could inform judgments about the potential for additional public health improvements associated with $PM_{2.5}$ exposure and related health effects and could help to place the evidence for specific effects into a broader public health context.

To this end, the PA includes a risk assessment that estimates population-level health risks 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 standards). The general approach to estimating $PM_{2.5}$-associated health risks combines concentration-response functions from epidemiological studies with model-based $PM_{2.5}$ air quality surfaces, baseline health incidence data, and population demographics for 47 urban study areas (U.S. EPA, 2020, section 3.3, Figure 3–10 and Appendix C).

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 from about 16,000 to 17,000 long-term $PM_{2.5}$ exposure-related deaths from ischemic heart disease in a single year (*i.e.,* confidence intervals range from about 12,000 to 21,000 deaths).[41] 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 by about 7 to 9% for a level of 11.0 $\mu g/m^3$, 14 to 18% for a level of 10.0 $\mu g/m^3$, and 21 to 27% for a level of 9.0 $\mu g/m^3$.

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 concentration-response relationship with mortality at low ambient PM concentrations, the potential for confounding and/or exposure measurement error in the underlying epidemiological studies, and the methods used to adjust $PM_{2.5}$ air quality. The PA characterizes these and other sources of uncertainty in risk estimates using a combination of quantitative and qualitative approaches (U.S. EPA, 2020, Appendix C, section C.3). As detailed further below in II.B.1, some members of CASAC advised that the risk assessment estimates did not provide useful information about whether the current standard is protective, while other members thought they were useful to understand potential impacts of alternative standards.

B. Conclusions on the Primary $PM_{2.5}$ Standards

In drawing conclusions on the adequacy of the current primary $PM_{2.5}$ 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 last review and reflects upon the body of evidence and information newly available in this review. In so doing, he considered the large body of evidence presented and assessed in the ISA (U.S.

[41] For the only other cause-specific mortality endpoint evaluated (*i.e.,* lung cancer), substantially fewer deaths were estimated (U.S. EPA, 2020, section 3.3.2, *e.g.,* Figure 3–5). Risk estimates were not generated for other ''likely to be causal'' outcome categories (*i.e.,* respiratory effects, nervous system effects).

EPA, 2019), the policy-relevant and risk-based conclusions and rationales as presented in the PA (U.S. EPA, 2020), views expressed by 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. Evidence-based considerations include the assessment of epidemiological, animal toxicologic, and controlled human exposure studies evaluating long- or short-term exposures to $PM_{2.5}$ and the integration of evidence across each of these disciplines. These considerations, as assessed in the ISA (U.S. EPA, 2019), focus on the policy-relevant considerations, as discussed in II.A.2 above and in the PA (U.S. EPA, 2020, section 3.2.1). Risk-based considerations draw from the results of the quantitative analyses and policy-relevant considerations as discussed in II.A.3 above and in the PA (U.S. EPA, 2020, section 3.3.2).

Section II.B.1 summarizes the advice and recommendations of the CASAC. Section II.B.2 below summarizes the basis for the Administrator's proposed decision, drawing from section II.C.3 of the proposal, and section II.B.3 addresses public comments on the proposed decision. The Administrator's conclusions in this review regarding the adequacy of the current primary standard and whether any revisions are appropriate are described in section II.B.4.

1. CASAC Advice in This Review

With regard to the process for reviewing the PM NAAQS, the CASAC requested the opportunity to review a second draft ISA (Cox, 2019b, p. 1 of letter) and recommended that ''the EPA reappoint the previous CASAC PM panel (or appoint a panel with similar expertise)'' (Cox, 2019b, p. 2 of letter). As discussed above in section I.D, the Agency's responses to these recommendations were described in a letter from the Administrator to the CASAC chair (Wheeler, 2019).

As part of its review of the draft PA, the CASAC provided advice on the adequacy of the public health protection afforded by the current primary $PM_{2.5}$ standards.[42] Its advice is documented in a letter sent to the EPA Administrator (Cox, 2019a). 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, 2019a, 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, 2019a, 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, 2019a, p. 8 of consensus responses). They noted that associations do not necessarily reflect causal effects, and they contended that recent epidemiological studies reporting 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, 2019a, p. 10), 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, 2019a, 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, 2019a, p. 8 of consensus responses).

These members of the CASAC further concluded that the $PM_{2.5}$ risk assessment 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, 2019a, 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, 2019a, p. 11 of consensus responses).

Drawing from their evaluation of the evidence and the risk assessment, 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 current 2012 $PM_{2.5}$ annual standard'' (Cox, 2019a, 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, 2019a, 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 epidemiological studies, but also includes support for biological

[42] The CASAC also provided advice on the draft ISA's assessment of the scientific evidence (Cox, 2019b). That advice, and the resulting changes made in the final ISA and final PA, are summarized in section II.B.3 of the proposal (85 FR 24114, April 30, 2020).

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, 2019a, 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 $\mu g/m^3$ 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, 2019a, 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, 2019a, p. 11 of consensus responses). These committee members concluded that the evidence available in this review 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, 2019a).

2. Basis for Proposed Decision

On April 14, 2020, the Administrator proposed to retain the current primary $PM_{2.5}$ standards. This proposal was published in the **Federal Register** on April 30, 2020 (85 FR 24094, April 30, 2020). In reaching his proposed decision to retain the current $PM_{2.5}$ standards (*i.e.,* annual and 24-hour $PM_{2.5}$ standards), the Administrator considered the assessment of the available evidence and conclusions reached in the ISA (U.S. EPA, 2019); the analyses in the PA (U.S. EPA, 2020), including uncertainties in the evidence and analyses; and the advice and recommendations from the CASAC. These considerations are summarized briefly below and discussed in detail in the proposal notice (85 FR 24094, April 30, 2020).

As described further in section II.A.2 of the proposal, the Administrator's consideration of the public health protection provided by the current primary $PM_{2.5}$ standards were based on his consideration of the combination of the annual and 24-hour standards, including the indicators ($PM_{2.5}$), averaging times, forms (arithmetic mean and 98th percentile, averaged over three years), and levels (12.0 $\mu g/m^3$, 35 $\mu g/m^3$) of those standards.

The Administrator's proposed decision noted that one of the methodological limitations highlighted by the CASAC members who support retaining the annual standard (see section II.B.1 above) is that associations reported in epidemiological studies are not necessarily indicative of causal relationships and such associations ''can reasonably be explained in light of uncontrolled confounding and other potential sources of error and bias'' (Cox, 2019a, p.8). In the proposed decision, the Administrator recognized that epidemiological studies examine associations between distributions of $PM_{2.5}$ air quality and health outcomes, and they do not identify particular $PM_{2.5}$ exposures that cause effects, as noted in the PA (U.S. EPA, 2020, section 3.1.2). The Administrator's proposed decision noted that experimental studies do provide evidence for health effects following particular $PM_{2.5}$ exposures under carefully controlled laboratory conditions and further notes that the evidence for a given $PM_{2.5}$-related health outcome is strengthened when results from experimental studies demonstrate biologically plausibility mechanisms through which such an outcome could occur. In the proposed decision, therefore, the Administrator expressed greatest confidence in the potential for $PM_{2.5}$ exposures to cause adverse effects at concentrations supported by multiple types of studies, including experimental studies as well as epidemiological studies.

In the proposed decision, in light of this approach to considering the evidence, the Administrator recognized that controlled human exposure and animal toxicology studies report a wide range of effects, many of which are plausibly linked to the serious cardiovascular and respiratory outcomes reported in epidemiological studies (including mortality), though he noted that the $PM_{2.5}$ exposures examined in these studies are above the concentrations typically measured in areas meeting the current annual and 24-hour standards (U.S. EPA, 2020, section 3.2.3.1). The Administrator was cautious about placing too much weight on reported $PM_{2.5}$ health effect associations for air quality meeting the current annual and 24-hour standards. He concluded in the proposed decision that such associations alone, without supporting experimental evidence at similar $PM_{2.5}$ considerations, left important questions unanswered regarding the degree to which the typical $PM_{2.5}$ exposures likely to occur in areas meeting the current standard could cause the mortality and morbidity outcomes reported in epidemiological studies. Given this concern, the Administrator noted in the proposal that he did not think that recent epidemiological studies reporting health effect associations at $PM_{2.5}$ air quality concentrations likely to have met the current primary standards support revising those standards. Rather, he judged that the overall body of evidence, including controlled human exposure and animal toxicologic studies, in addition to epidemiological studies, indicated continuing uncertainty in the degree to which adverse effects could result from $PM_{2.5}$ exposure in areas meeting the current annual and 24-hour standards.

The Administrator also considered the emerging body of evidence from accountability studies examining past reductions in ambient $PM_{2.5}$, and the degree to which those reductions resulted in public health improvements, but also recognized that interpreting such studies in the context of the current primary $PM_{2.5}$ standards was complicated by the fact that some of the available accountability studies have not evaluated $PM_{2.5}$ specifically, did not show changes in $PM_{2.5}$ air quality, or have not been able to disentangled health impacts of the interventions from background trends in health. The Administrator also recognized that the small number of available studies that do report public health improvements following past declines in ambient $PM_{2.5}$ have not examined air quality meeting the current standard. Together with the Administrator's concerns regarding the lack of experimental studies examining $PM_{2.5}$ exposures typical of areas meeting the current standards, the lack of demonstrated health improvements in areas with air quality meeting the current standards led him to conclude, at the time of proposal, 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 current primary $PM_{2.5}$ standards.

In addition to the evidence, the Administrator also considered the potential implications of the risk assessment for his proposed decision, noting that all risk assessments have limitations. He noted that such limitations in risk estimates can result from uncertainty in the shapes of concentration-response 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 epidemiological study. The Administrator noted agreement with some members of the CASAC who expressed concerns regarding limitations in the epidemiological evidence, which provides key inputs to the risk assessment. Thus, he judged it appropriate to place little weight on quantitative estimates of $PM_{2.5}$-associated mortality risk in reaching proposed conclusions on the primary $PM_{2.5}$ standards.

In reaching his proposed decision to retain the current primary $PM_{2.5}$ standards, the Administrator concluded that the scientific evidence assessed in the ISA (U.S. EPA, 2019), and the analyses based on that evidence in the PA (U.S. EPA, 2020), do not call into question the public health protection provided by the current annual and 24-hour $PM_{2.5}$ standards. In particular, the Administrator judged that there is considerable uncertainty in the potential for additional public health improvements from reducing ambient $PM_{2.5}$ below the concentrations achieved under the current primary standards and, therefore, that standards more stringent than the current standards (*e.g.,* with lower levels) are not supported. That is, he judged that such standards would be more than requisite to protect the public health with an adequate margin of safety. This judgment reflected his consideration of the uncertainties in the potential implications of recent epidemiological studies due in part to the lack of supporting evidence from experimental studies and accountability studies conducted at $PM_{2.5}$ concentrations meeting the current standards.

In addition, based on the Administrator's review of the science, including experimental and accountability studies conducted at levels just above the current standard, he judged that the degree of public health protection provided by the current 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 Administrator to conclude that standards less stringent than the current standards (*e.g.,* with higher levels) are also not supported.

Thus, based on his consideration of the available scientific evidence and technical information and his consideration of advice from the CASAC, the Administrator proposed to conclude that the current suite of primary standards, including the current 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), remain requisite to protect the public health. As discussed in detail in the proposal (85 FR 24094, April 30, 2020), this proposed conclusion reflected his judgment that limitations in the science lead to considerable uncertainty regarding the potential public health implications of revising the existing suite of $PM_{2.5}$ standards. Therefore, the Administrator proposed to retain the current standards, without revision.

3. Comments on the Proposed Decision

Overall, the EPA received a large number of unique public comments on the proposed decision to retain the annual and 24-hour $PM_{2.5}$ standards. These comments generally fall into one of two broad groups that expressed sharply divergent views. The first group is comprised of the many commenters, representing industries and industry groups, some state and local governments, and independent organizations, that support the Administrator's proposed decision to retain the primary $PM_{2.5}$ standards. The second group of commenters are those who asserted that the current primary $PM_{2.5}$ standards are not sufficient to protect public health with an adequate margin of safety. These commenters disagree with the EPA's proposed decision to retain the current $PM_{2.5}$ standards and generally recommend a revised annual standard of between 8–10 µg/m³ and a revised 24-hour standard between a range of 25–30 µg/m³. Among those calling for revisions to the current primary $PM_{2.5}$ standards were commenters representing national public health, medical, and environmental nongovernmental organization, tribes and tribal groups, some state and local governments and independent organizations and individuals.

We address the key public comments received on the proposal (85 FR 24094, April 30, 2020) and present the EPA's responses to those comments below. A more detailed summary of all significant comments, along with the EPA's responses (henceforth ''Response to Comments''), can be found in the docket for this rulemaking (Docket No. EPA–HQ–OAR–2015–0072). This document is available for review in the docket for this rulemaking and through the EPA's NAAQS website (*https://www.epa.gov/naaqs/particulate-matter-pm-air-quality-standards*).

With respect to the various elements of the standards, the EPA received very few comments related to indicator and none advocate for revising the current $PM_{2.5}$ indicator for fine particles. Those who express explicit support for retaining the current $PM_{2.5}$ indicator generally endorse the rationale put forward in the PA. The EPA agrees with these commenters, noting that the scientific evidence in this review, as in the last review, continues to provide strong support for health effects following short- and long-term $PM_{2.5}$ exposures and that the available information remains too limited to support a distinct standard for any specific $PM_{2.5}$ component or group of components or to support a distinct standard for the ultrafine fraction.

The EPA also received very few comments on averaging time and form. Those who did provide comments are mostly affiliated with public health organizations and environmental advocacy groups and generally discuss the need for future evaluation of the form and averaging time of the current 24-hour standard (98th percentile, averaged over three years). These commenters, acknowledging the current limitations and uncertainties in the available evidence, suggest that in future reviews the EPA should evaluate how well the current form of the 24-hour standard protects against potential sub-daily exposures based on new epidemiological and experimental evidence that considers sub-daily exposures, but these commenters support retaining the current indicators, averaging times, and forms.

The EPA acknowledges the comments related to averaging time and form of the 24-hour standard and agrees that the current information does not support a revision to the averaging time or form. The EPA will continue to evaluate the form and averaging time of the current 24-hour standard in future reviews based on any new relevant information.

With respect to the level of the 24-hour standard, commenters supporting revision generally support a revised level in the range of 25–30 µg/m³. They contend the available scientific evidence supports that lower levels within this range are required to protect public health, including the health of at-risk populations, with an adequate margin of safety, and that lower levels within this range will provide additional margin of safety. The commenters cite controlled human exposure studies that assess short-term exposures (*i.e.,* 2 to 5 hours) and epidemiological studies that report associations between adverse health effects and concentrations below the current standard level as supporting the need for this revision. They further add that while revising the 24-hour level to 25 µg/m³ would offer more health protection than 30 µg/m³, it would still not reduce the risk of adverse health outcomes to zero.

With respect to the level of the annual $PM_{2.5}$ standard, numerous comments were received that specifically focus on the Administrator's consideration of epidemiological evidence in this review. Commenters who support revision generally disagree with the Administrator's conclusions and judgments about the uncertainties in the epidemiological evidence and suggest that these studies support revision of the $PM_{2.5}$ annual standard to a level of 8–10 µg/m³. These commenters state that uncertainties in the epidemiological studies, alone, do not negate positive associations seen in studies using diverse study designs and capturing large geographic and population domains. These commenters note that the possibility of confounders and the other referenced uncertainties have been investigated and found not to be material given the overall strength and consistency of results from varying approaches. The commenters who support revising the primary $PM_{2.5}$ standards generally place substantial weight on epidemiologic evidence from multi-city U.S. and Canadian studies that captured a larger geographic domain and population size, and were included in the ISA and in the study-related analyses in the PA (U.S. EPA, 2020). Further, they also cite epidemiological studies in the ISA (U.S. EPA, 2019) that performed restricted/truncated analyses with populations living in areas of lower $PM_{2.5}$ concentrations and contend that associations still exist in these studies at the concentrations below the levels of the current annual and daily standards. Moreover, they state that there was no evidence for an ambient concentration threshold for adverse health effects at the lowest observed levels of either annual or 24-hour $PM_{2.5}$ concentrations.

The EPA disagrees with these commenters. First, the EPA notes that, consistent with past practices, the foremost consideration is the adequacy of the public health protection as provided by the combination of the annual and 24-hour standards together. The annual standard limits ''typical'' daily $PM_{2.5}$ concentrations that make up the bulk of the distribution, while the 24-hour standard adds supplemental protection against ''peak'' daily $PM_{2.5}$ concentrations. In the judgment of the Administrator, therefore, the current annual standard (arithmetic mean, averaged over three years) remains 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, while the current 24-hour standard (98th percentile, averaged over three years) continues to provide 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, 2020, section 3.5.2.3). Further, the Administrator notes 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. 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.

Thus, in considering the adequacy of the 24-hour standard, an important consideration is whether additional protection is needed against short-term exposures to peak $PM_{2.5}$ concentrations. In examining the scientific evidence, the EPA notes that controlled human exposure studies do provide evidence for health effects following single, short-term $PM_{2.5}$ exposures to concentrations. These types of exposures correspond best to those to ambient exposures that might be experienced in the upper end of the $PM_{2.5}$ air quality distribution in the U.S. (*i.e.,* ''peak'' concentrations). However, and as noted above in section II.A.2.c.i, most of these studies examine exposure concentrations considerably higher than are typically measured in areas meeting the current standards (U.S. EPA, 2020, section 3.2.3.1). In particular, controlled human exposure studies often 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 (at and above 149 µg/m³ for vascular impairment, the effect shown to be most consistent across studies). Commenters did specifically note one study (Hemmingsen et al., 2015b) and contend that this study shows significant effects on some outcomes at lower concentrations, following 5-hour exposures to 24 µg/m³. The PA notes that this study does not report effects consistent with other studies in the ISA that evaluate longer exposure durations (*i.e.,* longer than 2 hours) and lower $PM_{2.5}$ concentrations (*e.g.,* Bräuner et al., 2008 and Hemmingsen et al., 2015a). Furthermore, analyses in the PA show that the exposure concentrations included in this study are not observed in areas meeting the current standards (U.S. EPA, 2020, Figure A–2), suggesting that the current standards provide protection against these exposure concentrations. To provide insight into what these studies may indicate regarding the primary $PM_{2.5}$ standards, the PA (U.S. EPA, 2020, p.3–49) notes that 2-hour ambient concentrations of $PM_{2.5}$ at monitoring sites meeting the current standards almost never exceed 32 µg/m³. In fact, even the extreme upper end of the distribution of 2-hour $PM_{2.5}$ concentrations at sites meeting the current standards remains well-below the $PM_{2.5}$ 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 µg/m³ during the warm season). Thus, available $PM_{2.5}$ controlled human exposure studies do not indicate the need for additional protection against exposures to peak $PM_{2.5}$ concentrations, beyond the protection provided by the combination of the current 24-hour standard and the current annual standard (U.S. EPA, 2020, section 3.2.3.1). With respect to the epidemiological evidence and as noted above in section II.A.2.c.ii, the information from such studies is most applicable to examining potential health impacts associated with typical (*i.e.,* average or mean) exposures and thus are most applicable in informing decisions on the annual standard (with its arithmetic mean form). Furthermore, as noted above, the available epidemiological studies do not indicate that associations in these studies are strongly influenced by exposures to peak concentrations in the air quality distribution, and thus do not indicate the need for additional protection against short-term exposures to peak $PM_{2.5}$ concentrations. As discussed above, the annual standard provides protection against the typical 24-hour and annual $PM_{2.5}$ exposures. Thus, in the context of a 24-hour standard that is meant to provide supplemental protection (*i.e.,* beyond that provided by the annual standard alone) against short-term exposures to peak $PM_{2.5}$ concentrations, the available evidence supports the Administrator's proposed conclusion to retain the current 24-hour standard with its level of 35 µg/m³.

With respect to commenters that support revision of the annual standard, the EPA recognizes that there are a large number of studies, many of which include a variety of study populations and geographic locations, that show positive associations between mortality and morbidity and short-term and long-term $PM_{2.5}$ exposure. Furthermore, the EPA recognizes that while uncertainties exist, when the epidemiological evidence is viewed together in the context of the full body of evidence, the scientific information supports that exposure to $PM_{2.5}$ may cause adverse health effects (U.S.EPA, 2019, section 1.7.3, Table 1–4). Therefore, the EPA does not dispute commenters that note epidemiological studies support the conclusion that exposure to $PM_{2.5}$ is associated with morbidity and mortality.

However, while the epidemiological evidence when considered together with the full body of evidence supports health effects associated with $PM_{2.5}$ exposure, the EPA recognizes that important uncertainties and limitations in the health effects evidence remain. Epidemiological studies evaluating health effects associated with long- and short-term $PM_{2.5}$ exposures have reported heterogeneity in associations between cities and geographic regions within the U.S. Heterogeneity in the associations observed across $PM_{2.5}$ epidemiological 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 $PM_{2.5}$, models used in lieu of or to supplement ambient measurements, limitations in hybrid models and our limited understanding of factors that may influence exposures (*e.g.,* topography, the built environment, weather, source characteristics, ventilation usage, personal activity patterns, photochemistry) (U.S. EPA, 2020, p.3–25), all of which can introduce bias and/or increased uncertainty is associated health effects estimates. Heterogeneity is expected when the methods or underlying distribution of covariates vary across studies (U.S. EPA, 2019, p. 6–221). 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, 2019, section 1.5.1). The EPA also recognizes that methodological study designs to address confounding, such as causal inference methods, are an emerging field of study (U.S. EPA, 2019, section 11.2.2.4 or U.S. EPA, 2020, p. 3–24). The Administrator weighs these uncertainties in the reported associations of $PM_{2.5}$ concentrations in the studies and considers them in the context of the entire body of evidence before the Agency when reviewing the standards.

Additionally, while epidemiological studies indicate associations between exposure to $PM_{2.5}$ and health effects, they do not identify particular $PM_{2.5}$ exposures that cause effects (section II.A.2.c.ii above and U.S. EPA, 2020, section 3.1.2). Further, using information from epidemiological studies to inform decisions on $PM_{2.5}$ standards is complicated by the recognition that no population threshold, below which it can be concluded with confidence that $PM_{2.5}$-related effects do not occur, can be discerned from the available evidence. As a result, any general approach to reaching decisions on what standards are appropriate necessarily requires judgments about how to translate the information available from the epidemiological studies into a basis for appropriate standards. This includes consideration of how to weigh the uncertainties in the reported associations in the epidemiological studies and the uncertainties in quantitative estimates of risk, in the context of the entire body of evidence before the Agency. Such approaches are consistent with setting standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the CAA.

Commenters who support revising the $PM_{2.5}$ standards further contend that the Administrator has arbitrarily rejected an established practice of relying on epidemiological studies and of setting the standard below the long-term mean $PM_{2.5}$ concentrations reported in each of the studies that provide evidence of an array of serious health effects. The commenters state that in declaring that the latest epidemiological studies cannot justify a decision to strengthen the PM NAAQS, the Administrator has rejected—without acknowledgment or explanation—the EPA's long history of relying on such research as the basis for its primary standards.

As recognized in this and previous PM NAAQS reviews, including those completed in 2006 and 2012, evidence of an association in any epidemiological study is ''strongest at and around the long-term average where the data in the study are most concentrated.'' In the PA (U.S. EPA, 2020, section 3.2.3.2.1), the EPA assessed air quality distributions reported in key epidemiological studies included in the ISA, with a focus on characterizing the long-term average or mean $PM_{2.5}$ concentrations. In doing this, key studies [43] were identified that examined short- and long-term exposure and showed positive associations with either mortality or morbidity health outcomes. The studies either estimated $PM_{2.5}$ exposure using ground-based monitored data or using hybrid modeling data, which incorporate data from several sources, often including satellites and models, as well as ground-based monitors (U.S. EPA, 2020, section 2.3.3). The PA notes some important considerations in using study reported concentrations to inform conclusions on the primary $PM_{2.5}$ standards. In particular, it notes that the overall mean $PM_{2.5}$ concentrations reported by key epidemiological studies are not the same as the ambient concentrations used by the EPA to determine whether areas meet or violate the PM NAAQS. Mean $PM_{2.5}$ concentrations in key studies reflect averaging of short- or long-term $PM_{2.5}$ exposure estimates across locations (*i.e.,* across multiple monitors or across modeled grid cells) and over time (*i.e.,* over several years). In contrast, to determine whether areas meet or violate the PM NAAQS, the EPA measures air pollution concentrations at individual monitors (*i.e.,* concentrations are not averaged across monitors) and calculates design values [44] at monitors meeting appropriate data quality and completeness criteria.[45] For an area to meet the NAAQS, all valid design values in that area, including the highest annual and highest 24-hour monitoring values, must be at or below the standards. As a result, study reported mean concentration values are generally lower than the design value of the highest monitor in an area, which determines compliance.

The PA first presents results from key epidemiological studies that used ground-based monitoring data to estimate population exposure (U.S. EPA, 2020, section 3.2.3.2.1). Study reported mean (or medians) [46] were

[43] Studies included were multi-city studies in Canada and the U.S. that examined health endpoints with 'causal' or 'likely to be causal' determinations in the ISA.

[44] A design value is a statistic that summarizes the air quality data for a given area in terms of the indicator, averaging time, and form of the standard. Design values can be compared to the level of the standard and are typically used to designate areas as meeting or not meeting the standard and assess progress towards meeting the NAAQS.

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

[46] Some epidemiological studies report median versus mean air quality concentrations offering that

examined from the air quality distributions reported in key epidemiological studies included in the ISA exposures (U.S. EPA, 2020, Figure 3–7). The PA noted that these values are most useful in the context of considering the level of the primary $PM_{2.5}$ annual standard. This is because the mean concentration values from these studies, which include studies examining both short- and long-term exposures, represent ''typical'' or mean exposures, which are most relevant to the form and averaging time of the annual standard, and not as relevant to the daily standard, whose form and averaging time focuses on protecting against peak concentrations. Further, the PA noted that in using these data it should be recognized that these mean concentrations are generally below the design values in the corresponding areas. In fact, analyses included in the PA of recent air quality in U.S. CBSAs indicate that maximum annual $PM_{2.5}$ design values for a given three-year period are often 10% to 20% higher than average monitored concentrations (*i.e.,* averaged across multiple monitors in the same CBSA) (U.S. EPA, 2020, Appendix B, section B.7). As noted in the PA, the difference between the maximum annual design value and the average concentrations in an area will depend on a number of factors including the numbers of monitors, monitor citing characteristics, and the distribution of ambient $PM_{2.5}$ concentrations. The PA also recognized that the recent requirement for $PM_{2.5}$ monitoring at near-road locations in large urban areas may further increase the ratios of maximum annual design values to average concentrations in some areas (U.S. EPA, 2020, section 3.2.3.2.1).

As detailed more in section II.A.2.c.ii, the PA next presents data from the epidemiological studies that used hybrid modeling approaches to estimate exposures (U.S. EPA, 2020, Figure 3–8). While studies using hybrid modeling approaches provide valid methods to estimate exposures in epidemiological studies and can expand the characterization of $PM_{2.5}$ exposures in areas with sparse monitoring networks, these exposure estimation methods provide additional challenges to comparing study reported mean concentrations to the annual standard level. In these studies, $PM_{2.5}$ concentrations are typically estimated based on a hybrid approach of ''fusing'' data from air quality models, satellites and ground-based monitors. As such, the reported mean concentrations in an area (*e.g.,* county or zip-code) from these studies are calculated using the estimated concentrations from thousands of grid cells across the area. Generally, this means a larger number of lower concentration grid cells being included in the calculation of the mean, resulting in a mean concentration even further below the design value of the highest monitor in the area (which is used for determining whether the area is meeting the current standard) and even further below the mean concentration reported in epidemiological studies utilizing ground-based monitors to estimate exposure.

It is also important to note that the performance of these hybrid modeling approaches in estimating $PM_{2.5}$ concentrations, which are being used as surrogates for population exposure in the epidemiological study, depends on the availability of monitoring data, air quality model and the ability of the satellite to estimate ground level concentration and, thus, varies by location. Factors that contribute to poorer model performance often coincide with relatively low ambient $PM_{2.5}$ concentrations (U.S. EPA 2020, 2.3.3) Thus, uncertainty in hybrid model predictions becomes an increasingly important issue as lower predicted concentrations are considered. This additional source of uncertainty is an important consideration, particularly when all grid cell estimates are being used to calculate the study mean concentration, and further adds to why using study reported mean concentrations from epidemiological studies that use hybrid approaches to inform conclusions on the primary $PM_{2.5}$ standards is a challenge.

Given all of this, the EPA concludes that the overall mean $PM_{2.5}$ concentrations in hybrid modeling studies are more difficult to directly compare to design values than ground-based monitoring concentrations in the context of setting a standard level. In fact, recognizing this challenge, the PA tried to assess information from hybrid modelling studies by calculating ''pseudo-design values'' in locations of the key epidemiological studies (U.S. EPA, 2020, section 3.2.3.2.2), as noted above in section II.A.2.c.ii and detailed further in section II.C.1.a.ii of the proposal (85 FR 24117, April 30, 2020). However, this analysis and the associated approach were highly criticized by most commenters, with none suggesting the methodology be carried forward in the review. While the EPA believes that the PA's ''pseudo-design value'' approach was a step in the right direction, the specific methodology itself needs further development.

Given these considerations, and in light of the comments received, the EPA believes it is reasonable to focus on study reported mean (or median) concentrations [47] from key U.S.[48] epidemiological studies that used ground-based monitors when considering information most comparable to the current annual standard, while also weighing the uncertainties associated with these studies and considering support provided by other lines of evidence. Based on the information shown in Figure 3–7 of the PA (U.S. EPA, 2020), the mean concentrations in 19 of the 21 these studies were equal to or greater than the level of the current annual standard of 12 µg/m³. There were two studies, both included in last review, for which the mean concentration (11.8 µg/m³; Peng et al., 2009) or median concentration (10.7 µg/m³ (Central Region); Zeger et al., 2008 [49]) was somewhat below 12 µg/m³. While these studies were included in the last review, the air quality distributions were not used by the prior Administrator in making a judgment on the level of the standard. The reported study mean concentration for one other study was 12 µg/m³ (Kioumourtzoglou et al., 2016). The mean [50] of the study reported means (or medians) of these 21 studies is 13.5 µg/m³, a concentration level above the current level of the primary annual standard of 12 µg/m³. Additionally, based on analyses in the PA, it would be expected that most of the design values (the metric most relevant for comparison to the standard level) in the areas included in these studies would be greater than 12 µg/m³ [51] (section II.A.2.c.ii above and U.S.

median is a better metric since it is less skewed by outlying concentrations. In most studies, the mean and median concentrations are very similar and are generally used here interchangeably.

[47] Some epidemiological studies report median versus mean air quality concentrations offering that median is a better metric since it is less skewed by outlying concentrations. In most studies, the mean and median concentrations are very similar and are generally used here interchangeably.

[48] Given how air quality monitors in other countries differ from the U.S. EPA FRM monitors discussed here, a focus on U.S. studies ensures that the results most closely compare to the data being used for calculating the design values and for compliance of the standard.

[49] We note that in this study the population was divided into regions of the country, with statistically significant associations in the Central and Eastern Regions and with median long-term $PM_{2.5}$ concentrations of: Central: 10.7 µg/m³; Western: 13.1 µg/m³ and Eastern: 14.0 µg/m³.

[50] The median of the study reported mean (or median) $PM_{2.5}$ concentrations is 13.3 µg/m³.

[51] Recent air quality in U.S. CBSAs in the PA indicate that maximum annual $PM_{2.5}$ design values

Continued

EPA 2020, Appendix B, section B.7). This is also supported by the pseudo-design value analysis in Figure 3–9 of the PA (U.S. EPA, 2020).

Therefore, although recognizing that the proposal identified certain concerns about the proper weight to be placed on epidemiological studies, the EPA finds that its assessment of the mean concentrations of the key short-term and long-term epidemiological studies in the U.S. that use ground-based monitoring (*i.e.,* those studies that can provide information most directly comparable to the current annual standard) is fundamentally consistent with the assessment in the last review, which established the current primary $PM_{2.5}$ standards.

Some commenters supporting revision of the primary $PM_{2.5}$ standards contend that the quantitative risk assessment finds the number of avoided deaths resulting from retention of the standards will likely number in the many thousands, and a substantial reduction in these events could be achieved by a more stringent $PM_{2.5}$ standard. While commenters who support revising the $PM_{2.5}$ standards support the recommendation of the PA to use the evidence-based approach, as opposed to the risk-based approach, as a basis for ascertaining whether and how to revise the primary standards, the commenters state that the risk assessment does provide qualitative support to revise the standards.

With regard to the quantitative risk assessment described by some commenters as showing health impacts that would be avoided by a more stringent standard, the EPA notes that these analyses utilize epidemiological study effect estimates as concentration-response functions to predict the occurrence of primarily premature mortality under different air quality conditions (characterized by the metric used in the epidemiological study). While the epidemiological studies that are inputs to the quantitative risk assessment are part of the evidence base that supports the conclusion of a ''causal'' or ''likely to be causal'' determination in the ISA (U.S. EPA, 2019), there are uncertainties inherent in the derivation of estimates of health effects (*e.g.,* total mortality or ischemic heart disease mortality) ascribed to $PM_{2.5}$ exposures using effect estimates from these studies. For example, the PA recognized several important uncertainties associated with aspects of the quantitative risk assessment approach and that the EPA concluded to have a medium or greater magnitude on risk estimates (U.S. EPA, 2020, section C.3.1 and table C–32). These uncertainties limit the applicability of the risk results for selecting a specific standard. Uncertainties in the shapes of concentration-response 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 epidemiological study all limit utility (U.S. EPA, 2020, section 3.3.2.4). Further, the approach to weighing evidence-based and risk-based considerations is not a new approach and as in previous reviews, the selection of a specific approach to reaching final decisions on the primary $PM_{2.5}$ standards will reflect the judgments of the Administrator as to what weight to place on the various types of information available in the current review. The EPA notes that in the previous review, evidence-based considerations were given greater weight in the selection of standard levels than risk-based approaches (*e.g.,* 78 FR 3086, 3098–99, January 15, 2013) due to a recognition of similar limitations.

Some commenters who support the Administrator's rationale to retain the $PM_{2.5}$ standards contend that, due to uncertainties in extrapolating health effects observed in animal toxicology studies to humans, animal toxicology studies are of limited regarding the adequacy of the current standard. On the other hand, commenters who support revisions to the current suite of $PM_{2.5}$ standards generally contend that for experimental studies the Administrator: (1) Inappropriately tied the concept of biological plausibility to a specific concentration; (2) incorrectly interpreted animal/controlled human exposure studies; (3) ignored the limitations of experimental studies in relation to informing NAAQS levels and (4) gave inadequate weight to all of the evidence because the Administrator saw no absolute corroboration from clinical and accountability studies. The commenters emphasize their view that experimental studies provide important information regarding biological plausibility of numerous health effects (*e.g.,* cardiovascular, respiratory, nervous system, and cancer effects) associated with $PM_{2.5}$ exposure. Therefore, the commenters contend that experimental studies provide biological plausibility for human health effects linked to PM exposure in epidemiological studies and when viewed together, support revision of the current $PM_{2.5}$ standards.

The EPA notes that controlled human exposures studies provide crucial evidence in assessing whether protection is provided for short-term exposure concentrations consistently shown to elicit effects. In examining the controlled human exposure studies, the PA notes these studies provide evidence for health effects following single, short-term $PM_{2.5}$ exposures to concentrations, and thus, can be useful to assess whether these effects are likely to occur in the upper end of the $PM_{2.5}$ air quality distribution in the U.S. (*i.e.,* ''peak'' concentrations) (U.S. EPA, 2020, section 3.2.3.1). As noted by the commenters, most of these studies examine exposure concentrations considerably higher than are typically measured in areas meeting the current standards (U.S. EPA, 2020, section 3.2.3.1). As detailed in section II.A.2.c.i above, even the extreme upper end of the distribution of 2-hour $PM_{2.5}$ concentrations at sites meeting the current standards remains well-below the $PM_{2.5}$ exposure concentrations consistently shown to elicit effects. Further, human exposure studies have not reported health effects at $PM_{2.5}$ air quality concentrations likely to be seen in areas meeting the current primary $PM_{2.5}$ standards. As such, these studies do not call into question the protection provided by the current primary $PM_{2.5}$ standards.

Additionally, with respect to the experimental evidence, the EPA agrees that animal toxicologic studies can be useful in understanding and supporting the biological plausibility of various effects linked to $PM_{2.5}$ exposures. However, it is important to remember that for this body of evidence there is uncertainty in extrapolating from effects in animals to those in human populations. As such, animal toxicology studies are of limited utility in directly informing conclusions on the appropriate level of the standard. Thus, the available evidence from animal toxicologic studies do not call into question the protection provided by the current primary $PM_{2.5}$ standards.

Further, the ISA assesses both human exposures studies and animal toxicologic studies to evaluate the biological plausibility of various effects linked to $PM_{2.5}$ exposures, and thus, we agree with the commenters on the importance of experimental evidence on this account. Within the ISA's weight of evidence evaluation, which is based on the integration of findings from various lines of evidence, considerations in making causality determinations

for a given three-year period are often 10% to 20% higher than average monitored concentrations (*i.e.,* averaged across multiple monitors in the same CBSA) (U.S. EPA, 2020, Appendix B, section B.7).

include: ''determining whether laboratory studies of humans and animals, in combination with epidemiological studies, inform the biological mechanisms by which PM can impart health effects and provide evidence demonstrating that PM exposure can independently cause a health effect'' (U.S. EPA, 2019, p. ES–8). However, the ISA also notes that the strength of the $PM_{2.5}$ exposure-health effects relationship varies depending on the exposure duration (*i.e.,* short- or long-term) and broad health effects category (*e.g.,* cardiovascular effects, respiratory effects) examined, and that across the broad health effects categories examined, the evidence supporting biological plausibility varies. Additionally, while assessing plausible biological pathways is an important step in evaluating causality determinations, the degree of biological plausibility for different mechanisms and end points can also vary depending on the evidence available. As a result, without a more clear linkage between concentrations below the current standard levels and adverse health effects, the Administrator noted in the proposal that he was ''cautious about placing too much weight on reported $PM_{2.5}$ health effect associations'' observed in epidemiological studies (85 FR 24119, April 30, 2020). As discussed in the proposal, the Administrator's proposed decision was based on his evaluation of ''the overall body of evidence, including controlled human exposure and animal toxicologic studies, in addition to epidemiological studies'' (85 FR 24120, April 30, 2020). Thus, the experimental evidence does not suggest that the epidemiological evidence must be viewed differently than the Administrator has viewed such evidence in his proposed decision to retain the current primary standards.

Some commenters who support retaining the current primary $PM_{2.5}$ standards assert that the currently available accountability studies do not demonstrate that further reduction of the PM NAAQS would achieve a measurable improvement in public health. In contrast, commenters opposing the Administrator's proposed decision to retain the $PM_{2.5}$ standards criticize the Administrator's heavy reliance on accountability studies to guide his decision, while emphasizing that accountability studies are just one line of evidence to inform causality. The commenters acknowledge the importance of well-designed and conducted accountability studies but warn that accountability studies measuring past interventions that are highly localized may have actual effects too small to be reliably measured. Considering the limitations of the accountability studies, including findings leading to false negative results, such studies are not considered essential for the proof of evidence required by statute, according to these commenters.

The EPA agrees with the commenters that well-designed and conducted accountability studies can be informative and should be considered as one line of evidence, recognizing that that these studies offer insight into examples of how public health has responded to implementation of $PM_{2.5}$ reduction strategies. As discussed in the PA (U.S. EPA, 2020, section 3.2.3.2.1) and in section III.C.3 of the proposal (85 FR 24120, April 30, 2020), the EPA notes the availability of several such accountability studies and other retrospective health studies examining periods of declining $PM_{2.5}$ concentrations. As indicated in Table 3–3 of the PA (U.S. EPA, 2020), these studies conducted in the U.S. indicate that declines in ambient $PM_{2.5}$ concentrations over a period of years have been associated with decreases in mortality rates and increases in life expectancy, improvements in respiratory development, and decreased incidence of respiratory disease in children. When considering the overall means in these studies (*i.e.,* the part of the air quality distribution over which the studies provide the strongest support for reported health effect associations), we find that ''starting'' annual average $PM_{2.5}$ concentrations (*i.e.,* mean concentration prior to reductions being evaluated) range from 13.2–31.5 $\mu g/m^3$ and ''ending'' concentrations ranging from 11.6–17.8 $\mu g/m^3$. As such, the EPA notes that these retrospective studies tend to focus on time periods during which ambient $PM_{2.5}$ concentrations were substantially higher than those measured more recently, as well as ''starting'' annual average $PM_{2.5}$ concentrations above those allowed by the current primary $PM_{2.5}$ standards. As a result, the EPA believes that while these studies do provide evidence of public health improvements as ambient $PM_{2.5}$ has declined over time, no current studies have examined public health improvements following reductions in ambient $PM_{2.5}$ concentrations in areas where the ''starting'' concentration met the current primary standards. Thus, while acknowledging that this is an emerging field of study for $PM_{2.5}$-related health effects, the available evidence supports the Administrator's recognition that currently, there is a lack of accountability studies that clearly demonstrate that revising the current primary $PM_{2.5}$ standards would result in public health improvements.

Commenters opposed to the Administrator's proposed decision to retain the $PM_{2.5}$ standards contend that the EPA's proposed decision is a violation of the CAA because it fails to consider sensitive populations and contains no margin of safety for them, as required under the CAA. In particular, these commenters pointed to evidence drawn from epidemiological studies that included specific at-risk groups in their study design and results.

The EPA disagrees with these comments. As discussed above, the Administrator's proposed decision to retain the current primary $PM_{2.5}$ standards followed the same general approach used in previous reviews for reaching conclusions on what standards are appropriate. As such, the Administrator recognized that judgments of how to translate information available from epidemiological studies into a basis for appropriate standards must be considered in conjunction with the uncertainties in the epidemiological studies and in the context of the entire body of evidence before the Agency. This approach recognizes that the Administrator's judgment is particularly important for a pollutant where a population threshold cannot be clearly discerned with confidence from the evidence and where clinical evidence does not demonstrate health effects at typical ambient concentrations that meet the current standards. This approach is also consistent with the CAA requirement to set standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the CAA.

With respect to protection of at-risk populations, the EPA has carefully evaluated and considered evidence of effects in at-risk populations. Unlike some of the other NAAQS reviews where the epidemiological evidence may be less complete, this PM NAAQS review has the benefit of having an ISA that considered many epidemiological studies that assessed impacts for populations considered at-risk (*e.g.,* populations of older adults, children, or those with preexisting conditions, like cardiovascular disease). In addition, some of the key epidemiology studies that the EPA assessed (included in Figure 3–7 of the PA) also specifically focused on and evaluated at-risk populations, including epidemiology studies that assessed morbidity and mortality associations for age-specific populations (*e.g.,* Medicare populations), as well as epidemiology studies that evaluated associations between $PM_{2.5}$ exposure and specific health endpoints, like hospital admissions for cardiovascular effects in populations age 65 and older. The Agency takes note that it considered these studies to inform its review of the primary $PM_{2.5}$ standards, which include at-risk populations, as well as other studies in the full body of scientific evidence in evaluating effects associated with long or short-term $PM_{2.5}$ exposures (*i.e.,* premature mortality, cardiovascular effects, cancer, and respiratory effects).

More specifically, in weighing the scientific evidence to inform his decision on requisite $PM_{2.5}$ standards with an adequate margin of safety, including protection for at-risk populations, the Administrator's proposed conclusions recognized that epidemiological studies, many of which by design include at-risk populations, examine associations between distributions of $PM_{2.5}$ air quality and health outcomes. Further, in noting that epidemiological studies do not identify particular $PM_{2.5}$ exposures that cause effects, the PA focused on the reported mean concentrations from key epidemiological studies with the aim of providing a potential translation of information from epidemiological studies into the basis for consideration on standard levels (U.S. EPA, 2020, section 3.1.2). As discussed in more detail above, for the mean concentrations of the key epidemiological studies in the U.S. that use ground-based monitoring (*i.e.,* those studies that can provide information most directly comparable to the current annual standard), the majority of studies have long-term mean (or median) concentrations above the current NAAQS (12.0 μg/m³), with the mean of the study reported means or medians equal to 13.5 μg/m³, a concentration level above the current level of the primary annual standard of 12 μg/m³. The EPA notes that study reported mean (or median) concentration values are generally 10–20% lower than the design value of the highest monitor in an area, which determines compliance, and suggesting that that the current level of the standard provides even more protection than is suggested by the reported means.[52] In the proposal, the Administrator recognized that important uncertainties and limitations do remain in the epidemiological evidence and the Administrator weighed these uncertainties, while also considering support provided by other lines of evidence, in judging whether the current standards are requisite with an adequate margin of safety. The Administrator further considered the emerging body of evidence from accountability studies examining past reductions in ambient $PM_{2.5}$ and the degree to which those reductions have resulted in public health improvements. As discussed above, such studies have focused on time periods during which ambient $PM_{2.5}$ concentrations were substantially higher than those measured more recently and therefore do not demonstrate public health improvements attributable to reduction in ambient $PM_{2.5}$ at concentrations below the current standard.

Thus, the Administrator judged that the overall body of evidence indicates continued uncertainty in the degree to which adverse effects could result from $PM_{2.5}$ exposures in areas meeting the current annual and 24-hour standards. Additionally, the current annual standard is below the lowest ''starting'' concentration in the available accountability studies (*i.e.,* 13.2 μg/m³) and below the reported mean concentration in the majority of the key U.S. epidemiological studies using ground-based monitoring data[53] (*i.e.,* mean of the reported means was 13.5 μg/m³). In addition, concentrations in areas meeting the current 24-hour and annual standards remain well-below the $PM_{2.5}$ exposure concentrations consistently shown to elicit effects in controlled human exposure studies. In specifically assessing his proposed decision, the Administrator noted that more stringent standards would be more than requisite to protect public health with an adequate margin of safety.

4. Administrator's Conclusions

This section summarizes the Administrator's conclusions and final decisions related to the current primary $PM_{2.5}$ standards and presents his decision to retain those standards, without revision. As described above (section I.D) and in section II.A.2 of the proposal (85 FR 24105, April 30, 2020), the Administrator's approach to considering the adequacy of the current standards focuses on evaluating the public health protection afforded by the annual and 24-hour standards, taken together, against mortality and morbidity associated with long- or short-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 and that the protection provided by the suite of standards results from the combination of all of the elements of those standards (*i.e.,* indicator, averaging time, form, level). Thus, the Administrator's consideration of the public health protection provided by the current primary $PM_{2.5}$ standards is based on his consideration of the combination of the annual and 24-hour standards, including the indicators ($PM_{2.5}$), averaging times, forms (arithmetic mean and 98th percentile, averaged over three years), and levels (12.0 μg/m³, 35 μg/m³) of those standards.

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 review 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 notice.

As an initial matter, the Administrator recognizes that, with regard to effects classified as having evidence of a causal

[52] Analyses of recent air quality in U.S. CBSAs indicate that maximum annual $PM_{2.5}$ design values for a given three-year period are often 10% to 20% higher than average monitored concentrations (*i.e.,* averaged across multiple monitors in the same CBSA) (U.S. EPA, 2020, Appendix B, section B.7).

[53] As discussed above, the means from these studies are most relatable to the level of the annual standard. However, because the reported means in these studies are based on averaging the monitored concentration across an area, they are lower than the design value for that same area, since attainment of the standard is based on the measurements at the highest monitor (and not the average across multiple monitors.)

or likely causal relationship with long or short-term $PM_{2.5}$ exposures (*i.e.,* premature mortality, cardiovascular effects, cancer, and respiratory effects), the EPA considered the full range of studies evaluating these effects, including studies of at-risk populations, to inform its review of the primary $PM_{2.5}$ standards. Thus, the Administrator notes that his judgment in this final decision reflects placing the greatest weight on evidence of effects for which the ISA determined there is a causal or likely causal relationship with long- and short-term $PM_{2.5}$ exposures.

With respect to the indicator, the Administrator recognizes that the scientific evidence in this review, as in the last review, continues to provide strong support for health effects following short- and long-term $PM_{2.5}$ exposures. He notes the 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. Further, the Administrator notes that the EPA received very few comments on the indicator, with no commenters advocating for revising the current $PM_{2.5}$ indicator for fine particles. Thus, as proposed, the Administrator concludes that it is appropriate to retain $PM_{2.5}$ as the indicator for the primary standards for fine particulates.

With respect to averaging time and form, the Administrator notes that the scientific evidence continues 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 $PM_{2.5}$ and, consistent with the conclusions in the PA, judges that the current evidence does not support considering alternatives (U.S. EPA, 2020, section 3.5.2). The Administrator also notes that very few comments were received related to averaging time and form and none directly advocated for changing the form or averaging time. In the current review, epidemiological and controlled human exposure studies have examined a variety of $PM_{2.5}$ exposure durations. Epidemiological 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 the EPA notes that associations with sub-daily estimates are less consistent and, in some cases, smaller in magnitude (U.S. EPA, 2019, section 1.5.2.1; U.S. EPA, 2020, section 3.5.2.2). In addition, controlled human exposure and panel-based studies of sub-daily exposures typically examine subclinical effects, as the commenters acknowledge, 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 ISA concludes that epidemiological studies do not indicate that sub-daily averaging periods are more closely associated with health effects than the 24-hour average exposure metric (U.S. EPA, 2019, section 1.5.2.1). Additionally, 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, 2020, section 3.2.3.1). Thus, these studies also do not suggest the need for additional protection against sub-daily $PM_{2.5}$ exposures, beyond that provided by the current primary standards. Therefore, the Administrator's judgment is that the current 24-hour averaging time remains appropriate.

In relation to the form of the 24-hour standard (98th percentile, averaged over three years), the Administrator notes that epidemiological studies continue to provide strong support for health effect associations with short-term (*e.g.,* mostly 24-hour) $PM_{2.5}$ exposures (U.S. EPA, 2020, section 3.5.2.3) and that controlled human exposure studies provide evidence for health effects following single short-term ''peak'' $PM_{2.5}$ exposures. Thus, 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. The Administrator further notes that this 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, 2020, section 3.5.2.3). As such, the Administrator concludes, as proposed, to retain 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).

The Administrator also proposed to retain the current levels of the 24-hour standard (98th percentile, averaged over three years) at 35 $\mu g/m^3$ and annual standard (annual average, averaged over 3 years) at 12 $\mu g/m^3$. The majority of the comments received focused on this proposed decision to retain the current levels of both standards. In reaching his final decision regarding the level of the standards, the Administrator considered the large body of evidence presented and assessed in the ISA (U.S. EPA, 2019), the policy-relevant and risk-based conclusions and rationales as presented in the PA (U.S. EPA, 2020), views expressed by the CASAC, and public comments. In particular, in considering the ISA and PA, he considers key epidemiological studies that evaluate 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 this information.

As an initial matter, the Administrator recognizes that the current annual standard is most effective in controlling $PM_{2.5}$ concentrations near the middle of the air quality distribution (*i.e.,* around the mean of the distribution), but can also provide some control over short-term peak $PM_{2.5}$ concentrations. On the other hand, the 24-hour standard, with its 98th percentile form, is most effective at limiting peak 24-hour $PM_{2.5}$ concentrations, but in doing so will also have 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 are not expected to be equally effective at limiting both types of exposures. Thus, consistent with previous reviews, the Administrator's consideration of the public health protection provided by the current primary $PM_{2.5}$ standards is based on his consideration of the combination of the annual and 24-hour standards. Specifically, he recognizes that the annual standard is more likely to appropriately limit the ''typical'' daily and annual exposures that are most strongly associated with the health effects observed in epidemiological studies. The Administrator concludes that an annual standard (arithmetic mean, averaged over three years) remains 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) is more directly tied to short-term peak $PM_{2.5}$ concentrations, and thus more likely to appropriately limit exposures to such concentrations, the Administrator concludes that the current 24-hour standard (98th percentile, averaged over three years) remains 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 Administrator recognizes 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 Administrator further recognizes 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.

Thus, in considering the adequacy of the 24-hour standard, the Administrator notes the importance of considering whether additional protection is needed against short-term exposures to peak $PM_{2.5}$ concentrations. In examining the scientific evidence, he notes that controlled human exposure studies provide evidence for health effects following single, short-term $PM_{2.5}$ exposures to concentrations. These types of exposures correspond best to those to ambient exposures that might be experienced in the upper end of the $PM_{2.5}$ air quality distribution in the U.S. (*i.e.,* ''peak'' concentrations). However, most of these studies examine exposure concentrations considerably higher than are typically measured in areas meeting the current standards (U.S. EPA, 2020, section 3.2.3.1). In particular, controlled human exposure studies often 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 $\mu g/m^3$ (at and above 149 $\mu g/m^3$ for vascular impairment, the effect shown to be most consistent across studies). To provide insight into what these studies may indicate regarding the primary $PM_{2.5}$ standards, the PA (U.S. EPA, 2020, p.3–49) notes that 2-hour ambient concentrations of $PM_{2.5}$ at monitoring sites meeting the current standards almost never exceed 32 $\mu g/m^3$. In fact, even the extreme upper end of the distribution of 2-hour $PM_{2.5}$ concentrations at sites meeting the current standards remains well-below the $PM_{2.5}$ 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 $\mu g/m^3$ during the warm season). Additionally, the Administrator notes the limited utility of the animal toxicologic 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. Thus, the available experimental evidence does not indicate the need for additional protection against exposures to peak $PM_{2.5}$ concentrations, beyond the protection provided by the combination of the current 24-hour standard and the current annual standard (U.S. EPA, 2020, section 3.2.3.1).

With respect to the epidemiological evidence, the Administrator notes that the available epidemiological studies do not indicate that associations in those studies are strongly influenced by exposures to peak concentrations in the air quality distribution and thus do not indicate the need for additional protection against short-term exposures to peak $PM_{2.5}$ concentrations (U.S. EPA 2020, section 3.5.1). Lastly, the Administrator notes CASAC consensus support for retaining the current 24-hour standard. Thus, the Administrator concludes that the 24-hour standard with its level of 35 $\mu g/m^3$ is 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.

In reviewing the level of the annual standard, the Administrator recognizes that the annual standard, with its form based on the arithmetic mean concentration, is most appropriately meant to limit the ''typical'' daily and annual exposures that are most strongly associated with the health effects observed in epidemiological studies. However, the Administrator also recognizes that while epidemiological studies examine associations between distributions of $PM_{2.5}$ air quality and health outcomes, they do not identify particular $PM_{2.5}$ exposures that cause effects and thus, they cannot alone identify a specific level at which the standard should be set, as such a determination necessarily requires the Administrator's judgment. Thus, any approach that uses epidemiological information in reaching decisions on what standards are appropriate necessarily requires judgments about how to translate the information available from the epidemiological studies into a basis for appropriate standards. This includes consideration of how to weigh the uncertainties in the reported associations between daily or annual average $PM_{2.5}$ exposures and mortality or morbidity in the epidemiological 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 CAA.

The Administrator recognizes that important uncertainties and limitations that were present in epidemiological studies in previous reviews, remain in the current review. As discussed above, these uncertainties include 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. The Administrator also recognizes the advice given by the CASAC on this matter. As discussed above (section II.B.1), the CASAC members who support retaining the annual standard expressed their concerns with available $PM_{2.5}$ epidemiological studies. They assert that recent epidemiological studies do not provide a sufficient basis for revising the current standards. They also identify several key concerns regarding the associations reported in $PM_{2.5}$ epidemiological studies and conclude 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, 2019a, p. 8 consensus responses).

Taking into consideration the views expressed by these CASAC members, the Administrator recognizes that epidemiological studies examine associations between distributions of $PM_{2.5}$ air quality and health outcomes, and they do not identify particular $PM_{2.5}$ exposures that cause effects (U.S. EPA, 2020, section 3.1.2). While the Administrator remains concerned about placing too much weight on epidemiological studies to inform conclusions on the adequacy of the current primary standards, he notes that several commenters advocated for using the epidemiological studies in a manner they characterized as similar to the last review, to determine the level of the annual standard. The previous PM NAAQS review completed in 2012 noted that the evidence of an association in any epidemiological 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). Accordingly, the Administrator notes the characterization of study reported short-term and long-term mean $PM_{2.5}$ concentrations (section II.A.2.c.ii). As discussed in more detail above in section II.B.3 in responding to comments, when assessing the mean concentrations of the key short-term and long-term epidemiological studies in the U.S. that use ground-based monitoring (*i.e.,* those studies that can provide information most directly comparable to the current annual standard), the majority of studies (*i.e.,* 19 out of 21) have mean concentrations at or above the level of the current annual standard (12.0 μg/m^3), with the mean of the study reported means or medians equal to 13.5 μg/m^3, a concentration level above the current level of the primary annual standard of 12 μg/m^3.[54] The Administrator further notes his caution in directly comparing the reported study mean values to the standard level given that, as discussed in more detail above, study-reported mean concentrations, by design, are generally lower than the design value of the highest monitor in an area, which determines compliance. In fact, analyses of recent air quality in U.S. CBSAs indicate that maximum annual $PM_{2.5}$ design values for a given three-year period are often 10% to 20% higher than average monitored concentrations (*i.e.,* averaged across multiple monitors in the same CBSA) (U.S. EPA, 2020, Appendix B, section B.7). He further notes his concern in placing too much weight on any one epidemiological study but instead feels that it is more appropriate to focus on the body of studies together and therefore takes note of the calculation of the mean of study-reported means (or medians). Thus, in summary, while the Administrator is cautious about placing too much weight on the epidemiological evidence on its own, he notes: (1) The reported mean concentration in the majority of the key U.S. epidemiological 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 μg/m^3) is above the level of the current standard;[55] (3) air quality analyses show the study means to be lower than their corresponding design values by 10–20%; and (4) that these analyses must be considered in light of uncertainties inherent in the epidemiological evidence. When taken together, the Administrator judges that, even if he were to place greater weight on the epidemiological evidence, this information would not call into question the adequacy of the current standards.

In addition to the evidence, the Administrator also considers the potential implications of the risk assessment. He notes that all risk assessments have limitations and that he remains concerned about the uncertainties in the underlying epidemiological data used in the risk assessment. The Administrator also notes 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 have included uncertainty in the shapes of concentration-response 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 epidemiological study (U.S. EPA, 2020, section 3.3.2.4). Additionally, the Administrator notes similar concern expressed by members of the CASAC who support retaining the current standards; they highlighted similar uncertainties and limitations in the risk assessment (Cox, 2019a). In light of all of this, the Administrator judges 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.

The Administrator additionally considers the emerging body of evidence from accountability studies examining past reductions in ambient $PM_{2.5}$, and the degree to which those reductions have resulted in public health improvements. The Administrator agrees with public commenters who note that well-designed and conducted accountability studies can be informative. However, the Administrator also recognizes that interpreting such studies in the context of the current primary $PM_{2.5}$ standards is complicated by the fact that some of the available studies have not evaluated $PM_{2.5}$ specifically (*e.g.,* as opposed to PM_{10} or total suspended particulates), did not show changes in $PM_{2.5}$ air quality, or have not been able to disentangle health impacts of the interventions from background trends in health (U.S. EPA, 2020, section 3.5.1). He further recognizes that the small number of available studies that do report public health improvements following past declines in ambient $PM_{2.5}$ have not examined air quality meeting the current standards (U.S. EPA, 2020, Table 3–3). This includes recent U.S. studies that report increased life expectancy, decreased mortality, and decreased respiratory effects following past declines in ambient $PM_{2.5}$ concentrations. Such studies have examined ''starting'' annual average $PM_{2.5}$ concentrations (*i.e.,* prior to the reductions being evaluated) ranging from about 13.2 to >20 mg/m^3 (*i.e.,* U.S. EPA, 2020, 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 current standards, together with his broader concerns regarding the lack of experimental studies examining $PM_{2.5}$ exposures typical of areas meeting the current standards (discussed above), the Administrator judges that there is considerable uncertainty in the potential for increased public health protection from further reductions in ambient $PM_{2.5}$ concentrations beyond those achieved under the current primary $PM_{2.5}$ standards.

When the above considerations are taken together, the Administrator concludes that the scientific evidence that has become available since the last review of the PM NAAQS, together with the analyses in the PA based on that evidence and consideration of CASAC advice and public comments, does not call into question the adequacy of the public health protection provided by the current annual and 24-hour $PM_{2.5}$ standards. In particular, the Administrator judges that there is considerable uncertainty in the potential for additional public health improvements from reducing ambient $PM_{2.5}$ concentrations below the concentrations achieved under the current primary standards and, therefore, that standards more stringent than the current standards (*e.g.,* with lower levels) are not supported. That is, he judges that such standards would be more than requisite to protect the public health with an adequate margin of safety. This judgment reflects the Administrator's consideration of the uncertainties in the potential implications of the lower end of the air quality distributions from the epidemiological 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 current standards.

In reaching this conclusion, the Administrator notes that the current standards provide an adequate margin of safety. With respect to the annual standard, the level of 12 μg/m^3 is below the lowest ''starting'' concentration (*i.e.,*

[54] There were two studies, both included in the last review, for which the mean concentration (11.8 μg/m^3; Peng et al., 2009) or median concentration (10.7 μg/m^3 (Central Region); Zeger et al., 2008) was somewhat below 12 μg/m^3.

[55] The median of the study reported mean (or median) $PM_{2.5}$ concentrations is 13.3 μg/m^3, which is also above the level of the current standard.

13.2 μg/m³) in the available accountability studies that show public health improvements attributable to reductions in ambient $PM_{2.5}$. In addition, while the Administrator places less weight on the epidemiological evidence for the purposes of selecting a standard, he notes that the current level of the annual standard is below the reported mean (and median) concentrations in the majority of the key U.S. epidemiological studies using ground-based monitoring data [56] (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 μg/m³). In addition, the Administrator recognizes that concentrations in areas meeting the current 24-hour and annual standards remain well-below the $PM_{2.5}$ exposure concentrations consistently shown to elicit effects in human exposure studies.

In addition, based on the Administrator's review of the science, including controlled human exposure studies examining effects following short-term $PM_{2.5}$ exposures, the epidemiological studies described above, and accountability studies conducted at levels just above the current standard, he judges that the degree of public health protection provided by the current standard is not greater than warranted. This judgment, together with the fact that no CASAC member expressed support for a less stringent standard, leads the Administrator to conclude that standards less stringent than the current standards (*e.g.,* with higher levels) are also not supported.

When the above information is taken together, the Administrator concludes that the available scientific evidence and technical information continue to support the current annual and 24-hour $PM_{2.5}$ standards. This conclusion reflects the fact that important limitations in the evidence remain. The Administrator concludes that these limitations lead to considerable uncertainty regarding the potential public health implications of revising the existing suite of $PM_{2.5}$ standards. Given this uncertainty, and the advice from some CASAC members, he concludes that the current suite of primary standards, including the current 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, remain requisite to protect the public health. Therefore, the Administrator reaches the final conclusion that the current suite of primary $PM_{2.5}$ standards is requisite to protect public health from fine particles with an adequate margin of safety, including the health of at-risk populations, and is retaining the standards, without revision.

C. Decision on the Primary $PM_{2.5}$ Standards

For the reasons discussed above and taking into account information and assessments presented in the ISA and PA, the advice from the CASAC, and consideration of public comments, the Administrator concludes that the current annual and 24-hour primary $PM_{2.5}$ standards are requisite to protect public health from fine particles with an adequate margin of safety, including the health of at-risk populations, and is retaining the current standards without revision.

III. Rationale for Decisions on the Primary PM_{10} Standard

This section presents the rationale for the Administrator's decision to retain the existing primary PM_{10} standard. This decision is based on a thorough review of the latest scientific information, published through December 2017,[57] and assessed in the ISA, on human health effects associated with $PM_{10-2.5}$ in ambient air. This decision also accounts for considerations in the PA of the policy-relevant information, CASAC advice, and consideration of public comments received on the proposal.

Section III.A provides background on the general approach for this review and the basis for the existing standard, and also presents 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 decision to retain the existing primary PM_{10} 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 ISA and the PA information, advice from the CASAC, and comments from the public. Section III.C summarizes the Administrator's decision on the primary PM_{10} standard.

A. Introduction

As in prior reviews, the general approach to reviewing the current primary PM_{10} standard is based, most fundamentally, on using the EPA's assessment of the current scientific evidence to inform the Administrator's judgment regarding a primary PM_{10} standard that protects public health with an adequate margin of safety. In drawing conclusions with regard to the primary PM_{10} standard, the final decision on the adequacy of the current standard is largely a public health policy judgment to be made by the Administrator. The Administrator's final decision draws upon the scientific information about health effects, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence. The approach to informing these judgments, discussed more fully below, 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 in the CAA and with how the EPA and the courts have interpreted the Act. These provisions require the Administrator to establish primary standards that, in his judgment, 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 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 groups. 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.

In evaluating the appropriateness of retaining or revising the current primary

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[56] As discussed above, the means from these studies are most relatable to the level of the annual standard. However, because the reported means in these studies are based on averaging the monitored concentration across an area, they tend to be lower than the design value for that same area, since attainment of the standard is based on the measurements at the highest monitor (and not the average across multiple monitors.)

[57] In addition to the review's opening "call for information" (79 FR 71764, December 3, 2014), "the current ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009 and March 31, 2017. A limited literature update identified some additional studies that were published before December 31, 2017" (U.S. EPA, 2019, Appendix, p. A–3). References that are cited in the 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.*

PM_{10} standard, the EPA has adopted an approach which is similar to that used in the last review and which reflects the body of evidence and information now available. As summarized in section III.A.1 below, the Administrator's decisions in the prior review were based on an integration of information on health effects associated with exposure to $PM_{10-2.5}$, on the public health significance of key health effects, on policy judgments as to whether the standard is requisite to protect public health with an adequate margin of safety, and on consideration of the CASAC advice and public comments.

Similarly, in this review, as described in the PA, the proposal, and elsewhere in this document, we draw on the current evidence pertaining to the public health risk of $PM_{10-2.5}$ in ambient air. The past and current approaches are both based, most fundamentally, on the EPA's assessment of the current scientific and technical information. The EPA's assessments are primarily documented in the ISA and the PA, which have received CASAC review and public comment (83 FR 53471, October 23, 2018; 84 FR 47944, September 11, 2019). To bridge the gap between the scientific assessment of the ISA and the judgments required of the Administrator in determining whether the current standard is requisite to protect public health with an adequate margin of safety, the PA evaluates the policy implications of the current evidence in the ISA.

In considering the scientific and technical information, we consider both the information available at the time of the last review and information newly available since the last review, including most particularly that which has been critically analyzed and characterized in the current ISA. The evidence-based discussions presented below in section III.A.2 (and summarized more fully in the proposal) draw upon evidence from studies evaluating health effects related to exposures to $PM_{10-2.5}$, as discussed in the ISA.

1. Background on the Current Standard

The last review of the PM NAAQS was completed in 2012 (78 FR 3086, January 15, 2013). In that review, the EPA retained the existing primary 24-hour PM_{10} standard, with its level of 150 μg/m^3 and its one-expected-exceedance form on average over three years, to continue to provide public health protection against exposures to $PM_{10-2.5}$. In support of this decision, the prior Administrator emphasized her consideration of three issues: (1) The extent to which it was appropriate to retain a standard that provides some measure of protection against all $PM_{10-2.5}$ (regardless of composition or source of origin), (2) the extent to which a standard with a PM_{10} indicator can provide protection against exposures to $PM_{10-2.5}$, and (3) the degree of public protection provided by the existing PM_{10} standard.

First, the prior Administrator judged that the evidence provided ''ample support for a standard that protects against exposures to all thoracic coarse particles, regardless of their location or source of origin'' (78 FR 3176, January 15, 2013). In support of this, she noted that the epidemiological studies had reported positive associations between $PM_{10-2.5}$ and mortality or morbidity in a large number of cities across North America, Europe, and Asia, encompassing a variety of environments where $PM_{10-2.5}$ sources and composition were expected to vary widely. Though most of the available studies examined associations in urban areas, the Administrator noted that some studies had also found associations between mortality and morbidity and relatively high ambient concentrations of particles of non-urban crustal origin. In the last review, in considering this body of evidence, and consistent with the CASAC's advice, the Administrator concluded that it was appropriate to maintain a standard that provides some measure of protection against exposures to all thoracic coarse particles, regardless of their composition, location, or source of origin (78 FR 3176, January 15, 2013).

With regard to the appropriateness of retaining a PM_{10} indicator for a standard meant to protect against exposures to $PM_{10-2.5}$ in ambient air, the prior Administrator noted that PM_{10} mass included both coarse PM ($PM_{10-2.5}$) and fine PM ($PM_{2.5}$). As a result, the concentration of thoracic coarse particles ($PM_{10-2.5}$) allowed by a PM_{10} standard set at a single level declines as the concentration of $PM_{2.5}$ increases. Because $PM_{2.5}$ concentrations tend to be higher in urban areas than in rural areas, she observed that a PM_{10} standard would generally allow lower $PM_{10-2.5}$ concentrations in urban areas than in rural areas. She judged it appropriate to maintain such a standard given that much of the evidence for $PM_{10-2.5}$ toxicity, particularly at relatively low particle concentrations, came from study locations where thoracic coarse particles were of urban origin, and given that contaminants in urban areas would increase $PM_{10-2.5}$ particle toxicity. Therefore, in the last review, the Administrator concluded that it remained appropriate to maintain a standard that requires lower concentrations of $PM_{10-2.5}$ in ambient air in urban areas, where the strongest evidence was for associations between mortality and morbidity, and allows higher concentrations of $PM_{10-2.5}$ in non-urban areas, where the evidence of public health concerns was less certain. The Administrator concluded that the varying concentrations of coarse particles that would be permitted in urban versus non-urban areas under the 24-hour PM_{10} standard, based the varying levels of $PM_{2.5}$ present, appropriately reflected the differences in the strength of evidence regarding the health effects of coarse particles.

With regard to evaluating the degree of public health protection provided by the current primary PM_{10} standard, with its level of 150 μg/m^3 and its one-expected-exceedance form on average over three years, the Administrator recognized that the available scientific evidence and air quality information was much more limited for $PM_{10-2.5}$ than for $PM_{2.5}$. In particular, the strongest evidence for $PM_{10-2.5}$-related health effects was for cardiovascular effects, respiratory effects, and premature mortality following short-term exposures. For each of these categories of effects, the 2009 ISA concluded that the evidence was ''suggestive of a causal relationship'' (U.S. EPA, 2009c, section 2.3.3). The Administrator noted the significant uncertainties and limitations associated with the $PM_{10-2.5}$ scientific evidence leading to these causal determinations and questioned whether additional public health improvements would be achieved by revising the existing primary PM_{10} standard. She specifically took note of several uncertainties and limitations, including the following:

- There were a limited number of epidemiological studies that employed copollutant models to address the potential for confounding, particularly by $PM_{2.5}$, that would further the understanding of the extent to which $PM_{10-2.5}$ itself, rather than copollutants, contributed to the reported health effects.
- The plausibility of the associations between $PM_{10-2.5}$ and mortality and morbidity reported in epidemiological studies was uncertain given the limited number of experimental studies providing support for these associations.
- Limitations in $PM_{10-2.5}$ monitoring data (*i.e.,* limited data available from FRM/FEM sampling methods) and the different approaches used to estimate $PM_{10-2.5}$ concentrations across epidemiological studies resulted in uncertainties in the ambient $PM_{10-2.5}$ concentrations at which the reported

effects occur, increasing uncertainty in estimates of the extent to which changes in ambient $PM_{10-2.5}$ concentrations would likely impact public health.

- While $PM_{10-2.5}$ effect estimates reported for mortality and morbidity were generally positive, most were not statistically significant, even in single pollutant models. This included effect estimates reported in some study locations where the ambient PM_{10} concentrations were above those allowed by the current 24-hour PM_{10} standard.
- The composition of $PM_{10-2.5}$, and the effects associated with specific components, were also key uncertainties in the evidence. With a lack of information on the chemical speciation of $PM_{10-2.5}$, the apparent variability in associations across study locations was difficult to characterize.

In considering these uncertainties and limitations, the prior Administrator particularly took note of degree of uncertainty associated with the extent to which health effects reported in the epidemiological studies are due to $PM_{10-2.5}$ itself, as opposed to one or more copollutants, especially $PM_{2.5}$. This uncertainty reflects the relatively small number of studies available for $PM_{10-2.5}$ in ambient air that had evaluated copollutant models, and the very limited evidence from controlled human exposure studies supporting the plausibility of adverse health effects attributable to $PM_{10-2.5}$ at ambient concentrations.

When considering the available evidence overall, the prior Administrator concluded that the degree of public health protection provided by the current PM_{10} standard against exposures to $PM_{10-2.5}$ should be maintained (*i.e.,* neither increased nor decreased). Her judgment that a more stringent standard to provide additional protection was not necessary was supported by her consideration of the uncertainties in the overall body of evidence. Her judgment that a less stringent standard was not needed and that the degree of public health protection provided by the current standard was not greater than warranted was supported by the positive and statistically significant associations with mortality observed in some single-city study locations that were likely to have violated the current PM_{10} standard. Therefore, the prior Administrator concluded that the existing 24-hour standard, with its one-expected exceedance form on average over three years and a level of 150 μg/m³, was requisite to protect public health with an adequate margin of safety against effects that have been associated with $PM_{10-2.5}$. In light of this conclusion, the EPA retained the existing primary PM_{10} standard.

2. Overview of Health Effects Evidence

In this section, we provide an overview of the policy-relevant aspects of the $PM_{10-2.5}$-related health effects evidence available for consideration in this review. Section III.B of the proposal provides a detailed summary of key information contained in the ISA and the PA on the health effects associated with $PM_{10-2.5}$ exposures, and the related public health implications. As described in the proposal, the ISA does not identify any $PM_{10-2.5}$-related health outcomes for which the evidence supports either a ''causal'' or ''likely to be causal relationship'' (85 FR 24122, April 30, 2020). Therefore, for $PM_{10-2.5}$, we consider the evidence determined to be ''suggestive of, but not sufficient to infer, a causal relationship,'' recognizing the greater uncertainty in such evidence.[58]

While studies conducted since the time of the last review have strengthened support for relationships between $PM_{10-2.5}$ exposures and some key health outcomes, several key uncertainties from the last review have, to date, ''still not been addressed'' (U.S. EPA, 2019, section 1.4.2, p. 1–41). For example, in the last review, epidemiological studies relied on a number of methods to estimate $PM_{10-2.5}$ exposures, but the methods had not been systematically compared to evaluate spatial and temporal correlations in exposure estimates. Methods employed by these studies included: (1) Calculating the difference between PM_{10} and $PM_{2.5}$ at co-located monitors, (2) calculating the difference between county-wide averages of monitored PM_{10} and $PM_{2.5}$ based on monitors that are not necessarily co-located, and (3) direct measurement of $PM_{10-2.5}$ using a dichotomous sampler (U.S. EPA, 2019, section 1.4.2). More recent epidemiological studies, available since the last review, continue to use these approaches to estimate $PM_{10-2.5}$ concentrations. Some recent studies estimate long-term $PM_{10-2.5}$ exposures as the difference between PM_{10} and $PM_{2.5}$ concentrations based on information from spatiotemporal or land use regression (LUR) models, in addition to monitors. As in the last review, the methods used to estimate $PM_{10-2.5}$ concentrations have not been systematically evaluated (U.S. EPA, 2019, section 3.3.1.1), contributing to the uncertainty regarding spatial and temporal correlations in $PM_{10-2.5}$ concentrations across methods and in $PM_{10-2.5}$ exposure estimates used in epidemiological studies (U.S. EPA, 2019, sections 2.5.1.2.3 and 2.5.2.2.3). Given the greater spatial and temporal variability of $PM_{10-2.5}$ and fewer $PM_{10-2.5}$ monitoring sites compared to $PM_{2.5}$, this uncertainty is particularly important for the coarse size fraction.

In addition to the uncertainty associated with $PM_{10-2.5}$ exposure estimates in the epidemiological studies, information in the current review remains limited with regard to the potential for confounding by copollutants and provides limited support for the biological plausibility of serious effects following $PM_{10-2.5}$ exposures; both of these limitations continue to contribute broadly to uncertainty in the $PM_{10-2.5}$ health evidence. Uncertainty related to potential confounding is related to the relatively few epidemiological studies that have evaluated $PM_{10-2.5}$ health effect associations in copollutant models with both gaseous pollutants and other PM size fractions. Uncertainty related to the biological plausibility of serious effects caused by $PM_{10-2.5}$ exposures results from the limited number of controlled human exposure and animal toxicology[59] studies that have evaluated the health effects of experimental $PM_{10-2.5}$ inhalation exposures. The evidence supporting the ISA's ''suggestive'' causality determinations for $PM_{10-2.5}$ and health effects, including the uncertainties in the evidence, are summarized in the sections below.

a. Nature of Effects

i. Mortality

With regard to long-term $PM_{10-2.5}$ exposure and mortality, very few studies were available at the time of the last review. As such, the 2009 ISA concluded that the evidence was ''inadequate to determine if a causal relationship exists'' (U.S. EPA, 2009c). Since the time of the last review, there is limited new evidence and many of the limitations noted in the 2012 review persist. In the current review, some recent cohort studies conducted in the U.S. and Europe reported positive associations between long-term $PM_{10-2.5}$ exposure and total (nonaccidental) mortality, though results are

[58] As noted in the Preamble to the ISA, ''suggestive'' evidence is ''limited, and chance, confounding, and other biases cannot be ruled out'' (U.S. EPA, 2015, Table II).

[59] Compared to humans, smaller fractions of inhaled $PM_{10-2.5}$ penetrate into the thoracic regions of rats and mice (U.S. EPA, 2019, section 4.1.6), contributing to the relatively limited evaluation $PM_{10-2.5}$ exposures in animal studies.

inconsistent across studies (U.S. EPA, 2019, Table 11–11). The examination of copollutant models in these studies remains limited, and when copollutants are included, $PM_{10-2.5}$ effect estimates are often attenuated after adjusting for $PM_{2.5}$ (U.S. EPA, 2019, Table 11–11). These studies employed a number of approaches for estimating $PM_{10-2.5}$ exposures, including direct measurements from dichotomous samplers, calculating the difference between PM_{10} and $PM_{2.5}$ measured at co-located monitors, and calculating the difference of area-wide PM_{10} and $PM_{2.5}$ concentrations. As discussed above as a limitation in the last review, temporal and spatial correlations between these approaches still have not been evaluated, contributing to uncertainty regarding the potential for exposure measurement error (U.S. EPA, 2019, section 3.3.1.1, Table 11–11). The 2019 ISA concludes that this uncertainty ''reduces the confidence in the associations observed across studies'' (U.S. EPA, 2020, p. 11–125) and that the evidence for long-term $PM_{10-2.5}$ exposures and cardiovascular effects, respiratory morbidity, and metabolic disease provide limited biological plausibility for $PM_{10-2.5}$-related mortality (U.S. EPA, 2019, sections 11.4.1 and 11.4). Taken together, the 2019 ISA concludes that ''this body of evidence is suggestive, but not sufficient to infer, that a causal relationship exists between long-term $PM_{10-2.5}$ exposure and total mortality'' (U.S. EPA, 2019, p. 11–125).

With regard to short-term $PM_{10-2.5}$ exposures and mortality, the 2009 ISA concluded that the evidence is ''suggestive of a causal relationship between short-term exposure to $PM_{10-2.5}$ and mortality'' (U.S. EPA, 2009c). Since the last review, multicity epidemiological studies conducted primarily in Europe and Asia continue to provide consistent evidence of positive associations between short-term $PM_{10-2.5}$ exposure and total (nonaccidental) mortality (U.S. EPA, 2019, Table 11–9). These studies contribute to increasing confidence in the relationship between the short-term $PM_{10-2.5}$ exposures and mortality, however, the use of varying approaches to estimate $PM_{10-2.5}$ exposures continue to contribute uncertainty to the associations observed. Additionally, the 2019 ISA notes than an analysis by Adar et al. (2014) indicates ''possible evidence of publications bias, which was not observed for $PM_{2.5}$'' (U.S. EPA, 2019, section 11.3.2, p. 11–106). Studies newly available in this review expand the assessment of potential copollutant confounding of the short-term $PM_{10-2.5}$-mortality relationship and provide evidence that $PM_{10-2.5}$ associations generally remain positive in copollutant models, although associations are attenuated in some instances (U.S. EPA, 2019, section 11.3.4.1, Figure 11–28, Table 11–10). The 2019 ISA concludes that, overall, the assessment of potential copollutant confounding is limited by a lack of information on the correlation between $PM_{10-2.5}$ and gaseous pollutants and the small number of locations where copollutant analyses have been conducted. Associations with cause-specific mortality provide some support for associations with total (nonaccidental) mortality, though associations with cause-specific mortality, particularly respiratory mortality, are more uncertain (*i.e.,* wider confidence intervals) and less consistent (U.S. EPA, 2019, section 11.3.7). As discussed further below, the ISA concludes that evidence for $PM_{10-2.5}$-related cardiovascular and respiratory effects provides only limited support for the biological plausibility of a relationship between short-term $PM_{10-2.5}$ exposure and cause-specific mortality (U.S. EPA, 2019, section 11.3.7). Based on the overall evidence, the 2019 ISA concludes that ''this body of evidence is suggestive, but not sufficient to infer, that a causal relationship exists between short-term $PM_{10-2.5}$ exposure and total mortality'' (U.S. EPA, 2019, p. 11–120).

ii. Cardiovascular Effects

With regard to long-term exposures, the evidence available in the last review describing the relationship between long-term exposure to $PM_{10-2.5}$ and cardiovascular effects was characterized in the 2009 ISA as ''inadequate to infer the presence or absence of a causal relationship.'' The limited number of epidemiological studies available at that time reported contradictory results and experimental evidence demonstrating an effect of $PM_{10-2.5}$ on the cardiovascular system was lacking (U.S. EPA, 2019, section 6.4).

The evidence of long-term $PM_{10-2.5}$ exposures and cardiovascular mortality remains limited, with no consistent pattern of associations across studies, and as discussed above, uncertainty from the use of various approaches for estimating $PM_{10-2.5}$ concentrations (U.S. EPA, 2019, Table 6–70). The evidence for associations between $PM_{10-2.5}$ and cardiovascular morbidity has grown and, while results across studies are not entirely consistent, some epidemiological studies report positive associations with IHD and myocardial infarction (MI) (U.S. EPA, 2019, Figure 6–34); stroke (U.S. EPA, 2019, Figure 6–35); atherosclerosis (U.S. EPA, 2019, section 6.4.5); venous thromboembolism (VTE) (U.S. EPA, 2019, section 6.4.7); and blood pressure and hypertension (U.S. EPA, 2019, section 6.4.6). With respect to copollutant confounding, the effect estimates for $PM_{10-2.5}$-cardiovascular mortality are often attenuated, but remain positive, in copollutant models adjusted for $PM_{2.5}$. For cardiovascular morbidity outcomes, associations are inconsistent in copollutant models that adjust for $PM_{2.5}$, NO_2, and chronic noise pollution (U.S. EPA, 2019, p. 6–276). The 2019 ISA concluded that ''evidence from experimental animal studies is of insufficient quantity to establish biological plausibility'' (U.S. EPA, 2019, p. 6–277). Despite this substantial data gap in the toxicologic evidence for long-term $PM_{10-2.5}$ exposures and based largely on the observation of positive associations in some high-quality epidemiological studies, the ISA concludes that ''evidence is suggestive of, but not sufficient to infer, a causal relationship between long-term $PM_{10-2.5}$ exposure and cardiovascular effects'' (U.S. EPA, 2019, p. 6–277).

With regard to short-term $PM_{10-2.5}$ exposures and cardiovascular effects, the 2009 ISA found the available evidence was ''suggestive of a causal relationship,'' based primarily on several epidemiological studies reporting associations between short-term $PM_{10-2.5}$ exposure and cardiovascular effects, including IHD hospitalizations, supraventricular ectopy, and changes in heart rate variability (HRV). In addition, studies found increases in cardiovascular disease emergency department visits and hospital admissions linked to dust storm events resulting in high concentrations of crustal material. However, the 2009 ISA noted the potential for exposure measurement error and copollutant confounding in these studies. Moreover, there was only limited evidence of cardiovascular effects from a small number of controlled human exposure and animal toxicologic studies that examined $PM_{10-2.5}$ exposures (U.S. EPA, 2009c, section 6.2.12.2). Therefore, the potential for exposure measurement error and copollutant confounding, along with the limited evidence of biological plausibility for cardiovascular effects following inhalation exposure, contributed uncertainty to the scientific evidence available at the time of the last review (U.S. EPA, 2009c, section 6.3.13).

The evidence related to short-term $PM_{10-2.5}$ exposure and cardiovascular effects has somewhat expanded since the last review, but a number of important uncertainties persist. The 2019 ISA notes that there are a small number of epidemiological studies reporting positive associations between short-term $PM_{10-2.5}$ exposures and cardiovascular morbidity. There continues to be limited evidence, however, to suggest that these associations are biologically plausible, or independent of copollutant confounding. Additionally, the ISA concludes that it remains unclear how the approaches used to estimate $PM_{10-2.5}$ concentrations in epidemiological studies may impact exposure measurement error. The 2019 ISA concludes that overall ''the evidence is suggestive of, but not sufficient to infer, a causal relationship between short-term $PM_{10-2.5}$ exposures and cardiovascular effects'' (U.S. EPA, 2019, p. 6–254).

iii. Respiratory Effects

With regard to short-term $PM_{10-2.5}$ exposures and respiratory effects, the 2009 ISA concluded that, based on a small number of epidemiological studies observing some respiratory effects and limited evidence to support biological plausibility, the relationship is ''suggestive of a causal relationship.'' Epidemiological findings were consistent for respiratory infection and combined respiratory-related diseases, but not for COPD. Studies were characterized by overall uncertainty in the exposure assignment approach and limited information regarding potential copollutant confounding. Controlled human exposure studies of short-term $PM_{10-2.5}$ exposures found no lung function decrements and inconsistent evidence of pulmonary inflammation. Animal toxicologic studies were limited to those that used non-inhalation (*e.g.,* intra-tracheal instillation) routes of $PM_{10-2.5}$ exposure.

Recently available epidemiological studies link short-term $PM_{10-2.5}$ exposure with asthma exacerbation and respiratory mortality. Some associations remained positive in copollutant models including $PM_{2.5}$ or gaseous pollutants, although associations were attenuated in some studies of mortality. Limited evidence is available that observes positive associations with other respiratory outcomes, including COPD exacerbation, respiratory infection, and combined respiratory-related diseases (U.S. EPA, 2019, Table 5–36). The lack of systematic evaluation of the various methods used to estimate $PM_{10-2.5}$ concentrations and the resulting spatial and temporal variability in $PM_{10-2.5}$ concentrations compared to $PM_{2.5}$ continues to be an uncertainty in this evidence (U.S. EPA, 2019, sections 2.5.1.2.3 and 3.3.1.1). Based on the overall evidence, the 2019 ISA concludes that the ''evidence is suggestive of, but not sufficient to infer, a causal relationship between short-term $PM_{10-2.5}$ exposure and respiratory effects'' (U.S. EPA, 2019, p. 5–270).

iv. Cancer

In the last review, little information was available from studies of cancer following inhalation exposures to $PM_{10-2.5}$. Thus, the 2009 ISA concluded that the evidence was ''inadequate to assess the relationship between long-term $PM_{10-2.5}$ exposures and cancer'' (U.S. EPA, 2009c). Since the last review, the available studies of long-term $PM_{10-2.5}$ exposure and cancer remain limited, with a few recent epidemiological studies that report positive, but imprecise, associations with lung cancer incidence. Uncertainty remains in these studies due to exposure measurement error from the use of $PM_{10-2.5}$ predictions that have not been validated by monitored $PM_{10-2.5}$ concentrations (U.S. EPA, 2019, sections 3.3.2.3 and 10.3.4). Very few experimental studies of $PM_{10-2.5}$ exposures have been conducted, although the available studies indicate that $PM_{10-2.5}$ exhibits genotoxicity and oxidative stress, two key characteristics of carcinogens. While limited, these studies provide some evidence of biological plausibility for the findings in a small number of epidemiological studies (U.S. EPA, 2019, section 10.3.4). Taken together, the small number of available epidemiological and experimental studies, along with uncertainty related to exposure measurement error, contribute to the 2019 ISA conclusion that ''the evidence is suggestive of, but not sufficient to infer, a causal relationship between long-term $PM_{10-2.5}$ exposure and cancer'' (U.S. EPA, 2019, p. 10–87).

v. Metabolic Effects

The 2009 ISA did not make a causality determination for $PM_{10-2.5}$-related metabolic effects. Since the last review, one epidemiological study shows an association between long-term $PM_{10-2.5}$ exposure and incident diabetes, while additional cross-sectional studies report associations with effects on glucose or insulin homeostasis (U.S. EPA, 2019, section 7.4). Uncertainties with this evidence include the potential for copollutant confounding and exposure measurement error (U.S. EPA, 2019, Tables 7–14 7–15). There is limited evidence to support biological plausibility of metabolic effects, although a cross-sectional study that investigated biomarkers of insulin resistance and systemic and peripheral inflammation may support a pathway leading to type 2 diabetes (U.S. EPA, 2019, sections 7.4.1 and 7.4.3). Based on the somewhat expanded evidence available in this review, the 2019 ISA concludes that ''the evidence is suggestive of, but not sufficient to infer, a causal relationship between [long]-term $PM_{10-2.5}$ exposures and metabolic effects'' (U.S. EPA, 2019, p. 7–56).

vi. Nervous System Effects

The 2009 ISA did not make a causal determination for $PM_{10-2.5}$ exposures and nervous system effects. Newly available evidence since that time includes epidemiological studies that report associations between long-term $PM_{10-2.5}$ exposures and impaired cognition and anxiety in adults in longitudinal analyses (U.S. EPA, 2019, Table 8–25, section 8.4.5). Associations of long-term $PM_{10-2.5}$ exposure with neurodevelopmental effects are not consistently reported in children (U.S. EPA, 2019, section 8.4.4 and 8.4.5). Uncertainties in these studies include the potential for copollutant confounding, given that no studies examined copollutant models (U.S. EPA, 2019, section 8.4.5), and exposure measurement error based on the various methods used across studies to estimate $PM_{10-2.5}$ concentrations (U.S. EPA, 2019, Table 8–25). Additionally, there is very limited animal toxicologic evidence to provide support for biological plausibility of nervous system effects (U.S. EPA, 2019, sections 8.4.1 and 8.4.5). Considering the available studies and associated limitations, the 2019 ISA concludes that ''the evidence is suggestive of, but not sufficient to infer, a causal relationship between long-term $PM_{10-2.5}$ exposure and nervous system effects'' (U.S. EPA, 2019, p. 8–75).

B. Conclusions on the Primary PM_{10} Standard

In drawing conclusions on the adequacy of the current primary PM_{10} standard, 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 last review and reflects upon the body of evidence and information newly available in this review. In so doing, the Administrator has taken into account the evidence-based considerations, as well as advice from the CASAC and public comments. Evidence-based considerations draw upon the EPA's assessment and integrated synthesis of the scientific evidence from animal toxicologic, controlled human exposure studies, and epidemiological studies evaluating health effects related to exposures to $PM_{10-2.5}$ as presented in the ISA and discussed in section III.A.2. In addition to the evidence, the Administrator has weighed a range of policy-relevant considerations as discussed in the PA and summarized in sections III.B and III.C of the proposal and summarized in section III.B.2 below. These considerations, along with the advice from the CASAC (section III.B.1) and public comments (section III.B.3), are discussed below. A more detailed summary of all significant comments, along with the EPA's responses (henceforth ''Response to Comments''), can be found in the docket for this rulemaking (Docket No. EPA–HQ–OAR–2015–0072). This document is available for review in the docket for this rulemaking and through the EPA's NAAQS website (*https://www.epa.gov/naaqs/particulate-matter-pm-air-quality-standards*). The Administrator's conclusions in this review regarding the adequacy of the current primary PM_{10} standard and whether any revisions are appropriate are described in section III.B.4.

1. CASAC Advice in This Review

As a part of the review of the draft PA, the CASAC has provided advice on the adequacy of the public health protection afforded by the current primary PM_{10} standard. As for $PM_{2.5}$ (section II.B.1 above), the CASAC's advice is documented in a letter sent to the EPA Administrator (Cox, 2019a).

In its comments on the draft PA, the CASAC concurs with the draft PA's overall preliminary conclusions that it is appropriate to consider retaining the current primary PM_{10} standard without revision. The CASAC agrees with the draft PA ''that key uncertainties identified in the last review remain'' (Cox, 2019a, p. 13 of consensus responses) and that ''none of the identified health outcomes linked to $PM_{10-2.5}$'' were judged to be causal or likely causal. (Cox, 2019a, p. 12 of consensus responses). To reduce these uncertainties in future reviews, the CASAC recommends improvements to $PM_{10-2.5}$ exposure assessment, including a more extensive network for direct monitoring of the $PM_{10-2.5}$ fraction (Cox, 2019a, p. 13 of consensus responses). The CASAC also recommends additional controlled human exposure and animal toxicology studies of the $PM_{10-2.5}$ fraction to improve the understanding of biological causal mechanisms and pathway (Cox, 2019a, p. 13 of consensus responses). Overall, the CASAC agrees with the EPA that ''. . . the available evidence does not call into question the adequacy of the public health protection afforded by the current primary PM_{10} standard and that evidence supports consideration of retaining the current standard in this review'' (Cox, 2019a, p. 3 of letter).

2. Basis for the Proposed Decision

At the time of the proposal, the Administrator carefully considered the assessment of the current evidence and conclusions reached in the ISA, considerations and staff conclusions and associated rationales presented in the PA, and the advice and recommendations of the CASAC (85 FR 24125, April 30, 2020). In reaching his proposed decision on the primary PM_{10} standard, the Administrator first noted the decision to retain the primary PM_{10} standard in the last review recognized that epidemiological studies had reported positive associations between $PM_{10-2.5}$ and mortality and morbidity in cities across North America, Europe, and Asia. The studies encompassed a variety of environments where $PM_{10-2.5}$ sources and composition were expected to vary widely. Although many of the studies examined associations between $PM_{10-2.5}$ and health effects in urban areas, some of the studies also linked mortality and morbidity with relatively high ambient concentrations of particles of non-urban crustal origin. Drawing on this information, the EPA judged that it was appropriate to maintain a standard that provides some measure of protection against exposures to $PM_{10-2.5}$, regardless of location, source of origin, or particle composition (78 FR 3176, January 15, 2013).

The Administrator noted that the evidence for several $PM_{10-2.5}$-related health effects, particularly for long-term exposures, has expanded since the time of the last review. Recently available epidemiological studies conducted in North America, Europe, and Asia continue to report positive associations with mortality and morbidity in cities where $PM_{10-2.5}$ sources and composition are expected to vary widely, but uncertainties remain with respect to the methods used to assign exposure in the studies. While the Administrator recognized that important uncertainties persist in the scientific evidence, as described below and in section III.A.2 above, he also recognized that $PM_{10-2.5}$ exposures may be associated with a broader range of health effects that have been linked with $PM_{10-2.5}$ exposures. These studies provide an important part of the body of evidence supporting the ISA's revised causality determinations, including new determinations, for long-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, metabolic effects, nervous system effects, and cancer (U.S. EPA, 2019; U.S. EPA, 2020, section 4.2). Drawing on this information, the Administrator proposed to conclude that the scientific studies available since the last review continue to support a primary PM_{10} standard that provides some measure of public health protection against $PM_{10-2.5}$ exposures, regardless of location, source of origin, or particle composition.

With regard to the uncertainties in the scientific evidence, the Administrator noted that the decision in the last review highlighted limitations in the estimates of ambient $PM_{10-2.5}$ concentrations used in epidemiological studies, the limited evaluation of copollutant models to address potential confounding, and the limited number of experimental studies to support biologically plausible pathways for $PM_{10-2.5}$-related health effects. These and other limitations raised questions as to whether additional public health improvements would be achieved by revising the existing PM_{10} standard.

Despite some additional new evidence available in this review, the Administrator recognized that, similar to the last review, uncertainties remain in the scientific evidence for $PM_{10-2.5}$-related health effects. As summarized above (section III.A.2), these include uncertainties in the $PM_{10-2.5}$ exposure estimates used in epidemiological studies, in the independence of $PM_{10-2.5}$ health effect associations, and in support for the biologic plausibility of $PM_{10-2.5}$-related effects from controlled human exposure and animal toxicologic studies (U.S. EPA, 2020, section 4.2). These uncertainties contributed to the conclusions in the 2019 ISA that the evidence for key $PM_{10-2.5}$ health effects is ''suggestive of, but not sufficient to infer'' causal relationships (U.S. EPA, 2019). In light of his emphasis on evidence supporting ''causal'' or ''likely to be causal'' relationships in the current review, the Administrator judged that the evidence of health effects associated with $PM_{10-2.5}$ in ambient air provides an uncertain scientific foundation for making decisions for standard setting. As such, he further judged that, consistent with the last review, limitations in the evidence raise questions as to whether additional public health protections would be achieved by revising the existing PM_{10} standard.

In reaching his proposed conclusions on the primary PM_{10} standard, the Administrator additionally considered the advice and recommendations from the CASAC. As described above (section III.B.1), the CASAC recognized the uncertainties in the evidence for $PM_{10-2.5}$-related health effects, stating that ''key uncertainties identified in the last review remain'' (Cox, 2019a, p. 13 of consensus responses). Given these uncertainties, the CASAC agreed with the PA conclusion that the evidence available in this review ''does not call into question the adequacy of the public health protection afforded by the current primary PM_{10} standard'' (Cox, 2019a, p. 3 of letter). The CASAC further recommended that this evidence ''supports consideration of retaining the current standard in this review'' (Cox, 2019a, p. 3 of letter).

In considering the information above, the Administrator proposed to conclude that the available scientific evidence continues to support a PM_{10} standard to provide some measure of protection against $PM_{10-2.5}$ exposures. This conclusion reflected the expanded evidence available in this review for health effects from $PM_{10-2.5}$ exposures. However, important uncertainties and limitations in the evidence remain. Consistent with the decision in the last review, the Administrator proposed to conclude that these limitations contribute to considerable uncertainty regarding the potential public health implications of revising the existing PM_{10} standard. Given this uncertainty, and consistent with the advice from the CASAC, the Administrator proposed to conclude that the available evidence does not call into question the adequacy of the public health protection afforded by the current primary PM_{10} standard. Therefore, he proposed to retain the primary PM_{10} standard, without revision.

3. Comments on the Proposed Decision

Of the public comments received on the proposal, very few commenters provided comments on the primary PM_{10} standard. Of those commenters who did provide comments on the primary PM_{10} standard, the majority supported the Administrator's proposed decision to retain the current primary PM_{10} standard, without revision. This group includes primarily industries and industry groups. All of these commenters generally note their agreements with the rationale provided in the proposal and the CASAC concurrence with the PA conclusion that the current evidence does not support revision to the standard. Most also cite the EPA and CASAC statements that the newly available information in this review does not call into question the adequacy of the current standard. The EPA agrees with these comments and with the CASAC advice regarding the adequacy of the current primary standard and the lack of support for revision of the standard.

Some commenters disagreed with the Administrator's proposed conclusion to retain the current primary PM_{10} standard, primarily focusing their comments on the need for revisions to the form of the standard or the level of the standard. With regard to comments on the form of the standard, some commenters assert that the EPA should revise the standard by adopting a separate form (or a ''compliance threshold'' in their words)—the 99th percentile, averaged over three years—for the primary PM_{10} standard for continuous monitors, which provide data every day, while maintaining the current form of the standard (one exceedance, averaged over three years) for 1-in-6 samplers, given the widespread use of continuous monitoring and to ease the burden of demonstrating exceptional events. These commenters, in support of their comment, contend that the 99th percentile would effectively change the form from the 2nd high to the 4th high and would allow no more than three exceedances per year, averaged over three years. These commenters additionally highlight the EPA's decision in the 1997 review to adopt a 99th percentile form, averaged over three years, citing to advantages of a percentile-based form in the Administrator's rationale in that review. The comments further assert that a 99th percentile form for the primary PM_{10} standard is still more conservative than the form for other short-term NAAQS (*e.g.,* $PM_{2.5}$ and NO_2).

First, the EPA has long recognized that the form is an integral part of the NAAQS and must be selected together with the other elements of the NAAQS to ensure the appropriate stringency and requisite degree of public health protection. Thus, if the EPA were to change the form according to the monitoring method it would be establishing two different NAAQS, varying based on the monitoring method. The EPA has not done this to date, did not propose such an approach, and declines to adopt it for the final rule, as we believe such a decision in this final rule is beyond the scope of the proposal, and that each PM standard should have a single form, indicator, level and averaging time, chosen by the Administrator as necessary and appropriate. While certain continuous monitors may be established and approved as a Federal Equivalent Method (FEM) for PM_{10}, as an alternative to a Federal Reference Method (FRM), the use of an FEM is intended as an alternative means of determining compliance with the NAAQS, not as authorizing a different NAAQS.

Even if the commenters had asked that the change in form be made without regard to monitoring method, the EPA does not believe such a change would be warranted. The change in form for continuous monitors suggested by the commenters, without also lowering the level of such a standard, would allow more exceedances and thereby markedly reduce the public health protection provided against exposures to $PM_{10-2.5}$ in ambient air. These commenters have not provided new evidence or analyses to support their conclusion that an appropriate degree of public health protection could be achieved by allowing the use of an alternative form (*i.e.,* 99th percentile), while retaining the other elements of the standard.

With regard to the commenters' assertion that an alternate form of the standard would ease the burden of demonstrating exceptional events, the EPA first recognizes, consistent with the CAA, that it may be appropriate to exclude monitoring data influenced by ''exceptional'' events when making certain regulatory determinations. However, the EPA notes that the cost of implementation of the standards may not be considered by the EPA in reviewing the standards [60] and further the EPA believes it is unnecessary to alter the standard for the purpose of reducing the burden of demonstrating exceptional events. The EPA continues to update and develop documentation and tools to facilitate the implementation of the 2016 Exceptional Events Rule, including new documents intended to assist air agencies with the development of demonstrations for specific types of exceptional events. Moreover, with regard to the commenters' specific concerns for wildfires or high winds, the EPA released updated guidance documents on the preparation of exceptional event demonstrations related to wildfires in September 2016, high wind dust events in April 2019, and prescribed fires in August 2019. These guidance documents outline the regulatory requirements and provide examples for air agencies preparing demonstrations for wildfires, high wind dust, and prescribed fire events.

For all of the reasons discussed above, the EPA does not agree with the commenters that the form of the primary PM_{10} standard should be revised to a 99th percentile for continuous monitors.

[60] See generally *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 465–472, 475–76 (2001).

Some commenters who disagreed with the proposal to retain the current standard advocate for revision to the primary PM_{10} standard to protect public health with an adequate margin of safety. In their recommendations for revising the standard, some commenters contend that the current standard, with its indicator of PM_{10} to target exposures to $PM_{10-2.5}$, has become less protective as ambient concentrations of $PM_{2.5}$ have been reduced with revisions to that standard. These commenters assert that the current primary PM_{10} standard allows increased exposure to $PM_{10-2.5}$ in ambient air because retaining the primary PM_{10} would allow proportionately more $PM_{10-2.5}$ mass as the $PM_{2.5}$ standard has been revised downward. Moreover, in support of their recommendations, the commenters note that the available evidence of $PM_{10-2.5}$-related health effects has been expanded and strengthened since the time of the last review. Taken together, the commenters contend that the primary PM_{10} standard should be revised and failure to do so would be arbitrary and capricious.

We disagree with the commenters that the primary PM_{10} standard should be revised because reductions in ambient concentrations of $PM_{2.5}$ result in a less protective PM_{10} standard. As an initial matter, we note that overall, ambient concentrations of both PM_{10} and $PM_{2.5}$ have declined significantly over time. Ambient concentrations of PM_{10} have declined by 46% across the U.S. from 2000 to 2019,[61] while $PM_{2.5}$ concentrations in ambient air have declined by 43% during this same time period.[62] While trends data is not currently available for $PM_{10-2.5}$ concentrations in ambient air, the expanded availability of monitoring data from the NCore network in this review can provide insight into the relative contributions of fine and coarse PM to total PM_{10} concentrations.

The 2019 ISA provides a comparison of the relative contribution of $PM_{2.5}$ and $PM_{10-2.5}$ to PM_{10} concentrations by region and season using the more comprehensive monitoring data from the NCore network available in this review (U.S. EPA, 2019, section 2.5.1.1.4). The data indicate that, for urban areas, there are roughly equivalent amounts of $PM_{2.5}$ and $PM_{10-2.5}$ contributing to PM_{10} in ambient air, while rural locations have a slightly higher contribution of $PM_{10-2.5}$ contributing to PM_{10} concentrations than $PM_{2.5}$ (U.S. EPA, 2019, section 2.5.1.1.4, Table 2–7). There is generally a greater contribution from the $PM_{2.5}$ fraction in the East and a greater contribution from the $PM_{10-2.5}$ fraction in the West and Midwest. However, as described in the 2019 ISA, PM_{10} has become considerably coarser across the U.S. compared to similar observations in the 2009 ISA (U.S. EPA, 2019, section 2.5.1.1.4; U.S. EPA, 2009c).

The EPA recognizes that when the primary annual $PM_{2.5}$ standard was revised from 15 $\mu g/m^3$ to 12 $\mu g/m^3$ while leaving the 24-hour $PM_{2.5}$ standards unchanged at 35 $\mu g/m^3$ and the 24-hour PM_{10} standard unchanged at 150 $\mu g/m^3$, the $PM_{10-2.5}$ fraction of PM_{10} could increase in some areas as the $PM_{2.5}$ fraction decreases. Moreover, the EPA recognizes that in most areas of the country $PM_{2.5}$ and PM_{10} concentrations have declined and are well below their respective 24-hour standards, which may also allow the relative ratio of $PM_{2.5}$ to $PM_{10-2.5}$ to vary. In considering the available health effects evidence in this review, there continue to be significant uncertainties and limitations that make it difficult to fully assess the public health implications of revising the primary PM_{10} standard even considering the possibility for additional variability in the relative ratio of $PM_{2.5}$ to $PM_{10-2.5}$ in current PM_{10} air quality across the U.S. As described in detail above in section III.A.2 and in the proposal (85 FR 24125, April 30, 2020), these uncertainties contribute to the determinations in the 2019 ISA that the evidence for key $PM_{10-2.5}$ health effects is ''suggestive of, but not sufficient to infer, a causal relationship'' (U.S. EPA, 2019). Beyond these uncertainties, the EPA also notes that, while the NCore monitoring network has been expanded since the time of the last review, epidemiological studies available in this review do not use $PM_{10-2.5}$ NCore data in evaluating associations between $PM_{10-2.5}$ in ambient air and long- or short-term exposures. In the absence of such evidence, the public health implications of changes in ambient PM_{10} concentrations as $PM_{2.5}$ concentrations decrease remain unclear. Therefore, the EPA continues to recognize this as an area for future research, to address the existing uncertainties (U.S. EPA, 2020, section 4.5), and inform future reviews of the PM NAAQS.

Taken together, at the time of proposal, the Administrator concluded that these and other limitations in the $PM_{10-2.5}$ evidence raised questions as to whether additional public health improvements would be achieved by revising the existing PM_{10} standard. Therefore, the EPA does not agree with the commenters that the currently available air quality information or scientific evidence support revisions to the primary PM_{10} standard in this review.

4. Administrator's Conclusions

Having carefully considered advice from the CASAC and the public comments, as discussed above, the Administrator believes that the fundamental scientific conclusions on health effects of $PM_{10-2.5}$ in ambient air that were reached in the ISA and summarized in the PA remain valid. Additionally, the Administrator believes the judgments he proposed (85 FR 24125, April 30, 2020) with regard to the evidence remain appropriate. Further, in considering the adequacy of the current primary PM_{10} standard in this review, the Administrator has carefully considered the policy-relevant evidence and conclusions contained in the ISA; the rationale and conclusions presented in the PA; the advice and recommendations from the CASAC; and public comments, as addressed in section III.B.3 above. In the discussion below, the Administrator gives weight to the PA conclusions, with which the CASAC has concurred, as summarized in section III.D of the proposal, and takes note of the key aspects of the rationale for those conclusions that contribute to his decision in this review. After giving careful consideration to all of this information, the Administrator believes that the conclusions and policy judgments supporting his proposed decision remain valid, and that the current primary PM_{10} standard provides requisite protection of public health with an adequate margin of safety and should be retained.

In considering the PA evaluations and conclusions, the Administrator specifically notes that, while the health effects evidence is somewhat expanded since the last review, the overall conclusions are generally consistent with what was considered in the last review (U.S. EPA, 2020, section 4.4). In so doing, he additionally notes that the CASAC supports retaining the current standard, agreeing with the EPA that ''the available evidence does not call into question the adequacy of the public health protection afforded by the current primary PM_{10} standard'' (Cox, 2019a, p. 3 of letter). As noted below, the newly available evidence for several $PM_{10-2.5}$-related health effects has

[61] PM_{10} concentrations presented as the annual second maximum 24-hour concentration (in $\mu g/m^3$) at 262 sites in the U.S. For more information, see: *https://www.epa.gov/air-trends/particulate-matter-pm10-trends.*

[62] $PM_{2.5}$ concentrations presented as the seasonally-weighted annual average concentration (in $\mu g/m^3$) at 406 sites in the U.S. For more information, see: *https://www.epa.gov/air-trends/particulate-matter-pm25-trends.*

expanded since the last review, in particular for long-term exposures. The Administrator recognizes, however, that there are a number of uncertainties and limitations associated with the available information, as described in the proposal (85 FR 24125, April 30, 2020) and below.

With regard to the current evidence on $PM_{10-2.5}$-related health effects, the Administrator takes note of recent epidemiological studies that continue to report positive associations with mortality and morbidity in cities across North America, Europe, and Asia, where $PM_{10-2.5}$ sources and composition are expected to vary widely. While significant uncertainties remain, as described below, the Administrator recognizes that this expanded body of evidence has broadened the range of effects that have been linked with $PM_{10-2.5}$ exposures. These studies provide an important part of the scientific foundation supporting the ISA's revised causality determinations (and new determinations) for long-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, metabolic effects, nervous system effects, and cancer (U.S. EPA, 2019; U.S. EPA, 2020, section 4.2). Drawing from his consideration of this evidence, the Administrator concludes that the scientific information available since the time of the last review supports a decision to maintain a primary PM_{10} standard to provide public health protection against $PM_{10-2.5}$ exposures, regardless of location, source of origin, or particle composition.

With regard to uncertainties in the evidence, the Administrator first notes that a number of limitations were identified in the last review related to: (1) Estimates of ambient $PM_{10-2.5}$ concentrations used in epidemiological studies; (2) limited evaluation of copollutant models to address the potential for confounding; and (3) limited experimental studies supporting biological plausibility for $PM_{10-2.5}$-related effects. In the current review, despite the expanded body of evidence for $PM_{10-2.5}$ exposures and health effects, the Administrator recognizes that similar uncertainties remain. As summarized in section III.B.1 above and in responding to public comments, uncertainties in the current review continue to include those associated with the exposure estimates used in epidemiological studies, the independence of the $PM_{10-2.5}$ health effect associations, and the biologically plausible pathways for $PM_{10-2.5}$ health effects (U.S. EPA, 2020, section 4.2). These uncertainties contribute to the 2019 ISA determinations that the evidence is ''suggestive of, but not sufficient to infer'' causal relationships (U.S. EPA, 2019). In light of his emphasis on evidence supporting ''causal'' or ''likely to be causal'' relationships (sections II.A.2 and III.A.2 above), recognizing that the NAAQS should allow for a margin of safety but finding that there is too much uncertainty that a more stringent standard would improve public health, the Administrator judges that the available evidence provides support for his conclusion that the current standard provides the requisite level of protection from the effects of $PM_{10-2.5}$.

In making this judgment, the Administrator considers whether this level of protection is more than what is requisite and whether a less stringent standard would be appropriate to consider. He notes that there continues to be uncertainty associated with the evidence, for example exposure measurement error, as reflected by the ''suggestive of, but not sufficient to infer'' causal determinations. 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 evidence and technical information, as well as to provide a reasonable degree of protection against hazards that research has not yet identified. Based on all of the considerations noted here, and considering the current body of evidence, including uncertainties and limitations, the Administrator concludes that a less stringent standard would not provide the requisite protection of public health, including an adequate margin of safety.

The Administrator also considers whether the level of protection associated with the current standard is less than what is requisite and whether a more stringent standard would be appropriate to consider. In so doing, the Administrator considers, as discussed above, the level of protection offered from exposures for which public health implications are less clear. In so doing, he again notes the significant uncertainties and limitations that persist in the scientific evidence in this review. In particular, he notes limitations in the approaches used to estimate ambient $PM_{10-2.5}$ concentrations in epidemiological studies, limited examination of the potential for confounding by co-occurring pollutants, and limited support for the biological plausibility of the serious effects reported in many epidemiological studies that are reflected by the ''suggestive of, but not sufficient to infer'' causal determinations. Thus, in light of the currently available information, including the uncertainties and limitations of the evidence base available to inform his judgments regarding protection against $PM_{10-2.5}$-related effects, the Administrator does not find it appropriate to increase the stringency of the standard in order to provide the requisite public health protection. Rather, he judges it appropriate to maintain the level of protection provided by the current PM_{10} standard for $PM_{10-2.5}$ exposures and he does not judge the available information and the associated uncertainties to indicate the need for a greater level of public health protection.

In reaching his conclusions on the primary PM_{10} standard, the Administrator also considers advice from the CASAC, including that regarding uncertainties that remain in this review (summarized in section III.B.1 above). In their comments, the CASAC noted that uncertainties persist in the evidence for $PM_{10-2.5}$-related health effects, stating that ''key uncertainties identified in the last review remain'' (Cox, 2019a, p. 13 of consensus responses). In considering these comments, the Administrator takes note of the CASAC consideration of the uncertainties related to the evidence and its conclusion that ''evidence does not call into question the adequacy of the public health protection afforded by the current primary PM_{10} standard'' (Cox, 2019a, p. 3 of letter). The Administrator further notes the CASAC overall conclusion in this review that the current evidence ''supports consideration of retaining the current standard in this review'' (Cox, 2019a, p. 3 of letter).

Thus, in light of the currently available information, including uncertainties and limitations in the evidence base available to inform his judgments regarding public health protection, as well as CASAC advice, the Administrator does not find it appropriate to revise the standard. Rather, he judges it appropriate to retain the primary PM_{10} standard to provide the requisite degree of public health protection against $PM_{10-2.5}$ exposures, regardless of location, source of origin, or particle composition.

With regard to the uncertainties identified above, the Administrator notes that his final decision in this review is a public health policy judgment that draws upon scientific information, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the information. Accordingly, he recognizes that his decision requires judgments based on the interpretation of the evidence that neither overstates nor understates the strength or limitations of the evidence nor the appropriate inferences to be drawn. He recognizes, as described in section I.A above, that the Act does not require that primary standards be set at a zero-risk level; rather, the NAAQS must be sufficient but not more stringent than necessary to protect public health, including the health of sensitive groups with an adequate margin of safety.

Recognizing and building upon all of the above considerations and judgments, the Administrator has reached his conclusion in the current review. As an initial matter, he recognizes the control exerted by the current primary PM_{10} standard against exposures to $PM_{10-2.5}$ in ambient air. With regard to key aspects of the specific elements of a standard, the Administrator recognizes continued support in the current evidence base for PM_{10} as the indicator for the standard. In so doing, he notes that such an indicator provides protection from exposure to all coarse PM, regardless of location, source of origin, or particle composition. Similarly, with regard to averaging time, form, and level of the standard, the Administrator takes note of uncertainties in the available evidence and information and continues to find that the current standard, as defined by its current elements, is requisite. He has additionally considered the public comments regarding revisions to these elements of the standard and continues to judge that the existing level and the existing form, in all its aspects, together with the other elements of the existing standard provide an appropriate level of public health protection.

For all of the reasons discussed above, and recognizing the CASAC conclusion that the current evidence provides support for retaining the current standard, the Administrator concludes that the current primary PM_{10} standard (in all of its elements) is requisite to protect public health with an adequate margin of safety from effects of $PM_{10-2.5}$ in ambient air, and should be retained without revision.

C. Decision on the Primary PM_{10} Standard

For the reasons discussed above and taking into account information and assessments presented in the ISA and PA, the advice from the CASAC, and consideration of public comments, the Administrator concludes that the current primary PM_{10} standard is requisite to protect public health with an adequate margin of safety, including the health of at-risk populations, and is retaining the current standard without revision.

IV. Rationale for the Decision on the Secondary PM Standards

This section presents the rationale for the Administrator's decision to retain the current secondary PM standards, without revision. This decision is based on a thorough review of the latest scientific information generally published through December 2017,[63] as presented in the ISA, on non-ecological public welfare effects associated with PM and pertaining to the presence of PM in ambient air, specifically visibility, climate, and materials effects. This decision also accounts for analyses in the PA of policy-relevant information from the ISA and quantitative analyses of air quality related to visibility impairment; CASAC advice; and consideration of public comments received on the proposal.

The EPA is separately reviewing the ecological effects associated with PM in conjunction with reviews of other pollutants that, along with PM, contribute jointly to atmospheric deposition. As explained in both the PM IRP (U.S. EPA, 2016, p. 1–17) and the IRP for review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM (U.S. EPA, 2017, p. 1–1), and discussed in the proposal for this review (85 FR 24127, April 30, 2020), in recognition of the linkages between oxides of nitrogen, oxides of sulfur, and PM with respect to atmospheric deposition, and with respect to the ecological effects, the reviews of the ecological effects evidence and the secondary standards for these pollutants are being conducted together. Addressing the pollutants together enables the EPA to take a comprehensive approach to considering the nature and interactions of the pollutants, which is important for ensuring that all scientific information relevant to ecological effects is thoroughly evaluated. This combined review of the ecological criteria for oxides of nitrogen, oxides of sulfur, and particulate matter is ongoing.[64]

Section IV.A provides background on the general approach for this review and the basis for the existing secondary PM standards, and also presents brief summaries of key aspects of the currently available welfare effects evidence and quantitative information. Section IV.B summarizes the proposed conclusions and CASAC advice, addresses public comments received on the proposal, and presents the Administrator's conclusions on the adequacy of the current standards, drawing on consideration of this information, advice from the CASAC, and comments from the public. Section IV.C summarizes the Administrator's decision on the secondary PM standards.

A. Introduction

As in prior reviews, the general approach to reviewing the current secondary standards is based, most fundamentally, on using the EPA's assessment of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgment regarding secondary standards for PM that are requisite to protect the public welfare from known or anticipated adverse effects associated with the presence of PM in the ambient air. The EPA's assessments are primarily documented in the ISA and PA, both of which have received CASAC review and public comment (83 FR 53471, October 23, 2018; 84 FR 47944, September 11, 2019). To bridge the gap between the scientific assessments of the ISA and judgments required of the Administrator in determining whether the current standards provide the requisite welfare protection, the PA evaluates the policy implications of the assessment of the current evidence in the ISA and of the quantitative air quality information documented in the PA. In evaluating the public welfare protection afforded by the current standards, the four basic elements of the NAAQS (indicator, averaging time, level, and form) are considered collectively.

The secondary standard is to ''specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator . . . is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air'' (CAA, section 109(b)(2)). The secondary

[63] In addition to the review's opening ''call for information'' (79 FR 71764, December 3, 2014), ''the current ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009 and March 31, 2017. A limited literature update identified some additional studies that were published before December 31, 2017'' (U.S. EPA, 2019, Appendix, p. A–3). References that are cited in the 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.*

[64] The final ISA was released in October 2020: *https://www.epa.gov/isa/integrated-science-assessment-isa-oxides-nitrogen-oxides-sulfur-and-particulate-matter.*

standard is not meant to protect against all known or anticipated PM-related effects, but rather those that are judged to be adverse to the public welfare, and a bright-line determination of adversity is not required in judging what is requisite (78 FR 3212, January 15, 2013; 80 FR 65376, October 26, 2015). Thus, the level of protection from known or anticipated adverse effects to public welfare that is requisite for the secondary standard is a public welfare policy judgment to be made by the Administrator. In exercising that judgment, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that the standards be set at a zero-risk level, but rather at a level that reduces risk to protect the public welfare from known or anticipated adverse effects. In reaching conclusions on the standards, the Administrator's final decision draws upon the scientific information and analyses about welfare effects, environmental exposure and risks, and associated public welfare significance, as well as judgment about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and quantitative analyses. The approach to informing these judgments is based on the recognition that the available evidence generally reflects a continuum, consisting of levels at which scientists generally agree that effects are likely to occur, through lower levels at which the likelihood and magnitude of the responses become increasingly uncertain. This approach is consistent with the requirements of the CAA and with how the EPA and the courts have historically interpreted the Act.

In considering the scientific and technical information, we consider both the information available at the time of the last review and information newly available since the last review, including most particularly that which has been critically analyzed and characterized in the current ISA. We additionally consider the quantitative information described in the PA that estimated visibility impairment associated with current air quality conditions in areas with monitoring data that met completeness criteria (U.S. EPA, 2020, chapter 5). The evidence-based discussions presented below (and summarized more fully in the proposal) draw upon evidence from studies evaluating visibility, climate, and materials effects related to PM in ambient air, as discussed in the ISA. The quantitative-based discussions also presented below (and summarized more fully in the proposal) have been drawn from the quantitative analyses for PM-related visibility impairment, as discussed in the PA.

1. Background on the Current Standards

In the last review, completed in 2012,[65] the EPA retained the secondary 24-hour $PM_{2.5}$ standard, with its level of 35 µg/m³, and the 24-hour PM_{10} standard, with its level of 150 µg/m³ (78 FR 3228, January 15, 2013). The EPA also retained the level, set at 15 µg/m³, and averaging time of the secondary annual $PM_{2.5}$ standard, while revising the form. With regard to the form of the annual $PM_{2.5}$ standard, the EPA removed the option for spatial averaging (78 FR 3228, January 15, 2013). Key aspects of the Administrator's decisions on the secondary PM standards in the last review for non-visibility effects and visibility effects are described below. In the previous PM NAAQS review, the prior Administrator concluded that there was insufficient information available to base a national ambient air quality standard on climate impacts associated with ambient air concentrations of PM or its constituents (78 FR 3225–3226, January 15, 2013; U.S. EPA, 2011, section 5.2.3). In reaching this decision, the prior Administrator considered the scientific evidence, noting the 2009 ISA conclusion ''that a causal relationship exists between PM and effects on climate'' and that aerosols[66] alter climate processes directly through radiative forcing and by indirect effects on cloud brightness, changes in precipitation, and possible changes in cloud lifetimes (U.S. EPA, 2009c, section 9.3.10). She also noted that the major aerosol components with the potential to affect climate processes (*i.e.,* black carbon (BC), organic carbon (OC), sulfates, nitrates and mineral dusts) vary in their reflectivity, forcing efficiencies, and direction of climate forcing (U.S. EPA, 2009c, section 9.3.10). The prior Administrator recognized the strong evidence indicating that aerosols affect climate and further considered what the available information indicated regarding the adequacy of protection provided by the secondary PM standards. In particular, she noted that a number of uncertainties in the scientific information (*i.e.,* the spatial and temporal heterogeneity of PM components that contribute to climate forcing, uncertainties in the measurement of aerosol components, inadequate consideration of aerosol impacts in climate modeling, insufficient data on local and regional microclimate variations and heterogeneity of cloud formations) affected our ability to conduct a quantitative analysis to determine a distinct secondary standard based on climate.

In the last review, the prior Administrator concluded that that it is generally appropriate to retain the existing secondary standards and that it is not appropriate to establish any distinct secondary PM standards to address PM-related materials effects (78 FR 3225–3226, January 15, 2013; U.S. EPA, 2011, p. 5–29). In reaching this conclusion, she considered materials effects associated with the deposition of PM (*i.e.,* dry and wet deposition), including both physical damage (materials effects) and aesthetic qualities (soiling effects). She noted the 2009 ISA conclusion that evidence was ''sufficient to conclude that a causal relationship exists between PM and effects on materials'' (U.S. EPA, 2009c, sections 2.5.4 and 9.5.4), but also recognized that the 2011 PA noted that quantitative relationships were lacking between particle size, concentrations, and frequency of repainting and repair of surfaces and that considerable uncertainty exists in the contributions of co-occurring pollutants to materials damage and soiling processes (U.S. EPA, 2011, p. 5–29).

In considering non-visibility welfare effects in the last review, as discussed above, the prior Administrator concluded that, while it is important to maintain an appropriate degree of control of fine and coarse particles to address non-visibility welfare effects, ''[i]n the absence of information that would support any different standards . . . it is appropriate to retain the

[65] The 2012 decision on the adequacy of the secondary PM standards was based on consideration of the protection provided by those standards for visibility and for the non-visibility effects of materials damage, climate effects and ecological effects. As noted earlier, the current review of the public welfare protection provided by the secondary PM standards against ecological effects is occurring in the separate, on-going review of the secondary NAAQS for oxides of nitrogen and oxides of sulfur (U.S. EPA, 2016, Chapter 1, section 5.2; U.S. EPA, 2020, Chapter 1, section 5.1.1). Thus, the consideration of ecological effects in the 2012 review is not discussed here.

[66] In the climate sciences research community, PM is encompassed by what is typically referred to as aerosol. An aerosol is defined as a solid or liquid suspended in a gas, but PM refers to the solid or liquid phase of an aerosol. In this review of the secondary PM NAAQS the discussion on climate effects of PM uses the term PM throughout for consistency with the ISA (U.S. EPA, 2019) as well as to emphasize that the climate processes altered by aerosols are generally altered by the PM portion of the aerosol. Exceptions to this practice include the discussion of climate effects in the last review, when aerosol was used when discussing suspended aerosol particles, and for certain acronyms that are widely used by the climate community that include the term aerosol (*e.g.,* aerosol optical depth, or AOD).

existing suite of secondary standards'' (78 FR 3225–3226, January 15, 2013). Her decision was consistent with the CASAC advice related to non-visibility effects. Specifically, the CASAC agreed with the 2011 PA conclusions that, while these effects are important, ''there is not currently a strong technical basis to support revisions of the current standards to protect against these other welfare effects'' (Samet, 2010a, p. 5). Thus, in considering non-visibility welfare effects, the prior Administrator concluded that it was appropriate to retain all aspects of the existing 24-hour $PM_{2.5}$ and PM_{10} secondary standards. With regard to the secondary annual $PM_{2.5}$ standard, she concluded that it was appropriate to retain a level of 15.0 µg/m³ while revising only the form of the standard to remove the option for spatial averaging (78 FR 3225–3226, January 15, 2013).

Having reached the conclusion it is generally appropriate to retain the existing secondary standards and that it is not appropriate to establish any distinct secondary PM standards to address non-visibility PM-related welfare effects, the prior Administrator next considered the level of protection that would be requisite to protect public welfare against PM-related visibility impairment and whether to adopt a distinct secondary standard to achieve this level of protection. In reaching her final decision that the existing 24-hour $PM_{2.5}$ standard provides sufficient protection against PM-related visibility impairment (78 FR 3228, January 15, 2013), she considered the evidence assessed in the 2009 ISA (U.S. EPA, 2009c) and the analyses included in the Urban-Focused Visibility Assessment (2010 UFVA; U.S. EPA, 2010b) and the 2011 PA (U.S. EPA, 2011). She also considered the degree of protection for visibility that would be provided by the existing secondary standard, focusing specifically on the secondary 24-hour $PM_{2.5}$ standard with its level of 35 µg/m³. These considerations, and the prior Administrator's conclusions regarding visibility are summarized below and discussed in more detail in the proposal (85 FR 24128–24129, April 30, 2020).

In the last review, the ISA concluded that, ''collectively, the evidence is sufficient to conclude that a causal relationship exists between PM and visibility impairment'' (U.S. EPA, 2009c, p. 2–28). In consideration of the potential public welfare implication of various degrees of PM-related visibility impairment, the prior Administrator considered the available visibility preference studies that were part of the overall body of evidence in the 2009 ISA and reviewed as a part of the 2010 UFVA. These preference studies provided information about the potential public welfare implications of visibility impairment from surveys in which participants were asked questions about their preferences or the values they placed on various visibility conditions, as displayed to them in scenic photographs or in images with a range of known light extinction levels.[67]

In noting the relationship between PM concentrations and PM-related light extinction, the prior Administrator focused on identifying an adequate level of protection against visibility-related welfare effects. She first concluded that a standard in terms of a $PM_{2.5}$ visibility index would provide a measure of protection against PM-related light extinction that directly takes into account the factors (*i.e.,* PM species composition and relative humidity) that influence the relationship between $PM_{2.5}$ in ambient air and PM-related visibility impairment. A $PM_{2.5}$ visibility index standard would afford a relatively high degree of uniformity of visual air quality protection in areas across the country by directly incorporating the effects of differences of $PM_{2.5}$ composition and relative humidity. In defining a target level of protection in terms of a $PM_{2.5}$ visibility index, as discussed below, she considered specific elements of the index, including the basis for its derivation, as well as an appropriate averaging time, level, and form.

The prior Administrator concluded that it was appropriate to use an adjusted version of the original IMPROVE algorithm,[68] in conjunction with monthly average relative humidity data based on long-term climatological means, as the basis for deriving a visibility index. In so concluding, she noted the CASAC conclusion on the reasonableness of reliance on a $PM_{2.5}$ light extinction indicator calculated from $PM_{2.5}$ chemical composition and relative humidity, and she recognized that the mass monitoring methods available at that time were unable to measure the full water content of ambient $PM_{2.5}$ and did not provide information on the composition of $PM_{2.5}$, both of which contribute to visibility impacts (77 FR 38980, June 29, 2012). As noted at the time of the proposal, the prior Administrator recognized that suitable equipment and performance-based verification procedures did not then exist for direct measurement of light extinction and could not be developed within the time frame of the review (77 FR 38980–38981, June 29, 2012).

The prior Administrator concluded that a 24-hour averaging time would be appropriate for a visibility index (78 FR 3226, January 15, 2013). Although she recognized that hourly or sub-daily (4- to 6-hour) averaging times, within daylight hours and excluding hours with relatively high humidity, are more directly related to the short-term nature of the perception of PM-related visibility impairment and relevant exposure periods for segments of the viewing public than a 24-hour averaging time, she also noted that there were data quality uncertainties associated with the instruments used to provide the hourly $PM_{2.5}$ mass measurements required for an averaging time shorter than 24 hours. She also considered the results of analyses that compared 24-hour and 4-hour averaging times for calculating the index. These analyses showed good correlation between 24-hour and 4-hour average $PM_{2.5}$ light extinction, as evidenced by reasonably high city-specific and pooled R-squared values, generally in the range of over 0.6 to over 0.8. Based on these analyses and the 2011 PA conclusions regarding them, the prior Administrator concluded that a 24-hour averaging time would be a reasonable and appropriate surrogate for a sub-daily averaging time.

The statistical form of the index, 3-year average of annual 90th percentile values, was based on the prior Administrator's consideration of the analyses conducted in the 2011 UFVA of three different statistics and consistency of this statistical form with the Regional Haze Program, which targets the 20 percent most impaired days for improvements in visual air quality in Federal Class I areas. Moreover, the prior Administrator noted that a 3-year average form provided stability from the occasional effect of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year (78 FR 3198, January 15, 2013; U.S. EPA,

[67] Preference studies were available in four urban areas in the last review. Three western preference studies were available, including one in Denver, Colorado (Ely et al., 1991), one in the lower Fraser River valley near Vancouver, British Columbia, Canada (Pryor, 1996), and one in Phoenix, Arizona (BBC Research & Consulting, 2003). A pilot focus group study was also conducted for Washington, DC (Abt Associates, 2001), and a replicate study with 26 participants was also conducted for Washington, DC (Smith and Howell, 2009). More details about these studies are available in Appendix D of the PA.

[68] The revised IMPROVE algorithm (Pitchford et al., 2007) uses major PM chemical composition measurements and relative humidity estimates to calculate light extinction. For more information about the derivation of and input data required for the original and revised IMPROVE algorithms, see 78 FR 3168–3177, January 15, 2013.

2011, p. 4–58).[69] The Administrator also noted that the available studies on people's preferences did not address frequency of occurrence of different levels of visibility and did not identify a basis for a different target for urban areas than that for Class I areas (U.S. EPA, 2011, p. 4–59). These considerations led the prior Administrator to conclude that 90th percentile form was the most appropriate annual statistic to be averaged across three years (78 FR 3226, January 15, 2013).

In selecting a level for the index, the prior Administrator considered the ''candidate protection levels'' (CPLs)[70] identified in the 2011 PA based on the visibility preference studies, ranging from 20 to 30 deciviews (dv),[71] while noting the uncertainties and limitations in these public preference studies.[72] She concluded that that the current substantial degrees of variability and uncertainty inherent in the public preference studies should be reflected in a higher target protection level than would be appropriate if the underlying information were more consistent and certain. Therefore, she concluded that it was appropriate to set a target level of protection in terms of a 24-hour $PM_{2.5}$ visibility index at 30 dv (78 FR 3226–3227, January 15, 2013).

Based on her considerations and conclusions summarized above, the prior Administrator concluded that the protection provided by a secondary standard based on a 3-year visibility metric, defined in terms of a $PM_{2.5}$ visibility index with a 24-hour averaging time, a 90th percentile form averaged over 3 years, and a level of 30 dv, would be requisite to protect public welfare with regard to visual air quality (78 FR 3227, January 15, 2013). Having reached this conclusion, she next determined whether an additional distinct secondary standard in terms of a visibility index was needed given the degree of protection from visibility impairment afforded by the existing secondary standards. Specifically, she noted that the air quality analyses showed that all areas meeting the existing 24-hour $PM_{2.5}$ standard, with its level of 35 μg/m^3, had visual air quality at least as good as 30 dv, based on the visibility index defined above (Kelly et al., 2012b, Kelly et al., 2012a). Thus, the secondary 24-hour $PM_{2.5}$ standard would likely be controlling relative to a 24-hour visibility index set at a level of 30 dv. Additionally, areas would be unlikely to exceed the target level of protection for visibility of 30 dv without also exceeding the existing secondary 24-hour standard. Thus, the prior Administrator judged that the 24-hour $PM_{2.5}$ standard ''provides sufficient protection in all areas against the effects of visibility impairment—*i.e.,* that the existing 24-hour $PM_{2.5}$ standard would provide *at least* the target level of protection for visual air quality of 30 dv which [she] judges appropriate'' (78 FR 3227, January 15, 2013). She further judged that ''[s]ince sufficient protection from visibility impairment would be provided for all areas of the country without adoption of a distinct secondary standard, and adoption of a distinct secondary standard will not change the degree of over-protection for some areas of the country . . . adoption of such a distinct secondary standard is not needed to provide requisite protection for both visibility and nonvisibility related welfare effects'' (78 FR 3228, January 15, 2013).

2. Overview of Welfare Effects Evidence

In this section, we provide an overview of the policy-relevant aspects of the welfare effects evidence available for consideration in this review. Sections IV.B and IV.C of the proposal provide a detailed summary of key information contained in the ISA and in the PA on the visibility and non-visibility welfare effects associated with PM in ambient air, and the related public welfare implications (85 FR 24129, April 30, 2020). The subsections below briefly summarize the nature of PM-related visibility and non-visibility effects.

a. Nature of Effects

The evidence base available in the current review includes decades of research on visibility impairment, climate effects, and materials effects associated with PM (U.S. EPA, 2004, 2009c, 2019). Visibility impairment can have implications for people's enjoyment of daily activities and for their overall sense of well-being (U.S. EPA, 2009c, section 9.2). The strongest evidence for PM-related visibility impairment comes from the fundamental relationship between light extinction and PM mass (U.S. EPA, 2009c), as well as studies of the public perception of visibility impairment (U.S. EPA, 2010b), which confirm a well-established ''causal relationship exists between PM and visibility impairment'' (U.S. EPA, 2009c, p. 2–28). Beyond its effects on visibility, the 2009 ISA also identified a causal relationship ''between PM and climate effects, including both direct effects of radiative forcing and indirect effects that involve cloud and feedbacks that influence precipitation formation and cloud lifetimes'' (U.S. EPA, 2009, p. 2–29). The evidence also supports a causal relationship between PM and effects on materials, including soiling effects and materials damage (U.S. EPA, 2009, p. 2–31).

The evidence newly available in this review is consistent with the evidence available at the time of the last review and supports the conclusions of causal relationships between PM and visibility, climate, and materials effects (U.S. EPA, 2019, chapter 13). Evidence newly available in this review augments the previously available evidence of the relationship between PM and visibility impairment (U.S. EPA, 2019, section 13.2), climate effects (U.S. EPA, 2019, section 13.3), and materials effects (U.S. EPA, 2019, section 13.4).

i. Visibility

Visibility refers to the visual quality of a human's view with respect to color rendition and contrast definition. It is the ability to perceive landscape form, colors, and textures. Visibility involves optical and psychophysical properties involving human perception, judgment, and interpretation. Light between the observer and the object can be scattered into or out of the sight path and absorbed by PM or gases in the sight path. Consistent with conclusions of causality in the last review, the 2019 ISA concludes that ''the evidence is sufficient to conclude that a causal relationship exists between PM and visibility impairment'' (U.S. EPA, 2019, section 13.2.6). These conclusions are based on the strong and consistent evidence that ambient PM can impair visibility in both urban and remote areas (U.S. EPA, 2019, section 13.1; U.S. EPA, 2009c, section 9.2.5).

The fundamental relationship between light extinction and PM mass, and the EPA's understanding of this relationship, has changed little since the

[69] The EPA recognized that a percentile form averaged over multiple 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, thus reducing the potential for disruption of programs implementing the standard and reducing the potential for disruption of the protections provided by those programs.

[70] For comparison, 20 dv, 25 dv, and 30 dv are equivalent to 64, 112, and 191 megameters (Mm^{-1}), respectively.

[71] Deciview (dv) refers to a scale for characterizing visibility that is defined directly in terms of light extinction. The deciview scale is frequently used in the scientific and regulatory literature on visibility.

[72] Uncertainties and limitations in the public preference studies included the small number of stated preference studies available; the relatively small number of study participants and the extent to which the study participants may not be representative of the broader study area population in some of the studies; and the variations in the specific materials and methods used in each study.

2009 ISA (U.S. EPA, 2009c). The combined effect of light scattering and absorption by particles and gases is characterized as light extinction, *i.e.,* the fraction of light that is scattered or absorbed per unit of distance in the atmosphere. Light extinction is measured in units of 1/distance, which is often expressed in the technical literature as visibility per megameter (abbreviated Mm^{-1}). Higher values of light extinction (usually given in units of Mm^{-1} or dv) correspond to lower visibility. When PM is present in the air, its contribution to light extinction is typically much greater than that of gases (U.S. EPA, 2019, section 13.2.1). The impact of PM on light scattering depends on particle size and composition, as well as relative humidity. All particles scatter light, as described by the Mie theory, which relates light scattering to particle size, shape, and index of refraction (U.S. EPA, 2019, section 13.2.3; Van de Hulst, 1981; Mie, 1908). Fine particles scatter more light than coarse particles on a per unit mass basis and include sulfates, nitrates, organics, light-absorbing carbon, and soil (Malm et al., 1994). Hygroscopic particles like ammonium sulfate, ammonium nitrate, and sea salt increase in size as relative humidity increases, leading to increased light scattering (U.S. EPA, 2019, section 13.2.3).

As at the time of the last review, direct measurements of PM light extinction, scattering, and absorption continue to be considered more accurate for quantifying visibility than PM mass-based estimates because measurements do not depend on assumptions about particle characteristics (*e.g.,* size, shape, density, component mixture, etc.) (U.S. EPA, 2019, section 13.2.2.2). Measurements of light extinction can be made with high time resolution, allowing for characterization of sub-daily temporal patterns of visibility impairment. A number of measurement methods have been used for visibility impairment (*e.g.,* transmissometers, integrating nephelometers, teleradiometers, telephotometers, and photography and photographic modeling), although each of these methods has its own strengths and limitations (U.S. EPA, 2019, Table 13–1). As recognized in the last review, there are no common performance-based criteria to evaluate these methods and none have been deployed broadly across the U.S. for routine measurement of visibility impairment.

In the absence of a robust monitoring network for the routine measurement of light extinction across the U.S., estimation of light extinction based on existing PM monitoring can be used. The theoretical relationship between light extinction and PM characteristics, as derived from Mie theory (U.S. EPA, 2019, Equation 13.5), and can be used to estimate light extinction by combining mass scattering efficiencies of particles with particle concentrations (U.S. EPA, 2019, section 13.2.3; U.S. EPA, 2009c, sections 9.2.2.2 and 9.2.3.1). This estimation of light extinction is consistent with the method used in the last review. The algorithm used to estimate light extinction, known as the IMPROVE algorithm,[73] provides for the estimation of light extinction (b_{ext}), in units of Mm^{-1}, using routinely monitored components of fine ($PM_{2.5}$) and coarse ($PM_{10-2.5}$) PM. Relative humidity data are also needed to estimate the contribution by liquid water that is in solution with the hygroscopic components of PM. To estimate each component's contribution to light extinction, their concentrations are multiplied by extinction coefficients and are additionally multiplied by a water growth factor that accounts for their expansion with moisture. Both the extinction efficiency coefficients and water growth factors of the IMPROVE algorithm have been developed by a combination of empirical assessment and theoretical calculation using particle size distributions associated with each of the major aerosol components (U.S. EPA, 2019, section 13.2.3.1, section 13.2.3.3).

At the time of the last review, two versions of the IMPROVE algorithm were available in the literature—the *original IMPROVE algorithm* (Malm and Hand, 2007; Ryan et al., 2005; Lowenthal and Kumar, 2004) and the *revised IMPROVE algorithm* (Pitchford et al., 2007). As described in detail in the proposal (85 FR 24130, April 30, 2020) and the ISA (U.S. EPA, 2019, section 13.2.3), the algorithm has been further evaluated and refined since the time of the last review (Lowenthal and Kumar, 2016), particularly for PM characteristics and relative humidity in remote areas. All three versions of the IMPROVE algorithm were considered in evaluating visibility impairment in this review.

Consistent with the evidence available at the time of the last review, our understanding of public perception of visibility impairment comes from visibility preference studies conducted in four areas in North America.[74] The detailed methodology for these studies are described in the proposal (85 FR 24131, April 30, 2020), the 2019 ISA (U.S. EPA, 2019), and the 2009 ISA (U.S. EPA, 2009c). In summary, the study participants were queried regarding multiple images that were either photographs of the same location and scenery that had been taken on different days on which measured extinction data were available or digitized photographs onto which a uniform ''haze'' had been superimposed. Results of the studies indicated a wide range of judgments on what study participants considered to be acceptable visibility across the different study areas, depending on the setting depicted in each photograph. Based on the results of the four cities, a range encompassing the $PM_{2.5}$ visibility index values from images that were judged to be acceptable by at least 50 percent of study participants across all four of the urban preference studies was identified (U.S. EPA, 2010b, p. 4–24; U.S. EPA, 2020, Figure 5–2). Much lower visibility (considerably more haze resulting in higher values of light extinction) was considered acceptable in Washington, DC, than was in Denver, and 30 dv reflected the level of impairment that was determined to be ''acceptable'' by at least 50 percent of study participants (78 FR 3226–3227, January 15, 2013). As noted in the proposal (85 FR 24131, April 30, 2020), the evidence base for public preferences of visibility impairment has not been augmented since the last review. There are no new visibility preference studies that have been conducted in the U.S. since the time of the last review and there is very little new information available regarding acceptable levels of visibility impairment in the U.S.

ii. Climate

The current evidence continues to support the conclusion of a causal relationship between PM and climate effects (U.S. EPA, 2019, section 13.3.9). Since the last review, climate impacts and been extensively studied and recent research reinforces and strengthens the evidence evaluated in the 2009 ISA. New evidence provides greater specificity about the details of radiative

[73] The algorithm is referred to as the IMPROVE algorithm as it was developed specifically to use monitoring data generated at IMPROVE network sites and with equipment specifically designed to support the IMPROVE program and was evaluated using IMPROVE optical measurements at the subset of monitoring sites that make those measurements (Malm et al., 1994).

[74] Preference studies were available in four urban areas in the last review: Denver, Colorado (Ely et al., 1991), Vancouver, British Columbia, Canada (Pryor, 1996), Phoenix, Arizona (BBC Research & Consulting, 2003), and Washington, DC (Abt Associates, 2011; Smith and Howell, 2009).

forcing effects [75] and increases the understanding of additional climate impacts driven by PM radiative effects. The Intergovernmental Panel on Climate Change (IPCC) assesses the role of anthropogenic activity in past and future climate change, and since the last review, has issued the Fifth IPCC Assessment Report (AR5; IPCC, 2013) which summarizes any key scientific advances in understanding the climate effects of PM since the previous report. As in the last review, the ISA draws substantially on the IPCC report to summarize climate effects. As discussed in more detail in the proposal (85 FR 24131, April 30, 2020), the general conclusions are similar between the IPCC AR4 and AR5 reports with regard to effects of PM on global climate. Consistent with the evidence available in the last review, the key components, including sulfate, nitrate, organic carbon (OC), black carbon (BC), and dust, that contribute to climate processes vary in their reflectivity, forcing efficiencies, and direction of forcing. Since the last review, the evidence base has expanded with respect to the mechanisms of climate responses and feedbacks to PM radiative forcing; however, the new literature published since the last review does not reduce the considerable uncertainties that continue to exist related these mechanisms.

As described in the proposal (85 FR 24133, April 30, 2020), PM has a very heterogeneous distribution globally and patterns of forcing tend to correlate with PM loading, with the greatest forcings centralized over continental regions. The climate response to this PM forcing, however, is more complicated since the perturbation to one climate variable (*e.g.,* temperature, cloud cover, precipitation) can lead to a cascade of effects on other variables. While the initial PM radiative forcing may be concentrated regionally, the eventual climate response can be much broader spatially or be concentrated in remote regions, and may be quite complex, affecting multiple climate variable with possible differences in the direction of the forcing in different regions or for different variables (U.S. EPA, 2019, section 13.3.6). The complex climate system interactions lead to variation among climate models, which have suggested a range of factors which can influence large-scale meteorological processes and may affect temperature, including local feedback effects involving soil moisture and cloud cover, changes in the hygroscopicity of the PM, and interactions with clouds (U.S. EPA, 2019, section 13.3.7). Further research is needed to better characterize the effects of PM on regional climate in the U.S. before PM climate effects can be quantified.

iii. Materials

Consistent with the last review, the current evidence continues to support the conclusion that there is a causal relationship between PM deposition and materials effects. Effects of deposited PM, particularly sulfates and nitrates, to materials include both physical damage and impaired aesthetic qualities, generally involving soiling and/or corrosion (U.S. EPA, 2019, section 13.4.2; 85 FR 24133, April 30, 2020). Because of their electrolytic, hygroscopic, and acidic properties and their ability to sorb corrosive gases, particles contribute to materials damage by adding to the effects of natural weathering processes, by potentially promoting or accelerating the corrosion of metals, degradation of painted surfaces, deterioration of building materials, and weakening of material components.[76] There is a limited amount of new data for consideration in this review from studies primarily conducted outside of the U.S. on buildings and other items of cultural heritage. However, these studies involved concentrations PM in ambient air greater than those typically observed in the U.S. (U.S. EPA, 2019, section 13.4).

Building on the evidence available in the 2009 ISA, and as described in detail in the proposal (85 FR 24134, April 30, 2020) and in the 2019 ISA (U.S. EPA, 2019, section 13.4), research has progressed on: (1) The theoretical understanding of soiling of items of cultural heritage; (2) the quantification of degradation rates and further characterization of factors that influence damage of stone materials; (3) materials damage from PM components besides sulfate and black carbon and atmospheric gases besides SO_2; (4) methods for evaluating soiling of materials by PM mixtures; (5) PM-attributable damage to other materials, including glass and photovoltaic panels; (6) development of dose-response relationships for soiling of building materials; and (7) damage functions to quantify material decay as a function of pollutant type and load. While the evidence of PM-related materials effects has expanded somewhat since the last review, there remains insufficient evidence to relate soiling or damage to specific PM levels in ambient air or to establish a quantitative relationship between PM and materials degradation. The current evidence is generally similar to the evidence available in the last review, including associated limitations and uncertainties and a lack of evidence to inform quantitative relationships between PM and materials effects, therefore leading to similar conclusions about the PM-related effects on materials.

3. Overview of Air Quality and Quantitative Information

a. Visibility Effects

In the current review, quantitative analyses were conducted to further our understanding of the relationship between recent air quality and calculated light extinction. As at the time of the last review, these analyses explored this relationship as an estimate of visibility impairment in terms of the 24-hour $PM_{2.5}$ standard and the visibility index. Generally, the results of the updated analyses are similar to those based on the data available at the time of the last review (U.S. EPA, 2020, section 5.2.1.1). Compared to the last review, updated analyses incorporate several refinements, including: (1) The evaluation of three versions of the IMPROVE equation [77] to calculate light extinction (U.S. EPA, 2020, Appendix D, Equations D–1 through D–3) in order to better understand the influence of variability in equation inputs; [78] (2) the

[75] Radiative forcing (RF) for a given atmospheric constituent is defined as the perturbation in net radiative flux, at the tropopause (or the top of the atmosphere) caused by that constituent, in watts per square meter (Wm^{-2}), after allowing for temperatures in the stratosphere to adjust to the perturbation but holding all other climate responses constant, including surface and tropospheric temperatures (Fiore et al., 2015; Myhre et al., 2013). A positive forcing indicates net energy trapped in the Earth system and suggests warming of the Earth's surface, whereas a negative forcing indicates net loss of energy and suggests cooling (U.S. EPA, 2019, section 13.3.2.2).

[76] As discussed in the ISA (U.S. EPA, 2019, section 13.4.1), corrosion typically involves reactions of acidic PM (*i.e.,* acidic sulfate or nitrate) with material surfaces, but gases like SO_2 and nitric acid (HNO_3) also contribute. Because ''the impacts of gaseous and particulate N and S wet deposition cannot be clearly distinguished'' (U.S. EPA, 2019, p. 13–1), the assessment of the evidence in the ISA considers the combined impacts.

[77] Given the lack of new information to inform a different visibility metric, the metric used in the updated analyses is that defined by the EPA in the last review as the target level of protection for visibility (discussed above in section IV.A.1): A $PM_{2.5}$ visibility index with a 24-hour averaging time, a 90th percentile form averaged over 3 years, and a level of 30 dv (U.S. EPA, 2020, section 5.2.1.2).

[78] While the $PM_{2.5}$ monitoring network has an increasing number of continuous FEM monitors reporting hourly $PM_{2.5}$ mass concentrations, there continue to be data quality uncertainties associated with providing hourly $PM_{2.5}$ mass and component measurements that could be input into IMPROVE equation calculations for sub-daily visibility impairment estimates. As detailed in the PA, there are uncertainties associated with the precision and

use of 24-hour relative humidity data, rather than monthly average relative humidity as was used in the last review (U.S. EPA, 2020, section 5.2.1.2, Appendix D); and (3) the inclusion of the coarse fraction in the estimation of light extinction in the subset of areas with $PM_{10-2.5}$ monitoring data available for the time period of interest (U.S. EPA, 2020, section 5.2.1.2, Appendix D). The analyses in the current review are updated from the last review and include 67 monitoring sites that measure $PM_{2.5}$, including 20 sites that measure both PM_{10} and $PM_{2.5}$, that are geographically distributed across the U.S. in both urban and rural areas (U.S. EPA, 2020, Appendix D, Figure D–1).

In areas that meet the current 24-hour $PM_{2.5}$ standard for the 2015–2017 time period, all sites have light extinction estimates at or below 27 dv using the original and revised IMPROVE equations (and most areas are below 25 dv; U.S. EPA, 2020, section 5.2.1.2). In the one location that exceeds the current 24-hour $PM_{2.5}$ standard, light extinction estimates are at or below 27 dv (U.S. EPA, 2020, Figure 5–3). These findings are consistent with the findings of the analysis in the last review with older air quality data (Kelly et al., 2012b; 78 FR 3201, January 15, 2013).

Using the recently modified IMPROVE equation from Lowenthal and Kumar (2016), new in this review, the resulting 3-year visibility index is slightly higher at all of the sites compared to the original and revised IMPROVE equation estimates (U.S. EPA, 2020, Figure 5–4). These higher estimates are to be expected, given the higher OC multiplier included in the IMPROVE equation from Lowenthal and Kumar (2016), which reflects the use of data from remote areas with higher concentrations of organic PM when validating the equation. As such, it is important to note that the Lowenthal and Kumar (2016) version of the equation may overestimate light extinction in non-remote areas, including the urban areas in the updated analyses in this review.

Nevertheless, when light extinction is calculated using the Lowenthal and Kumar (2016) equation for those sites that meet the current 24-hour $PM_{2.5}$ standard, the 3-year visibility metric is generally at or below 30 dv. The one exception to this is a site in Fairbanks, Alaska that just meets the current 24-hour $PM_{2.5}$ standard in 2015–2017 and has a 3-year visibility index value just above 30 dv, rounding to 31 dv (compared to 27 dv when light extinction is calculated with the original IMPROVE equations) (U.S. EPA, 2020, Appendix D, Table D–3). The unique conditions at this urban site (*e.g.,* higher OC concentrations, much lower temperatures, and the complete lack of sunlight for long periods) that affect quantitative relationships between OC, OM and visibility (*e.g.,* Hand et al., 2012; Hand et al., 2013) may differ considerably from those under which the Lowenthal and Kumar (2016) equation has been evaluated, making the most appropriate approach for characterizing light extinction in this area unclear.

At the time of the last review, the EPA noted that $PM_{2.5}$ is the size fraction of PM responsible for most of the visibility impairment in urban areas (77 FR 38980, June 29, 2012). Data available at the time of the last review suggested that $PM_{10-2.5}$ was a minor contributor to visibility impairment (U.S. EPA, 2010b), although this fraction may be responsible for a larger contribution in some areas in the desert southwestern region of the U.S. However, at the time of the last review, there was very little data available from $PM_{10-2.5}$ monitors to quantify the contribution of coarse PM to calculated light extinction.

Since the last review, the expansion of $PM_{10-2.5}$ monitoring efforts has increased the availability of data for use in estimating light extinction. As such, both $PM_{2.5}$ and $PM_{10-2.5}$ concentrations can be included as inputs in the equations in the updated analyses in this review. For 2015–2017, 20 of the 67 $PM_{2.5}$ sites analyzed have collocated $PM_{10-2.5}$ monitoring data available. These 20 sites meet both the 24-hour $PM_{2.5}$ and 24-hour PM_{10} standards. All of these sites have 3-year visibility metrics at or below 30 dv regardless of whether light extinction is calculated with or without the coarse fraction, and for all three versions of the IMPROVE equation. Generally, the coarse fraction contribution to light extinction is minimal, contributing less than 1 dv to the 3-year visibility metric. The 20 locations with collocated $PM_{2.5}$ and $PM_{10-2.5}$ monitoring data available in this review would be expected to have relatively low concentrations of coarse PM. In areas with higher concentrations of coarse PM, such as the southwestern U.S., the coarse fraction may be a more important contributor to light extinction and visibility impairment than in the locations included in the updated analyses in this review.

Overall, the results of the updated analyses in this review are consistent with those in the last review. The 3-year visibility metric is generally at or below 27 dv in areas that meet the current secondary standards, with only small differences observed for the three versions of the IMPROVE equation. Though such differences are modest, the IMPROVE equation from Lowenthal and Kumar (2016) results in higher light extinction values, which were expected given the higher OC multiplier in the equation and its validation using data from remote areas far away from emission sources. There are only small differences in estimates of light extinction when the coarse fraction is included in the equation, although a somewhat larger coarse fraction contribution to light extinction would be expected in areas with higher concentrations of coarse PM. Overall, the updated analyses indicate that the current secondary PM standards provide a degree of protection against visibility impairment similar to the target level of protection identified in the last review, in terms of a 3-year visibility index.

b. Non-Visibility Effects

Consistent with the evidence available at the time of the last review, and as described in detail in the PA (U.S. EPA, 2020, section 5.2.2.2), the data remain insufficient to conduct quantitative analyses for PM effects on climate and materials. For PM-related climate effects, as explained in more detail in the proposal (85 FR 24131–24133, 24136, April 30, 2020), our understanding of PM-related climate effects is still limited by significant key uncertainties. The newly available evidence does not appreciably improve our understanding of the spatial and temporal heterogeneity of PM components that contribute to climate forcing (U.S. EPA, 2020, sections 5.2.2.1.1 and 5.4). Significant uncertainties also persist related to quantifying the contributions of PM and PM components to the direct and indirect effects on climate forcing, such as changes to the pattern of rainfall, changes to wind patterns, and effects on vertical mixing in the atmosphere (U.S. EPA, 2020, sections 5.2.2.1.1 and 5.4). Additionally, while improvements have been made to climate models since the time of the last review, the models continue to exhibit variability in estimates of the PM-related climate effects on regional scales (*e.g.,* ~100 km) compared to simulations at the global scale (U.S. EPA, 2020, sections 5.2.2.1.1 and 5.4). While our understanding of

bias of 24-hour $PM_{2.5}$ measurements (U.S. EPA, 2020, p. 2–18), as well as to the fractional uncertainty associated with 24-hour PM component measurements (U.S. EPA, 2020, p. 2–21). Given the uncertainties present when evaluating data quality on a 24-hour basis, the uncertainty associated with sub-daily measurements may be even greater. Therefore, the inputs to these light extinction calculations are based on 24-hour average measurements of $PM_{2.5}$ mass and components, rather than sub-daily information.

climate forcing on a global scale is somewhat expanded since the last review, significant limitations remain to quantifying potential adverse PM-related climate effects in the U.S. and how they would vary in response to incremental changes in PM concentrations across the U.S. As such, while new research is available on climate forcing on a global scale, the remaining limitations and uncertainties are significant, and the new global scale research does not translate directly for use at regional spatial scales. Therefore, the evidence does not provide a clear understanding at the necessary spatial scales for quantifying the relationship between PM mass in ambient air and the associated climate-related effects in the U.S. that would be most relevant to informing consideration of a national PM standard on climate in this review (U.S. EPA, 2020, section 5.2.2.2.1; U.S. EPA, 2019, section 13.3).

For PM-related materials effects, as explained in more detail in the proposal (85 FR 24133–24134, 24137, April 30, 2020), the available evidence has been somewhat expanded to include additional information about the soiling process and the types of materials impacted by PM. This evidence provides some limited information to inform dose-response relationships and damage functions associated with PM, although most of these studies were conducted outside of the U.S. where PM concentrations in ambient air are typically above those observed in the U.S. (U.S. EPA, 2020, section 5.2.2.1.2; U.S. EPA, 2019, section 13.4). The evidence available in this review also includes studies examining effects of PM on the energy efficiency of solar panels and passive cooling building materials, although the evidence remains insufficient to establish quantitative relationships between PM in ambient air and these or other materials effects (U.S. EPA, 2020, section 5.2.2.1.2). While the available evidence is somewhat expanded since the time of the last review, quantitative relationships have not been established for PM-related soiling and corrosion and frequency of cleaning or repair that would help inform our understanding of the public welfare implications of materials effects (U.S. EPA, 2020, section 5.2.2.2.2; U.S. EPA, 2019, section 13.4). Therefore, there is insufficient information to inform quantitative analyses assessing materials effects to inform a consideration of a national PM standard on materials in this review (U.S. EPA, 2020, section 5.2.2.2.2; U.S. EPA, 2019, section 13.4).

B. Conclusions on the Secondary Standards

In drawing conclusions on the adequacy of the current secondary PM 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 last review and reflects upon the body of information and evidence available in this review. In so doing, the Administrator has taken into account both evidence-based and quantitative information-based considerations, as well as advice from the CASAC and public comments. Evidence-based considerations draw upon the EPA's assessment and integrated synthesis of the scientific evidence from studies evaluating welfare effects related to visibility, climate, and materials associated with PM in ambient air as discussed in the PA (summarized in sections IV..B, V.C, and IV.D.1 of the proposal, and section IV.A.2 above). The quantitative information-based considerations draw from the results of the quantitative analyses of visibility impairment presented in the PA (as summarized in section IV.D.1 of the proposal and section IV.A.3 above) and consideration of these results in the PA.

Consideration of the evidence and quantitative information in the PA and by the Administrator is framed by consideration of a series of policy-relevant questions. Section IV.B.2 below summarizes the rationale for the Administrator's proposed decision, drawing from section IV.D.3 of the proposal. The advice and recommendations of the CASAC and public comments on the proposed decision are addressed below in sections IV.D.2 and IV.D.3, respectively. The Administrator's conclusions in this review regarding the adequacy of the secondary PM standards and whether any revisions are appropriate are described in section IV.D.4.

1. CASAC Advice in This Review

In comments on the draft PA, the CASAC concurred with the staff's overall preliminary conclusions that it is appropriate to consider retaining the current secondary standards without revision (Cox, 2019a). The CASAC ''finds much of the information . . . on visibility and materials effects of $PM_{2.5}$ to be useful, while recognizing that uncertainties and controversies remain about the best ways to evaluate these effects'' (Cox, 2019a, p. 13 of consensus responses). Regarding climate, while the CASAC agreed that research on PM-related effects has expanded since the last review, it also concluded that ''there are still significant uncertainties associated with the accurate measurement of PM to the direct and indirect effects of PM on climate'' (Cox, 2019a, pp. 13–14 of consensus responses). The committee recommended that the EPA summarize the ''current scientific knowledge and quantitative modeling results for effects of reducing $PM_{2.5}$'' on several climate-related outcomes (Cox, 2019a, p. 14 of consensus responses), while also recognizing that ''it is appropriate to acknowledge uncertainties in climate change impacts and resulting welfare impacts in the United States of reductions in $PM_{2.5}$ levels'' (Cox, 2019a, p. 14 of consensus responses). When considering the overall body of scientific information for PM-related effects on visibility, climate, and materials, the CASAC agreed that ''the available evidence does not call into question the protection afforded by the current secondary PM standards and concurs that they should be retained'' (Cox, 2019a, p. 3 of letter).

2. Basis for the Proposed Decision

At the time of the proposal, the Administrator carefully considered the assessment of the current evidence and conclusions reached in the ISA; the currently available quantitative information, including associated limitations and uncertainties, described in detail and characterized in the PA; considerations and staff conclusions and associated rationales presented in the PA; and the advice and recommendations from the CASAC (85 FR 24137, April 30, 2020).

In reaching his proposed decision on the secondary PM standards, the Administrator first recognized the longstanding body of evidence for PM-related visibility impairment. The Administrator recognized that visibility impairment can have implications for people's enjoyment of daily activities and for their overall sense of well-being. In so doing, and consistent with the approach used in the last review (section IV.A.1 above), the Administrator first defined a target level of protection in terms of a PM visibility index that accounts for the factors that influence the relationship between PM in ambient air and visibility (*i.e.,* size fraction, species composition, and relative humidity). He then considered air quality analyses examining the relationship between this PM visibility index and the current 24-hour $PM_{2.5}$ and 24-hour PM_{10} standards in areas that met data completeness criteria for inclusion in the analyses.[79]

To identify a target level of protection, the Administrator first defined the specific characteristics of the visibility index, noting that in the last review, the EPA used an index based on estimates of light extinction by $PM_{2.5}$ components calculated using the IMPROVE algorithm. As described in section IV.A.2 above, the IMPROVE algorithm estimates light extinction using routinely monitored components of $PM_{2.5}$ and $PM_{10-2.5}$,[80] along with estimates of relative humidity. The Administrator recognized that, despite revisions to the IMPROVE algorithm since the last review (U.S. EPA, 2020, section 5.2.1.1), our fundamental understanding of the relationship between PM in ambient air and light extinction has changed little and that the various IMPROVE algorithms can appropriately reflect this relationship across the U.S. In the absence of a robust monitoring network to measure light extinction (85 FR 24130, 24135, April 30, 2020), the Administrator judged that estimated light extinction, as calculated using the IMPROVE algorithms, continued to provide a reasonable basis for defining a target level of protection against PM-related visibility impairment in the current review.

In further defining the characteristics of a visibility index based on estimates of light extinction, the Administrator considered the appropriate averaging time, form, and level of the index. The Administrator judged that the decisions made in the last review with regard to averaging time and form remain reasonable. In the last review, a 24-hour averaging time was judged to be an appropriate surrogate for the sub-daily periods relevant for visual perception,[81] recognizing the relatively strong correlations between 24-hour and sub-daily (*i.e.,* 4-hour) average $PM_{2.5}$ light extinction and that this longer averaging time may be less influenced by atypical conditions and/or atypical instrument performance (78 FR 3226, January 15, 2013). In the decision to set the form as the 3-year average of annual 90th percentile values in the last review, it was noted that: (1) A 3-year average provided stability from the occasional effect of interannual meteorological variability (78 FR 3198, January 15, 2013); (2) the 90th percentile corresponds to the 20 percent worst days for visibility, which are targeted in Class I areas by the Regional Haze program; and (3) available studies on people's visibility preferences did not identify a basis for a different target than that identified for Class I areas (U.S. EPA, 2011, p. 4–59). Recognizing that the information available in the current review is similar to that available in the last review, at the time of proposal the Administrator judged that these decisions remain reasonable, and it remains appropriate to define a visibility index based on estimated light extinction in terms of a 24-hour averaging time and a form based on the 3-year average of annual 90th percentile values.

At the time of the last review, the level of the visibility index was set at 30 dv, based on the upper end of the range of levels of visibility impairment judged to be acceptable by at least 50% of study participants in the available visibility preference studies (U.S. EPA, 2020, section 5.2.1.1). (78 FR 3226–27, January 15, 2013; 85 FR 24131 April 30, 2020).[82] In the last review, the Administrator concluded that the substantial degree of variability and uncertainty in the public preference studies should be reflected in a target protection level at the upper end of the 20 dv to 30 dv range of CPLs. Therefore, she concluded that it was appropriate to set a target level of protection in terms of a 24-hour $PM_{2.5}$ visibility index at 30 dv (78 FR 3226–27, January 15, 2013).

In considering the preference studies in this review, the Administrator first noted that, as a part of the last review, a range of levels was identified for the $PM_{2.5}$ visibility index based on an aggregated evaluation of the results of these studies that reflected variability in levels of visibility that were considered acceptable in the four study areas (U.S. EPA, 2010b). Because no visibility preference studies have been conducted in the U.S. since the last review, and given the general lack of new preference studies over the last several reviews, the Administrator proposed to conclude that the range considered in the last review remained appropriate to consider in the current review.

The Administrator highlighted the following uncertainties and limitations in the underlying public preference studies (U.S. EPA, 2020, section 5.2.1.1), consistent with those identified in the last review:

• The available studies may not capture the full range of visibility preferences in the U.S. population, particularly given the potential for preferences to vary based on the visibility conditions commonly encountered and the types of scenes being viewed.

• The available preference studies were conducted 15 to 30 years ago and may not reflect visibility preferences in the U.S. population today.

• The available preference studies have used a variety of methods, potentially influencing responses as to what level of visibility impairment is deemed acceptable.

• Factors that are not captured by the methods used in available preference studies may influence people's judgments on acceptable visibility, including the duration of visibility impairment, the time of day during which light extinction is greatest, and the frequency of episodes of visibility impairment.

After considering these preference studies, along with their inherent uncertainties and limitations, the Administrator judged in the proposal that a level of 30 dv continued to be an appropriate target level of protection for the visibility index in the current review.[83]

Having defined a target level of protection in terms of a visibility index based on the elements described above, (*i.e.,* with a 24-hour averaging time; a 3-year average of the annual 90th

[79] As described in detail in section IV.A.3.a above, the EPA's updated quantitative analyses in this review included 67 areas that met data completeness criteria for inclusion in the analyses (see U.S. EPA, 2020, Appendix D for details of the criteria). Of those monitoring locations that met the data completeness criteria, all but one location met the current secondary $PM_{2.5}$ standard (U.S. EPA, 2020, Table D–7).

[80] In the last review, the focus was on $PM_{2.5}$ components given their prominent role in PM-related visibility impairment in urban areas and the limited data available for $PM_{10-2.5}$ (77 FR 38980, June 29, 2010; U.S. EPA, 2020, section 5.2.1.2).

[81] While the $PM_{2.5}$ monitoring network has an increasing number of continuous FEM monitors reporting hourly $PM_{2.5}$ mass concentrations, there continue to be data quality uncertainties associated with providing hourly $PM_{2.5}$ mass and component measurements that could be input into IMPROVE equation calculations for sub-daily visibility impairment estimates. As detailed in the PA, there are uncertainties associated with the precision and bias of 24-hour $PM_{2.5}$ measurements (U.S. EPA, 2020, p. 2–18), as well as to the fractional uncertainty associated with 24-hour PM component measurements (U.S. EPA, 2020, p. 2–21). Given the uncertainties present when evaluating data quality on a 24-hour basis, the uncertainty associated with sub-daily measurements may be even greater. Therefore, the inputs to these light extinction calculations are based on 24-hour average measurements of $PM_{2.5}$ mass and components, rather than sub-daily information.

[82] Based on the preference studies, the 2011 PA identified a range of levels from 20 to 30 deciviews (dv) as being a reasonable range of ''candidate protection levels'' or ''CPLs'' for a visibility index (U.S. EPA, 2011, p. 4–61; U.S. EPA, 2020, section 5.2.1.1).

[83] As noted above, in the last review, the Administrator explained that the current substantial degrees of variability and uncertainty inherent in the public preference studies should be reflected in a higher target protection level than would be appropriate if the underlying information were more consistent and certain (78 FR 3216, January 15, 2013).

percentile form; and a level of 30 dv), the Administrator next considered the degree of protection from visibility impairment afforded by the existing secondary standards. In so doing, he considered the updated analyses of PM-related visibility impairment (U.S. EPA, 2020, section 5.2.1.2), specifically noting the improvements over the analyses in the last review, in particular the use of multiple versions of the IMPROVE algorithm, including the version incorporating revisions since the last review (85 FR 24135–24136, April 30, 2020). The analyses in this review expand upon our understanding of how variation in equation inputs impacts calculated light extinction (U.S. EPA, 2020, Appendix D) and also better characterizes the influence of the coarse fraction on light extinction for the subset of sites with available $PM_{10-2.5}$ monitoring data (U.S. EPA, 2020, section 5.2.1.2).

The Administrator noted that the results of the updated analyses are consistent with the results from the last review, regardless of the IMPROVE equation used. The results of the analyses demonstrated that, in areas meeting the 24-hour $PM_{2.5}$ standard, the 3-year visibility metric is at or below about 30 dv,[84] and is below 25 dv in most of the areas. In those locations with $PM_{10-2.5}$ monitoring data available, which met both the current 24-hour $PM_{2.5}$ and 24-hour PM_{10} standards, 3-year visibility metrics were at or below 30 dv regardless of if the coarse fraction was included in the calculation (U.S. EPA, 2020, section 5.2.1.2). In considering these updated analyses, the Administrator proposed to conclude that the scientific and quantitative information available in this review support the adequacy of the current secondary $PM_{2.5}$ and PM_{10} standards to protect against PM-related visibility impairment.

With respect to non-visibility welfare effects, the Administrator considered the evidence related to climate and materials effects and proposed to conclude that it is generally appropriate to retain the existing secondary standards and that it is not appropriate to establish any distinct secondary PM standards to address non-visibility PM-related welfare effects. With regard to climate, the Administrator recognized that a number of improvements and refinements have been made to climate models since the last review, while also noting that significant limitations continue to exist in quantifying the contributions of the direct and indirect effects of PM and PM components on climate forcing (85 FR 24139, April 30, 2020; U.S. EPA, 2020, sections 5.2.2.1.1 and 5.4). The Administrator also recognized that climate models continue to exhibit considerable variability in estimates of PM-related climate impacts at regional scales (*e.g.,* ~100 km) compared to simulations at global scales (85 FR 24139, April 30, 2020; U.S. EPA, 2020, section 5.2.2.1.1 and 5.4). In considering this uncertainty, the Administrator proposed to conclude that the scientific information available in the current review remains insufficient to quantify the impacts of ambient PM on climate in the U.S. with confidence (85 FR 34139, April 30, 2020; U.S. EPA, 2020, sections 5.2.2.1.1 and 5.4) and that there is insufficient information available in this review to base a national ambient air quality standard on climate impacts.

With respect to materials effects, the Administrator recognized that deposition of fine or coarse particles can result in physical damage and/or impaired aesthetic qualities. Particles can contribute to materials damage by adding to the effects of weathering processes and by promoting the corrosion of metals, the degradation of painted surfaces, the deterioration of building materials, and the weakening of material components. The Administrator, while recognizing that some new evidence of PM-related materials effects is available in this review, noted that this evidence is primarily from studies conducted outside of the U.S. with PM concentrations that are higher than those typically observed in ambient air in the U.S. (U.S. EPA, 2019, section 13.4). Consistent with the information available at the time of the last review, the Administrator recognized a limited amount of information available on the quantitative relationships between PM and materials effects in the U.S., and uncertainties in the degree to which those effects could be adverse to public welfare. Therefore, at the time of proposal, the Administrator judged that the scientific information available in this review remains insufficient to quantify the public welfare impacts of PM in ambient air on materials with confidence and that there is insufficient information available in this review to support a distinct national ambient standard based on materials effects.

Thus, based on consideration of the scientific and quantitative information available in this review, with its uncertainties and limitations, and information that might inform his public welfare judgments, as well as consideration of advice from the CASAC, including their concurrence with the PA conclusions that the current evidence does not support revision of the secondary PM standards (discussed in section IV.B.1 above). The Administrator proposed to conclude that it is appropriate to retain the current secondary PM standards without revision based on his judgment that the current secondary PM standards are requisite to protect against PM-related effects on visibility and that there is insufficient information available in this review to base a national ambient air quality standard for PM on climate and materials impacts.

3. Comments on the Proposed Decision

Of the public comments received on the proposal, very few were specific to the secondary PM standards. Of those commenters who did provide comments on the secondary PM standards, the majority support the Administrator's proposed decision to retain the current standards. Some commenters disagree with the Administrator's proposed conclusion to retain the current secondary standards, primarily focusing their comments on the need for a revised standard to protect against visibility impairment. In addition to the comments addressed in this notice, the EPA has prepared a Response to Comments document that addresses other specific comments related to setting the secondary PM standards. This document is available for review in the docket for this rulemaking and through the EPA's NAAQS website (*https://www.epa.gov/naaqs/particulate-matter-pm-air-quality-standards*).

Of the comments addressing the proposed decision, many of the commenters support the Administrator's proposed decision to retain the current secondary PM standards, without revision. This group includes industries and industry groups and state and local governments and organizations. All of these commenters generally note their agreement with the rationale provided in the proposal and with the views expressed by the CASAC that the current evidence does not support revision to the standards. Most also cite the EPA and CASAC statements that the scientific evidence and quantitative information in this review has not substantially altered our previous

[84] As discussed above and in the PA (U.S. EPA, 2020, section 5.2.1.2), one site in Fairbanks, Alaska just meets the current 24-hour $PM_{2.5}$ standard and has a 3-year visibility index value of 27 dv based on the original IMPROVE equation and 31 dv based on the Lowenthal and Kumar (2016) equation. At this site, use of the Lowenthal and Kumar (2016) equation may not be appropriate given that PM composition and meteorological conditions may differ considerably from those under which revisions to the equation have been validated.

understanding of the effects of PM on visibility, climate, and materials beyond what was previously examined and does not call into question the adequacy of the current standards. They all find the proposed decision to retain the current standards to be well supported and a reasonable exercise of the Administrator's public welfare policy judgment under the CAA. The EPA agrees with these comments and with the CASAC advice regarding the adequacy of the current secondary PM standards and the lack of support for revision of these standards.

Of the commenters who disagree with the proposal to retain the current standards, nearly all of these commenters recommend more stringent standards, primarily to protect against visibility impairment. These comments were submitted primarily by national public health, medical, and environmental nongovernmental organizations, and some individuals. The commenters who recommend strengthening the standards state their support for revisions to provide greater public welfare protection, generally claiming that the current standards are inadequate and do not provide the requisite protection against known or anticipated welfare effects. Additionally, some of the commenters who disagree with the proposal did not specifically recommend revising the current standards, but instead recommend additional research to address key uncertainties and limitations in the available scientific and quantitative information that would inform decisions regarding a national standard to protect against PM-related non-visibility and visibility effects.

The EPA received relatively few comments on the proposed decision that it is not appropriate to establish any distinct secondary PM standards to address PM-related climate effects. The majority of the comments that were received agree with the EPA that the currently available information is not sufficient for supporting quantitative analyses for the climate effects of PM in ambient air. These commenters support the Administrator's proposed decision not to set a distinct standard for climate. Several commenters note, however, that the EPA should frequently reconsider the available evidence and quantitative information and should revise the standard as necessary to provide requisite protection against PM-related climate effects. The EPA agrees with the commenters that quantitative analyses of the relationship between PM and climate effects are not supported by the available information in this review, and new information about PM-related welfare effects, including climate, will be assessed consistent with CAA requirements in the next review of the PM NAAQS.

There were also very few commenters who commented on the proposed decision that it is not appropriate to establish any distinct secondary PM standards to address PM-related material effects. As with comments on climate effects, commenters generally agree with the EPA that the evidence is not sufficient to support quantitative analyses for PM-related materials effects. However, some commenters contend that the EPA failed to consider the following information: (1) Studies conducted outside of the U.S. on the cost of soiling of materials that are also found in the U.S.; (2) recent work related to soiling of photovoltaic modules and other surfaces, and; (3) quantitative relationships between PM in ambient air and materials effects used in several studies. These commenters further assert that the EPA failed to specify a level of air quality that protects against adverse effects of PM on materials and failed to propose a standard that provides requisite protection against materials effects attributable to PM.

We disagree with the commenters that the EPA failed to consider the relevant scientific information about materials effects available in this review. As an initial matter, the ISA considered and included studies related to materials effects of PM, including studies conducted in and outside of the U.S., on newly studied materials including photovoltaic modules that were published prior to the cutoff date for the literature search.[85] These include the Besson et al. (2017) study referenced by the commenters (U.S. EPA, 2019, section 13.4.2). The Grøntoft et al. (2019) study referenced by the same commenters was published after the cutoff date for the literature search. However, the EPA has provisionally considered new studies, including the new studies highlighted by the commenters, in the context of the findings of the ISA (see Appendix in Response to Comments document).[86] Based on this provisional consideration, the EPA concludes that the new studies are not sufficient to alter the conclusions reached in the ISA regarding PM and materials effects.

Moreover, we disagree with the commenters that the EPA failed to consider quantitative information from studies available in this review. As detailed in section 5.2.2.1.2 of the PA, a number of new studies are available that apply new methods to characterize PM-related effects on previously studied materials; however, the evidence remains insufficient to relate soiling or damage to specific levels of PM in ambient air or to establish quantitative relationships between PM and materials degradation. The uncertainties in the evidence identified in the last review persist in the evidence in the current review, with significant uncertainties and limitations to establishing quantitative relationships between particle size, concentration, chemical components, and frequency of painting or repair of materials. While some new evidence is available in this review, overall, the data are insufficient to conduct quantitative analyses for PM-related materials effects. Quantitative relationships have not been established between characteristics of PM and frequency of repainting or cleaning of materials, including photovoltaic panels and other energy-efficient materials, that would help inform our understanding of the public welfare implications of soiling (U.S. EPA, 2020, section 5.2.2.2.2; U.S. EPA, 2019, section 13.4). Similarly, the information does not support quantitative analyses between microbial deterioration of surfaces and the contribution of carbonaceous PM to the formation of black crusts that contribute to soiling (U.S. EPA, 2020, section 5.2.2.2.2; U.S. EPA, 2019, section 13.4). We also note that quantitative relationships are difficult to assess, in particular those characterized using damage functions as these approaches depend on human perception of the level of soiling deemed to be acceptable and evidence in this area remains limited in the current review (U.S. EPA, 2020, section 5.2.2.1.2). Additionally, we note the CASAC's concurrence with conclusions in the PA that uncertainties remain about the best way to evaluate materials effects of PM in ambient air (Cox, 2019a, p. 13 of consensus responses). Further, no new studies are available in this review to link human perception of reduced aesthetic appeal of buildings

[85] As noted earlier in section IV, ''the current ISA identified and evaluated studies and reports that that have undergone scientific peer review and were published or accepted for publication between January 1, 2009 and March 31, 2017. A limited literature update identified some additional studies that were published before December 31, 2017'' (U.S. EPA, 2019, Appendix, p. A–3).

[86] As discussed in section I.D, the EPA has provisionally considered studies that were highlighted by commenters and that were published after the ISA. These studies are generally consistent with the evidence assessed in the ISA, and they do not materially alter our understanding of the scientific evidence or the Agency's conclusions based on that evidence or warrant reopening of the air quality criteria.

and other objects to materials effects and PM in ambient air. Finally, uncertainties remain about deposition rates of PM in ambient air to surfaces and the interaction of PM with copollutants on these surfaces (U.S. EPA, 2020, p. 5–34).

As summarized above and in the proposal, the evidence in this review for PM effects on materials is not substantively changed from that in the last review. There continues to be a lack of evidence related to materials effects that establishes quantitative relationships and supports quantitative analyses of PM-related materials soiling or damage. While the information available in this review continues to support a causal relationship between PM in ambient air and materials effects (U.S. EPA, 2019, section 13.4), the EPA is unable to relate soiling or damage to specific levels of PM in ambient air and is unable to evaluate or consider a level of air quality to protect against such materials effects. Although the EPA did not propose a distinct level of air quality or a national standard based on air quality impacts (85 FR 24139, April 30, 2020), we did identify data gaps that prevented us from doing so. The EPA identified a number of key uncertainties and areas of future research (U.S. EPA, 2020, p. 5–42) that may inform consideration of the materials effects of PM in ambient air in future reviews of the PM NAAQS.

Commenters who disagreed with the Administrator's proposed decision to retain the current secondary PM standards provided a number of comments on the scientific evidence and quantitative analyses for visibility impairment. These commenters criticize various aspects of the EPA's proposal to retain the standards, including specific aspects of the visibility index, the target level of protection identified by the Administrator, and the appropriateness of a single national standard for purposes of protecting against PM-related visibility impairment. In general, these comments indicated support for a more stringent standard for visibility impairment, although the commenters did not necessarily specify the alternative standard that would, in their judgment, address the concerns raised. Rather, most of these commenters focused on particular aspects of the visibility metric underlying the current secondary standard, including the form, averaging time, and target level of protection necessary to protect against visibility impairment.

Several commenters argue that the evidence does not support a single level of ''acceptable'' visibility. Commenters expressed the view that the public preference studies present important evidence related to the importance of visibility, but that they do not provide enough information to set a national standard for visibility impairment because the results show that visibility preferences vary regionally and/or locally for a variety of reasons. Commenters additionally state that the EPA failed to explain and analyze the uncertainties associated with the public preference studies, including: (1) The different methods used in the studies and their influence on the responses; (2) the impact of different scenes being viewed on the full range of public preferences; and (3) factors that were not considered in the study methods that could impact judgments in the studies. These commenters suggest that the secondary standards should account for regional variability, although they did not provide specific recommendations regarding how to accomplish this.

The EPA agrees with commenters that the available scientific evidence indicates that public preferences for ''acceptable'' visibility and air quality depends in large part on the characteristics of the scene being viewed. The EPA understands that there is a wide range of urban and rural scenes within the U.S. and included in the public preference studies, including natural vistas such as the Rocky Mountains in Colorado and man-made urban structures such as the Washington Monument. However, the EPA disagrees with commenters that the available evidence cannot support a national standard to protect against PM-related visibility impairment. As at the time of the last review, the EPA believes that the scenes presented in the public preference studies include important types of valued scenic views, and therefore, when considered together, can inform consideration of an acceptable level of visual air quality at the national scale, taking into account variation across the U.S. as evidenced in the studies.

With regard to the comments that these studies do not provide enough information to account for regional variability that is important to consider when setting a national standard for visibility protection, the EPA recognizes that there may be regional variability in the available evidence but believes that these studies provide significant information that is useful for the Administrator to consider in his judgments on the public welfare implications of PM-related visibility effects. While the EPA acknowledges that there may be regional differences in the stated preferences for visibility, the EPA finds there is not enough information available at this time to take such regional differences into account. The commenter did not provide specific recommendations for the EPA's consideration of such information even if such information were available, and the EPA finds the question of how, or if, to account for regional preferences in setting a national standard is a substantial question that should be addressed when it is presented by the available information.

With regard to the commenters' assertion that the current secondary standards are inadequate to protect the public welfare from PM-related visibility impairment, the EPA disagrees that the currently available information is sufficient to suggest that a more stringent standard is warranted. The EPA identified and addressed in great detail the limitations and uncertainties associated with the public preference studies as a part of the last review (78 FR 3210, January 15, 2013). Given that the evidence related to public preferences is the same in this review as it was at the time of the last review, the EPA reiterated the limitations and uncertainties inherent in this evidence as a part of the PA (U.S. EPA, 2020, section 5.5). The PA highlights key uncertainties associated with public perception of visibility impairment and identifies areas for future research to inform future PM NAAQS reviews, including those raised by the commenters (U.S. EPA, 2020, p. 5–41). For example, the PA notes the critical need for information to further our understanding of human perception of visibility impairment in public preference studies in order to address uncertainties and limitations in the evidence, including an expansion of the number and geographic coverage of preference studies in urban, rural, and Class I areas to account for the potential for people to have different preferences based on the conditions that they commonly encounter and potential differences in preferences based on the scene types (U.S. EPA, 2020, p. 5–41).

These same commenters further argue that the EPA omitted recent studies that could further inform our understanding of the public welfare implications of visibility impairment. Commenters specifically point to a recent meta-analysis of available preference studies (Malm et al., 2019) and also cites to several related studies (Malm et al., 2011; Malm, 2013, 2016; Molenar and Malm, 2012). Commenters additionally contend that studies of the economic effects of impaired visibility were omitted from the ISA and PA and were not considered in the EPA's approach for evaluating visibility.

The EPA disagrees with the commenters that studies related to visibility were inappropriately omitted from the ISA in this review. As an initial matter, the ISA considered and included studies related to PM-related visibility impairment and public preferences that were published prior to the cutoff date for the literature search.[87] As described in the Preamble to the ISA, ''studies and reports that have undergone scientific peer review and have been published (or accepted for publication) are considered for inclusion in the ISA'' (U.S. EPA, 2015, p. 6). The meta-analysis by Malm et al. (2019) was published after the cutoff date for the literature search for the ISA, and therefore, was not included in the ISA. Malm et al. (2019) was provisionally considered, along with other studies published after the cut-off date, and the EPA concluded that these studies did not materially change the broad scientific conclusions of the ISA regarding welfare effects, including visibility impairment. Moreover, the other citations provided by the commenters (Malm et al., 2011; Malm, 2013, 2016; Molenar and Malm, 2012) are not peer-reviewed publications and as such do not meet the criteria for inclusion in the ISA. With regard to studies of economic effects, these studies were not considered to be within the scope of the ISA, and therefore were not included in this review (U.S. EPA, 2019, p. P–16). The studies submitted by the commenters, together with other new evidence, will be assessed consistent with CAA requirements in the next review of the PM NAAQS.

Some commenters contend that the EPA's visibility analyses only focused on locations that met the current standards. These commenters argue that the EPA concluded at the beginning of the analysis that the current standards do not need to be revised and that the EPA's approach ignores information available since the last review, leading to the Administrator to propose no revisions to the standards based on this flawed approach.

We disagree with commenters that the updated analyses of visibility impairment in this review only considered air quality in areas that meet the current standards. As described in detail in the PA, locations included in the analyses were those that met specific data completeness criteria for the monitoring data required as inputs to the IMPROVE equations for estimating light extinction (U.S. EPA, 2020, Appendix D). The data set used for the updated analyses is comprised of sites with data for the 2015–2017 period that supported a valid 24-hour $PM_{2.5}$ design value and met strict criteria for PM species. For $PM_{2.5}$ concentrations, data were screened so that all days either had a valid filter-based 24-hour concentration measurement or at least 18 valid hourly concentration measurements (U.S. EPA, 2020, section D.2.1.2).[88] For coarse PM concentrations, data were included for sites with ≥11 valid days for each quarter of 2015–2017. For $PM_{2.5}$ component concentrations, data were included for days with valid data for all chemical components listed in Table D–1 in the PA and for sites with ≥11 valid days for each quarter of 2015–2017.[89] Of all of the PM monitoring locations in the U.S., 67 monitoring sites met the data completeness criteria and light extinction was calculated without the coarse fraction in the IMPROVE equations. Of these 67 monitoring sites, 20 locations met the data completeness criteria for coarse PM, and as such, light extinction was also estimated with the coarse fraction as an input to the IMPROVE equation at these sites (U.S. EPA, 2020, section 5.2.1.2, Appendix D). For the sites that met the data completeness criteria for inclusion in the analyses, all of the sites met the annual $PM_{2.5}$ and 24-hour PM_{10} standards, and all but one site (located in southern California) met the 24-hour $PM_{2.5}$ standard. Therefore, we disagree with the commenters that the analysis was designed to consider only locations that met the current standards and did not consider locations that did not meet the current secondary PM standards. Moreover, the EPA notes that data from areas exceeding the current standard are generally of limited use in deciding whether to retain the standard, or lower it, because it is not representative or informative of circumstances and effects that would be expected to be seen upon attainment of the standard.

Furthermore, it is unclear what additional information the commenters contend that the EPA omitted from its consideration in this review. All scientific information available in this review has been considered and integrated as a part of the ISA. The Administrator, in considering the adequacy of the current secondary PM standards, considered the available scientific evidence and quantitative information in this review, along with CASAC advice and public comments, and concluded that the current secondary PM standards provide requisite protection against visibility impairment.

Some commenters additionally contend that the EPA's evaluation of public welfare effects of PM in the proposal solely focuses on fine PM and ignores coarse PM. These commenters assert that trends data show that coarse PM is increasing, which they believe to be a concern to public welfare.

We disagree with the commenters that the EPA's proposal failed to consider the public welfare implications of coarse PM. First, we note that there is limited new scientific evidence available in this review on climate- and materials-related effects of coarse PM beyond that of the last review (85 FR 24131, April 30, 2020). With regard to the contribution of coarse PM to visibility impairment, we first note that at the time of the last review, the EPA noted that $PM_{2.5}$ is the size fraction of PM responsible for most of the visibility impairment in urban areas (U.S. EPA, 2020, p. 5–22). Data available for $PM_{10-2.5}$ was very limited in the last review and was not used in quantitative analyses of estimated $PM_{2.5}$ light extinction (U.S. EPA, 2020, Appendix D, section D–1). Since the time of the last review, an expansion of $PM_{10-2.5}$ monitoring efforts has increased the availability of data for use in estimating light extinction with both fine and coarse fractions of PM. As described in the PA, the analyses of visibility impairment were updated in this review to include consideration of the coarse fraction of PM in estimating light extinction in the subset of areas with $PM_{10-2.5}$ monitoring data available for the time period of interest (U.S. EPA, 2020, section 5.2.1.2, Appendix D). The updated analyses in this review included 20 sites that measured both PM_{10} and $PM_{2.5}$ (U.S. EPA, 2020, section 5.2.1.2, Appendix D), all of which meet the current 24-hour $PM_{2.5}$ and PM_{10} standards. All of these sites have 3-year visibility at or below 30 dv regardless of whether light extinction is calculated

[87] As noted earlier in section IV, ''the current ISA identified and evaluated studies and reports that that have undergone scientific peer review and were published or accepted for publication between January 1, 2009 and March 31, 2017. A limited literature update identified some additional studies that were published before December 31, 2017'' (U.S. EPA, 2019, Appendix, p. A–3).

[88] A valid filter-based 24-hour concentration measurement is one collected via FRM, and that has undergone laboratory equilibration (at least 24 hours at standardized conditions of 20–23 °C and 30–40% relative humidity) prior to analysis (see Appendix L of 40 CFR part 50 for the 2012 NAAQS for PM).

[89] For coarse PM and $PM_{2.5}$ components, data completeness criteria were selected for the quantitative analyses consistent with those in Appendix N of 40 CFR part 50 for the 2012 NAAQS for PM.

with or without the coarse fraction, and for all three versions of the IMPROVE equation used in this review. Generally, the contribution of the coarse fraction of PM to light extinction in these locations was minimal, contributing less than 1 dv to the 3-year visibility metric (U.S. EPA, 2020, section 5.2.1.2, Appendix D). While there were not monitoring data available to evaluate the impact of coarse PM on estimates of light extinction in locations expected to have higher concentrations of coarse PM, the coarse fraction may be a more important contributor to light extinction and visibility impairment than in those areas included in the PA analyses in this review. As additional information and monitoring data become available to further evaluate the impact of coarse PM on estimates of light extinction in more locations, including geographical locations expected to have high concentrations of coarse PM, such information will be considered in a future PM NAAQS review.

Several commenters in support of revising the secondary PM standards to protect against visibility impairment, generally recommend revisions to elements of the secondary standard and visibility index (indicator, averaging time, form, and level) consistent with those supported by the CASAC and public comments in previous PM reviews. We address comments on the elements of a visibility index and a revised standard for visibility effects below.

With regard to an indicator for the secondary standards to protect against visibility impairment, a number of commenters suggest that the EPA failed to explain why the current indicator is adequate and pointed to recommendations from the CASAC in the PM reviews completed in 2012 and 2006 with regard to alternate indicators. As noted by the commenters, in the 2012 review, the CASAC recommended three alternate indicators for a secondary standard to protect against visibility impairment: (1) Using direct, continuous measurement of PM light extinction to support hourly or multi-hour daylight-only averaging time(s); (2) using PM speciation data to calculate seasonal (or monthly) regional species and relative humidity values to combine with the denser continuous $PM_{2.5}$ monitoring network to calculate hourly PM light extinction; or, (3) using hourly $PM_{2.5}$ as a basis for a sub-daily (hourly or multi-hour) daylight-only indicator, which would intentionally remove the variable influence of water from the regulatory metric. In the 2006 review, as noted by the commenters, the CASAC recommended a $PM_{2.5}$ mass indicator, coupled with revisions to the averaging time, form, and level of the standard, to protect against visibility impairment.

The EPA generally agrees with commenters that an indicator based on directly measured light extinction would provide the most direct link between PM in ambient air and PM-related visibility impairment. However, as noted in the proposal (85 FR 24138, April 30, 2020, sections IV.B.1 and IV.D.1), the Administrator concluded that in the absence of a monitoring network to directly measure light extinction, he judged that estimated light extinction, as calculated using the IMPROVE algorithms, continues to provide a reasonable basis for defining a target level of protection against PM-related visibility impairment in the current review. There has been little progress in development of such a monitoring network since the time of the last review when CASAC concluded that, in the absence of such a monitoring network, relying on a calculated $PM_{2.5}$ light extinction indicator based on $PM_{2.5}$ components and relative humidity represented a reasonable approach and that the inputs for calculating light extinction were readily available through existing monitoring networks and approved monitoring protocols (78 FR 3205, January 15, 2013). Further, in this review, the CASAC generally agreed with the EPA that the available evidence does not call into question the protection afforded by the current secondary PM standards and concurs that they should be retained.

With regard to the elements of the visibility index, in considering the adequacy of the current secondary PM standards to protect against visibility impairment, as described in the proposal (85 FR 24135, April 30, 2020), the Administrator first defined an appropriate target level of protection in terms of a PM visibility index. In defining this target level of protection, the Administrator first considered the indicator of such an index. He noted that, given the lack of availability of methods and an established network for directly measuring light extinction, a visibility index based on estimates of light extinction by $PM_{2.5}$ components derived from an adjusted version of the original IMPROVE algorithm would be most appropriate, consistent with the last review. As described in the proposal and above (section IV.A.2.a.i), the IMPROVE algorithm estimates light extinction using routinely monitored components of $PM_{2.5}$ and $PM_{10-2.5}$, along with estimates of relative humidity. The Administrator, while recognizing that some revisions to the IMPROVE algorithm have been made since the time of the last review, noted that the fundamental relationship between ambient PM and light extinction has changed very little and the different versions of the IMPROVE algorithms can appropriately reflect this relationship across the U.S. (85 FR 24138, April 30, 2020). As such, he judged that defining a target level of protection in terms of estimated light extinction continues to be a reasonable approach in the current review.

With regard to averaging time, commenters were critical of the 24-hour averaging time to protect against visibility impairment and argue for a sub-daily averaging time. While some comments clearly focused on the averaging time of the current secondary $PM_{2.5}$ standard, other comments were unclear as to whether they recommended a sub-daily averaging time for the secondary $PM_{2.5}$ standard or for the visibility index used in defining a target level of the protection. Nonetheless, all of these commenters contend that people do not perceive visibility impairment over a 24-hour period, but rather their perception of impairment ranges from minutes to multiday, and that daylight hours are much more important in terms of visibility impairment, particularly in urban areas. As with comments on the indicator of the standard, some commenters also point to previous CASAC advice on the need for a sub-daily standard.

In defining the characteristics of a visibility index, the EPA continues to believe that a 24-hour averaging time is reasonable. This is in part based on analyses conducted in the last review that showed relatively strong correlations between 24-hour and sub-daily (*i.e.,* 4-hour average) $PM_{2.5}$ light extinction from the analyses conducted in the last review (85 FR 24138, April 30, 2020; 78 FR 3226, January 15, 2013), indicating that a 24-hour averaging time is an appropriate surrogate for the sub-daily time periods relevant for visual perception. The EPA believes that these analyses continue to provide support for consideration of a 24-hour averaging time for the visibility index in this review. The EPA also recognizes that the longer averaging time may be less influenced by atypical conditions and/or atypical instrument performance (85 FR 24138, April 30, 2020; 78 FR 3226, January 15, 2013). When taken together, the available scientific information and updated analyses of calculated light extinction available in this review continue to support that a 24-hour averaging time is appropriate when defining a target level of protection against visibility impairment in terms of a visibility index.

Moreover, the EPA disagrees with commenters that a secondary $PM_{2.5}$ standard with a 24-hour averaging time does not provide requisite protection against the public welfare impacts of visibility impairment. At the time of the last review, the EPA recognized that hourly or sub-daily (*i.e.,* 4- to 6-hour) averaging times, within daylight hours and excluding hours with high relative humidity, are more directly related to the short-term nature of visibility impairment and the relevant viewing periods for segments of the viewing public than a 24-hour averaging time. At that time, the EPA agreed that a sub-daily averaging time would generally be preferable. However, the Agency noted significant data quality uncertainties associated with the instruments that would provide hourly $PM_{2.5}$ mass concentrations necessary to inform a sub-daily averaging time. These uncertainties, as described in the last review, included short-term variability in hourly data from available continuous monitoring methods, which would prohibit establishing a sub-daily averaging time (78 FR 3209, January 15, 2013). For all of these reasons, the EPA continues to believe that a sub-daily averaging time is not supported by the information available in this review.

With regard to the form of the visibility index, many of the commenters contend that the form used in evaluating visibility impairment is not appropriate. First, commenters contend that a 90th percentile form is too low and excludes too many days that could have visibility impairment. These same commenters also suggest that a 3-year average form is not justified and does not protect visibility and public welfare. These commenters also argue that the EPA failed to consider the 98th percentile form for the visibility index as a part of the proposal. Second, some commenters recommend a form for the visibility index within the range of 95th to 98th percentile, coupled with a multi-hour sub-daily averaging time, consistent with the CASAC advice in the 2006 review.

The EPA disagrees with these commenters on both points. With regard to the form of the visibility index, the EPA continues to conclude that a 3-year average of annual 90th percentile values is appropriate. In so doing, the EPA notes that a 3-year average form provides stability from the occasional effect of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year, consistent with the decision in the last review (78 FR 3198, January 15, 2013; U.S. EPA, 2011, p. 4–58). With regard to the annual statistical form to be averaged over 3-years, the EPA considers the evaluation in the 2010 UFVA of three different statistics: 90th, 95th, and 98th percentiles (U.S. EPA, 2010b, chapter 4). In considering the alternative statistical forms, the 2011 PA noted that the Regional Haze Program targets the 20 percent most impaired days for improvements in visual air quality in Federal Class I areas and that the median of the distribution of these 20 percent worst days would be the 90th percentile. The 2011 PA further noted that strategies that are implemented so that 90 percent of days would have visual air quality that is at or below the level of the standard would reasonably be expected to lead to improvements in visual air quality for the 20 percent most impaired days. Finally, the 2011 PA recognized that the public preference studies available at the time of the last review did not address frequency of occurrence of different levels of visibility and did not identify a basis for a different target for urban areas than for Federal Class I areas (U.S. EPA, 2011, p. 4–59). The analyses and considerations for the form of a visibility index from the 2011 PA continue to provide support for a 90th percentile form, averaged across three years, in defining the characteristics of a visibility index in this review.

Some commenters contend that the EPA's proposal to retain the level of 30 dv for a visibility index is arbitrary, capricious, and not technically sound. These commenters assert that the EPA failed to consider recent research studies that provide a meta-analysis of visibility preference studies that suggest that a level of 30 dv is unacceptable to study participants included in the meta-analysis.

As an initial matter, as described above, the studies cited by the commenters in support of their rationale were either published after the cutoff date for the literature search for the ISA (Malm et al., 2019) or were not peer-reviewed studies that met the inclusion criteria for the ISA (Malm et al., 2011; Malm, 2013, 2016; Molenar and Malm, 2012). The EPA provisionally considered the Malm et al. (2019) study and concludes that this study does not sufficiently alter the conclusions reached in the ISA regarding PM and visibility effects.

With regard to a level of 30 dv for the visibility index, the EPA believes that it is appropriate to establish a target level of protection based on the upper end of the range of levels of visibility impairment judged to be acceptable by at least 50% of study participants in the available visibility preference studies (U.S. EPA, 2020, section 5.2.1.1). The 2011 PA identified a range of levels from 20 to 30 dv based on the responses in the public preference studies available at that time. Given the lack of new preferences studies available in this review, the EPA again relies on the same studies and the range of levels identified in those studies in the current review. As described in detail in the PA (U.S. EPA, 2020, sections 5.2.1.1 and 5.5), there are a number of uncertainties and limitations associated with the public preference studies, including those described in section IV.B.2 above. Recognizing these uncertainties and limitations, the EPA concludes that substantial degrees of variability and uncertainty in the public preference studies should be reflected in a target level of protection at the upper end of the range than if the information was more consistent and certain. Therefore, the EPA believes that 30 dv is an appropriate level for a visibility index in this review.

A number of commenters advocate for a more stringent standard, recommending that the level of the secondary $PM_{2.5}$ standards be lowered. Some commenters reference the recommendations of previous CASAC panels for revisions to the secondary 24-hour $PM_{2.5}$ standard. Additionally, some commenters contend that the secondary $PM_{2.5}$ standards should be set equal to the primary $PM_{2.5}$ standards, with some of the commenters aligning their support for their position with their recommendations for revisions to the primary $PM_{2.5}$ standards in this review.

We disagree with the commenters that the secondary $PM_{2.5}$ standard should be revised to provide additional public welfare protection beyond that achieved under the current standard. Based on the available scientific and quantitative information, and for the reasons discussed above, the EPA concludes that it is appropriate to define a target level of protection in terms of a visibility index based on estimated light extinction with a 24-hour averaging time, a 3-year 90th percentile form, and a level of 30 dv. In having concluded that this visibility index is appropriate, the EPA then considers the degree of protection from visibility impairment afforded by the existing standard. In so doing, we consider results of updated analyses of calculated light extinction that demonstrate that, in areas meeting the current PM mass-based standards, the target level of protection in terms of a visibility index is also achieved (85 FR 24135, April 30, 2020; U.S. EPA, 2020, section 5.2.1.2). The results of these analyses (as described in detail in section IV.A.3.a above and in section 5.2.1.2 of the PA) demonstrate that the 3-year visibility metric is at or below about 30 dv in all areas meeting the current $PM_{2.5}$ standard, and below 25 dv in most areas. For those areas with available $PM_{10-2.5}$ monitoring data, which met both the current 24-hour $PM_{2.5}$ and PM_{10} standards, 3-year visibility metrics were at or below 30 dv regardless of if the coarse fraction was included in the calculation (U.S. EPA, 2020, section 5.2.1.2). Given the results of these analyses, the Administrator concluded at the time of proposal that the updated scientific evidence and quantitative information support the adequacy of the current secondary $PM_{2.5}$ and PM_{10} standards to protect against PM-related visibility impairment (85 FR 24138–24139, April 30, 2020).

With regard to comments recommending to set the secondary $PM_{2.5}$ standards equal to the current primary $PM_{2.5}$ standards, these commenters do not provide a basis for their recommendation, nor do they provide a rationale for revising the secondary $PM_{2.5}$ standards to their recommended revised levels of the primary $PM_{2.5}$ standards. However, we note that the primary annual $PM_{2.5}$ standard, with its lower level, would be the controlling standard. The EPA disagrees that such revisions would be appropriate, for all of the reasons discussed above.

4. Administrator's Conclusions

In considering the adequacy of the current secondary PM standards in this review, the Administrator has carefully considered the: (1) Policy-relevant evidence and conclusions contained in the ISA; (2) the quantitative information presented and assessed in the PA; (3) the evaluation of this evidence, the quantitative information, and the rationale and conclusions presented in the PA; (4) the advice and recommendations from the CASAC; and (5) public comments, as addressed in section IV.B.3 above. In the discussion below, the Administrator gives weight to the PA conclusions, with which the CASAC concurred, as summarized in section IV.D of the proposal, and takes note of key aspects of the rationale for those conclusions that contribute to his decision in this review. After giving careful consideration to all of this information, the Administrator believes that the conclusions and policy judgments supporting his proposed decision remain valid and the secondary PM standards should be retained.

In considering the PA evaluations and conclusions, the Administrator specifically takes note of the overall conclusions that the welfare effects evidence and quantitative information are generally consistent with what was considered in the last review (U.S. EPA, 2020, section 5.4). In so doing, he additionally notes that the CASAC supports retaining the current standard agreeing with the EPA ''that the available evidence does not call into question the protection afforded by the current secondary PM standards'' (Cox, 2019a, p. 3 of letter). As noted below, the newly available welfare effects evidence, critically assessed in the ISA as part of the full body of current evidence, reaffirms conclusions on the visibility, climate, and materials effects recognized in the last review, including key conclusions on which the current standard is based. Further, as discussed in more detail above, the updated quantitative analyses of visibility impairment for areas meeting the current standards support the adequacy of the current secondary $PM_{2.5}$ and PM_{10} standards to protect against PM-related visibility impairment. The Administrator also recognizes limitations and uncertainties continue to be associated with the available information.

With regard to the current evidence on visibility effects, as summarized in the PA and discussed in detail in the ISA, the Administrator takes note of the long-standing body of evidence for PM-related visibility impairment. This evidence, which is based on the fundamental relationship between light extinction and PM mass, demonstrates that ambient PM can impair visibility in both urban and remote areas, and has changed very little since the last review (U.S. EPA, 2019, section 13.1; U.S. EPA, 2009a, section 9.2.5). The evidence related to public perception of visibility impairment comes from studies from four areas in North America. These studies provide information to inform our understanding of levels of visibility impairment that the public judged to be ''acceptable'' (U.S. EPA, 2010b; 85 FR 24131, April 30, 2020). In considering these public preference studies, the Administrator notes that, as described in the ISA, no new visibility studies have been conducted in the U.S. and there is little newly available information with regard to acceptable levels of visibility impairment in the U.S. The Administrator recognizes that visibility impairment can have implications for people's enjoyment of daily activities and their overall well-being, and therefore, considers the degree to which the current secondary standards protect against PM-related visibility impairment.

Based on the considerations discussed above in sections IV.B.2 and IV.B.3, the Administrator first concludes, consistent with the last review, that a target level of protection for a secondary PM standard is most appropriately defined in terms of a visibility index that directly takes into account the factors (*i.e.,* species composition and relative humidity) that influence the relationship between $PM_{2.5}$ in ambient air and PM-related visibility impairment. In defining a target level of protection, the Administrator has considered the specific aspects of such an index, including the appropriate indicator, averaging time, form, and level.

First, with regard to indicator, the Administrator notes that in the last review, the EPA used an index based on estimates of light extinction by $PM_{2.5}$ components calculated using an adjusted version of the IMPROVE algorithm. As described above (section IV.A.3), this algorithm allows the estimation of light extinction using routinely monitored components of $PM_{2.5}$ and $PM_{10-2.5}$, along with estimates of relative humidity. The Administrator recognizes that, while there have been some revisions to the IMPROVE algorithm since the time of the last review, our fundamental understanding of the relationship between PM in ambient air and light extinction has changed little and the various IMPROVE algorithms can appropriately reflect this relationship across the U.S. In the absence of a monitoring network for direct measurement of light extinction (section IV.A.3), he concludes that calculated light extinction indicator that utilizes the IMPROVE algorithms continues to provide a reasonable basis for defining a target level of protection against PM-related visibility impairment in the current review.

In further defining the characteristics of a visibility index, the Administrator next considers the appropriate averaging time, form, and level of the index. Given the available scientific information in this review, and in considering the CASAC's advice and public comments, the Administrator concludes that, consistent with the decision in the last review, a visibility index with a 24-hour averaging time and a form based on the 3-year average of annual 90th percentile values remains reasonable in this review. With regard to the averaging time and form of such an index, the Administrator takes note of analyses conducted in the last review that demonstrated relatively strong correlations between 24-hour and sub-daily (*i.e.,* 4-hour average) $PM_{2.5}$ light extinction (78 FR 3226, January 15, 2013), indicating that a 24-hour averaging time is an appropriate surrogate for the sub-daily time periods of the perception of PM-related visibility impairment and the relevant exposure periods for segments of the viewing public. This decision also recognized that a 24-hour averaging time may be less influenced by atypical conditions and/or atypical instrument performance (78 FR 3226, January 15, 2013). The Administrator recognizes that there is no new information in the current review to support updated analyses of this nature, and therefore, he believes these analyses continue to provide support for consideration of a 24-hour averaging time for a visibility index in this review. With regard to the statistical form of the index, the Administrator notes that, consistent with the last review: (1) A multi-year percentile form offers greater stability from the occasional effect of inter-annual meteorological variability (78 FR 3198, January 15, 2013; U.S. EPA, 2011, p. 4–58); (2) a 90th percentile represents the median of the distribution of the 20 percent worst visibility days, which are targeted in Federal Class I areas by the Regional Haze Program; and (3) public preference studies did not provide information to identify a different target than that identified for Federal Class I areas (U.S. EPA, 2011, p. 4–59). Therefore, the Administrator judges that a visibility index based on estimates of light extinction, with a 24-hour averaging time and a 90th percentile form, averaged over three years, remains appropriate.

With regard to the level of a visibility index, the Administrator judges that it is 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 (78 FR 3226, January 15, 2013). The 2011 PA identified a range of levels from 20 to 30 dv based on the responses in the public preference studies available at that time. At the time of the last review, the Administrator noted a number of uncertainties and limitations in public preference studies, including the small number of stated preference studies available, the relatively small number of study participants and the extent to which the study participants may not be representative of the broader study area population in some of the studies, and the variations in the specific materials and methods used in each study. In considering the available preference studies, with their inherent uncertainties and limitations, the prior Administrator concluded that the substantial degree of variability and uncertainty in the public preference studies should be reflected in a target level of protection based on the upper end of the range of CPLs.

Given that there are no new preference studies available in this review, the Administrator notes that his judgments are based on the same studies, with the same range of levels, available in the last review. The Administrator recognizes a number of limitations and uncertainties associated with these studies, as identified in the PA (U.S. EPA, 2020, section 5.5), including the following: (1) Available studies may not represent the full range of preferences for visibility in the U.S. population, particularly given the potential variability in preferences based on the conditions commonly encountered and the scenes being viewed; (2) available preference studies were conducted 15 to 30 years ago and may not accurately represent the current day preferences of people in the U.S.; (3) the variety of methods used in the preference studies may potentially influence the responses as to what level of impairment is deemed acceptable; and (4) factors that are not captured in the methods of the preference studies, such as the time of day when light extinction is the greatest or the frequency of impairment episodes, may influence people's judgment on acceptable visibility (U.S. EPA, 2020, section 5.2.1.1). Therefore, in considering the scientific information, with its uncertainties and limitations, as well as public comments on the level of the target level of protection against visibility impairment, the Administrator concludes that it is appropriate to again use a level of 30 dv for the visibility index.

Having concluded that the protection provided by a standard defined in terms of a $PM_{2.5}$ visibility index, with a 24-hour averaging time, and a 90th percentile form, averaged over 3 years, set at a level of 30 dv, is requisite to protect public welfare with regard to visual air quality, the Administrator next considers the degree of protection from visibility impairment afforded by the existing secondary PM standards. This determination requires considering such protection not in isolation but in the context of the full suite of secondary standards.

In this context, the Administrator has considered the degree of protection from visibility afforded by the existing secondary $PM_{2.5}$ standards. The Administrator has considered both whether the existing 24-hour $PM_{2.5}$ standard of 35 µg/m³ is sufficient (*i.e.,* not under-protective) and whether it is not more stringent than necessary (*i.e.,* not over-protective).

As discussed in section IV.A.3 above, the Administrator considers the updated analyses of visibility impairment presented in the PA (U.S. EPA, 2020, section 5.2.1.2), which reflect a number of improvements since the last review. Specifically, the updated analyses examine multiple versions of the IMPROVE equation, including the version incorporating revisions since the time of the last review (section IV.A.3.a above). These updated analyses provide a further understanding of how variation in the inputs to the algorithms impact the estimates of light extinction (U.S. EPA, 2020, Appendix D). Additionally, for a subset of monitoring sites with available $PM_{10-2.5}$ data, the updated analyses better characterize the influence of coarse PM on light extinction than in the last review (U.S. EPA, 2020, section 5.2.1.2).

As discussed above in section IV.A.3.a, the results of the updated analyses are consistent with those from the last review. Regardless of which version of the IMPROVE equation is used, the analyses demonstrate that, based on 2015–2017 data, the 3-year visibility metric is at or below about 30 dv in all areas meeting the current 24-hour $PM_{2.5}$ standard, and below 25 dv in most of those areas. In locations with available $PM_{10-2.5}$ monitoring, which met both the current 24-hour secondary $PM_{2.5}$ and PM_{10} standards, 3-year visibility index metrics were at or below 30 dv regardless of whether the coarse fraction was included as an input to the algorithm for estimating light extinction (U.S. EPA, 2020, section 5.2.1.2). While the inclusion of the coarse fraction had a relatively modest impact on the estimates of light extinction, as noted in responding to comments in section IV.B.3 above, the Administrator recognizes the continued importance of the PM_{10} standard given the potential for larger impacts on light extinction in areas with higher coarse particle concentrations, which were not included in the PA's analyses due to a lack of available data (U.S. EPA, 2019, section 13.2.4.1; U.S. EPA, 2020, section 5.2.1.2). He notes that the air quality analyses showed that all areas meeting the existing 24-hour $PM_{2.5}$ standard, with its level of 35 µg/m³, had visual air quality at least as good as 30 dv, based on the visibility index. Thus, the secondary 24-hour $PM_{2.5}$ standard would likely be controlling relative to a 24-hour visibility index set at a level of 30 dv. Additionally, areas would be unlikely to exceed the target level of protection for visibility of 30 dv without also exceeding the existing secondary 24-hour standard. Thus, the Administrator judges that the 24-hour $PM_{2.5}$ standard provides sufficient protection in all areas against the effects of visibility impairment—*i.e.,* that the existing 24-hour $PM_{2.5}$ standard would provide at least the target level of protection for visual air quality of 30 dv which he judges appropriate.

With respect to the non-visibility welfare effects of PM in ambient air, the Administrator concludes that it is generally appropriate to retain the existing standards and that there is insufficient information to establish any distinct secondary PM standards to address climate and materials effects of PM. With regard to climate, he recognizes that there have been a number of improvements and refinements to climate models since the last review. However, as discussed in sections IV.A.3.b and IV.B.3 above, while the evidence continues to support a causal relationship between PM and climate effects (U.S. EPA, 2019, section 13.3.9), the Administrator notes that significant limitations continue to exist related to quantifying the contributions of direct and indirect effects of PM and PM components on climate forcing (U.S. EPA, 2020, sections 5.2.2.1.1 and 5.4). He also recognizes that that models continue to exhibit considerable variability in estimates of PM-related climate impacts at regional scales (*e.g.,* ~100 km) as compared to simulations at global scales. Therefore, the resulting uncertainty leads the Administrator to conclude that the available scientific information in this review remains insufficient to quantify climate impacts associated with particular concentrations of PM in ambient air (U.S. EPA, 2020, section 5.2.2.2.1) or to evaluate or consider a level of PM air quality in the U.S. to protect against climate effects and that there is insufficient information available at this time to base a national ambient standard on climate impacts.

With regard to materials effects, the Administrator notes that the evidence available in this review continues to support a causal relationship between materials effects and PM deposition (U.S. EPA, 2019, section 13.4). He recognizes that the deposition of fine and coarse particles to materials can lead to physical damage and/or impaired aesthetic qualities. Particles can contribute to materials damage by adding to the natural weathering processes and by promoting the corrosion of metals, the degradation of painted surfaces, the deterioration of building materials, and the weakening of material components. While some new information is available in this review, as discussed in sections IV.A.3.b and IV.B.3 above, this information is primarily conducted outside the U.S. in areas where PM concentrations in ambient air are typically higher than those observed in the U.S. (U.S. EPA, 2020, section 13.4). Additionally, the newly available information in this review does not support quantitative analyses of PM-related materials effects in this review (U.S. EPA, 2020, section 5.2.2.2.2). Given the limited amount of information available and its inherent uncertainties and limitations, the Administrator concludes that he is unable to relate soiling or damage to specific levels of PM in ambient air or to evaluate or consider a level of air quality to protect against such materials effects, and that there is insufficient information available in this review to support a distinct national ambient standard based on materials effects.

With regard to the secondary PM standards, the Administrator concludes that it is appropriate to retain the existing secondary PM standards, without revision. This conclusion is based on the considerations discussed above in sections IV.A.3.b and IV.B.2, including the latest scientific information and the advice of the CASAC, and the public comments received on the proposal, as discussed above in section IV.B.3. For visibility effects, this decision also reflects his consideration of the evidence for PM-related light extinction, together with his consideration of the updated analyses of the protection provided against visibility impairment by the current secondary $PM_{2.5}$ and PM_{10} standards. For climate and materials effects, this conclusion reflects his judgment that, although it remains important to maintain secondary $PM_{2.5}$ and PM_{10} standards to provide some degree of control over long- and short-term concentrations of both fine and coarse particles, there is insufficient information to establish distinct secondary PM standards to address non-visibility PM-related welfare effects. The Administrator concurs with the advice of the CASAC, which agrees ''that the available evidence does not call into question the protection afforded by the current secondary PM standards'' and recommends that the secondary standards ''should be retained'' (Cox, 2019a, p. 3 of letter). This is also consistent with the conclusions at the time of the proposal (IV.B.2) and with the majority of public comments received on the proposed decision (section IV.B.3).

In addition, the Administrator judges that, based on his review of the science and his judgment that air quality should be maintained to provide the target level of protection for visual air quality of 30 dv (as discussed in more detail above), the degree of public welfare protection provided by the current secondary standards is not greater than warranted. This judgment, together with the fact that no CASAC member expressed support for a less stringent standard, leads the Administrator to conclude that standards less stringent than the current secondary standards (*e.g.,* with higher levels) are also not supported.

Thus, based on his consideration of the evidence and analyses for welfare effects, his consideration of the CASAC's advice and public comments on the secondary standards, and in the absence of information that would support establishment of any different standards, the Administrator concludes that it is appropriate to retain the current 24-hour and annual $PM_{2.5}$ standards and the 24-hour PM_{10} standard, without revision.

D. Decision on the Secondary PM Standards

For the reasons discussed above and taking into account information and assessments presented in the ISA and PA, advice from the CASAC, and consideration of public comments, the Administrator concludes that the current secondary PM standards are requisite to protect public welfare from known or anticipated adverse effects and is retaining the standards, without revision.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

The Office of Management and Budget (OMB) determined that this action is a significant regulatory action and it was submitted to OMB for review. Changes made during Executive Order 12866 review have been documented in the docket. Because this action does not change the existing PM NAAQS, it does not impose costs or benefits relative to the baseline of continuing with the current NAAQS in effect. Thus, the EPA has not prepared a Regulatory Impact Analysis for this action.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory action. There are no costs or cost savings compared to the current baseline for this action because EPA is retaining the current standards.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. There are no information collection requirements directly associated with a decision to retain a NAAQS without any revision under section 109 of the CAA and this action retains the current PM NAAQS without any revisions.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. Rather, this action retains, without revision, existing national standards for allowable concentrations of PM in ambient air as required by section 109 of the CAA. See also *American Trucking Associations* v. *EPA,* 175 F.3d 1027, 1044–45 (D.C. Cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities), reviewed in part on other grounds, *Whitman* v. *American Trucking Associations,* 531 U.S. 457 (2001).

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in the UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes. This action does not change existing regulations; it retains the existing PM NAAQS, without revision. Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866. The health effects evidence for this action, which includes evidence for effects in children, is summarized in section II.B above and is described in the ISA and PA, copies of which are in the public docket for this action.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' as defined by Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy and has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs (OIRA).

J. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The action described in this document is to retain without revision the existing PM NAAQS based on the Administrator's conclusions that the existing primary standards protect public health, including the health of sensitive groups, with an adequate margin of safety, and the existing secondary standards protect public welfare from known or anticipated adverse effects. As discussed in section II, the EPA expressly considered the available information regarding health effects among at-risk populations in reaching the decision that the existing standard is requisite.

L. Determination Under Section 307(d)

Section 307(d)(1)(V) of the CAA provides that the provisions of section 307(d) apply to ''such other actions as the Administrator may determine.'' Pursuant to section 307(d)(1)(V), the Administrator determines that this action is subject to the provisions of section 307(d).

M. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The Administrator of OIRA has not determined that this action is a ''major rule'' as defined by 5 U.S.C. 804(2).

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List of Subjects in 40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

Dated: December 4, 2020.

Andrew Wheeler,

Administrator.

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