TITLE 45
LEGISLATIVE RULE
DEPARTMENT OF ENVIRONMENTAL PROTECTION
AIR QUALITY

SERIES 8
AMBIENT AIR QUALITY STANDARDS

§45-8-1. General.

1.1. Scope. -- This rule establishes and adopts ambient air quality standards in West Virginia for sulfur oxides, particulate matter, carbon monoxide, lead, nitrogen dioxide, ozone, nitrogen dioxide particulate matter, and lead sulfur dioxide, equivalent to the national primary and secondary ambient air quality standards established under Section 109 of the Clean Air Act and promulgated by the United States Environmental Protection Agency under 40 C.F.R. Part 50. National primary ambient air quality standards define levels of air quality which the Administrator judges are necessary, with an adequate margin of safety, to protect the public health. National secondary ambient air quality standards define levels of air quality which the Administrator judges necessary to protect the public welfare from any known or anticipated adverse effects of a pollutant. This rule also establishes and adopts ambient air monitoring reference methods and equivalent methods promulgated by the United States Environmental Protection Agency under 40 C.F.R. Part 53. The Secretary hereby adopts these standards and methods by reference. The Secretary also adopts the appendices to these standards and methods. These standards and methods are subject to revision, and additional primary and secondary standards may be promulgated as the Administrator deems necessary to protect the public health and welfare.

1.2. Authority. -- W.Va. Code § 22-5-4.

1.3. Filing Date. -- April 28, 2021.

1.4. Effective Date. -- June 1, 2021.

1.5. Sunset Provision. -- Does not apply.

1.6. Incorporation by Reference. -- Federal Counterpart Regulation. The Secretary has determined that a federal counterpart regulation exists, and in accordance with the Secretary's recommendation this rule incorporates by reference 40 C.F.R. Part 50, "National Primary and Secondary Ambient Air Quality Standards," and 40 C.F.R. Part 53, "Ambient Air Monitoring Reference and Equivalent Methods," effective June 1, 2020 2021.

§45-8-2. Definitions.

2.1. "Administrator" means the Administrator of the United States Environmental Protection Agency or his or her authorized representative.

2.2. "Clean Air Act" ("CAA") means the federal Clean Air Act, as amended, 42 U.S.C. § 7401, et seq..

2.3. "Secretary" means the Secretary of the Department of Environmental Protection or other person to whom the Secretary has delegated authority or duties pursuant to W.Va. Code §§ 22-1-6 or 22-1-8.

2.4. Other words and phrases used in this rule, unless otherwise indicated, shall have the meaning ascribed to them in 40 C.F.R. § 50.1. Words and phrases not defined therein shall have the meaning given to them in the federal Clean Air Act.

§45-8-3. Adoption of standards.

3.1. The Secretary hereby adopts and incorporates by reference the national primary and secondary ambient air quality standards promulgated by the United States Environmental Protection Agency under 40 C.F.R. Part 50, effective June 1, ~~2020~~ 2021. These standards are adopted for the purpose of establishing ambient air quality standards in West Virginia that are equivalent to those established under Section 109 of the Clean Air Act, as amended.

3.2. The Secretary hereby adopts and incorporates by reference the ambient air monitoring reference methods and equivalent methods promulgated by the United States Environmental Protection Agency under 40 C.F.R. Part 53, effective June 1, ~~2020~~ 2021. These standards are adopted for the purpose of establishing ambient air monitoring reference methods and equivalent methods in West Virginia.

§45-8-4. Inconsistency between rules.

4.1. In the event of any inconsistency between this rule and any other rule of the Division of Air Quality, the inconsistency shall be resolved by the determination of the Secretary and the determination shall be based upon the application of the more stringent provision, term, condition, method, or rule.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51, 60, 61, and 63

[EPA–HQ–OAR–2018–0815; FRL–10012–11–OAR]

RIN 2060–AU39

Test Methods and Performance Specifications for Air Emission Sources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action corrects and updates regulations for source testing of emissions. These revisions include corrections to inaccurate testing provisions, updates to outdated procedures, and approved alternative procedures that will provide flexibility to testers. These revisions will improve the quality of data and will not impose any new substantive requirements on source owners or operators.

DATES: The final rule is effective on December 7, 2020. The incorporation by reference of certain materials listed in the rule is approved by the Director of the Federal Register as of December 7, 2020]. The incorporation by reference of certain other materials listed in the rule was approved by the Director of the Federal Register as of July 6, 2006.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2018–0815. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information 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. Publicly available docket materials are available electronically through *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Mrs. Lula H. Melton, Office of Air Quality Planning and Standards, Air Quality Assessment Division (E143–02), Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541–2910; fax number: (919) 541–0516; email address: *melton.lula@epa.gov*.

SUPPLEMENTARY INFORMATION:

The supplementary information in this preamble is organized as follows:

Table of Contents

I. General Information

A. Does this action apply to me?

The revisions promulgated in this final rule apply to industries that are subject to the current provisions of 40 Code of Federal Regulations (CFR) parts 51, 60, 61, and 63. We did not list all of the specific affected industries or their North American Industry Classification System (NAICS) codes herein since there are many affected sources in numerous NAICS categories. If you have any questions regarding the applicability of this action to a particular entity, consult either the air permitting authority for the entity or your EPA Regional representative as listed in 40 CFR 63.13.

B. What action is the Agency taking?

We are promulgating corrections and updates to regulations for source testing of emissions. More specifically, we are correcting typographical and technical errors, updating testing procedures, and adding alternative equipment and methods the Agency has deemed acceptable to use.

C. Judicial Review

Under section 307(b)(1) of the Clean Air Act (CAA), judicial review of this final rule is available by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit by December 7, 2020. Under section 307(d)(7)(B) of the CAA, only an objection to this final rule that was raised with reasonable specificity during the period for public comment can be raised during judicial review. Moreover, under section 307(b)(2) of the CAA, the requirements that are the spectrometry (ICP–MS) analysis. These standards were developed and adopted by the Environmental Protection Agency and may be obtained from *http://www.epa.gov* or from the U.S. Environmental Protection Agency at 1200 Pennsylvania Avenue NW, Washington, DC 20460.

The EPA used API Manual of Petroleum Measurement Standards, Chapter 14—Natural Gas Fluids Measurement (Section 1) in Subpart KKKK of Part 60. This API standard involves the collecting and handling of natural gas samples for custody transfer. This API standard was developed and adopted by the American Petroleum Institute and may be obtained from *https://www.api.org/* or from the American Petroleum Institute at 1220 L Street NW, Washington, DC 20005.

The EPA used GPA 2166 in Subpart KKKK of Part 60, which involves procedures for obtaining samples from gaseous fuels. The EPA used GPA 2174 in Subpart KKKK of Part 60, which involves procedures for obtaining samples from liquid fuels. The EPA used GPA 2140 in subpart KKKK of Part 60, which involves liquefied petroleum gas specifications and test methods. The EPA used GPA 2261 in subpart KKKK of Part 60, which is a procedure for analyzing natural gas and similar gaseous mixtures. These GPA standards were developed and adopted by the GPA Midstream Association and may be obtained from *https://www.gpamidstream.org/* or from the GPA Midstream Association, Sixty Sixty American Plaza, Suite 700, Tulsa, OK 74135.

The EPA used ISO 10715 in subpart KKKK of Part 60. This standard involves procedures for obtaining samples from gaseous fuels. This standard was developed by the International Organization for Standardization and may be obtained from *https://www.iso.org/home.html* or from the ISH Inc., 15 Inverness Way East, Englewood, CO 80112.

Multiple ASTM and GPA standards were previously approved on July 6, 2006, and are already included in the regulatory text. Therefore, the current the IBR is unchanged in this rule for the following methods: ASTM D129–00, ASTM D1072–90 (Reapproved 1999); ASTM D1266–98 (Reapproved 2003)ε,1; ASTM D1552–03, ASTM D2622–05, ASTM D3246–05, ASTM D4057–95 (Reapproved 2000), ASTM D4084–05, ASTM D4177–95 (Reapproved 2000); ASTM D4294–03, ASTM D4468–85 (Reapproved 2000); ASTM D4810–88 (Reapproved 1999); ASTM D5287–97 (Reapproved 2002); ASTM D5453–05, ASTM D6228–98 (Reapproved 2003); ASTM D6667–04, and GPA 2377–86.

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

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This action is a technical correction to previously promulgated regulatory actions and does not have an impact on human health or the environment.

L. 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. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 51

Environmental protection, Air pollution control, Performance specifications, Test methods and procedures.

40 CFR Part 60

Environmental protection, Air pollution control, Incorporation by reference, Performance specifications, Test methods and procedures.

40 CFR Parts 61 and 63

Environmental protection, Air pollution control, Incorporation by reference, Performance specifications, Test methods and procedures.

Andrew Wheeler,
Administrator.

For the reasons set forth in the preamble, the EPA amends 40 CFR parts 51, 60, 61, and 63 as follows:

PART 51—REQUIREMENTS FOR PREPARATION, ADOPTION, AND SUBMITTAL OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 51 continues to read as follows:

Authority: 23 U.S.C. 101; 42 U.S.C. 7401–7671q.

■ 2. In appendix M to part 51, in Method 201A, revise sections ''1.2'', ''1.6'', ''6.2.1(d)'', and ''8.6.6'' and ''Figure 7'' to read as follows:

Appendix M to Part 51—Recommended Test Methods for State Implementation Plans

* * * * *

Method 201A—Determination of PM_{10} and $PM_{2.5}$ Emissions From Stationary Sources (Constant Sampling Rate Procedure)

* * * * *

1.2 *Applicability.* This method addresses the equipment, preparation, and analysis necessary to measure filterable PM. You can use this method to measure filterable PM from stationary sources only. Filterable PM is collected in stack with this method (*i.e.,* the method measures materials that are solid or liquid at stack conditions). If the gas filtration temperature exceeds 29.4 °C (85 °F), then you may use the procedures in this method to measure only filterable PM (material that does not pass through a filter or a cyclone/filter combination). If the gas filtration temperature exceeds 29.4 °C (85 °F), and you must measure both the filterable and condensable (material that condenses after passing through a filter) components of total primary (direct) PM emissions to the atmosphere, then you must combine the procedures in this method with the procedures in Method 202 of appendix M to this part for measuring condensable PM. However, if the gas filtration temperature never exceeds 29.4 °C (85 °F), then use of Method 202 of appendix M to this part is not required to measure total primary PM.

* * * * *

1.6 *Conditions.* You can use this method to obtain particle sizing at 10 micrometers and or 2.5 micrometers if you sample within 80 and 120 percent of isokinetic flow. You can also use this method to obtain total filterable particulate if you sample within 90 to 110 percent of isokinetic flow, the number of sampling points is the same as required by Method 5 of appendix A–3 to part 60 or Method 17 of appendix A–6 to part 60, and the filter temperature is within an acceptable range for these methods. For Method 5, the acceptable range for the filter temperature is generally 120 °C (248 °F) unless a higher or lower temperature is specified. The acceptable range varies depending on the source, control technology and applicable rule or permit condition. To satisfy Method 5 criteria, you may need to remove the in-stack filter and use an out-of-stack filter and recover the PM in the probe between the $PM_{2.5}$ particle sizer and the filter. In addition, to satisfy Method 5 and Method 17 criteria, you may need to sample from more than 12 traverse points. Be aware that this method determines in-stack PM_{10} and $PM_{2.5}$ filterable emissions by sampling from a required maximum of 12 sample points, at a constant flow rate through the train (the constant flow is necessary to maintain the size cuts of the cyclones), and with a filter that is at the stack temperature. In contrast, Method 5 or Method 17 trains are operated isokinetically with varying flow rates through the train. Method 5 and Method 17 require sampling from as many as 24 sample points. Method 5 uses an out-of-stack filter that is maintained at a constant temperature of 120 °C (248 °F). Further, to use this method in place of Method 5 or Method 17, you must extend the sampling time so that you collect the minimum mass necessary for weighing each portion of this sampling train. Also, if you are using this method as an alternative to a test method specified in a regulatory requirement (*e.g.,* a requirement to conduct a compliance or performance test), then you must receive approval from the authority that established the regulatory requirement before you conduct the test.

* * * * *

6.2.1 * * *

(d) Petri dishes. For filter samples; glass, polystyrene, or polyethylene, unless otherwise specified by the Administrator.

* * * * *

8.6.6 *Sampling Head.* You must preheat the combined sampling head to the stack temperature of the gas stream at the test location (±28 °C, ±50 °F). This will heat the sampling head and prevent moisture from condensing from the sample gas stream.

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17.0 * * *

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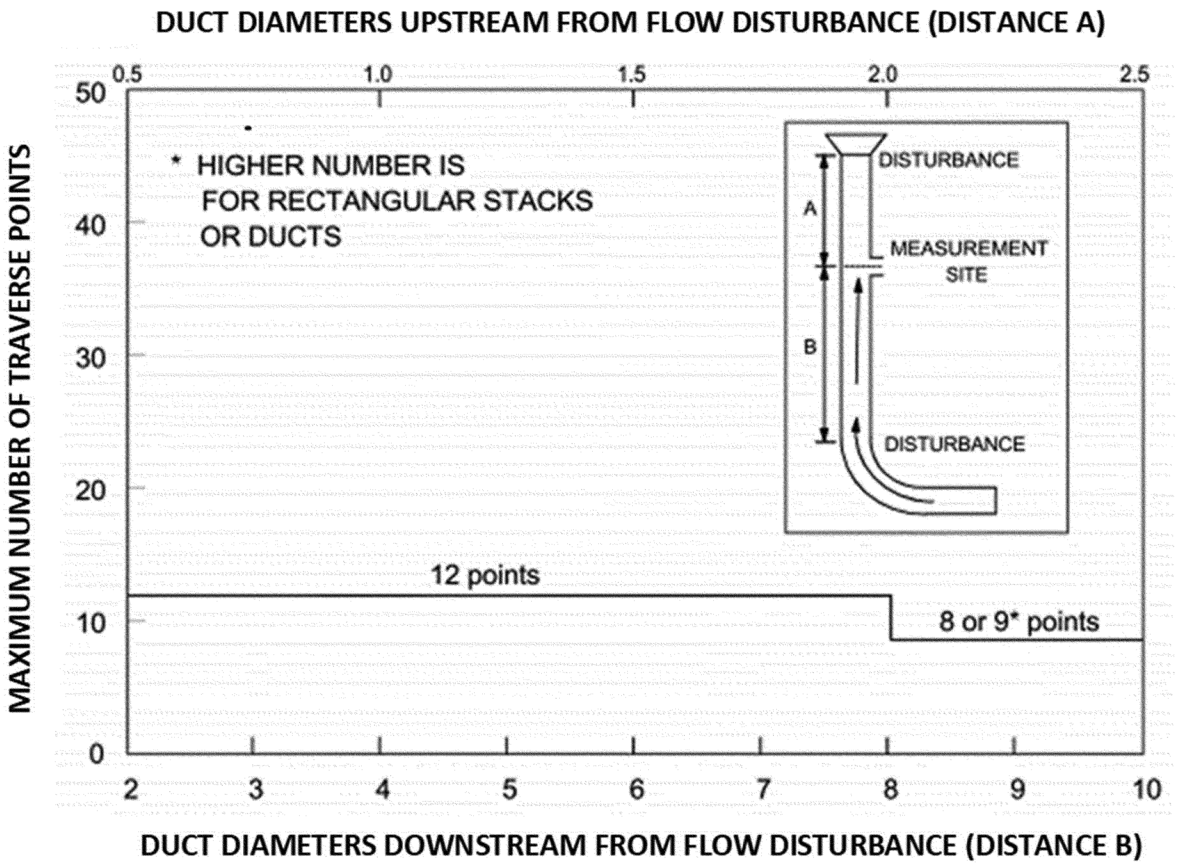

Figure 7. Maximum Number of Required Traverse Points

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PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 3. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 4. Amend § 60.17 by:

■ a. Removing the text ‘‘appendix A–8 to part 60: Method 24,’’ and add in its place, ‘‘appendix A–7 to part 60: Method 24,’’ everywhere it appears;

■ b. Revising the last sentence in paragraph (a);

■ c. Redesignating paragraph (e)(2) as (e)(3) and adding a new paragraph (e)(2);

■ d. Redesignating paragraphs (h)(192) through (209) as (h)(195) through (212), (h)(174) through (191) as (h)(176) through (193), and (h)(95) through (173) as (h)(96) through (174), respectively;

■ e. Adding new paragraphs (h)(95), (175), and (194);

■ f. Adding paragraphs (j)(3) and (4);

■ g. Revising paragraph (k) introductory text;

■ h. Redesignating paragraphs (k)(2) and (3) as paragraphs (k)(5) and (6) and redesignating paragraph (k)(1) as paragraph (k)(3), respectively;

■ i. Adding new paragraphs (k)(1), (2), and (4);

■ j. Revising newly redesignated paragraph (k)(5); and

■ k. Adding paragraph (l)(2).

The revisions and additions read as follows:

§ 60.17 Incorporations by reference.

(a) * * * For information on the availability of this material at NARA,

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.

Table of Contents

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 µg/m^3 and a 24-hour standard with a 98th percentile form and a level of 35 µg/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 µg/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 µg/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/m³, 24-hour average, not to be exceeded more than once per year, and 75 μg/m³, annual geometric mean. The secondary standards were set at 150 μg/m³, 24-hour average, not to be exceeded more than once per year, and 60 μg/m³, 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/m³, 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/m³, 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/m³, 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/m³, 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

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[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 $\mu g/m^3$ and retained the 24-hour $PM_{2.5}$ standard, with its level of 35 $\mu g/m^3$. 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.

[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 $\mu g/m^3$ 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 $\mu g/m^3$ 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 $\mu g/m^3$ 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 $\mu g/m^3$ 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 $\mu g/m^3$ 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 $\mu g/m^3$, the prior Administrator concluded that the evidence supported retaining the 35 $\mu g/m^3$ level of the 24-hour $PM_{2.5}$ standard. She noted that the existing 24-hour standard, with its 35 $\mu g/m^3$ 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 $\mu g/m^3$ combined with a 24-hour standard with a level of 35 $\mu g/m^3$.

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 µg/m³ (Lee et al., 2015),[37] below 30 µg/m³ (Shi et al., 2016), and below 25 µg/m³ (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 µg/m³ 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 µg/m³.

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 μg/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 μg/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 μg/m³ are excluded from analyses. They found it ''highly unlikely'' that the extensive body of evidence indicating positive associations at low estimated exposures could be fully explained by confounding or by other non-causal explanations (Cox, 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 μg/m³, 35 μg/m³) 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 $\mu g/m^3$, 35 $\mu g/m^3$), 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 $\mu g/m^3$ and a revised 24-hour standard between a range of 25–30 $\mu g/m^3$. 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 $\mu g/m^3$. 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 µg/m^3 (at and above 149 µg/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 µg/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 µg/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 µg/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.,*

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[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/m^3) 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/m^3). 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/m^3, 35 μg/m^3), 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

[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 $\mu g/m^3$, 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/m^3, and the 24-hour PM_{10} standard, with its level of 150 µg/m^3 (78 FR 3228, January 15, 2013). The EPA also retained the level, set at 15 µg/m^3, 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).

References

Abt Associates, Inc. (2001). Assessing public opinions on visibility impairment due to air pollution: Summary report. Research Triangle Park, NC, U.S. Environmental Protection Agency.

Abt Associates, Inc. (2005). Particulate matter health risk assessment for selected urban areas: Draft report. Research Triangle Park, NC, U.S. Environmental Protection Agency: 164.

Adar, SD, Filigrana, PA, Clements, N and Peel, JL (2014). Ambient coarse particulate matter and human health: A systematic review and meta-analysis. Current Environmental Health Reports 1: 258–274.

BBC Research & Consulting (2003). Phoenix area visibility survey. Denver, CO.

Besson, P; Munoz, C; Ramirez-Sagner, G; Salgado, M; Escobar, R; Platzer, W. (2017). Long-term soiling analysis for three photovoltaic technologies in Santiago Region. IEEE J Photovolt 7: 1755–1760.

Bräuner, EV; Møller, P; Barregard, L; Dragsted, LO; Glasius, M; Wåhlin, P; Vinzents, P; Raaschou-Nielsen, O; Loft, S. (2008). Exposure to ambient concentrations of particulate air pollution does not influence vascular function or inflammatory pathways in young healthy individuals. Part Fibre Toxicol 5: 13.

Burns, J, Boogaard, H, Polus, S, Pfadenhauer, LM, Rohwer, AC, van Erp, AM, Turley, R and Rehfuess, E (2019). Interventions to reduce ambient particulate matter air pollution and their effect on health. Cochrane Database of Systematic Reviews(5).

Cangerana Pereira, FA, Lemos, M, Mauad, T, de Assuncao, JV and Nascimento Saldiva, PH (2011). Urban, traffic-related particles and lung tumors in urethane treated mice. Clinics 66(6): 1051–1054.

Chan, EAW, Gantt, B and McDow, S (2018). The reduction of summer sulfate and switch from summertime to wintertime $PM_{2.5}$ concentration maxima in the United States. Atmos Environ 175: 25–32.

Correia, AW, Pope, CA, III, Dockery, DW, Wang, Y, un, Ezzati, M and Dominici, F

(2013). Effect of air pollution control on life expectancy in the United States: an analysis of 545 U.S. counties for the period from 2000 to 2007. Epidemiology 24(1): 23–31.

Cox, LA. (2019a). Letter from Louis Anthony Cox, Jr., Chair, Clean Air Scientific Advisory Committee, to Administrator Andrew R. Wheeler. Re: CASAC Review of the EPA's *Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft—September 2019).* December 16, 2019. EPA–CASAC–20–001. U.S. EPA HQ, Washington DC. Office of the Administrator, Science Advisory Board. Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/E2F6C71737201612852584D20069DFB1/$File/EPA-CASAC-20-001.pdf.*

Cox, LA. (2019b). Letter from Louis Anthony Cox, Jr., Chair, Clean Air Scientific Advisory Committee, to Administrator Andrew R. Wheeler. Re: CASAC Review of the EPA's *Integrated Science Assessment for Particulate Matter (External Review Draft—October 2018).* April 11, 2019. EPA–CASAC–19–002. U.S. EPA HQ, Washington DC. Office of the Administrator, Science Advisory Board. Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/932D1DF8C2A9043F852581000048170D?OpenDocument&TableRow=2.3#2.*

Di, Q, Kloog, I, Koutrakis, P, Lyapustin, A, Wang, Y and Schwartz, J (2016). Assessing $PM_{2.5}$ exposures with high spatiotemporal resolution across the Continental United States. Environ Sci Technol 50(9): 4712–4721.

Di, Q, Dai, L, Wang, Y, Zanobetti, A, Choirat, C, Schwartz, JD and Dominici, F (2017a). Association of short-term exposure to air pollution with mortality in older adults. J Am Med Assoc 318(24): 2446–2456.

Di, Q, Wang, Y, Zanobetti, A, Wang, Y, Koutrakis, P, Choirat, C, Dominici, F and Schwartz, JD (2017b). Air pollution and mortality in the Medicare population. New Engl J Med 376(26): 2513–2522.

Ely, DW, Leary, JT, Stewart, TR and Ross, DM (1991). *The establishment of the Denver Visibility Standard.* Denver, Colorado, Colorado Department of Health.

Fiore, AM, Naik, V and Leibensperger, EM (2015). Air quality and climate connections. J Air Waste Manage Assoc 65(6): 645–685.

Grøntoft, T, Verney-Carron, A, Tidbla, J. (2019). Cleaning costs for European sheltered white painted steel and modern glass surfaces due to air pollution since the year 2000. Atmosphere, 10 (4): 167.

Hand, JL, Schichtel, BA, Pitchford, M, Malm, WC and Frank, NH (2012). Seasonal composition of remote and urban fine particulate matter in the United States. Journal of Geophysical Research: Atmospheres 117(D5).

Hand, JL, Schichtel, BA, Malm, WC and Frank, NH (2013). Spatial and Temporal Trends in $PM_{2.5}$ Organic and Elemental Carbon across the United States. Advances in Meteorology.

Hemmingsen, JG; Jantzen, K; Møller, P; Loft, S. (2015a). No oxidative stress or DNA damage in peripheral blood mononuclear cells after exposure to particles from urban street air in overweight elderly. Mutagenesis 30: 635–642.

Hemmingsen, JG; Rissler, J; Lykkesfeldt, J; Sallsten, G; Kristiansen, J; Møller, P; Loft, S. (2015b). Controlled exposure to particulate matter from urban street air is associated with decreased vasodilation and heart rate variability in overweight and older adults. Part Fibre Toxicol 12: 6.

Henneman, LR, Liu, C, Mulholland, JA and Russell, AG (2017). Evaluating the effectiveness of air quality regulations: A review of accountability studies and frameworks. Journal of the Air Waste Management Association 67(2): 144–172.

Huang, Ra, Zhai, X, Ivey, CE, Friberg, MD, Hu, X, Liu, Y, Di, Q, Schwartz, J, Mulholland, JA and Russell, AG (2018). Air pollutant exposure field modeling using air quality model data fusion methods and comparison with satellite AOD-derived fields: application over North Carolina, USA. Air Quality, Atmosphere and Health 11(1): 11–22.

IPCC (2013). Climate change 2013: The physical science basis. Contribution of working group I to the fifth assessment report of the Intergovernmental Panel on Climate Change. T. F. Stocker, D. Qin, G. K. Plattner et al. Cambridge, UK, Cambridge University Press.

Jerrett, M, Turner, MC, Beckerman, BS, Pope, CA, van Donkelaar, A, Martin, RV, Serre, M, Crouse, D, Gapstur, SM, Krewski, D, Diver, WR, Coogan, PF, Thurston, GD and Burnett, RT (2017). Comparing the health effects of ambient particulate matter estimated using ground-based versus remote sensing exposure estimates. Environ Health Perspect 125(4): 552–559.

Jin, X, Fiore, AM, Civerolo, K, Bi, J, Liu, Y, van Donkelaar, A, Martin, RV, Al-Hamdan, M, Zhang, Y, Insaf, TZ, Kioumourtzoglou, M–A, He, MZ and Kinney, PL (2019). Comparison of multiple $PM_{2.5}$ exposure products for estimating health benefits of emission controls over New York State, USA. Environmental Research Letters 14(8): 084023.

Kelly, J, Schmidt, M and Frank, N. (2012a). Memorandum to PM NAAQS Review Docket (EPA–HQ–OAR–2007–0492). Updated comparison of 24-hour $PM_{2.5}$ design values and visibility index design values. December 14, 2012. Docket ID No. EPA–HQ–OAR–2007–0492. Research Triangle Park, NC. Office of Air Quality Planning and Standards. Available at: *https://www3.epa.gov/ttn/naaqs/standards/pm/data/20121214kelly.pdf.*

Kelly, J, Schmidt, M, Frank, N, Timin, B, Solomon, D and Venkatesh, R. (2012b). Memorandum to PM NAAQS Review Docket (EPA–HQ–OAR–2007–0492). Technical Analyses to Support Surrogacy Policy for Proposed Secondary $PM_{2.5}$ NAAQS under NSR/PSD Programs. June 14, 2012. . Docket ID No. EPA–HQ–OAR–2007–0492. Research Triangle Park, NC. Office of Air Quality Planning and Standards. Available at: *https://www3.epa.gov/ttn/naaqs/standards/pm/data/20120614Kelly.pdf.*

Kelly, JT, Koplitz, SN, Baker, KR, Holder, AL, Pye, HOT, Murphy, BN, Bash, JO, Henderson, BH, Possiel, NC, Simon, H, Eyth, AM, Jang, CJ, Phillips, S and Timin, B (2019). Assessing $PM_{2.5}$ model performance for the conterminous U.S. with comparison to model performance statistics from 2007–2015. Atmos Environ 214: 116872.

Kioumourtzoglou, MA, Schwartz, J, James, P, Dominici, F and Zanobetti, A (2016). $PM_{2.5}$ and mortality in 207 us cities: Modification by temperature and city characteristics. Epidemiology 27(2): 221–227.

Kloog, I, Ridgway, B, Koutrakis, P, Coull, BA and Schwartz, JD (2013). Long- and short-term exposure to $PM_{2.5}$ and mortality: Using novel exposure models. Epidemiology 24(4): 555–561.

Krewski, D, Jerrett, M, Burnett, RT, Ma, R, Hughes, E, Shi, Y, Turner, MC, Pope, CA, III, Thurston, G, Calle, EE, Thun, MJ, Beckerman, B, Deluca, P, Finkelstein, N, Ito, K, Moore, DK, Newbold, KB, Ramsay, T, Ross, Z, Shin, H and Tempalski, B (2009). Extended follow-up and spatial analysis of the American Cancer Society study linking particulate air pollution and mortality. Boston, MA, Health Effects Institute. 140: 5–114; discussion 115–136.

Laden, F, Schwartz, J, Speizer, FE and Dockery, DW (2006). Reduction in fine particulate air pollution and mortality: extended follow-up of the Harvard Six Cities study. Am J Respir Crit Care Med 173(6): 667–672.

Lee, M, Koutrakis, P, Coull, B, Kloog, I and Schwartz, J (2015). Acute effect of fine particulate matter on mortality in three Southeastern states from 2007–2011. Journal of Exposure Science and Environmental Epidemiology 26(2): 173–179.

Lepeule, J, Laden, F, Dockery, D and Schwartz, J (2012). Chronic exposure to fine particles and mortality: An extended follow-up of the Harvard Six Cities study from 1974 to 2009. Environ Health Perspect 120(7): 965–970.

Lippmann, M, Chen, LC, Gordon, T, Ito, K and Thurston, GD (2013). National Particle Component Toxicity (NPACT) Initiative: Integrated epidemiologic and toxicologic studies of the health effects of particulate matter components: Investigators' Report. Boston, MA, Health Effects Institute: 5–13.

Lowenthal, DH and Kumar, N (2004). Variation of mass scattering efficiencies in IMPROVE. Journal of the Air and Waste Management Association (1990–1992) 54(8): 926–934.

Lowenthal, DH and Kumar, N (2016). Evaluation of the IMPROVE Equation for estimating aerosol light extinction. J Air Waste Manage Assoc 66(7): 726–737.

Malm, WC, Sisler, JF, Huffman, D, Eldred, RA and Cahill, TA (1994). Spatial and seasonal trends in particle concentration and optical extinction in the United States. J Geophys Res 99(D1): 1347–1370.

Malm, WC and Hand, JL (2007). An examination of the physical and optical properties of aerosols collected in the IMPROVE program. Atmos Environ 41(16): 3407–3427.

Malm, WC, Molenar, JV, Pitchford, ML, Deck, L. (2011). ''Which Visibility Indicators Best Represent a Population's Preference for a Level of Visual Air Quality?'' Paper 2011–A–596–AWMA, Air & Waste Management Ass'n. 104th Annual Conference, Orlando, FL (June 21–24, 2011). Available at: *http://www.proceedings.com/13671.html.*

Malm, William C. (2013). ''What Level of Perceived Visual Air Quality Is Acceptable?'' Project 13–C–01–01. Available at: *https://www.firescience.gov/projects/13-C-01-01/project/13-C-01-01_Malm_Acceptable_Levels_Report_3.pdf.*

Malm, William C. ''Visibility: The Seeing of Near and Distant Landscape Features (2016). Available at: *https://www.elsevier.com/books/visibility/malm/978-0-12-804450-6.*

Malm, WC, Schichtel, B, Molenar, J, Prenni, A, Peters, M. (2019). ''Which Visibility Indicators Best Represent a Population's Preference for a Level of Visual Air Quality?'' Journal of the Air & Waste Management Association 169(2): 145–61.

Mauad, T, Rivero, DH, de Oliveira, RC, Lichtenfels, AJ, Guimaraes, ET, de Andre, PA, Kasahara, DI, Bueno, HM and Saldiva, PH (2008). Chronic exposure to ambient levels of urban particles affects mouse lung development. Am J Respir Crit Care Med 178(7): 721–728.

McGuinn, LA, Ward-Caviness, C, Neas, LM, Schneider, A, Di, Q, Chudnovsky, A, Schwartz, J, Koutrakis, P, Russell, AG, Garcia, V, Kraus, WE, Hauser, ER, Cascio, W, Diaz-Sanchez, D and Devlin, RB (2017). Fine particulate matter and cardiovascular disease: Comparison of assessment methods for long-term exposure. Environ Res 159: 16–23.

Mie, G (1908). Beitrage zur Optik truber Medien, speziell kolloidaler Metallosungen [Optics of cloudy media, especially colloidal metal solutions]. Annalen der Physik 25(3): 377–445.

Miller, KA, Siscovick, DS, Sheppard, L, Shepherd, K, Sullivan, JH, Anderson, GL and Kaufman, JD (2007). Long-term exposure to air pollution and incidence of cardiovascular events in women. New Engl J Med 356(5): 447–458.

Molenar, JV, Malm, WC. (2012). ''Effect of Clouds on the Perception of Regional and Urban Haze.'' Paper presented at the Specialty Conference on Aerosol and Atmospheric Optics: Visibility and Air Pollution, Whitefish, MT. Available at: *http://www.proceedings.com/17145.html.*

Myhre, G, Shindell, D, Bréon, FM, Collins, W, Fuglestvedt, J, Huang, J, Koch, D, Lamarque, JF, Lee, D, Mendoza, B, Nakajima, T, Robock, A, Stephens, G, Takemura, T and Zhang, H, Eds. (2013). Anthropogenic and natural radiative forcing. Cambridge, UK, Cambridge University Press.

Peng, RD; Chang, HH; Bell, ML; McDermott, A; Zeger, SL; Samet, JM; Dominici, F. (2008). Coarse particulate matter air pollution and hospital admissions for cardiovascular and respiratory diseases among Medicare patients. JAMA 299: 2172–2179.

Pitchford, M, Maim, W, Schichtel, B, Kumar, N, Lowenthal, D and Hand, J (2007). Revised algorithm for estimating light extinction from IMPROVE particle speciation data. J Air Waste Manage Assoc 57(11): 1326–1336.

Pope, CA, III, I, Burnett, RT, Thurston, GD, Thun, MJ, Calle, EE, Krewski, D and Godleski, JJ (2004). Cardiovascular mortality and long-term exposure to particulate air pollution: Epidemiological evidence of general pathophysiological pathways of disease. Circulation 109(1): 71–77.

Pope, CA, III, Ezzati, M and Dockery, DW (2009). Fine-particulate air pollution and life expectancy in the United States. New Engl J Med 360(4): 376–386.

Pruitt, E. (2018). Memorandum from E. Scott Pruitt, Administrator, U.S. EPA to Assistant Administrators. Back-to-Basics Process for Reviewing National Ambient Air Quality Standards. May 9, 2018. U.S. EPA HQ, Washington DC. Office of the Administrator. Available at: *https://www.epa.gov/criteria-air-pollutants/back-basics-process-reviewing-national-ambient-air-quality-standards.*

Pryor, SC (1996). Assessing public perception of visibility for standard setting exercises. Atmos Environ 30(15): 2705–2716.

Puett, RC, Hart, JE, Yanosky, JD, Spiegelman, D, Wang, M, Fisher, JA, Hong, B and Laden, F (2014). Particulate matter air pollution exposure, distance to road, and incident lung cancer in the Nurses' Health Study cohort. Environ Health Perspect 122(9): 926–932.

Raaschou-Nielsen, O, Andersen, ZJ, Beelen, R, Samoli, E, Stafoggia, M, Weinmayr, G, Hoffmann, B, Fischer, P, Nieuwenhuijsen, MJ, Brunekreef, B, Xun, WW, Katsouyanni, K, Dimakopoulou, K, Sommar, J, Forsberg, B, Modig, L, Oudin, A, Oftedal, B, Schwarze, PE, Nafstad, P, De Faire, U, Pedersen, NL, Östenson, CG, Fratiglioni, L, Penell, J, Korek, M, Pershagen, G, Eriksen, KT, Sørensen, M, Tjønneland, A, Ellermann, T, Eeftens, M, Peeters, PH, Meliefste, K, Wang, M, Bueno-De-mesquita, B, Key, TJ, De Hoogh, K, Concin, H, Nagel, G, Vilier, A, Grioni, S, Krogh, V, Tsai, MY, Ricceri, F, Sacerdote, C, Galassi, C, Migliore, E, Ranzi, A, Cesaroni, G, Badaloni, C, Forastiere, F, Tamayo, I, Amiano, P, Dorronsoro, M, Trichopoulou, A, Bamia, C, Vineis, P and Hoek, G (2013). Air pollution and lung cancer incidence in 17 European cohorts: Prospective analyses from the European Study of Cohorts for Air Pollution Effects (ESCAPE). The Lancet Oncology 14(9): 813–822.

Ryan, PA, Lowenthal, D and Kumar, N (2005). Improved light extinction reconstruction in interagency monitoring of protected visual environments. J Air Waste Manage Assoc 55(11): 1751–1759.

Samet, J. (2009). Letter from Jonathan Samet, Chair, Clean Air Scientific Advisory Committee, to Administrator Lisa Jackson. Re: CASAC Particulate Matter Review of Integrated Science Assessment for Particulate Matter (Second External Review Draft, July 2009). November 24, 2009. EPA–CASAC–10–001. U.S. EPA HQ, Washington DC. Office of the Administrator, Science Advisory Board. Available at: *http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P1005PH9.txt.*

Samet, J. (2010a). Letter from Jonathan Samet, Chair, Clean Air Scientific Advisory Committee, to Administrator Lisa Jackson. Re: CASAC Review of Policy Assessment for the Review of the PM NAAQS—First External Review Draft (March 2010). May 17, 2010. EPA–CASAC–10–011. U.S. EPA HQ, Washington DC. Office of the Administrator, Science Advisory Board. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=9101XOXQ.txt.*

Samet, J. (2010b). Letter from Jonathan Samet, Chair, Clean Air Scientific Advisory Committee, to Administrator Lisa Jackson. Re: CASAC Review of Quantitative Health Risk Assessment for Particulate Matter—Second External Review Draft (February 2010). April 15, 2010. EPA–CASAC–10–008. U.S. EPA HQ, Washington DC. Office of the Administrator, Science Advisory Board. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P1007CVB.txt.*

Samet, J. (2010c). Letter from Jonathan Samet, Chair, Clean Air Scientific Advisory Committee, to Administrator Lisa Jackson. Re: CASAC Review of Policy Assessment for the Review of the PM NAAQS—Second External Review Draft (June 2010). September 10, 2010. EPA–CASAC–10–015. U.S. EPA HQ, Washington DC. Office of the Administrator, Science Advisory Board. Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/CCF9F4C0500C500F8525779D0073C593/$File/EPA-CASAC-10-015-unsigned.pdf.*

Shi, L, Zanobetti, A, Kloog, I, Coull, BA, Koutrakis, P, Melly, SJ and Schwartz, JD (2016). Low-concentration $PM_{2.5}$ and mortality: Estimating acute and chronic effects in a population-based study. Environ Health Perspect 124(1): 46–52.

Smith, AE and Howell, S (2009). An assessment of the robustness of visual air quality preference study results. Washington, DC, CRA International.

Turner, MC; Krewski, D; Pope, CA, III; Chen, Y; Gapstur, SM; Thun, MJ. (2011). Long-term ambient fine particulate matter air pollution and lung cancer in a large cohort of never smokers. Am J Respir Crit Care Med 184: 1374–1381.

U.S. DHEW. (1969). Air Quality Criteria for Sulfure Oxides. National Center for Air Pollution Control, Bureau of Disease Prevention and Environmental Control, Public Health Service Publication No. 1619, March 1967. Available at: *https://www3.epa.gov/ttn/naaqs/standards/so2/_so2_pr.html.*

U.S. EPA. (2004). Air Quality Criteria for Particulate Matter. (Vol I and II). Research Triangle Park, NC. Office of Research and Development. U.S. EPA. EPA–600/P–99–002aF and EPA–600/P–99–002bF. October 2004. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100LFIQ.txt.*

U.S. EPA. (2005). Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper. Research Triangle Park, NC. Office of Air Quality Planning and Standards. U.S. EPA. EPA–452/R–05–005a. December 2005. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P1009MZM.txt.*

U.S. EPA. (2008). Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter Research Triangle Park, NC. Office of Research and Development, National Center for Environmental Assessment; Office of Air Quality Planning and Standards, Health and Environmental Impacts Division. U.S. EPA. EPA 452/R–08–004. March 2008. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P1001FB9.txt.*

U.S. EPA. (2009a). Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment Research Triangle Park, NC. Office of Air Quality Planning and Standards, Health and Environmental Impacts Division. U.S. EPA. EPA–452/P–09–002. February 2009. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100FLWP.txt.*

U.S. EPA. (2009b). Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Urban Visibility Impact Assessment Research Triangle Park, NC. Office of Air Quality Planning and Standards, Health and Environmental Impacts Division. U.S. EPA. EPA–452/P–09–001. February 2009. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100FLUX.txt.*

U.S. EPA. (2009c). Integrated Science Assessment for Particulate Matter (Final Report). Research Triangle Park, NC. Office of Research and Development, National Center for Environmental Assessment. U.S. EPA. EPA–600/R–08–139F. December 2009. Available at: *https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=216546.*

U.S. EPA. (2010a). Quantitative Health Risk Assessment for Particulate Matter (Final Report). Research Triangle Park, NC. Office of Air Quality Planning and Standards, Health and Environmental Impacts Division. U.S. EPA. EPA–452/R–10–005. June 2010. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P1007RFC.txt.*

U.S. EPA. (2010b). Particulate Matter Urban-Focused Visibility Assessment (Final Document). Research Triangle Park, NC. Office of Air Quality Planning and Standards, Health and Environmental Impacts Division. U.S. EPA. EPA–452/R–10–004 July 2010. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100FO5D.txt.*

U.S. EPA. (2011). Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards Research Triangle Park, NC. Office of Air Quality Planning and Standards, Health and Environmental Impacts Division. U.S. EPA. EPA–452/R–11–003 April 2011. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100AUMY.txt.*

U.S. EPA. (2012). Responses to Significant Comments on the 2012 Proposed Rule on the National Ambient Air Quality Standards for Particulate Matter (June 29, 2012; 77 FR 38890). Research Triangle Park, NC. U.S. EPA. Docket ID No. EPA–HQ–OAR–2007–0492. Available at: *https://www3.epa.gov/ttn/naaqs/standards/pm/data/20121214rtc.pdf.*

U.S. EPA. (2015). Preamble to the integrated science assessments. Research Triangle Park, NC. U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, RTP Division. U.S. EPA. EPA/600/R–15/067. November 2015. Available at: *https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244.*

U.S. EPA. (2016). Integrated review plan for the national ambient air quality standards for particulate matter. Research Triangle Park, NC. Office of Air Quality Planning and Standards. U.S. EPA. EPA–452/R–16–005. December 2016. Available at: *https://www3.epa.gov/ttn/naaqs/standards/pm/data/201612-final-integrated-review-plan.pdf.*

U.S. EPA. (2017). Integrated review plan for the secondary national ambient air quality standards for ecological effects of oxides of nitrogen, oxides of sulfur and particulate matter. Research Triangle Park, NC. Office of Air Quality Planning and Standards. U.S. EPA. EPA–452/R–17–002. Available at: *https://www.epa.gov/naaqs/nitrogen-dioxide-no2-and-sulfur-dioxide-so2-secondary-standards-planning-documents-current.*

U.S. EPA. (2018). Review of the Secondary Standards for Ecological Effects of Oxides of Nitrogen, Oxides of Sulfur, and Particulate Matter: Risk and Exposure Assessment Planning Document. Research Triangle Park, NC. Office of Air Quality Planning and Standards. U.S. EPA. EPA–452/D–18–001. Available at: *https://www.epa.gov/naaqs/nitrogen-dioxide-no2-and-sulfur-dioxide-so2-secondary-standards-planning-documents-current.*

U.S. EPA. (2019). Integrated Science Assessment (ISA) for Particulate Matter (Final Report). Washington, DC. U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. U.S. EPA. EPA/600/R–19/188. December 2019. Available at: *https://www.epa.gov/naaqs/particulate-matter-pm-standards-integrated-science-assessments-current-review.*

U.S. EPA. (2020). Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter. Research Triangle Park, NC. U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Heath and Environmental Impacts Division. U.S. EPA. EPA–452/R–20–002. January 2020. Available at: *https://www.epa.gov/naaqs/particulate-matter-pm-standards-policy-assessments-current-review-0.*

U.S. National Institutes of Health. (2013). NHLBI fact book, fiscal year 2012: Disease statistics. Bethesda, MD. U.S. National Institutes of Health, National Heart, Lung, and Blood Institute. U.S. National Institutes of Health, NH, Lung, and Blood Institute,. February 2013. Available at: *https://www.nhlbi.nih.gov/files/docs/factbook/FactBook2012.pdf.*

Van de Hulst, H (1981). *Light scattering by small particles.* New York, Dover Publications, Inc.

Van Donkelaar, A, Martin, RV, Li, C and Burnett, RT (2019). Regional estimates of chemical composition of fine particulate matter using a combined geoscience-statistical method with information from satellites, models, and monitors. Environ Sci Technol 53(5).

Wheeler, AR. (2019). Letter from Administrator Andrew R. Wheeler to Louis Anthony Cox, Jr.. Re: CASAC Review of the *EPA's Integrated Science Assessment for Particulate Matter (External Review Draft—October 2018).* July 25, 2019. Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002_Response.pdf.*

Yorifuji, T, Kashima, S and Doi, H (2016). Fine-particulate air pollution from diesel emission control and mortality rates in Tokyo: A quasi-experimental study. Epidemiology 27(6): 769–778.

Zeger, S; Dominici, F; McDermott, A; Samet, J. (2008). Mortality in the Medicare population and chronic exposure to fine particulate air pollution in urban centers (2000–2005). Environ Health Perspect 116: 1614–1619.

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.

[FR Doc. 2020–27125 Filed 12–17–20; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[EPA–HQ–OAR–2018–0279; FRL–10019–04–OAR]

RIN 2060–AU40

Review of the Ozone National Ambient Air Quality Standards

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 photochemical oxidants including ozone (O_3), the EPA is retaining the current standards, without revision.

DATES: This final action is effective December 31, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2018–0279. Incorporated into this docket is a separate docket established for the Integrated Science Assessment for this review (Docket ID No. EPA–HQ–ORD–2018–0274). All documents in these dockets are listed on the *www.regulations.gov* website. 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.*

Availability of Information Related to This Action

A number of the documents that are relevant to this action are available through the EPA's website at *https://www.epa.gov/naaqs/ozone-o3-air-quality-standards.* These documents include the Integrated Review Plan for the Ozone National Ambient Air Quality Standards (IRP [U.S. EPA, 2019b]), available at *https://www.epa.gov/naaqs/ozone-o3-standards-planning-documents-current-review,* the Integrated Science Assessment for Ozone and Related Photochemical Oxidants (ISA [U.S. EPA, 2020a]), available at *https://www.epa.gov/naaqs/ozone-o3-standards-integrated-science-assessments-current-review,* the Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (PA [U.S. EPA, 2020b]), available at *https://www.epa.gov/naaqs/ozone-o3-standards-policy-assessments-current-review.* These and other related documents are also available for inspection and copying in the EPA docket identified above.

FOR FURTHER INFORMATION CONTACT: Dr. Deirdre Murphy, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C504–06, Research Triangle Park, NC 27711; telephone: (919) 541–0729; fax: (919) 541–0237; email: *murphy.deirdre@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 consistent with APA section 553(d) to make this action effective December 31, 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.

Table of Contents

The following topics are discussed in this preamble:

Executive Summary

This document presents the Administrator's decisions in the current review of the primary (health-based) and secondary (welfare-based) O_3 NAAQS, to retain the current standards, without revision. In reaching these decisions, the Administrator has considered the currently available scientific evidence in the ISA, quantitative and policy analyses presented in the PA, advice from the Clean Air Scientific Advisory Committee (CASAC), and public comments on the proposed decision. This document provides background and summarizes the rationale for these decisions.

This review of the O_3 standards, required by the Clean Air Act (CAA) on a periodic basis, was initiated in 2018. In the last review, completed in 2015, the EPA significantly strengthened the primary and secondary O_3 standards by revising the level of both standards from 75 parts per billion (ppb) to 70 ppb and retaining their indicators (O_3), forms (annual fourth-highest daily maximum, averaged across three consecutive years) and averaging times (eight hours) (80 FR 65291, October 26, 2015). In subsequent litigation on the 2015 decisions, the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) upheld the 2015 primary standard but remanded the 2015 secondary standard to the EPA for further justification or reconsideration. The court's remand of the secondary standard has been considered in reaching the decision described in this document on this standard, and in associated conclusions and judgments, also described here. Accordingly, this decision incorporates the EPA's response to the judicial remand of the 2015 secondary standard.

In this review as in past reviews of the air quality criteria and NAAQS for O_3 and related photochemical oxidants, the health and welfare effects evidence evaluated in the ISA is focused on O_3. Ozone is the most prevalent photochemical oxidant in the atmosphere and the one for which there is a large body of scientific evidence on health and welfare effects. A component of smog, O_3 in ambient air is a mixture of mostly tropospheric O_3 and some stratospheric O_3. Tropospheric O_3 forms in the atmosphere when emissions of precursor pollutants, such as nitrogen oxides and volatile organic compounds (VOCs), interact with solar radiation. Such emissions result from man-made sources (*e.g.* motor vehicles and power plants) and natural sources (*e.g.* vegetation and wildfires). In addition, O_3 that is created naturally in the stratosphere also mixes with tropospheric O_3 near the tropopause, and, less frequently can mix nearer the earth's surface.

Based on the current health effects evidence and quantitative information, as well as consideration of CASAC advice and public comment, the Administrator concludes that the current primary standard is requisite to protect public health, including the health of at-risk populations, with an adequate margin of safety, and should be retained, without revision. This decision has been informed by key aspects of the health effects evidence newly available in this review, in conjunction with the full body of evidence critically evaluated in the ISA, that continues to support prior conclusions that short-term O_3 exposure causes and long-term O_3 exposure is likely to cause respiratory effects. The strongest evidence continues to come from studies of short- and long-term O_3 exposure and an array of respiratory health effects, including effects related to asthma exacerbation in people with asthma, particularly children with asthma. The clearest evidence comes from controlled human exposure studies, available at the time of the last review, of individuals exposed for 6.6 hours during quasi-continuous exercise, that report an array of respiratory responses including lung function decrements and respiratory symptoms. Epidemiologic studies additionally describe consistent, positive associations between O_3 exposures and hospital admissions and emergency department visits, particularly for asthma exacerbation in children. Populations and lifestages at risk include people with asthma, children, the elderly, and outdoor workers. The quantitative analyses of population exposure and risk, as well as policy considerations in the PA, summarized in this document and described in detail in the PA, also inform the decision on the primary standard. The general approach and methodology used for the exposure-based assessment is similar to that used in the last review, although a number of updates and improvements have been implemented. These include a more recent period (2015–2017) of ambient air monitoring data in which O_3 concentrations in the areas assessed are at or near the current standard, as well as improvements and updates to models, model inputs and underlying databases.

In its advice to the Administrator, the CASAC stated that the newly available health effects evidence does not differ substantially from that available in the last review when the standard was set. Part of CASAC concluded that the primary standard should be retained. Another part of CASAC expressed concern regarding the margin of safety provided by the current standard, pointing to comments from the 2014 CASAC, who while agreeing that the evidence supported a standard level of 70 ppb, additionally provided policy advice expressing support for a lower standard. In summary, the current evidence and quantitative analyses, advice from the CASAC and consideration of public comments have informed the Administrator's judgments in reaching his decision that the current primary standard of 70 ppb O_3, as the annual fourth-highest daily maximum 8-hour concentration averaged across three consecutive years, provides the requisite public health protection, with an adequate margin of safety.

Based on the current welfare effects evidence and quantitative information, as well as consideration of CASAC advice and public comment, the Administrator concludes that the current secondary standard is requisite to protect the public welfare from known or anticipated adverse effects of O_3 and related photochemical oxidants in ambient air, and should be retained, without revision. This decision has been informed by key aspects of the welfare effects evidence newly available in this review, in conjunction with the full body of evidence critically evaluated in the ISA, that supports, sharpens and expands somewhat on the conclusions reached in the last review. The currently available evidence describes an array of O_3 effects on vegetation and related ecosystem effects, as well as the role of O_3 in radiative forcing and subsequent climate-related effects. The ISA includes findings of causal or likely causal relationships for a number of such effects with O_3 in the ambient air. As in the last review, the strongest evidence, including quantitative characterizations of relationships between O_3 exposure and occurrence and magnitude of effects, is for vegetation effects. The scales of these effects range from the individual plant scale to the ecosystem scale, with potential for impacts on the public welfare.

While the welfare effects of O_3 vary widely with regard to the extent and level of detail of the available information that describes the exposure circumstances that may elicit them, such information is most advanced for plant growth-related effects. For example, the information on exposure metric and relationships for these effects with the cumulative, concentration-weighted exposure index, W126, is long-standing, having been first described in the 1997 review. Utilizing this information in reviewing the public welfare protection provided by the current secondary standard, reduced growth has been considered as proxy or surrogate for a broad array of related vegetation effects. Quantitative analyses of air quality and vegetation exposure, including in terms of the W126 index, as well as policy-relevant considerations discussed in the PA, have also informed the Administrator's decision on the secondary standard. These include analyses of air quality monitoring data in areas meeting the current standard across the U.S., as well as in Class I areas, updated and expanded from analyses conducted in the last review. Lastly, in its advice to the Administrator on the secondary standard, the full CASAC found the current evidence to support the current standard and concurred with the draft PA that it should be retained without revision. In summary, the current evidence and quantitative analyses, advice from the CASAC and consideration of public comments have informed the Administrator's judgments in reaching his decision that the current secondary standard of 70 ppb O_3, as the annual fourth-highest daily maximum 8-hour concentration averaged across three consecutive years, provides the requisite public welfare protection.

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.'' [1] 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.'' [2]

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 Ass'ns,* 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.'' See *American Petroleum Institute* v. *Costle,* 665 F.2d 1176, 1185 (D.C. Cir. 1981); *accord Murray Energy Corp.* v. *EPA,* 936 F.3d 597, 623–24 (D.C. Cir. 2019). At the same time, courts have clarified the EPA may consider ''relative proximity to peak background . . . concentrations'' as a factor in deciding how to revise the NAAQS in the context of considering standard levels within the range of reasonable values supported by the air quality criteria and judgments of the Administrator. See *American Trucking Ass'ns,* v. *EPA,* 283 F.3d 355, 379 (D.C. Cir. 2002), hereafter referred to as ''*ATA III.*''

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 Ass'n* 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),[3]

[1] 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).

[2] 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.''

[3] As used here and similarly throughout this document, the term population (or group) refers to persons having a quality or characteristic in common, such as a specific pre-existing illness or a specific age or life stage. As summarized in section II.A.2.c below, the identification of sensitive groups (called at-risk groups or at-risk populations) involves consideration of susceptibility and vulnerability.

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

Section 109(d)(1) of the Act requires periodic review and, if appropriate, revision of existing air quality criteria to reflect advances in scientific knowledge concerning the effects of the pollutant on public health and welfare. Under the same provision, the EPA is also to periodically review and, if appropriate, revise the NAAQS, based on the revised air quality criteria.[4]

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 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.

As previously noted, the Supreme Court has held that section 109(b) ''unambiguously bars cost considerations from the NAAQS-setting process,'' in *Whitman* v. *American Trucking Ass'ns,* 531 U.S. 457, 471 (2001). Accordingly, while some of the issues listed in section 109(d)(2)(C) as those on 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.[5]

B. Related O_3 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 through 185 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 of air quality program that covers these pollutants. *See* 42 U.S.C. 7470–7479. In addition, federal programs provide for nationwide reductions in emissions of O_3 precursors and other air pollutants under Title II of the Act, 42 U.S.C. 7521–7574, which involves controls for automobile, truck, bus, motorcycle, nonroad engine and equipment, and aircraft emissions; the new source performance standards under section 111 of the Act, 42 U.S.C. 7411; and the national emissions standards for hazardous air pollutants under section 112 of the Act, 42 U.S.C. 7412.

C. History of the Air Quality Criteria and Standards

Primary and secondary NAAQS were first established for photochemical oxidants in 1971 (36 FR 8186, April 30, 1971) based on the air quality criteria developed in 1970 (U.S. DHEW, 1970; 35 FR 4768, March 19, 1970). The EPA set both primary and secondary standards at 0.08 parts per million (ppm), as a 1-hour average of total photochemical oxidants, not to be exceeded more than one hour per year. Since that time, the EPA has reviewed the air quality criteria and standards a number of times, with the most recent review being completed in 2015.

The EPA initiated the first periodic review of the NAAQS for photochemical oxidants in 1977. Based on the 1978 air quality criteria document (AQCD [U.S. EPA, 1978]), the EPA proposed revisions to the original NAAQS in 1978 (43 FR 26962, June 22, 1978) and adopted revisions in 1979 (44 FR 8202, February 8, 1979). At that time, the EPA changed the indicator from photochemical oxidants to O_3, revised the level of the primary and secondary standards from 0.08 to 0.12 ppm and revised the form of both standards from a deterministic (*i.e.,* not to be exceeded more than one hour per year) to a statistical form. With these changes, attainment of the standards was defined to occur when the average number of days per calendar year (across a 3-year period) with maximum hourly average O_3 concentration greater than 0.12 ppm equaled one or less (44 FR 8202, February 8, 1979; 43 FR 26962, June 22, 1978). Several petitioners challenged the 1979 decision. Among those, one claimed natural O_3 concentrations and other physical phenomena made the standard unattainable in the Houston area.[6] The U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) rejected this argument, holding (as noted in section I.A above) that attainability and technological feasibility are not relevant considerations in the promulgation of the NAAQS (*American Petroleum Institute* v. *Costle,* 665 F.2d at 1185). The court also noted that the EPA need not tailor the NAAQS to fit each region or locale, pointing out that Congress was aware of the difficulty in meeting standards in some locations and had addressed it through various compliance-related provisions in the CAA (*id.* at 1184–86).

The next periodic reviews of the criteria and standards for O_3 and other

[4] This section of the Act requires the Administrator to complete these reviews and make any revisions that may be appropriate ''at five-year intervals.''

[5] Because some of these issues are not relevant to standard setting, some aspects of CASAC advice may not be relevant to 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* v. *American Trucking Ass'ns,* 531 U.S. 457, 471 n.4 (2001). At the same time, the CAA directs 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 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).

[6] The EPA has determined that air quality in the area including Houston has attained the 1979 1-hour standard (85 FR 8411, February 14, 2020).

photochemical oxidants began in 1982 and 1983, respectively (47 FR 11561, March 17, 1982; 48 FR 38009, August 22, 1983). As part of these reviews, the EPA published an AQCD, a Staff Paper, and a supplement to the AQCD (U.S. EPA, 1986; U.S. EPA, 1989; U.S. EPA, 1992). The schedule for completion of this review was governed by court order. In August of 1992, the EPA proposed to retain the existing primary and secondary standards (57 FR 35542, August 10, 1992). In March 1993, the EPA concluded this review by finalizing its proposed decision to retain the standards, without revision (58 FR 13008, March 9, 1993).

In the next review of the air quality criteria and standards for O_3 and other photochemical oxidants, for which the EPA had announced in August 1992 its intention to proceed rapidly, the EPA developed an AQCD and Staff Paper (57 FR 35542, August 10, 1992; U.S. EPA, 1996a; U.S. EPA, 1996b). Based on consideration of these assessments, the EPA proposed revisions to both the primary and secondary standards (61 FR 65716, December 13, 1996). The EPA completed this review in 1997 by revising both standards to 0.08 ppm, as the annual fourth-highest daily maximum 8-hour average concentration, averaged over three years (62 FR 38856, July 18, 1997).

In response to challenges to the EPA's 1997 decision revising the standards, the D.C. Circuit remanded the standards to the EPA, finding that section 109 of the CAA, as interpreted by the EPA, effected an unconstitutional delegation of legislative authority. See *American Trucking Ass'ns* v. *EPA,* 175 F.3d 1027, 1034–1040 (D.C. Cir. 1999). The court also directed that, in responding to the remand, the EPA should consider the potential beneficial health effects of O_3 pollution in shielding the public from the effects of solar ultraviolet (UV) radiation, as well as adverse health effects (*id.* at 1051–53). See *American Trucking Ass'ns* v. *EPA,* 195 F.3d 4, 10 (D.C. Cir. 1999) (granting panel rehearing in part but declining to review the ruling on consideration of the potential beneficial effects of O_3 pollution). After granting petitions for *certiorari,* the U.S. Supreme Court unanimously reversed the judgment of the D.C. Circuit on the constitutional issue, holding that section 109 of the CAA does not unconstitutionally delegate legislative power to the EPA. See *Whitman* v. *American Trucking Ass'ns,* 531 U.S. 457, 472–74 (2001). The Court remanded the case to the D.C. Circuit to consider challenges to the 1997 O_3 NAAQS that had not yet been addressed. On remand, the D.C. Circuit found the 1997 O_3 NAAQS to be ''neither arbitrary nor capricious,'' and so denied the remaining petitions for review. See *ATA III,* 283 F.3d at 379.

Coincident with the continued litigation of the other issues, the EPA responded to the court's 1999 remand to consider the potential beneficial health effects of O_3 pollution in shielding the public from effects of UV radiation (66 FR 57268, Nov. 14, 2001; 68 FR 614, January 6, 2003). In 2001, the EPA proposed to leave the 1997 primary standard unchanged (66 FR 57268, Nov. 14, 2001). After considering public comment on the proposed decision, the EPA published its final response to this remand in 2003, re-affirming the 8-hour primary standard set in 1997 (68 FR 614, January 6, 2003).

The EPA initiated the fourth periodic review of the air quality criteria and standards for O_3 and other photochemical oxidants with a call for information in September 2000 (65 FR 57810, September 26, 2000). In this review, the EPA developed an AQCD, Staff Paper and related technical support documents and proposed revisions to the primary and secondary standards (U.S. EPA, 2006; U.S. EPA, 2007; 72 FR 37818, July 11, 2007). The review was completed in March 2008 with revision of the levels of both the primary and secondary standards from 0.08 ppm to 0.075 ppm, and retention of the other elements of the prior standards (73 FR 16436, March 27, 2008). A number of petitioners filed suit challenging this decision.

In September 2009, the EPA announced its intention to reconsider the 2008 O_3 standards,[7] and initiated a rulemaking to do so. At the EPA's request, the court held the consolidated cases in abeyance pending the EPA's reconsideration of the 2008 decision. In January 2010, the EPA issued a notice of proposed rulemaking to reconsider the 2008 final decision (75 FR 2938, January 19, 2010). Later that year, in view of the need for further consideration and the fact that the Agency's next periodic review of the O_3 NAAQS required under CAA section 109 had already begun (as announced in September 2008),[8] the EPA consolidated the reconsideration with its statutorily required periodic review.[9]

In light of the EPA's decision to consolidate the reconsideration with the review then ongoing, the D.C. Circuit proceeded with the litigation on the 2008 O_3 NAAQS decision. On July 23, 2013, the court upheld the EPA's 2008 primary standard, but remanded the 2008 secondary standard to the EPA. See *Mississippi* v. *EPA,* 744 F.3d 1334 (D.C. Cir. 2013). With respect to the secondary standard, the court held that the EPA's explanation for the setting of the secondary standard identical to the revised 8-hour primary standard was inadequate under the CAA because the EPA had not adequately explained how that standard provided the required public welfare protection.

At the time of the court's decision, the EPA had already completed significant portions of its next statutorily required periodic review of the O_3 NAAQS, which had been formally initiated in 2008, as summarized above. The documents developed for this review included the ISA,[10] Risk and Exposure Assessments (REAs) for health and welfare, and PA (Frey, 2014a, Frey, 2014b, Frey, 2014c, U.S. EPA, 2013, U.S. EPA, 2014a, U.S. EPA, 2014b, U.S. EPA, 2014c).[11] In late 2014, the EPA proposed to revise the 2008 primary and secondary standards (79 FR 75234, December 17, 2014). The EPA's final decision in this review established the now-current standards (80 FR 65292, October 26, 2015; 40 CFR 50.19). In this decision, based on consideration of the health effects evidence on respiratory effects of O_3 in at-risk populations, the EPA revised the primary standard from a level of 0.075 ppm to a level of 0.070 ppm, while retaining all other elements of the standard (80 FR 65292, October 26, 2015). The EPA's decision on the level for the standard was based on the weight of the scientific evidence and quantitative exposure/risk information. The level of the secondary standard was also revised from 0.075 ppm to 0.070 ppm based on the scientific evidence of O_3 effects on welfare, particularly the evidence of O_3 impacts on vegetation, and quantitative analyses available in the review. The other elements of the standard were retained. This decision on the secondary standard also incorporated the EPA's response to the

[7] The press release of this announcement is available at: *https://archive.epa.gov/epapages/newsroom_archive/newsreleases/85f90b7711acb0c88525763300617d0d.html.*

[8] A ''Call for Information'' initiated the review (73 FR 56581, September 29, 2008).

[9] This rulemaking, completed in 2015, concluded the reconsideration process.

[10] The ISA, as the AQCD in prior reviews, serves the purpose of reviewing the air quality criteria.

[11] The PA presents an evaluation, for consideration by the Administrator, of the policy implications of the currently available scientific information, assessed in the ISA; the quantitative air quality, exposure or risk analyses presented in the PA and developed in light of the ISA findings; and related limitations and uncertainties. The role of the PA is to help ''bridge the gap'' between the Agency's scientific assessment and quantitative technical analyses, and the judgments required of the Administrator in his decisions in the NAAQS review.

D.C. Circuit's remand of the 2008 secondary standard in *Mississippi* v. *EPA,* 744 F.3d 1344 (D.C. Cir. 2013).[12]

After publication of the final rule, a number of industry groups, environmental and health organizations, and certain states filed petitions for judicial review in the D.C. Circuit. The industry and state petitioners argued that the revised standards were too stringent, while the environmental and health petitioners argued that the revised standards were not stringent enough to protect public health and welfare as the Act requires. On August 23, 2019, the court issued an opinion that denied all the petitions for review with respect to the 2015 primary standard while also concluding that the EPA had not provided a sufficient rationale for aspects of its decision on the 2015 secondary standard and remanding that standard to the EPA. See *Murray Energy Corp.* v. *EPA,* 936 F.3d 597 (D.C. Cir. 2019). The court's decision on the secondary standard focused on challenges to particular aspects of EPA's decision. The court concluded that EPA's identification of particular benchmarks for evaluating the protection the standard provided against welfare effects associated with tree growth loss was reasonable and consistent with CASAC's advice. However, the court held that EPA had not adequately explained its decision to focus on a 3-year average for consideration of the cumulative exposure, in terms of W126, identified as providing requisite public welfare protection, or its decision to not identify a specific level of air quality related to visible foliar injury. The EPA's decision not to use a seasonal W126 index as the form and averaging time of the secondary standard was also challenged, but the court did not reach a decision on that issue, concluding that it lacked a basis to assess the EPA's rationale because the EPA had not yet fully explained its focus on a 3-year average W126 in its consideration of the standard. See *Murray Energy Corp.* v. *EPA,* 936 F.3d 597, 618 (D.C. Cir. 2019). Accordingly, the court remanded the secondary standard to EPA for further justification or reconsideration. The court's remand of the secondary standard has been considered in reaching the decision, and associated conclusions and judgments, described in section III.B.3 below.

In the August 2019 decision, the court additionally addressed arguments regarding considerations of background O_3 concentrations, and socioeconomic and energy impacts. With regard to the former, the court rejected the argument that the EPA was required to take background O_3 concentrations into account when setting the NAAQS, holding that the text of CAA section 109(b) precluded this interpretation because it would mean that if background O_3 levels in any part of the country exceeded the level of O_3 that is requisite to protect public health, the EPA would be obliged to set the standard at the higher nonprotective level (*id.* at 622–23). Thus, the court concluded that the EPA did not act unlawfully or arbitrarily or capriciously in setting the 2015 NAAQS without regard for background O_3 (*id.* at 624). Additionally, the court denied arguments that the EPA was required to consider adverse economic, social, and energy impacts in determining whether a revision of the NAAQS was ''appropriate'' under section 109(d)(1) of the CAA (*id.* at 621–22). The court reasoned that consideration of such impacts was precluded by *Whitman's* holding that the CAA ''unambiguously bars cost considerations from the NAAQS-setting process'' (531 U.S. at 471, summarized in section I.A above). Further, the court explained that section 109(d)(2)(C)'s requirement that CASAC advise the EPA ''of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance'' of revised NAAQS had no bearing on whether costs are to be considered in setting the NAAQS (*Murray Energy Corp.* v. *EPA,* 936 F.3d at 622). Rather, as described in *Whitman* and discussed further in section I.A above, most of that advice would be relevant to implementation but not standard setting (*id.*).

D. Current Review of the Air Quality Criteria and Standards

In May 2018, the Administrator directed his Assistant Administrators to initiate this current review of the O_3 NAAQS (Pruitt, 2018). In conveying this direction, the Administrator further directed the EPA staff to expedite the review, implementing an accelerated schedule aimed at completion of the review within the statutorily required period (Pruitt, 2018). Accordingly, the EPA took immediate steps to proceed with the review. In June 2018, the EPA announced the initiation of the periodic reviews of the air quality criteria for photochemical oxidants and of the O_3 NAAQS and issued a call for information in the **Federal Register** (83 FR 29785, June 26, 2018). Two types of information were called for: Information regarding significant new O_3 research to be considered for the ISA for the review, and policy-relevant issues for consideration in this NAAQS review. Based in part on the information received in response to the call for information, the EPA developed a draft IRP, which was made available for consultation with the CASAC and for public comment (83 FR 55163, November 2, 2018; 83 FR 55528, November 6, 2018). Comments from the CASAC (Cox, 2018) and the public were considered in preparing the final IRP (U.S. EPA, 2019b).

Under the plan outlined in the IRP and consistent with revisions to the process identified by the Administrator in his 2018 memo directing initiation of the review, the current review of the O_3 NAAQS has progressed on an accelerated schedule (Pruitt, 2018). The EPA has incorporated a number of efficiencies in various aspects of the review process, as summarized in the IRP, to support the accelerated schedule (Pruitt, 2018). As one example of such an efficiency, rather than produce separate documents for the PA and associated quantitative analyses, the human exposure and health risk analyses (that inform the decision on the primary standard) and the air quality and exposure analyses (that inform the decision on the secondary standard) are included as appendices in the PA, along with other technical appendices that inform these standards decisions. The draft PA (including these analyses as appendices) was reviewed by the CASAC and made available for public comment while the draft ISA was also being reviewed by the CASAC and was available for public comment (84 FR 50836, September 26, 2019; 84 FR 58711, November 1, 2019).[13] The CASAC was assisted in its review by a pool of consultants with expertise in a number of fields (84 FR 38625, August 7, 2019). The approach employed by the CASAC in utilizing outside technical expertise represents an additional modification of the process from past reviews. Rather than join with some or all of the CASAC members in a CASAC review panel as has been common in other NAAQS reviews in the past, in this O_3 NAAQS review (and also in the recent CASAC review of the PA for the

[12] The 2015 revisions to the NAAQS were accompanied by revisions to the data handling procedures, ambient air monitoring requirements, the air quality index and several provisions related to implementation (80 FR 65292, October 26, 2015).

[13] The draft ISA and draft PA were released for public comment and CASAC review on September 26, 2019 and October 31, 2019, respectively. The charges for the CASAC review summarized the overarching context for the document review (including reference to Pruitt [2018], and the CASAC's functions under section 109(d)(2)(B) and (C) of the Act), as well as specific charge questions for review of each of the documents.

particulate matter NAAQS), the consultants comprised a pool of expertise that CASAC members drew on through the use of specific questions, posed in writing prior to the public meeting, regarding aspects of the documents being reviewed, obtaining subject matter expertise for their review in a focused, efficient and transparent manner.

The CASAC discussed its review of both the draft ISA and the draft PA over three days at a public meeting in December 2019 (84 FR 58713, November 1, 2019).[14] The CASAC discussed its draft letters describing its advice and comments on the documents in a public teleconference in early February 2020 (85 FR 4656; January 27, 2020). The letters to the Administrator conveying the CASAC advice and comments on the draft PA and draft ISA were released later that month (Cox, 2020a; Cox, 2020b).

The letters from the CASAC and public comment on the draft ISA and draft PA informed completion of the final documents and further informed development of the Administrator's proposed and final decisions in this review. Comments from the CASAC on the draft ISA were considered by the EPA and led to a number of revisions in developing the final document. The CASAC review of the draft ISA and the EPA's consideration of CASAC comments are described in Appendix 10, section 10.4.5 of the final ISA. In his reply to the CASAC letter conveying its review, "Administrator Wheeler noted, 'for those comments and recommendations that are more significant or cross-cutting and which were not fully addressed, the Agency will develop a plan to incorporate these changes into future O_3 ISAs as well as ISAs for other criteria pollutant reviews' " (ISA, p. 10–28; Wheeler, 2020). The ISA was completed and made available to the public in April 2020 (85 FR 21849, April 20, 2020).[15] Based on the rigorous scientific approach utilized in its development, summarized in Appendix 10 of the final ISA, the EPA considers the final ISA 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 [O_3] in the ambient air, in varying quantities" as required by the CAA (42 U.S.C. 7408(a)(2)).

The CASAC comments additionally provided advice with regard to the primary and secondary standards, as well as a number of comments intended to improve the PA. These comments were considered in completing that document (85 FR 31182, May 22, 2020). The CASAC advice to the Administrator regarding the O_3 standards has also been described and considered in the PA, and in sections II and III below. The CASAC advice on the primary standard is summarized in II.B.2 below and its advice on the secondary standard is summarized in section III.B.1.b.

Materials upon which this proposed decision is based, including the documents described above, are available to the public in the docket for the review.[16] 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 O_3 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 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 O_3 in

[14] While simultaneous review of first drafts of both documents has not been usual in past reviews, there have been occurrences of the CASAC review of a draft PA (or draft REA when the process involved a policy assessment being included within the REA document) simultaneous with review of a second (or later) draft ISA (*e.g.,* 73 FR 19835, April 11, 2008; 73 FR 34739, June 18, 2008; 77 FR 64335, October 19, 2012; 78 FR 938, January 7, 2013).

[15] The ISA builds on evidence and conclusions from previous assessments, focusing on synthesizing and integrating the newly available evidence (ISA, section IS.1.1). Past assessments are generally cited when providing further, still relevant, details that informed the current assessment but are not repeated in the latest assessment.

[16] The docket for this review, EPA–HQ–OAR–2018–0279, has incorporated the ISA docket (EPA–HQ–ORD–2018–0274) by reference. Both are publicly accessible at *www.regulations.gov.*

[17] In addition to the review's opening "Call for Information" (83 FR 29785, June 26, 2018), systematic review methodologies were applied to identify relevant scientific findings that have emerged since the 2013 ISA, which included peer reviewed literature published through July 2011. Search techniques for 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, 2011 (providing some overlap with the cutoff date for the last ISA) and March 30, 2018. Studies published after the literature cutoff date for this ISA were also considered if they were submitted in response to the Call for Information or identified in subsequent phases of ISA development, particularly to the extent that they provide new information that affects key scientific conclusions (ISA, Appendix 10, section 10.2). 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/index.cfm/project/page/project_id/2737.*

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 O_3 air quality criteria that have undergone rigorous review by the EPA, the CASAC and the public. The EPA will consider these ''new'' studies for inclusion in the air quality criteria for the next O_3 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, the CASAC, and the public.

E. Air Quality Information

Ground level O_3 concentrations are a mix of mostly tropospheric O_3 and some stratospheric O_3. Tropospheric O_3 is formed due to chemical interactions involving solar radiation and precursor pollutants including VOCs and nitrogen oxides (NO_X). Methane (CH_4) and carbon monoxide (CO) are also important precursors, particularly at the regional to global scale. The precursor emissions leading to tropospheric O_3 formation can result from both man-made sources (*e.g.,* motor vehicles and electric power generation) and natural sources (*e.g.,* vegetation and wildfires). In addition, O_3 that is created naturally in the stratosphere also contributes to O_3 in the troposphere. The stratosphere routinely mixes with the troposphere high above the earth's surface and, less frequently, there are intrusions of stratospheric air that reach deep into the troposphere and even to the surface. Once formed, O_3 near the surface can be transported by winds before eventually being removed from the atmosphere via chemical reactions or deposition to surfaces. In sum, O_3 concentrations are influenced by complex interactions between precursor emissions, meteorological conditions, and topographical characteristics (PA, section 2.1; ISA, Appendix 1).

For compliance and other purposes, state and local environmental agencies operate O_3 monitors across the U.S. and submit the data to the EPA. At present, there are approximately 1,300 monitors across the U.S. reporting hourly O_3 averages during the times of the year when local O_3 pollution can be important (PA, section 2.3.1).[18] Most of this monitoring is focused on urban areas where precursor emissions tend to be largest, as well as locations directly downwind of these areas. There are also over 100 routine monitoring sites in rural areas, including sites in the Clean Air Status and Trends Network (CASTNET) which is specifically focused on characterizing conditions in rural areas. Based on the monitoring data for the three year period from 2016 to 2018, the EPA identified 142 counties, in which together approximately 106 million Americans reside where O_3 design values [19] were above 0.070 ppm, the level of the existing NAAQS (PA, section 2.4.1). Across these areas, the highest design values are typically observed in California, Texas, Denver, around Lake Michigan and along the Northeast Corridor, locations with some of the most densely populated areas in the country (*e.g.,* PA, Figure 2–8).

From a temporal perspective, the highest O_3 concentrations tend to occur during the afternoon and within the warmer months of the year due to higher levels of solar radiation and other conducive meteorological conditions during these times. The exceptions to this general rule include (1) some rural sites where transport of O_3 from upwind urban areas can occasionally result in high nighttime levels of O_3, (2) high-elevation sites which can be episodically influenced by stratospheric intrusions in other months of the year, and (3) mountain basins in the western U.S. where large quantities of O_3 precursors emissions associated with oil and gas development can be trapped in a shallow inversion layer and form O_3 under clear, calm skies with snow cover during the colder months (PA, section 2.1; ISA, Appendix 1).

Monitoring data indicate long-term reductions in peak O_3 concentrations. For example, monitoring sites operating since 1980 indicate a 32% reduction in the national average annual fourth highest daily maximum 8-hour concentration from 1980 to 2018. (PA, Figure 2–10). This has been accompanied by appreciable reductions in peak 1-hour concentrations, as seen by reductions in annual second highest daily maximum 1-hour concentrations (PA, Figure 2–17).

Concentrations of O_3 in ambient air that result from natural and non-U.S. anthropogenic sources are collectively referred to as U.S. background O_3 (USB; PA, section 2.5). As in the last review, we generally characterize O_3 concentrations that would exist in the absence of U.S. anthropogenic emissions (as USB). Findings from air quality modeling analyses performed for this review to investigate patterns of USB in the U.S. are largely consistent with conclusions reached in the last review (PA, section 2.5.4). The current modeling analysis indicates spatial variation in USB O_3 concentrations that is related to geography, topography and proximity to international borders and is also influenced by seasonal variation, with long-range international anthropogenic transport contributions peaking in the spring while U.S. anthropogenic contributions tend to peak in summer. The West is predicted to have higher USB concentrations than the East, with higher contributions from natural and international anthropogenic sources that exert influences in western high-elevation and near-border areas. The modeling predicts that for both the West and the East, days with the highest 8-hour concentrations of O_3 generally occur in summer and are likely to have substantially greater concentrations due to U.S. anthropogenic sources. While the USB contributions to O_3 concentrations on days with the highest 8-hour concentrations are generally predicted to come largely from natural sources, the modeling also indicates that some areas near the Mexico border may receive appreciable contributions from a combination of natural and international anthropogenic sources on these days. In such locations, the modeling suggests the potential for relatively infrequent events with substantial background contributions where daily maximum 8-hour O_3 concentrations approach or exceed the level of the current NAAQS (*i.e.,* 70 ppb). This contrasts with most monitor locations in the U.S. for which international contributions are predicted to be the lowest during the season with the most frequent occurrence of daily maximum 8-hour O_3 concentrations above 70 ppb. This is generally because, except for in near-border areas, larger international contributions are associated with long-distance transport and that is most efficient in the springtime (PA, section 2.5.4).

II. Rationale for Decision on the Primary Standard

This section presents the rationale for the Administrator's decision to retain the current primary O_3 standard. This rationale is based on the scientific information presented in the ISA, on human health effects associated with

[18] O_3 monitoring seasons in each state vary from five months (May to September in Oregon and Washington) to year round (in 11 states), with March to October being most common (27 states).

[19] 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.

photochemical oxidants including O_3 and pertaining to the presence of these pollutants in ambient air. As summarized in section I.D above, the ISA was developed based on a thorough review of the latest scientific information generally published between January 2011 and March 2018, as well as more recent studies identified during peer review, submitted in response to the Call for Information, or public comments on the draft ISA, integrated with the information and conclusions from previous assessments (ISA, section IS.1.2 and Appendix 10, section 10.2). The Administrator's rationale also takes into account: (1) The PA evaluation of the policy-relevant information in the ISA and presentation of quantitative analyses of air quality, human exposure and health risks; (2) CASAC advice and recommendations, as reflected in discussions of drafts of the ISA and PA at public meetings and in the CASAC's letters to the Administrator; and (3) public comments on the proposed decision.

Within this section, introductory and background information is presented in section II.A. Section II.A.1 summarizes the 2015 establishment of the existing standard, as background for this review. Section II.A.2 provides an overview of the currently available health effects evidence, and section II.A.3 provides an overview of the current exposure and risk information, drawing on the quantitative analyses presented in the PA. Section II.B summarizes the basis for the proposed decision (II.B.1), discusses public comments on the proposed decision (II.B.2), and presents the Administrator's considerations, conclusions and decision in this review of the primary standard (II.B.3). The decision on the current primary standard is summarized in section II.C.

A. Introduction

As in prior reviews, the general approach to reviewing the current primary standard is based, most fundamentally, on using the Agency's assessments of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgment regarding a primary standard for photochemical oxidants that is requisite to protect the public health with an adequate margin of safety. The EPA's assessments are primarily documented in the ISA and PA, both of which have received CASAC review and public comment (84 FR 50836, September 26, 2019; 84 FR 58711, November 1, 2019; 84 FR 58713, November 1, 2019; 85 FR 21849, April 20, 2020; 85 FR 31182, May 22, 2020). In bridging the gap between the scientific assessments of the ISA and the judgments required of the Administrator in his decisions on the current standard, the PA evaluates policy implications of the assessment of the current evidence in ISA and the quantitative exposure and risk analyses documented extensively in appendices of the PA. In evaluating the public health protection afforded by the current standard, the four basic elements of the NAAQS (indicator, averaging time, level, and form) are considered collectively.

The final decision on the adequacy of the current primary standard is a public health policy judgment to be made by the Administrator. In reaching conclusions on the standard, the decision draws on the scientific information and analyses about health effects, population exposure and risks, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and analyses. This approach is based on the recognition that the available health effects evidence generally reflects a continuum, consisting of levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. This approach is consistent with the requirements of the NAAQS provisions of the Clean Air Act and with how the EPA and the courts have historically interpreted the Act (summarized in section I.A. above). These provisions require the Administrator to establish primary standards that, in the judgment of the Administrator, are requisite to protect public health with an adequate margin of safety. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that primary standards be set at a zero-risk level, but rather at a level that avoids unacceptable risks to public health, including the health of sensitive groups.[20]

1. Background on the Current Standard

As a result of the last O_3 NAAQS review, completed in 2015, the level of the primary standard was revised from 0.075 to 0.070 ppm,[21] in conjunction with retaining the existing indicator, averaging time, and form. This revision, establishing the current standard, was based on the scientific evidence and quantitative exposure and risk analyses available at that time, as well as the Administrator's judgments regarding the available health effects evidence, the appropriate degree of public health protection for the revised standard, and the available exposure and risk information regarding the exposures and risk that may be allowed by such a standard (80 FR 65292, October 26, 2015). In establishing this standard, the Administrator considered the extensive body of evidence spanning several decades documenting the causal relationship between O_3 exposure and a broad range of respiratory effects (80 FR 65292, October 26, 2015; 2013 ISA, p. 1–14),[22] that had been augmented by evidence available since the prior review was completed in 2008. Such effects range from small, reversible changes in pulmonary function and pulmonary inflammation (documented in controlled human exposure studies involving exposures ranging from 1 to 8 hours)[23] to more serious health outcomes such as asthma-related emergency department visits and hospital admissions, which have been associated with ambient air concentrations of O_3 in epidemiologic studies (2013 ISA, section 6.2).[24] The 2015 decision, which provided increased protection for at-risk populations,[25] such as children and

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

[21] Although ppm are the units in which the level of the standard is defined, the units, ppb, are more commonly used throughout this document for greater consistency with the more recent literature. The level of the current primary standard, 0.070 ppm, is equivalent to 70 ppb.

[22] In addition to concluding there to be a causal relationship between short-term O_3 exposures and respiratory effects, and that the relationship between longer-term exposure and respiratory effects was likely to be causal, the 2013 ISA also concluded there likely to be a causal relationship between short-term exposure and mortality, as well as short-term exposure and cardiovascular effects, including related mortality, and that the evidence was suggestive of causal relationships between long-term exposures and total mortality, cardiovascular effects and reproductive, developmental effects, and between short- and long-term exposure and nervous system effects (2013 ISA, p. 1–14, section 2.5.2).

[23] Study subjects in most of the controlled human exposure studies are generally healthy adults.

[24] The evidence base also includes experimental animal studies that provide insight into potential modes of action, contributing to the coherence and robust nature of the evidence.

[25] As used here and similarly throughout the document, the term population refers to persons having a quality or characteristic in common, such as, and including, a specific pre-existing illness or a specific age or lifestage. A lifestage refers to a distinguishable time frame in an individual's life characterized by unique and relatively stable behavioral and/or physiological characteristics that are associated with development and growth. Identifying at-risk populations includes consideration of intrinsic (*e.g.,* genetic or developmental aspects) or acquired (*e.g.,* disease or smoking status) factors that increase the risk of health effects occurring with exposure to a

people with asthma, against an array of adverse health effects, drew upon the available scientific evidence assessed in the 2013 ISA, the exposure and risk information presented and assessed in the 2014 health REA (HREA), the consideration of that evidence and information in the 2014 PA, the advice and recommendations of the CASAC, and public comments on the proposed decision (79 FR 75234, December 17, 2014).

Across the different study types, the controlled human exposure studies, which were recognized to provide the most certain evidence indicating the occurrence of health effects in humans following specific O_3 exposures, additionally document the roles of ventilation rate [26] and exposure duration, in addition to exposure concentration, in eliciting responses to O_3 exposure (80 FR 65343, October 26, 2015; 2014 PA, section 3.4).[27] These aspects of the evidence were represented in exposure-based analyses developed to inform the NAAQS decision with estimates of exposure and risk associated with air quality conditions just meeting the then-existing standard, and also for air quality conditions just meeting potential alternative standards (U.S. EPA, 2014a, hereafter 2014 HREA). The exposure-based analyses given greatest weight in the Administrator's consideration of the HREA estimates involved comparison of estimates for study area populations of children of exposure at elevated exertion to exposure benchmark concentrations (exposures of concern). The benchmark concentrations (60, 70 and 80 ppb) were identified from controlled human exposure studies (conducted with generally healthy adults).

In weighing the health effects evidence and making judgments regarding the public health significance of the quantitative estimates of exposures and risks allowed by the then-existing standard and potential alternative standards considered, as well as judgments regarding margin of safety, the Administrator's 2015 decision considered the currently available information and commonly accepted guidelines or criteria within the public health community, including statements of the American Thoracic Society (ATS), an organization of respiratory disease specialists, advice from the CASAC, and public comments. In so doing, she recognized that the determination of what constitutes an adequate margin of safety is expressly left to the judgment of the EPA Administrator. See *Lead Industries Ass'n* v. *EPA,* 647 F.2d 1130, 1161–62 (D.C. Cir 1980); *Mississippi* v. *EPA,* 744 F.3d 1334, 1353 (D.C. Cir. 2013). In NAAQS reviews generally, evaluations of how particular primary standards address the requirement to provide an adequate margin of safety include consideration of such factors as the nature and severity of the health effects, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties present. Consistent with past practice and long-standing judicial precedent, the Administrator took the need for an adequate margin of safety into account as an integral part of her decision-making.

In the decisions regarding adequacy of protection provided by the then-existing primary standard and on alternatives for a new revised standard, primary consideration was given to the evidence of respiratory effects from controlled human exposure studies, including those newly available in the review, and for which the exposure concentrations were at the lower end of those studied (80 FR 65342–47 and 65362–66, October 26, 2015). This emphasis was consistent with comments on the strength of this evidence from the CASAC at that time (Frey, 2014b, p. 5). In placing weight on these studies, the Administrator at that time took note of the variety of respiratory effects reported from the studies of healthy adults engaged in quasi-continuous exercise within a 6.6-hour exposure to O_3 concentrations of 60 ppb and higher.[28] The lowest exposure concentration in such studies for which a combination of statistically significant reduction in lung function and increase in respiratory symptoms was somewhat above 70 ppb,[29] while reduced lung function and increased pulmonary inflammation were reported following such exposures to O_3 concentrations as low as 60 ppb. In considering these findings, the Administrator noted that the combination of O_3-induced lung function decrements and respiratory symptoms met ATS criteria for an adverse response,[30] and noted CASAC comments, which included a caution regarding the potential for effects in some groups of people, such as people with asthma, at exposure concentrations below those affecting healthy subjects (Frey, 2014b, pp. 5–6; 80 FR 65343, October 26, 2015). With regard to the epidemiologic evidence, the Administrator noted the ISA finding that the pattern of effects observed across the range of exposures assessed in the controlled human exposure studies, increasing in severity at higher exposures, is coherent with (*i.e.,* reasonably related to) the health outcomes reported to be associated with ambient air concentrations in epidemiologic studies. Additionally, while recognizing that most O_3 epidemiologic studies reported health outcome associations with O_3 concentrations in ambient air that violated the then-existing standard, the Administrator took note of a study that reported associations between short-term O_3 concentrations and asthma emergency department visits in children and adults in a U.S. location that would have met the then-existing standard over the entire 5-year study period (80 FR 65344, October 26, 2015; Mar and Koenig, 2009).[31] Taken together, the Administrator concluded that the scientific evidence from controlled human exposure and epidemiologic studies called into question the adequacy of the public health protection provided by the 75 ppb standard that had been set in 2008.

In considering the exposure and risk information, the Administrator's 2015 decision gave particular attention to the exposure-based comparison-to-benchmarks analysis, focusing on the estimates of exposures of concern for

substance (such as O_3) as well as extrinsic, nonbiological factors, such as those related to socioeconomic status, reduced access to health care, or exposure.

[26] Ventilation rate ($\dot{V}_E$) is a specific technical term referring to breathing rate in terms of volume of air taken into the body per unit of time. A person engaged in different activities will exert themselves at different levels and experience different ventilation rates.

[27] For example, the exposure concentrations eliciting a given level of response in subjects at rest are higher than those eliciting such response in subjects exposed while at elevated ventilation, such as while exercising (2013 ISA, section 6.2.1.1).

[28] The studies given primary focus were those in which O_3 exposures occurred over the course of 6.6 hours during which the subjects engaged in six 50-minute exercise periods separated by 10-minute rest periods, with a 35-minute lunch period occurring after the third hour (*e.g.,* Folinsbee et al., 1988 and Schelegle et al., 2009). Responses after O_3 exposure were compared to those after filtered air exposure.

[29] For the 70 ppb target exposure, Schelegle et al. (2009) reported, based on O_3 measurements during the six 50-minute exercise periods, that the mean O_3 concentration during the exercise portion of the study protocol was 72 ppb. Based on the six exercise period measurements, the time weighted average concentration across the full 6.6-hour exposure was 73 ppb (Schelegle et al., 2009).

[30] The most recent statement from the ATS available at the time of the 2015 decision stated that ''[i]n drawing the distinction between adverse and nonadverse reversible effects, this committee recommended that reversible loss of lung function in combination with the presence of symptoms should be considered as adverse'' (ATS, 2000).

[31] The design values in this location during the study period were at or somewhat below 75 ppb (Wells, 2012).

children [32] in 15 urban study areas for air quality conditions just meeting the then-current standard. Consistent with the finding that larger percentages of children than adults were estimated to experience exposures at or above benchmarks, the Administrator focused on the results for all children and for children with asthma, noting that the results for these two groups, in terms of percent of the population group, are virtually indistinguishable (2014 HREA, sections 5.3.2, 5.4.1.5 and section 5F–1). The Administrator placed the greatest weight on estimates of two or more days with occurrences of exposures at or above the benchmarks, in light of her increased concern about the potential for adverse responses with repeated occurrences of such exposures, noting that the types of effects shown to occur following exposures to O_3 concentrations from 60 ppb to 80 ppb, such as inflammation, if occurring repeatedly as a result of repeated exposure, could potentially result in more severe effects (80 FR 65343, 65345, October 26, 2015; 2013 ISA, section 6.2.3).[33] The Administrator also considered estimates for single exposures at or above the higher benchmarks of 70 and 80 ppb (80 FR 65345, October 26, 2015). With regard to the 60 ppb benchmark, while the Administrator recognized the effects reported from controlled human exposure studies of 60 ppb to be less severe than those for higher O_3 concentrations, she also recognized there were limitations and uncertainties in the evidence base with regard to unstudied population groups. As a result, she judged it appropriate for the standard, in providing an adequate margin of safety, to provide some control of exposures at or above the 60 ppb benchmark (80 FR 65345–65346, October 26, 2015).

In considering public health implications of the exposure and risk information, the Administrator concluded that the exposures and risks projected to remain upon meeting the then-current (75 ppb) standard were reasonably judged important from a public health perspective. This conclusion was particularly based on her judgment that it is appropriate to set a standard that would be expected to eliminate, or almost eliminate, the occurrence of exposures, while at moderate exertion, at or above 70 and 80 ppb (80 FR 65346, October 26, 2015). In addition, given that in the air quality scenario for the existing standard, the average percent of children estimated to experience two or more days with exposures at or above the 60 ppb benchmark approached 10% in some urban study areas (on average across the analysis years), the Administrator concluded that the existing standard did not incorporate an adequate margin of safety against the potentially adverse effects that could occur following repeated exposures at or above 60 ppb (80 FR 65345–46, October 26, 2015). Thus, the exposure and risk estimates [34] were judged to support a conclusion that the existing standard was not sufficiently protective and did not incorporate an adequate margin of safety. In consideration of all of the above, as well as the CASAC advice, which included the unanimous recommendation ''that the Administrator revise the current primary ozone standard to protect public health'' (Frey, 2014b, p. 5),[35] the Administrator concluded that the then-current primary O_3 standard (with its level of 75 ppb) was not requisite to protect public health with an adequate margin of safety, and should be revised to provide increased public health protection (80 FR 65346, October 26, 2015).

With regard to the most appropriate indicator for the revised standard, key considerations included the finding that O_3 is the only photochemical oxidant (other than nitrogen dioxide) that is routinely monitored and for which a comprehensive database exists, and the consideration that, since the precursor emissions that lead to the formation of O_3 also generally lead to the formation of other photochemical oxidants, measures leading to reductions in population exposures to O_3 can generally be expected to lead to reductions in other photochemical oxidants (2013 ISA, section 3.6; 80 FR 65347, October 26, 2015). The CASAC also indicated O_3 to be the appropriate indicator ''based on its causal or likely causal associations with multiple adverse health outcomes and its representation of a class of pollutants known as photochemical oxidants'' (Frey, 2014b, p. ii). Based on all of these considerations and public comments, the Administrator retained O_3 as the indicator for the primary standard (80 FR 65347, October 26, 2015).

With regard to averaging time, eight hours was the duration established in 1997 with the replacement of the then-existing 1-hour standard (62 FR 38856, July 18, 1997). The decision at that time was based on evidence from numerous controlled human exposure studies reporting adverse respiratory effects resulting from 6- to 8-hour exposures, as well as quantitative analyses indicating the control provided by an 8-hour averaging time of both 8-hour and 1-hour peak exposures and associated health risk (62 FR 38861, July 18, 1997; U.S. EPA, 1996b). The 1997 decision was also consistent with CASAC advice at that time (62 FR 38861, July 18, 1997; 61 FR 65727, December 13, 1996). For similar reasons, the 8-hour averaging time was retained in the subsequent 2008 review (73 FR 16436, March 27, 2008). In 2015, the decision, based on then-available health effects information, was to again retain the 8-hour averaging time, as appropriate for addressing health effects associated with short-term exposures to ambient air O_3, and based on the conclusion that it could effectively limit health effects attributable to both short- and long-term O_3 exposures (80 FR 65348, 65350, October 26, 2015).

With regard to the form for the standard, the existing *n*th-high metric form had been established in the 1997 review, when the form was revised from an expected exceedance form. At that time, it was recognized that a concentration-based form, by giving proportionally more weight to years when 8-hour O_3 concentrations are well above the level of the standard than years when concentrations are just above the level, better reflects the continuum of health effects associated with increasing O_3 concentrations than does an expected exceedance form (80 FR 65350–65352, October 26, 2015).[36] The subsequent 2008 review also

[32] Consideration focused on estimates for children, reflecting the finding that the estimates for percent of children experiencing an exposure at or above the benchmarks were higher than percent of adults due to the greater time children spend outdoors engaged in activities at elevated exertion (2014 HREA, section 5.3.2).

[33] In addition to recognizing the potential for continued inflammation to evolve into other outcomes, the 2013 ISA also recognized that inflammation induced by a single exposure (or several exposures over the course of a summer) can resolve entirely (2013 ISA, p. 6–76; 80 FR 65331, October 26, 2015).

[34] Although the Administrator recognized increased uncertainty in and placed less weight on the other types of HREA risk estimates, she found they supported her conclusion of public health importance on a broad national scale (80 FR 65347).

[35] The Administrator also noted that the CASAC for the prior review (2008) likewise recommended the standard level be revised below 75 ppb based on the evidence and information in the record for the 2008 decision (Samet, 2011; Frey and Samet, 2012).

[36] With regard to a specific concentration-based form, the fourth-highest daily maximum was selected in 1997, recognizing that a less restrictive form (*e.g.,* fifth highest) would allow a larger percentage of sites to experience O_3 peaks above the level of the standard, and would allow more days on which the level of the standard may be exceeded when the site attains the standard (62 FR 38868–38873, July 18, 1997), and there was no basis identified for selection of a more restrictive form (62 FR 38856, July 18, 1997).

considered the potential value of a percentile-based form, but the EPA concluded that, because of the differing lengths of the monitoring season for O_3 across the U.S., such a form would not be effective in ensuring the same degree of public health protection across the country (73 FR 16474–75, March 27, 2008). Additionally, the EPA recognized the importance of a form that provides stability to ongoing control programs and insulation from the impacts of extreme meteorological events that are conducive to O_3 occurrence (73 FR 16474–16475, March 27, 2008). In the 2015 decision, based on all of these considerations, and including advice from the CASAC, which stated that this form ''provides health protection while allowing for atypical meteorological conditions that can lead to abnormally high ambient ozone concentrations which, in turn, provides programmatic stability'' (Frey, 2014b, p. 6), the existing form (the annual fourth-highest daily maximum 8-hour O_3 average concentration, averaged over three consecutive years) was retained (80 FR 65352, October 26, 2015).

As for the decision on adequacy of protection provided by the combination of all elements of the existing standard, the 2015 decision to set the level of the revised standard at 70 ppb placed the greatest weight on the results of controlled human exposure studies and on quantitative analyses based on information from these studies, particularly analyses of O_3 exposures of concern, consistent with CASAC advice and interpretation of the scientific evidence (80 FR 65362, October 26, 2015; Frey, 2014b).[37] This weighting reflected the recognition that controlled human exposure studies provide the most certain evidence indicating the occurrence of health effects in humans following specific O_3 exposures, and, in particular, that the effects reported in the controlled human exposure studies are due solely to O_3 exposures, and are not complicated by the presence of co-occurring pollutants or pollutant mixtures (as is the case in epidemiologic studies) (80 FR 65362–65363, October 26, 2015). With regard to this evidence, the Administrator at that time recognized that: (1) The largest respiratory effects, and the broadest range of effects, have been studied and reported following exposures to 80 ppb O_3 or higher (*i.e.,* decreased lung function, increased airway inflammation, increased respiratory symptoms, airway hyperresponsiveness, and decreased lung host defense); (2) exposures to O_3 concentrations somewhat above 70 ppb have been shown to both decrease lung function and to result in respiratory symptoms; and (3) exposures to O_3 concentrations as low as 60 ppb have been shown to decrease lung function and to increase airway inflammation (80 FR 65363, October 26, 2015). The Administrator also noted that 70 ppb was well below the O_3 exposure concentration documented to result in the widest range of respiratory effects (*i.e.,* 80 ppb), and below the lowest O_3 exposure concentration shown in 6.6 hour exposures with quasi-continuous exercise to result in the combination of lung function decrements and respiratory symptoms (80 FR 65363, October 26, 2015).

In considering the degree of protection to be provided by a revised standard, and the extent to which that standard would be expected to limit population exposures to the broad range of O_3 exposures shown to result in health effects, the Administrator focused particularly on the HREA estimates of two or more exposures of concern. Placing the most emphasis on a standard that limits repeated occurrences of exposures at or above the 70 and 80 ppb benchmarks, while at elevated ventilation, the Administrator noted that a revised standard with a level of 70 ppb was estimated to eliminate the occurrence of two or more days with exposures at or above 80 ppb and to virtually eliminate the occurrence of two or more days with exposures at or above 70 ppb for all children and children with asthma, even in the worst-case year and location evaluated (80 FR 65363–65364, October 26, 2015).[38] The Administrator's consideration of exposure estimates at or above the 60 ppb benchmark (focused most particularly on multiple occurrences), an exposure to which the Administrator was less confident would result in adverse effects,[39] as discussed above, was primarily in the context of considering the extent to which the health protection provided by a revised standard included a margin of safety against the occurrence of adverse O_3-induced effects (80 FR 65364, October 26, 2015). In this context, the Administrator noted that a revised standard with a level of 70 ppb was estimated to protect the vast majority of children in urban study areas (*i.e.,* about 96% to more than 99% of children in individual areas) from experiencing two or more days with exposures at or above 60 ppb (while at moderate or greater exertion). This represented a more than 60% reduction in repeated exposures over the estimates for the then-existing standard, with its level of 75 ppb.

Given the considerable protection provided against repeated exposures of concern for all three benchmarks, including the 60 ppb benchmark, the Administrator judged that a standard with a level of 70 ppb would incorporate a margin of safety against the adverse O_3-induced effects shown to occur in the controlled human exposure studies following exposures (while at moderate or greater exertion) to a concentration somewhat higher than 70 ppb (80 FR 65364, October 26, 2015).[40] The Administrator also judged the HREA estimates of one or more exposures (while at moderate or greater exertion) at or above 60 ppb to also provide support for her somewhat broader conclusion that ''a standard with a level of 70 ppb would incorporate an adequate margin of safety against the occurrence of O_3 exposures that can result in effects that are adverse to public health'' (80 FR 65364, October 26, 2015).[41] Although she placed less

[37] The Administrator viewed the results of other quantitative analyses in this review—the lung function risk assessment, analyses of O_3 air quality in locations of epidemiologic studies, and epidemiologic-study-based quantitative health risk assessment—as being of less utility for selecting a particular standard level among a range of options (80 FR 65362, October 26, 2015).

[38] Under conditions just meeting an alternative standard with a level of 70 ppb across the 15 urban study areas, the estimate for two or more days with exposures at or above 70 ppb was 0.4% of children, in the worst year and worst area (80 FR 65313, Table 1, October 26, 2015).

[39] The Administrator was ''notably less confident in the adversity to public health of the respiratory effects that have been observed following exposures to O_3 concentrations as low as 60 ppb,'' based on her consideration of the ATS statement on judging adversity from transient lung function decrements alone, the uncertainty in the potential for such decrements to increase the risk of other, more serious respiratory effects in a population (per ATS recommendations on population-level risk), and the less clear CASAC advice regarding potential adversity of effects at 60 ppb compared to higher concentrations studied (80 FR 65363, October 26, 2015).

[40] In so judging, she noted that the CASAC had recognized the choice of a standard level within the range it recommended based on the scientific evidence (which was inclusive of 70 ppb) to be a policy judgment (80 FR 65355, October 26, 2015; Frey, 2014b).

[41] While the Administrator was less concerned about single exposures, especially for the 60 ppb benchmark, she judged the HREA one-or-more estimates informative to margin of safety considerations. In this regard, she noted that ''a standard with a level of 70 ppb is estimated to (1) virtually eliminate all occurrences of exposures of concern at or above 80 ppb; (2) protect the vast majority of children in urban study areas from experiencing any exposures of concern at or above 70 ppb (*i.e.,* ≥ about 99%, based on mean estimates; Table 1); and (3) to achieve substantial reductions, compared to the [then-]current standard, in the occurrence of one or more exposures of concern at or above 60 ppb (*i.e.,* about a 50% reduction; Table 1)'' (80 FR 65364, October 26, 2015).

weight on the other HREA risk estimates and epidemiologic evidence for considering the standard level, in light of associated uncertainties, the Administrator judged that a standard with a level of 70 ppb would be expected to result in important reductions in the population-level risk of endpoints on which these types of information are focused and provide associated additional public health protection, beyond that provided by the then-existing standard (80 FR 65364, October 26, 2015). In summary, based on the evidence, exposure and risk information, advice from the CASAC, and public comments, the 2015 decision was to revise the primary standard to be 70 ppb, in terms of the 3-year average of annual fourth-highest daily maximum 8-hour average O_3 concentrations, to provide the requisite protection of public health, including the health of at-risk populations, with an adequate margin of safety (80 FR 65365, October 26, 2015).

2. Overview of Health Effects Information

The information summarized in this section is an overview of the scientific assessment of the health effects evidence available in this review; the assessment is documented in the ISA and its policy implications are further discussed in the PA. In this review, as in past reviews, the health effects evidence evaluated in the ISA for O_3 and related photochemical oxidants is focused on O_3 (ISA, section IS.1.1). Ozone is concluded to be the most prevalent photochemical oxidant present in the atmosphere and the one for which there is a very large, well-established evidence base of its health and welfare effects (ISA, section IS.1.1). Thus, the current health effects evidence and the Agency's review of the evidence, including the evidence newly available in this review,[42] continues to focus on O_3. The subsections below briefly summarize the following aspects of the evidence: The nature of O_3-related health effects, the potential public health implications and populations at risk, and exposure concentrations associated with health effects.

a. Nature of Effects

The evidence base available in the current review includes decades of extensive evidence that clearly describes the role of O_3 in eliciting an array of respiratory effects and recent evidence indicates the potential for relationships between O_3 exposure and metabolic effects. As was established in prior reviews, the effects for which the evidence is strongest are transient decrements in pulmonary function and respiratory symptoms, such as coughing and pain on deep inspiration, as a result of short-term exposures particularly when breathing at elevated rates (ISA, section IS.4.3.1; 2013 ISA, p. 2–26). These effects are demonstrated in the large, long-standing evidence base of controlled human exposure studies[43] (1978 AQCD, 1986 AQCD, 1996 AQCD, 2006 AQCD, 2013 ISA, ISA). The epidemiologic evidence base documents consistent, positive associations of O_3 concentrations in ambient air with lung function effects in panel studies (2013 ISA, section 6.2.1.2; ISA, Appendix 3, section 3.1.4.1.3), and with more severe health outcomes, including asthma-related emergency department visits and hospital admissions (2013 ISA, section 6.2.7; ISA, Appendix 3, sections 3.1.5.1 and 3.1.5.2). Extensive experimental animal evidence informs a detailed understanding of mechanisms underlying the short-term respiratory effects, and studies in animal models describe effects of longer-term O_3 exposure on the developing lung (ISA, Appendix 3, sections 3.1.11 and 3.2.6).

The full body of evidence continues to support the conclusions of a causal relationship of respiratory effects with short-term O_3 exposures and of a relationship of respiratory effects with longer-term exposures that is likely to be causal (ISA, sections IS.4.3.1 and IS.4.3.2). Further, the ISA determines that the relationship between short-term O_3 exposure and metabolic effects[44] is likely to be causal, based primarily on newly available experimental animal evidence (ISA, section IS.4.3.3). The newly available evidence, particularly from controlled human exposure studies of cardiovascular endpoints, has altered conclusions from the last review with regard to relationships between short-term O_3 exposures and cardiovascular effects and mortality, such that the evidence no longer supports conclusions that the relationships are likely to be causal.[45]

With regard to respiratory effects from short-term O_3 exposure, the strongest evidence comes from controlled human exposure studies, also available in the last review, demonstrating O_3-related respiratory effects in generally healthy adults (ISA, section IS.1.3.1).[46] As in the last review, the key evidence comes from the body of controlled human exposure studies that document respiratory effects in people exposed for short periods (6.6 to 8 hours) during quasi-continuous exercise.[47] The potential for O_3 exposure to elicit health outcomes more serious than those assessed in the controlled human exposure studies continues to be indicated by the epidemiologic evidence of associations of O_3 concentrations in ambient air with increased incidence of hospital admissions and emergency department visits for an array of health outcomes, including asthma exacerbation, chronic obstructive pulmonary disease (COPD) exacerbation, respiratory infection, and combinations of respiratory diseases (ISA, Appendix 3, sections 3.1.5 and 3.1.6). The strongest such evidence is for asthma-related outcomes and specifically asthma-related outcomes for children, indicating an increased risk for people with asthma and particularly children with asthma (ISA, Appendix 3, section 3.1.5.7).

Respiratory responses observed in human subjects exposed to O_3 for periods of 8 hours or less, while intermittently or quasi-continuously exercising, include lung function decrements (*e.g.,* based on forced expiratory volume in one second [FEV_1] measurements),[48] respiratory symptoms,

[42] More than 1600 studies are newly available and considered in the ISA, including more than 1000 health studies (ISA, Appendix 10, Figure 10–2).

[43] The vast majority of the controlled human exposure studies (and all of the studies conducted at the lowest exposures) involved young healthy adults (typically 18–35 years old) as study subjects (2013 ISA, section 6.2.1.1). There are also some controlled human exposure studies of one to eight hours duration in older adults and adults with asthma, and there are still fewer controlled human exposure studies in healthy children (*i.e.,* individuals aged younger than 18 years) or children with asthma (See, for example, PA, Appendix 3A, Table 3A–3).

[44] The term metabolic effects is used in the ISA to refer metabolic syndrome (a collection of risk factors including alterations in glucose and insulin homeostasis, high blood pressure, adiposity, elevated triglycerides and low high density lipoprotein cholesterol), diabetes, metabolic disease mortality, and indicators of metabolic syndrome that include peripheral inflammation, liver function, neuroendocrine signaling, and serum lipids (ISA, section IS.4.3.3).

[45] The currently available evidence for cardiovascular, reproductive and nervous system effects, as well as mortality, is ''suggestive of, but not sufficient to infer'' a causal relationship with short- or long-term O_3 exposures (ISA, Table IS–1). The evidence is inadequate to infer the presence or absence of a causal relationship between long-term O_3 exposure and cancer (ISA, section IS.4.3.6.6).

[46] The phrases ''healthy adults'' or ''healthy subjects'' are used to distinguish from subjects with asthma or other respiratory diseases because the ''the study design generally precludes inclusion of subjects with serious health conditions,'' such as individuals with severe respiratory diseases (2013 ISA, p. lx).

[47] A quasi-continuous exercise protocol is common to these controlled exposure studies where study subjects complete six 50-minute periods of exercise, each followed by 10-minute periods of rest (*e.g.,* ISA, Appendix 3, section 3.1.4.1.1, and p. 3–11; 2013 ISA, section 6.2.1.1).

[48] In summarizing FEV_1 responses from controlled human exposure studies as

increased airway responsiveness, mild bronchoconstriction (measured as an increase in specific airway resistance [sRaw]), and pulmonary inflammation, with associated injury and oxidative stress (ISA, Appendix 3, section 3.1.4; 2013 ISA, sections 6.2.1 through 6.2.4). The available mechanistic evidence, discussed in greater detail in the ISA, describes pathways involving the respiratory and nervous systems by which O_3 results in pain-related respiratory symptoms and reflex inhibition of maximal inspiration (inhaling a full, deep breath), commonly quantified by decreases in forced vital capacity (FVC) and total lung capacity. This reflex inhibition of inspiration combined with mild bronchoconstriction contributes to the observed decrease in FEV_1, the most common metric used to assess O_3-related lung function effects. The evidence also indicates that the additionally observed inflammatory response is correlated with mild airway obstruction, generally measured as an increase in sRaw (ISA, Appendix 3, section 3.1.3). As described below, the prevalence and severity of respiratory effects in controlled human exposure studies, including symptoms (*e.g.,* pain on deep inspiration, shortness of breath, and cough), increases with increasing O_3 concentration, exposure duration, and ventilation rate of exposed subjects (ISA, Appendix 3, sections 3.1.4.1 and 3.1.4.2).

Within the evidence base from controlled human exposure studies, the majority of studies involve healthy adult subjects (generally 18 to 35 years), although there are studies involving subjects with asthma, and a limited number of studies, generally of durations shorter than four hours, involving adolescents and adults older than 50 years. A summary of salient observations of O_3 effects on lung function, based on the controlled human exposure study evidence reviewed in the 1996 and 2006 AQCDs, and recognized in the 2013 ISA, continues to pertain to this evidence base as it exists today: ''(1) young healthy adults exposed to ≥80 ppb ozone develop significant reversible, transient decrements in pulmonary function and symptoms of breathing discomfort if minute ventilation (Ve) or duration of exposure is increased sufficiently; (2) relative to young adults, children experience similar spirometric responses [*i.e.,* as measured by FEV_1 and/or FVC] but lower incidence of symptoms from O_3 exposure; (3) relative to young adults, ozone-induced spirometric responses are decreased in older individuals; (4) there is a large degree of inter-subject variability in physiologic and symptomatic responses to O_3, but responses tend to be reproducible within a given individual over a period of several months; and (5) subjects exposed repeatedly to O_3 for several days experience an attenuation of spirometric and symptomatic responses on successive exposures, which is lost after about a week without exposure'' (ISA, Appendix 3, section 3.1.4.1.1, p. 3–11).[49] Repeated daily exposure studies at higher concentrations, such as 300 ppb, have found FEV_1 responses to be enhanced on the second day of exposure. This enhanced response is absent, however, with repeated exposure at lower concentrations, perhaps as a result of a more complete recovery or less damage to pulmonary tissues (2013 ISA, section pp. 6–13 to 6–14; Folinsbee et al., 1994).

With regard to airway inflammation and the potential for repeated occurrences to contribute to further effects, O_3-induced respiratory tract inflammation ''can have several potential outcomes: (1) Inflammation induced by a single exposure (or several exposures over the course of a summer) can resolve entirely; (2) continued acute inflammation can evolve into a chronic inflammatory state; (3) continued inflammation can alter the structure and function of other pulmonary tissue, leading to diseases such as fibrosis; (4) inflammation can alter the body's host defense response to inhaled microorganisms, particularly in potentially at-risk populations such as the very young and old; and (5) inflammation can alter the lung's response to other agents such as allergens or toxins'' (2013 ISA, p. 6–76; ISA Appendix 3, section 3.1.5.6). With regard to O_3-induced increases in airway responsiveness, the controlled human exposure study evidence for healthy adults generally indicates resolution within 18 to 24 hours after exposure, with slightly longer persistence in some individuals (ISA, Appendix 3, section 3.1.4.3.1; 2013 ISA, p. 6–74; Folinsbee and Hazucha, 2000).

The array of O_3-associated respiratory effects, including reduced lung function, respiratory symptoms, increased airway responsiveness, and inflammation are of increased significance to people with asthma given aspects of the disease that contribute to a baseline status that includes chronic airway inflammation and greater airway responsiveness than people without asthma (ISA, section 3.1.5). For example, O_3 exposure of a magnitude that increases airway responsiveness may put such people at potential increased risk for prolonged bronchoconstriction in response to asthma triggers (ISA, Appendix 3, p. 3–7, 3–28; 2013 ISA, section 6.2.9; 2006 AQCD, section 8.4.2). The increased significance of effects in people with asthma and risk of increased exposure for children (from greater frequency of outdoor exercise)[50] is illustrated by the epidemiologic findings of positive associations between O_3 exposure and asthma-related emergency department visits and hospital admissions for children with asthma. Thus, the evidence indicates O_3 exposure to increase the risk of asthma exacerbation, and associated outcomes, in children with asthma.

With regard to an increased susceptibility to infectious diseases, the experimental animal evidence continues to indicate, as described in the 2013 ISA and past AQCDs, the potential role for O_3 exposures through effects on defense mechanisms of the respiratory tract (ISA, section 3.1.7.3; 2013 ISA, section 6.2.5). The evidence base regarding respiratory infections and associated effects has been augmented in this review by a number of epidemiologic studies reporting positive associations between short-term O_3 concentrations and emergency department visits for a variety of respiratory infection endpoints (ISA, Appendix 3, section 3.1.7).

Although the long-term exposure conditions that may contribute to further respiratory effects are less well understood, experimental studies, including with nonhuman infant primates, have provided evidence relating O_3 exposure to asthma-like effects, and epidemiologic cohort studies have reported associations of O_3 concentrations in ambient air with asthma development in children (ISA, IS.4.3.2 and Appendix 3, sections 3.2.4.1.3 and 3.2.6). The biological plausibility of such a role for O_3 has been indicated by animal toxicological

''decrements'', an O_3-induced change in FEV_1 is typically the difference between the change observed with O_3 exposure ([post-exposure FEV_1 minus pre-exposure FEV_1] divided by pre-exposure FEV_1) and what is generally an improvement observed with filtered air (FA) exposure ([post-exposure FEV_1 minus pre-exposure FEV_1] divided by pre-exposure FEV_1).

[49] A spirometric response refers to a change in the amount of air breathed out of the body (forced expiratory volumes) and the associated time to do so (*e.g.,* FEV_1).

[50] Children are the age group most likely to be outdoors at activity levels corresponding to those that have been associated with respiratory effects in the human exposure studies (PA, Appendix 3D, section 3D.2.5.3), as recognized in section II.A.2.b below.

evidence on biological mechanisms (ISA, Appendix 3, sections 3.2.3 and 3.2.4.1.2).

Overall, the respiratory effects evidence newly available in this review is consistent with the evidence base in the last review, supporting a generally similar understanding of the respiratory effects of O_3 (ISA, Appendix 3, section 3.1.4). A few recent studies provide insights in previously unexamined areas, both with regard to human study groups and animal models for different effects, while other studies confirm and provide depth to prior findings with updated protocols and techniques (ISA, Appendix 3, sections 3.1.11 and 3.2.6). Newly available epidemiologic studies of hospital admissions and emergency department visits for a variety of respiratory outcomes supplement the previously available evidence with additional findings of consistent associations with O_3 concentrations across a number of study locations (ISA, Appendix 3, sections 3.1.4.1.3, 3.1.5, 3.1.6.1.1, 3.1.7.1 and 3.1.8). These studies include a number that report positive associations for asthma-related outcomes, as well as a few for COPD-related outcomes. Together these epidemiologic studies continue to indicate the potential for O_3 exposures to contribute to such serious health outcomes, particularly for people with asthma.

As was the case for the evidence available in the last review, the currently available evidence for health effects other than those of O_3 exposures on the respiratory system is more uncertain than that for respiratory effects.[51] Further, the evidence now available has contributed to changes in conclusions for some of these effects. For example, the current evidence for cardiovascular effects and mortality, expanded from that in the last review, is no longer considered sufficient to conclude that the relationships of short-term exposure with these effects are likely to be causal (ISA, sections IS.4.3.4 and IS.4.3.5). These changes stem from newly available evidence in combination with the uncertainties recognized for the evidence available in the last review.[52] Although there exists largely consistent evidence for a limited number of O_3-induced cardiovascular endpoints in animal toxicological studies and cardiovascular mortality in epidemiologic studies, there is a general lack of coherence between these results and findings in controlled human exposure and epidemiologic studies of cardiovascular health outcomes (ISA, section IS.1.3.1, Appendix 6, section 6.1.8). The relationships are now characterized as suggestive of, but not sufficient to infer, a causal relationship (ISA, Appendix 4, section 4.1.17; Appendix 6, section 6.1.8).

With regard to metabolic effects of short-term O_3 exposures, the evidence comes primarily from experimental animal study findings, with a limited number of epidemiologic studies (ISA, section IS.4.3.3 and Appendix 5, section 5.1.8 and Table 5–3). The exposure conditions from the animal studies generally involve much higher O_3 concentrations (*e.g.,* 4-hour concentrations of 400 to 800 ppb [ISA, Appendix 5, Tables 5–8 and 5–10]) than those commonly occurring in areas of the U.S. where the current standard is met, and the concentration in the available controlled human exposure study is similarly high, at 300 ppb (ISA, sections 5.1.3, 5.1.5 and 5.1.8, Table 5–3). The evidence for metabolic effects and long-term exposures is concluded to be suggestive of, but not sufficient to infer, a causal relationship (ISA, section IS.4.3.6.2).

b. Public Health Implications and At-Risk Populations

The public health implications of the evidence regarding O_3-related health effects, as for other effects, are dependent on the type and severity of the effects, as well as the size of the population affected. Judgments or interpretative statements developed by public health experts, particularly experts in respiratory health, also inform consideration of public health implications.

With regard to O_3 in ambient air, the potential public health impacts relate most importantly to respiratory effects. Controlled human exposure studies have documented reduced lung function, respiratory symptoms, increased airway responsiveness, and inflammation, among other effects, in healthy adults exposed while at elevated ventilation, such as while exercising. Ozone effects in individuals with compromised respiratory function, such as individuals with asthma, are plausibly related to emergency department visits and hospital admissions for asthma which have been associated with ambient air concentrations of O_3 in epidemiologic studies (as summarized in section II.A.2.a above; 2013 ISA, section 6.2.7; ISA, Appendix 3, sections 3.1.5.1 and 3.1.5.2).

The clinical significance of individual responses to O_3 exposure depends on the health status of the individual, the magnitude of the responses, the severity of respiratory symptoms, and the duration of the response. While a particular reduction in FEV_1 or increase in inflammation or airway responsiveness may not be of concern for a healthy group, it may increase the risk of a more severe effect in a group with asthma. As a more specific example, the same increase in inflammation or airway responsiveness in individuals with asthma could predispose them to an asthma exacerbation event triggered by an allergen to which they may be sensitized (*e.g.,* ISA, Appendix 3, section 3.1.5.6.1; 2013 ISA, sections 6.2.3 and 6.2.6). Duration and frequency of documented effects is also reasonably expected to influence potential adversity and interference with normal activity.[53] In summary, consideration of differences in magnitude or severity, and also the relative transience or persistence of the responses (*e.g.,* FEV_1 changes) and respiratory symptoms, as well as pre-existing sensitivity to effects on the respiratory system, and other factors, are important to characterizing implications for public health effects of an air pollutant such as O_3 (ATS, 2000; Thurston et al., 2017).

Decisions made in past reviews of the O_3 primary standard and associated judgments regarding adversity or health significance of measurable physiological responses to air pollutants have been informed by guidance, criteria or interpretative statements developed within the public health community, including the ATS, an organization of respiratory disease specialists, as well as

[51] For example, the available evidence for reproductive and developmental effects, as well as for effects on the nervous system, is suggestive of, but not sufficient to infer, a causal relationship (ISA, section IS.4.3.6.5 and Table IS–1).

[52] These aspects of the current evidence base include: (1) A now-larger body of controlled human exposure studies providing evidence that is not consistent with a cardiovascular effect in response to short-term O_3 exposure; (2) a paucity of epidemiologic evidence indicating more severe cardiovascular morbidity endpoints (*e.g.,* emergency department visits and hospital visits for cardiovascular endpoints including myocardial infarctions, heart failure or stroke) that could connect the evidence for impaired vascular and cardiac function from animal toxicological studies with the evidence from epidemiologic studies of cardiovascular mortality; and (3) the remaining uncertainties and limitations recognized in the 2013 ISA (*e.g.,* lack of control for potential confounding by copollutants in epidemiologic studies) still remain.

[53] For example, for most healthy individuals moderate effects on pulmonary function, such as transient FEV_1 decrements smaller than 20% or transient respiratory symptoms, such as cough or discomfort on exercise or deep breath, would not be expected to interfere with normal activity, while larger effects on pulmonary function (*e.g.,* FEV_1 decrements of 20% or larger lasting longer than 24 hours) and/or more severe respiratory symptoms are more likely to interfere with normal activity (*e.g.,* PA, p. 3–30; 2006 AQCD, Table 8–2).

the advice from the CASAC. The ATS released its initial statement (titled *Guidelines as to What Constitutes an Adverse Respiratory Health Effect, with Special Reference to Epidemiologic Studies of Air Pollution*) in 1985 and updated it in 2000 (ATS, 1985; ATS, 2000). The ATS described its 2000 statement, considered in the last review of the O_3 standard, as being intended to ''provide guidance to policy makers and others who interpret the scientific evidence on the health effects of air pollution for the purposes of risk management'' (ATS, 2000). The recent statement further notes that it does not offer ''strict rules or numerical criteria, but rather proposes considerations to be weighed in setting boundaries between adverse and nonadverse health effects,'' providing a general framework for interpreting evidence that proposes a ''set of considerations that can be applied in forming judgments'' for this context (Thurston et al., 2017). Similarly, in the 2000 statement, the ATS describes it as proposing ''principles to be used in weighing the evidence and setting boundaries'' and states that ''the placement of dividing lines should be a societal judgment'' (ATS, 2000). The ATS explicitly states that it does ''not attempt to provide an exact definition or fixed list of health impacts that are, or are not, adverse,'' providing instead ''a number of generalizable 'considerations''' (ATS, 2000). The ATS state there ''cannot be precise numerical criteria, as broad clinical knowledge and scientific judgments, which can change over time, must be factors in determining adversity'' (ATS, 2000).

With regard to pulmonary function decrements, the earlier ATS statement concluded that ''small transient changes in forced expiratory volume in 1 s[econd] (FEV_1) alone were not necessarily adverse in healthy individuals but should be considered adverse when accompanied by symptoms'' (ATS, 2000). The more recent ATS statement continues to support this conclusion and also gives weight to findings of small lung function changes in the absence of respiratory symptoms in individuals with pre-existing compromised function, such as that resulting from asthma (Thurston et al., 2017). In keeping with the intent of these statements to avoid specific criteria, neither statement provides more specific descriptions of such responses, such as with regard to magnitude, duration or frequency, for consideration of such conclusions. The earlier ATS statement, in addition to emphasizing clinically relevant effects, also emphasized both the need to consider changes in ''the risk profile of the exposed population,'' and effects on the portion of the population that may have a diminished reserve that puts its members at potentially increased risk if affected by another agent (ATS, 2000). These concepts, including the consideration of the magnitude of effects occurring in just a subset of study subjects, continue to be recognized as important in the more recent ATS statement (Thurston et al., 2017) and continue to be relevant to the evidence base for O_3.

The information newly available in this review regarding O_3 exposure and health effects among sensitive populations, thoroughly evaluated in the ISA, has not altered our understanding of human populations at particular risk of health effects from O_3 exposures (ISA, section IS.4.4). The respiratory effects evidence, extending decades into the past and augmented by new studies in this review, supports the conclusion that ''individuals with pre-existing asthma are at greater risk of ozone-related health effects based on the substantial and consistent evidence within epidemiologic studies and the coherence with toxicological studies'' (ISA, p. IS–57). Numerous epidemiologic studies document associations of O_3 with asthma exacerbation. Such studies indicate the associations to be strongest for populations of children which is consistent with their generally greater time outdoors while at elevated exertion. Together, these considerations indicate people with asthma, including particularly children with asthma, to be at relatively greater risk of O_3-related effects than other members of the general population (ISA, section IS.4.4.2 and Appendix 3).[54]

With respect to people with asthma, the limited evidence from controlled human exposure studies (which are primarily in adult subjects) indicates similar magnitude of FEV_1 decrements as in people without asthma (ISA, Appendix 3, section 3.1.5.4.1). Across studies of other respiratory effects of O_3 (*e.g.,* increased respiratory symptoms, increased airway responsiveness and increased lung inflammation), the responses observed in study subjects generally do not differ due to the presence of asthma, although the evidence base is more limited with regard to study subjects with asthma (ISA, Appendix 3, section 3.1.5.7). However, the features of asthma (*e.g.,* increased airway responsiveness) contribute to a risk of asthma-related responses, such as asthma exacerbation in response to asthma triggers, which may increase the risk of more severe health outcomes (ISA, section 3.1.5). For example, a particularly strong and consistent component of the epidemiologic evidence is the appreciable number of epidemiologic studies that demonstrate associations between ambient O_3 concentrations and hospital admissions and emergency department visits for asthma (ISA, section IS.4.4.3.1). The strongest associations (*e.g.,* highest effect estimates) or associations more likely to be statistically significant are those for childhood age groups, which are age groups most likely to spend time outdoors during afternoon periods (when O_3 may be highest) and at activity levels corresponding to those that have been associated with respiratory effects in the human exposure studies (ISA, Appendix 3, sections 3.1.4.1 and 3.1.4.2).[55] The epidemiologic studies of hospital admissions and emergency department visits are augmented by a large body of individual-level epidemiologic panel studies that demonstrated associations of short-term ozone concentrations with respiratory symptoms in children with asthma. Additional support comes from epidemiologic studies that observed O_3-associated increases in indicators of airway inflammation and oxidative stress in children with asthma (ISA, section IS.4.3.1). Together, this evidence continues to indicate the increased risk of population groups with asthma,

[54] Populations or lifestages can be at increased risk of an air pollutant-related health effect due to one or more of a number of factors. These factors can be intrinsic, such as physiological factors that may influence the internal dose or toxicity of a pollutant, or extrinsic, such as sociodemographic, or behavioral factors.

[55] Evaluations of activity pattern data in current and last review indicate children to more frequently spend time outdoors during afternoon and early evening hours, while at moderate or greater exertion level, than other age groups (PA, Appendix 3D, section 3D.2.5.3, including Figure 3D–9; 2014 HREA, section 5.4.1.5 and Appendix 5G, section 5G–1.4). For example, for days with some time spent outdoors, children spend, on average, approximately 2¼ hours of afternoon time outdoors, 80% of which is at a moderate or greater exertion level, regardless of their asthma status (PA, Appendix 3D, section 3D.2.5.3). Adults, for days having some time spent outdoors, also spend approximately 2¼ hours of afternoon time outdoors regardless of their asthma status but the percent of afternoon time at moderate or greater exertion levels for adults (about 55%) is lower than that observed for children. Such analyses also note greater participation in outdoor events during the afternoon, compared to other times of day, for children ages 6 through 19 years old during the warm season months (ISA, Appendix 2, section 2.4.1, Table 2–1). Analyses of the limited activity pattern data by health status do not indicate asthma status to have appreciable impact (PA, Appendix 3D, section 3D.2.5.3; 2014 HREA, section 5.4.1.5).

including particularly, children (ISA, Appendix 3, section 3.1.5.7).

Children, and also outdoor adult workers, are at increased risk largely due to their generally greater time spent outdoors while at elevated exertion rates (including in summer afternoons and early evenings when O_3 levels may be higher). This behavior makes them more likely to be exposed to O_3 in ambient air, under conditions contributing to increased dose, *e.g.,* elevated ventilation taking greater air volumes into the lungs [56] (2013 ISA, section 5.2.2.7). In light of the evidence summarized in the prior paragraph, children and outdoor workers with asthma may be at increased risk of more severe outcomes, such as asthma exacerbation. Further, there is experimental evidence from early life exposures of nonhuman primates that indicates potential for effects in childhood when human respiratory systems are under development [57] (ISA, section IS.4.4.4.1). Overall, the evidence available in the current review, while not increasing our knowledge about susceptibility or at-risk status of these population groups, is consistent with that in the last review (ISA, section IS.4.4).[58]

The ISA also expressly considered the evidence regarding O_3 exposure and health effects among populations with several other potential risk factors. As in the last review, the evidence for low income and minority populations, remains ''suggestive'' of increased risk, and includes several inconsistencies (ISA, Tables IS–9 and IS–10).[59] The ISA in the last review additionally identified a role for dietary anti-oxidants such as vitamins C and E in influencing risk of O_3-related effects, such as inflammation, as well as a role for genetic factors to also confer either an increased or decreased risk (2013 ISA, sections 8.1 and 8.4.1). No newly available evidence has been evaluated that would inform or change these prior conclusions (ISA, section IS.4.4 and Table IS–10).

The magnitude and characterization of a public health impact is dependent upon the size and characteristics of the populations affected, as well as the type or severity of the effects. As summarized above, a population most at risk of health effects associated with O_3 in ambient air is people with asthma. The National Center for Health Statistics data for 2017 indicate that approximately 7.9% of the U.S. populations has asthma (CDC, 2019; PA, Table 3–1) and this is one of the principal populations that the primary O_3 NAAQS is designed to protect (80 FR 65294, October 26, 2015). Children under the age of 18 account for 16.7% of the total U.S. population, with 6.2% of the total population being children under 5 years of age (U.S. Census Bureau, 2019). Another at-risk population group, also due to time and activity outdoors, is outdoor workers.[60] Population groups with relatively greater asthma prevalence, such as populations in poverty and children [61] (CDC, 2019, Tables 3–1 and 4–1; PA, Table 3–1), might be expected to have a relatively greater potential for O_3-related health impacts.[62]

c. Exposure Concentrations Associated With Effects

The extensive evidence base for O_3 health effects, compiled over several decades, continues to indicate respiratory responses to short-term exposures as the most sensitive effects. As at the time of the last review, our conclusions regarding O_3 exposure concentrations associated with respiratory effects reflect the extensive longstanding evidence base of controlled human exposure studies of short-term exposures of people with and without asthma (ISA, Appendix 3). As summarized in section II.A.2.a above, these studies have documented an array of respiratory effects, including reduced lung function, respiratory symptoms, increased airway responsiveness, and inflammation, in study subjects following 1- to 8-hour exposures, primarily while exercising.[63]

The current evidence, including that newly available in this review, does not alter the scientific conclusions reached in the last review on exposure duration and concentrations associated with O_3-related health effects. These conclusions were largely based on the body of evidence from the controlled human exposure studies. A limited number of controlled human exposure studies are newly available in the current review, with none involving lower exposure concentrations than those previously studied or finding effects not previously reported (ISA, Appendix 3, section 3.1.4).[64]

The severity of observed responses, the percentage of individuals responding, and strength of statistical significance at the study group level have been found to increase with increasing exposure (ISA; 2013 ISA; 2006 AQCD). For example, the magnitude of respiratory response (*e.g.,* size of lung function reductions and magnitude of symptom scores) documented in the controlled human exposure studies is influenced by ventilation rate, exposure duration, and exposure concentration. When performing physical activities requiring elevated exertion, ventilation rate is increased, leading to greater potential for health effects due to an increased internal dose (2013 ISA, section 6.2.1.1, pp. 6–5 to 6–11). Accordingly, the exposure concentrations eliciting a given level of response after a given exposure duration is lower for subjects exposed while at elevated ventilation, such as while exercising (2013 ISA, pp.

[56] Additionally, compared to adults, children have higher ventilation rates relative to their lung volume which tends to increase the dose normalized to lung surface area. (ISA, p. IS–60).

[57] Human lung development begins during the fetal period and continues into early adulthood. This continued development comprises an extended window of potential vulnerability to O_3 (ISA, p. 3–99).

[58] Evidence available in the current review for older adults, a population identified as at risk in the last review, adds little to the evidence previously available (ISA, sections IS.4.4.2 and IS.4.4.4.2). The ISA notes, however, that ''[t]he majority of evidence for older adults being at increased risk of health effects related to ozone exposure comes from studies of short-term ozone exposure and mortality evaluated in the 2013 Ozone ISA'' (ISA, p. IS–52). Such studies are part of the larger evidence base that is now concluded to be suggestive, but not sufficient to infer a causal relationship of O_3 with mortality (ISA, sections IS.4.3.5 and IS.4.4.4.2, Appendix 4, section 4.1.16.1 and 4.1.17).

[59] The 2013 ISA concluded that the overall evidence is suggestive of socioeconomic economic status (SES) as a factor affecting risk of O_3-related health outcomes ''based on collective evidence from epidemiologic studies of respiratory hospital admissions but inconsistency among epidemiologic studies of mortality and reproductive outcomes,'' additionally stating that ''[f]urther studies are needed to confirm this relationship, especially in populations within the U.S.'' (2013 ISA, p. 8–28). The evidence available in the current review adds little to the evidence available at the time of the last review in this area (ISA, section IS.4.4.2 and Table IS–10). Other factors for which the evidence remains suggestive of an influence on risk status are being male or being female and pre-existing obesity (ISA, Table IS–10).

[60] For example, jobs in construction and extraction occupations and protective service occupations, as well as installation, maintenance and repair occupations and building and grounds cleaning and maintenance operations, had high percentages of employees who spent part of their workday outdoors (Bureau of Labor Statistics, 2017). Such jobs often include physically demanding tasks and involve increased ventilation rates, increasing the potential for exposure to O_3.

[61] In 2017 and 2018, the prevalence of asthma in children 0 to 17 years old was 8.4% and 7.5% respectively (CDC, 2019).

[62] As the current standard was set to protect at-risk populations, such as people with asthma, populations with asthma living in areas not meeting the standard would be expected to be at greater risk of effects than others in those areas.

[63] The risk of more severe health outcomes associated with such effects is increased in people with asthma as illustrated by the epidemiologic findings of positive associations between O_3 exposure and asthma-related ED visits and hospital admissions.

[64] The newly available 3-hour controlled human exposure studies (involving intermittent exercise) reported statistically significant respiratory response at 120 ppb in adults 55 to 70 years old (ISA, Appendix 3, section 3.1.4; PA, Appendix 3A, Table 3A–3).

6–5 to 6–6; ISA Appendix 3, section 3.1.4.2). For example, in studies of healthy young adults exposed while at rest for 2 hours, 500 ppb is the lowest concentration eliciting a statistically significant O_3-induced group mean lung function decrement, while a 1- to 2-hour exposure to 120 ppb produces a statistically significant response in lung function when the ventilation rate of the group of study subjects is sufficiently increased with exercise (2013 ISA, pp. 6–5 to 6–6).[65]

The exposure conditions (*e.g.,* duration and exercise) given primary focus in the past several O_3 NAAQS reviews are those of the 6.6-hour study design, which involves six 50-minute exercise periods during which subjects maintain a moderate level of exertion to achieve a ventilation rate of approximately 20 L/min per m² body surface area while exercising.[66] The 6.6 hours of exposure in these quasi-continuous exercise studies has generally occurred in an enclosed chamber and the study design includes three hours in each of which is a 50-minute exercise period and a 10-minute rest period, followed by a 35-minute lunch (rest) period, which is followed by three more hours of exercise and rest, as before lunch.[67] Most of these studies performed to date involve exposure maintained at a constant (unchanging) concentration for the full duration, although a subset of studies have concentrations that vary (generally in a stepwise manner) across the exposure period and are selected so as to achieve a specific target concentration as the exposure average.[68]

Evidence from studies with similar duration and quasi-continuous exercise aspects (6.6-hour duration with six 50-minute exercise periods) demonstrates an exposure-response (E–R) relationship for O_3-induced reduction in lung function (Table 1; ISA, Appendix 3, Figure 3–3 PA, Figure 3–2).[69] No studies of the 6.6-hour design are newly available in this review. The previously available studies of this design document statistically significant O_3-induced reduction in lung function (FEV_1) and increased pulmonary inflammation in young healthy adults exposed to O_3 concentrations as low as 60 ppb. Statistically significant group mean changes in FEV_1, also often accompanied by statistically significant increases in respiratory symptoms, become more consistent across such studies of exposures to higher O_3 concentrations, such as somewhat above 70 ppb (73 ppb),[70] and 80 ppb (Table 1 and Appendix 3A, Table 3A–1). The lowest exposures concentration for which these studies document a statistically significant increase in respiratory symptoms is somewhat above 70 ppb, at 73 ppb (Schelegle et al., 2009). In the 6.6-hour studies, the group means of O_3-induced[71] FEV_1 reductions for target exposure concentrations at or below 70 ppb are approximately 6% or lower (Table 1). For example, the group means of O_3-induced FEV_1 decrements reported in these studies that are statistically significantly different from the responses in filtered air are 6.1% for 70 ppb and 1.7% to 3.5% for 60 ppb (Table 1).

The group mean O_3-induced FEV_1 decrements generally increase with increasing O_3 exposures, reflecting increases in both the number of the individuals experiencing FEV_1 reductions and the magnitude of the FEV_1 reduction (Table 1; ISA, Appendix 3, Figure 3–3; PA, Figure 3–2). For example, following 6.6-hour exposures to a lower concentration (40 ppb), for which decrements were not statistically significant at the group mean level, none of 60 subjects across two separate studies experienced an O_3-induced FEV_1 reduction as large as 15% or more (Table 1; PA, Appendix 3D, Table 3D–19). The group mean O_3-induced FEV_1 decrements generally increase with increasing O_3 exposures, reflecting increases in both the number of the individuals experiencing FEV_1 reductions and the magnitude of the FEV_1 reduction (Table 1; ISA, Appendix 3, Figure 3–3; PA, Figure 3–2). For example, following 6.6-hour exposures to a lower concentration (40 ppb), for which decrements were not statistically significant at the group mean level, none of 60 subjects across two separate studies experienced an O_3-induced FEV_1 reduction as large as 15% or more (Table 1; PA, Appendix 3D, Table 3D–19). Across the four experiments (with number of subjects ranging from 30 to 59) that have reported results for a 60 ppb target exposure,[72] the number of subjects experiencing this magnitude of FEV_1 reduction (at or above 15%) varied (zero of 30, one of 59, two of 31 and two of 30 exposed subjects), while, together, they represent 3% of all 150 subjects. This percentage of subjects (with reductions of 15% or more) increased to 10% (three of 31 subjects) for the study at 73 ppb (70 ppb target) (PA, Appendix 3D, Table 3D–19; Schelegle et al., 2009), and is higher still (16%) in a variable exposure study at 80 ppb (PA, Appendix 3D, Table 3D–20; Schelegle et al., 2009). In addition to illustrating the E–R relationship, these findings also illustrate the considerable variability in magnitude of responses observed among study subjects (ISA, Appendix 3, section 3.1.4.1.1; 2013 ISA, p. 6–13).[73]

[65] The lowest exposure concentration that has elicited a statistically significant O_3-induced reduction in group mean lung function in an exposure of 2 hours or less is 120 ppb, occurring in trained cyclists after a 1-hour exposure during continuous, very heavy exercise (2013 ISA, section 6.2.1.1; Gong et al., 1986) and in young healthy adults after a 2-hour exposure during intermittent heavy exercise (2013 ISA, section 6.2.1.1; McDonnell et al., 1983).

[66] Ventilation rate ($\dot{V}_E$) is a specific technical term referring to breathing rate in terms of volume of air taken into the body per unit of time. The units for $\dot{V}_E$ are usually liters (L) per minute (min). Another related term is equivalent ventilation rate (EVR), which refers to $\dot{V}_E$ normalized by a person's body surface area in square meters (m²). Accordingly, the units for EVR are generally L/min per m².

[67] A few studies have involved exposures by facemask rather than freely breathing in a chamber. To date, there is little research differentiating between exposures conducted with a facemask and in a chamber since the pulmonary responses of interest do not seem to be influenced by the exposure mechanism. However, similar responses have been seen in studies using both exposure methods at higher O_3 concentrations (Adams, 2002; Adams, 2003). In the facemask designs, there is a short period of zero O_3 exposure, such that the total period of exposure is closer to 6 hours than 6.6 (Adams, 2000; Adams, 2002; Adams, 2003).

[68] In these studies, the exposure concentration changes for each of the six hours in which there is exercise and the concentration during the 35-minute lunch is the same as in the prior (third) hour with exercise. For example, in the study by Adams (2006), the protocol for the 6.6-hour period is as follows: 60 minutes at 40 ppb, 60 minutes at 70 ppb, 95 minutes at 90 ppb, 60 minutes at 70 ppb, 60 minutes at 50 ppb and 60 minutes at 40 ppb.

[69] The relationship also exists for size of FEV_1 decrement with alternative exposure or dose metrics, including total inhaled O_3 and intake volume averaged concentration (ISA, Appendix 3).

[70] The design for the study on which the 70 ppb benchmark concentration is based, Schelegle et al. (2009), involved varying concentrations across the full exposure period, with a 35-minute lunch period following the third exposure hour during which the exposure concentration remains the same as in the third hour. The study reported the average O_3 concentration measured during each of the six exercise periods. The mean concentration across these six values is 72 ppb. The time weighted average for the full 6.6-hour exposure period, based on the six reported measurements and the study design, is 73 ppb (Schelegle et al., 2009). Other 6.6-hour studies have not reported measured concentrations for each exposure, but have generally reported an exposure concentration precision at or tighter than 3 ppb (*e.g.,* Adams 2006).

[71] Consistent with the ISA and 2013 ISA, the phrase "O_3-induced" decrement or reduction in lung function or FEV_1 refers to the percent change from pre-exposure measurement of the O_3 exposure minus the percent change from pre-exposure measurement of the filtered air exposure (2013 ISA, p. 6–4).

[72] For these four experiments, the average concentration across the 6.6 hour period ranged from 60 to 63 ppb (PA, Appendix 3A, Table 3A–2).

[73] With regard to decrements at or above 10%, the percentages of study subjects with such a response

Continued

TABLE 1—SUMMARY OF 6.6-HOUR CONTROLLED HUMAN EXPOSURE STUDY-FINDINGS, HEALTHY ADULTS

Endpoint	O_3 target exposure concentration [A]	Statistically significant effect [B]	O_3-induced group mean response [B]	Study
FEV_1 Reduction	120 ppb	Yes	−10.3% to −15.9% [C]	Horstman et al. 1990; Adams 2002; Folinsbee et al. (1988); Folinsbee et al. (1994); Adams, 2002; Adams 2000; Adams and Ollison 1997.[D]
	100 ppb	Yes	−8.5% to −13.9% [C]	Horstman et al., 1990; McDonnell et al., 1991.[D]
	87 ppb	Yes	−12.2%	Schelegle et al., 2009.
	80 ppb	Yes	−7.5%	Horstman et al., 1990.
			−7.7%	McDonnell et al., 1991.
			−6.5%	Adams, 2002.
			−6.2% to −5.5% [C]	Adams, 2003.
			−7.0% to −6.1% [C]	Adams, 2006.
			−7.8%	Schelegle et al., 2009.
		ND [E]	−3.5%	Kim et al., 2011.[F]
	70 ppb	Yes	−6.1%	Schelegle et al., 2009.
	60 ppb	Yes [G]	−2.9%	Adams, 2006; Brown et al., 2008.
			−2.8%	
		Yes	−1.7%	Kim et al., 2011.
		No	−3.5%	Schelegle et al., 2009.
	40 ppb	No	−1.2%	Adams, 2002.
		No	−0.2%	Adams, 2006.
Increased Respiratory Symptoms	120 ppb	Yes	Increased symptom scores.	Horstman et al. 1990; Adams 2002; Folinsbee et al. 1988; Folinsbee et al. 1994; Adams, 2002; Adams 2000; Adams and Ollison 1997; Horstman et al., 1990; McDonnell et al., 1991; Schelegle et al., 2009; Adams, 2003; Adams, 2006.[H]
	100 ppb	Yes		
	87 ppb	Yes		
	80 ppb	Yes		
	70 ppb	Yes		
	60 ppb	No		Adams, 2006; Kim et al., 2011; Schelegle et al., 2009; Adams, 2002.[H]
	40 ppb	No		
Airway Inflammation	80 ppb	Yes	Multiple indicators [I]	Devlin et al., 1991; Alexis et al., 2010.
	60 ppb	Yes	Increased neutrophils	Kim et al., 2011.
Increased Airway Resistance and Responsiveness.	120 ppb	Yes	Increased	Horstman et al., 1990; Folinsbee et al., 1994 (O_3 induced sRaw not reported).
	100 ppb	Yes		Horstman et al., 1990.
	80 ppb	Yes		Horstman et al., 1990.

[A] This refers to the average concentration across the six exercise periods as targeted by authors. This differs from the time-weighted average concentration for the full exposure periods (targeted or actual). For example, as shown in Appendix 3A, Table 3A–2, in chamber studies implementing a varying concentration protocol with targets of 0.03, 0.07, 0.10, 0.15, 0.08 and 0.05 ppm, the exercise period average concentration is 0.08 ppm while the time weighted average for the full exposure period (based on targets) is 0.082 ppm due to the 0.6 hour lunchtime exposure between periods 3 and 4. In some cases this also differs from the exposure period average based on study measurements. For example, based on measurements reported in Schelegle et al., (2009), the full exposure period average concentration for the 70 ppb target exposure is 73 ppb, and the average concentration during exercise is 72 ppb.

[B] Statistical significance based on the O_3 compared to filtered air response at the study group mean (rounded here to decimal).

[C] Ranges reflect the minimum to maximum FEV_1 decrements across multiple exposure designs and studies. Study-specific values and exposure details provided in the PA, Appendix 3A, Tables 3A–1 and 3A–2, respectively.

[D] Citations for specific FEV_1 findings for exposures above 70 ppb are provided in PA, Appendix 3A, Table 3A–1.

[E] ND (not determined) indicates these data have not been subjected to statistical testing.

[F] The data for 30 subjects exposed to 80 ppb by Kim et al. (2011) are presented in Figure 5 of McDonnell et al. (2012).

[G] Adams (2006) reported FEV_1 data for 60 ppb exposure by both constant and varying concentration designs. Subsequent analysis of the FEV_1 data from the former found the group mean O_3 response to be statistically significant ($p < 0.002$) (Brown et al., 2008; 2013 ISA, section 6.2.1.1). The varying-concentration design data were not analyzed by Brown et al., 2008.

[H] Citations for study-specific respiratory symptoms findings are provided in the PA, Appendix 3A, Table 3A–1.

[I] Increased numbers of bronchoalveolar neutrophils, permeability of respiratory tract epithelial lining, cell damage, production of proinflammatory cytokines and prostaglandins (ISA, Appendix 3, section 3.1.4.4.1; 2013 ISA, section 6.2.3.1).

For shorter exposure periods (*e.g.,* one to two hours), with heavy intermittent or very heavy continuous exercise, higher exposure concentrations, ranging up from 80 ppb up to 400 ppb, have been studied (ISA, section 3.1; 2013 ISA, section 6.2.1.1; 2006 AQCD, chapter 6; PA, Appendix 3A, Table 3A–3). Across these shorter-duration studies (which involved ventilation rates 2–3 times greater than in the prolonged [6.6- or 8-hour] exposure studies) the lowest exposure concentration for which statistically significant respiratory effects were reported is 120 ppb, for a 1-hour exposure combined with continuous very heavy exercise and a 2-hour exposure with intermittent heavy exercise. As recognized above, the increased ventilation rate associated with increased exertion increases the

increased from 7% of the 150 subjects of the four studies with target exposures of 60 ppb (average exposure ranged from 60 to 63) to 19% for the study at 73 ppb to more than 32% in one variable exposure study of 80 ppb (PA, Appendix 3D, Table 3D–20).

amount of O_3 entering the lung, where depending on dose and the individual's susceptibility, it may cause respiratory effects (2013 ISA, section 6.2.1.1). Thus, for exposures involving a lower exertion level, a comparable response would not be expected to occur without a longer exposure duration (ISA, Appendix 3, Figure 3–3; PA, Appendix 3A, Table 3A–1).

With regard to the epidemiologic studies reporting associations between O_3 and respiratory health outcomes such as asthma-related emergency department visits and hospitalizations, these studies are generally focused on investigating the existence of a relationship between O_3 occurring in ambient air and specific health outcomes. Accordingly, while as a whole, this evidence base of epidemiologic studies provides strong support for the conclusions of causality,[74] these studies provide less information on details of the specific O_3 exposure circumstances that may be eliciting health effects associated with such outcomes, and whether these occur under air quality conditions that meet the current standard.[75] Further, the vast majority of these studies were conducted in locations and during time periods that would not have met the current standard.[76] The extent to which reported associations with health outcomes in the resident populations in these studies are influenced by the periods of higher concentrations during times that did not meet the current standard is unknown. While this does not lessen their importance in the evidence base documenting the causal relationship between O_3 and respiratory effects, it means they are less informative in considering O_3 exposure concentrations occurring under air quality conditions allowed by the current standard.

With regard to the experimental animal evidence (largely in rodents) and exposure conditions associated with respiratory effects, the exposure concentrations are generally much greater than those examined in the controlled human exposure studies (summarized above), and higher than concentrations commonly occurring in ambient air in areas of the U.S. where the current standard is met. This is also true for the small number of early life studies in nonhuman primates that reported O_3 to contribute to asthma-like effects in infant primates.[77] The exposures eliciting the effects in these studies included multiple 5-day periods with O_3 concentrations of 500 ppb over 8-hours per day (ISA, Appendix 3, section 3.2.4.1.2).

Thus, as in the last review the exposures given greatest attention in this review, particularly with regard to considering O_3 exposures expected under air quality conditions that meet the current standard, are those informed by the controlled human exposure studies. The full body of evidence continues to indicate respiratory effects as the effects associated with lowest exposures, with conditions of exposure (duration, ventilation rate, as well as concentration) influencing dose and associated response. Evidence for other categories of effects does not indicate effects at comparably low exposures.[78]

3. Overview of Exposure and Risk Information

Consideration of the scientific evidence available in the current review, as at the time of the last review, is informed by results from quantitative analyses of estimated population exposure and consequent risk of respiratory effects. These analyses in this review have focused on exposure-based risk analyses, producing two types of risk metrics. The first metric estimates population occurrences of daily maximum 7-hour average exposure concentrations (during periods of elevated breathing rates) at or above concentrations of potential concern (benchmark concentrations). The second metric (lung function risk) uses E–R information for O_3 exposures and FEV_1 decrements to estimate the portion of the simulated at-risk population expected to experience one or more days with an O_3-related FEV_1 decrement of at least 10%, 15% or 20%. Both of these metrics were used to characterize health risk associated with O_3 exposures among the simulated population during periods of elevated breathing rates. Similar risk metrics were also derived in the 2014 HREA for the last review and the associated estimates informed the Administrator's 2015 decision on the current standard (80 FR 65292, October 26, 2015).

The currently available evidence in this review continues to demonstrate a causal relationship between short-term O_3 exposures and respiratory effects, with the current evidence base for respiratory effects largely consistent with that for the last review, as summarized in section II.A.2 above. Accordingly, the exposure-based analyses performed in this review, summarized below, are conceptually similar to those in the last review while also incorporating a number of updates that contribute to reduced uncertainty. Drawing on the summary in section II.C of the proposal, while giving relatively greater focus on the comparison-to-benchmarks analysis, the short sections below provide an overview of key aspects of the assessment design (II.A.3.a), key limitations and uncertainties (II.A.3.b), and exposure/risk estimates (II.A.3.c).

a. Key Design Aspects

Exposure and risk estimates were derived for air quality conditions just meeting the current primary O_3 standard, and for two additional scenarios reflecting conditions just meeting design values just lower and just higher than the level of the current

[74] Combined with the coherent evidence from experimental studies, the epidemiologic studies ''can support and strengthen determinations of the causal nature of the relationship between health effects and exposure to ozone at relevant ambient air concentrations'' (ISA, p. ES–17).

[75] For example, these studies generally do not measure personal exposures of the study population or track individuals in the population with a defined exposure to O_3 alone.

[76] Consistent with the evaluation of the epidemiologic evidence of associations between O_3 exposure and respiratory health effects in the ISA, this focuses on those studies conducted in the U.S. and Canada as including populations and air quality characteristics that may be most relevant to circumstances in the U.S. (ISA, Appendix 3, section 3.1.2). Among the epidemiologic studies finding a statistically significant positive relationship of short- or long-term O_3 concentrations with respiratory effects, there are no single-city studies conducted in the U.S. in locations with ambient air O_3 concentrations that would have met the current standard for the entire duration of the study (ISA, Appendix 3, Tables 3–13, 3–14, 3–39, 3–41, 3–42 and Appendix 6, Tables 6–5 and 6–8; PA, Appendix 3B, Table 3B–1). There are two single city studies conducted in Canada that include locations for which the highest-monitor design values calculated in the PA fell below 70 ppb, at 65 and 69 ppb (PA, Appendix 3B, Table 3B–1; Kousha and Rowe, 2014; Villeneuve et al., 2007). These studies did not include analysis of correlations with other co-occurring pollutants or of the strength of the associations when accounting for effects of copollutants in copollutant models (ISA, Appendix 3, Tables 3–14 and 3–39).

[77] These studies indicate that sufficient early-life O_3 exposure can cause structural and functional changes that could potentially contribute to airway obstruction and increased airway responsiveness (ISA, Table IS–10, p. 3–92 and p.3–113).

[78] For example, the evidence base for metabolic effects is comprised primarily of experimental animal studies, and generally involve much higher O_3 concentrations (400–800 ppb, [ISA, Appendix 5, Table 5–87]) than those examined in the controlled human exposure studies of respiratory effects (and much higher than concentrations commonly occurring in ambient air in areas of the U.S. where the current standard is met). There are only two epidemiologic studies reporting statistically significant positive associations of O_3 with metabolic effects (*e.g.,* changes in glucose, insulin, metabolic clearance), both based in Asian countries, in which there is a potential for appreciable differences from the U.S. in air quality patterns, limiting their usefulness for informing our understanding of exposure concentrations and conditions eliciting such effects in the U.S. (ISA, Appendix 5, section 5.1).

standard (65 and 75 ppb).[79] The analyses estimated population exposure and risk for simulated populations in eight urban study areas which represent a variety of circumstances with regard to population exposure to short-term concentrations of O_3 in ambient air. The areas (Atlanta, Boston, Dallas, Detroit, Philadelphia, Phoenix, Sacramento and St. Louis) range in total population size from approximately two to eight million and are distributed across seven regions of the U.S.: Northeast, Southeast, Central, East North Central, South, Southwest and West (PA, Appendix 3D, Table 3D–1). Study-area-specific characteristics contribute to variation in the estimated magnitude of exposure and associated risk across the urban study areas that reflect an array of air quality, meteorological, and population exposure conditions. The current set of study areas, streamlined compared to the 15-area set in the last review, was chosen to ensure it reflects the full range of air quality and exposure variation expected in major urban areas in the U.S. with air quality that just meets the current standard. Seven of the eight study areas were also included in the 2014 HREA; the eighth study area (Phoenix) is newly added in the current assessment to insure representation of a large city in the southwest. Additionally, the O_3 concentrations simulated in these areas are somewhat nearer the current standard than was the case for the 2014 HREA (PA, Appendix 3C, Table 3C and 2014 HREA, Table 4–1). This contributes to a reduction in the uncertainty associated with development of the air quality scenarios of interest, particularly the one reflecting air quality conditions that just meet the current standard.

With regard to the objectives for the analysis approach, the analyses and the use of a case study approach are intended to provide assessments of air quality scenarios, including particularly one just meeting the current standard, for a diverse set of areas and associated exposed populations. These analyses are not intended to provide a comprehensive national assessment (PA, section 3.4.1). Nor is the objective to present an exhaustive analysis of exposure and risk in the areas that currently just meet the current standard and/or of exposure and risk associated with air quality adjusted to just meet the current standard in areas that currently do not meet the standard. Rather, the purpose is to assess, based on current tools and information, the potential for exposures and risks beyond those indicated by the information available at the time the standard was established. Accordingly, use of this approach recognizes that capturing an appropriate diversity in study areas and air quality conditions [80] is an important aspect of the role of the exposure and risk analyses in informing the Administrator's conclusions on the public health protection afforded by the current standard.

Consistent with the health effects evidence in this review (summarized in section II.A.2 above), the focus of the quantitative assessment is on short-term exposures of individuals in the population during times when they are breathing at an elevated rate. Exposure and risk are characterized for four population groups. Two are populations of school-aged children, aged 5 to 18 years: All children and children with asthma; two are populations of adults: All adults and adults with asthma. Estimates for adults, in terms of percentages, are generally lower due to the lesser amount and frequency of time spent outdoors at elevated exertion (PA, Appendix 3D, section 3D.3.2). The exception is outdoor workers who, due to the requirements of their job, spend more time outdoors at elevated exertion. For a number of reasons, including the appreciable data limitations (*e.g.,* related to specific durations of time spent outdoors and activity data), and associated uncertainties summarized in Table 3D–64 of Appendix 3D of the PA, the group was not simulated in these analyses, a decision also made for past exposure assessments.[81] Asthma prevalence estimates for the full populations in the eight study areas range from 7.7 to 11.2%; the rates for children in these areas range from 9.2 to 12.3% (PA, Appendix 3D, section 3D.3.1).

The approach for this analysis incorporates an array of models and data (PA, section 3.4.1). Ambient air O_3 concentrations were estimated in each study area for the air quality conditions of interest by adjusting hourly ambient air concentrations, from monitoring data for the years 2015–2017, using a photochemical model-based approach and then applying a spatial interpolation technique to produce air quality surfaces with high spatial and temporal resolution (PA, Appendix 3C). The final products were datasets of ambient air O_3 concentration estimates with high temporal and spatial resolution (hourly concentrations in 500 to 1,700 census tracts) for each of the eight study areas (PA, section 3.4.1 and Appendix 3C, section 3C.7) representing the three air quality scenarios assessed.

Population exposures were estimated using the EPA's Air Pollutant Exposure model (APEX) version 5, which probabilistically generates a large sample of hypothetical individuals from population demographic and activity pattern databases and simulates each individual's movements through time and space to estimate their time series of O_3 exposures occurring within indoor, outdoor, and in-vehicle microenvironments (PA, Appendix 3D, section 3D.2).[82] The APEX model accounts for the most important factors that contribute to human exposure to O_3 from ambient air, including the temporal and spatial distributions of people and ambient air O_3 concentrations throughout a study area, the variation of ambient air-related O_3 concentrations within various microenvironments in which people conduct their daily activities, and the effects of activities involving different levels of exertion on breathing rate (or ventilation rate) for the exposed individuals of different sex, age, and body mass in the study area (PA, Appendix 3D, section 3D.2).[83] By incorporating individual activity

[79] All analyses are summarized more fully in the PA section 3.4 and Appendices 3C and 3D.

[80] A broad variety of spatial and temporal patterns of O_3 concentrations can exist when ambient air concentrations just meet the current standard. These patterns will vary due to many factors including the types, magnitude, and timing of emissions in a study area, as well as local factors, such as meteorology and topography. We focused our current assessment on specific study areas having ambient air concentrations close to conditions that reflect air quality that just meets the current standard. Accordingly, assessment of these study areas is more informative to evaluating the health protection provided by the current standard than would be an assessment that included areas with much higher and much lower concentrations.

[81] Limited exploratory analyses of a hypothetical outdoor worker population in the 2014 HREA (single study area, single year) for the 75 ppb air quality scenario estimated an appreciably greater portion of this population to experience exposures at or above benchmark concentrations than the full adult or child populations simulated, although there are a number of uncertainties associated with the estimates due to appreciable limitations in the data underlying the analyses (2014 HREA, section 5.4.3.2). It is expected that if an approach similar to that used in the 2014 HREA had been used for this assessment a generally similar pattern might be observed, although with somewhat lower overall percentages based on the comparison of current estimates with estimates from the 2014 HREA (PA, Appendix 3D, section 3D.3.2.4).

[82] The APEX model has a history of application, evaluation, and progressive model development in estimating human exposure, dose, and risk for reviews of NAAQS for gaseous pollutants, including the last review of the O_3 NAAQS (U.S. EPA, 2008; U.S. EPA, 2009; U.S. EPA, 2010; U.S. EPA, 2014a; U.S. EPA, 2018).

[83] The APEX model generates each simulated person or profile by probabilistically selecting values for a set of profile variables, including demographic variables, health status and physical attributes (*e.g.,* residence with air conditioning, height, weight, body surface area), and activity-specific ventilation rate (PA, Appendix 3D, section 3D.2).

patterns, and estimating physical exertion for each exposure event, the model addresses an important determinant of their exposure (2013 ISA, section 4.4.1).[84] For each exposure event, the APEX model tracks activity performed, ventilation rate, exposure concentration, and duration for all simulated individuals throughout the assessment period, and then utilizes the time-series of exposure events in derivation of the exposure and risk estimates.

The general approach and methodology for the exposure-based assessment used in this review is similar to that used in the last review, although a number of updates and improvements, related to the air quality, exposure, and risk aspects of the assessment, have been implemented (Appendices 3C and 3D). These include (1) a more recent period (2015–2017) of ambient air monitoring data in which O_3 concentrations in the eight study areas are at or near the current standard; (2) the most recent version of the photochemical air quality model, CAMx (comprehensive air quality model with extensions), with updates to the treatment of atmospheric chemistry and physics within the model; (3) a significantly expanded CHAD, that now has nearly 180,000 diaries, with over 25,000 school aged children; (4) updated National Health and Nutrition Examination Survey data (2009–2014), which are the basis for the age- and sex-specific body weight distributions used to specify the individuals in the modeled populations; (5) updated algorithms used to estimate age- and sex-specific resting metabolic rate, a key input to estimating a simulated individual's activity-specific ventilation (or breathing) rate; (6) updates to the ventilation rate algorithm itself; and (7) an approach that better matches the simulated exposure estimates with the 6.6-hour duration of the controlled human exposure studies and with the study subject ventilation rates. Further, the current APEX model uses the most recent U.S. Census demographic and commuting data (2010), NOAA Integrated Surface Hourly meteorological data to reflect the assessment years studied (2015–2017), and updated estimates of asthma prevalence for all census tracts in all study areas based on 2013–2017 National Health Interview Survey and Behavioral Risk Factor Surveillance System data. Additional details are described in the PA (*e.g.,* PA, section 3.4.1, Appendices 3C and 3D).

The comparison-to-benchmarks analysis characterizes the extent to which individuals in at-risk populations could experience O_3 exposures, while engaging in their daily activities, with the potential to elicit the effects reported in controlled human exposure studies for concentrations at or above specific benchmark concentrations. Results are characterized through comparison of exposure concentrations to three benchmark concentrations of O_3: 60, 70, and 80 ppb. These are based on the three lowest concentrations targeted in studies of 6- to 6.6-hour exposures, with quasi-continuous exercise, and that yielded different occurrences, of statistical significance, and severity of respiratory effects, as summarized in section II.A.2.c above and section II.C.1 of the proposal (PA, section 3.3.3; PA, Appendix 3A, section 3A.1; PA, Appendix 3D, section 3D.2.8.1). The lowest benchmark, 60 ppb, represents the lowest exposure concentration for which controlled human exposure studies have reported statistically significant respiratory effects, as summarized in section II.A.2.c above. Exposure to approximately 70 ppb averaged over 6.6 hours resulted in a larger group mean lung function decrement, as well as a statistically significant increase in prevalence of respiratory symptoms (Table 1; ISA, Appendix 3, Figure 3–3 and section 3.1.4.1.1; Schelegle et al., 2009). Studies of exposures to approximately 80 ppb have reported larger lung function decrements at the study group mean than following exposures to 60 or 70 ppb, in addition to an increase in airway inflammation, increased respiratory symptoms, increased airway responsiveness, and decreased resistance to other respiratory effects (ISA, Appendix 3, sections 3.1.4.1—3.1.4.4; PA, Figure 3–2 and section 3.3.3).

The APEX-generated exposure concentrations for comparison to these benchmark concentrations is the average of concentrations encountered by an individual while at an activity level that elicits the specified elevated ventilation rate. The incidence of such exposures above the benchmark concentrations are summarized for each simulated population, study area, and air quality scenario in Appendix 3D of the PA.

The lung function risk analysis estimates the extent to which individuals in exposed populations could experience O_3-induced lung function decrements of different sizes in two different ways. The population-based E–R function approach uses quantitative descriptions of the E–R relationships for study group incidence of different magnitudes of lung function decrements based on individual study subject observations (PA, Appendix 3D, section 3D.2.8.2.1). The individual-based McDonnell-Smith-Stewart (MSS) model uses quantitative estimates of biological processes identified as important in eliciting the different sizes of decrements at the individual level, with a factor that also provides a representation of intra- and inter-individual response variability (PA, Appendix 3D, section 3D.2.8.2.2; McDonnell et al., 2013). The two approaches, summarized in sections II.C and II.D.1 of the proposal and described in detail in Appendix 3D of the PA, utilize evidence from the 6.6-hour controlled human exposure studies in different ways, and accordingly, differ in strengths, limitations and uncertainties.

While the lung function risk analysis focuses only on the specific O_3 effect of FEV_1 reduction, the comparison-to-benchmark analysis, with its use of multiple benchmark concentrations, provides for risk characterization of the array of respiratory effects elicited by O_3 exposure, the type and severity of which increase with increased exposure concentration. In this way, the comparison-to-benchmark analysis (involving comparison of daily maximum 7-hour average exposure concentrations that coincide with 7-hour average elevated ventilation rates at or above the target rate to benchmark concentrations) provides perspective on the extent to which the air quality being assessed could be associated with discrete exposures to O_3 concentrations reported to result in an array of respiratory effects. For example, estimates of such exposures can indicate the potential for O_3-related effects in the exposed population, including effects for which we do not have E–R functions that could be used in quantitative risk analyses. Thus, the comparison-to-benchmark analysis provides for a broader risk characterization with consideration of the array of O_3-related respiratory effects.

b. Key Limitations and Uncertainties

Uncertainty in the exposure and risk analyses was characterized using a

[84] To represent personal time-location-activity patterns of simulated individuals, the APEX model draws from the consolidated human activity database (CHAD) developed and maintained by the EPA (McCurdy, 2000; U.S. EPA, 2019a). The CHAD provides data on human activities through a database system of human diaries or daily time series or daily time location activity logs collected in surveys at city, state, and national levels. Included are personal attributes of survey participants (*e.g.,* age, sex), along with the locations they visited, activities performed throughout a day, time-of-day the activities occurred and activity duration (PA, Appendix 3D, section 3D.2.5.1).

largely qualitative approach adapted from the World Health Organization approach for characterizing uncertainty in exposure assessment (WHO, 2008) augmented by several quantitative sensitivity analyses for key aspects of the assessment approach (PA, section 3.4.4 and Appendix 3D, section 3D.3.4). This characterization and associated analyses build on information generated from a previously conducted quantitative uncertainty analysis of population-based O_3 exposure modeling (Langstaff, 2007), considering the various types of data, algorithms, and models that together yield exposure and risk estimates for the eight study areas. In this way, we considered the limitations and uncertainties underlying these data, algorithms, and models and the extent of their influence on the resultant exposure/risk estimates using the general approach applied in past risk and exposure assessments for O_3, nitrogen dioxide, carbon monoxide, and sulfur dioxide (U.S. EPA, 2008; U.S. EPA, 2010; U.S. EPA, 2014a; U.S. EPA, 2018).

Key uncertainties and limitations in data and tools that affect the quantitative estimates of exposure and risk and their interpretation in the context of considering the current standard are summarized here. These include uncertainty related to estimation of the concentrations in ambient air for the current standard and the additional air quality scenarios; lung function risk approaches that rely, to varying extents, on extrapolating from controlled human exposure study conditions to lower exposure concentrations, lower ventilation rates, and shorter durations; and characterization of risk for particular population groups that may be at greatest risk, particularly for people with asthma, and particularly children with asthma. Areas in which uncertainty has been reduced by new or updated information or methods include the use of updated air quality modeling, with a more recent model version and model inputs, applied to study areas with design values near the current standard, as well as updates to several inputs to the exposure model, including changes to the exposure duration to better match those in the controlled human exposure studies and an alternate approach to characterizing periods of activity while at moderate or greater exertion for simulated individuals.

With regard to the analysis approach overall, two updates since the 2014 HREA reduce uncertainty in the results. The first relates to identifying when simulated individuals may be at moderate or greater exertion, with the new approach reducing the potential for overestimation of the number of people achieving the associated ventilation rate, which was an important uncertainty in the 2014 HREA. Additionally, the current analysis focus on exposures of 7 hours duration better represents the 6.6-hour exposures from the controlled human exposure studies (than the 8-hour exposure durations used for the 2014 HREA and prior assessments).

Additional aspects of the analytical design pertaining to both exposure-based risk metrics include the estimation of ambient air O_3 concentrations for the air quality scenarios, and main components of the exposure modeling. Uncertainties include the modeling approach used to adjust ambient air concentrations to meet the air quality scenarios of interest and the method used to interpolate monitor concentrations to census tracts. While the adjustment to conditions near, just above, or just below the current standard is an important area of uncertainty, the size of the adjustment needed to meet a given air quality scenario is minimized with the selection of study areas for which recent O_3 design values were near the level of the current standard. Also, more recent data are used as inputs for the air quality modeling, such as more recent O_3 concentration data (2015–2017), meteorological data (2016) and emissions data (2016), as well as a recently updated air quality photochemical model which includes state-of-the-science atmospheric chemistry and physics (PA, Appendix 3C). Further, the number of ambient monitors sited in each of the eight study areas provides a reasonable representation of spatial and temporal variability for the air quality conditions simulated in those areas. Among other key aspects, there is uncertainty associated with the simulation of study area populations (and at-risk populations), including those with particular physical and personal attributes. As also recognized in the 2014 HREA, exposures could be underestimated for some population groups that are frequently and routinely outdoors during the summer (*e.g.,* outdoor workers, children). In addition, longitudinal activity patterns do not exist for these and other potentially important population groups (*e.g.,* those having respiratory conditions other than asthma), limiting the extent to which the exposure model outputs reflect information that may be particular to these groups. Important uncertainties in the approach used to estimate energy expenditure (*i.e.,* metabolic equivalents of work or METs used to estimate ventilation rates), include the use of longer-term average MET distributions to derive short-term estimates, along with extrapolating adult observations to children. Both of these approaches are reasonable based on the availability of relevant data and appropriate evaluations conducted to date, and uncertainties associated with these steps are somewhat reduced in the current analyses (compared to the 2014 HREA) because of the added specificity, and use of redeveloped METs distributions (based on newly available information), which is expected to more realistically estimate activity-specific energy expenditure.

There are some uncertainties that apply to the estimation of lung function risk and not to the comparison-to-benchmarks analysis. For example, both lung function risk approaches utilized in the risk analyses incorporate some degree of extrapolation beyond the exposure circumstances evaluated in the controlled human exposure studies. Accordingly, the uncertainty in the lung function risk estimates increases with decreasing exposure concentration and is particularly increased for concentrations below those evaluated in controlled human exposure studies (85 FR 49857–49859, PA, section 3.4.4 and Appendix 3D, section 3D.3.4). The two lung function risk approaches differ in how they extrapolate beyond the controlled human exposure study conditions and in the impact on the estimates. The E–R function approach generates nonzero predictions from the full range of nonzero concentrations for 7-hour average durations in which the average exertion levels meets or exceeds the target. The MSS model, which draws on evidence-based concepts of how human physiological processes respond to O_3, extrapolates beyond the controlled experimental conditions with regard to exposure concentration, duration and ventilation rate (both magnitude and duration). Differences in percent of the risk estimates for days for which the highest 7-hour average concentration is below the lowest 6.6-hour exposure concentration tested, as presented in the PA, Tables 3–6 and 3–7, illustrate the impact.

An overarching area of uncertainty, remaining from the last review and important to consideration of the exposure and risk analysis results, relates to the underlying health effects evidence base. Although the quantitative analysis focuses on the evidence providing the ‘‘strongest evidence’’ of O_3 respiratory effects (ISA,

p. IS–1), the controlled human exposure studies, and on the array of respiratory responses documented in those studies, evidence is lacking from controlled human exposure studies at the lower concentrations (*e.g.,* 60, 70 and 80 ppb) for children and for people of any age with asthma. While the limited evidence informing our understanding of potential risk to people with asthma is uncertain, it indicates the potential for this group, given their disease status, to be at great risk, as summarized in section II.A.2 above. Such a conclusion is consistent with the epidemiologic study findings of positive associations of O_3 concentrations with asthma-related ED visits and hospital admissions (and the higher effect estimates from these studies).

c. Summary of Exposure and Risk Estimates

The benchmark-based risk metric results are summarized in terms of the percent of the simulated populations of all children and children with asthma estimated to experience at least one day per year [85] with a 7-hour average exposure concentration at or above the different benchmark concentrations while breathing at elevated rates under air quality conditions just meeting the current standard (Table 2). Given the recognition of people with asthma as an at-risk population and the relatively greater amount and frequency of time spent outdoors at elevated exertion of children, this summary focuses on the estimates from the comparison-to-benchmarks analysis for children, including children with asthma, which were the focus of the Administrator's proposed decision. Under air quality conditions just meeting the current standard, less than 0.1% of any study area's children with asthma, on average, were estimated to experience any days per year with a 7-hour average exposure at or above 80 ppb, while breathing at elevated rates (Table 3; PA, section 3.4 and Appendix 3D). With regard to the 70 ppb benchmark, the study areas' estimates for children with asthma range up to 0.7 percent (0.6% for all children), on average across the 3-year period, and range up to 1.0% in a single year. Approximately 3% to nearly 9% of each study area's simulated children with asthma, on average across the 3-year period, are estimated to experience one or more days per year with a 7-hour average exposure at or above 60 ppb. This range is very similar for the populations of all children.

Regarding multiday occurrences, the analyses indicate that no children would be expected to experience more than a single day with a 7-hour average exposure at or above 80 ppb in any year simulated in any location (Table 2). For the 70 ppb benchmark, the estimate is less than 0.1% of any area's children (on average across 3-year period), both those with asthma and all children. The estimates for the 60 ppb benchmark are slightly higher, with up to 3% of children estimated to experience more than a single day with a 7-hour average exposure at or above 60 ppb, on average (and more than 4% in the highest year across all eight study area locations).

Framed from the perspective of estimated protection provided by the current standard, these results indicate that, in the single year with the highest concentrations across the 3-year period, 99% of the population of children with asthma would not be expected to experience such a day with an exposure at or above the 70 ppb benchmark; 99.9% would not be expected to experience such a day with exposure at or above the 80 ppb benchmark. The estimates, on average across the 3-year period, indicate that over 99.9%, 99.3% and 91.2% of the population of children with asthma would not be expected to experience a day with a 7-hour average exposure while at elevated ventilation that is at or above 80 ppb, 70 ppb and 60 ppb, respectively (Table 1). Further, more than approximately 97% of all children or children with asthma are estimated to be protected against multiple days of exposures at or above 60 ppb.

TABLE 2—PERCENT AND NUMBER OF SIMULATED CHILDREN AND CHILDREN WITH ASTHMA ESTIMATED TO EXPERIENCE AT LEAST ONE OR MORE DAYS PER YEAR WITH A 7-HOUR AVERAGE EXPOSURE AT OR ABOVE INDICATED CONCENTRATION WHILE BREATHING AT AN ELEVATED RATE IN AREAS JUST MEETING THE CURRENT STANDARD

Exposure concentration (ppb)	One or more days		Two or more days		Four or more days	
	Average per year	Highest in a single year	Average per year	Highest in a single year	Average per year	Highest in a single year
Children with asthma—percent of simulated population [A]						
≥80	0 [B]–<0.1 [C]	0.1	0	0	0	0
≥70	0.2–0.7	1.0	<0.1	0.1	0	0
≥60	3.3–8.8	11.2	0.6–3.2	4.9	<0.1–0.8	1.3
—number of individuals [A]						
≥80	0–67	202	0	0	0	0
≥70	93–1145	1616	3–39	118	0	0
≥60	1517–8544	11776	282–2609	3977	23–637	1033
All children—percent of simulated population [A]						
≥80	0 [B]–<0.1	0.1	0	0	0	0
≥70	0.2–0.6	0.9	<0.1	0.1	0–<0.1	<0.1
≥60	3.2–8.2	10.6	0.6–2.9	4.3	<0.1–0.7	1.1
—number of individuals [A]						
≥80	0–464	1211	0	0	0	0
≥70	727–8305	11923	16–341	660	0–5	14

[85] While the duration of an O_3 season for each year may vary across the study areas, for the purposes of the exposure and risk analyses, the O_3 season in each study area is considered synonymous with a year. These seasons capture the times during the year when concentrations are elevated (80 FR 65419–65420, October 26, 2015).

TABLE 2—PERCENT AND NUMBER OF SIMULATED CHILDREN AND CHILDREN WITH ASTHMA ESTIMATED TO EXPERIENCE AT LEAST ONE OR MORE DAYS PER YEAR WITH A 7-HOUR AVERAGE EXPOSURE AT OR ABOVE INDICATED CONCENTRATION WHILE BREATHING AT AN ELEVATED RATE IN AREAS JUST MEETING THE CURRENT STANDARD—Continued

Exposure concentration (ppb)	One or more days		Two or more days		Four or more days	
	Average per year	Highest in a single year	Average per year	Highest in a single year	Average per year	Highest in a single year
≥60	14928–69794	96261	2601–24952	36643	158–5997	9554

[A] Estimates for each study area were averaged across the 3-year assessment period. Ranges reflect the ranges of averages.
[B] A value of zero (0) means that there were no individuals estimated to have the selected exposure in any year.
[C] An entry of <0.1 is used to represent small, non-zero values that do not round upwards to 0.1 (*i.e.,* <0.05).

These estimates are of generally similar magnitude to those which were the focus in the 2015 decision establishing the current standard (Table 3; PA, sections 3.1 and 3.4, Appendix 3D, section 3D.3.2.4, Table 3D–38).[86] The differences observed are generally slight, likely reflecting influences of a number of the differences in the quantitative modeling and analyses performed in the current assessment from those for the 2014 HREA, summarized in section II.A.3.a above (*e.g.,* 2015–2017 vs. 2006–2010 distribution of ambient air O_3 concentrations, better matching of simulated exposure estimates with the 6.6-hour duration of the controlled human exposure studies and with the study subject ventilation rates). Much larger differences are seen between different air quality scenario results for the same benchmark. For example, for the 70 ppb benchmark, the differences between the 75 ppb and current standard scenario (or between the 65 ppb and current standard scenarios) in either assessment are appreciably larger than the slight differences between the two assessments for any one air quality scenario.

TABLE 3—COMPARISON OF CURRENT ASSESSMENT AND 2014 HREA (ALL STUDY AREAS) FOR PERCENT OF CHILDREN ESTIMATED TO EXPERIENCE AT LEAST ONE, OR TWO, DAYS WITH AN EXPOSURE AT OR ABOVE BENCHMARKS WHILE AT MODERATE OR GREATER EXERTION

Air Quality Scenario (DV,[C] ppb)	Estimated average % of simulated children with at least one day per year at or above benchmark (highest in single season)		Estimated average % of simulated children with at least two days per year at or above benchmark (highest in single season)	
	Current PA[A]	2014 HREA[B]	Current PA[A]	2014 HREA[B]
Benchmark Exposure Concentration of 80 ppb				
75	<0.1[A]–0.3 (0.6)	0–0.3 (1.1)	0–<0.1 (<0.1)	0 (0.1)
70	0–<0.1 (0.1)	0–0.1 (0.2)	0 (0)	0 (0)
65	0–<0.1 (<0.1)	0 (0)	0 (0)	0 (0)
Benchmark Exposure Concentration of 70 ppb				
75	1.1–2.0 (3.4)	0.6–3.3 (8.1)	0.1–0.3 (0.7)	0.1–0.6 (2.2)
70	0.2–0.6 (0.9)	0.1–1.2 (3.2)	<0.1 (0.1)	0–0.1 (0.4)
65	0–0.2 (0.2)	0–0.2 (0.5)	0–<0.1 (<0.1)	0 (0)
Benchmark Exposure Concentration of 60 ppb				
75	6.6–15.7 (17.9)	9.5–17.0 (25.8)	1.7–8.0 (9.9)	3.1–7.6 (14.4)
70	3.2–8.2 (10.6)	3.3–10.2 (18.9)	0.6–2.9 (4.3)	0.5–3.5 (9.2)
65	0.4–2.3 (3.7)	0–4.2 (9.5)	<0.1–0.3 (0.5)	0–0.8 (2.8)

[A] For the current analysis, calculated percent is rounded to the nearest tenth decimal using conventional rounding. Values equal to zero are designated by "0" (there are no individuals exposed at that level). Small, non-zero values that do not round upwards to 0.1 (i.e., <0.05) are given a value of "<0.1".
[B] For the 2014 HREA. calculated percent was rounded to the nearest tenth decimal using conventional rounding. Values that did not round upwards to 0.1 (i.e., <0.05) were given a value of "0".
[C] The monitor location with the highest concentrations in each area had a design value just equal to the indicated value.

[86] For example, the 2015 decision to set the standard level at 70 ppb noted that "a revised standard with a level of 70 ppb is estimated to eliminate the occurrence of two or more exposures of concern to O_3 concentrations at or above 80 ppb and to virtually eliminate the occurrence of two or more exposures of concern to O_3 concentrations at or above 70 ppb for all children and children with asthma, even in the worst-case year and location evaluated" (80 FR 65363, October 26, 2015). This statement remains true for the current assessment (Table 3). For the 60 ppb benchmark, on which the 2015 decision placed relatively greater weight for multiple (versus single) occurrences of exposures at or above it, the Administrator at that time noted the 2014 HREA estimates for the 70 ppb air quality scenario that estimated 0.5 to 3.5% of children to experience multiple such occurrences on average across the study areas, stating that the now-current standard "is estimated to protect the vast majority of children in urban study areas . . . from experiencing two or more exposures of concern at or above 60 ppb" (80 FR 65364, October 26, 2015). The corresponding estimates, on average across the 3-year period in the current assessments, are remarkably similar at 0.6 to 2.9% (Table 3).

B. Conclusions on the Primary Standard

In drawing conclusions on the adequacy of the current primary standard, in view of the advances in scientific knowledge and additional information now available, the Administrator has considered the currently available health effects evidence and exposure/risk information. He additionally has considered the evidence base, information, and policy judgments that were the foundation of the last review, to the extent they remain relevant in light of the currently available information. The Administrator has taken into account both evidence-based and exposure- and risk-based considerations discussed in the PA, 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, particularly that from controlled human exposure studies and epidemiologic studies evaluating health effects related to O_3 exposures as presented in the ISA, with a focus on policy-relevant considerations as discussed in the PA (summarized in sections II.B and II.D.1 of the proposal and section II.A.2 above). The exposure- and risk-based considerations draw from the results of the quantitative analyses presented and considered in the PA (as summarized in section II.C of the proposal and section II.A.3 above).

The consideration of the evidence and exposure/risk information in the PA informed the Administrator's proposed conclusions and judgments in this review, and his associated proposed decision. Section II.B.1 below briefly summarizes the basis for the Administrator's proposed decision, drawing from section II.D of the proposal. Section II.B.1.a provides a brief overview of key aspects of the policy evaluations presented in the PA, and the advice and recommendations of the CASAC are summarized in section II.B.1.b. An overview of the Administrator's proposed conclusions is presented in section II.B.1.c. Public comments on the proposed decision are addressed in section II.B.2, and the Administrator's conclusions and decision in this review regarding the adequacy of the current primary standard and whether any revisions are appropriate are described in section II.B.3.

1. Basis for Proposed Decision

a. Policy-Relevant Evaluations in the PA

The main focus of the policy-relevant considerations in the PA is consideration of the question: Does the currently available scientific evidence- and exposure/risk-based information support or call into question the adequacy of the protection afforded by the current primary O_3 standard? The PA response to this overarching question takes into account discussions that address the specific policy-relevant questions for this review, focusing first on consideration of the evidence, as evaluated in the ISA, including that newly available in this review, and the extent to which it alters key conclusions supporting the current standard. The PA also considers the quantitative exposure and risk estimates drawn from the exposure/risk analyses (presented in detail in Appendices 3C and 3D of the PA), including associated limitations and uncertainties, and the extent to which they may indicate different conclusions from those in the last review regarding the magnitude of risk, as well as level of protection from adverse effects, associated with the current standard. The PA additionally considers the key aspects of the evidence and exposure/risk estimates that were emphasized in establishing the current standard, as well as the associated public health policy judgments and judgments about the uncertainties inherent in the scientific evidence and quantitative analyses that are integral to the Administrator's consideration of whether the currently available information supports or calls into question the adequacy of the current primary O_3 standard (PA, section 3.5).

As summarized in section II.D.1 of the proposal, based on the evidence in the ISA, the PA concludes that the respiratory effects evidence newly available in this review is consistent with the evidence base in the last review, supporting a generally similar understanding of the respiratory effects of O_3 (PA, section 3.5.4; ISA, Appendix 3). As was the case for the evidence available in the last review, the currently available evidence for health effects other than those of O_3 exposures on the respiratory system is more uncertain than that for respiratory effects. Such effects include metabolic effects, for which the evidence available in this review is sufficient to conclude there to likely be a causal relationship with short-term O_3 exposures and suggestive of, but not sufficient to infer, such a relationship between long-term O_3 exposure (ISA, section IS.1.3.1). These new determinations are based on evidence largely from experimental animal studies, that is newly available in this review (ISA, Appendix 5). Additionally, newly available evidence regarding cardiovascular effects and mortality, in combination with uncertainties in the previously available evidence that had been identified in the last review, contributes to conclusions that the evidence is suggestive of, but not sufficient to infer, causal relationships with O_3 exposures (ISA, Appendix 4, section 4.1.17 and Appendix 6, section 6.1.8). As in the last review, the evidence is also suggestive of such relationships for reproductive and developmental effects, and nervous system effects (ISA, section IS.1.3.1).

In evaluating the policy implications of the current evidence, the PA observes that within the respiratory effects evidence base, the most certain evidence comes from controlled human exposure studies, the majority of which involve healthy adult subjects (generally 18 to 35 years), although there are studies (generally not at the lowest studied exposures) involving subjects with asthma, and a limited number of studies, generally of durations shorter than four hours, involving adolescents and adults older than 50 years. Respiratory responses observed in human subjects exposed to O_3 for periods of 8 hours or less, while intermittently or quasi-continuously exercising, include lung function decrements (*e.g.,* based on FEV_1 measurements), respiratory symptoms, increased airway responsiveness, mild bronchoconstriction (measured as an increase in sRaw), and pulmonary inflammation, with associated injury and oxidative stress (ISA, Appendix 3, section 3.1.4; 2013 ISA, sections 6.2.1 through 6.2.4). Newly available epidemiologic studies of hospital admissions and emergency department visits for a variety of respiratory outcomes supplement the previously available evidence with additional findings of consistent associations with O_3 concentrations across a number of study locations (ISA, Appendix 3, sections 3.1.4.1.3, 3.1.5, 3.1.6.1.1, 3.1.7.1 and 3.1.8). Together, the clinical and epidemiological bodies of evidence, in combination with the insights gained from the experimental animal evidence, continue to indicate the potential for O_3 exposures to contribute to serious health outcomes and to indicate the increased risk of population groups with asthma, including particularly, children (ISA, Appendix 3, section 3.1.5.7).

The PA concludes that the newly available evidence in this review does not alter conclusions from the last review on exposure duration and concentrations associated with O_3-related effects, observing that the 6.6-hour controlled human exposure studies of respiratory effects remain the focus for our consideration of exposure circumstances associated with O_3 health effects. The PA additionally recognizes that while the evidence clearly demonstrates that short-term O_3 exposures cause respiratory effects, as was the case in the last review, uncertainties remain in several aspects of our understanding of these effects. These include uncertainties related to exposures likely to elicit effects (and the associated severity and extent) in population groups not studied, or less well studied (including individuals with asthma and children) and also the severity and prevalence of responses to short (*e.g.,* 6.6- to 8-hour) O_3 exposures, at and below 60 ppb, while at increased exertion levels.

The PA additionally includes exposure/risk analyses of air quality scenarios in eight study areas, with a focus on the scenario for air quality that just meets the current standard, as described in section II.C of the proposal and summarized in section II.A.3 above. In considering the results of these analyses, the PA gives particular emphasis to the comparison-to-benchmarks analysis, which provides a characterization of the extent to which population exposures to O_3 concentrations, similar to those evaluated in controlled human exposure studies, have the potential to occur in areas of the U.S. when air quality just meets the current standard (PA, section 3.4). The policy evaluations of the exposure/risk analyses focus on children and children with asthma as key at-risk populations, and consideration of the potential for one versus multiple exposures to occur. The PA recognizes that consideration of differences in magnitude or severity of responses (*e.g.,* FEV_1 changes) including the relative transience or persistence of the responses and respiratory symptoms, as well as pre-existing sensitivity to effects on the respiratory system, and other factors, are important to characterizing implications for public health effects of an air pollutant such as O_3 (PA, sections 3.3.2, 3.4.5 and 3.5).

In summary, the PA concludes that the newly available health effects evidence, critically assessed in the ISA as part of the full body of evidence, reaffirms conclusions on the respiratory effects recognized for O_3 in the last review on which the current standard is based. The PA additionally draws on the quantitative exposure and risk estimates for conditions just meeting the current standard (PA, sections 3.4 and 3.5.2). Limitations and uncertainties associated with the available information remain (PA, sections 3.5.1 and 3.5.2). The PA recognizes that the newly available quantitative exposure/risk estimates for conditions just meeting the current standard indicate a generally similar level of protection for at-risk populations from respiratory effects, as that described in the last review for the now-current standard (section II.A.3, Table 3, above; PA, sections 3.1 and 3.4, Appendix 3D, section 3D.3.2.4, Table 3D–38). Collectively, in consideration of the evidence and quantitative exposure/risk information available in the current review, as well as advice from the CASAC, the PA concludes that it is appropriate to consider retaining the current primary standard of 0.070 ppm O_3, as the fourth-highest daily maximum 8-hour concentration averaged across three years, without revision.

b. CASAC Advice in This Review

In comments on the draft PA, the CASAC agreed with the draft PA findings that the health effects evidence newly available in this review does not substantially differ from that available in the 2015 review, stating that, ''[t]he CASAC agrees that the evidence newly available in this review that is relevant to setting the ozone standard does not substantially differ from that of the 2015 Ozone NAAQS review'' (Cox, 2020a, Consensus Responses to Charge Questions p. 12). With regard to the adequacy of the current standard, views of individual CASAC members differed. Part of the CASAC ''agree with the EPA that the available evidence does not call into question the adequacy of protection provided by the current standard, and thus support retaining the current primary standard'' (Cox, 2020a, p. 1). Another part of the CASAC indicated its agreement with the previous CASAC's advice, based on review of the 2014 draft PA, that a primary standard with a level of 70 ppb may not be protective of public health with an adequate margin of safety, including for children with asthma (Cox, 2020a, p. 1 and Consensus Responses to Charge Questions p. 12).[87] Additional comments from the CASAC in the ''Consensus Responses to Charge Questions'' on the draft PA attached to the CASAC letter provide recommendations on improving the presentation of the information on health effects and exposure and risk estimates in completing the final PA. The EPA considered these comments, making a number of revisions to address them in completing the PA. The comments from the CASAC also took note of uncertainties that remain in this review of the primary standard and identified a number of additional areas for future research and data gathering that would inform the next review of the primary O_3 NAAQS (Cox, 2020a, Consensus Responses to Charge Questions p. 14). The recommendations from the CASAC were considered in the proposed decision and have been considered by the Administrator in his decision in this review, summarized in section II.B.3 below.

c. Administrator's Proposed Conclusions

In reaching conclusions on the adequacy and appropriateness of protection provided by the current primary standard and his proposed decision to retain the standard, the Administrator carefully considered: (1) The assessment of the current evidence and conclusions reached in the ISA; (2) the currently available exposure and risk information, including associated limitations and uncertainties, described in detail in the PA; (3) the considerations and staff conclusions and associated rationales presented in the PA, including consideration of commonly accepted guidelines or criteria within the public health community, including the ATS, an organization of respiratory disease specialists; (4) the advice and recommendations from the CASAC; and (5) public comments that had been offered up to that point (85 FR 49830, August 14, 2020). In so doing, he considered the evidence base on health effects associated with exposure to photochemical oxidants, including O_3, in ambient air, noting the health effects evidence newly available in this review, and the extent to which it alters key scientific conclusions in the last review. He additionally considered the quantitative exposure and risk estimates

[87] In the last review, the advice from the prior CASAC included a range of recommended levels for the standard, with the CASAC concluding that ''there is adequate scientific evidence to recommend a range of levels for a revised primary ozone standard from 70 ppb to 60 ppb'' (Frey, 2014b, p. ii). In so doing, the prior CASAC noted that ''[i]n reaching its scientific judgment regarding a recommended range of levels for a revised ozone primary standard, the CASAC focused on the scientific evidence that identifies the type and extent of adverse effects on public health'' and further acknowledged ''that the choice of a level within the range recommended based on scientific evidence is a policy judgment under the statutory mandate of the Clean Air Act'' (Frey, 2014b, p. ii). The prior CASAC then described that its ''*policy advice* [emphasis added] is to set the level of the standard lower than 70 ppb within a range down to 60 ppb, taking into account [the Administrator's] judgment regarding the desired margin of safety to protect public health, and taking into account that lower levels will provide incrementally greater margins of safety'' (Frey, 2014b, p. ii).

developed in this review, including associated limitations and uncertainties, and what they indicate regarding the magnitude of risk, as well as level of protection from adverse effects, associated with the current standard. The Administrator also considered the key aspects of the evidence and exposure/risk estimates from the 2015 review that were emphasized in establishing the standard at that time. Further, he considered uncertainties in the current evidence and the exposure/risk information, as a part of public health judgments that are essential and integral to his decision on the adequacy of protection provided by the standard, similar to the judgments made in establishing the current standard. Such judgments include public health policy judgments and judgments about the uncertainties inherent in the scientific evidence and quantitative analyses. The Administrator drew on the considerations and conclusions in the current PA, taking note of key aspects of the associated rationale, and he considered the advice and conclusions of the CASAC, including particularly its overall agreement that the currently available evidence does not substantially differ from that which was available in the 2015 review when the current standard was established.

As an initial matter, the Administrator recognized the continued support in the current evidence for O_3 as the indicator for photochemical oxidants, taking note that no newly available evidence has been identified in this review regarding the importance of photochemical oxidants other than O_3 with regard to abundance in ambient air, and potential for health effects. For such reasons, described with more specificity in the ISA and PA and summarized in the proposal, he proposed to conclude it is appropriate for O_3 to continue to be the indicator for the primary standard for photochemical oxidants and focused on the current information for O_3 (85 FR 49830, August 14, 2020).

With regard to O_3 health effects, the Administrator recognized the long-standing evidence that has established there to be a causal relationship between respiratory effects and short-term O_3 exposures. He recognized that the strongest and most certain evidence for this conclusion, as in the last review, is that from controlled human exposure studies that report an array of respiratory effects in study subjects (which are largely generally healthy adults) engaged in quasi-continuous or intermittent exercise. He also recognized the supporting experimental animal and epidemiologic evidence, including the epidemiologic studies reporting positive associations for asthma-related hospital admissions and emergency department visits, which are strongest for children, with short-term O_3 exposures (85 FR 49830, August 14, 2020).

Regarding the current evidence and EPA conclusions for populations at increased risk of O_3-related health effects (ISA, section 4.4), the Administrator took particular note of the robust evidence that continues to identify people with asthma as being at increased risk of O_3 related respiratory effects, including specifically asthma exacerbation and associated health outcomes, and also children, particularly due to their generally greater time outdoors while at elevated exertion (PA, section 3.3.2; ISA, sections IS.4.3.1, IS.4.4.3.1, and IS.4.4.4.1, Appendix 3, section 3.1.11). Based on this evidence and related factors, the Administrator proposed to conclude it appropriate to give particular focus to people with asthma and children (population groups for which the evidence of increased risk is strongest) in evaluating whether the current standard provides requisite protection based on the judgment that such a focus will also provide protection of other population groups, identified in the ISA, for which the current evidence is less robust and clear as to the extent and type of any increased risk, and the exposure circumstances that may contribute to it.

The Administrator additionally recognized newly available evidence and conclusions regarding O_3 exposures and metabolic effects. In so doing, he also noted that the basis for the conclusions is largely experimental animal studies in which the exposure concentrations were well above those in the controlled human exposure studies for respiratory effects, and also above those likely to occur in areas of the U.S. that meet the current standard. In light of these considerations, he further proposed to judge the current standard to be protective of such circumstances, leading him to continue to focus on respiratory effects in evaluating whether the current standard provides requisite protection (85 FR 49830, August 14, 2020).

With regard to exposure circumstances of interest for respiratory effects, the Administrator focused particularly on the 6.6-hour controlled human exposure studies involving exposure, with quasi-continuous exercise, that examine exposures from 60 to 80 ppb. In so doing, he recognized that this information on exposure concentrations that have been found to elicit effects in exercising study subjects is unchanged from what was available in the last review. He additionally recognized that while, as a whole, the epidemiologic studies of associations between O_3 and respiratory effects and health outcomes (*e.g.,* asthma-related hospital admission and emergency department visits) provide strong support for the conclusions of causality, they are less useful for his consideration of the potential for O_3 exposures associated with air quality conditions allowed by the current standard to contribute to such health outcomes, taking note of the scarcity of U.S. studies conducted in locations in which and during time periods when the current standard would have been met (85 FR 49830, August 14, 2020).

In reaching his proposed decision to retain the 2015 standard, the Administrator took note of several aspects of the rationale by which it was established, giving weight to the considerations summarized here. The 2015 decision considered the breadth of the O_3 respiratory effects evidence, recognizing the relatively greater significance of effects reported for exposures while at elevated exertion to average O_3 concentrations at and above 80 ppb, as well as to the greater array of effects elicited. The decision also recognized the significance of effects observed at the next lower studied exposures (slightly above 70 ppb) that included both lung function decrements and respiratory symptoms. The standard level was set to provide a high level of protection from such exposures. The decision additionally emphasized consideration of lower exposures down to 60 ppb, particularly with regard to consideration of a margin of safety in setting the standard. In this context, the 2015 decision identified the appropriateness of a standard that provided a degree of control of multiple or repeated occurrences of exposures, while at elevated exertion, at or above 60 ppb (80 FR 65365, October 26, 2015).[88] The controlled human exposure study evidence as a whole provided context for consideration of the 2014 HREA estimates for the

[88] With the 2015 decision, the prior Administrator judged there to be uncertainty in the adversity of the effects shown to occur following exposures to 60 ppb O_3, including the inflammation reported by the single study at the level, and accordingly placed greater weight on estimates of multiple, *versus* single, exposures for the 60 ppb benchmark, particularly when considering the extent to which the current and revised standards incorporate a margin of safety (80 FR 65344–45, October 26, 2015). She based this, at least in part, on consideration of effects at this exposure level, the evidence for which remains the same in the current review, and she considered this information in judgments regarding the 2014 HREA estimates for the 60 ppb benchmark.

comparison-to-benchmarks analysis (80 FR 65363, October 26, 2015). The current Administrator proposed to similarly consider the currently available exposure and risk analyses in this review (85 FR 49830, August 14, 2020).

The Administrator also recognized some uncertainty, reflecting limitations in the evidence base, with regard to the exposure levels eliciting effects (as well as the severity of the effects) in some population groups not well represented in the available controlled human exposure studies, such as children and individuals with asthma. In so doing, the Administrator recognizes that the controlled human exposure studies, primarily conducted in healthy adults, on which the depth of our understanding of O_3-related health effects is based, provide limited, but nonetheless important information with regard to responses in people with asthma or in children. Additionally, some aspects of our understanding continue to be limited, as in the 2015 review; among these aspects are the risk posed to these less studied population groups by 7-hour exposures with exercise to concentrations as low as 60 ppb that are estimated in the exposure analyses. Collectively, these aspects of the evidence and associated uncertainties contribute to a recognition that for O_3, as for other pollutants, the available evidence base in a NAAQS review generally reflects a continuum, consisting of ambient 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.

As in the 2015 decision, the Administrator's proposed decision in this review recognized that the exposure and risk estimates developed from modeling exposures to O_3 in ambient air are critically important to consideration of the potential for exposures and risks of concern under air quality conditions of interest, and consequently are critically important to judgments on the adequacy of public health protection provided by the current standard. Thus taking into consideration related information, limitations and uncertainties recognized in the proposal, the Administrator considered the exposure and risk estimates across the eight study areas (with their array of exposure conditions) for air quality conditions just meeting the current standard. In light of factors recognized above and summarized in section II.D.4 of the proposal, the Administrator, in his consideration of the exposure and risk analyses, focused in the proposal on the results for children and children with asthma. In considering the public health implications of estimated occurrences of exposures, while at increased exertion, at or above the three benchmark concentrations (60, 70, and 80 ppb), the Administrator considered the effects reported in controlled human exposure studies of this range of concentrations during 6.6 hours of quasi-continuous exercise. While the Administrator noted reduced uncertainty in several aspects of the exposure and risk approaches as compared to the analyses in the last review, he recognized the relatively greater uncertainty associated with the lung function risk estimates compared to the results of the comparison-to-benchmarks analysis. In light of these uncertainties, as well as the recognition that the comparison-to-benchmarks analysis provides for characterization of risk for the broad array of respiratory effects compared to a narrower focus limited to lung function decrements, the Administrator focused in the proposal primarily on the estimates of exposures at or above different benchmark concentrations that represent different levels of significance of O_3-related effects, both with regard to the array of effects and severity of individual effects (85 FR 49830, August 14, 2020).

In his consideration of the exposure analysis estimates for exposures at or above the different benchmark concentrations (with reduced associated uncertainty compared to the analysis available in 2015) and based on the greater severity of responses reported in controlled human exposures, with quasi-continuous exercise, at and above 73 ppb, the Administrator focused in the proposal first on the higher two benchmark concentrations (which at 70 and 80 ppb are, respectively, slightly below and above this level) and the estimates for one-or-more-day occurrences. In this context, he proposed to judge it desirable that the standard provide a high level of protection against one or more occurrences of days with exposures, while breathing at an elevated rate, to concentrations at or above 70 ppb. With regard to the 60 ppb benchmark, the Administrator gave greater weight to estimates of occurrences of two or more (rather than one or more) days with an exposure at or above that benchmark, taking note of the lesser severity of responses observed in studies of the lowest benchmark concentration of 60 ppb and other considerations summarized in the proposal, including potential risks for at-risk populations. Based on this weighting of the exposure analysis results for the eight urban study areas, the Administrator noted what was indicated by the exposure estimates for air quality conditions just meeting the current standard with regard to protection for the simulated at-risk populations. Some 97% to more than 99% of all children (including those with asthma), on average, and more than 95% in the single highest year, are estimated to be protected from experiencing two or more days with exposures at or above 60 ppb while at elevated exertion. More than 99% of children with asthma (and of all children), on average per year, are estimated to be protected from a day or more with an exposure at or above 70 ppb. Lastly, the percentage (for both population groups) for at least one day with such an exposure at or above 80 ppb is 99.9% or more in each of the three years simulated, with no simulated children estimated to experience more than a single such day. The Administrator proposed to judge that protection from this set of exposures provides a strong degree of protection to at-risk populations, such as children with asthma. In so doing, he found that the updated exposure and risk analyses continue to support a conclusion of a high level of protection, including for at-risk populations, from O_3-related effects of exposures that might be expected with air quality conditions that just meet the current standard (85 FR 49830, August 14, 2020).

In reaching his proposed conclusion, the Administrator additionally took note of the comments and advice from the CASAC, including the CASAC conclusion that the newly available evidence does not substantially differ from that available in the last review, and the conclusion expressed by part of the CASAC, that the currently available evidence supports retaining the current standard (85 FR 49873, August 14, 2020). He also noted that another part of the CASAC indicated its agreement with the prior CASAC comments on the 2014 draft PA, in which the prior CASAC opined that a standard set at 70 ppb may not provide an adequate margin of safety (Cox, 2020a, p. 1). With regard to the latter view (that referenced 2014 comments from the prior CASAC), the Administrator additionally noted that the 2014 advice from the prior CASAC also concluded that the scientific evidence supported a range of standard levels that included 70 ppb and recognized the choice of a level within its recommended range to be ''a policy judgment under the statutory mandate of the Clean Air Act'' (Frey, 2014b, p. ii).[89]

In reflecting on all of the information currently available, the Administrator also considered the extent to which the currently available information might indicate support for a less stringent standard, noting that the CASAC advice did not convey support for such a standard. He additionally considered the current exposure and risk estimates for the air quality scenario for a design value just above the level of the current standard (at 75 ppb), in comparison to the scenario for the current standard, with its level of 70 ppb. In so doing, he found the markedly increased estimates of exposures to the higher benchmarks under air quality for a higher standard level to be of concern and indicative of less than the requisite protection. Thus, in light of considerations raised in the proposal, including the need for an adequate margin of safety, the Administrator proposed to judge that a less stringent standard would not be appropriate to consider (85 FR 49830, August 14, 2020).

Similarly, the Administrator also considered whether it would be appropriate to consider a more stringent standard that might be expected to result in reduced O_3 exposures. As an initial matter in this regard, he considered the advice from the CASAC (summarized in section II.B.1.b above). With regard to the CASAC advice, he noted that while part of the Committee concluded that the evidence supported retaining the current standard without revision, another part of the Committee reiterated advice from the prior CASAC, which while including the current standard level among the range of recommended standard levels, also provided policy advice to set the standard at a lower level (85 FR 49873, August 14, 2020). In considering the reference to the 2014 CASAC advice, the Administrator noted the slight differences of the current exposure and risk estimates from the 2014 HREA estimates considered by the prior CASAC. The Administrator additionally recognized the PA finding that the factors contributing to these differences, which include the use of air quality data reflecting concentrations much closer to the now-current standard than was the case in the 2015 review, also contribute to a reduced uncertainty in the estimates. Thus, he noted that the current exposure analysis estimates indicate the current standard to provide appreciable protection against multiple days with a maximum exposure at or above 60 ppb. He considered this in the context of the adequacy of protection provided by the standard and of the CAA requirement that the standard protect public health, including the health of at-risk populations, with an adequate margin of safety, and proposed to conclude that the current standard provides an adequate margin of safety, and that a more stringent standard is not needed (85 FR 49873, August 14, 2020).

In light of all of the above, including advice from the CASAC, the Administrator proposed to judge the current exposure and risk analysis results to describe appropriately strong protection of at-risk populations from O_3-related health effects. Thus, based on his consideration of the evidence and exposure/risk information, including that related to the lowest exposures studied and the associated uncertainties, the Administrator proposed to judge that the current standard provides the requisite protection, including an adequate margin of safety, and thus should be retained, without revision (85 FR 49874, August 14, 2020). In so doing, he recognized that the protection afforded by the current standard can only be assessed by considering its elements collectively, including the standard level of 70 ppb, the averaging time of eight hours and the form of the annual fourth-highest daily maximum concentration averaged across three years. The Administrator proposed to judge that the current evidence presented in the ISA and considered in the PA, as well as the current air quality, exposure and risk information presented and considered in the PA, provide continued support to these elements, as well as to the current indicator.

In summary, in the proposal the Administrator recognized that the ISA found the newly available health effects evidence, critically assessed in the ISA as part of the full body of evidence, consistent with the conclusions on the respiratory effects recognized for O_3 in the last review. He additionally noted that the evidence newly available in this review, such as that related to metabolic effects, does not include information indicating a basis for concern for exposure conditions associated with air quality conditions meeting the current standard. Further, the Administrator noted the quantitative exposure and risk estimates for conditions just meeting the current standard that indicate a high level of protection for at-risk populations from respiratory effects. Collectively, these considerations (including those discussed more completely in the proposal) provided the basis for the Administrator's proposed judgments regarding the public health protection provided by the current primary standard of 0.070 ppm O_3, as the fourth-highest daily maximum 8-hour concentration averaged across three years. On this basis, the Administrator proposed to conclude that the current standard is requisite to protect the public health with an adequate margin of safety, and that it is appropriate to retain the standard without revision (85 FR 49874, August 14, 2020).

2. Comments on the Proposed Decision

Over 50,000 individuals and organizations indicated their views in public comments on the proposed decision. Most of these are associated with mass mail campaigns or petitions. Approximately 40 separate submissions were also received from individuals, and 75 from organizations and groups of organizations; forty elected officials also submitted comments. Among the organizations commenting were state and local agencies and organizations of state agencies, organizations of health professionals and scientists, environmental and health protection advocacy organizations, industry organizations and regulatory policy-focused organizations. The comments on the proposed decision to retain the current primary standard are addressed here. Those in support of the proposed decision are addressed in section II.B.2.a and those in disagreement are addressed in section II.B.2.b. Comments related to aspects of the process followed in this review of the O_3 NAAQS (described in section I.D above), as well as comments related to other legal, procedural or administrative issues, and those related to issues not germane to this review are addressed in the separate Response to Comments document.

a. Comments in Support of Proposed Decision

Of the commenters supporting the Administrator's proposed decision to retain the current primary standard, without revision, all generally note their agreement with the rationale provided in the proposal, with the CASAC conclusion that the current evidence is generally consistent with that available in the last review, and with the CASAC members that conclude the evidence does not call into question the adequacy of the current standard. Some commenters further remarked that the primary standard was upheld in the litigation following its 2015

[89] This 2014 advice was considered in the last review's decision to establish the current standard with a level of 70 ppb (80 FR 65362, October 26, 2015).

establishment (*Murray Energy Corp.* v. *EPA,* 936 F.3d 597 [D.C. Cir. 2019]) and that this review is based largely on the same body of respiratory effects evidence. These commenters all find the process for the review to conform to Clean Air Act requirements and the proposed decision to retain the current standard to be well supported, noting that the there are no new controlled human exposure studies (of the type given primary focus in the establishment of the current standard) and concurring with the proposed judgment that at-risk populations are protected with an adequate margin of safety. Some commenters also variously cited EPA statements that the recent metabolic studies, as well as the epidemiologic and toxicological studies newly available in this review for other health endpoints, do not demonstrate effects of O_3 when the current standard is met and thus do not call into question the protection provided by the standard. The EPA agrees with these commenters' conclusion on the current standard.

Further, these comments concur with the EPA's consideration of epidemiologic and toxicological studies of respiratory effects, and with the weight the proposed decision placed on the evidence for other effects, including metabolic and cardiovascular effects, and total mortality. Some of these comments also express the view that health benefits of a more restrictive O_3 standard are highly uncertain, while such a standard would likely cause an increase in nonattainment areas and socioeconomic impacts that the EPA should consider and find to outweigh the uncertain benefits. While, as discussed in section II.B.3 below, the Administrator does not find a more stringent standard necessary to provide requisite public health protection, he does not consider the number of nonattainment areas or economic impacts of alternate standards in reaching this judgment.[90] As summarized in section I.A. above, in setting primary and secondary standards that are ''requisite'' to protect public health and welfare, respectively, as provided in section 109(b), the EPA may not consider the costs of implementing the standards. See generally, *Whitman* v. *American Trucking Ass'ns,* 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 Corp.* v. *EPA,* 936 F.3d 597, 623–24 [D.C. Cir. 2019]). Arguments such as the views on socioeconomic impacts expressed by these commenters have been rejected by the courts, as summarized in section I.A above, including in *Murray Energy,* with the reasoning that consideration of such impacts was precluded by *Whitman'*s holding that the ''plain text of the Act 'unambiguously bars cost considerations from the NAAQS-setting process' '' (*Murray Energy Corp.* v. *EPA,* 936 F.3d at 621, quoting *Whitman,* 531 U.S. at 471).

We also note that some commenters that stated their support for retaining the current standard without revision additionally claimed that, based on the results of the exposure and risk analyses in this review, the current standard provides somewhat more public health protection than the EPA recognized in the 2015 decision establishing it. As support for this view, these commenters cite conclusions (including those in the PA) that the exposure and risk estimates are equivalent or slightly lower than those from the 2014 HREA. In generally agreeing with the commenters' observation with regard to the differences in exposure/risk estimates from analyses in this review compared to those from 2014, we note that the current exposure/risk estimates, while based on conceptually similar approaches to those used in the 2014 HREA, reflect a number of improvements to input data and modeling approaches, summarized in section II.A.3 above, which have reduced uncertainties. These updated analyses inform the Administrator's judgments in this review.

b. Comments in Disagreement With Proposed Decision

Of the commenters that disagreed with the proposal to retain the current standard, some recommend tightening the standard, while one submission recommends a less stringent standard. The commenters supporting a less stringent standard generally assert that the current standard is overprotective, stating that information they provide supports returning to the pre-2015 standard of 75 ppb and/or revising the form from the 4th highest daily maximum to the seventh highest daily maximum. The commenters that recommended a more stringent standard describe a need for revision to provide greater public health protection, generally claiming that the current standard is inadequate and does not provide an adequate margin of safety for potentially vulnerable groups. We address these sets of comments in turn below.

(i) Comments in Disagreement With Proposed Decisions—Calling for Less Stringent Standard

The commenters recommending revision to a less stringent standard generally expressed the view that the current standard is more stringent than necessary to protect public health. In support of this view the commenters argue (1) that in this review the EPA ''discredited'' a cardiovascular mortality study on which commenters assert the 2015 decision had placed especially heavy weight; (2) that in light of limitations they assert for the exposure and risk estimate analyses conducted in this review, a 75 ppb standard would meet 2015 objectives; and, (3) that additional factors they identify indicate that the current standard of 70 ppb is too close to background levels while a standard of 75 ppb or one with a form that uses the seventh (*versus* fourth) highest daily maximum 8-hour O_3 concentration would not be.

With regard to the first argument, the EPA knows of no cardiovascular mortality study, much less any health study, that was relied on in the 2015 review that has been discredited, and the commenters provide no citation for such a study. To the extent that the commenter may be intending to refer to the difference of the current review from the 2015 review with regard to the Agency's causality determinations for cardiovascular effects and all-cause mortality, we note that these changes did not involve ''discrediting'' of any studies in the 2013 ISA. Rather, as summarized in section II.A.2.a above, since the time of the last review the controlled human exposure study evidence base has been appreciably expanded from one study to several, none of which report O_3-induced cardiovascular endpoints. This update to the evidence base for cardiovascular effects, which also includes epidemiologic studies, has contributed to a change in the weight of evidence that supports the Agency's causality determinations for both cardiovascular effects and mortality. To the extent that the commenters intend to suggest that these changes in causality determinations indicate that the current standard is more stringent than necessary to protect public health, the Agency disagrees. The Administrator's reasons for concluding that the current standard provides the requisite public

[90] Comments related to implementation programs are not addressed here because, as described in section I.A above, this action is being taken pursuant to CAA section 109(d)(1) and relevant case law. Accordingly, concerns related to implementation of the existing or an alternate standard are outside the scope of this action.

health protection are explained in section II.B.3 below.

With regard to the risk and exposure analyses, the comment argues that 2019 O_3 ambient air monitoring data for locations meeting a design value of 75 ppb indicate that a 75 ppb standard could achieve comparable exposure estimates to those derived for air quality just meeting the current standard by the EPA's exposure/risk analyses. The comment also asserts that uncertainty in the controlled human exposure evidence base with regard to children with asthma suggests ''some latitude'' is needed in the risk calculations. The analysis provided in the comment appears to focus on counties in designated nonattainment areas with 2019 design values ranging from 71 to 75. For these counties, the commenters' analysis appears to sum the population of the subset of these counties with at least one daily maximum 8-hour average concentration in 2019 falling in the range from 73 to 79 ppb (and, separately, the population of counties with at least one such value above 80 ppb). From these population counts, the analysis derives estimates of the subpopulations of children with asthma spending afternoons outdoors (using national estimates for representation of children in the total population, of children with asthma in the total child population, and of children in asthma spending afternoons outdoors using analysis of CHAD diaries for children). The analysis divides the two values by the commenters' estimate of children with asthma in the U.S. (304 million [total population of the U.S.] × 10.5% [percentage representing children] × 9.7% [percentage representing children with asthma]).

There are many aspects of the analysis submitted with the comment that are not focused on the objective of estimating exposures of concern that might be expected to be experienced by at-risk populations in U.S. areas that just meet a standard with an alternative level of 75 ppb. As just one example of these aspects, the denominator in the final step of the commenters' calculation is inflated by population counts for areas of the U.S. excluded from the commenters' analysis (with this larger population multiplied by a national estimates of percent that are children, 10.5%, and a national estimate of percent of children that have asthma, 9.7%), yielding a percentage of unclear relevance to consideration of exposures occurring in areas just meeting an alternative standards of 75 ppb. If the population of the nonattainment areas on which the commenters' focus is substituted in the calculation for the total population of the U.S. as the denominator (29.5 million × 10.5% × 9.7% = 146,664), with the commenters' estimates of children in those areas that may experience an exposure at or above 80 ppb (4,788) or below 80 ppb and at or above 73 ppb (12,641), the percentages are 3.3% and 8.6%, respectively (and the percentage for at or above 73 ppb would be 5.8%).[91] Thus, contrary to the commenters' assertion, their analytical approach, with use of a denominator that reflects the commenters' focus areas, results in higher estimates of the percentage of at-risk children that may experience particular exposures of concern in areas meeting a 75 ppb standard than does the EPA's analysis, which takes into account a number of factors in much greater detail (*e.g.,* through the use of exposure modeling and human activity data to estimate time series contributing to 7-hour exposure periods with average O_3 concentrations at or above benchmarks), and focuses on temporal and spatial patterns of air quality in areas just meeting a standard of 75 ppb. The commenters analysis is not focused on the factors that are key determinants of population exposures of concern, leading to results that are inconsistent with and less informative than the findings of EPA's more detailed, extensive and technically sound exposure and risk analyses (summarized in section II.A.3 above and Appendices 3C and 3D of the PA). Based on consideration of these analyses, among other factors, as described in section II.B.3 below, the EPA disagrees that the available evidence and quantitative analyses supports the conclusion that the current standard is overprotective and that a standard of 75 ppb would protect public health with an adequate margin of safety.

In support of the commenters' additional argument that the current standard is too close to background and that a 75 ppb standard (or a standard using the seventh highest form) would not be, the commenters (1) state that just because a D.C. Circuit decision has stated that EPA is not required to take U.S. background O_3 (USB) into consideration in NAAQS decisions does not mean that such considerations are precluded; (2) cite the lower number of counties (and associated population) that would be in nonattainment for a 75 ppb standard as compared to the current standard (while also suggesting that revision of the form to a seventh highest would appropriately allow for additional high O_3 days due to wildfires); and (3) suggest that the EPA is underestimating USB by a factor of three.

With regard to the legal point, the EPA agrees that while it is not required to take USB into account in NAAQS decisions, it may do so when such consideration is consistent with the Clean Air Act and prior court decisions. The EPA is not relying on consideration of background O_3 levels to support its decision in this review. Moreover, given the differences in public health protection, as noted in the Administrator's proposed conclusions and described in his conclusions in section II.B.3 below, we do not believe that we could use proximity to background concentrations as a basis for revising the current 70 ppb standard to a potential 75 ppb standard.[92] On the commenters' second point, the EPA notes that the number of counties that would or would not be in nonattainment, the size of population living in them, and the increasing number of days for high O_3 due to wildfires are not relevant factors in judging whether a particular standard is requisite under the Clean Air Act. Regardless of such implications of a decision to retain or revise a NAAQS, the key consideration for the review of a primary standard is whether the standard is judged to provide the requisite protection of public health with an adequate margin of safety.[93] The commenters have provided no evidence suggesting that the current standard provides more than the requisite public health protection under the CAA or indicating that an alternate standard

[91] The EPA's exposure and risk analyses estimate <.1 to 0.3% of children with asthma might be expected to experience at least one exposure, while at increased exertion, at or above 80 ppb, on average across a 3-year period in areas just meeting a potential alternative standard of 75 ppb (85 FR 49865,Table 4, August 14, 2020). For the 70 ppb benchmark, these percentages are 1.1 to 2.0%.

[92] Taken together, the EPA generally understands prior court decisions addressing consideration of background O_3 in NAAQS reviews to hold that while the Agency may not establish a NAAQS that is outside the range of reasonable values supported by the air quality criteria and the judgments of the Administrator because of proximity to background concentrations, it is not precluded from considering relative proximity to background O_3 as one factor in selecting among standards that are within that range (*American Trucking Ass'ns* v. *EPA,* 283 F.3d 355, 379 [D.C. Cir. 2002]; *Murray Energy* v. *EPA,* 936 F.3d at 622–624; *American Petroleum Institute* v. *Costle,* 665 F.2d 1176, 1185 [D.C. Cir. 1982]).

[93] Comments related to implementation programs are not addressed here because, as described in section I.A above, this action is being taken pursuant to CAA section 109(d)(1) and relevant case law. Furthermore, leaving the NAAQS unaltered will not require the EPA to make new air quality designations, nor require States or authorized tribes to undertake new planning or control efforts. Accordingly, concerns related to implementation of the existing or an alternate standard are outside the scope of this action.

with a level of 75 ppb or with a seventh highest form would provide requisite protection. For these reasons, we do not find these comments persuasive in supporting consideration of revising the current standard to an alternate standard with a level of 75 ppb or with a seventh highest form.

With regard to USB, the commenters present an argument focused on an urban/''rural'' comparison and one focused on a 1-month analysis of O_3 concentrations in response to population mobility changes attributed to restrictions placed to manage infections of Corona virus 19 disease (COVID–19). We find there to be limitations in both arguments that undercut the conclusions reached by the commenter. As a result, we disagree that the observations made by the commenters support their statements regarding USB and with the implication that they contradict the EPA's findings from the detailed and extensive analyses presented in the PA (PA, section 2.5 and Appendix 2B).

With regard to the urban/''rural'' comparison, the commenters' first cite EPA's analysis in the PA which indicated, based on daily maximum 8-hour (MDA8) concentrations for the nation as a whole, that from one quarter (10 out of 42 ppb) to one third (14 out of 45 ppb) of average MDA8 concentrations in spring and summer, respectively, are derived from anthropogenic sources. They then state that differences in monthly mean MDA8 concentration between two sets of monitoring sites in the Philadelphia metropolitan area that they identify as the three highest and the three most rural was 3.3 ppb in April 2020. The commenters suggest that this amount is much smaller than the 10 to 14 ppb that EPA estimated to be from anthropogenic sources. Based on these two statements, they contend that USB is being underestimated by a factor of three.

We find the commenters' analysis to have several flaws that undercut their conclusion. First, the difference between the two sets of sites, all of which fall in the Philadelphia metropolitan area, are not indicative of either USA (*i.e.,* U.S. anthropogenic) or USB contributions. There is no evidence that this difference is indicative of either USB or USA, and it is especially anomalous given that the commenters' analysis is based on 2020 data (affected by reduced emissions during the reduced travel during the initial months of the COVID–19 epidemic in the U.S.) while EPA's is based on 2016 data. Second, the authors cite a country-wide seasonal average despite the fact that the U.S. anthropogenic contributions are clearly higher in the nonattainment area (than a U.S. average) being referenced. Further, the conclusions about USB underestimation appear quantitatively incorrect and to perhaps confuse USA and USB in the calculations. Even if all USA anthropogenic contributions cited (10 USA and 30 USB of total 40 ppb) in spring of 2016 were actually USB, the underestimation of USB would be 25% at most (0 USA and 40 USB of total 40 ppb; $(40-30)/40 = 25\%$), thus it is unclear how the commenter concluded a factor of three (300%) under-estimation of USB. In addition, the commenter's dataset is for the Philadelphia-Wilmington-Atlantic City CSA, where O_3 more frequently exceeds the level of the standard in May through September (*e.g.,* PA, Appendix 3C, Figure 3C–79), months that have lower USB and higher US anthropogenic than month of April, which the commenters analyzed. Finally, the commenter has focused on low concentration days (averaging ~40–45ppb) that the PA shows tend to be different than high days (PA, section 2.5 and Appendix 2B).

The second argument is based on data on Apple Mobility data [94] and O_3 and NO_2 concentrations for the period from 3/22/2020 to 4/20/2020 (when transportation activity was affected by the behavioral changes in response to COVID–19) and differences from the same period in prior years. Based on the differences, the commenters conclude that O_3 concentrations were less responsive to the 40 to 60% reduction in mobility than were NO_2 concentrations (7% vs 22% difference), indicating to the commenters that society is reaching a period of diminishing returns of actions to control O_3 concentrations. We note, however, that the period of the commenters' analysis is April, while the majority of days with MDA8 greater than 70 ppb in the Philadelphia nonattainment area occur in May to September. In the mid to late summer period, local production of O_3 is increased (see PA section 2.5.3.2) and MDA8 concentrations in the Philadelphia nonattainment area more frequently are above the level of the standard. Thus, the analysis does not support the commenters' argument for a less stringent standard.[95]

(ii) Comments in Disagreement With Proposed Decision and Calling for More Stringent Standard

Among the commenters that disagree with the proposed decision and call for a more stringent standard, most express concerns regarding the process for reviewing the criteria and standards in this review and assert that the proposal must be withdrawn, and a new review conducted. The commenters expressing the view that a more stringent standard is needed variously cite a number of concerns. Some state that EPA cannot, as some commenters imply it does, simply base its decision on a judgment that the available evidence is similar to that when the standard was established in a prior review, and some argue that the available health effects evidence indicates that adverse health effects occur from exposures allowed by the current standard. Further some commenters express their views that the combined consideration of the complete evidence base indicates that sensitive or vulnerable populations are not protected by the current standard; and/or that the standard does not provide an adequate margin of safety. Additionally, in support of their view that the standard should be made more stringent, some commenters disagree with the conclusions of the exposure and risk analyses, characterizing the analyses as deficient, and contending that other quantitative analyses they cite indicate health impacts that would be avoided by a lower standard level. Most of the commenters advocating a more stringent standard recommend revision of the level to a value at or below 60 ppb and others support a level at or below 65 ppb. Some of these commenters additionally note they had raised similar concerns during the 2015 review.[96] Some commenters also express the view that the EPA should establish a separate long-term standard.

With regard to the process by which this review has been conducted, we disagree with the commenters that it is arbitrary and capricious or that it does not comport with legislative requirements. The review process, summarized in section I.D, implemented a number of features, some of which have been employed in past reviews and others which have not,

[94] *https://covid19.apple.com/mobility.*

[95] We also note, contrary to the commenters' premise, NO_2 and/or NO_X are not conserved over a day. Rather, the overall lifetime of NO_X is on the order of six hours. Further, while the commenter describes the ''local'' nature of O_3, it is well established that O_3 has a large transport component. The diurnal pattern of O_3 concentrations highlighted on this point is likely illustrating O_3 concentrations subject to local NO_X-titration rather than purely local formation as suggested by the commenters.

[96] We note that comments raised in the prior review were fully considered in reaching the decision in that review. Such comments are addressed in the decision and associated Response to Comments (80 FR 65292, October 26, 2020; U.S. EPA, 2015). To the extent that commenters are raising similar issues in support of their comments on the proposed decision in this review, we have addressed them in the current decision, based on the information now available.

and several which represent efficiencies in consideration of the statutorily required time frame for completion of the review. The comments that raise concerns regarding specific aspects of the process are addressed in the separate Response to Comments document. As indicated there, the EPA disagrees with these comments. The EPA finds the review to have been lawfully conducted, the process reasonably explained, and thus finds no reason to withdraw the proposal.

We disagree with some commenters' contention that the EPA based its proposed decision simply on the similarity of the health effects evidence to that available in the last review. While the health effects information is generally similar to that available in the last review, particularly with regard to respiratory effects (the effects causally related to O_3 exposure), the current health effects evidence base includes hundreds of new health studies. Based on consideration of the full evidence base, including that the newly available in the current review, the EPA has reached different conclusions regarding some categories of effects (as summarized in II.A.2.a above). The EPA's observation that the nature of the evidence has not substantially changed with regard to effects causally related to O_3 exposure, was not, as implied by the comment, the primary consideration in the Administrator's proposed decision. The Administrator considered a number of factors in reaching his proposed decision, including the full extent of the currently available health effects evidence, and the details in which it is, and is not, similar to the last review, which has led to conclusions similar to prior conclusions for some categories of O_3 effects and resulted in changes to others (85 FR 49868–49874, August 14, 2020).[97] Further, in reaching his final decision in this review, as described in section II.B.3 below, he has again considered the currently available information, now in light of the public comments received on the proposal, among other factors.[98] In sum, while we have noted the similarities in the health effects information between this review and the last review (particularly for respiratory effects), we have engaged in independent analysis and assessment of the health effects information in this review, and the Administrator has exercised his independent judgment based on the current health effects assessment, in combination with current exposure/risk information, advice from the CASAC and public comment. Thus, contrary to the suggestion by these commenters, the decision on the primary standard has been made in consideration of the current health effects evidence, current analyses of air quality, exposure and risk, advice from the CASAC, and public comments, consistent with requirements under the CAA.

In support of their position that the available health effects evidence indicates that O_3 exposures occurring in areas that meet the current standard are causing adverse effects, some commenters cite studies that investigate associations of O_3 concentrations and effects, such as respiratory effects, mortality, and preterm birth.[99] These studies include some already evaluated in the air quality criteria,[100] [101] some published subsequent to the literature cutoff date for the ISA, and some which some commenters claim the EPA arbitrarily dismissed or inconsistently weighed in reaching the proposed decision.[102] As discussed in I.D above, we have provisionally considered these ''new'' studies that have not already been evaluated in the air quality criteria and that were cited by commenters in support of their comments on the proposed decision (Luben et al., 2020). Based on this consideration, we conclude that these studies do not materially change the broad conclusions of the ISA with regard to these health effects, including the conclusions that there is a causal relationship of short-term respiratory effects with O_3 exposures; a relationship of long-term respiratory effects with O_3 exposure that is likely to be causal; evidence that is suggestive of, but not sufficient to infer, causal relationships of cardiovascular effects and total mortality with short- or long-term O_3 exposure; evidence that is suggestive of, but not sufficient to infer, causal relationships of central nervous system effects with short- or long-term O_3 exposure; and, evidence that is suggestive of, but not sufficient to infer, causal relationships of reproductive and developmental effects with long-term O_3 exposure (ISA, section IS.1.3.1). Nor do we find that these studies warrant reopening the air quality criteria for further review (Luben et al., 2020). Thus, we do not find these publications to be contrary to the discussions and associated conclusions in the PA and proposal or to indicate the current standard to be inadequate. We disagree that studies cited by commenters show these categories of effects to be caused by O_3 exposures associated with O_3 air quality that meets the current standard. We continue to focus on the studies of respiratory effects as most important to the Administrator's judgments concerning the public health protection provided by the current standard.

The epidemiologic studies of respiratory effects identified by the commenters include some investigating associations of O_3 exposure with hospital admissions or emergency department visits for respiratory outcomes, or with various respiratory effects for selected population groups. Studies of O_3 and respiratory effects cited by these commenters in support of their comment include studies that have already been evaluated in the air quality criteria (Goodman et al., 2017; O'Lenick et al., 2017; Jerrett et al., 2009; Lin et al., 2008; Islam et al., 2009; Galizia et al., 1999; Peters et al., 1999; Wendt et al., 2014), and also several ''new'' studies, including four that investigate a relationship between O_3 and COVID–19 (Ware et al., 2016; Strosnider et al., 2019; Wang et al., 2019a; Adhikari and Yin, 2020; Zhu et al., 2020; Zoran et al., 2020; Petroni et al., 2020).[103] We do not

[97] As just one example, the causal determinations for cardiovascular effects and total mortality in this review differ from those made in the last review, as described in section II.A.2.a.

[98] In so doing, to the extent the current evidence before the Administrator continues to support or reinforce conclusions reached in prior reviews, he may reasonably reach those same conclusions.

[99] With regard to effects other than respiratory effects, studies cited by these commenters include studies of cardiovascular effects (Day et al., 2017; Shin et al., 2019; Wang et al., 2019b), all-cause mortality (Bell et al., 2014; Cohen et al., 2017; Di et al., 2017a, b), neurological effects (Cleary et al., 2018), and reproductive and developmental effects (Wallace et al., 2016; Lavigne et al., 2016; Salam et al., 2005; Steib et al, 2019; Morello-Frosch et al., 2010).

[100] In updating the air quality criteria in the current review, the current ISA evaluates relevant scientific literature published since the 2013 ISA, integrating with key information and judgments contained in the 2013 Ozone ISA and previous assessments (ISA, p. lxix; 2013 ISA; U.S. EPA, 2006; U.S. EPA, 1996a; U.S. EPA, 1982; U.S. EPA, 1986; U.S. EPA 1978; NAPCA, 1969).

[101] This commenter cited a epidemiologic study (Day et al., 2017) that had been among studies of short term O_3 and cardiovascular effects excluded from the draft ISA due to location, however this study was considered by the EPA in response to advice from the CASAC on the draft ISA (Luben, 2020). This consideration of these studies did not change EPA's analysis of the weight of evidence from that described in the draft ISA, thus supporting the causality determination for cardiovascular effects described in the final ISA (ISA, section IS.4.3).

[102] We note that one study identified by a commenter to support their view that O_3 concentrations allowed by the current standard is causing health effects does not include O_3 among the pollutants it examines (Gan et al., 2014). Accordingly, we do not find the study to provide support to the commenter's point.

[103] As discussed in section I.D above, the ''new'' studies identified by commenters have not been through the comprehensive CASAC and public review process that the air quality criteria went through. To address these comments, we have provisionally considered these studies, as discussed in I.D above, and found they do not materially

Continued

find these studies to contradict any of the scientific conclusions on respiratory effects described in the ISA.

With regard to the four studies on COVID–19, we disagree with the commenters that they provide evidence that O_3 exposure contributes to COVID–19 incidence, much less that they indicate that O_3 concentrations occurring when the current standard is met would do so. These studies investigate an association between O_3 and COVID–19 cases or deaths. We note, however, that the time-series study design used in three of these studies (Zhu et al., 2020 [incorrectly cited by some commenters as Yongiian et al, 2020]; Adhikari and Yin, 2020; Zoran et al., 2020) is not appropriate for infectious disease cases, which do not follow a Poisson distribution, as they increase exponentially with community spread. The fourth study, an ecological study (Petroni et al. 2020), is also limited by its study design, which is susceptible to confounding or other biases related to ecologic fallacy,[104] as well as its manner of assigning exposure to the population.[105] Further, the time periods in none of the four studies is long enough to rule out a coincidental increase in the community spread of COVID–19 with the increased O_3 concentrations expected with the beginning of O_3 season in these areas (*e.g.,* March–April). Lastly, the biological basis by which a gaseous pollutant such as O_3 would be expected to contribute to incidence of this disease is unclear.[106] Thus, we do not find these studies to support a conclusion that O_3 exposure causes COVID–19 morbidity or mortality.[107]

With regard to the commenters' claims that effects other than respiratory effects (see above) are occurring as a result of O_3 concentrations allowed by the current standard, we note that the standard is exceeded in nearly all of the locations and time periods analyzed in these studies.[108] Although some studies analyzed multiple cities or locations in which the current standard was met during some time periods, air quality during other time periods or locations in the dataset does not meet the current standard. As noted in past reviews, compared to single-city studies, there is additional uncertainty in interpreting relationships between O_3 air quality in individual study cities and reported O_3 multicity effect estimates. Specifically, as recognized in section II.A.2.c above, the available multicity effect estimates in studies of short-term O_3 do not provide a basis for considering the extent to which O_3 health effect associations are influenced by individual locations with ambient O_3 concentrations low enough to meet the current O_3 standards versus locations with O_3 concentrations that violate this standard (85 FR 49853, August 14, 2020; 80 FR 65344, October 26, 2015).[109] Thus, based on this information and the full health effects evidence base for O_3, we disagree with commenters about the implications of the cited epidemiologic studies regarding health risks of O_3 exposures resulting from the O_3 concentrations in ambient air allowed by the current standard.

Protection of Sensitive Groups: Commenters expressing the view that the current standard does not protect sensitive or at-risk populations, variously state that the EPA does not consider risks to a number of population groups the commenters identify as at higher risk for O_3-related health effects, and that retaining the current standard ''creates additional and unacceptable risks'' for Black and low-income communities. Further, some commenters express the views that together the evidence from controlled human exposure studies and from epidemiologic studies indicates adverse effects associated with exposures allowed by the current standard; and that the EPA has not appropriately considered a number of aspects of the evidence related to risks to people with asthma.

Some commenters, in addition to contending that the current standard will not protect populations for which the EPA has concluded there is adequate evidence for identification of increased risk (*e.g.,* people with asthma, children, and outdoor workers), additionally assert that the current standard will not protect populations of color, American Indian/American Native groups, low SES communities, people of any age with respiratory issues other than asthma, diabetes or atrial fibrillation and pregnant women. As described in section I.A. above, primary NAAQS are intended to protect the public health, including at-risk populations, with an adequate margin of safety. Accordingly, in reviewing the air quality criteria, the EPA evaluates the evidence with regard to factors that place some populations at increased risk of harm from the subject pollutant. In this review, the populations for which the evidence indicates increased risk include people with asthma, children and outdoor workers, among other groups, as summarized in section II.A.2.b above (ISA, section IS.4.4).

In support of their argument that individuals with atrial fibrillation are at increased risk of O_3-related health effects, the commenter cited a study of O_3 exposure and total mortality that has been evaluated in the ISA (Medina-Ramon and Schwartz, 2008). It was initially evaluated in the last review and explicitly discussed again as part of the evidence base available in the current review (ISA, section 6.1.5.2 and Table IS–10; 2013 ISA, sections 6.6.2.2 and 8.2.4). Based on consideration of that study and others investigating a potential for increased risk among populations with cardiovascular disease

change the broad scientific conclusions of the ISA with regard to respiratory effects, or warrant re-opening the air quality criteria for further review (Luben et al., 2020).

[104] Ecologic fallacy is a specific type of bias that results when group- or population-level data are used to estimate individual-level risks in an epidemiologic study

[105] This study uses 2016 summertime average O_3 as a surrogate for O_3 from 3/1/2020 to 7/11/2020 (Petroni et al., 2020). Yet COVID–19 cases did not surge in many parts of the U.S. until late summer or fall 2020. To the extent these areas (*e.g.,* rural upper midwest) have lower O_3 concentrations than areas of the country where COVID–19 cases surged earlier (*e.g.,* New York City), a correlation between O_3 concentrations and COVID–19 deaths would be overestimated.

[106] While there may be correlations between O_3 concentrations and COVID–19 cases and deaths, they could be explained by coincidental timing of the COVID–19 community transmission period in New York City and Milan with the early part of the O_3 seasons in those areas, and neither the investigators or commenters provide evidence supporting an alternative plausible basis (Adhikari and Yin, 2020; Zoran et al., 2020).

[107] While the full evidence base indicates the potential for O3 to increase susceptibility to some respiratory infections, the studies cited by commenters do not provide evidence that short-term or long-term O_3 exposure increases susceptibility to COVID–19.

[108] Locations and time periods analyzed in these studies include three large metropolitan areas in Texas before 2012 (Goodman et al., 2017); Atlanta, Dallas and St. Louis from 2002 to 2008 (O'Lenick et al., 2017); large cities across the U.S. from late 1970s through 2000 (Jerrett et al., 2009); New York State, primarily during the 1990s (Lin et al., 2008); U.S. location chosen for O3 concentrations not meeting the standard (Galizia and Kinney, 1999); a set of southern California communities during period (1990s) recognized to be exceeding the NAAQS (Peters et al., 1999; Islam et al., 2009); Houston metropolitan area during 2005 to 2007 (Wendt et al., 2014); multiple locations including St. Louis, Memphis and Atlanta 2003 through 2012 (Ware et al., 2016); six U.S. metropolitan areas, including Los Angeles, Baltimore and New York City, from 1999 thru 2018 (Wang et al., 2019a); and 894 U.S. counties, including those for New York City and Los Angeles, 2001 to 2014 (Strosnider et al., 2019). Air quality data and design values derived by the U.S. indicate that the current 70 ppb standard was not met throughout the study period, or, for multicity studies for which single-city analyses not performed, was not met in all cities throughout the study (PA, Appendix 3B and Excell files available at: *https://www.epa.gov/air-trends/air-quality-design-values*).

[109] This uncertainty applies specifically to interpreting air quality analyses within the context of multicity effect estimates for short-term O_3 concentrations, where effect estimates for individual study cities are not presented, as is the case for some of the multicity studies identified by commenters (85 FR 49870, August 14, 2020).

(CVD), the 2013 ISA concluded that the evidence was ''inadequate to classify pre-existing CVD as a potential at-risk factor for O_3-related health effects'' (2013 ISA, sections 8.2.4). In the current review, while a limited number of recent studies add to the evidence available in the 2013 ISA,[110] collectively the evidence remains inadequate to conclude whether individuals with pre-existing CVD are at greater risk of O_3-related health effects (ISA, Table IS–10, section IS.4.4.3.5). Thus, the evidence does not support the commenters assertion that populations with atrial fibrillation are at increased risk of O_3-related effects and that the current standard does not protect these groups.

The commenters who contend pregnant women are at increased risk do not provide supporting evidence, and the ISA does not reach such a conclusion based on the currently available evidence. Further, the ISA determined the evidence to be suggestive of, but not sufficient to infer, a causal relationship between O_3 exposure and reproductive effects (ISA, section IS.4.3.6.3). Thus, we disagree with the commenters that pregnant women may be at increased risk of O_3-related effects and disagree that the current standard does not protect these groups.

With regard to a potential for increased risk of O_3-related health effects based upon race or ethnicity, including American Indians or Native Americans), the available evidence is inadequate to make such a determination (ISA, section IS.4.4, Tables IS–9 and IS–10).[111] Additionally, the evidence of increased O_3 risk based on SES has been evaluated in the ISA and concluded to be ''suggestive,'' but the evidence is limited by inconsistencies (ISA, section IS.4.4). Thus, contrary to the view expressed by some commenters, the EPA has considered this factor in this review and the evidence was not adequate to identify SES as a risk factor for O_3 related health effects. As noted by the commenters, the evidence for low SES populations is ''suggestive'' of increased risk (ISA, section IS.4.4), in part because it includes several inconsistencies (as summarized in section II.A.2.b above), including studies that did not find O_3-related risk to be higher in lower SES communities.[112] While we agree with the commenters that populations of some particular races or ethnic backgrounds or with low SES have higher rates of some health conditions, including asthma,[113] the available evidence is not adequate to conclude an increased risk status based solely on racial, ethnic or income variables alone (ISA, section IS.4.4). Thus, we disagree with commenters that EPA has arbitrarily not considered such factors in reaching the decision on the primary standard.

Some commenters further claim that tribal populations and communities of color are at increased risk of O_3-related health effects due to increased impacts of COVID–19. We disagree with commenters that the studies they cite provide support for the role of O_3 exposure in the observed increase in prevalence. The studies cited simply describe greater prevalence of COVID–19 among such communities and do not investigate and therefore do not provide evidence for a role for O_3 exposure.[114] An additional study cited by one commenter in support of their statement that people with COVID–19 are more susceptible to effects of O_3, does not include any analyses with O_3 among its analyses (Wu et al, 2020). With regard to diabetes, we note that the evidence related to a potential for this to affect risk of O_3-related effects has been explicitly evaluated and found to be inadequate, thus indicating a lack of basis in the evidence for the statement by some commenters that diabetes prevalence in a community increases the risk of O_3-related effects (ISA, Table IS–10).

Additionally, commenters that contend that retaining the current standard ''creates additional and unacceptable risks'' for minority and low-income populations variously cite higher rates of asthma and other preexisting conditions in these populations and higher levels of pollution.[115] In making this claim, these commenters state that non-Hispanic Blacks have been found to be more likely to live in counties with higher O_3 pollution. To the extent that such patterns in the distribution of certain population groups and O_3 concentrations result in these populations residing in areas that do not currently meet the current standard, we note that they are at greater risk than populations residing in areas that meet the current standard, and implementing the standard will reduce their risks. But we disagree with the commenters' conclusion that retaining the current standard, without any change, creates additional risks for these populations.

Thus, contrary to statements by some commenters, the EPA's proposed decision to retain the current standard did consider evidence regarding risk to and thus protection of specific populations, such as those of particular races or ethnicities or low-income populations. The proposed decision, and the Administrator's decision described in section II.B.3 below, are based on consideration of the currently available evidence, particularly that with regard to populations that may be at greater risk of O_3-related health effects than the general population. As described in section II.B.3 below, the Administrator judges that by basing his decision on consideration of these populations, including adults and children with asthma, the at-risk population groups for which the

[110] Further, we note that a more recent study than that cited by the commenters investigated the potential for an association of O_3-related mortality risk with individuals with atrial fibrillation and observed no evidence of an association (ISA, Appendix 6, p. 6–11).

[111] In support of their view that O_3-related risk is increased in Black populations, some commenters cite a study published after the ISA (Gharibi et al., 2019). We have provisionally considered this study, as described in section I.D. above, and found that it does not materially affect the broad conclusions in the ISA, including those regarding the adequacy of evidence for finding an influence on O_3-related risk of different categories of population status, or warrant reopening the air quality criteria for further review (Luben et al., 2020).

[112] We note that two studies described by one commenter as indicating that those with low SES or who live in low SES communities face higher risk of hospital admissions and emergency department visits related to O_3 pollution have been evaluated by the EPA and found not to report such findings (2013 ISA, section 8.3.3; ISA, Table IS–10). In the first, a study of O_3 exposure and respiratory hospital admissions in 10 Canadian cities (Cakmak et al., 2006) ''no consistent trend in the effect was seen across quartiles of income,'' and the second, a study of O_3 exposure and asthma hospital admissions and emergency visits (Burra et al., 2009), ''reported inverse effects for all levels of SES'' (2013 ISA, p. 8–27; ISA, Table IS–10).

[113] This is noted in the PA and proposal with regard to Black non-Hispanic and several Hispanic population groups (PA, Table 3–1). As some commenters note, this is also the case for American Indian and Native American population groups. Based on the recently available, 2016–2018 National Health Interview Survey, while just under 8% of the U.S. population is estimated to have asthma, the estimate is more than 10% for American Indian or Native American populations in the U.S. (*https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm;* document identifier EPA–HQ–OAR–2018–0279–0086).

[114] The commenter cites Price-Haywood et al. (2020), Stokes et al. (2020), Millett et al. (2020), Killerby et al. (2020), and Gold et al. (2020). These studies present information regarding COVID–19 cases, hospitalizations and/or deaths among various population groups, but they do not investigate association of those occurrences with O_3.

[115] In making their argument, these commenters do not provide any explanation for why retaining the existing standard (*i.e.,* making no regulatory change) would create additional risk for these populations. Rather, these commenters seem to be describing differences in predicted risk or mortality of air quality associated with a lower standard level and that of the current standard. In that way, they are claiming that retaining the current standard ''creates'' additional risk. We address comments advocating a lower standard based on commenter-cited risk estimates (*e.g.,* mortality) further below.

evidence is strongest and most extensive, will also provide protection for other at-risk populations for which the evidence is less certain and less complete.

The commenters who express the view that the current standard does not provide sufficient protection of people with asthma raise concerns with the EPA's consideration of this group and O_3-related effects. Further, some commenters state that the EPA has not adequately explained how its approach for decision-making in this review protects at-risk populations, such as people with asthma. Such commenters state that the EPA does not explain how the proposed decision accounts for the greater vulnerability of people with asthma, given the attention to evidence from controlled human exposure studies of largely healthy subjects. Some commenters contend that the EPA arbitrarily focuses on lung function decrements and respiratory symptoms ahead of lung inflammation, and/or that the EPA has not rationally considered the most recent ATS statement with regard to consideration of effects in people with respiratory disease, such as asthma (which the commenters describe as a difference from past reviews).

We disagree with these commenters. In this review, as in past reviews, the EPA has fully considered the health effects evidence in this review, including for sensitive populations, such as people with asthma, and explained its conclusions regarding the adequacy of public health protection offered by the current standard, including for such populations. Thus, the decision in this review, as described in section II.B.3 below, is based on the current scientific information. Further, our approach in this review does not differ appreciably from our approach in the last review. This approach is consistent with the applicable legal requirements for this review, including with provisions of the CAA related to the review of the NAAQS, and with how the EPA and the courts have historically interpreted the CAA. The approach is based fundamentally on the current health effects evidence in the ISA and quantitative analyses of exposure and risk in the PA. The policy implications of this information, along with guidance, criteria or interpretive statements developed within the public health community, including, also, statements from the ATS, in addition to advice from the CASAC are evaluated in the PA for consideration by the Administrator. The PA evaluations inform the Administrator's public health policy judgments and conclusions. Thus, as in past reviews, the Administrator's decision on the adequacy of the current primary standard draws upon the scientific evidence for health effects, quantitative analyses of population exposures and health risks, CASAC advice, and judgments about how to consider the uncertainties and limitations that are inherent in the scientific evidence and quantitative analyses, as well as public comments on the proposed decision.

As described in section II.B.3 below, key aspects of the evidence informing the Administrator's decision-making in this review include: (1) The causal relationship of O_3 with respiratory effects, based on the full health effects evidence base, including both the controlled human exposure studies conducted primarily in largely healthy adult subjects, and the epidemiologic studies of health outcomes for people with asthma, and particularly children with asthma; (2) the increased risk to children and people with asthma, among other groups (3) the respiratory effects reported at the lowest exposures in the controlled human exposure studies; and (4) features of asthma that contribute to the susceptibility of people with asthma to O_3-related effects. As a whole, the evidence base in this NAAQS review generally reflects a continuum, consisting of exposure 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. As summarized in section I.A above, 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. The Administrator's consideration of the scientific evidence is informed by the quantitative estimates of exposure and risk for air quality allowed by the current standard, and associated judgments on the adequacy of public health protection provided by the current standard are informed by advice from the CASAC and statements from ATS on adversity.

With regard to the most recent ATS statement, the commenters' claim that the EPA does not adequately consider the implications of the sentence that ''small lung function changes should be considered adverse in individuals with extant compromised function, such as that resulting from asthma, even without accompanying respiratory symptoms'' and to consider the importance of examining effects in susceptible subsets of broader populations (Thurston et al., 2017). We disagree. The ATS statements (from the initial statement in 1985 to the recent 2017 statement) and their role in primary O_3 standard reviews, summarized in section II.A.2.b above, occupy a prominent role in consideration of public health implications in the PA and the proposal (PA, section 3.3.2; 85 FR 49848, 49866, 49871, August 14, 2020), and the Administrator considers them in his decision, as described in section II.B.3 below. The PA presentation includes summaries of the purpose and intentions articulated by the ATS, and of the evolution and areas of consistency across the statements. The PA gave particular attention to the ATS emphasis on consideration of the significance or adversity of effects, particularly for more susceptible individuals. It recognized both the 2000 ATS statement concluding that ''small transient changes in forced expiratory volume in 1 s[econd] (FEV_1) alone were not necessarily adverse in healthy individuals, but should be considered adverse when accompanied by symptoms'' (ATS, 2000), and also the more recent statement that also gives weight to findings of such lung function changes in the absence of respiratory symptoms in individuals with pre-existing compromised function, such as that resulting from asthma (Thurston et al., 2017). With regard to population risk (another aspect of the ATS statement cited by commenters), the PA and proposal summarized the 2000 and 2017 ATS statements, recognizing that the 2017 statement references and further describes concepts described in the 2000 statement, such as its discussion of considering effects on the portion of the population that may have a diminished reserve that puts its members at potentially increased risk if affected by another agent (ATS, 2000).[116] As described in section II.B.3 below, the Administrator considers the ATS statements in reaching his conclusions in this review.

In support of their claim that the EPA has not appropriately considered the ATS statements, some commenters

[116] The sentence in the 2017 statement of which one commenter quoted only a part, ''As discussed in the previous ATS statement, a small but statistically significant mean reduction in FEV_1 in a population means that some people had larger reductions, with the likelihood that reductions in a subset of susceptible subjects can have passed a threshold for clinical importance'' This paragraph goes on to note that a study in which the mean decrement is about 3%, included two subjects with decrements greater than 10% (Thurston et al., 2017).

additionally take issue with the EPA's use of the number of subjects experiencing at least a 15% FEV_1 decrement in its description in the proposal of the increased response evident by comparing from the lowest exposure levels studied (40 ppb) up to 70 ppb (85 FR 49851, August 14, 2020). These comments also state that EPA did not discuss the clinical significance of FEV_1 decrements of 10% or higher for people with existing lung disease, while stating that the ATS statement mentions this magnitude of decrement. The ATS statement references decrements at or above 10% in illustrating a point about variation of subject responses beyond a group mean, noting that while the mean of an exposed group of study subjects may be small, some group members have larger reductions and can have passed a threshold for clinical importance. It does not provide a discussion of thresholds of clinical importance.[117] In claiming that EPA's discussion on this represents a difference from the last review, the commenters cite the 2014 HREA and state that we have not considered FEV_1 decrements at or above 10% in the current review, however this is not the case.[118] Furthermore, the PA states that the mid- to upper-end of the range of moderate levels of functional responses and higher (*i.e.,* FEV_1 decrements ≥15% and ≥20%) are included to generally represent potentially adverse lung function decrements in active healthy adults, while for people with asthma or lung disease, a focus on moderate functional responses (FEV_1 decrements down to 10%) may be appropriate (PA, Appendix 3D, p. 3D–76).

In objecting to the EPA's approach to considering the ATS statement, these commenters cite a reference to the ATS statement in CASAC's advice as additional evidence that the EPA approach to considering the ATS statement is arbitrary.[119] This comment was made within the context of the CASAC comments on the draft PA that emphasized the need to improve discussion of the susceptibility of people with asthma, including giving attention to the occurrence of lung function decrements in susceptible groups, specifically children with asthma. This section of the CASAC letter also cautions against too great a focus on lung function decrements and emphasizes the need for fuller consideration of respiratory effects that are likely to be important in people with asthma due to features of that disease. In consideration of these comments, the final PA includes an improved discussion on the unique vulnerability of people with asthma (PA, sections 3.3.1.1, 3.3.2, 3.3.4, and 3.5.1) that contributes to due consideration of this population group in decision-making on the primary O_3 standard. Further, in considering the exposure and risk analysis results, we recognize the comparison-to-benchmarks analysis as providing a more robust consideration of risk to sensitive groups as it provides the ability to consider O_3 effects more broadly, with each benchmark representing the array of effects, at different severities, associated with that exposure level. This is one of the reasons (consistent with the CASAC advice) that this analysis (rather than the lung function risk analysis) receives greater emphasis in the PA, consistent with the CASAC advice in this area.

In light of the above discussion, we note that the PA, the proposal, and the decision described in section II.B.3 below, focus specifically on consideration of people with asthma, and particularly children with asthma. While the evidence regarding the susceptibility of people with asthma to the effects of O_3 is robust, our understanding of the exposures at which various effects (of varying severity) would be elicited is less defined. For example, the inherent characteristics of asthma contribute to a risk of asthma-related responses, such as asthma exacerbation in response to asthma triggers, which may increase the risk of more severe health outcomes (ISA, section 3.1.5). This is supported by the strong and consistent epidemiologic evidence that demonstrates associations between ambient O_3 concentrations and hospital admissions and emergency department visits for asthma (ISA, section IS.4.4.3.1). In moving to consideration of the potential specific exposure scenarios (*e.g.,* multiple-hour exposures to 60 to 80 ppb O_3 during quasi-continuous exercise), we note that the evidence is for largely healthy adult subjects. With regard to lung function decrements, the limited evidence from controlled human exposure studies (primarily at higher exposures and in adult subjects) indicates similar magnitude of O_3-related FEV_1 decrements for people with as for people without asthma (ISA, Appendix 3, section 3.1.5.4.1). Further, across other respiratory effects of O_3 (*e.g.,* increased respiratory symptoms, increased airway responsiveness and increased lung inflammation), the evidence has also found the observed responses to generally not differ due to the presence of asthma, although the evidence base is more limited with regard to study subjects with asthma (ISA, Appendix 3, section 3.1.5.7). Thus, in light of the uncertainties in the evidence base with respect to people with asthma and exposures eliciting effects and the severity of those effects, other aspects of the evidence are informative to the necessary judgments. Accordingly, the advice from the CASAC and the statements from the ATS are important to the judgments made by the Administrator in basing his decision on the current evidence and ensuring a primary standard that protects at-risk populations, such as people with asthma.

Contrary to the claim from some commenters, our consideration of effects in people with asthma did not focus solely on lung function responses. As noted above, we recognize that the inherent characteristics of asthma as a disease provide the potential for O_3 exposures to trigger asthmatic responses, such as through causing an increase in airway responsiveness. Based on the available evidence, we consider the potential for such a response to be greater, in general, at relatively higher, versus lower, exposure concentrations, noting 80 ppb to be the lowest exposure concentration at which increased airway responsiveness has been reported in generally healthy adults. We recognize that this evidence and the evidence represented by the three benchmark concentrations used in the exposure/risk analyses (60, 70 and 80 ppb) is for largely healthy adults and does not include data for people with

[117] With regard to 10% as a magnitude decrement, the prior ATS statement noted that the EPA had graded this ''mild'' in a prior review, while noting that such a grading has not been evaluated against other measures (ATS, 2000). In this review, as in past reviews, the EPA has summarized study results with regard to multiple magnitudes of lung function decrement, including 10%, recognizing that 10% has been used in clinical settings to detect a FEV_1 change likely indicative of a response rather than intrasubject variability, *e.g.,* for purposes of identifying subjects with responses to increased ventilation (Dryden, 2010). For example, the PA in the current review provides such a summary (PA, Appendix 3D, p. 3D–77).

[118] Contrary to this claim, the lung function risk analysis in the current review (which is an update of the very same analysis in the 2014 HREA to which the commenters cite) presents the results for exactly the same categories of lung function decrement (at/above 10%, at/above 15% and at/above 20%) as in the 2014 HREA (*e.g.,* PA, Table 3–4).

[119] The citation provided by the commenters is the CASAC letter on the draft PA; in this letter the CASAC cites the ATS statement in making a comment on the draft PA indicating that the concept that lung function decrements in the absence of symptoms do not represent an adverse health effect should not apply to the susceptible group of children with asthma (Cox, 2020a, Consensus Responses to Charge Questions, pp. 8–9).

asthma. In reaching his decision in this review, the Administrator gives additional consideration to the effects of particular concern for people with asthma, such as asthma exacerbation, in light of the limitations of the evidence represented by the benchmarks in this regard, as discussed in section II.B.3 below.

In support of their view that the EPA gives too little weight to effects reported in studies of 60 ppb, some commenters assert that the EPA arbitrarily focused on the evidence for lung function decrements and respiratory symptoms, and does not explain how the proposed decision protects against the harm posed by inflammatory responses to O_3. In making this statement they cite the study by Kim et al. (2011) and discussions in the ISA regarding studies documenting the role of O_3 in eliciting inflammatory responses and regarding possible conceptual mechanisms by which inflammatory responses can contribute to other effects (including cardiovascular effects). In so doing, they contend that exposures lower than those for which the current standard is intended can cause inflammation resulting in permanent lung damage and the development of severe lung disease. They additionally state that airway inflammation of O_3 is of particular concern for people with asthma as airway inflammation is a feature in the definition of asthma.

Contrary to the view of some commenters, the Administrator has given significant consideration (in the proposal and in section II.B.3 below) to the exposure estimates for the 60 ppb benchmark. In considering the O_3 inflammatory response, we note that inflammation induced by a single exposure (or several exposures over the course of a summer) can resolve entirely (2013 ISA, p. 6–76). Thus, the inflammatory response observed following the single exposure to 60 ppb in the study by Kim et al. (2011) of largely healthy subjects is not necessarily an adverse response.[120] We further consider the comments from the CASAC regarding airway inflammation as an important aspect of asthma, including the CASAC's description of increased airway inflammation in people with asthma as having the potential to increase the risk of an asthma exacerbation. As described in section II.B.3 below, the Administrator also considers this, while noting also the lack of evidence from studies of people with asthma at 60 ppb. In so doing, he recognizes that, due to interindividual variability in responsiveness, both in regard to O_3 and in regard to asthma exacerbation triggering events, not every occurrence of an exposure considered to have the potential to increase airway inflammation will result in such an adverse effect. We find it important to note, however, that continued acute inflammation can contribute to a chronic inflammatory state, with the potential to affect the structure and function of the lung (2013 ISA, p. 6–76; ISA, sections 3.1.4.4.2 and 3.1.5.6.2).[121] In light of this evidence, the Administrator, in his consideration of the exposure/risk estimates of exposures at or above the 60 ppb benchmark (described in section II.B.3 below), is less concerned about such estimates representing a single occurrence, and gives weight to estimates of multiple occurrences and their associated greater risk. Thus, rather than a sole focus on a single exposure level or type of effect (such as lung function decrements), the Administrator considers the quantitative estimates for all three benchmarks (with regard to single and multiple occurrences), recognizing that they represent differing levels of significance and severity of O_3-related effects, both with regard to the array of effects and severity of each type of effects, as well as the implications for the at-risk populations, including people with asthma. The comparison-to-benchmarks analysis provides for this full characterization of risk for the broad array of respiratory effects, including inflammation and airway responsiveness, thus avoiding an inadequate and narrower focus, *e.g.,* limited to lung function decrements (85 FR 49872, August 14, 2020).

Contrary to the commenters' claims, the Administrator, in reaching his proposed decision, and in his final decision, as described in section II.B.3 below, placed primary focus on what the evidence indicates with regard to health effects in the at-risk population of people with asthma, particularly children with asthma, and on results of the exposure and risk analysis for this population. In so doing, he recognizes key aspects of the evidence, as summarized in section II.A.2.a above, that indicate the array of O_3-associated respiratory effects to be of increased significance to people with asthma given aspects of the disease that may put such peoples at increased risk for prolonged bronchoconstriction in response to asthma triggers. The increased significance of effects in people with asthma and risk of increased exposure for children (from greater frequency of outdoor exercise) is illustrated by the epidemiologic findings of positive associations between O_3 exposure and asthma-related emergency department visits and hospital admissions for children with asthma. In this context, the Administrator focuses on the breadth of O_3 respiratory effects evidence at the lowest exposures tested in the controlled human exposure studies which provide the most certain evidence, considering this in light of the fuller evidence base which provides a foundation for necessary judgments in light of uncertainties.

Thus, we disagree with commenters that we have not considered the full body of evidence and quantitative information available in this review with regard to exposures that might be expected to elicit effects in at-risk populations. In so doing, as summarized in section II.A.2.a above, section II.B.1.a of the proposal, and the PA, we recognize that the currently available evidence supports the conclusion of a causal relationship between short-term O_3 exposure and respiratory effects, with the strongest evidence coming from controlled human exposure studies that document subtle reversible effects in 6.6-hour exposures of largely healthy adult subjects, engaged in quasi-continuous exercise, to average concentrations as low as 60 ppb. The epidemiologic evidence of associations of O_3 concentrations in ambient air with

[120] One commenter contends that inflammation is apparent from short-term O_3 exposures ranging from 12 to 35 ppb, based on air quality metrics reported in some epidemiologic studies, such as mean 24-hour averages or monthly averages of 8-hour concentrations (ISA, Table 4–28). The commenter implies that such values for these metrics are lower than the level of the standard (70 ppb) means that exposures allowed by the standard are causing outcomes analyzed in the study. However, none of the metrics for which values are cited by the commenter are in terms of design values for the current standard, such that a direct comparison of the values is not meaningful.

[121] The currently available evidence does not support the implication of the commenters that the inflammatory response reported in some individuals after a 6.6-hour exposure to 60 ppb, during quasi-continuous exercise (as in Kim et al., 2011), causes permanent lung damage or development of severe lung disease. While the experimental animal evidence indicates the potential for repeated exposures to elevated concentrations (*e.g.,* at or above 500 ppb over multiple days) can contribute to other effects in animal models or to other asthmatic responses in animal models of asthma, the full evidence base for single exposures to lower concentrations does not provide such a finding (ISA, sections 3.1.4.4, 3.1.4.4.2 and 3.1.5.6.2; 2013 ISA, section 6.2.3). Thus, the potential for effects reported from 6.6-hour exposures to 60 ppb O_3, during quasi-continuous exercise, including the inflammation reported by Kim et al. (2011) to contribute to adverse health effects is uncertain. Newly available evidence in this review does not reduce this uncertainty or provide a contradiction to conclusion regarding the implications of inflammation induced by single or isolated exposures (ISA, Appendix 3).

increased incidence of hospital admissions and emergency department visits for an array of respiratory health outcomes further indicates the potential for O_3 exposures to elicit health outcomes more serious than those assessed in the experimental studies, particularly for children with asthma, and the evidence base of such epidemiologic studies as a whole provides strong support for the conclusion of causality for respiratory effects.[122] Further as described in the PA and the proposal and summarized in section II.A.2.a above, very few of these studies were conducted in locations during periods when the current standard was met. While some commenters cite the low values of some of the air quality metrics analyzed in such studies, those metrics are not in the form of the design value for the current standard and so, contrary to commenters' assertion, cannot show that serious health effects are occurring under air quality conditions allowed by the current 70 ppb standard.

Protection With an Adequate Margin of Safety: Some commenters expressed the view that the current standard does not provide an adequate margin of safety variously argue that the EPA is ignoring precedent and CAA requirements for considering scientific uncertainty in its judgments regarding an adequate margin of safety, and that statements from the prior CASAC and new evidence suggests that the current 70 ppb standard provides little margin of safety for protection of sensitive subpopulations from harm. These commenters generally advocate revision to a 60 ppb standard to address this concern. In support of their views, some state that the EPA is ignoring findings of a statistically significant lung function response to 6.6-hour exposure to 60 ppb during quasi-continuous exercise while others cite the EPA consideration of epidemiologic evidence, claiming that the EPA is inappropriately using identified uncertainties as a basis for not revising the standard. We disagree with these characterizations.

As an initial matter, we note that, contrary to the statements made by these commenters, the Administrator, in reaching his proposed decision, as in reaching his final decision, has considered legal precedent and CAA requirements for a primary standard that protects public health, including the health of sensitive groups, with an adequate margin of safety. With regard to scientific uncertainty, as summarized in section I.A above, the CAA 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 Ass'n* 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). Thus, in considering whether the primary standard includes an adequate margin of safety, the Administrator is seeking to ensure that the standard not only prevents pollution levels that have been demonstrated to be harmful but also prevents lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. In so doing, however, 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 the proposed decision, as in the decision described in section II.B.3 below, the Administrator's consideration of the kind and degree of uncertainties associated with the current information (as some of the factors the EPA considers in addressing the requirement for an adequate margin of safety) involved a number of judgments. With regard to his consideration of the epidemiologic evidence, for example, the Administrator recognizes that, as a whole, investigations of associations between O_3 and respiratory effects and health outcomes (*e.g.,* asthma-related hospital admission and emergency department visits) provide strong support for the overarching conclusion of that O_3 causes respiratory effects, and its risks to people with asthma. In his consideration of O_3 exposures of concern, the Administrator, agrees with staff evaluations in the PA, that such studies available in this review are less informative to his judgments related to air quality conditions allowed by the current standard (85 FR 49870, August 14, 2020). For example, as summarized in section II.A.2.c above, none of the U.S. studies that show associations between O_3 and the clearly adverse health outcomes of hospital admissions or emergency department visits for respiratory causes were based in locations during time periods when the current standard was always met (PA, section 3.3.3). While there were two such studies based in single cities in Canada, as discussed above, the interpretation of individual single-city results is complicated by the presence of co-occurring pollutants or pollutant mixtures (PA, section 3.3.3).[123] Thus, as in reaching his decision in this review, the Administrator has fully considered conclusions reached in the ISA regarding the epidemiologic evidence and the policy evaluations in the PA, and does not find the currently available epidemiologic studies to provide insights regarding exposure concentrations associated with health outcomes that might be expected under air quality conditions that meet the current standard (85 FR 49870, August 14, 2020). Thus, the EPA's decision on the standard in this review fully and appropriately considers the full evidence base, including the epidemiologic evidence, and associated uncertainties and limitations.

With regard to the controlled human exposure studies, and the nature and degree of effects that might be expected at exposures lower than those studied or in unstudied population groups, the Administrator has considered first what the evidence base indicates with regard to the lowest exposures as well as differences and similarities between the studied populations and the less well studied population groups recognized to be at increased risk. In so doing, he considers the findings of statistically significant respiratory responses in the studies of 60 ppb exposures in largely healthy subjects, particularly in his consideration of the exposure and risk estimates. For example, in reaching his decision in section II.B.3 below, as for his proposed decision, he finds it appropriate to consider the level of protection provided by the current standard from single exposures, but to give greater weight to multiple exposures, in judging adequacy of the margin of safety provided by the current standard.[124] Such considerations

[122] As described in section II.A.2.c above and in the PA, these studies generally do not detail the specific exposure circumstances eliciting such effects.

[123] Accordingly, uncertainties remain with regard to the independent role of O_3 exposures in eliciting the reported health outcomes analyzed, and in the absence of analyses that might reduce such uncertainties (*e.g.,* analyses of the presence and effects of co-occurring pollutants).

[124] Contrary to implications of some commenters, this judgment by the current Administrator is

Continued

contributed to the Administrator's proposed judgments with regard to the requisite level of protection needed to protect at-risk populations with an adequate margin of safety, as required by the Act and consistent with the factors recognized in the relevant case law. Thus, consistent with the CAA requirements and prior judicial decisions, the Administrator based his proposed decision, and bases his final decision (as summarized in II.B.4 below) on the scientific evidence, our current understanding of it, and his judgments concerning associated uncertainties, both those associated with inconclusive scientific and technical information, and those associated with hazards that research has not yet identified. These judgments, along with the factors recognized above that the EPA generally considers in each NAAQS review, contribute to his reasoned decision making in this review, as described in section II.B.3 below.

With regard to advice provide by CASAC in the last review as a general matter, we disagree with the commenters' presumption that it is necessary for EPA to address in this review each statement a prior CASAC made in a prior review. The Clean Air Act does not impose such a requirement. We further note that a prior CASAC's advice would be based on review of the prior air quality criteria, exposure/risk analyses and standard, as well as considerations pertinent in the prior review (which may, depending on the issue, differ from the pertinent evidence, information and considerations before a current CASAC). We note, however, that this specific advice from the prior CASAC on the adequacy of the margin of safety was cited by part of the CASAC in the current review. As summarized in the proposal and in section II.B.1.b above, while the prior CASAC advised that the size of the margin of safety provided varied across different standard levels within the range from 70 to 60 ppb that the prior CASAC recommended, it found a level of 70 ppb could be supported by the scientific evidence. Further, the prior CASAC recognized, as summarized in section II.B.1.b above, that with regard to the ''size'' of the margin of safety, the selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment (*Lead Industries Ass'n* v. *EPA,* 647 F.2d at 1161–62; *Mississippi* v. *EPA,* 744 F.3d at 1353; section I.A above). Thus, in reaching his proposed decision, the Administrator explicitly considered the advice provided by the prior CASAC to the extent it was represented in advice from the current CASAC as emphasized by part of the current CASAC (85 FR 49873, August 14, 2020), and he has similarly again considered it reaching his final decision, as described in section II.B.3 below, in light of public comments raising it.

Some commenters also express the view that EPA is using limited data in sensitive population groups as an excuse for not establishing a level at which there is ''an absence of adverse effect'' in sensitive groups. In support of their view, some commenters claim that the EPA has not addressed a statement of the prior CASAC regarding the potential for lung function decrements and respiratory symptoms to occur in people with asthma with exposure to 70 ppb (while at elevated exertion). Contrary to this claim,[125] the EPA considered in the last review the point made by the prior CASAC in the statement highlighted by the commenters. The statement from the prior CASAC that the commenters reference was provided in the CASAC review of a draft PA in the last review, fully considered in completing the final 2014 PA, and, along with the totality of the prior CASAC advice, taken into account in establishing the current primary standard (80 FR 65292, October 26, 2020). It is not necessary for the EPA to address in this review each statement a prior CASAC made in a prior review.

We agree with commenters who express the view that to protect sensitive populations from effects reported in some largely healthy subjects from the 6.6 hour exposure to 73 ppb (with quasi-continuous exercise), the standard should provide protection against somewhat lower exposures. As summarized in section II.B.3 below, this is an objective the Administrator identifies for the standard and, based on the exposure/risk estimates, he finds the standard to provide strong protection from such exposures (and associated risk of such effects). In addition, in highlighting this isolated statement from the last review, the commenters fail to distinguish CASAC advice on the primary standard from consideration of the exposure benchmark for comparison to a multi-hour exposure while engaged in quasi-continuous exercise.

With regard to the prior CASAC's scientific and policy advice on the primary standard,[126] the prior CASAC concluded that the scientific evidence supported a range of standard levels that included 70 ppb, and also recognized the choice of a level within that range to be ''a policy judgment under the statutory mandate of the Clean Air Act'' (85 FR 49873).[127] We further note that the current CASAC concludes in this review that newly available evidence relevant to standard setting does not substantially differ from that available in the last review (Cox, 2020a, Consensus Responses to Charge Questions p. 12; 85 FR 49873, August 14, 2020). As discussed further below, we note that 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.

Some commenters also state that the primary NAAQS must be set at a level at which there is an absence of adverse effects in sensitive populations. While the EPA agrees that the NAAQS must be set to protect sensitive populations with an adequate margin of safety, it is well established that the NAAQS are not

consistent with that made by the prior Administrator in establishing the current standard, as seen from the summary of the prior Administrator's judgment in that regard that was summarized in the proposal and that these commenters cite:

Further, while the Administrator recognized the effects documented in the controlled human exposure studies for exposures to 60 ppb to be less severe than those associated with exposures to higher O_3 concentrations, she also recognized there to be limitations and uncertainties in the evidence base with regard to unstudied population groups. As a result, she judged it appropriate for the standard, in providing an adequate margin of safety, to provide some control of exposures at or above the 60 ppb benchmark (80 FR 65345–65346, October 26, 2015). [85 FR 49841, August 14, 2020]

[125] The context for this statement is in considering the benchmark concentrations utilized in the exposure-to-benchmarks analysis of the 2014 HREA and reflecting on responses reported in controlled human exposure studies of healthy subjects exposed for 6.6 hours with quasi-continuous exercise. With regard to the responses reported from exposure to 72 ppb, on average across the exercise periods, the prior CASAC stated its view ''that these effects almost certainly occur in some people, including asthmatics and others with low lung function . . . at levels of 70 ppb and below'' (Frey, 2014b, p. 6).

[126] In their 2014 advice, the prior CASAC concluded by explicitly stating ''our policy advice is to set the level of the standard lower than 70 ppb within a range down to 60 ppb, taking into account your judgment regarding the desired margin of safety to protect public health.''

[127] 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.''

meant to be zero risk standards. See *Lead Industries* v. *EPA,* 647 F.2d at 1156 n.51; *ATA III,* 283 F. 3d at 360 (''[t]he lack of a threshold concentration below which these pollutants are known to be harmless makes the task of setting primary NAAQS difficult, as EPA must select standard levels that reduce risks sufficiently to protect public health even while recognizing that a zero-risk standard is not possible''); *Mississippi,* 744 F. 3d at 1351 (same); see also id. at 1343 (''[d]etermining what is 'requisite' to protect the 'public health' with an 'adequate' margin of safety may indeed require a contextual assessment of acceptable risk. See *Whitman,* 531 U.S. at 494–95 (Breyer J. concurring)''). As the Court of Appeals for the D.C. Circuit said in reviewing the 2015 O_3 NAAQS, ''the primary standard for a non-threshold pollutant like ozone is not required to produce zero risk, and '[t]he task of determining what standard is 'requisite' to protect the qualitative value of public health or what margin of safety is 'adequate' to protect sensitive subpopulations necessarily requires the exercise of policy judgment.' '' *Murray Energy,* 936 F.3d at 610 (quoting *Mississippi* v. *EPA*).[128] The Administrator's judgments in this review are rooted in his evaluation of the evidence, which reflects the scientific uncertainty as to the O_3 concentrations at which sensitive subpopulations would experience adverse health effects, and his judgments weigh both the risks and the uncertainties. This is a legitimate, and well recognized, exercise of ''reasoned decision-making.'' *ATA III.* 283 F. 3d at 370; see also id. at 370 (''EPA's inability to guarantee the accuracy or increase the precision of the . . . NAAQS in no way undermines the standards' validity. Rather, these limitations indicate only that significant scientific uncertainty remains about the health effects of fine particulate matter at low atmospheric concentration. . . .''); *Mississippi,* 744 F. 3d at 1352–53 (appropriate for EPA to balance scientific uncertainties in determining level of revised O_3 NAAQS).

Exposure/risk Analyses: In expressing the view that the standard should be made more stringent, some commenters disagree with EPA conclusions based on the exposure/risk analyses, and point to other analyses that they state show that a lower standard level (*e.g.* 65 ppb or lower) would avoid important health effects. These commenters' claims of deficiencies with the exposure/risk analyses include claims that the study area selection is not explained, that population size of the study areas analyzed is too small to support conclusions and does not include particular areas; that the analysis does not include adults, and other groups of interest, and that selection of study areas with air quality close to the current standard contributed to underestimates of population exposures. We disagree with these commenters' claims.

With regard to study area selection and population size for the analysis, we note that an exposure and risk analysis based on eight study areas, all of which are major metropolitan areas provides a robust foundation for population exposure estimates. The eight study areas included reflect the full range of air quality and exposure variation expected across major urban areas in the U.S and seven different NOAA climate regions (PA, section 3.4.1).[129] This number of areas (8) and combined population size (more than 45 million in the combined metropolitan areas [PA, Appendix 3D, Table 3D–1]) are much larger than similar analyses in recent NAAQS reviews for other pollutants (*e.g.,* sulfur dioxide [U.S. 2018]), and not that dissimilar to similar analyses in past O_3 NAAQS reviews.[130] Some commenters claim that the exclusion of specific urban areas in which O_3 concentrations are much higher than those analyzed resulted in underestimates of exposure. We disagree with this claim as the air quality analyzed across all study areas was adjusted to just meet the current standard (or alternative scenarios). Thus, an urban area that currently has O_3 concentrations well in exceedance of the current standard would not necessarily have been found to have higher exposure estimates if it were simulated to have air quality just meeting the current standard. Such estimates would, however, have greater uncertainty, which is the reason such study areas as those identified by commenters (*e.g.,* Los Angeles) were excluded. Areas included were those for which only small adjustments were required for the air quality to just meet the current standard (and alternative scenarios), yielding reduced uncertainty (*e.g.,* given the need for larger air quality adjustments to achieve conditions that just meet the current standard) in these estimates compared to those from the 2014 HREA (PA, sections 3.4.1 and 3.4.4, and Appendix 3D). In selecting such areas, however, we considered a number of other characteristics in order to achieve a varied set of study areas, including with regard to air quality patterns.[131] This variation contributed to variation in exposure estimates, even for the same air quality scenario (PA, Appendix 3D, Tables 3D–26, 3D–28 and 3D–30). Thus, in addition to focusing on study areas with ambient air concentrations close to conditions that reflect air quality that just meets the current standard that would be more informative to evaluating the health protection provided by the current standard than areas with much higher (or much lower) concentrations, the approach employed recognizes that capturing an appropriate diversity in study areas and air quality conditions (that reflect the current standard scenario) is an important aspect of the role of the exposure and risk analyses in informing the Administrator's conclusions on the public health protection afforded by the current standard.

Contrary to one commenter's assertion that adults were not included in the exposure assessment, the populations assessed included two adult populations groups: All adults and

[128] The legislative history of the Clean Air Act provides further support for these holdings, as do the statutory deadlines for attainment. See H. Rep. 95–294, 95th Cong. 1st sess. 127, 123 Cong. Rec. S9423 (daily ed. June 10, 1977) (statement of Senator Muskie during the floor debates on the 1977 Amendments that ''there is no such thing as a threshold for health effects. Even at the national primary standard level, which is the health standard, there are health effects that are not protected against.''

[129] Contrary to the commenters' assertion of a lack of explanation for the study areas included in the analyses, the PA describes the study area selection criteria and process, including steps taken to include adequate representation of diverse conditions. As observed in the PA, seven of the eight study areas were also included in the 2014 HREA, and the eighth study area (Sacramento) was newly added in the current review to insure representation of a large city in the southwest (PA, section 3.4.1 and Appendix 3D, section 3D.2.1). Clarification on this point in the final PA was responsive to the only CASAC comment on completeness of the description of study area selection (Cox, 2020a). We disagree with the implication by some commenters that each review's analyses must focus on the same areas. There is no such requirement under the Act, and such a view ignores the need to consider the current information in each review in planning appropriate analyses.

[130] For example, the exposure assessment for the 1997 O_3 NAAQS review included nine urban study areas, for which the combined population simulated was 41.7 million. The exposure assessment for the current review included eight urban study areas with a combined simulated population size of approximately 39 million (PA, p. 3D–96; U.S. EPA, 1996b, p. 76). We additionally note the focus on analysis results in terms of population percentages rather than population counts.

[131] A broad variety of spatial and temporal patterns of O3 concentrations can exist when ambient air concentrations just meet the current standard. These patterns will vary due to many factors including the types, magnitude, and timing of emissions in a study area, as well as local factors, such as meteorology and topography.

adults with asthma.[132] The results for these groups and all of the populations assessed are presented in detail in the PA (PA, Appendix 3D). As described in the PA and proposal, the estimates for adults as a percentage of the study populations were generally lower than those for children. Thus, we focused discussion on the estimates for children, including particularly children with asthma. As recognized by the Administrator in section II.B.3 below, his judgments on the adequacy of protection provided by the current standard takes into account protection provided to the U.S. population, including those population groups at increased risk, which includes children and people of all ages with asthma, among other groups.

Some commenters claimed that the EPA should have separately assessed exposure for certain additional population subgroups, such as children at summer camps, adults with lung impairments other than asthma or outdoor workers. As an initial matter, we recognize appreciably increased uncertainty regarding key aspects of the information necessary for such simulations for all of these groups. Of the three groups, only outdoor workers are identified as an at-risk population in this review (ISA, Table IS–10), and accordingly this group was explicitly considered in designing the exposure analyses.[133] The information available, however, was considered to be too uncertain to produce estimates for this population, as a separate group, with confidence. As described in the PA, important uncertainties exist in generating the simulated activity patterns for this group, including the limited number of CHAD diary days available for outdoor workers, assignment of diaries to proper occupation categories, and in approximating number of days/week and hours/day outdoors, among other pertinent aspects (PA, Appendix 3D, Table 3D–64). We note that these appreciable data limitations and associated uncertainties were also recognized in the 2014 HREA in which a limited sensitivity analyses was conducted for this subgroup. Those limited analyses, conducted for a single area with air quality just meeting the prior 75 ppb standard, indicated that when diaries were selected to mimic exposures that could be experienced by outdoor workers, the percentages of modeled individuals estimated to experience exposures of concern were generally similar to the percentages estimated for children (*i.e.,* using the full database of diary profiles) in the urban study areas and years with the largest exposure estimates (2014 HREA, section 5.4.3.2, Figure 5–14).[134] Accordingly, in this review, in recognition of the data limitations that remain in the current review,[135] outdoor workers were not assessed as a separate population group, and in light of our consideration of conclusions from the sensitivity analyses in the last review, we have generally given primary focus to the estimates for the populations of children.

In summary, we disagree with comments stating that the exposure/risk analyses were deficient and do not provide support for their conclusions. As summarized above, in planning and conducting the exposure/risk analyses, we have appropriately considered issues raised by the commenters, such that the analyses reasonably reflect current understanding, information, tools and methodologies. Further, in presenting the analyses in the PA, we have recognized any associated limitations and uncertainties in an uncertainty characterization that utilized a largely qualitative approach adapted from the World Health Organization approach (and commonly utilized in NAAQS exposure/risk assessments, as discussed in the PA and proposal [85 FR 49857, August 14, 2020]), accompanied by a number of quantitative sensitivity analyses. This characterization and accompanying analyses build on previously conducted work in the 2014 HREA and provide a transparent and explicit recognition of strengths, limitations and uncertainties of the current exposure/risk analysis that were described the PA, considered in the proposal and also in the Administrator's decision described in section II.B.3 below. Thus, the exposure/risk analyses conducted for this review appropriately and soundly reflect current information and methodologies; and we have interpreted their results appropriately in light of any associated limitations and uncertainties.

With regard to other quantitative analyses identified by some commenters and described as showing health impacts that would be avoided by a more stringent standard (*e.g.* with a level of 65 ppb or lower), we note that these analyses utilize epidemiologic study effect estimates as concentration-response functions to generate predictions of the occurrence of health outcomes, primarily mortality, under different air quality conditions (characterized by the metric used in the epidemiologic study).[136] As an initial matter, we note that our understanding of the relationship between O_3 exposures and total mortality is different in this review than it was in the last review, based on the more extensive evidence base now available. As summarized in section II.A.2.a above, and noted earlier in this section, while our conclusion in the last review was that the relationship of O_3 exposure with mortality was likely to be causal, the current evidence base does not support that conclusion because of limited evidence for cardiovascular mortality, which is by far the largest contributor to total mortality. Rather, the EPA has concluded the evidence in

[132] Further, contrary to the implication of one comment, the exposure/risk analyses did not exclude athletes, hikers and others who exercise outdoors, using their full lung capacity, a group the commenter characterizes as at increased risk. In fact, it is just such individuals who are most likely, depending on their locations, to experience exposures of concern due to their high exertion levels. As described in the PA, the comparison to benchmarks analysis identifies the portion of the exposed population whose 7-hour average concentration, while at moderate or greater exertion, is at or above the benchmarks (PA, section 3.4 and Appendix 3D).

[133] With regard to the other two groups, we note the ISA explicitly evaluated evidence for people with the lung disease, COPD, and concluded the evidence was inadequate to determine whether this lung impairment confers increased risk of O_3 related effects (ISA, Table IS–10). With regard to children at summer camp, we note that to the extent that the behaviors of such children (*e.g.,* exercising outdoors) are represented in the CHAD, they are represented among the at-risk populations of children and children with asthma that were simulated in the exposure/risk analyses.

[134] Similarly, the EPA also did not conduct an exposure analysis for outdoor workers in the 2008 review and instead focused on children since it was judged that school aged children presented the greatest likelihood of being outdoors and exposed under moderate exertion averaged over the critical time period based on prior analysis findings. Thus, while as recognized in multiple reviews, outdoor workers are also at risk, the EPA has focused, in past reviews as in the current one, on children, the population group for which the analysis estimates in terms of percentage of population are greatest (PA, section 3.4.2). Accordingly, providing protection for this population group will provide protection for other at-risk populations as well.

[135] In support of their view that estimates should have been derived for outdoor workers, one group of commenters cites a study on research priorities for assessing climate change impacts on outdoor workers (Moda et al., 2019). We note, that other than being focused on outdoor workers and recognizing there to be significant research needed for impacts assessment, this paper has little relevance in this review. The paper is focused on climate change impacts in tropical developing countries with a focus on sub-Saharan Africa and does not discuss exposure modeling of outdoor workers or O_3.

[136] The analyses cited by these commenters include Cromar et al (2019) and OTC (2020). To address these comments, we have provisionally considered the documents, as discussed in I.D above, and found they do not materially change the broad scientific conclusions of the ISA with regard to respiratory effects, or warrant re-opening the air quality criteria for further review (Luben et al., 2020). Further, some of these commenters reference epidemiologic study based risk, analyses in the 2014 HREA.

this review to be suggestive of, but not sufficient to infer, causal relationships of total mortality with short- or long-term O_3 exposure, as summarized in section II.A.2.a above (ISA, Appendix 6). Thus, we do not find the weight the commenter is suggesting we place on predictions of total mortality from the epidemiologic study based risk analyses cited by commenters to appropriately reflect the current evidence base for O_3 and mortality, or the evidence base for O_3 and cardiovascular effects (the primary contributor to mortality in the U.S.).

With regard to estimates of avoided respiratory mortality from the analyses cited by these commenters, we note that, while the epidemiologic studies that are inputs to the quantitative analyses cited by the commenters are part of the evidence base that supports our conclusion of a causal relationship between short-term O_3 exposure and respiratory effects, there are uncertainties inherent in the derivation of estimates of mortality ascribed to O_3 exposures using effect estimates from these studies. For example, in planning for analyses in this review, the IRP recognized several important uncertainties associated with aspects of the O_3 epidemiologic study-based approach used in the 2014 HREA (one of the analyses cited by commenters), and similar to the approach used in other analyses cited by commenters, that the EPA concluded to have a moderate or greater impact on risk estimates (IRP, Appendix 5A). Such uncertainties include complications posed by the presence of co-occurring pollutants or pollutant mixtures, as well as those involving the correlation of population O_3 exposures and ambient air monitor concentrations (including the use of area wide average O_3 concentrations) and uncertainties in the derived concentration-response functions (IRP, Appendix 5A; PA, Appendix 34D, section 3D.1.4). Specifically with regard to the 2014 HREA estimates of respiratory mortality, the EPA has recognized uncertainty about the extent to which mortality estimates based on the long-term metric in Jerrett et al. (2009) (*i.e.,* seasonal average of 1-hour daily maximum concentrations) reflect associations with long-term average O_3 versus repeated occurrences of elevated short-term concentrations; and given potential nonlinearity of the C–R function to reflect a threshold of the mortality response, these estimates should be viewed with caution (IRP, Appendix 5A). Accordingly, the 2014 HREA concluded that lower confidence should be placed in the results of the assessment of respiratory mortality risks associated with long-term O_3, primarily because that analysis relies on just one study (Jerrett et al., 2009), and because of the uncertainty in that study about the existence and identification of a potential threshold in the concentration-response function (2014 HREA, section 9.6; 80 FR 65316, October 26, 2015). The other analysis cited by the commenters for predictions of respiratory mortality is also based its estimates on Jerrett et al. (2009). Thus, we find the conclusions regarding uncertainty and low confidence recognized for the 2014 HREA estimates to also apply to the other analysis by commenters and disagree with the conclusions reached by these commenters on this analysis. Further, we do not find that the 2014 HREA or other analyses cited by the commenters, in combination with the full body of evidence currently available, support a conclusion of significant health outcomes for O_3 air quality that meets the current standard.

Long-term Standard Consideration: In support of their view that EPA should establish an additional primary standard that targets long-term exposure, some commenters stated that recent epidemiologic studies indicate causal linkages between long-term exposures and adverse health outcomes, while also suggesting there was support for such a standard in a statement made by the CASAC in reviewing the draft PA. With regard to the epidemiologic studies, these commenters cite several studies published after the literature cut-off date for the ISA [137] that they describe as showing linkages of long-term O_3 exposure to a number of outcomes, including mortality, smokers progression to COPD, hospital admissions for acute respiratory disease syndrome and emergency department visits (Dominici et al., 2019; Seltzer et al., 2020; Limaye and Knowlton, 2020; Dedoussi et al., 2020; Lim et al., 2019; Paulin et al,. 2020; [138] Rhee et al., 2019; Strosnider et al., 2019).[139] We have provisionally considered these ''new'' studies in addressing these comments consistent with section I.D above (Luben et al., 2020). Of the studies focused on mortality that these commenters cite as providing new information in support of a long-term standard, just three represent new evidence related to investigation of associations of long-term O_3 exposure with mortality (Lim et al., 2019) or respiratory morbidity (Paulin et al., 2020 and Rhee et al., 2019).[140] The study by Lim et al. (2019) analyzes associations between long-term O_3 exposure and respiratory mortality in a U.S. population of older adults in the U.S., reporting a positive association with an effect estimate lower than a previously published study included in the ISA. These results contribute to the evidence base for respiratory effects, *e.g.,* with an additional high-quality study of a previously studied population group (Lim et al., 2019) or with studies investigating additional populations and respiratory outcomes (Paulin et al., 2020; Rhee et al., 2019), albeit with limitations,[141] without reducing uncertainties in the evidence base as a whole. These studies are

[137] These commenters also assert that some other studies published after the ISA cut-off date were arbitrarily included in the ISA, citing just a single study (Garcia et al., 2019). Contrary to implication by the commenters, such an occurrence is clearly described in the ISA, which states ''[s]tudies published after the literature cutoff date for this review were also considered if they were submitted in response to the Call for Information or identified in subsequent phases of ISA development . . ., particularly to the extent that they provide new information that affects key scientific conclusions'' (ISA, Appendix 10, p. 10–1).

[138] Although the commenters submitted a document that appears to be an unpublished draft of an earlier manuscript of this paper, to which they assigned a 2019 publication date and a very slightly different title (rather than the published paper, it is the published study, Paulin et al., (2020) that we have provisionally considered (Luben et al., 2020).

[139] Some commenters imply that projections of increasing O_3 concentrations in response to climate change in the future will ''heighten'' long-term O_3 concentrations and chronic exposures and indicate a need for a long-term standard. In making this claim, they cite an analysis of air quality projected in 2045 through 2055 (Nassikas et al., 2020) and an evaluation of the effects of climate change on air quality including O_3 concentrations. (Archer et al., 2019). The former ''new'' study has been provisionally considered and found not to materially affect the broad scientific conclusions regarding the air quality criteria documented in the ISA or to warrant reopening the air quality criteria (Luben et al., 2020) As neither is evaluating health effects associated with air quality under the current standard, we do not find these studies informative to consideration of a need for a long-term standard to protect public health.

[140] Two others (Dedoussi et al 2020; Seltzer et al, 2020) are quantitative assessments that estimate O_3 impacts based on use of effect estimates from previously published studies that are included in the ISA, another (Dominici et al., 2019) is the full technical report from the Health Effects Institute, the main results of which were previously published in studies that are included in the ISA, and a fourth (Limaye and Knowlton., 2020) is commentary on a previously published study that is included in the ISA. One other study cited by the commenters is focused on short-term O_3 exposures, not long-term O_3 exposure as indicated by the commenters (Strosnider et al., 2019)

[141] While studies by Paulin et al. (2020) and Rhee et al. (2019) provide evidence for a novel population sub-group (smokers) or endpoint (*e.g.,* acute respiratory distress syndrome, ARDS), each study has limitations. For example, the cross-sectional design of Paulin et al. (2020) is a major limitation, while limitations associated with Rhee et al. (2019) relate to linking long-term exposure with hospital admissions for ARDS based on exposure timing and the mechanism for acute vs. chronic development of disease, and to power in the study (*e.g.,* very low hospital admission counts per year per ZIP code [Rhee et al., 2019, Table 2]).

generally consistent with the evidence assessed in the ISA, and they do not materially change the broad conclusions in the ISA regarding the scientific evidence.

We additionally note that the O_3 concentrations did not meet the current standard in all locations and time periods analyzed in these three multicity studies. Although two of these studies include some locations across the U.S. in which the current standard was likely met during some portions of the study period, air quality during other time periods of locations in the dataset did not meet the current standard.[142] Further, the multicity effect estimates in these studies do not provide a basis for considering the extent to which O_3 health effect associations are influenced by individual locations with ambient O_3 concentrations low enough to meet the current O_3 standards versus locations with O_3 concentrations that violate this standard. Thus, while these more recent studies may be consistent with the existing evidence base evaluated in the ISA, they do not provide a basis for conclusions regarding whether the O_3 exposures occurring under air quality conditions allowed by the current standard may be eliciting the effects analyzed.

We additionally note that while epidemiologic studies evaluate the relationship between health effects and specific O_3 concentrations during a defined study period and the generally consistent and coherent associations observed in these epidemiologic studies contribute to the causality determinations and conclusions regarding the causal nature of the effect of O_3 exposure on health effects, ''they do not provide information about which averaging times or exposure metrics may be eliciting the health effects under study'' (ISA, section IS.6.1). As noted in the ISA, ''disentangling the effects of short-term ozone exposure from those of long-term ozone exposure (and vice-versa) is an inherent uncertainty in the evidence base,'' as ''the populations included in epidemiologic studies have long-term, variable, and uncharacterized exposures to ozone and other ambient pollutants'' (ISA, section IS.6.1). As summarized in the proposal, however, we have also considered the toxicological studies of effects associated with long-term exposures and note that they involve much higher exposures than those occurring at the current standard (85 FR, 49853, August 14, 2020).

Lastly, we disagree with the commenters' implication that the EPA has not addressed a CASAC recommendation. The commenters appear to be asserting that the CASAC recommended that EPA consider a long-term standard. However, the CASAC did not make such a recommendation (Cox, 2020a). In making this assertion, the commenter cites a comment the CASAC makes with regard to a sentence in the draft PA that is drawn from the Administrator's conclusions section of the 2015 decision. Rather than ignoring this CASAC comment, as asserted by the commenters, we made a revision to that section of the PA (moving the statement from the draft PA to a footnote in the final PA with the objective of retaining an accurate description of a consideration related to that 2015 decision, while lessening the potential for confusion of a 2015 consideration with considerations in the current review).[143] Notwithstanding sentences pertaining to the last review, we note the PA evaluates the information in the current review with regard to the protection offered by the current standard (and that the Administrator considered the PA evaluation, as well as the CASAC advice in his proposed decision [summarized in section II.B.1.c above] as in his final decision below). We further note that the description of the Administrator's conclusion in the last review, which is also summarized in the proposal (and in section II.A.1 above), does not describe health effects associated with long-term average concentrations likely under the current standard.

Further, in considering an implication of the commenters' claim that a ''long-term standard'' is needed in order to provide protection from health effects that may be elicited by long-term exposures to O_3, we note that the impact of standards with short averaging times, such as eight hours, is not limited to reducing short-term exposures. This is because a reduction in magnitude of short-term exposure concentrations (*e.g.,* daily maximum 8-hour concentrations) is also a reduction in exposure to such concentrations over the longer term. For example, a standard, such as the current one, that limits daily maximum 8-hour concentrations to not exceed 70 ppb as a 3-year average of the annual fourth highest value, in addition to limiting the magnitude of concentrations to which a population is exposed in eight hour periods, also limits the frequency to which the population is exposed to such concentrations over the long term. That is, the reduction in frequency of the higher concentrations reduces exposures to such concentrations over the short and long term. Thus, given that, as indicated by the current and established evidence, the O_3 concentrations most likely to contribute to health effects are the higher concentrations, the current standard provides control of exposures to such concentrations over both the short and long term. In light of all of the considerations raised here, we disagree with the commenters assertion of the need for a long-term O_3 standard.

4. Administrator's Conclusions

Having carefully considered the public comments, as discussed above, the Administrator believes that the fundamental scientific conclusions on effects of photochemical oxidants, including O_3, in ambient air that were reached in the ISA and summarized in the PA, and estimates of potential O_3 exposures and risks described in the PA, and summarized above and in sections II.B and II.C of the proposal, remain valid. Additionally, the Administrator believes the judgments he proposed to reach in the proposal (section II.D.3) with regard to the evidence and the quantitative exposure/risk information remain appropriate. Thus, as described below, the Administrator concludes that the current primary O_3 standard provides the requisite protection of the public health with an adequate margin of safety, including for at-risk populations, and should be retained. In considering the adequacy of the current primary O_3 standard, the Administrator has carefully considered the assessment of the available health effects evidence and conclusions contained in the ISA; the evaluation of policy-relevant aspects of the evidence and quantitative analyses in the PA (summarized in sections II.A.2 and II.A.3 above); the advice and recommendations from the CASAC (summarized in section II.B.1.b above); and public comments (discussed in section II.B.2 above and in the separate RTC document).

[142] The studies by Lim et al (2019) and Rhee et al (2019) include zip codes across the entire U.S., while Paulin et al (2020) includes the cities of Baltimore, Maryland, New York City, New York, Los Angeles and San Francisco, California, Ann Arbor, Michigan, Salt Lake City, Utah and Winston-Salem, North Carolina. The study time periods include ten or more years extending from the early 2000s to the late 2010s; a period within which the design values for most of those identified cities and many other U.S. metropolitan areas exceeded the level of the current standard (as seen by the design values presented for those areas during those time periods at *https://www.epa.gov/air-trends/air-quality-design-values*).

[143] In its comments regarding the 2015 statement, the CASAC and its consultants stated that controls that reduce peak O_3 concentrations will not consistently reduce mean O_3 concentrations. We don't disagree with this statement, and we note that we did not make a statement to the contrary in either the proposal or this final decision document.

In the discussion below, the Administrator considers the key aspects of the evidence and exposure/risk estimates important to his judgment regarding the adequacy of protection provided by the current standard. First, the Administrator considers the evidence base on health effects associated with exposure to photochemical oxidants, including O_3, in ambient air. He additionally considers the quantitative exposure and risk estimates developed in this review, including associated limitations and uncertainties, and what they indicate regarding the magnitude of risk, as well as degree of protection from adverse health effects, associated with the current standard. He additionally considers uncertainties in the evidence and the exposure/risk information, as a part of public health judgments that are essential and integral to his decision on the adequacy of protection provided by the standard. Such judgments include public health policy judgments and judgments about the implications of the uncertainties inherent in the scientific evidence and quantitative analyses. The Administrator draws on the PA considerations, and PA conclusions in the current review, taking note of key aspects of the rationale presented for those conclusions. Further, the Administrator considers the advice and conclusions of the CASAC, including particularly its overall agreement that the currently available evidence does not substantially differ from that which was available in the 2015 review when the current standard was established.

As an initial matter, the Administrator recognizes the continued support in the current evidence for O_3 as the indicator for photochemical oxidants (as recognized in section II.D.1 of the proposal). As recognized in the proposal, no newly available evidence has been identified in this review regarding the importance of photochemical oxidants other than O_3 with regard to abundance in ambient air, and potential for health effects, and the ''the primary literature evaluating the health and ecological effects of photochemical oxidants includes ozone almost exclusively as an indicator of photochemical oxidants'' (ISA, p. IS–3). Accordingly, the information relating health effects to photochemical oxidants in ambient air is also focused on O_3. Thus, the Administrator concludes it is appropriate for O_3 to continue to be the indicator for the primary standard for photochemical oxidants.

With regard to the extensive evidence base for health effects of O_3, the Administrator gives particular attention to the longstanding evidence of respiratory effects causally related to short-term O_3 exposures (summarized in section II.A.2.a above). He recognizes that the strongest and most certain evidence for this conclusion, as in the last review, is that from controlled human exposure studies that report an array of respiratory effects in study subjects (largely generally healthy adults) engaged in quasi-continuous or intermittent exercise. He additionally recognizes the supporting experimental animal and epidemiologic evidence. In so doing, he takes note of the epidemiologic evidence of positive associations for increased incidence of hospital admissions and emergency department visits for an array of respiratory outcomes, with the strongest such evidence being for asthma-related outcomes and specifically asthma-related outcomes for children, with short-term O_3 exposures. As a whole, this strong evidence base continues to demonstrate a causal relationship between short-term O_3 exposures and respiratory effects, including in people with asthma. The Administrator also notes the ISA conclusion that the relationship between long-term exposures and respiratory effects is likely to be causal. These conclusions are also consistent with the conclusions in the last review and reflect a general similarity in the underlying evidence base for such effects.

With regard to conclusions regarding the health effects evidence that differ from those in the last review, the Administrator recognizes the new conclusions regarding metabolic effects, cardiovascular effects and mortality (as summarized in section II.A.2.a above; ISA, Table ES–1). As an initial matter, he takes note of the fact that while the 2013 ISA considered the evidence available in the last review sufficient to conclude that the relationships for short-term O_3 exposure with cardiovascular health effects and mortality were likely to be causal, that conclusion is no longer supported by the now more expansive evidence base which the current ISA determines to be suggestive of, but not sufficient to infer, a causal relationship for these health effect categories (ISA, Appendix 4, section 4.1.17; Appendix 6, section 6.1.8). Further, the Administrator recognizes the new ISA determination that the relationship between short-term O_3 exposure and metabolic effects is likely to be causal (ISA, section IS.4.3.3). In so doing, he takes note that the basis for this conclusion is largely experimental animal studies in which the exposure concentrations were well above those in the controlled human exposure studies for respiratory effects as well as above those likely to occur in areas of the U.S. that meet the current standard (as summarized in section II.A.2.c above). Thus, while recognizing the ISA's conclusion regarding this potential hazard of O_3, he also recognizes that the evidence base is largely focused on circumstances of elevated concentrations above those occurring in areas that meet the current standard. In light of these considerations, he judges the current standard to be protective of such circumstances leading him to continue to focus on respiratory effects in his evaluation of whether the current standard provides requisite protection.

With regard to populations at increased risk of O_3-related health effects, the Administrator notes the populations and lifestages identified in the ISA and summarized in section II.A.2.b above. In so doing, he takes note of the longstanding and robust evidence that supports identification of people with asthma as being at increased risk of O_3-related respiratory effects, including specifically asthma exacerbation and associated health outcomes, and also children, particularly due to their generally greater time outdoors while at elevated exertion (PA, section 3.3.2; ISA, sections IS.4.3.1, IS.4.4.3.1, and IS.4.4.4.1, Appendix 3, section 3.1.11). This tendency of children to spend more time outdoors while at elevated exertion than other age groups, including in the summer when O_3 levels may be higher, makes them more likely to be exposed to O_3 in ambient air under conditions contributing to increased dose due to greater air volumes taken into the lungs. Based on these considerations, the Administrator concludes it is appropriate to give particular focus to people with asthma and children, population groups for which the evidence of increased risk is strongest, in evaluating whether the current standard provides requisite protection. He judges that such a focus will also provide protection of other potentially at-risk population groups, identified in the ISA, for which the current evidence is less robust and clear as to the extent and type of any increased risk, and the exposure circumstances that may contribute to it.

With regard to exposures of interest for respiratory effects, the Administrator refers to the controlled human exposure studies of 6.6-hour exposures, with quasi-continuous exercise,[144] to concentrations ranging from as low as approximately 40 ppb to 120 ppb (as considered in the PA, and summarized in sections II.A.2.c above). He also notes that, as in the last review, these studies, and particularly those that examine exposures from 60 to 80 ppb, are the primary focus of the PA consideration of exposure circumstances associated with O_3 health effects important to the Administrator's judgments regarding the adequacy of the current standard. The Administrator further recognizes that this information on exposure concentrations that have been found to elicit effects in exercising study subjects is unchanged from what was available in the last review.

With regard to the epidemiologic studies of respiratory effects, the Administrator recognizes that, as a whole, these investigations of associations between O_3 and respiratory effects and health outcomes (*e.g.,* asthma-related hospital admission and emergency department visits) provide strong support for the conclusions of causality (as summarized in section II.A.2.a above). He additionally takes note of the PA observation that these studies are generally focused on investigating the existence of relationships between O_3 in ambient air and specific health outcomes and not on detailing the specific exposure circumstances eliciting such effects (PA, section 3.3.3). In so doing, he takes note of the PA conclusions in this regard, including the scarcity of U.S. studies [145] conducted in locations in which and during time periods when the current standard would have been met (as summarized in sections II.A.2.c above).[146] He also recognizes the additional considerations raised in the PA and summarized in section II.A.2.c above regarding information on exposure concentrations in these studies during times and locations that would not have met the current standard, including considerations such as complications in disentangling specific O_3 exposures that may be eliciting effects (PA, section 3.3.3; ISA, p. IS–86 to IS–88). He takes note that such considerations do not lessen the importance of these studies in the evidence base documenting the causal relationship between O_3 and respiratory effects. With regard to his consideration of exposure concentrations associated with O_3 air quality conditions that meet the current standard, based on information cited here and discussed in the PA and section II.B.2.b(ii) above, he judges these studies that are available in the current review to be less informative. Thus, the Administrator agrees with the PA conclusions in consideration of this evidence from controlled human exposure and epidemiologic studies (as assessed in the ISA and summarized in the PA), and in consideration of public comments in section II.B.2.b(ii) above, that the evidence base in this review does not include new evidence of respiratory effects associated with appreciably different exposure circumstances than the evidence available in the last review, including particularly any circumstances that would also be expected to be associated with air quality conditions likely to occur under the current standard. In light of these considerations, he finds it appropriate to focus on the studies of 6.6-hour exposures with quasi-continuous exercise, and particularly on study results for concentrations ranging from 60 to 80 ppb.

In considering the significance of responses documented in these studies and the full evidence base for his purposes in judging implications of the current information on public health protection provided by the current standard, notes that the responses reported from exposures ranging from 60 to 80 ppb are transient and reversible in the study subjects. In so doing, he also notes that these studies are in largely healthy adult subjects, that such data are lacking at these exposure levels for children and people with asthma, and that the evidence indicates that such responses, if repeated or sustained, particularly in people with asthma, pose risks of effects of greater concern, including asthma exacerbation, as cautioned by the CASAC.[147] The Administrator also takes note of statements from the ATS (summarized in section II.A.2.b above), as well as judgments made by the EPA in considering similar effects (and ATS statements) in previous NAAQS reviews (80 FR 65343, October 26, 2015). With regard to the ATS statements, including the one newly available in this review (Thurston et al., 2017), the Administrator recognizes the role of such statements, as described by the ATS, as proposing principles or considerations for weighing the evidence rather than offering ''strict rules or numerical criteria'' (ATS, 2000, Thurston et al., 2017).

The more recent ATS statement is generally consistent with the prior statement (that was considered in the last O_3 NAAQS review) and the attention that statement gives to at-risk or vulnerable population groups, while also broadening the discussion of effects, responses and biomarkers to reflect the expansion of scientific research in these areas. In this way, the most recent statement updates the prior statement, while retaining previously identified considerations, including, for example, its emphasis on consideration of vulnerable populations, thus expanding upon (*e.g.,* with some increased specificity), while retaining core consistency with, the earlier ATS statement (Thurston et al., 2017; ATS, 2000). One example of this increased specificity that was raised in public comments and discussed in section II.B.2 above, is in the discussion of small changes in lung function (in terms of FEV_1) in people with compromised function, such as people with asthma (Thurston et al., 2017). In considering these statements, the Administrator notes that, in keeping with the intent of these statements to avoid specific criteria, the statements, in discussing what constitutes an adverse health effect, do not comprehensively describe all the biological responses raised, *e.g.,* with regard to magnitude, duration or frequency of small pollutant-related changes in lung function. In so doing, he also recognizes the limitations in the current evidence base with regard to our

[144] These studies employ a 6.6-hour protocol that includes six 50-minute periods of exercise at moderate or greater exertion.

[145] Consistent with the evaluation of the epidemiologic evidence of associations between short-term O_3 exposure and respiratory health effects in the ISA, we focus on those studies conducted in the U.S. and Canada, and most particularly in the U.S., to provide a focus on study populations and air quality characteristics that are most relevant to circumstances in the U.S. (PA, p. 3–45).

[146] Among the epidemiologic studies finding a statistically significant positive relationship of short- or long-term O_3 concentrations with respiratory effects, there are no single-city studies conducted in the U.S. in locations with ambient air O_3 concentrations that would have met the current standard for the entire duration of the study. Nor is there a U.S. multicity study for which all cities met the standard for the entire study period. The extent to which reported associations with health outcomes in the resident populations in these studies are influenced by the periods of higher concentrations during times that did not meet the current standard is unknown. These and additional considerations are summarized in section II.A.2.c above and in the PA.

[147] The CASAC noted that ''[a]rguably the most important potential adverse effect of acute ozone exposure in a child with asthma is not whether it causes a transient decrement in lung function, but whether it causes an asthma exacerbation'' and that increases in airway inflammation also have the potential to increase the risk for an asthma exacerbation. The CASAC further cautioned with regard to repeated episodes of such responses, *e.g.,* airway inflammation, indicating that they have the potential to contribute to irreversible reductions in lung function (Cox, 2020a, Consensus Responses to Charge Questions pp. 7–8).

understanding of these aspects of such changes that may be associated with exposure concentrations of interest. Notwithstanding these limitations and associated uncertainties, he takes note of the emphasis of the ATS statement on consideration of individuals with pre-existing compromised function, such as that resulting from asthma (an emphasis which is reiterated and strengthened in the current statement), and agrees that these are important considerations in his judgment on the adequacy of protection provided by the current standard for at-risk populations, as recognized below.

The Administrator recognizes some uncertainty, reflecting limitations in the evidence base, with regard to the exposure levels eliciting effects (as well as the severity of the effects) in some population groups not included in the available controlled human exposure studies, such as children and individuals with asthma. In so doing, the Administrator recognizes that the controlled human exposure studies, primarily conducted in healthy adults, on which the depth of our understanding of O_3-related health effects is based, in combination with the larger evidence base, informs our conceptual understanding of O_3 responses in people with asthma and in children. Aspects of our understanding continue to be limited, however, including with regard to the risk of particular effects and associated severity for these less studied population groups that may be posed by 7-hour exposures with exercise to concentrations as low as 60 ppb that are estimated in the exposure analyses. Collectively, these aspects of the evidence and associated uncertainties contribute to the Administrator's recognition that for O_3, as for other pollutants, the available evidence base in a NAAQS review generally reflects a continuum, consisting of levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain.

In light of these uncertainties in the evidence, as well as those associated with the exposure and risk analyses, the Administrator notes that, as is the case in NAAQS reviews in general, his decision regarding the primary O_3 standard in this review depends on a variety of factors, including his science policy judgments and public health policy judgments. These factors include judgments regarding aspects of the evidence and exposure/risk estimates, such as judgments concerning his interpretation of the different benchmark concentrations, in light of the available evidence and of associated uncertainties, as well as judgments on the public health significance of the effects that have been observed at the exposures evaluated in the health effects evidence. These judgments are rooted in his interpretation of the evidence, which reflects a continuum of health-relevant exposures, with less confidence and greater uncertainty in the existence of adverse health effects as one considers lower O_3 exposures. The factors relevant to judging the adequacy of the standards also include the interpretation of, and decisions as to the relative weight to place on, different aspects of the results of the exposure and risk assessment for the eight areas studied and the associated uncertainties. Together, factors described here inform the Administrator's judgment about the degree of protection that is requisite to protect public health with an adequate margin of safety, including the health of sensitive groups, and, accordingly, his conclusion that the current standard is requisite to protect public health with an adequate margin of safety.

As in prior O_3 NAAQS reviews, the Administrator considers the exposure estimates developed from modeling exposures to O_3 in ambient air in this review to be critically important to consideration of the potential for exposures and risks of concern under air quality conditions of interest, and consequently important to his judgments on the adequacy of public health protection provided by the current standard. The exposure/risk analysis provides a framework within which to consider implications of the health effects evidence with regard to protection afforded by the current standard. In his consideration of the exposure/risk estimates, the Administrator places greater weight and gives primary attention to the comparison-to-benchmarks analysis. This focus reflects his recognition of multiple factors, including the relatively greater uncertainty associated with the lung function risk estimates compared to the results of the comparison-to-benchmarks analysis. Additionally, he recognizes that, as noted in the PA, the comparison-to-benchmarks analysis provides for characterization of risk for the broad array of respiratory effects documented in the controlled human exposure studies. Accordingly, this analysis facilitates consideration of an array of respiratory effects, including but not limited to lung function decrements. Accordingly, the Administrator focuses primarily on the estimates of exposures at or above different benchmark concentrations that represent different levels of significance of O_3-related effects, both with regard to the array of effects and severity of individual effects. In so doing, he notes that this assures his consideration of the protection provided by the standard from the array of respiratory effects documented in the currently available evidence base.

In considering the public health implications of estimated occurrences of exposures (while at increased exertion) to the three benchmark concentrations (60, 70 and 80 ppb), the Administrator considers the respiratory effects reported in controlled human exposure studies of this range of concentrations (during quasi-continuous exercise). Accordingly, the controlled human exposure study evidence base, as a whole, provides context for consideration of the exposure/risk estimates. The Administrator recognizes the three benchmarks to represent exposure conditions associated with different levels of respiratory response in the subjects studied and to inform his judgments on different levels of risk that might be posed to unstudied members of at-risk populations. The highest benchmark concentration (80 ppb) represents an exposure where multiple controlled human exposure studies involving 6.6-hour exposures during quasi-continuous exercise demonstrate a range of O_3-related respiratory effects including inflammation and airway responsiveness, as well as respiratory symptoms and lung function decrements in healthy adult subjects. Findings for this O_3 exposure include: A statistically significant increase in multiple types of respiratory inflammation indicators in multiple studies; statistically significantly increased airway resistance and responsiveness; statistically significant FEV_1 decrements; and statistically significant increases in respiratory symptoms (Table 1). In one variable exposure study for which this (80 ppb) was the exposure period average concentration, the study subject mean FEV_1 decrement was nearly 8%, with individual decrements of 15% or greater (moderate or greater) in 16% of subjects and decrements of 10% or greater in 32% of subjects (Schelegle et al 2009); the percentages of individual subjects with decrements great than 10 or 15% were lower in other studies for this exposure. The second benchmark (70 ppb) represents an exposure level below the lowest exposures that have reported both statistically significant FEV_1

decrements [148] and increased respiratory symptoms (reported at 73 ppb, Schelegle et al 2009) or statistically significant increases in airway resistance and responsiveness (reported at 80 ppb, Horstman et al., 1990). The lowest benchmark (60 ppb) represents still lower exposure, and a level for which findings from controlled human exposure studies of largely healthy subjects have included: Statistically significant decrements in lung function (with mean decrements ranging from 1.7% to 3.5% across the four studies with average exposures of 60 to 63 ppb [149]), but not respiratory symptoms; and, a statistically significant increase in a biomarker of airway inflammatory response relative to filtered air exposures in one study (Kim et al, 2011).

In turning to the exposure/risk analysis results, the Administrator considers the evidence represented by these benchmarks noting that due to differences among individuals in responsiveness, not all people experiencing such exposures experience a response, such as a lung function decrement, as illustrated by the percentages cited above. Further, among those that experience a response, not all will experience an adverse effect. Accordingly, the Administrator notes that not all people estimated to experience an exposure of 7-hour duration while at elevated exertion above even the highest benchmark would be expected to experience an adverse effect, even members of at-risk populations. With these considerations in mind, he notes that while single occurrences could be adverse for some people, particularly for the higher benchmark concentration where the evidence base is stronger, the potential for adverse response increases with repeated occurrences (as cautioned by the CASAC).[150] In so doing, he also notes that while the exposure/risk analyses provide estimates of exposures of the at-risk population to concentrations of potential concern, they do not provide information on how many of such populations will have an adverse health outcome. Accordingly, in considering the exposure/risk analysis results, while giving due consideration to occurrences of one or more days with an exposure at or above a benchmark, particularly the higher benchmarks, he judges multiple occurrences to be of greater concern than single occurrences.

In this context, the Administrator considers the exposure risk estimates, focusing first on the results for the highest benchmark concentration (80 ppb), which represents an exposure well established to elicit an array of responses in sensitive individuals among study groups of largely healthy adult subjects, exposed while at elevated exertion. Similar to judgments of past Administrators, the current Administrator judges these effects in combination and severity to represent adverse effects for individuals in the population group studied, and to pose risk of adverse effects for individuals in at-risk populations, most particularly people with asthma, as noted above. Accordingly, he judges that the primary standard should provide protection from such exposures. In considering the exposure/risk estimates, he focuses on the results for children, and children with asthma, given the higher frequency of exposures of potential concern for children compared to adults, in terms of percent of the population groups.[151] The exposure/risk estimates indicate more than 99.9% to 100% of children and children with asthma, on average across the three years, to be protected from one or more occasions of exposure at or above this level; the estimate is 99.9% of children with asthma and of all children for the highest year and study area (Table 2). Further, no children in the simulated populations (zero percent) are estimated to be exposed more than once (two or more occasions) in the 3-year simulation to 7-hr concentrations, while at elevated exertion, at or above 80 ppb (Table 2). These estimates indicate strong protection against exposures of at-risk populations that have been demonstrated to elicit a wide array of respiratory responses in multiple studies.

The Administrator next considers the results for the second benchmark concentration (70 ppb), which is just below the lowest exposure concentration (73 ppb) for which a study has reported a combination of a statistically significant increase in respiratory symptoms and statistically significant lung function decrements in sensitive individuals in a study group of largely healthy adult subjects, exposed while at elevated exertion (Schelegle et al., 2009). Recognizing the lack of evidence for people with asthma from studies at 80 ppb and 73 ppb, as well as the emphasis in the ATS statement on the vulnerability of people with compromised respiratory function, such as people with asthma, the Administrator judges it appropriate that the standard protect against exposure, particularly multiple occurrences of exposure, to somewhat lower levels. In so doing, he notes that the exposure/risk estimates indicate more than 99% of children with asthma, and of all children, to be protected from one or more occasions in a year, on average, of 7-hour exposures to concentrations at or above 70 ppb, while at elevated exertion (Table 2). The estimate is 99% of children with asthma for the highest year and study area (Table 2). Further, he notes that 99.9% of these groups are estimated to be protected from two or more such occasions, and 100% from still more occasions. These estimates also indicate strong protection of at-risk populations against exposures similar to those demonstrated to elicit lung function decrements and increased respiratory symptoms in healthy subjects, a response described as adverse by the ATS.

In consideration of the exposure/risk results for the lowest benchmark (60 ppb), the Administrator notes that the lung function decrements in controlled human exposure studies of largely healthy adult subjects exposed while at elevated exertion to concentrations of 60 ppb, although statistically significant, are much reduced from that observed in the next higher studied concentration (73 ppb), both at the mean and individual level, and are not reported to be associated with increased respiratory symptoms in healthy subjects.[152] In light of these results and the transient nature of the responses, the Administrator does not judge these responses to represent adverse effects for generally healthy individuals. However, he further considers these findings specifically with regard to protection of at-risk populations, such as people with asthma. In so doing, he notes that such data are lacking for at-risk groups, such as people with asthma, and considers the evidence and

[148] The study group mean lung function decrement for the 73 ppb exposure was 6%, with individual decrements of 15% or greater (moderate or greater) in about 10% of subjects and decrements of 10% or greater in 19% of subjects. Decrements of 20% or greater were reported in 6.5% of subjects (Schelegle et al., 2009; PA, Table 3–2 and Appendix 3D, Table 3D–20). In studies of 80 ppb exposure, the percent of study subjects with individual FEV_1 decrements of this size ranged up to nearly double this (PA, Appendix 3D, Table 3D–20).

[149] Among subjects in all four of these studies, individual FEV_1 decrements of at least 15% were reported in 3% of subjects, with 7% of subjects reported to have decrements at or above a lower value of 10% (PA, Appendix 3D, Table 3D–20).

[150] For example, for people with asthma, the risk of an asthma exacerbation event may be expected to increase with repeated occurrences of lung function decrements of 10% or 15% as compared to a single occurrence.

[151] This finding relates to children's greater frequency and duration of outdoor activity, as well as their greater activity level while outdoors (PA, section 3.4.3).

[152] The response for the 60 ppb studies is also somewhat lower than that for the 63 ppb study (Table 1; PA, Appendix 3D, Table 3D–20).

comments from the CASAC regarding the need to consider endpoints of particular importance for this population group, such as risk of asthma exacerbation and prolonged inflammation. He takes note of comments from the CASAC (and also noted in the ATS statement) that small lung function decrements in this at-risk group may contribute to a risk of asthma exacerbation, an outcome described by the CASAC as ''arguably the most important potential adverse effect'' of O_3 exposure for a child with asthma. Thus, he judges it important for the standard to provide protection that reduces such risks. However, he recognizes gaps in our ability to predict risk of such events at the low concentrations such as those represented by the lowest benchmark in the exposure/risk analysis. With regard to the inflammatory response he notes the evidence, discussed in section II.B.2 above, indicating the role of repeated occurrences of inflammation in contributing to severity of response. Thus, he finds repeated occurrences of exposure events of potential concern to pose greater risk than single events, leading him to place greater weight to exposure/risk estimates for multiple occurrences.

In light of the uncertainties associated with the lack of controlled human exposure data for people with asthma, particularly with regard to the extent to which the lower exposure concentrations studied in generally healthy adults might be expected to elicit asthmatic responses in this at-risk population, the Administrator notes that the CASAC also recognized this, describing the gap in clinical studies to be a ''key knowledge gap'' important to considerations of margin of safety for the standard. The Administrator further notes that the CAA 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. 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 (summarized in section I.A. above). These provisions require the Administrator to establish primary standards that, in the judgment of the Administrator, are requisite to protect public health with an adequate margin of safety. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that primary standards be set at a zero-risk level, but rather at a level that avoids unacceptable risks to public health, including the health of sensitive groups.[153]

Thus, in this context, and given that the 70 ppb benchmark represents an exposure level somewhat below the lowest exposure concentration for which both statistically significant lung function decrements and increased respiratory symptoms have been reported in largely healthy adult subjects, the Administrator considers the exposure/risk estimates for the third benchmark of 60 ppb to be informative most particularly to his judgments on an adequate margin of safety. In that context, the Administrator turns to the third benchmark concentration (60 ppb). In so doing, he takes note that these estimates indicate more than 96% to more than 99% of children with asthma to be protected from more than one occasion in a year (two or more), on average, of 7-hour exposures to concentrations at or above this level, while at elevated exertion (Table 2). Additionally, the analysis estimates more than 90% of all children, on average across the three years, to be protected from one or more occasions of exposure at or above this level. The Administrator finds this to indicate an appropriate degree of protection from such exposures.

The Administrator additionally takes note of the new finding in this review of evidence of a likely to be causal relationship between O_3 and metabolic effects. In so doing, he notes the lack of evidence that would suggest such effects to be associated with exposures likely to occur with air quality conditions meeting the current standard, as discussed in section II.A.2.c above. Thus, he judges the current standard to provide protection from effects other than respiratory effects, for which the evidence is less certain. Accordingly, the Administrator concludes that the standard does not need to be revised to provide additional protection from such effects.

In reflecting on all of the information currently available, the Administrator considers the extent to which the currently available information might indicate support for a less stringent standard. He recognizes the advice from the CASAC, which generally indicates support for retaining the current standard without revision or for revision to a more stringent level based on additional consideration of the margin of safety for at-risk populations. He notes that the CASAC advice did not convey support for a less stringent standard. He additionally considers the current exposure and risk estimates for the air quality scenario for a design value just above the level of the current standard (at 75 ppb), in comparison to the scenario for the current standard, as summarized in section II.A.3 above. In so doing, he finds the markedly increased estimates of exposures to the higher benchmarks under air quality for a higher standard level to be of concern and indicative of less than the requisite protection (Table 2). Thus, in light of the considerations raised here, including the need for an adequate margin of safety, the Administrator judges that a less stringent standard would not be appropriate.

The Administrator additionally considers whether it would be appropriate to consider a more stringent standard that might be expected to result in reduced O_3 exposures. As an initial matter, he considers the advice from the CASAC. With regard to the CASAC advice, while part of the Committee concluded the evidence supported retaining the current standard without revision, another part of the Committee reiterated advice from the prior CASAC, which while including the current standard level among the range of recommended standard levels, also provided policy advice to set the standard at a lower level. In considering this advice now in this review, as it was raised by part of the current CASAC, the Administrator notes the slight differences of the current exposure and risk estimates from the 2014 HREA estimates for the lowest benchmark, which were those considered by the prior CASAC (Table 4). For example, while the 2014 HREA estimated 3.3 to 10.2% of children, on average, to experience one or more days with an exposures at or above 60 ppb (and as many as 18.9% in a single year), the comparable estimates for the current analyses are lower, particularly at the upper end (3.2 to 8.2% and 10.6%). While the estimates for two or more days with occurrences at or above 60 ppb, on average across the assessment period, are more similar between the two assessments, the current estimate for the single highest year is much lower (9.2 versus 4.3%). The Administrator additionally recognizes the PA finding that the factors contributing to these differences, which includes the use of air quality data reflecting concentrations much closer to the now-current standard than was the case in the 2015 review, also contribute to a reduced

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

uncertainty in the current estimates, as summarized in section II.A.3 above (PA, sections 3.4 and 3.5). Thus, he notes that the current exposure analysis estimates indicate the current standard to provide appreciable protection against multiple days with a maximum exposure at or above 60 ppb. In the context of his consideration of the adequacy of protection provided by the standard and of the CAA requirement that the standard protect public health, including the health of at-risk populations, with an adequate margin of safety, the Administrator concludes, in light of all of the considerations raised here, that the current standard provides appropriate protection, and that a more stringent standard would be more than requisite to protect public health.

In light of all of the above, including advice from the CASAC, the Administrator finds the current exposure and risk analysis results to describe appropriately strong protection of at-risk populations from exposures associated with O_3-related health effects. Therefore, based on his consideration of the evidence and exposure/risk information, including that related to the lowest exposures studied in controlled human exposure studies, and the associated uncertainties, the Administrator judges that the current standard provides the requisite protection of public health, including an adequate margin of safety, and thus should be retained, without revision. Accordingly, he concludes that a more stringent standard is not needed to provide requisite protection and that the current standard provides the requisite protection of public health under the Act. With regard to key aspects of the specific elements of the standard, the Administrator recognizes the support in the current evidence base for O_3 as the indicator for photochemical oxidants. In so doing, he notes the ISA conclusion that O_3 is the most abundant of the photochemical oxidants in the atmosphere and the one most clearly linked to human health effects. He additionally recognizes the control exerted by the 8-hour averaging time on associated exposures of importance for O_3-related health effects. Lastly, with regard to form and level of the standard, the Administrator takes note of the exposure and risk results as discussed above and the level of protection that they indicate the elements of the current standard to provide. Beyond his recognition of this support in the available information for the elements of the current standard, the Administrator has considered the elements collectively in evaluating the health protection afforded by the current standard. For all of the reasons discussed above, the Administrator concludes that the current primary O_3 standard (in all of its elements) is requisite to protect public health with an adequate margin of safety, including the health of at-risk populations, and thus should be retained, without revision.

C. Decision on the Primary 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 O_3 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.

III. Rationale for Decision on the Secondary Standard

This section presents the rationale for the Administrator's decision to retain the current secondary O_3 standard. This rationale is based on the scientific information presented in the ISA, on welfare effects associated with photochemical oxidants including O_3 and pertaining to the presence of these pollutants in ambient air. As summarized in section I.D above, the ISA was developed based on a thorough review of the latest scientific information generally published between January 2011 and March 2018, as well as more recent studies identified during peer review or by public comments on the draft ISA integrated with the information and conclusions from previous assessments (ISA, section IS.1.2 and Appendix 10, section 10.2). The Administrator's rationale also takes into account: (1) The PA evaluation of the policy-relevant information in the ISA and presentation of quantitative analyses of air quality, exposure, and risk; (2) CASAC advice and recommendations, as reflected in discussions of drafts of the ISA and PA at public meetings, and in the CASAC's letters to the Administrator; (3) public comments on the proposed decision; and also (4) the August 2019 decision of the D.C. Circuit remanding the secondary standard established in the last review to the EPA for further justification or reconsideration. See *Murray Energy Corp.* v. *EPA,* 936 F.3d 597 (D.C. Cir. 2019).

Within this section, introductory and background information is presented in section III.A. Section III.A.1 summarizes the 2015 establishment of the existing standard, as background for this review. Sections III.A.2 and III.A.3 provide overviews of the currently available welfare effects evidence and current air quality and environmental exposure information, respectively. Section III.B summarizes the basis for the proposed decision (III.B.1), including CASAC advice, discusses public comments on the proposed decision (III.B.2), and presents the Administrator's considerations, conclusions and decision in this review of the secondary standard (III.B.3). The decision is summarized in section III.C.

A. Introduction

As in prior reviews, the general approach to reviewing the current secondary standard is based, most fundamentally, on using the Agency's assessments of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgment regarding a secondary standard for photochemical oxidants that is requisite to protect the public welfare from known or anticipated adverse effects associated with the pollutant's presence 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 (84 FR 50836, September 26, 2019; 84 FR 58711, November 1, 2019; 84 FR 58713, November 1, 2019; 85 FR 21849, April 20, 2020; 85 FR 31182, May 22, 2020). In bridging the gap between the scientific assessments of the ISA and the judgments required of the Administrator in his decisions on the current standard, the PA evaluates policy implications of the assessment of the current evidence in the ISA and the quantitative air quality, exposure and risk analyses and information documented in the PA. In evaluating the public welfare protection afforded by the current standard, the four basic elements of the NAAQS (indicator, averaging time, level, and form) are considered collectively.

The final decision on the adequacy of the current secondary standard is a public welfare policy judgment to be made by the Administrator. In reaching conclusions on the standard, the decision draws on the scientific information and analyses about welfare effects, environmental exposure and risks, and associated public welfare significance, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and analyses. This approach is based on the recognition that the available evidence generally reflects a continuum that includes ambient air exposures at which scientists generally agree that effects are likely to occur through lower levels at which the likelihood and magnitude of responses become increasingly uncertain. This approach is consistent with the requirements of the provisions of the Clean Air Act related to the review of NAAQS and with how the EPA and the courts have historically interpreted the Act. These provisions require the Administrator to establish secondary standards that, in the judgment of the Administrator, are requisite to protect the public welfare from known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. 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 standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect the public welfare from known or anticipated adverse effects.

This decision on the secondary O_3 standard also considers the August 2019 decision by the D.C. Circuit and issues raised by the court in its remand of the 2015 standard to the EPA such that the decision in this review incorporates the EPA's response to the court's remand. The opinion issued by the court concluded, in relevant part, that EPA had not provided a sufficient rationale for aspects of its 2015 decision on the secondary standard. See *Murray Energy Corp.* v. *EPA,* 936 F.3d 597 (D.C. Cir. 2019). Accordingly, the court remanded that standard to EPA for further justification or reconsideration, particularly in relation to its decision to focus on a 3-year average for consideration of the cumulative exposure for vegetation, in terms of W126, identified as providing requisite public welfare protection, and its decision to not identify a specific level of air quality related to visible foliar injury.[154] Thus, in addition to considering the currently available welfare effects evidence and quantitative air quality, exposure and risk information, the decision described here, and the associated conclusions and judgments, also consider the court's remand. In consideration of the court remand, for example, certain analyses in this review are expanded compared with those conducted in the last review, issues raised in the remand have been discussed, and additional explanation of rationales for conclusions on these points is provided in this review.

1. Background on the Current Standard

As a result of the last O_3 review, completed in 2015, the level of the secondary standard was revised to 0.070 ppm, in conjunction with retaining the indicator, averaging time and form. This revision, establishing the current standard, was based on the scientific evidence and technical analyses available at that time, as well as the Administrator's judgments regarding the available welfare effects evidence, the appropriate degree of public welfare protection for the revised standard, and available air quality information on seasonal cumulative exposures that may be allowed by such a standard (80 FR 65292, October 26, 2015). In establishing this standard, the Administrator considered the extensive welfare effects evidence base compiled from more than fifty years of extensive research on the phytotoxic effects of O_3, conducted both in and outside of the U.S., that documents the impacts of O_3 on plants and their associated ecosystems (U.S. EPA, 1978, 1986, 1996, 2006, 2013). As was established in prior reviews, O_3 can interfere with carbon gain (photosynthesis) and allocation of carbon within the plant, making fewer carbohydrates available for plant growth, reproduction, and/or yield (U.S. EPA, 1996b, pp. 5–28 and 5–29).[155] The 2015 decision drew upon: (1) The available scientific evidence assessed in the 2013 ISA; (2) assessments in the 2014 PA of the most policy-relevant information in the 2013 ISA regarding evidence of adverse effects of O_3 to vegetation and ecosystems, information on biologically-relevant exposure metrics, 2014 welfare REA (WREA) analyses of air quality, exposure, and ecological risks and associated ecosystem services, and staff analyses of relationships between levels of a W126-based exposure index[156] and potential alternative standard levels in combination with the form and averaging time of the existing standard; (3) additional air quality analyses of the W126 index and design values based on the form and averaging time of the existing standard; (4) CASAC advice and recommendations; and (5) public comments received during the development of these documents and on the 2014 proposal (80 FR 65292, October 26, 2015). In addition to reviewing the most recent scientific information as required by the CAA, the 2015 rulemaking also incorporated the EPA's response to the judicial remand of the 2008 secondary O_3 standard in *Mississippi* v. *EPA,* 744 F.3d 1334 (D.C. Cir. 2013) and, in light of the court's decision in that case, explained the Administrator's conclusions as to the level of air quality judged to provide the requisite protection of public welfare from known or anticipated adverse effects.

Across the different types of studies, the strongest evidence for effects from O_3 exposure on vegetation was from controlled exposure studies of many species of vegetation (2013 ISA, p. 1–15). Primary consideration in the decision was given to the studies of O_3 exposures that reduced growth in tree seedlings from which E–R functions of seasonal relative biomass loss (RBL) have been established (80 FR 65385–86, 65389–90, October 26, 2015). The Administrator considered the effects of O_3 on tree seedling growth, as suggested by the CASAC, as a surrogate or proxy for the broader array of vegetation-related effects of O_3, ranging from effects on sensitive species to broader ecosystem-level effects (80 FR 65369, 65406, October 26, 2015). The metric used for quantifying effects on tree seedling growth in the review was RBL, with the evidence base providing robust and established E–R functions for seedlings of 11 tree species (80 FR 65391–92, October 26, 2015; 2014 PA, Appendix 5C).[157] The Administrator used this metric in her judgments on O_3 effects on the public welfare. In this context, exposure was evaluated in terms of the W126 cumulative seasonal

[154] The EPA's decision not to use a seasonal W126 index as the form and averaging time of the secondary standard was also challenged in this case, but the court did not reach a decision on that issue, concluding that it lacked a basis to assess the EPA's rationale on this point because the EPA had not yet fully explained its focus on a 3-year average W126 in its consideration of the standard. See *Murray Energy Corp.* v. *EPA,* 936 F.3d 597, 618 (D.C. Cir. 2019).

[155] In addition to concluding there to be causal relationships between O_3 and visible foliar injury, reduced vegetation growth, reduced productivity, reduced growth and yield of agricultural crops, and alteration of below-ground biogeochemical cycles, the 2013 ISA also concluded there likely to be a causal relationships between O_3 and reduced carbon sequestration in terrestrial ecosystems, alteration of terrestrial ecosystem water cycling and alteration of terrestrial community composition (2013 ISA, p. lxviii and Table 9–19). The 2013 ISA also found there to be a causal relationship between changes in tropospheric O_3 concentrations and radiative forcing, and likely to be a causal relationship between tropospheric O_3 concentrations and effects on climate as quantified through surface temperature response (2013 ISA, section 10.5).

[156] The W126 index is a cumulative seasonal metric described as the sigmoidally weighted sum of all hourly O_3 concentrations during a specified daily and seasonal time window, with each hourly O_3 concentration given a weight that increases from zero to one with increasing concentration (80 FR 65373–74, October 26, 2015). The units for W126 index values are ppm-hours (ppm-hrs).

[157] These functions for RBL estimate the reduction in a year's growth as a percentage of that expected in the absence of O_3 (2013 ISA, section 9.6.2; 2014 WREA, section 6.2).

exposure index, an index supported by the evidence in the 2013 ISA for this purpose and that was consistent with advice from the CASAC (2013 ISA, section 9.5.3, p. 9–99; 80 FR 65375, October 26, 2015).

The 2015 decision was a public welfare policy judgment made by the Administrator, that drew upon the available scientific evidence for O_3-attributable welfare effects and on quantitative analyses of exposures and public welfare risks, as well as judgments about the appropriate weight to place on the range of uncertainties inherent in the evidence and analyses. Included in this decision were judgments on the weight to place on the evidence of specific vegetation-related effects estimated to result across a range of cumulative seasonal concentration-weighted O_3 exposures; on the weight to give associated uncertainties, including uncertainties of predicted environmental responses (based on experimental study data); variability in occurrence of the specific effects in areas of the U.S., especially in areas of particular public welfare significance; and on the extent to which such effects in such areas may be considered adverse to public welfare. For example, in considering the public welfare protection provided by the then-existing standard, the Administrator gave primary consideration to an analysis of cumulative seasonal exposures in or near Class I areas,[158] which are lands that Congress set aside for specific uses intended to provide benefits to the public welfare, including lands that are to be protected so as to conserve the scenic value and the natural vegetation and wildlife within such areas, and to leave them unimpaired for the enjoyment of future generations.[159] The decision additionally recognized that states, tribes and public interest groups also set aside areas that are intended to provide similar benefits to the public welfare for residents on those lands, as well as for visitors to those areas (80 FR 65390, October 26, 2015). In recognizing that her judgments regarding effects that are adverse to the public welfare consider the intended use of the natural resources and ecosystems affected, the Administrator utilized the RBL as a quantitative tool within a larger framework of considerations pertaining to the public welfare significance of O_3 effects (80 FR 65389, October 26, 2015; 73 FR 16496, March 27, 2008).

In the Administrator's consideration of the adequacy of public welfare protection afforded by the existing standard, she gave particular attention to the air quality analysis for Class I areas that estimated cumulative exposures, in terms of 3-year average W126 index values, at and above 19 ppm-hrs, to have occurred under the standard in nearly a dozen areas distributed across two NOAA climatic regions of the U.S (80 FR 65385–86, October 26, 2015). The Administrator took note of these occurrences of exposures in Class I areas during periods when the existing standard was met, for which the associated estimates of growth effects across the species with E–R functions extend above a magnitude considered to be ''unacceptably high'' by the CASAC (80 FR 65385–65386, 65389–65390, October 26, 2015).[160] Based on this analysis and the considerations summarized above, including consideration of CASAC advice and public comment, the Administrator concluded that the protection afforded by the then-existing standard was not sufficient and that the standard needed to be revised to provide additional protection from known and anticipated adverse effects to public welfare, related to effects on sensitive vegetation and ecosystems, most particularly those occurring in Class I areas, and also in other areas set aside by states, tribes and public interest groups to provide similar benefits to the public welfare. In so doing, she further noted that a revised standard would provide increased protection for other growth-related effects, including relative yield loss (RYL) of crops, reduced carbon storage, and types of effects for which it is more difficult to determine public welfare significance, as well as other welfare effects of O_3, such as visible foliar injury[161] (80 FR 65390, October 26, 2015).

In light of the judicial remand of the 2008 secondary O_3 standard referenced above, the 2015 decision on selection of a revised secondary standard first considered the available evidence and quantitative analyses in the context of an approach for considering and identifying public welfare objectives for the revised standard (80 FR 65403–65408, October 26, 2015). In light of the extensive evidence base of O_3 effects on vegetation and associated terrestrial ecosystems, the Administrator focused on protection against adverse public welfare effects of O_3-related effects on vegetation, giving particular attention to such effects in natural ecosystems, such as those in areas with protection designated by Congress, and areas similarly set aside by states, tribes and public interest groups, with the intention of providing benefits to the public welfare for current and future generations.[162]

In reaching a conclusion on the amount of public welfare protection from the presence of O_3 in ambient air that is appropriate to be afforded by a revised secondary standard, the Administrator gave particular consideration to the following: (1) The nature and degree of effects of O_3 on vegetation, including her judgments as to what constitutes an adverse effect to the public welfare; (2) the strengths and limitations of the available and relevant information; (3) comments from the public on the Administrator's proposed decision, including comments related to identification of a target level of protection; and (4) the CASAC's views regarding the strength of the evidence and its adequacy to inform judgments on public welfare protection. The Administrator recognized that such judgments should neither overstate nor understate the strengths and limitations of the evidence and information nor the appropriate inferences to be drawn as to risks to public welfare, and that the choice of the appropriate level of protection is a public welfare policy judgment entrusted to the Administrator under the CAA taking into account both the available evidence and the uncertainties (80 FR 65404–05, October 26, 2015).[163]

[158] Areas designated as Class I include all international parks, national wilderness areas which exceed 5,000 acres in size, national memorial parks which exceed 5,000 acres in size, and national parks which exceed 6,000 acres in size, provided the park or wilderness area was in existence on August 7, 1977. Other areas may also be Class I if designated as Class I consistent with the CAA.

[159] This emphasis on such lands was consistent with a similar emphasis in the 2008 review of the standard (73 FR 16485, March 27, 2008).

[160] The Administrator focused on the median RBL estimate across the eleven tree species for which robust established E–R functions were available and took note of the CASAC's consideration of RBL estimates presented in the 2014 draft PA, in which it characterized an estimate of 6% RBL in the median studied species as being ''unacceptably high,'' (Frey, 2014b).

[161] As described in the ISA, ''[t]ypical types of visible injury to broadleaf plants include stippling, flecking, surface bleaching, bifacial necrosis, pigmentation (*e.g.,* bronzing), and chlorosis or premature senescence'' and ''[t]ypical visible injury symptoms for conifers include chlorotic banding, tip burn, flecking, chlorotic mottling, and premature senescence of needles'' (ISA, Appendix 8, p. 8–13).

[162] The Administrator additionally recognized that providing protection for this purpose will also provide a level of protection for other vegetation that is used by the public and potentially affected by O_3 including timber, produce grown for consumption, and horticultural plants used for landscaping (80 FR 65403, October 26, 2015).

[163] The CAA does not require that a secondary standard be protective of all effects associated with a pollutant in the ambient air but rather those known or anticipated effects judged adverse to the public welfare (CAA section 109).

With regard to the extensive evidence of welfare effects of O_3, including visible foliar injury and crop RYL, the RBL information available for seedlings of a set of 11 tree species was judged to be more useful (particularly in a role as surrogate for the broader array of vegetation-related effects) in informing judgments regarding the nature and severity of effects associated with different air quality conditions and associated public welfare significance (80 FR 65405–06, October 26, 2015). With regard to visible foliar injury, while the Administrator recognized the potential for this effect to affect the public welfare in the context of affecting value ascribed to natural forests, particularly those afforded special government protection, she also recognized limitations in the available information that might inform consideration of potential public welfare impacts related to this vegetation effect noting the significant challenges in judging the specific extent and severity at which such effects should be considered adverse to public welfare (80 FR 65407, October 26, 2015).[164] Similarly, while O_3-related growth effects on agricultural and commodity crops had been extensively studied and robust E–R functions developed for a number of species, the Administrator found this information less useful in informing her judgments regarding an appropriate level of public welfare protection (80 FR 65405, October 26, 2015).[165] Thus, and in light of the extensive evidence base in this regard, the Administrator focused on the information related to trees and growth impacts in identifying the public welfare objectives for the revised secondary standard.

Accordingly, consideration of the appropriate public welfare protection objective for a revised standard focused on the estimates of tree seedling growth impacts (in terms of RBL) for a range of W126 index values, developed from the E–R functions for 11 tree species (80 FR 65391–92, Table 4, October 26, 2015). The Administrator also incorporated into her considerations the broader evidence base associated with forest tree seedling biomass loss, including other less quantifiable effects of potentially greater public welfare significance. That is, in drawing on these RBL estimates, the Administrator was not simply making judgments about a specific magnitude of growth effect in seedlings that would be acceptable or unacceptable in the natural environment. Rather, though mindful of associated uncertainties, the Administrator used the RBL estimates as a surrogate or proxy for consideration of the broader array of related vegetation-related effects of potential public welfare significance, which included effects on individual species and extending to ecosystem-level effects (80 FR 65406, October 26, 2015). This broader array of vegetation-related effects included those for which public welfare implications are more significant but for which the tools for quantitative estimates were more uncertain.

In using the RBL estimates as a proxy, the Administrator focused her attention on a revised standard that would generally limit cumulative exposures to those for which the median RBL estimate for seedlings of the 11 species with robust and established E–R functions would be somewhat below 6% (80 FR 65406–07, October 26, 2015). In so doing, she noted that the median RBL estimate was 6% for a cumulative seasonal W126 exposure index of 19 ppm-hrs (80 FR 65391–92, Table 4, October 26, 2015).[166] Given the information on median RBL at different W126 exposure levels, using a 3-year cumulative exposure index for assessing vegetation effects,[167] the potential for single-season effects of concern, and CASAC comments on the appropriateness of a lower value for a 3-year average W126 index, the Administrator concluded it was appropriate to identify a standard that would restrict cumulative seasonal exposures to 17 ppm-hrs or lower, in terms of a 3-year W126 index, in nearly all instances (80 FR 65407, October 26, 2015). Based on such information, available at that time, to inform consideration of vegetation effects and their potential adversity to public welfare, the Administrator additionally judged that the RBL estimates associated with marginally higher exposures in isolated, rare instances were not indicative of effects that would be adverse to the public welfare, particularly in light of variability in the array of environmental factors that can influence O_3 effects in different systems and uncertainties associated with estimates of effects associated with this magnitude of cumulative exposure in the natural environment (80 FR 65407, October 26, 2015).

Using these objectives, the Administrator's decision regarding a revised standard was based on extensive air quality analyses that included the most recently available data (monitoring year 2013) and extended back more than a decade (80 FR 65408, October 26, 2015; Wells, 2015). These analyses evaluated the cumulative seasonal exposure levels in locations meeting different alternative levels for a standard of the existing form and averaging time. Based on these analyses, the Administrator judged that the desired level of public welfare protection, considered in terms of cumulative exposure (quantified as the W126 index), could be achieved by a standard with a revised level in combination with the existing form and averaging time (80 FR 65408, October 26, 2015).

In the most recent period of air quality data (2011–2013), across the more than 800 monitor locations meeting the existing standard (with its level of 75 ppb), the 3-year average W126 index values were above 17 ppm-hrs in 25 sites distributed across different NOAA climatic regions, and

[164] These limitations included the lack of established E–R functions that would allow prediction of visible foliar injury severity and incidence under varying air quality and environmental conditions, a lack of consistent quantitative relationships linking visible foliar injury with other O_3-induced vegetation effects, such as growth or related ecosystem effects, and a lack of established criteria or objectives relating reports of foliar injury with public welfare impacts (80 FR 65407, October 26, 2015).

[165] With respect to commercial production of commodities, the Administrator noted the difficulty in discerning the extent to which O_3-related effects on commercially managed vegetation are adverse from a public welfare perspective, given that the extensive management of such vegetation (which, as the CASAC noted, may reduce yield variability) may also to some degree mitigate potential O_3-related effects. Management practices are highly variable and are designed to achieve optimal yields, taking into consideration various environmental conditions. Further, changes in yield of commercial crops and commercial commodities, such as timber, may affect producers and consumers differently, complicating the assessment of overall public welfare effects still further (80 FR 65405, October 26, 2015).

[166] When stated to the first decimal place, the median RBL was 6.0% for a cumulative seasonal W126 exposure index of 19 ppm-hrs. For 18 ppm-hrs, the median RBL estimate was 5.7%, which rounds to 6%, and for 17 ppm-hrs, the median RBL estimate was 5.3%, which rounds to 5% (80 FR 65407, October 26, 2015).

[167] Based on a number of considerations, the Administrator recognized greater confidence in judgments related to public welfare impacts based on a 3-year average metric than a single-year metric, and consequently concluded it to be appropriate to use a seasonal W126 index averaged across three years for judging public welfare protection afforded by a revised secondary standard. For example, she recognized uncertainties associated with interpretation of the public welfare significance of effects resulting from a single-year exposure, and that the public welfare significance of effects associated with multiple years of critical exposures are potentially greater than those associated with a single year of such exposure. She additionally concluded that use of a 3-year average metric could address the potential for adverse effects to public welfare that may relate to shorter exposure periods, including a single year (80 FR 65404, October 26, 2015).

above 19 ppm-hrs at nearly half of these sites, with some well above (Wells, 2015). In comparison, among the more than 500 sites meeting an alternative standard of 70 ppb across 46 of the 50 states, there were no occurrences of a W126 value above 17 ppm-hrs and fewer than five occurrences that equaled 17 ppm-hrs (Wells, 2015 and associated dataset [document identifier, EPA–HQ–OAR–2008–0699–4325]). For the full air quality dataset (extending back to 2001), among the nearly 4000 instances where a monitoring site met a standard level of 70 ppb, the Administrator noted that there was only ''a handful of isolated occurrences'' of 3-year W126 index values above 17 ppm-hrs, ''all but one of which were below 19 ppm-hrs'' (80 FR 65409, October 26, 2015). The Administrator concluded that that single value of 19.1 ppm-hrs (just equaling 19, when rounded), observed at a monitor for the 3-year period of 2006–2008, was reasonably regarded as an extremely rare and isolated occurrence, and, as such, it was unclear whether it would recur, particularly as areas across the U.S. took further steps to reduce O_3 to meet revised primary and secondary standards. Further, based on all of the then available information, as noted above, the Administrator did not judge RBL estimates associated with marginally higher exposures in isolated, rare instances to be indicative of adverse effects to the public welfare. The Administrator concluded that a standard with a level of 70 ppb and the existing form and averaging time would be expected to limit cumulative exposures, in terms of a 3-year average W126 exposure index, to values at or below 17 ppm-hrs, in nearly all instances, and accordingly, to eliminate or virtually eliminate cumulative exposures associated with a median RBL of 6% or greater (80 FR 65409, October 26, 2015). Thus, using RBL as a proxy in judging effects to public welfare, the Administrator judged that such a standard with a level of 70 ppb would provide the requisite protection from adverse effects to public welfare by limiting cumulative seasonal exposures to 17 ppm-hrs or lower, in terms of a 3-year W126 index, in nearly all instances, and decided to revise the standard level to 70 ppb.

In summary, the Administrator judged that the revised standard would protect natural forests in Class I and other similarly protected areas against an array of adverse vegetation effects, most notably including those related to effects on growth and productivity in sensitive tree species. The Administrator additionally judged that the revised standard would be sufficient to protect public welfare from known or anticipated adverse effects. This judgment by the Administrator appropriately recognized that the CAA does not require that standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect the public welfare from known or anticipated adverse effects. Thus, based on the conclusions drawn from the air quality analyses which demonstrated a strong, positive relationship between the 8-hour and W126 metrics and the findings that indicated the significant amount of control provided by the fourth-high metric, the evidence base of O_3 effects on vegetation and her public welfare policy judgments, as well as public comments and CASAC advice, the Administrator decided to retain the existing form and averaging time and revise the level to 0.070 ppm, judging that such a standard would provide the requisite protection to the public welfare from any known or anticipated adverse effects associated with the presence of O_3 in ambient air (80 FR 65409–10, October 26, 2015).

2. Overview of Welfare Effects Information

The information summarized here is an overview of the scientific assessment of the welfare effects evidence available in this review; this assessment is documented in the ISA and its policy implications are further discussed in the PA. As in past reviews, the welfare effects evidence evaluated in the ISA for O_3 and related photochemical oxidants is focused on O_3 (ISA, p. IS–3). Ozone is the most prevalent photochemical oxidant present in the atmosphere and the one for which there is a very large, well-established evidence base of its health and welfare effects (ISA, p. IS–3). Thus, the current welfare effects evidence and the Agency's review of the evidence, including the evidence newly available in this review,[168] continues to focus on O_3. The subsections below briefly summarize the following aspects of the evidence: the nature of O_3-related welfare effects, the potential public welfare implications, and exposure concentrations associated with effects.

a. Nature of Effects

The welfare effects evidence base available in the current review includes more than sixty years of extensive research on the phytotoxic effects of O_3 and subsequent effects on associated ecosystems (1978 AQCD, 1986 AQCD, 1996 AQCD, 2006 AQCD, 2013 ISA, 2020 ISA). As described in past reviews, O_3 can interfere with carbon gain (photosynthesis) and allocation of carbon within the plant, making fewer carbohydrates available for plant growth, reproduction, and/or yield (2013 ISA, p. 1–10; 1996 AQCD, pp. 5–28 and 5–29). As described in the 2013 ISA, the strongest evidence for effects from O_3 exposure on vegetation is from controlled exposure studies, which ''have clearly shown that exposure to O_3 is causally linked to visible foliar injury, decreased photosynthesis, changes in reproduction, and decreased growth'' in many species of vegetation (2013 ISA, p. 1–15). Such effects at the plant scale can also be linked to an array of effects at larger spatial scales (and higher levels of biological organization), with the evidence available in the last review indicating that ''O_3 exposures can affect ecosystem productivity, crop yield, water cycling, and ecosystem community composition'' (2013 ISA, p. 1–15, Chapter 9, section 9.4). Beyond its effects on plants, the 2013 ISA also recognized O_3 in the troposphere as a major greenhouse gas (ranking behind carbon dioxide and methane in importance), with associated radiative forcing and effects on climate, and recognized the accompanying ''large uncertainties in the magnitude of the radiative forcing estimate . . . making the impact of tropospheric O_3 on climate more uncertain than the effect of the longer-lived greenhouse gases'' (2013 ISA, sections 10.3.4 and 10.5.1 [p. 10–30]).

The evidence newly available in this review supports, sharpens and expands somewhat on the conclusions reached in the last review (ISA, Appendices 8 and 9). Consistent with the evidence in the last review, the currently available evidence describes an array of O_3 effects on vegetation and related ecosystem effects, as well as the role of O_3 in radiative forcing and subsequent climate-related effects. The ISA concludes there to be causal relationships between O_3 and visible foliar injury,[169] reduced vegetation growth and reduced plant reproduction,[170] as well as reduced

[168] More than 1600 studies are newly available and considered in the ISA, including nearly 600 studies on welfare effects (ISA, Appendix 10, Figure 10–2).

[169] Evidence continues to indicate that ''visible foliar injury usually occurs when sensitive plants are exposed to elevated ozone concentrations in a predisposing environment,'' with a major factor for such an environment being the amount of soil moisture available to the plant (ISA, Appendix 8, p. 8–23; 2013 ISA, section 9.4.2).

[170] The 2013 ISA did not include a separate causality determination for reduced plant reproduction. Rather, it was included with the

yield and quality of agricultural crops, reduced productivity in terrestrial ecosystems, alteration of terrestrial community composition,[171] and alteration of belowground biogeochemical cycles (ISA, section IS.5). The current ISA also concludes there likely to be a causal relationship between O_3 and alteration of ecosystem water cycling, reduced carbon sequestration in terrestrial ecosystems, and with increased tree mortality (ISA, section IS.5). Additionally, evidence newly available in this review augments more limited previously available evidence related to insect interactions with vegetation, contributing to the ISA conclusion that the evidence is sufficient to infer that there are likely to be causal relationships between O_3 exposure and alteration of plant-insect signaling (ISA, Appendix 8, section 8.7) and of insect herbivore growth and reproduction (ISA, Appendix 8, section 8.6). Thus, conclusions reached in the last review continue to be supported by the current evidence base and conclusions are also reached in a few new areas based on the now expanded evidence.

As in the last review, the strongest evidence and the associated findings of causal or likely causal relationships with O_3 in ambient air, and the quantitative characterizations of relationships between O_3 exposure and occurrence and magnitude of effects are for vegetation effects. Visible foliar injury has long been used as a bioindicator of O_3 exposure, although it is not always a reliable indicator of other negative effects on vegetation (ISA, sections IS.5.1.2 and 8.2). Effects of O_3 on physiology of individual plants at the cellular level, such as through photosynthesis and carbon allocation, can impact plant growth and reproduction (ISA, section IS.5.1.2). The scales of these effects range from the individual plant scale to the ecosystem scale, with potential for impacts on the public welfare (as discussed in section III.A.2.b below). The effects of O_3 on plants and plant populations have implications for ecosystems. Effects at the ecosystem scale include reduced terrestrial productivity and carbon storage, and altered terrestrial community composition, as well as impacts on ecosystem functions, such as belowground biogeochemical cycles and ecosystem water cycling (ISA, Appendix 8, sections 8.11 and 8.9).

Ozone welfare effects also extend beyond effects on vegetation and associated biota due to it being a major greenhouse gas and radiative forcing agent.[172] The current evidence, augmented since the 2013 ISA, continues to support a causal relationship between the global abundance of O_3 in the troposphere and radiative forcing, and a likely causal relationship between the global abundance of O_3 in the troposphere and effects on temperature, precipitation, and related climate variables[173] (ISA, section IS.5.2 and Appendix 9; Myhre et al., 2013). Uncertainty in the magnitude of radiative forcing estimated to be attributed to tropospheric O_3 contributes to the relatively greater uncertainty associated with climate effects of tropospheric O_3 compared to such effects of the well mixed greenhouse gases, such as carbon dioxide and methane (ISA, section IS.6.2.2).

Lastly, the evidence regarding tropospheric O_3 and UV–B shielding (shielding of ultraviolet radiation at wavelengths of 280 to 320 nanometers) was evaluated in the 2013 ISA and determined to be inadequate to draw a causal conclusion (2013 ISA, section 10.5.2). The current ISA concludes there to be no new evidence since the 2013 ISA relevant to the question of UV–B shielding by tropospheric O_3 (ISA, IS.1.2.1 and Appendix 9, section 9.1.3.4).

b. Public Welfare Implications

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)). As recognized in prior reviews of secondary standards, the secondary standard is not meant to protect against all known or anticipated O_3-related welfare 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; see also 73 FR 16496, March 27, 2008). The significance of each type of welfare effect with regard to potential effects on the public welfare depends on the type and severity of effects, as well as the extent of such effects on the affected environmental entity, and on the societal use of the affected entity and the entity's significance to the public welfare. Such factors have been considered in the context of judgments and conclusions made in some prior reviews regarding public welfare effects. For example, judgments regarding public welfare significance in the last two O_3 NAAQS decisions gave particular attention to O_3 effects in areas with special federal protections (such as Class I areas), and lands set aside by states, tribes and public interest groups to provide similar benefits to the public welfare (73 FR 16496, March 27, 2008; 80 FR 65292, October 26, 2015).[174] In the 2015 review, the EPA recognized the ''clear public interest in and value of maintaining these areas in a condition that does not impair their intended use and the fact that many of these lands contain O_3-sensitive species'' (73 FR 16496, March 27, 2008).

Judgments regarding effects on the public welfare can depend on the intended use for, or service (and value) of, the affected vegetation, ecological receptors, ecosystems and resources and the importance of that use to the public welfare (73 FR 16496, March 27, 2008; 80 FR 65377, October 26, 2015). Uses or services provided by areas that have been afforded special protection can flow in part or entirely from the vegetation that grows there. Ecosystem services range from those directly related to the natural functioning of the ecosystem to ecosystem uses for human recreation or profit, such as through the production of lumber or fuel (Costanza et al., 2017; ISA, section IS.5.1). Services of aesthetic value and outdoor recreation depend, at least in part, on

conclusion of a causal relationship with reduced vegetation growth (ISA, Table IS–12).

[171] The 2013 ISA had concluded alteration of terrestrial community composition to be likely causally related to O_3 based on the then available information (ISA, Table IS–12).

[172] Radiative forcing is a metric used to quantify the change in balance between radiation coming into and going out of the atmosphere caused by the presence of a particular substance (ISA, Appendix 9, section 9.1.3.3).

[173] Effects on temperature, precipitation, and related climate variables were referred to as ''climate change'' or ''effects on climate'' in the 2013 ISA (ISA, p. IS–82; 2013 ISA, pp. 1–14 and 10–31).

[174] For example, the fundamental purpose of parks in the National Park System ''is to conserve the scenery, natural and historic objects, and wild life in the System units and to provide for the enjoyment of the scenery, natural and historic objects, and wild life in such manner and by such means as will leave them unimpaired for the enjoyment of future generations'' (54 U.S.C. 100101). Additionally, the Wilderness Act of 1964 defines designated ''wilderness areas'' in part as areas ''protected and managed so as to preserve [their] natural conditions'' and requires that these areas ''shall be administered for the use and enjoyment of the American people in such manner as will leave them unimpaired for future use and enjoyment as wilderness, and so as to provide for the protection of these areas, [and] the preservation of their wilderness character . . .'' (16 U.S.C. 1131(a) and (c)). Other lands that benefit the public welfare include national forests which are managed for multiple uses including sustained yield management in accordance with land management plans (see 16 U.S.C. 1600(1)–(3); 16 U.S.C. 1601(d)(1)).

the perceived scenic beauty of the environment. Additionally, public surveys have indicated that Americans rank as very important the existence of resources, the option or availability of the resource and the ability to bequest or pass it on to future generations (Cordell et al., 2008).

The different types of O_3 effects on vegetation recognized in section III.A.2.a above differ with regard to aspects important to judging their public welfare significance. For example, in the case of effects on crop yield, such judgments may consider aspects such as the heavy management of agriculture in the U.S., while judgments for other categories of effects may generally relate to considerations regarding natural areas, including specifically those areas that are not managed for harvest. In this context, it may be important to consider that O_3 effects on tree growth and reproduction could, depending on severity, extent and other factors, lead to effects on a larger scale including reduced productivity, altered forest and forest community (plant, insect and microbe) composition, reduced carbon storage and altered ecosystem water cycling (ISA, section IS.5.1.8.1; 2013 ISA, Figure 9–1, sections 9.4.1.1 and 9.4.1.2). For example, the composition of vegetation or of terrestrial community composition can be affected through O_3 effects on growth and reproductive success of sensitive species in the community, with the extent of compositional changes dependent on factors such as competitive interactions (ISA, section IS.5.1.8.1; 2013 ISA, sections 9.4.3 and 9.4.3.1). Impacts on some of these characteristics (*e.g.,* forest or forest community composition) may be considered of greater public welfare significance when occurring in Class I or other protected areas, due to value for particular services that the public places on such areas.

Agriculture and silviculture provide ecosystem services with clear public welfare benefits. With regard to agriculture-related effects of O_3, however, there are complexities in this consideration related to areas and plant species that are heavily managed to obtain a particular output (such as commodity crops or commercial timber production). In light of this, the degree to which O_3 impacts on agriculturally important vegetation would impair the intended use at a level that might be judged adverse to the public welfare has been less clear (80 FR 65379, October 26, 2015; 73 FR 16497, March 27, 2008). While having sufficient crop yields is of high public welfare value, important commodity crops are typically heavily managed to produce optimum yields. Moreover, based on the economic theory of supply and demand, increases in crop yields would be expected to result in lower prices for affected crops and their associated goods, which would primarily benefit consumers. Analyses in past reviews have described how these competing impacts on producers and consumers complicate consideration of these effects in terms of potential adversity to the public welfare (2014 WREA, sections 5.3.2 and 5.7).

Other ecosystem services valued by people that can be affected by reduced tree growth, productivity and associated forest effects include aesthetic value; provision of food, fiber, timber, other forest products, habitat, and recreational opportunities; climate and water regulation; erosion control; air pollution removal, and desired fire regimes (PA, Figure 4–2; ISA, section IS.5.1; 2013 ISA, sections 9.4.1.1 and 9.4.1.2). In considering such services in past reviews, the Agency has given particular attention to effects in natural ecosystems, indicating that a protective standard, based on consideration of effects in natural ecosystems in areas afforded special protection, would also ‘‘provide a level of protection for other vegetation that is used by the public and potentially affected by O_3 including timber, produce grown for consumption and horticultural plants used for landscaping’’ (80 FR 65403, October 26, 2015). For example, locations potentially vulnerable to O_3-related impacts might include forested lands, both public and private, where trees are grown for timber production. Forests in urbanized areas also provide a number of services that are important to the public in those areas, such as air pollution removal, cooling, and beautification. There are also many other tree species, such as various ornamental and agricultural species (*e.g.,* Christmas trees, fruit and nut trees), that provide ecosystem services that may be judged important to the public welfare.

With its effect on the physical appearance of plants, visible foliar injury has the potential to be significant to the public welfare, depending on its severity and spatial extent, by impacting aesthetic or scenic values and outdoor recreation in Class I and other similarly protected areas valued by the public. To assess evidence of injury to plants in forested areas on national and regional scales, the U.S. Forest Service (USFS) conducted surveys of the occurrence and severity of visible foliar injury on sensitive (bioindicator) species at biomonitoring sites across most of the U.S., beginning in 1994 (in eastern U.S.) and extending through 2011 (Smith et al., 2003; Coulston et al., 2003). At these sites (biosites), a national protocol, including verification and quality assurance procedures and a scoring system, was implemented. The resultant biosite index (BI) scores may be described with regard to one of several categories ranging from little or no foliar injury to severe injury (*e.g.,* Smith et al., 2003; Campbell et al., 2007; Smith et al., 2007; Smith, 2012).[175] However, the available information does not yet address or describe the relationships expected to exist between some level of injury severity (*e.g.,* little, low/light, moderate or severe) and/or spatial extent affected and scenic or aesthetic values. This gap impedes consideration of the public welfare implications of different injury severities, and accordingly judgments on the potential for public welfare significance. That notwithstanding, while minor spotting on a few leaves of a plant may easily be concluded to be of little public welfare significance, some level of severity and widespread occurrence of visible foliar injury, particularly if occurring in specially protected areas, where the public can be expected to place value (*e.g.,* for recreational uses), might reasonably be concluded to impact the public welfare.

The tropospheric O_3-related effects of radiative forcing and subsequent effects on temperature, precipitation and related climate also have important public welfare implications, although their quantitative evaluation in response to O_3 concentrations in the U.S. is complicated by ‘‘[c]urrent limitations in climate modeling tools, variation across models, and the need for more comprehensive observational data on these effects’’ (ISA, section IS.6.2.2). An ecosystem service provided by forested lands is carbon sequestration or storage (ISA, section IS.5.1.4 and Appendix 8, section 8.8.3; 2013 ISA, section 2.6.2.1 and p. 9–37)[176], which has an extremely valuable role in counteracting the impact of greenhouse gases on radiative forcing and related climate effects on the public welfare. Accordingly, the

[175] Authors of studies presenting USFS biomonitoring program data have suggested what might be ‘‘assumptions of risk’’ (*e.g.,* for the forest resource) related to scores in these categories, *e.g.,* none, low, moderate and high for BI scores of zero to five, five to 15, 15 to 25 and above 25, respectively (*e.g.,* Smith et al., 2003; Smith et al., 2012. For example, maps of localized moderate to high risk areas may be used to identify areas where more detailed evaluations are warranted (Smith et al., 2012).

[176] While carbon sequestration or storage also occurs for vegetated ecosystems other than forests, it is relatively larger in forests given the relatively greater biomass for trees compared to other plants.

service of carbon storage can be of paramount importance to the public welfare no matter in what location the trees are growing or what their intended current or future use (*e.g.,* 2013 ISA, section 9.4.1.2). This benefit exists as long as the trees are growing, regardless of what additional functions and services it provides.

Categories of effects newly identified as likely causally related to O_3 in ambient air, such as alteration of plant-insect signaling and insect herbivore growth and reproduction, also have potential public welfare implications (*e.g.,* given the role of the plant-insect signaling process in pollination and seed dispersal). Uncertainties and limitations in the current evidence (*e.g.,* summarized in sections III.B.3.c and III.D.1 of the proposal) preclude an assessment of the extent and magnitude of O_3 effects on these endpoints, which thus also precludes an evaluation of the potential for associated public welfare implications.

In summary, several considerations are recognized as important to judgments on the public welfare significance of the array of welfare effects of different O_3 exposure conditions. These include uncertainties and limitations associated with the magnitude of key welfare effects that might be concluded to be adverse to ecosystems and associated services. Additionally, the presence of O_3-sensitive tree species may contribute to a vulnerability of numerous locations to public welfare impacts from O_3 related to tree growth, productivity and carbon storage and their associated ecosystems and services. Other important considerations include the exposure circumstances that may elicit effects and the potential for the significance of the effects to vary in specific situations due to differences in sensitivity of the exposed species, the severity and associated significance of the observed or predicted O_3-induced effect, the role that the species plays in the ecosystem, the intended use of the affected species and its associated ecosystem and services, the presence of other co-occurring predisposing or mitigating factors, and associated uncertainties and limitations.

c. Exposures Associated With Effects

The welfare effects identified in section III.A.2.a above vary widely with regard to the extent and level of detail of the available information that describes the O_3 exposure circumstances that may elicit the effects. The information on exposure metric and E–R relationships for effects related to vegetation growth is long-standing, having been first described in the 1997 review, while such information is much less established for visible foliar injury. The evidence base for other categories of effects is also lacking in information that might support characterization of potential impacts of changes in O_3 concentrations.

(i) Growth-Related Effects

The long-standing body of vegetation effects evidence includes a wealth of information on aspects of O_3 exposure that influence its effects on plant growth and yield, and that has been described in the scientific assessments across the last several decades (1996 AQCD; 2006 AQCD; 2013 ISA; 2020 ISA). A variety of factors have been investigated, and a number of mathematical approaches have been developed for summarizing O_3 exposure for the purpose of assessing effects on vegetation, including several that cumulate exposures over some specified period while weighting higher more than lower concentrations (2013 ISA, sections 9.5.2 and 9.5.3; ISA, Appendix 8, section 8.2.2.2). Over this period, the EPA's scientific assessments have focused on the use of a cumulative, seasonal [177] concentration-weighted index when considering the growth-related effects evidence and when analyzing exposures for purposes of reaching conclusions on the secondary standard. Such metrics have included SUM06,[178] in the past, and more recently (since the 2008 review), the focus has been on the W126-based, seasonal metric, termed the ''W126 index'' [179] (ISA, section IS.3.2, Appendix 8, sections 8.1 and 8.13).

Quantifying exposure using cumulative, concentration-weighted indices of exposure, such as the W126 index, has been found to improve the explanatory power of E–R models for growth and yield over using indices based only on mean and peak exposure values (ISA, section IS.5.1.9, p. IS–79; 2013 ISA, section 2.6.6.1, p. 2–44). The most well-analyzed datasets in such evaluations are two detailed datasets established two decades ago, one for seedlings of 11 tree species [180] and one for 10 crops (*e.g.,* Lee and Hogsett, 1996, Hogsett et al., 1997). These datasets, which include species-specific seedling growth and crop yield response information across multiple seasonal cumulative exposures, were used to develop robust quantitative E–R functions to predict growth reduction relative to a zero-O_3 setting (RBL) in seedlings of the tree species [181] and similarly, E–R functions for predicting RYL for a set of 10 common crops (ISA, Appendix 8, section 8.13.2; 2013 ISA, section 9.6.2).

The tree seedling E–R functions were derived from data for multiple studies documenting effects on tree seedling growth under a variety of O_3 exposures [182] and growing conditions. Importantly the data included hourly concentrations recorded across the duration of the exposure, which allowed for derivation of various metrics that were analyzed for association with reduced growth (2013 ISA, section 9.6.2; Lee and Hogsett, 1996). In producing E–R functions of consistent duration across the experiments, the E–R functions were derived first based on the exposure duration of the experiment [183] and then normalized to 3-month (seasonal) periods [184] (see Lee and Hogsett, 1996, section I.3; PA, Appendix 4A). The species-specific composite E–R functions developed from the experiment-specific functions indicate the wide variation in growth

[177] The ''seasonal'' descriptor refers to the duration of the period quantified (3 months) rather than a specific season of the year.

[178] The SUM06 index received attention across past O_3 NAAQS reviews. It is the seasonal sum of hourly concentrations at or above 0.06 ppm during a specified daily time window (2006 AQCD, p. AX9–161; 2013 ISA, section 9.5.2).

[179] The W126 index is described in section III.B.3.a(i) of the proposal (85 FR 49887, August 14, 2020) and in the PA (PA, Appendix 4D, section 4D.2.2).

[180] In total, the 11 species-specific composite E–R functions are based on 51 tree seedling studies or experiments, many of which employed open top chambers, an established experimental approach (PA, Appendix 4A, section 4A.1.1; ISA, section 8.1.2.1.2). For six of the 11 species, this function is based on just one or two studies, while for other species there were as many as 11 studies available.

[181] While the 11 species represent only a small fraction of the total number of native tree species in the contiguous U.S., this subset includes eastern and western species, deciduous and coniferous species, and species that grow in a variety of ecosystems and represent a range of tolerance to O_3 (PA, Appendix 4B; 2013 ISA, section 9.6.2).

[182] Across the experiments for the 11 tree species, the exposure levels assessed are more extensive for relatively higher seasonal exposures (*e.g.,* at/above a SUM06 of 30 ppm-hrs). Across these experiments, there is more limited representation of lower cumulative exposure levels, such as SUM06 values below those that may correspond to a W126 index of 20 ppm-hrs. These lowest levels did not always yield a statistically significant effect (PA, section 4.5.1.2 and Appendix 4A; 85 FR 49901, August 14, 2020).

[183] The exposure durations varied from periods of 82 to 140 days over a single year to periods of 180 to 555 days across two years (Lee and Hogsett, 1996; PA, Appendix 4A, Table 4A–5).

[184] Underlying the adjustment is a simplifying assumption of uniform W126 distribution across the exposure periods and of a linear relationship between duration of cumulative exposure in terms of the W126 index and plant growth response (85 FR 49901; August 14, 2020; PA). Some functions for experiments that extended over two seasons were derived by distributing responses observed at the end of two seasons of varying exposures equally across the two seasons (*e.g.,* essentially applying the average to both seasons).

sensitivity of the studied tree species at the seedling stage (PA, Appendix 4A, section 4A.1.1).

Since the initial set of tree seedling growth studies were completed, several additional studies, focused on aspen, have been published based on the Aspen FACE experiment in a planted forest in Wisconsin; the findings were consistent with earlier open top chamber (OTC) studies [185] (ISA, Appendix 8, section 8.13.2). Newly available studies that investigated growth effects of O_3 exposures are also consistent with the existing evidence base, and generally involve particular aspects of the effect rather than expanding the conditions under which plant species, particularly tree species, have been assessed (ISA, section IS.5.1.2). These publications include a compilation of previously available studies on plant biomass response to O_3; the compilation reports linear regressions conducted on the associated varying datasets. Based on these regressions, this study describes distributions of sensitivity to O_3 effects on biomass across many tree and grassland species, including 17 species native to the U.S. and 65 introduced species (ISA, Appendix 8, section 8.13.2; van Goethem et al., 2013). Additional information is needed to more completely describe O_3 exposure response relationships for these species in the U.S.[186]

(ii) Visible Foliar Injury

Current evidence ''continues to show a consistent association between visible injury and ozone exposure,'' while also recognizing the role of modifying factors such as soil moisture and time of day (ISA, section IS.5.1.1). The ISA summarizes several recently available studies that continue to document that O_3 elicits visible foliar injury in many plant species. As in the prior review, the evidence in the current review, while documenting that elevated O_3 conditions in ambient air generally results in visible foliar injury in sensitive species (when in a predisposing environment),[187] does not include a quantitative description of the relationship of incidence or severity of visible foliar injury in natural areas of the U.S. with specific metrics of seasonal O_3 exposure.

Although studies of the incidence of visible foliar injury in national forests, wildlife refuges, and similar areas have often used cumulative indices (*e.g.,* SUM06) to investigate variations in incidence of foliar injury, studies also suggest an additional role for metrics focused on peak concentrations (ISA; 2013 ISA; 2006 AQCD; Hildebrand et al., 1996; Smith, 2012). Other studies have indicated this uncertainty regarding the influential metric(s), *e.g.,* by recognizing the need for research to help develop a ''better linkage between air levels and visible injury'' (Campbell et al., 2007).[188] Some studies of visible foliar injury incidence data have investigated such a role for peak concentrations quantified by an O_3 exposure index that is a count of hourly concentrations (*e.g.,* in a growing season) above a threshold concentration of 100 ppb, N100 (*e.g.,* Smith, 2012; Smith et al., 2012). For example, a study describing injury patterns over 16 years at USFS biosites in 24 states in the Northeast and North Central regions, in the context of the SUM06 index and N100 metrics, suggested that there may be a threshold exposure needed for injury to occur, and that the number of hours of elevated O_3 concentrations during the growing season (such as what is captured by a metric like N100) may be more important than cumulative exposure in determining the occurrence of foliar injury (Smith, 2012).[189] This finding is consistent with statistical analyses of seven years of visible foliar injury data from a wildlife refuge in the mid-Atlantic area (Davis and Orendovici, 2006).[190]

The established significant role of higher or peak O_3 concentrations, as well as pattern of their occurrence, in plant responses has also been noted in prior ISAs or AQCDs. The evidence has included studies that use indices to summarize the incidence of injury on bioindicator species present at specific monitored sites, as well as experimental studies that assess varying O_3 treatments on cultured stands of different tree species (2013 ISA, section 9.5.3.1; 2006 AQCD, p. AX9–169; Oksanen and Holopainen, 2001; Yun and Laurence, 1999). In identifying support for such O_3 metrics with regard to foliar injury as the response, the 2013 ISA and 2006 AQCD both cite studies that support the ''important role that peak concentrations, as well as the pattern of occurrence, plays in plant response to O_3'' (2013 ISA, p. 9–105; 2006 AQCD, p. AX9–169).

A recent study (by Wang et al. [2012]) involved a statistical modeling analysis on a subset of the years of USFS BI data that were described in Smith (2012). This analysis tested a number of models for their ability to predict the presence of visible foliar injury (a nonzero biosite score), regardless of severity, and generally found that the type of O_3 exposure metric (*e.g.,* SUM06 *versus* N100) made only a small difference, although the models that included both a cumulative index (SUM06) and N100 had a just slightly better fit (Wang et al., 2012). Based on their investigation of 15 different models, using differing combinations of several types of potential predictors, the study authors concluded that they were not able to identify environmental conditions under which they ''could reliably expect plants to be damaged'' (Wang et al., 2012). This is indicative of the current state of knowledge, in which there remains a lack of established quantitative functions describing E–R relationships that would allow prediction of visible foliar injury severity and incidence under varying air quality and other environmental conditions.

The information related to O_3 exposures associated with visible foliar injury of varying severity available in this review also includes quantitative

[185] These studies included experiments that used OTCs to investigate tree seedling growth response and crop yield over a growing season under a variety of O_3 exposures and growing conditions (2013 ISA, section 9.6.2; Lee and Hogsett, 1996).

[186] The studies compiled in this publication included at least 21 days exposure above 40 ppb O_3 (expressed as AOT40 [seasonal sum of the difference between an hourly concentration above 40 ppb and 40 ppb]); and had a maximum hourly concentration that was no higher than 100 ppb (van Goethem et al., 2013). The publication does not report study-specific exposure durations, details of biomass response measurements or hourly O_3 concentrations, making it less useful for describing E–R relationships that might support estimation of specific impacts associated with air quality conditions meeting the current standard (*e.g.,* 2013 ISA, p. 9–118).

[187] As a major modifying factor is the amount of soil moisture available to a plant, dry periods decrease the incidence and severity of ozone-induced visible foliar injury, such that the incidence of visible foliar injury is not always higher in years and areas with higher ozone, especially with co-occurring drought (ISA, Appendix 8, p. 8–23; Smith, 2012; Smith et al., 2003).

[188] In considering their findings, the authors expressed the view that ''[a]lthough the number of sites or species with injury is informative, the average biosite injury index (which takes into account both severity and amount of injury on multiple species at a site) provides a more meaningful measure of injury'' for their assessment at a statewide scale (Campbell et al., 2007).

[189] Although the ISA and past assessments have not described extensive evaluations of specific peak concentration metrics such as the N100, in summarizing this study in the last review, the ISA observed that ''[o]verall, there was a declining trend in the incidence of foliar injury as peak O3 concentrations declined'' (2013 ISA, p. 9–40).

[190] The models evaluated included several with cumulative exposure indices alone. These included SUM60 (*i.e.,* SUM06 in ppb), SUM0, and SUM80 (SUM08 in ppb), but not W126. They did not include a model with W126 that did not also include N100. Across all of the models evaluated, the model with the best fit to the data was found to be the one that included N100 and W126, along with the drought index (Davis and Orendovici, 2006).

presentations of the dataset (developed by the EPA in the last review) of USFS BI scores, collected during the years 2006 through 2010 at locations in 37 states. In developing this dataset, the BI scores were combined with estimates of soil moisture [191] and estimates of seasonal cumulative O_3 exposure in terms of W126 index [192] (PA, Appendix 4C). This dataset includes more than 5,000 records of which more than 80 percent have a BI score of zero (indicating a lack of visible foliar injury). While the estimated W126 index assigned to records in this dataset ranges from zero to somewhat above 50 ppm-hrs, more than a third of all the records (and also of records with BI scores above zero or five) [193] are at sites with W126 index estimates below 7 ppm-hrs. In an extension of analyses developed in the last review, the presentation in the PA [194] describes the BI scores for the records in this dataset in relation to the W126 index estimate for each record, using ''bins'' of increasing W126 index values. The PA presentation utilizes the BI score breakpoints in the scheme used by the USFS to categorize severity. This presentation indicates that, across the W126 bins, there is variation in both the incidence of particular magnitude BI scores and in the average score per bin. In general, however, the greatest incidence of records with BI scores above zero, five, or higher—and the highest average BI score—occurs with the highest W126 bin, *i.e.,* the bin for W126 index estimates greater than 25 ppm-hrs (PA, Appendix 4C, Table 4C–6).

Overall, the dataset described in the PA generally indicates the risk of injury, and particularly injury considered at least light, moderate or severe, to be higher at the highest W126 index values, with appreciable variability in the data for the lower bins (PA, Appendix 4C). This appears to be consistent with the conclusions of the detailed quantitative analysis studies, summarized above, that the pattern is stronger at higher O_3 concentrations. A number of factors may contribute to the observed variability in BI scores and lack of a clear pattern with W126 index bin; among other factors, these may include uncertainties in assignment of W126 estimates and soil moisture categories to biosite locations, variability in biological response among the sensitive species monitored, and the potential role of other aspects of O_3 air quality not captured by the W126 index. Thus, the dataset has limitations affecting associated conclusions, and uncertainty remains regarding the tools for and the appropriate metric (or metrics) for quantifying O_3 exposures, as well as perhaps for quantifying soil moisture conditions, with regard to their influence on extent and/or severity of injury in sensitive species in natural areas, as quantified via BI scores (Davis and Orendovici, 2006, Smith et al., 2012; Wang et al., 2012).

(iii) Other Effects

With regard to radiative forcing and subsequent climate effects associated with the global tropospheric abundance of O_3, the newly available evidence in this review does not provide more detailed quantitative information regarding response to O_3 concentrations at the national scale. Rather, it is noted that ''the heterogeneous distribution of ozone in the troposphere complicates the direct attribution of spatial patterns of temperature change to ozone induced [radiative forcing]'' and there are ''ozone climate feedbacks that further alter the relationship between ozone [radiative forcing] and temperature (and other climate variables) in complex ways'' (ISA, Appendix 9, section 9.3.1, p. 9–19). Further, ''precisely quantifying the change in surface temperature (and other climate variables) due to tropospheric ozone changes requires complex climate simulations that include all relevant feedbacks and interactions'' (ISA, section 9.3.3, p. 9–22). Yet, there are limitations in current climate modeling capabilities for O_3; an important one is representation of important urban- or regional-scale physical and chemical processes, such as O_3 enhancement in high-temperature urban situations or O_3 chemistry in city centers where NO_X is abundant. Such limitations impede our ability to quantify the impact of incremental changes in O_3 concentrations in the U.S. on radiative forcing and subsequent climate effects.

With regard to tree mortality, the evidence available in the last several reviews included field studies of pollution gradients that concluded O_3 damage to be an important contributor to tree mortality although ''several confounding factors such as drought, insect outbreak and forest management'' were identified as potential contributors (2013 ISA, p. 9–81, section 9.4.7.1). Among the newly available studies, there is only limited experimental evidence that isolates the effect of O_3 on tree mortality [195] and might be informative regarding O_3 concentrations of interest in the review, and evidence is lacking regarding exposure conditions closer to those occurring under the current standard and any contribution to tree mortality.

With regard to alteration of herbivore growth and reproduction, although ''[t]here are multiple studies demonstrating ozone effects on fecundity and growth in insects that feed on ozone-exposed vegetation'', ''no consistent directionality of response is observed across studies and uncertainties remain in regard to different plant consumption methods across species and the exposure conditions associated with particular severities of effects'' (ISA, pp. ES–18). The evidence for alteration of plant-insect signaling draws on new research yielding clear evidence of O_3 modification of volatile plant signaling compounds and behavioral responses of insects to the modified chemical signals (ISA, section IS.6.2.1). The evidence includes a relatively small number of plant species and plant-insect associations and is limited to short controlled exposures, posing limitations for consideration of the potential for associated impacts to be elicited by air quality conditions that meet the current standard (ISA, section IS.6.2.1 and Appendix 8, section 8.7).

For categories of vegetation-related effects that were recognized in past reviews, other than growth and visible foliar injury (*e.g.,* reduced plant reproduction, reduced productivity in terrestrial ecosystems, alteration of terrestrial community composition and alteration of below-ground biogeochemical cycles), the newly available evidence includes a variety of studies that quantify exposure of varying duration in various countries using a variety of metrics (ISA, Appendix 8, sections 8.4, 8.8 and 8.10).

[191] This dataset, including associated uncertainties and limitations in the assignment of soil moisture categories (dry, wet or normal), such as the substantial spatial variation in soil moisture and large size of NOAA climate divisions, is described in the PA, Appendix 4C.

[192] The W126 index estimates assigned to the biosite locations were developed for 12 kilometer (km) by 12 km cells in a national-scale spatial grid for each year. A spatial interpolation technique was applied to annual W126 values derived from O_3 measurements at ambient air monitoring locations for the years of the BI data (PA, Appendix 4C, sections 4.C.2 and 4C.5).

[193] One third (33%) of scores above 15 are at sites with W126 below 7 ppm-hrs (PA, Appendix 4C, Table 4C–3).

[194] Beyond the presentation of a statistical analysis developed in the last review, the PA presentations are primarily descriptive (as compared to statistical) in recognition of the limitations and uncertainties of the dataset (PA, Appendix 4C, section 4C.5).

[195] Of the three new studies on tree mortality described in the ISA is another field study of a pollution gradient that, like such studies in prior reviews, recognizes O_3 exposures as one of several contributing environmental and anthropogenic stressors (ISA, p. 8–55).

The ISA also describes publications that analyze and summarize previously published studies. For example, a meta-analysis of reproduction studies categorized the reported O_3 exposures into bins of differing magnitude, grouping differing concentration metrics and exposure durations together, and performed statistical analyses investigating associations with an O_3-related effect (ISA, Appendix 8, section 8.4.1). While such studies continue to support conclusions of O_3 ecological hazards, they do not improve capabilities for characterizing the likelihood of such effects under patterns of environmental O_3 concentrations occuring with air quality conditions that meet the current standard (*e.g.,* factors such as variation in exposure assessments and limitations in response information preclude detailed analysis for such conditions), as discussed further in the PA.

As at the time of the last review, growth impacts, most specifically as evaluated by RBL for tree seedlings and RYL for crops, remain the type of vegetation-related effects for which we have the best understanding of exposure conditions likely to elicit them. Accordingly, as was the case in the last review, the quantitative analyses of exposures occurring under air quality that meets the current standard, summarized below, are focused primarily on the W126 index, given its established relationship with growth effects.

3. Overview of Air Quality and Exposure Information

The air quality and exposure analyses developed in this review, like those in the last review, are of two types: (1) W126-based cumulative exposure estimates in Class I areas; and (2) analyses of W126-based exposures and their relationship with the current standard for all U.S. monitoring locations (PA, Appendix 4D). We recognize relatively lower uncertainty associated with the use of these types of analyses (compared to the national or regional-scale modeling analyses performed in the last review) to inform a characterization of cumulative O_3 exposure (in terms of the W126 index) associated with air quality just meeting the current standard (IRP, section 5.2.2). As in the last review, the lower uncertainty of these air quality monitoring-based analyses contributes to their value in informing the current review.

The analyses conducted in this review focus on design values (3-year average annual fourth-highest 8-hour daily maximum concentration, also termed the ''4th max metric'') and W126 index values (in terms of the 3-year average) for the recent 2016 to 2018 period and across the historical record back to 2000 (PA, Section 4.3). These analyses are based primarily on the hourly air monitoring data that were reported to EPA from O_3 monitoring sites nationwide and in or near Class 1 areas.[196]

a. Influence of Form and Averaging Time of Current Standard on Environmental Exposure

The findings of the quantitative analyses in this review of relationships between air quality in terms of the form and averaging time of the current standard and environmental exposures in terms of the W126 index are similar to those based on the data available during the last review (PA, Appendix 4D, section 4D.2.2).[197] As previously, the current analysis of data spanning 19 years and including seventeen 3-year periods documented a positive nonlinear relationship between cumulative seasonal exposure (quantified using the W126 index) and design values (based on the form and averaging time of the current standard). In the current analysis, which revealed the variability in the annual W126 index values across a 3-year period to be relatively low,[198] the positive nonlinear relationship is shown for both the average W126 index across the 3-year design value period and for W126 index values for individual years within the period (PA, Figure 4–7; Appendix 4D, section 4D.3.1.2). That is, W126 index values (in a single year or averaged across years) are lower at monitoring sites with lower design values. This is seen both for design values above the standard and across lower design values, indicating the effectiveness of the averaging time and form of the current standard at controlling W126-based cumulative exposures.

Further, analysis of the relationship between trends or long-term changes in design value and long-term changes in W126 index shows there to be a positive, linear relationship at monitoring sites across the U.S. (PA, Appendix 4D, section 4D.3.2.3). The existence of this relationship means that a change in the design value at a monitoring site was generally accompanied by a similar change in the W126 index. The relationship varies across the NOAA climate regions, with the greatest change in W126 index per unit change in design value observed in the Southwest and West regions, the regions which had the highest W126 index values at sites meeting the current standard (PA, Appendix 4D, Figures 4D–6 and 4D–14, Table 4D–12). Thus, this analysis indicates that going forward, as design values are reduced in areas that are presently not meeting the current standard, the W126 index in those areas would also be expected to decline and the greatest improvement in W126 index per unit decrease in design value would be expected in the Southwest and West regions (PA, Appendix 4D, section 4D.3.2.3 and 4D.5). The overall trend showing reductions in the W126 index concurrent with reductions in the design value metric for the current standard is positive whether the W126 index is expressed in terms of the average across the 3-year design value period or the annual value (PA, Appendix 4D, section 4D.3.2.3).

The available air quality information also indicates that the current standard's form and averaging time exerts control on other vegetation exposures of potential concern, such as days with particularly high O_3 concentrations that may contribute to visible foliar injury. The current form and averaging time, by their very definition, limit occurrences of such concentrations. This is demonstrated by reductions in daily maximum 8-hour concentrations, as well as in the frequency of elevated 1-hour concentrations, including concentrations at or above 100 ppb, with decreasing design values (PA, Figure 2–11, Appendix 2A, section 2A.2). As the form and averaging time of the secondary standard have not changed since 1997, the analyses have been able to assess the amount of control exerted by these aspects of the standard, in combination with reductions in the standard level (*i.e.,*

[196] Across the seventeen 3-year periods from 2000–2002 to 2016–2018, the number of monitoring sites with sufficient data for calculation of valid design values and W126 index values (across the 3-year design value period) ranged from a low of 992 in 2000–2002 to a high of 1119 in 2015–2017 (PA, Section 4.3).

[197] In 2015 the Administrator concluded that, with revision of the standard level, the existing form and averaging time provided the control of cumulative seasonal exposure circumstances needed for the public welfare protection desired (80 FR 65408, October 26, 2015).

[198] This evaluation, performed for all U.S. monitoring sites with sufficient data available in the most recent 3-year period, 2016 to 2018, indicates the extent to which the three single-year W126 index values within a 3-year period deviate from the average for the period. Across the full set of sites, regardless of W126 index magnitude (or whether or not the current standard is met), single-year W126 index values differ less than 15 ppm-hrs from the average for the 3-year period (PA, Appendix 4D, Figure 4D–6). For the approximately 850 sites meeting the current standard, over 99% of single-year W126 index values differ from the 3-year average by no more than 5 ppm-hrs, and 87% by no more than 2 ppm-hrs (PA, Appendix 4D, Figure 4D–7).

from 0.08 ppm in 1997 to 0.075 ppm in 2008 to 0.070 ppm in 2015), on cumulative seasonal exposures in terms of W126 index, and on the magnitude of short-term peak concentrations. These analyses indicate that the long-term reductions in the design values, presumably associated with implementation of the revised standards, were accompanied by reductions in W126 index, as well as in short-term peak concentrations.

b. Environmental Exposures in Terms of W126 Index

The analyses summarized here describe the nature and magnitude of vegetation exposures associated with conditions meeting the current standard at sites across the U.S., particularly in specially protected areas, such as Class I areas. Given the evidence indicating the W126 index to be strongly related to growth effects and its use in the E–R functions for tree seedling RBL (as summarized in section III.A.2.c above), exposure is quantified using the W126 metric. These analyses include a particular focus on monitoring sites in or near Class I areas,[199] in light of the greater public welfare significance of many O_3 related impacts in such areas, as described in section III.A.2.b above, and consider both recent air quality (2016–2018) and the air quality record since 2000 (PA, Appendix 4D). As was the case in the last review, the currently available quantitative information continues to indicate appreciable control of seasonal W126 index-based cumulative exposure at all sites with air quality meeting the current standard.

Among sites nationwide meeting the current standard in the recent period of 2016 to 2018, there are none with a W126 index, based on the 3-year average, above 19 ppm-hrs, and just one with such a value above 17 ppm-hrs (Table 4).[200] Additionally, the full historical dataset includes no occurrences of a 3-year average W126 index above 19 ppm-hrs for sites meeting the current standard, and just eight occurrences of a W126 index above 17 ppm-hrs (less than 0.1% of the dataset), with the highest such occurrence just equaling 19 ppm-hrs (Table 4; PA, Appendix 4D, section 4D.3.2.1).

With regard to Class I areas, the updated air quality analyses include data from sites in or near 65 Class I areas. The findings for these sites, which are distributed across all nine NOAA climate regions in the contiguous U.S., as well as Alaska and Hawaii, mirror the findings for the analysis of all U.S. sites in the dataset. Among the Class I area sites meeting the current standard (*i.e.,* having a design value at or below 70 ppb) in the most recent period of 2016 to 2018, there are none with a W126 index (averaged over the design value period) above 17 ppm-hrs (Table 4). The historical dataset includes just seven occurrences (all dating from the 2000–2010 period) of a Class I area site meeting the current standard and having a 3-year average W126 index above 17 ppm-hrs, and no such occurrences above 19 ppm-hrs (Table 4).

The W126 index values at sites that do not meet the current standard are much higher, with values at such sites ranging as high as approximately 60 ppm-hrs (PA, Appendix 4D, Figure 4D–3). Among all sites across the U.S. that do not meet the current standard in the 2016 to 2018 period, more than a quarter have average W126 index values above 19 ppm-hrs and a third exceed 17 ppm-hrs (Table 4). A similar situation exists for Class I area sites (Table 4). For example, out of the 11 Class I area sites with design values above 70 ppb during the most recent period, eight sites had a 3-year average W126 index above 19 ppm-hrs (with a maximum value of 47 ppm-hrs) and for nine, it was above 17 ppm-hrs (Table 4; PA, Appendix 4D, Table 4D–17).

TABLE 4—DISTRIBUTION OF 3-YR AVERAGE SEASONAL W126 INDEX FOR SITES IN CLASS I AREAS AND ACROSS U.S. THAT MEET THE CURRENT STANDARD AND FOR THOSE THAT DO NOT

3-year periods	Number of occurrences or site-DVs[A]							
	In Class I areas				Across all monitoring sites (urban and rural)			
	Total	W126 (ppm-hrs)			Total	W126 (ppm-hrs)		
		>19	>17	≤17		>19	>17	≤17
At sites that meet the current standard (design value at or below 70 ppb)								
2016–2018	47	0	0	47	849	0	1	848
All from 2000 to 2018	498	0	7	491	8,292	0	8	8,284
At sites that exceed the current standard (design value above 70 ppb)								
2016–2018	11	8	9	2	273	78	91	182
All from 2000 to 2018	362	159	197	165	10,695	2,317	3,174	7,521

[A] Counts presented here are drawn from the PA, Appendix D, Tables 4D–1, 4D–4, 4D–5, 4D–6, 4D–9, 4D–10 and 4D–13 through 16.

B. Conclusions on the Secondary Standard

In drawing conclusions on the adequacy of the current secondary standard, in view of the advances in scientific knowledge and additional information now available, the Administrator has considered the currently available welfare effects evidence and air quality and ecological exposure information. He additionally has considered the evidence base, information, and policy judgments that were the foundation of the last review, to the extent they remain relevant in light of the currently available information. The Administrator has taken into account both evidence-based and air quality and exposure-based considerations discussed in the PA, as well as advice from the CASAC and

[199] This includes monitors sited within Class I areas or the closest monitoring site within 15 km of the area boundary.

[200] Rounding conventions are described in detail in the PA, Appendix 4D, section 4D.2.2.

public comments. Evidence-based considerations draw upon the EPA's assessment and integrated synthesis of the scientific evidence as presented in the ISA, with a focus on policy-relevant considerations as discussed in the PA (summarized in sections III.B and III.D.1 of the proposal and section III.A.2 above). The air quality and exposure-based considerations draw from the results of the quantitative air quality analyses presented and considered in the PA (as summarized in section III.C of the proposal and section III.A.3 above). The Administrator additionally considered the August 2019 decision of the D.C. Circuit remanding the 2015 secondary standard for further justification or reconsideration.

The consideration of the evidence and air quality/exposure information in the PA informed the Administrator's proposed conclusions and judgments in this review, and his associated proposed decision. Section III.B.1 below briefly summarizes the basis for the Administrator's proposed decision, drawing from section III.D of the proposal. Section III.B.1.a provides a brief overview of key aspects of the policy evaluations presented in the PA, and the advice and recommendations of the CASAC are summarized in III.B.1.b. An overview of the Administrator's proposed conclusions is presented in section III.B.1.c. Public comments on the proposed decision are addressed below in sections III.B.2 and the Administrator's conclusions and decision in this review regarding the adequacy of the current secondary standard and whether any revisions are appropriate are described in section III.B.3.

1. Basis for Proposed Decision

a. Policy-Relevant Evaluations in the PA

The main focus of the policy-relevant considerations in the PA is consideration of the question: Does the currently available scientific evidence- and air quality and environmental exposure-based information support or call into question the adequacy of the protection afforded by the current secondary O_3 standard? The PA response to this overarching question takes into account discussions that address the specific policy-relevant questions for this review, focusing first on consideration of the evidence, as evaluated in the ISA, including that newly available in this review. The PA also considers the quantitative information available in this review that relates O_3 environmental exposures to vegetation responses (presented in Appendices 4A and 4C of the PA) and the air quality analyses that investigate relationships between air quality that meets the current standard and cumulative and peak exposures (presented in detail in Appendix 4D of the PA). The PA additionally discusses the key aspects of the evidence and exposure/risk estimates that were emphasized in establishing the current standard, and key aspects of the 2019 court remand on the standard. In so doing, the PA also considers associated public welfare policy judgments and judgments about the uncertainties inherent in the scientific evidence and quantitative analyses that are integral to the Administrator's consideration of whether the currently available information supports or calls into question the adequacy of the current secondary O_3 standard (PA, section 3.5).

Key policy-relevant considerations identified by the PA included the following. The new information available is consistent with that available in the last review for the principal effects for which the evidence is strongest (*e.g.,* growth, reproduction, and related larger-scale effects, as well as, visible foliar injury) and for key aspects of the decision in that review. The currently available information does not provide established quantitative relationships and tools for estimating incidence and severity of visible foliar injury in protected areas across the U.S. or provide information linking extent and severity of injury to aesthetic values that might be useful for considering public welfare implications. Further, the currently available evidence for forested locations across the U.S., such as studies of USFS biosites, does not indicate widespread incidence of significant visible foliar injury. Additionally, the evidence regarding RBL and air quality in areas meeting the current standard does not appear to call into question the adequacy of protection. For other vegetation-related effects that the ISA newly concludes likely to be causally related to O_3, the new information does not provide us an indication of the extent to which such effects might be anticipated to occur in areas that meet the current standard of a significance reasonably judged significant to public welfare. Thus, the PA does not find the current information for these newly identified categories to call into question the adequacy of the current standard. Similarly, the current information regarding O_3 contribution to radiative forcing or effects on temperature, precipitation and related climate variables is not strengthened from that available in the last review, including with regard to uncertainties that limit quantitative evaluations. Based on such considerations, discussed in detail in the PA, it concludes that the currently available evidence and quantitative exposure/risk information does not call into question the adequacy of the current secondary standard such that it is appropriate to consider retaining the current standard without revision. In so doing, it recognized that, as is the case in NAAQS reviews in general, the extent to which the Administrator judges the current secondary O_3 standard to be adequate will depend on a variety of factors, including science policy judgments and public welfare policy judgments.

b. CASAC Advice in This Review

In comments on the draft PA, the CASAC concurred with the PA conclusions, stating that it ''finds, in agreement with the EPA, that the available evidence does not reasonably call into question the adequacy of the current secondary ozone standard and concurs that it should be retained'' (Cox, 2020a, p. 1). The CASAC additionally stated that it ''commends the EPA for the thorough discussion and rationale for the secondary standard'' (Cox, 2020a, p. 2). The CASAC also provided comments particular to the consideration of climate and growth-related effects.

With regard to O_3 effects on climate, the CASAC recommended quantitative uncertainty and variability analyses, with associated discussion (Cox, 2020a, p. 2 and Consensus Responses to Charge Questions p. 22).[201] With regard to growth-related effects and consideration of the evidence in quantitative exposure analyses, it stated that the W126 index ''appears reasonable and scientifically sound,'' ''particularly [as] related to growth effects'' (Cox, 2020a, Consensus Responses to Charge Questions p. 16). Additionally, with regard to the prior Administrator's expression of greater confidence in judgments related to public welfare impacts based on a seasonal W126 index estimated by a three-year average and accordingly relying on that metric the CASAC expressed the view that this ''appears of reasonable thought and scientifically

[201] As recognized in the ISA, ''[c]urrent limitations in climate modeling tools, variation across models, and the need for more comprehensive observational data on these effects represent sources of uncertainty in quantifying the precise magnitude of climate responses to ozone changes, particularly at regional scales'' (ISA, section IS.6.2.2, Appendix 9, section 9.3.3, p. 9–22). These complexities impede our ability to consider specific O_3 concentrations in the U.S. with regard to specific magnitudes of impact on radiative forcing and subsequent climate effects.

sound'' (Cox, 2020a, Consensus Responses to Charge Questions p. 19). Further, the CASAC stated that ''RBL appears to be appropriately considered as a surrogate for an array of adverse welfare effects and based on consideration of ecosystem services and potential for impact to the public as well as conceptual relationships between vegetation growth effects and ecosystem scale effects'' and that it agrees ''that biomass loss, as reported in RBL, is a scientifically-sound surrogate of a variety of adverse effects that could be exerted to public welfare,'' concurring that this approach is not called into question by the current evidence which continues to support ''the use of tree seedling RBL as a proxy for the broader array of vegetation related effects, most particularly those related to growth that could be impacted by ozone'' (Cox, 2020a, Consensus Responses to Charge Questions p. 21). The CASAC additionally concurred that the strategy of a secondary standard that generally limits 3-year average W126 index values somewhat below those associated with a 6% RBL in the median species is ''scientifically reasonable'' and that, accordingly, a W126 index target value of 17 ppm-hrs for generally restricting cumulative exposures ''is still effective in particularly protecting the public welfare in light of vegetation impacts from ozone'' (Cox, 2020a, Consensus Responses to Charge Questions p. 21).

With regard to the court's remand of the 2015 secondary standard to the EPA for further justification or reconsideration (''particularly in relation to its decision to focus on a 3-year average for consideration of the cumulative exposure, in terms of W126, identified as providing requisite public welfare protection, and its decision to not identify a specific level of air quality related to visible foliar injury''), while the CASAC stated that it was not clear whether the draft PA had fully addressed this concern (Cox, 2020a, Consensus Responses to Charge Questions p. 21), it described there to be a solid scientific foundation for the current secondary standard and also commented on areas related to the remand. With regard to support in the information available in the current review for the focus on the 3-year average W126 index in assessing different patterns of air quality using median tree seedling RBL, in addition to the comments summarized above, the CASAC concluded, in considering the approach used in the last review, that reliance on the 3-year average and associated judgments in doing so ''appears of reasonable thought and scientifically sound'' (Cox, 2020a, Consensus Responses to Charge Questions p. 19). Further, while recognizing the existence of established E–R functions that relate cumulative seasonal exposure of varying magnitudes to various incremental reductions in expected tree seedling growth (in terms of RBL) and in expected crop yield, the CASAC letter also noted that while decades of research also recognizes visible foliar injury as an effect of O_3, ''uncertainties continue to hamper efforts to quantitatively characterize the relationship of its occurrence and relative severity with ozone exposures'' (Cox, 2020a, Consensus Responses to Charge Questions p. 20). In summary, the CASAC stated that the approach described in the draft PA to considering the evidence for welfare effects ''is laid out very clearly, thoroughly discussed and documented, and provided a solid scientific underpinning for the EPA conclusion leaving the current secondary standard in place'' (Cox, 2020a, Consensus Responses to Charge Questions p. 22).

c. Administrator's Proposed Conclusions

In reaching conclusions on the adequacy and appropriateness of protection provided by the current secondary standard and his proposed decision to retain the standard, the Administrator carefully considered: (1) The assessment of the available welfare effects evidence and conclusions contained in the ISA, with supporting details in the 2013 ISA and past AQCDs; (2) the evaluation of policy-relevant aspects of the evidence and quantitative analyses in the PA; (3) the advice and recommendations from the CASAC; (4) the August 2019 decision of the D.C. Circuit remanding the secondary standard established in the last review to the EPA for further justification or reconsideration; and (5) public comments that had been received up to that point (85 FR 49830, August 14, 2020). In considering the evidence base on welfare effects associated with exposure to photochemical oxidants, including O_3, in ambient air, he noted the newly available evidence, and the extent to which it alters key scientific conclusions from the last review. He additionally considered the quantitative analyses developed in this review, and their associated limitations and uncertainties, with regard to what they indicate regarding the protection provided by the current standard. Key aspects of the evidence and air quality and exposure information emphasized in establishing the current standard were also considered. Further, he considered uncertainties in the evidence and quantitative information as a part of public welfare policy judgments that are essential and integral to his decision on the adequacy of protection provided by the standard. In considering the CASAC advice, he noted the CASAC characterization of the ''thorough discussion and rationale for the secondary standard'' presented in the PA (Cox, 2020a, p. 2), and also considered the Committee's overall agreement that the currently available evidence does not call into question the adequacy of the current standard and that it should be retained (Cox, 2020a, p. 1).

As an initial matter, the Administrator recognized the continued support in the current evidence for O_3 as the indicator for photochemical oxidants, noting that no newly available evidence has been identified in this review on the importance of photochemical oxidants other than O_3 with regard to abundance in ambient air and potential for welfare effects. For such reasons, described with more specificity in the ISA and PA and summarized in the proposal, he proposed to conclude it to be appropriate to retain O_3 as the indicator for the secondary NAAQS for photochemical oxidants and he focused on the current information for O_3.

With regard to the currently available welfare effects evidence, the Administrator recognized that, consistent with the evidence in the last review, the currently available evidence describes an array of effects on vegetation and related ecosystem effects causally or likely to be causally related to O_3 in ambient air, as well as the causal relationship of tropospheric O_3 in radiative forcing and subsequent likely causally related effects on temperature, precipitation and related climate variables. The evidence for three additional categories of effects was newly determined in this review to be sufficient to infer likely causal relationships with O_3. However, the Administrator did not find the evidence for these effects to be informative to his proposed decision in review of the standard. For example, the Administrator noted the PA did not find the current evidence to indicate air quality under the current standard to cause increased tree mortality, and, accordingly, he found it appropriate to focus on more sensitive effects, such as tree seedling growth, in his review of the standard. With regard to the two insect-related categories of effects with new ISA determinations (alteration of plant-insect signaling and alteration of insect herbivore growth and reproduction), the Administrator noted the associated uncertainties in the evidence that preclude a full understanding of key aspects of the effects and indicate there to be insufficient information to judge the current standard inadequate based on these effects as described in the proposal.

In considering the evidence documenting tropospheric O_3 as a greenhouse gas causally related to radiative forcing, and likely causally related to subsequent effects on variables such as temperature and precipitation, the Administrator took note of the limitations and uncertainties in the evidence base that affect characterization of the extent of any relationships between O_3 concentrations in ambient air in the U.S. and climate-related effects. He found this to preclude quantitative characterization of climate responses to changes in O_3 concentrations in ambient air at regional (*versus* global) scales. This lack of quantitative tools precluding important analyses and the resulting uncertainty led the Administrator to conclude there to be insufficient information available for these effects in the current review to support judging the existing standard inadequate or to identify an appropriate revision.

With regard to visible foliar injury, the Administrator recognized that, depending on its severity and spatial extent, as well as the location(s) and intended use(s), the impact of visible foliar injury on the physical appearance of plants has the potential to be significant to the public welfare. For example, depending on its extent and severity, its occurrence in specially protected natural areas may affect aesthetic and recreational values, such as the aesthetic value of scenic vistas in protected natural areas (*e.g.,* national parks and wilderness areas). While recognizing there to be a paucity of information that relates incidence or severity of injury on vegetation in public lands to impacts on the public welfare (*e.g.,* related to recreational services), the Administrator noted the USFS BI scoring scheme, and proposed to judge that occurrence of the lower categories of BI scores does not pose concern for the public welfare, but that findings of BI scores categorized as ''moderate to severe'' injury by the USFS scheme would be an indication of visible foliar injury occurrence that, depending on extend and severity, may raise public welfare concerns.

While recognizing that important uncertainties remain in the understanding of the O_3 exposure conditions that will elicit visible foliar injury of varying severity and extent in natural areas, the Administrator took note of the evidence indicating a general association of injury incidence and severity with cumulative exposure metrics, including the W126 index, and also an influence of peak concentrations, as well as the quantitative analyses in the PA of USFS biosite data and of air quality monitoring data. In the PA analysis of biosite scores, the incidence of nonzero BI scores, and particularly of relatively higher scores, such as those indicative of ''moderate to severe'' injury in the USFS scheme, appear to markedly increase only with W126 index values above 25 ppm-hrs. The Administrator noted that such a magnitude of W126 index (either as a 3-year average or in a single year) is not seen to occur at monitoring locations in or near Class I areas where the current standard is met (and such a W126 index, in a single year, has occurred only once in 19 years of monitoring data at sites across the U.S.), and that values above 17 or 19 ppm-hrs are rare (PA, Appendix 4C, section 4C.3; Appendix 4D, section 4D.3.2.3; 85 FR 49911, August 14, 2020). The Administrator further took note of the PA consideration of the USFS publications that identify an influence of peak concentrations on BI scores (beyond an influence of cumulative exposure) and the PA observation of the appreciable control of peak concentrations exerted by the form and averaging time of the current standard, as evidenced by the air quality analyses which document reductions in 1-hour daily maximum concentrations with declining design values. Based on these considerations, the Administrator agreed with the PA finding that the current standard provides control of air quality conditions that contribute to increased BI scores and to scores of a magnitude indicative of ''moderate to severe'' foliar injury. Based on his consideration of PA findings that areas that meet the current standard are unlikely to have BI scores reasonably considered to be impacts of public welfare significance, the Administrator further proposed to conclude that the current standard provides sufficient protection of natural areas, including particularly protected areas such as Class I areas, from O_3 concentrations in the ambient air that might be expected to elicit visible foliar injury of such an incidence and severity as would reasonably be judged adverse to the public welfare.

With regard to the welfare effects of reduced plant growth or yield, the Administrator recognized that the evidence base continues to indicate growth-related effects as sensitive welfare effects, with the potential for ecosystem-scale ramifications. While recognizing associated uncertainties, the Administrator took note of the PA conclusion and CASAC advice that the approach taken in the last review of using estimates of O_3 impacts on tree seedling growth (in terms of RBL) as a surrogate for comparable information on other species and lifestages, as well as a proxy or surrogate for other vegetation-related effects, including larger-scale effects, continues to appear to be a reasonable judgment in the current review (85 FR 49910, August 14, 2020; PA, section 4.5.3). These estimates were medians based on the established E–R functions for 11 tree species. In light of this and the lack of an alternative metric or approach being indicated by the current evidence, the Administrator found it appropriate to adopt this approach in the current review.

The Administrator additionally took note of considerations in the PA regarding aspects of the derivation of the tree seedling E–R functions that he found informative to his consideration of issues discussed in the court's remand of the 2015 secondary standard with respect to use of a 3-year average W126. In this context, the Administrator considered whether aspects of this evidence support making judgments using the E–R functions with W126 index derived as an average across multiple years. He noted that such averaging would have some conceptual similarity to the assumptions underlying the adjustment made to develop seasonal W126 E–R functions from exposures that extended over multiple seasons (or less than a single season).[202] The Administrator also noted uncertainties in regard to estimated RBL at lower cumulative exposure levels, given the more limited data and fewer findings of statistical significance supporting the functions at the relatively lower cumulative exposure levels most commonly

[202] The E–R functions for the 11 species were derived in terms of a seasonal W126 index from experiments that varied in duration from less than three months to many more. Underlying the adjustments made to derive the functions for a 3-month season duration are simplifying assumptions of uniform W126 distribution over the exposure period and linear relationship between cumulative exposure duration and response. Averaging of seasonal W126 across three years, with its reduction of the influence of annual variations in seasonal W126, would give less influence to RBL estimates derived from such potentially variable representations of W126, thus providing an estimate of W126 considered more suitably paired with the E–R functions.

associated with the current standard (*e.g.,* at or below 17 ppm-hrs). The Administrator additionally took note of the PA summary of different comparisons that had been performed in the 2013 ISA and the current ISA of RBL estimated via the aspen E–R function using either a cumulative average multi-year W126 index (2013 ISA) or a single-year W126 index (current ISA) with RBL estimates derived directly from aspen growth information in a multi-year O_3 exposure study. In this context, he noted the PA finding that consideration of these two different comparisons illustrate the variability inherent in the magnitude of growth impacts of O_3 and in the quantitative relationship of O_3 exposure and RBL,[203] while also providing general agreement of predictions (based on either metric) with observations. In light of these considerations, the Administrator recognized that such factors as identified in the proposal, including the currently available evidence and its recognized limitations, variability and uncertainties, support a conclusion that it is reasonable to use a seasonal RBL averaged over multiple years, such as a 3-year average (85 FR 49910, August 14, 2020). The Administrator additionally took note of the CASAC advice reaffirming the EPA's focus on a 3-year average W126, concluding such a focus to be reasonable and scientifically sound. In light of these considerations, the Administrator found there to be support for use of an average seasonal W126 index derived from multiple years (with their representation of variability in environmental factors), concluding the use of such averaging to provide an appropriate representation of the evidence and attention to considerations summarized above. In so doing, he found that a reliance on single year W126 estimates for reaching judgments with regard to magnitude of O_3-related RBL and associated judgments of public welfare protection would ascribe a greater specificity and certainty to such estimates than supported by the current evidence. Thus, he proposed to conclude that it is appropriate to use a seasonal W126 averaged over a 3-year period, which is the design value period for the current standard, to estimate median RBL using the established E–R functions for purposes in this review of considering the public welfare protection provided by the standard.

[203] For example, there is variability associated with tree growth in the natural environment (*e.g.,* related to variability in plant, soil, meteorological and other factors), as well as variability associated with plant responses to O_3 exposures in the natural environment (85 FR 49910, August 14, 2020).

In reaching his proposed conclusions and judgments related to the use of RBL as a surrogate for the broad array of vegetation-related effects, the Administrator recognized a number of important public welfare policy judgments. The Administrator proposed to conclude that the current evidence base and available information (qualitative and quantitative) continue to support consideration of the potential for O_3-related vegetation impacts in terms of the RBL estimates from established E–R functions as a quantitative tool within a larger framework of considerations pertaining to the public welfare significance of O_3 effects. He judged the framework to include consideration of effects that are associated with effects on vegetation, and particularly those that conceptually relate to growth, and that are causally or likely causally related to O_3 in ambient air, yet for which there are greater uncertainties affecting estimates of impacts on public welfare. In his consideration of the adequacy of protection provided by the current standard, the Administrator also noted judgments of the prior Administrator in considering the public welfare significance of small magnitude estimates of RBL and associated unquantified potential for larger-scale related effects. In light of CASAC advice and based on the current evidence as evaluated in the PA, the Administrator proposed to conclude that the approach or framework initially described with the 2015 decision, with its focus on controlling air quality such that cumulative exposures at or above 19 ppm-hrs, in terms of a 3-year average W126 index, are isolated and rare, is appropriate for a secondary standard that provides the requisite public welfare protection and proposed to use such an approach in this review (85 FR 49911, August 14, 2020).

With this approach and protection target in mind, the Administrator considered the analyses of air quality at sites across the U.S., particularly including those sites in or near Class I areas. In virtually all design value periods and all locations at which the current standard was met (*i.e.,* in more than 99.9% of such instances) across the 19 years of the data analyzed, the 3-year average W126 metric was at or below 17 ppm-hrs. Further, in all such design value periods and locations the 3-year average W126 index was at or below 19 ppm-hrs. The Administrator additionally considered the protection provided by the current standard from the occurrence of O_3 exposures within a single year with potentially damaging consequences, such as a significantly increased incidence of areas with visible foliar injury that might be judged moderate to severe. In so doing, he noted the PA findings that incidence of sites with BI scores above 15 (termed ''moderate to severe injury'' by the USFS categorization scheme) markedly increases with W126 index estimates above 25 ppm-hrs, and the scarcity of single-year W126 index values above 25 ppm-hrs at sites that meet the current standard, with just a single occurrence across all U.S. sites with design values meeting the current standard in the 19-year historical dataset dating back to 2000 (PA, section 4.4 and Appendix 4D). In light of the evidence indicating that peak short-term concentrations (*e.g.,* of durations as short as one hour) may also play a role in the occurrence of visible foliar injury, the Administrator additionally recognized the control of peak 1-hour concentrations provided by the form and averaging time of the current standard and noted there to be less than one day per site with a maximum hourly concentration at or above 100 ppb (PA, Appendix 2A, section 2A.2). In consideration of these findings, the Administrator proposed to judge that the current standard provides adequate protection from air quality conditions with the potential to be adverse to the public welfare (85 FR 49912, August 14, 2020).

In reaching his proposed decision, the Administrator gave primary attention to the principal effects of O_3 as recognized in the current ISA, the 2013 ISA and past AQCDs, and for which the evidence is strongest (*e.g.,* growth, reproduction, and related larger-scale effects, as well as visible foliar injury). With respect to the currently available information related to O_3-related visible foliar injury, the Administrator considered air quality analyses that may be informative with regard to air quality conditions associated with appreciably increased incidence and severity of BI scores at USFS biomonitoring sites, noting that this information does not indicate a potential for public welfare impacts of concern under air quality conditions that meet the current standard. In light of these and other considerations discussed more completely in the proposal, and with particular attention to Class I and other areas afforded special protection, the Administrator proposed to conclude that the evidence regarding visible foliar injury and air quality in areas meeting the current standard indicates that the current standard provides adequate protection for this effect.

The Administrator additionally considered O_3 effects on crop yield, taking note of the long-standing evidence, qualitative and quantitative, of the reducing effect of O_3 on the yield of many crops, as summarized in the PA and current ISA and characterized in detail in past reviews (*e.g.,* 2013 ISA, 2006 AQCD, 1997 AQCD, 2014 WREA). In so doing, he recognized that not every effect on crop yield will be adverse to public welfare and in the case of crop yield effects in particular there are a number of complexities related to the heavy management of many crops to obtain a particular output for commercial purposes, and to other factors, that contribute uncertainty to predictions of potential O_3-related public welfare impacts, as summarized in sections III.B.2 and III.D.1 of the proposal (PA, sections 4.5.1.3 and 4.5.3). Thus, in judging the extent to which the median RYL estimated for the W126 index values generally occurring in areas meeting the current standard would be expected to be of public welfare significance, he recognized the potential for a much larger influence of extensive management of such crops, and also considered other factors recognized in the PA and proposal, including similarities in median estimates of RYL and RBL (PA, sections 4.5.1.3 and 4.5.3). With this context, the information for crop yield effects did not lead the Administrator to identify this endpoint as requiring separate consideration or to provide a more appropriate focus for the standard than RBL, in its role as a proxy or surrogate for the broader array of vegetation-related effects, as discussed above. Rather, in light of these considerations, he proposed to judge that a decision based on RBL as a proxy for other vegetation-related effects will provide adequate protection against crop related effects. In light of the current information and considerations discussed more completely in the proposal, the Administrator further proposed to conclude that the evidence regarding RBL, and its use as a proxy or surrogate for the broader array of vegetation-related effects, in combination with air quality in areas meeting the current standard, provide adequate protection for these effects (85 FR 49912, August 14, 2020).

In reaching his proposed conclusion on the current standard, the Administrator also considered the extent to which the current information may provide support for an alternative standard, proposing to conclude that the appreciably greater occurrence of higher levels of cumulative exposure, in terms of the W126 index, as well as an appreciably greater occurrence of peak concentrations (both hourly and 8-hour average concentrations) in areas that do not meet the current standard (*e.g.,* areas meeting a higher standard level), would not provide the appropriate protection of public welfare in light of the potential for adverse effects on the public welfare. The Administrator also considered an alternative based solely on the W126 metric, as was considered in the last review, based on such a concentration-weighted, cumulative exposure metric having been identified as quantifying exposure in a way that relates to reduced plant growth (ISA, Appendix 8, section 8.13.1). While recognizing a role for W126 index in quantifying exposure to develop estimates of RBL that the Administrator considers appropriately used as a proxy or surrogate for the broader array of vegetation-related effects, he notes that the evidence indicates there to be aspects of O_3 air quality not captured by measures of cumulative exposure like W126 index that may pose a risk of harm to the public welfare (*e.g.,* risk of visible foliar injury related to peak concentrations). Thus, in light of the information available in this review, the Administrator proposed to conclude that such an alternative standard in terms of a W126 index would be less likely to provide sufficient protection against such occurrences and accordingly would not provide the requisite control of aspects of air quality that pose risk to the public welfare.

In summary, the Administrator recognized that his proposed decision on the public welfare protection afforded by the current secondary O_3 standard from identified O_3-related welfare effects, and from their potential to present adverse effects to the public welfare, is based in part on judgments regarding uncertainties and limitations in the available information, such as those identified above. In this context, he considered what the available evidence and quantitative information indicated with regard to the protection provided from the array of O_3 welfare effects, finding it to not indicate the current standard to allow air quality conditions with implications of concern for the public welfare. He additionally took note of the advice from the CASAC in this review. Based on all of the above considerations, described in more detail in the proposal, including his consideration of the currently available evidence and quantitative exposure/risk information, the Administrator proposed to conclude that the current secondary standard provides the requisite protection against known or anticipated effects to the public welfare, and thus that the current standard should be retained, without revision.

3. Comments on the Proposed Decision

Over 50,000 individuals and organizations indicated their views in public comments on the proposed decision. Most of these are associated with mass mail campaigns or petitions. Approximately 40 separate submissions were also received from individuals, and 75 from organizations and groups of organizations; 40 elected officials also submitted comments. Among the organizations commenting were state and local agencies and organizations of state agencies, organizations of health professionals and scientists, environmental and health protection advocacy organizations, industry organizations and regulatory policy-focused organizations. The comments on the proposed decision to retain the current secondary standard are addressed here. Those in support of the proposed decision are addressed in section III.B.2.a and those in disagreement are addressed in section III.B.2.b. Comments related to aspects of the process followed in this review of the O_3 NAAQS (described in section I.D above), as well as comments related to other legal, procedural or administrative issues, and those related to issues not germane to this review are addressed in the separate Response to Comments document.

a. Comments in Support of Proposed Decision

Of the comments supporting the Administrator's proposed decision to retain the current secondary standard without revision, all generally state that the record supports the proposed decision, and note the CASAC conclusion that the current evidence is generally consistent with that available in the last review, and the CASAC conclusion that the evidence does not call into question the adequacy of the current standard and should be retained. In support of their views, some of these commenters state that new evidence is lacking that might call into question the objective for the standard to generally protect against cumulative exposures associated with median RBL estimates above 6%. They additionally state that the proposed decision appropriately addresses the *Murray Energy* remand issues. Further, these commenters conclude that the available evidence with regard to areas meeting the current standard does not call into question the adequacy of protection provided by the current standard from the array of vegetation effects, including in Class I areas. Lastly, these commenters find the EPA's proposed judgments regarding the uncertainties associated with predicting responses of climate-related effects to changes in O_3 concentrations across the U.S., as well as the limitations in the availability of tools for such purposes, to be appropriate and well supported. The EPA agrees with these comments.

Some of these comments also express the view that welfare benefits of a more restrictive O_3 standard are highly uncertain, while such a standard would likely cause socioeconomic impacts that the EPA should consider and find to outweigh the uncertain benefits. While as discussed in section III.B.3 below, the Administrator does not find a more stringent secondary standard requisite to protect the public welfare, he does not consider economic impacts of alternate standards in reaching this judgment. As summarized in section I.A. above, in setting primary and secondary standards that are ''requisite'' to protect public health and welfare, respectively, as provided in section 109(b), the EPA may not consider the costs of implementing the standards. See generally *Whitman* v. *American Trucking Ass'ns,* 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.'' See *American Petroleum Institute* v. *Costle,* 665 F.2d 1176, 1185 (D.C. Cir. 1981); *accord Murray Energy Corp.* v. *EPA,* 936 F.3d 597, 623–24 (D.C. Cir. 2019). Arguments such as the views on socioeconomic impacts expressed by these commenters have been rejected by the courts, as summarized in section I.A above, including in the recent *Murray Energy* decision, with the reasoning that consideration of such impacts was precluded by *Whitman's* holding that the ''plain text of the Act unambiguously bars cost considerations from the NAAQS-setting process'' (*Murray Energy Corp.* v. *EPA,* 936 F.3d at 621, quoting *Whitman* [531 U.S. at 471]).

b. Comments in Disagreement With Proposed Decision

Among those submitting comments that disagreed with the proposed decision to retain the current secondary standard, or that raised concerns with the basis for the decision, most of these commenters expressed concerns regarding the process for reviewing the criteria and standards and state that the proposal must be withdrawn, and a new review conducted. Most of these commenters also disagree with the EPA's proposed conclusion that the current standard, with its current averaging time and form, provides the requisite public welfare protection from known or anticipated adverse public welfare effects associated with the array of O_3-related effects, and generally state that the standard should be revised to be in terms of a single-year W126 index. Among the claims made in describing the basis for their view, these commenters claim that EPA failed to describe the basis for its proposed conclusion; to explain why a standard using the W126 index was not proposed, consistent with 2014 advice from the former CASAC, and to address the issues raised by court remand of the 2015 standard. Some commenters expressing the view that the standard should be revised also express the view that an additional standard should be established to protect from O_3 effects on climate.

With regard to the process by which this review has been conducted, we disagree with the commenters that claim that it is arbitrary and capricious or that it does not comport with legislative requirements. The review process, summarized in section I.D, implemented a number of features, some of which have been employed in past reviews and others which have not, and several which represent efficiencies in consideration of the statutorily required time frame for completion of the review. The comments received that raise concerns regarding specific aspects of the process are addressed in the separate Response to Comments document. As indicated there, the EPA disagrees with these comments. The EPA finds the review to have been lawfully conducted and the process reasonably explained. Accordingly, the EPA is not withdrawing the proposal and restarting the review.

(i) Metric for Standard

The premise of many of the comments expressing disagreement with the proposed decision is that the secondary standard must be a ''biologically relevant'' metric, which they identify to be the W126 index. Similarly, some commenters assert that EPA cannot lawfully or rationally set a secondary standard using the metric of the current standard, which is also the metric used for the primary standard, claiming that this contradicts EPA's recognition of the relevance of the W126 index as an exposure metric for assessing the level of protection from welfare effects, such as RBL. These commenters also claim that this approach arbitrarily disregards the recommendations of the prior CASAC, and, in doing so, imply that EPA must establish a W126 based standard because of prior CASAC advice.

We disagree with these commenters. The Clean Air Act includes no requirements with respect to what metrics should be used to establish the secondary standards. As is clear from the text of Section 109(b)(2) of the CAA, the critical test for NAAQS is whether they achieve the requisite protection. In so doing, it is not uncommon for the form and averaging time of a NAAQS to differ from exposure metrics most relevant to assessment of particular effects. These exposure metrics are based on the health or welfare effects evidence for the specific pollutant and commonly, in assessments for primary standards, on established exposure-response relationships or health-based benchmarks (doses or exposures of concern) for effects associated with specific exposure circumstances. Evidence for this is found in the common use, in assessments conducted for NAAQS reviews, of exposure metrics that differ in a variety of ways from the ambient air concentration metrics of those standards.[204] Across reviews for the various NAAQS pollutants over the years, the EPA has used a variety of exposure metrics to evaluate the protection afforded by the standards (see examples identified at 80 FR 65399–65400, October 26, 2015). Further, a single standard may provide protection from multiple different effects, the protection for which may be assessed using different exposure metrics. One standard may also provide protection from multiple pathways of exposure. Both the primary and secondary Pb standards provide examples of this. While these standards are expressed in terms of the concentration of lead in particles suspended in air, different exposure metrics have been used to evaluate the protection provided by the Pb standards. The salient exposure metric for assessment of protection provided by the primary standard has been blood Pb, while for the secondary standard, concentrations of lead in soil, surface water and sediment are pertinent, and have been evaluated to assess the potential for welfare effects related to lead deposition from air (73 FR 67009, November 12, 2008). In somewhat similar manner, the exposure metric used to evaluate health impacts in the primary sulfur dioxide standard review includes a 5-minute exposure

[204] The term design value, defined above, is used in this discussion to refer to the metric for the standard.

concentration. In contrast, the health-based standard for this pollutant is the average across three years of the 99th percentile of 1-hour daily maximum concentration of sulfur dioxide in ambient air (75 FR 35520, June 22, 2010; 84 FR 9866, March 18, 2019).

We disagree with the comment that a secondary standard with the same form and averaging time as the primary standard does not comply with the CAA. The CAA does not require that the secondary standard be established in a specific form or averaging time. The Act, at Section 109(b)(2), provides only that any secondary NAAQS ''shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on [the air quality] criteria, 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. . . . [S]econdary standards may be revised in the same manner as promulgated.'' The EPA interprets this provision to leave it considerable discretion to determine whether a particular form and averaging time are appropriate, in combination with the other aspects of the standard (level and indicator), for specifying the air quality that provides the requisite protection, and to determine whether, once a standard has been established in a particular form, that form must be revised. Moreover, nothing in the Act or the relevant case law precludes the EPA from establishing a secondary standard equivalent to the primary standard in some or all respects, as long as the Agency has engaged in reasoned decision-making.[205]

Thus, we note that particular metrics may logically, reasonably, and for technically or scientifically sound reasons, be used in assessing exposures of concern or characterizing risk. The purpose, and use, of exposure metrics is different from the purpose, and use, of metrics for the standard, and as a result the metrics may differ from one use to the other. Exposure metrics are used to assess the likely occurrence and/or frequency and extent of effects under different air quality conditions, while the air quality standards are intended to control air quality to the extent requisite to protect from the occurrence of public health or welfare effects judged to be adverse. In this review of the O_3 secondary standard, the EPA agrees that based on evidence summarized in section III.A above, metrics such as the W126 index are appropriate for assessing exposures of concern for vegetation, characterizing risk to public welfare, and evaluating what air quality conditions might provide the appropriate degree of public welfare protection. We disagree, however, that the secondary standard must be established using those same metrics. Rather, when the Administrator judges that a standard using a different metric provides the requisite protection, in light of his consideration of all the elements of the standard together, he may reasonably establish or retain such a standard.

With regard to the commenter's emphasis on recommendations from the CASAC on the form of the secondary standard, the EPA generally agrees with the importance of giving such recommendations careful consideration. However, it is not necessary for EPA to address in this review each statement a prior CASAC made in a prior review. In addition, if a recommendation of a prior CASAC is raised in a subsequent review (*e.g.,* in public comments or as a focus in court decision being addressed), it is reasonable for the Agency to consider it in the context both of the current review and of consideration of all the other now available scientific, technical and policy-relevant information, including advice from the current CASAC. We note that in this review of the secondary standard, the current CASAC, based on its review of the information and analyses available in the current review, concurs with retention of a secondary standard with a metric that differs from commonly used vegetation exposure metrics, such as the W126 index (Cox, 2020a). We further note, under the relevant provisions of the CAA and case law interpreting them, the Administrator is never bound by the CASAC's conclusions but rather may depart from them when he has provided an explanation of the reasons for such differences.[206] While the EPA does not interpret the requirements of CAA sections 307(d)(3) and 307(d)(6)(A) to apply to every recommendation it has received from a prior CASAC, even assuming there are some circumstances in which EPA were required to comply with the requirements of CAA section 307(d)(3) and (6)(A) with respect to particular recommendations from a prior CASAC, these same principles would apply. Thus, the Administrator would not be bound to follow those recommendations, but rather could depart from them when he had explained his reasons for doing so. Accordingly, in reaching conclusions on the revised secondary standard in this review, the Administrator has given careful consideration to the current CASAC advice in this review and to issues raised by the prior CASAC that are subject to the *Murray Energy* remand. When he has differed from those CASAC recommendations, the reasons and judgments that led to a different conclusion are explained, as summarized in this section and in section III.B.3 below. Consistent with his consideration of all significant issues raised in public comments, the Administrator has also considered the issues raised by commenters that have also been raised by a prior CASAC, together with the Agency's responses to those comments, as summarized in this section and in section III.B.3 below.

The current air quality analyses demonstrate the successfulness of the current form and averaging time in controlling cumulative exposures, in terms of W126. These extensive air quality analyses, presented in the PA and summarized in the proposal, are based on data collected across the U.S. over a time span of nearly 20 years (85 FR 49892–49895, 49903–49904, August 14, 2020). One of these analyses describes the positive, linear relationship between long-term changes in the O_3 design value and long-term changes in the W126 index at monitoring sites across the U.S.[207] This positive, linear relationship exists for the O_3 design value with both a 3-year average and single-year W126 index (PA, Appendix 4D, Figure 4D–11). The existence of this relationship means that a change (*e.g.,* reduction) in the design value at a monitoring site was generally accompanied by a similar change (*e.g.,* reduction) in the W126 index, both in the 3-year average and in the single-year values. As the form and averaging time of the secondary standard have not changed since 1997, the analyses performed have been able to assess the amount of control exerted by these aspects of the standard, in combination

[205] In fact, the D.C. Circuit has upheld secondary NAAQS that were identical to the corresponding primary standard for the pollutant (*e.g., ATA III,* 283 F.3d at 375, 380 [D.C. Cir. 2002, upholding secondary standards for $PM_{2.5}$ and O_3 that were identical to primary standards]).

[206] See CAA sections 307(d)(3) and 307(d)(6)(A); see also *Mississippi* v. *EPA,* 744 F.3d 1334, 1354 (D.C. Cir. 2013) (''Although EPA is not bound by CASAC's recommendations, it must fully explain its reasons for any departure from them''); *id.* at 1358 (noting CASAC, like EPA, exercises both scientific judgment and public health policy judgment). Selection of a metric for the standard is a public health or public welfare policy judgment about what standards will control air quality to the extent judged requisite to protect from adverse public health or welfare effects.

[207] This analysis focuses on the relationship between changes (at each monitoring site) in the 3-year design value across the 17 design value periods from 2000–2002 to 2016–2018 and changes in the W126 index over the same period (PA, Appendix 4D, section 4D.3.2.3).

with reductions in the level (*i.e.,* from 80 ppb in 1997 to 75 ppb in 2008 to 70 ppb in 2015) on cumulative seasonal exposures in terms of W126 index. The analyses have found that the reductions in design value, presumably associated with implementation of the revised standards, have been accompanied by reductions in cumulative seasonal exposures in terms of W126 index (PA, section 4.4.1). Further, while the formulation of the W126 metric gives more weight to higher concentrations (in the context of its focus on cumulative exposure), it is much less effective at curbing elevated hourly concentrations (that can be important in altering plant growth and yield) than the current design value metric, as discussed in section III.B.2.b(ii) below.

In expressing the view that the secondary standard should be in terms of a W126 index, some commenters describe the EPA's statements regarding the protection from cumulative exposures that is provided by the current form and averaging time to be ''incidental'' and ''happenstance,'' which leads them to claim the EPA's findings of protection to be arbitrary. In support of their view, the commenters quote a statement of the prior CASAC cautioning against interpreting the W126 index levels in the W126 index scenario created for the 2014 WREA, by first adjusting air quality to meet the then-existing fourth maximum standard of 75 ppb, to be representative of implementation of a W126 index standard. The issue described by the prior CASAC related to the application to all monitoring sites of the precursor reduction necessary for the highest monitoring site in a region to just meet the scenario target; the prior CASAC's concern was that actual implementation of the target as a standard would not necessarily yield such reductions. We disagree with the commenters that this is relevant to the air quality analysis in the current review, in which we simply observe the W126 index values that exist in reality at sites that have met the existing secondary standard. Contrary to the context for the prior CASAC's caution, the analysis in the current review is not showing the results of a theoretical scenario created by modeling theoretical precursor reductions estimated for attaining a particular W126-based or fourth high standard. Rather, we are observing what the W126-based cumulative exposure is at ambient air monitoring sites that meet the current secondary standard. Thus, regardless of the labels assigned by the commenter to the findings of the air quality analyses in the current review, these analyses clearly document the success of the existing standard (with its fourth maximum form and 8-hour averaging time) in controlling exposure in terms of the W126 index.

Thus, in light of this evidence, the EPA disagrees with the commenters who express the view that to provide the requisite protection the secondary standard must be a W126 index standard. In assessing the air quality necessary to provide the requisite degree of protection, particularly for growth and related vegetation and ecosystem effects, the Agency has recognized the importance of cumulative exposures, but also the significance of higher peak exposures (as summarized in section III.B.2.b(ii) below) that can be characterized through other metrics (*e.g.,* N100). As a result, in assessing the protection provided by the current standard, the Agency has focused on the W126 index, expressed in terms of the average of three consecutive years (in light of considerations discussed below), as a metric for cumulative exposure, but has also considered the frequency and magnitude of elevated single-year W126 index values, and of elevated hourly O_3 concentrations (as discussed further below).

(ii) Protection Against Unusually Damaging Years

In the last review, the Administrator relied on the 70 ppb standard (as the fourth highest daily maximum 8-hour average concentration averaged over three consecutive years) to achieve a level of air quality that would restrict cumulative seasonal exposures to 17 ppm-hrs or lower, in terms of a 3-year average W126 value, in nearly all instances. The *Murray Energy* court found in relevant part that the EPA had not explained why that level of protection was requisite, in light of certain comments from the CASAC in 2014 recommending that EPA base a standard on a one-year W126 metric, in part to limit exposures in single unusually damaging years.[208] In responding to the remand,[209] we are explaining in this document that the EPA is looking to prevent the damaging effects of O_3 on tree growth as a proxy for public welfare effects related to the broad array of O_3's vegetation-related effects conceptually related to growth effects, including ecosystem-level effects (as discussed in section III.B.2.b(v) below). In this review, in assessing the air quality requisite to prevent adverse effects on public welfare from these effects, the EPA is not relying solely on maintaining a particular 3-year W126 value. Rather, we are considering air quality patterns that are associated with meeting the current standard, including control of peak hourly concentrations, and the exposures that would be expected under the current standard, including in terms of W126 values, particularly those averaged over a 3-year period. The EPA is explaining the grounds for our conclusion that use of the 3-year average W126 index is a reasonable basis for assessing protection from RBL, but also that the Administrator is using other exposure information in reaching the conclusion that retention of the existing standard (with its form and averaging time of the fourth highest annual daily maximum 8-hour average concentration, averaged over three years) provides the needed protection of RBL, including from what the *Murray Energy* court noted that the prior CASAC termed ''unusually damaging years.''

In disagreeing with the EPA's proposed decision, some commenters object to the EPA's use of a 3-year average W126 index in assessing different patterns of air quality using median tree seedling RBL as a surrogate for an array of vegetation-related effects, particularly those related to growth and productivity. In so doing, these commenters variously claim that this use of a 3-year average W126 index (rather than a single-year W126 index) is inconsistent with recommendations from the prior CASAC, does not address the court remand on this point, and that it is inadequate to protect vegetation from high years or years with hourly O_3 concentrations that can be most important in eliciting adverse effects.

The EPA disagrees with these commenters and notes that it has taken such concerns, as well as the court's remand, into account in the final decision. In evaluating the air quality

[208] The prior CASAC comments on this matter were in the context of its recommendation for a secondary standard in the form of a single-year W126 index, which as discussed below would be expected to provide relatively less control against high-concentration years compared with the current secondary standard. The prior CASAC additionally commented that it ''favor[ed] a single-year period'' which it stated would ''provide more protection for annual crops and for the anticipated cumulative effects on perennial species.'' The prior CASAC continued on to state that if the Administrator preferred, instead, to establish a secondary standard as a 3-year average W126 index, as a policy matter, the level should be revised downward (Frey, 2014b, p. iii). The prior CASAC stated the purpose for this step would be to be protecting ''against single unusually damaging years that will be obscured in the average'' (Frey, 2014b, p. 13).

[209] The Agency intends this decision, associated analyses conducted for this review in consideration of issues raised by the court's remand, and the discussions herein to constitute its response to the Murray Energy remand on this issue.

conditions allowed by the current standard, the EPA has focused on the W126 metric averaged over 3 years as the most appropriate measure of cumulative exposure for consideration of adverse effects on public welfare, but EPA has also considered other relevant exposure information, including higher exposures that might be expected to occur in an ''unusually damaging year.'' The Administrator's decision on the adequacy of protection provided by the current standards is based on the full scope of exposure information he has considered.

The EPA concludes that the 3-year average W126 index is a reasonable metric for assessing the level of protection provided by the current standard from cumulative seasonal exposures related to RBL, while noting that our evaluation for the protection provided by the current standard has also been informed by our consideration of other metrics (as described further below). In reaching this conclusion, we have taken into account the available evidence base and air quality analyses, with a focus on two types of considerations, as well as consideration of the context for RBL as a proxy for an array of other vegetation effects (discussed in section III.B.2.b(v) below). The first of the two consideration types concerns the E–R functions and their use with a 3-year average W126 index, and the second concerns the control by the W126 index metric of exposures that might be termed ''unusually damaging.'' With regard to the first, we find our use of the 3-year average W126 index appropriate in light of the approach used in deriving the E–R functions from the underlying data (from exposures of varying durations, including of multiple years), and the evidence available for evaluating these functions across multiyear exposures.[210] Additionally, with regard to the second consideration, we recognize limitations associated with a reliance solely on W126 index as a metric to control exposures that might be termed ''unusually damaging.'' For example, two different air quality patterns for which the associated W126 index is the same may have very different incidence of elevated O_3 concentrations, and accordingly pose different risks to vegetation. As discussed below, however, the occurrence of such concentrations (and any associated risk of damage) are controlled by the current secondary standard.

In light of this evidence, and recognizing the role for both peak and cumulative exposures in eliciting growth and related vegetation and ecosystem effects, the EPA concludes that focusing solely on W126 index (either in terms of a single year or 3-year average) in considering the public welfare protection provided by the current standard would not be considering all the relevant scientific information. To the extent that the prior CASAC advised that the EPA should focus solely on single-year W126 index values in evaluating the protection provided by the secondary standard, the EPA disagrees that this would provide the needed protection, for the reasons explained more fully below. In this regard, we additionally note that the current CASAC concluded that focusing on three-year average W126 index values in considering the public welfare protection offered by the secondary standard ''appears of reasonable thought and scientifically sound'' (Cox, 2020a, p. 19).

With regard to the established tree seedling E–R functions, we note there are aspects of the datasets and methodology on which the E–R functions are based which provide support for a 3-year average approach. As summarized in section III.A.2.c(i) above, in deriving the E–R functions from studies of durations that varied from shorter than 90 days to multiple years or growing seasons, the results were normalized to the duration of a single 90-day seasonal period (PA, section 4.5.1.2 and Appendix 4A, pp. 4A–28 to 4A–29 and footnote 17). Inherent in this approach is an assumption that the growth impacts relate generally to the cumulative O_3 exposure across the multiple growing seasons, *i.e.,* with little additional influence related to any year to year differences in the exposures. As discussed in the proposal, the use of a 3-year average in assessing RBL using the established tree seedling E–R functions is compatible with the normalization step taken to derive functions for a seasonal 90-day period from the underlying data with its varying exposure durations (85 FR 49901, August 14, 2020).

This concept of the importance of cumulative multiyear O_3 exposure to multiyear impacts, and its representation as an average, is also reflected in the evaluation of the predicted growth impacts compared to observations from the multiyear study of O_3 impacts on aspen by King et al (2005), as presented in the 2013 and 2020 ISAs and summarized in the PA (PA, Section 4.5.1.2). The ISAs considered the 6-year experimental dataset of O_3 exposures and aspen growth effects with regard to correspondence of E–R function predictions with study observations (2020 ISA, Appendix 8, section 8.13.2 and Figure 8–17; 2013 ISA, section 9.6.3.2, Table 9–15, Figure 9–20). The analysis in the 2013 ISA compared observed reductions in growth for each of the six years to those predicted by applying the established E–R function for Aspen to cumulative multi-year average W126 index values (2013 ISA, section 9.6.3.2).[211] [212] The evaluation in the 2020 ISA applied the E–R functions to the single-year W126 index for each year rather than the cumulative multi-year W126 (2020 ISA, Appendix 8, Figure 8–17), with this approach indicating a somewhat less tight fit to the experimental observations (2020 ISA, Appendix 8, p. 8–192),[213] Both ISAs reach similar conclusions regarding general support for the E–R functions across a multiyear study of trees in naturalistic settings (ISA, Appendix 8, section 8.13.3 and p. 8–192; 2013 ISA, p. 9–135).

Based on all of the above considerations, the EPA finds the evidence to support a 3-year average W126 index for use in assessing the level of protection provided by the current standard from cumulative seasonal exposures related to RBL of concern based on the established E–R functions. As discussed in section III.B.3 below, the EPA additionally finds the 3-year average metric to be reasonable in the context of the use of RBL as a proxy to represent an array of vegetation-related effects. In the discussion immediately below, we additionally and specifically address the issue of protection from ''unusually damaging years'' of vegetation exposure.

With regard to the comment that cited a recommendation from the prior CASAC on protection of vegetation

[210] Additionally, as described in section III.B.1.c above and III.B.2.b(v) below, the EPA's identification of 17 ppm-hrs for a target W126 index of 17 ppm-hrs (*e.g.,* versus 18 ppm-hrs) was in consideration of the prior CASAC recommendation for considering a ''lower'' level ppm-hrs.

[211] For example, the growth impact estimate for year 1 used the W126 index for year 1; the estimate for year 2 used the average of W126 index in year 1 and W126 index in year 2; the estimate for year 3 used the average of W126 index in years 1, 2 and 3; and so on.

[212] One finding of this evaluation was that ''the function based on one year of growth was shown to be applicable to subsequent years'' (2013 ISA, p. 9–135).

[213] Based on information drawn from Figure 8–17 in the 2020 ISA, the correlation metric (r^2) for the percent difference (estimated vs observed biomass) and year of growth can be estimated to be approximately 0.7, while using values reported in Table 9–15 of the 2013 ISA (which are plotted in Figure 9–20), the r^2 for predicted O_3 impact *versus* observed impact is 0.99 and for the percent difference *versus* year is approximately 0.85.

against ''unusually damaging years'' and the part of the court remand referencing that CASAC recommendation, we have considered the CASAC discussion using this term, in the context of the court remand. Use of this term by the prior CASAC occurs in the 2014 letter on the second draft PA in the 2015 review (Frey, 2014b). Most prominently, the prior CASAC defined as damage ''injury effects that reach sufficient magnitude as to reduce or impair the intended use or value of the plant to the public, and thus are adverse to public welfare'' (Frey, 2014b, p. 9). The prior CASAC additionally provided advice with regard to surrogate metrics for judging such ''damage,'' *e.g.,* use of RBL for judging effects on trees and their related functions and ecosystem services, use of crop RYL for judging public welfare effects of crop effects (Frey, 2014b, p. 10). We also note that the context for the prior CASAC's use of the phrase ''unusually damaging years'' is in considering the form and averaging time for a revised secondary standard in terms of a W126 index (Frey, 2014b, p. 13), which as discussed below is relatively less controlling of high-concentration years, rather than in the context of the current secondary standard and its fourth highest daily maximum 8-hour metric.

While the prior CASAC did not provide any specificity or details as to the exposure circumstances and damage intended by its more general phrasing, nor did it cite to specific evidence in scientific publications, we agree with the general concept that particular air quality patterns in a year may pose particular risk of vegetation damage, in terms of both or either growth-related effects or visible foliar injury (discussed in section III.B.2(iii) below). Across past O_3 NAAQS reviews, the air quality criteria for vegetation effects have emphasized the risk posed to vegetation from higher hourly average O_3 concentrations (*e.g.,* ''[h]igher concentrations appear to be more important than lower concentrations in eliciting a response'' [ISA, p. 8–180]; ''higher hourly concentrations have greater effects on vegetation than lower concentrations'' [2013 ISA, p. 91–4] ''studies published since the 2006 O_3 AQCD do not change earlier conclusions, including the importance of peak concentrations, . . . in altering plant growth and yield'' [2013 ISA, p. 9–117]). In fact, the EPA has recognized the W126 index for E–R models for growth and yield (in the current and prior ISA and prior AQCD) in part due to its preferential weighting of higher concentrations (ISA, p. 8–130).

We note, however, that while the W126 index weights higher hourly concentrations, it cannot, given its definition as an index that sums three months of weighted hourly concentrations into a single value, always differentiate between air quality patterns with high peak concentrations and those without such concentrations. This is illustrated by the following two hypothetical examples. In the first example, two air quality monitors have a similar pattern of generally lower average hourly concentrations, but differ in the occurrence of higher concentrations (*e.g.,* hourly concentrations at or above 100 ppb). The W126 index describing these two monitors would differ. In the second example, one monitor has appreciably more hourly concentrations above 100 ppb compared to a second monitor; but the second monitor has higher average hourly concentrations than the first. In the second example, the two monitors may have the same W126 index, even though the air quality patterns observed at those monitors are quite different, particularly with regard to the higher concentrations, which have been recognized to be important in eliciting responses (as noted above).

Thus, the EPA disagrees with a view implied by many of the commenters (who object to the EPA's proposed decision) that the sole focus for assessing public welfare protection, related to vegetation damage, and air quality control provided by the secondary standard should be on the W126 index. This view ignores both the limitations of the W126 index itself in distinguishing among different patterns of hourly O_3 concentrations and the fact that the current secondary standard has, by virtue of its form, a metric that does. With regard to these limitations of the W126 index, as described above, two different locations or years may have different patterns of hourly concentrations but the same W126 index value. This was recognized in the study by Lefohn et al. (1997), which observed the appreciable differences between the prevalence of hourly concentrations at or above 100 ppb in exposures on which the E–R functions are based and those common in ambient air.[214]

This potential for such a difference in peak concentrations between two different locations with the same W126 index was noted by one commenter who objected to the EPA's focus on a 3-year average W126 index in assessing RBL and advocated use of a single-year W126 index. This commenter stated that the same 3-year average could be maintained in two different locations in which the annual exposure may differ due to ''variability of the higher hourly average concentrations associated with vegetation effects.'' In emphasizing the higher hourly average concentrations associated with effects, the commenter cited the support provided by the evidence for the San Bernardino National Forest, described in the 2013 ISA and prior CDs (*e.g.,* 2013 ISA, section 9.5.3.1). We agree with this point and additionally note that this point also applies to two locations with the same single-year W126 index, given its definition (as noted above).

Given the mathematics inherent in calculation of the W126 index, while the metric is useful for comparing cumulative exposures, it can conceal peak concentrations that can be of concern (as described above). More specifically, one year or location could have few, or even no, hourly concentrations above 100 ppb[215] and the second could have many such concentrations; yet each of the two years or locations could have the identical W126 index (*e.g.,* equal to 25 or 17 or 10 ppm-hrs, or some other value). However, as can be seen by the historical ambient air monitoring dataset of O_3 concentrations, the form of the current standard limits the occurrence of such elevated concentrations, *e.g.,* at or above 100 ppb (PA, Appendix 2A, section 2A.2; Wells, 2020).

Analyses of hourly concentrations for different air quality scenarios developed in consideration of the remand and such comments (and documented in a technical memorandum to the docket) show the form and averaging time of the existing standard to be much more effective than the W126 index in limiting the number of hours with O_3 concentrations at or above 100 ppb (N100) and in limiting the number of days with any such hours (Wells,

[214] For example, many of the experimental exposures of elevated O_3 on which the established E–R functions for the 11 tree seedling species are based, had hundreds of hours of O_3 concentrations above 100 ppb, far more than are common in (unadjusted) ambient air, including in areas that meet the current standard (Lefohn et al. 1997; PA, Appendix 2A, section 2A.2; Wells, 2020). Similarly, the experimental exposures in studies supporting some of the established E–R functions for 10 crop species also include many hours with hourly O_3 concentrations at or above 100 ppb (Lefohn and Foley, 1992).

[215] The value of 100 ppb is used here as it has been in some studies focused on O_3 effects on vegetation, simply as an indicator of elevated or peak hourly O_3 concentrations (*e.g.,* Lefohn et al. 1997, Smith, 2012; Davis and Orendovici, 2006; Kohut, 2007a). Values of 95 ppb and 110 ppb have also been considered in this way (2013 ISA, section 9.5.3.1).

2020).[216] For example, during the recent design value period (2016–2018), across all sites that met the current standard, few sites had any hours at or above 100 ppb in a year (6% in the highest year, Wells, 2020, Table 2).[217] Among the sites with any such hours, the vast majority had fewer than five such hours (99.5% in the highest year, Wells, 2020, Table 2), with none having more than ten such hours,[218] and no site having more than three days in any one year with any such concentrations (Wells, 2020, Figures 4 and 5). In comparison, sites with an annual W126 index below 15 ppm-hrs recorded nearly 40 hourly concentrations at or above 100 ppb, and as many as seven days with such a concentration (Wells, 2020, *e.g.,* Figures 10 and 11).[219] A similar pattern is seen using the historical dataset extending back to 2000. This historical dataset also shows the appreciable reductions in peak concentrations (via either the N100 or D100 metric) that have been achieved in the U.S. as air quality has improved under O_3 standards of the existing form and averaging time (Wells, 2020, Figures 12 and 13). Thus, based on the findings of both the analyses in the PA (PA, Appendix 2A) and the additional analyses (Wells, 2020), the EPA disagrees with the commenter that the proposed decision ignores the importance of elevated hourly O_3 concentrations in eliciting effects on vegetation. Rather, the proposed decision, and final decision to retain the existing standard, which controls peak concentrations and also cumulative seasonal exposure in terms of W126 index, explicitly considers this importance and address it in a way that is more effective than a standard expressed in terms of the W126 index would be, even based on a single-year W126 well below 17 ppm-hrs (as shown in the additional air quality analyses [Wells, 2020]).

In summary, we find that a 3-year average is appropriate for use in assessing protection for RBL based on the established tree seedling E–R functions, in light of the discussion above, while also finding it important to consider additional aspects of O_3 air quality, that influence vegetation exposures of potential concern, in reaching conclusions about the adequacy of the current standard. We disagree with the commenters and the prior CASAC that focus on a single year W126 index is needed to protect against years with O_3 concentrations with the potential to be ''unusually damaging,'' Rather, as described here, the metric of the current standard provides strong protection against elevated hourly concentrations that might contribute to ''unusually damaging'' years with the potential to be adverse to the public welfare, as well as providing protection against effects of cumulative exposures seen in experimental studies. Accordingly, we disagree with those commenters that express the view that the current standard does not provide such protection.

(iii) Visible Foliar Injury

In support of their disagreement with the EPA's proposed decision, some commenters express the view that the EPA's proposed conclusion that the current standard provides sufficient protection from an incidence and severity of visible foliar injury that would reasonably be judged adverse to the public welfare is unlawful. These commenters variously claim that EPA analyses are flawed, arbitrary, and ignore conclusions and judgments of the prior CASAC; cite some studies that they state indicate a threshold for foliar injury lower than 25 or 17 ppm-hrs; claim that the EPA must, yet does not, identify a level of injury that is adverse; state that the EPA does not explain its use of USFS biosite scores in this regard, and state that the EPA does not adequately address the *Murray Energy* remand related to these effects. With regard to the latter, the Agency intends this decision, associated analyses conducted for this review in consideration of issues raised by the court remand, and the discussions herein to constitute its response to the *Murray Energy* remand on these effects.

With regard to EPA's analyses of the current information on O_3-related visible foliar injury, some commenters claim that the EPA needs to and has not adequately explained why it disagrees with the conclusions and judgments of the prior CASAC in comments on the 2014 draft PA regarding a W126 index value of 10 ppm-hrs. As an initial matter, we note that in discussing this topic, these commenters conflate the prior CASAC's scientific evidence-based recommendations on the secondary standard with its judgments of scientific information in the context of its policy recommendations. In its letter on the draft PA, the prior CASAC explicitly separates into two separate paragraphs its scientific judgment based recommendations to the Administrator on the standard from its additional policy recommendations, with this statement regarding visible foliar injury occurring in the second paragraph (that addresses policy recommendations) (Frey, 2014b, p. iii).[220] Thus, we

[216] The impact of the current form of the standard on occurrence of elevated hourly concentrations is also seen by a recent study submitted with comments (Neufeld et al., 2019). For example, the frequency of episodes defined by three consecutive hours at or above 60 ppb, as well as the magnitude of W126 index, has appreciably declined at locations within and immediately adjacent to the Smoky Mountains National Park, and the periods of respite from elevated episodes has appreciably increased (Neufeld et al., 2019). This was found for low elevation sites, and also high elevation Park sites, which generally have higher levels (Neufeld et al., 2019).

[217] In these analyses the N100 and D100 metrics are based on counts of hourly O_3 concentrations at or above 100 ppb across the consecutive 3-month period with the highest total (Wells, 2020). The metric D100 is the count of days with an hour at or above 100 ppb.

[218] We note that we are not intending to ascribe specific significance to five days with an hour at or above 100 ppb or ten hours such, *per se.* Rather, these are used simply as reference points to facilitate comparison to illustrate the point that such high concentrations, which based on toxicological principles, pose greater risk to biota than lower concentrations (*e.g.,* ''[h]igher concentrations appear to be more important than lower concentrations in eliciting a response'' [ISA, p. 8–180]; ''higher hourly concentrations have greater effects on vegetation than lower concentrations'' [2013 ISA, p. 91–4] ''studies published since the 2006 O_3 AQCD do not change earlier conclusions, including the importance of peak concentrations, . . . in altering plant growth and yield'' [2013 ISA, p. 9–117]).

[219] We also note the higher percentages of sites with an N100 above five among sites meeting a single-year W126 index of 7 ppm-hrs than sites meeting the current standard (Wells, 2020, Table 2). Sites with an annual W126 index of 7 ppm-hrs also record a greater percentage of sites with more than two days with an hour at or above 100 ppb (Wells, 2020, Table 2).

[220] The first paragraph, conveying scientific judgment provides a range of levels for a revised standard (Frey, 2014b, p. iii). The second begins by noting that the ''scientific judgment'' regarding a revised secondary standard, in prior paragraph, are based on the scientific evidence. Midway through that paragraph, as shown below, the prior CASAC turns to its policy recommendations, in which it relates various W126 index values in different ways to various effect categories, including crop yield loss, foliar injury, and relative biomass loss (Frey, 2014b, p. iii). Given that the prior CASAC recommended multiple times in this letter a standard level range that extends higher than 10 ppm-hrs (to 15 ppm-hrs), the fact that the sentence regarding visible foliar injury in the version of this second paragraph that appears within the attachment to the letter begins with the phrase ''[b]ased on its scientific judgment'' cannot reasonably be interpreted to be overriding the Committee's scientific advice on the standard. Rather, the prior CASAC appears to be implying that to the extent the Administrator judges, as a matter of public welfare policy, it important to consider such a focus on foliar injury, the prior CASAC's scientific judgment is that 10 ppm-hrs is required to reduce it (Frey, 2014b, pp. iii and 15). In relevant part, the second paragraph reads:

In reaching its scientific judgment regarding the indicator, form, summation time, and range of levels for a revised secondary standard, the CASAC has focused on the scientific evidence for the identification of the kind and extent of adverse effects on public welfare. The CASAC acknowledges that the choice of a level within the range recommended based on scientific evidence is a policy judgment under the statutory mandate of the Clean Air Act. . . . *As a policy recommendation,* separate from its advice above regarding scientific findings, the CASAC advises reasonably interpreted the statement by the prior CASAC as simply indicating a consideration of the prior CASAC in reaching its decision on the recommended range of levels, stated multiple times in the same letter and including levels higher than 10 ppm-hrs, that the Committee thought might be useful (*e.g.,* as a ''policy recommendation'') to the Administrator in exercising the discretion granted him under the Act for specifying a secondary standard (Frey, 2014b, p. iii). The prior CASAC statement regarding a W126 index value of 10 ppm-hrs, is related to visible foliar injury at biosites, and, more specifically, is based on its consideration of an EPA cumulative analysis of a biomonitoring dataset presented in the 2013 draft WREA.[221] This analysis, the dataset for which is further described in Appendix 3C of the PA for the current review, does not show, as implied by the 2014 CASAC comments, that, in considering sites with W126 index values from highest to lowest, there is no reduction in prevalence of sites with visible foliar injury above a W126 index of 10 ppm-hrs (*i.e.,* there are not differences in the occurrence of injury across higher values).[222] The 2014 WREA analysis could not and was not addressing this issue.

The 2014 WREA analysis is a cumulative analysis of the proportion of records with nonzero BI scores; each point graphed in the analysis includes the records for the same and lower W126 index values. Not only is the analysis silent with regard to severity of injury, but it also does not compare the incidence of visible foliar injury for records of differing W126 index values. Rather, each point in the cumulative frequency figure represents all the records included in the group (thus far), which increase by one with each new point (moving through dataset). Where the record added to the group has the same W126 index value as the prior included record, the point is at the same location along the x-axis, but at a slightly higher location along the y-axis (if it has a nonzero BI), thus contributing to an increase in the proportion of sites (the metric assessed on the y-axis). Thus, where there are many records with quite similar W126 index values, the points do not appreciably move along the x-axis, yet when they have a nonzero BI score, they are placed higher along the y-axis (as each represents another nonzero record in the dataset, thus increasing the proportion of records). At such a location along the x-axis, an inflection occurs (*i.e.,* a location along the x-axis for which each additional record had the same or quite similar W126 index as the prior record such that the point is at a similar location on the x-axis but contributes to increasing values along the y-axis). As the addition of each new record makes the dataset larger, such increases (or decreases for zero BI records) become progressively smaller (along the y-axis), making such changes or inflections less pronounced at higher W126 index values. Accordingly, given the much greater representation in the dataset of relatively lower W126 index records (some two thirds of the dataset has W126 index values at/below 11 ppm-hrs), the prominent inflection point noted by the prior CASAC on the cumulative frequency graph occurs around 11 ppm-hrs, and the figure from the 2014 WREA shows only small changes in the height of the line with increasing W126 index. This does not mean that records with higher W126 index values have no greater occurrence of foliar injury than values below 11 ppm-hrs; in fact, they do, most particularly the records with W126 index values above 25 ppm-hrs (PA, Figure 4–5). Thus, we disagree with the prior CASAC statement that W126 index values below 10 ppm-hrs are required for any reduction in visible foliar injury and with the suggestion that the WREA cumulative analysis supports such a conclusion. Given that the statement by the prior CASAC did not provide any information to indicate another basis for its statement and because the 2014 WREA analysis cannot and does not address this issue, we conclude that the prior CASAC's statement lacks scientific support. Based on this conclusion, the Administrator does not find this statement from the prior CASAC informative to his consideration of the adequacy of the protection provided by the current standard for adverse public welfare effects related to visible foliar injury (discussed in section III.B.3 below).

Unlike the 2014 WREA cumulative frequency analysis, the presentations in the PA for this review allow for comparison of injury incidence, and severity, at distinctly different exposures. As can be seen by graphs of the distribution of nonzero BI scores for bins of increasing W126 index estimates, the greatest representation of nonzero BI scores occurs in the bin with the highest W126 index estimates, which for the normal soil moisture category is above 25 ppm-hrs (PA, Figure 4–5). In disagreeing with the EPA's observations from this analysis, these commenters express the view that the higher percentage at the higher W126 index level is not meaningful because there are fewer records for the higher W126 index levels. While we agree that there are fewer records in the higher W126 index bins, as noted above, we disagree that there are too few records in those bins to support some interpretation for some soil moisture categories (such as the normal or dry categories), although for other soil moisture categories (*i.e.,* wet), the small sample size does limit interpretation. Sample size in each bin was considered in the PA analysis and was recognized as placing a limitation on interpretation of patterns for the wet soil moisture category. Contrary to these commenters' view that EPA provides no reason for giving little focus to the higher W126 index bins for the wet soil moisture category, the PA explains that interpretations of patterns across the higher W126 bins are limited for the wet soil moisture category, noting that the number of records in each of the W126 bins above 13 ppm-hrs comprise less than 1% of the records available for that soil moisture category (PA, Appendix 4C, section 4C.6). Thus, we agree with these commenters that sample size is an important consideration in reaching conclusions from this dataset, and, contrary to the commenters' assertion of providing no valid reasons with regard to the EPA's lesser emphasis on the wet soil moisture category, the proposal stated that the PA observations focused primarily on the records for the normal or dry soil moisture categories explicitly in recognition of those categories having adequate sample size which the bins above 13 ppm-hrs did not for the wet soil moisture category (85 FR 49890, August 14, 2020). While the dataset includes an extremely small number of records in the wet soil moisture category that fall into the higher W126 index bins

that a level . . . below 10 ppm-hrs is required to reduce foliar injury. A level of 7 ppm-hrs . . . offers additional protection against crop yield loss and foliar injury. . . . Thus, lower levels within the recommended range offer a greater degree of protection of more endpoints than do higher levels within the range. (Frey, 2014b, p. iii, [emphasis added]).

[221] In reference to the 2013 draft WREA cumulative frequency analysis (*e.g.,* 2013 draft WREA, Figures 7–9 to 7–12), a 2014 CASAC comment cited by commenters states that ''W126 values below 10 ppm-hrs [are] required to reduce the number of sites showing visible foliar symptoms'' (Frey, 2014b, p. 14).

[222] We note that in light of, and subsequent to, the prior CASAC's 2014 letter in the last review, the EPA had considered the extensive evidence documented in the 2013 ISA, as well as analyses of USFS data in the 2008 and 2015 reviews, including technical memos developed after the prior CASAC provided its 2014 advice (80 FR 65376, 65395–96, October 26, 2015). In the current review, the now expanded available data and analyses augment the support for EPA's conclusions in this regard.

(just 18 distributed across the three W126 index bins above 13 ppm-hrs),[223] there are more than 550 records categorized as normal soil moisture distributed across all five bins for W126 index above 13 ppm-hrs, more than 40 in each bin (PA, Appendix 4C, Table 4C–4). To the extent that the commenters are suggesting that the EPA is disregarding data for sites categorized as wet soil moisture, we disagree. In recognition of the role of soil moisture in contributing to a condition ''necessary for visible foliar injury to occur,'' the PA analysis presents BI scores separated into groups based on categorization related to soil moisture (ISA, Appendix 8, p. 8–13; 85 FR 49881; PA, pp. 4–40 to 4–41). The EPA thus considered the available evidence for all of the soil moisture categories, but with regard to any patterns evidenced for the higher W126 index bins (above 13 ppm-hrs), the EPA reasonably explained its focus on two of the three categories (the normal or dry soil moisture categories), and lesser attention to the third category (wet soil moisture) due to the extremely small number of records in that category that fall into the higher W126 index bins.

Further, in addition to incidence of sites with any injury, the PA presentations indicate that the severity of injury is also highest in records for the highest W126 index values, appreciably higher that it is in all of the lower W126 index bins. For normal soil moisture category, the median BI score across the nonzero records in the highest W126 bin (greater than 25 ppm-hrs) is just over 10 (with an average over 15), compared to well below 5 (averages below 7) for each of the lower W126 bins (PA, Figure 4–5, Appendix 4C, Table 4C–5). Both of these observations are consistent with an E–R relationship of O_3 with visible foliar injury, while the variability observed across the full dataset, in addition to perhaps indicating limitations in some aspects of the dataset (*e.g.,* categorization by soil moisture, among others [PA, Appendix 4C, section 4C.5]), no doubt also indicates the role of other factors that have not been completely accounted for. Given the evidence from controlled experiments documented across many years, the lack of noticeable change in incidence or severity across lower W126 index values may, as recognized in the PA, relate to a number of factors, including uncertainties in the assignment of W126 index estimates to the biosite locations and the soil moisture categorization of sites, as well as potential for differences in individual plant responses in controlled experiments from plant communities in natural environmental settings. Although such factors may contribute to an unclear pattern at lower exposures, precluding reaching conclusions regarding O_3-related response across the lower W126 index bins, the observed response for the highest bin clearly indicates an O_3-related response for W126 index values above 25 ppm-hrs.

Some commenters question the significance EPA ascribes to its observation that the BI scores are appreciably higher for records in the highest W126 index bin, cryptically characterizing the observation as describing a ''derivative of a derivative.'' Yet, this observation is simply focused on the response (*e.g.,* incidence of BI score greater than 0 or 5 or 15) exhibited across the range of exposure levels evaluated. The EPA makes this observation in assessing the dataset as to whether an E–R relationship is exhibited and if so, at what part of the exposure range is there a noticeable increase in response. This assessment, in combination with related evidence, then informs the Agency's conclusions regarding O_3 exposure circumstances that influence BI scores, as well as levels of W126 for which such an influence is indicated.[224] The commenters quote the prior CASAC as characterizing the 2014 WREA analysis as ''a change in the E–R slope,''[225] but, as discussed in detail above, the 2014 WREA figure is presenting a cumulative frequency analysis, which, by its design, does not show ''a change in the E–R slope.'' Such an analysis, because responses are not compared among distinct and discrete exposures, as explained above, is not well described as an exposure-response assessment (*i.e.,* an analysis of responses occurring across a range of different exposures). This is in contrast to the current PA presentation of BI scores across bins of increasing W126 index, which presents the occurrence of responses, quantified by magnitude of BI score, associated with multiple different exposures (presented as bins). Thus, the EPA finds the current analyses in the PA, and not the cumulative frequency analysis in the 2014 WREA, to be informative to the consideration of relationships between extent of visible foliar injury and W126 index, and finds the 2014 WREA analysis to be mistakenly interpreted by the commenters.

Further some commenters, who object to the Administrator's proposed focus on BI scores above 15 for his consideration of visible foliar injury that may be adverse to the public welfare, additionally suggest that EPA should give weight to all nonzero BI scores in considering the appropriate protection against this effect for the standard. As an initial matter, contrary to the implication of the commenters that any amount of visible foliar injury is adverse to the affected plant, we note the long-standing conclusions that visible foliar injury ''is not always a reliable indicator of other negative effects on vegetation,'' such as growth and reproduction, and the ''significance of ozone injury at the leaf and whole-plant levels depends on how much of the total leaf area of the plant has been affected, as well as the plant's age, size, developmental stage, and degree of functional redundancy, among the existing leaf area'' (ISA, p. 8–24; 2013 ISA, section 9.4.2). Further, we disagree with the further implication of these commenters that any occurrence of a nonzero BI score in the PA dataset can be used to identify O_3 exposure conditions that are adverse to the public

[223] The records for the wet soil moisture category in the higher W126 bins are more limited than the other categories, with nearly 90% of the wet soil moisture records falling into the bins for W126 index at or below 9 ppm-hrs, limiting interpretations for higher W126 bins (PA, Appendix 4C, Table 4C.4 and section 4C.6). The number of records in each of the W126 bins above 13 ppm-hrs (sample size ranging from zero to 9) comprise less than 1% of the wet soil moisture category. Accordingly, the PA observations focused primarily on the records for the normal or dry soil moisture categories, for which all W126 index in the analysis, including those above 13 ppm-hrs, are better represented (85 FR 49890, August 14, 2020). For the wet soil moisture category, we agree with the commenter's statement that ''higher percentage at higher levels isn't necessarily meaningful, because there are fewer sites with any data at those levels,'' however note that there is much greater representation of the normal and dry soil moisture categories in each of the higher bins, extending to the highest bins, than is the case for the wet soil moisture category bins.

[224] Such information informs the Administrator's consideration of the currently available evidence and the extent to which it can inform his judgments on O_3 air quality associated with visible foliar injury of such an extent and severity in the environment as to indicate adverse effects to the public welfare. Such judgments, as discussed further below, rely on information on relationships between different O_3 air quality metrics and injury incidence and severity as well as factors influencing the public welfare significance of different incidence and severity of foliar injury in vegetated areas valued by the public (*e.g.,* as summarized in section III.A.2.b).

[225] This characterization was made in the 2014 letter providing the prior CASAC's review of the second draft WREA. As noted by some commenters, the letter goes on to state, ''[b]ased on this E–R slope change, 10 ppm-hrs is a reasonable candidate level for consideration in the WREA, along with other levels'' (Frey, 2014c, p. 7). Although the EPA did not examine the specific value of 10 ppm-hrs in the 2014 WREA, as observed by these commenters, the EPA did consider this recommendation in the 2015 decision, contrary to the claim of the commenters (80 FR 65395–96, October 26, 2020).

welfare. As discussed in section III.A.2.b above, a number of factors influence the public welfare implications of visible foliar injury, and as discussed further below, the Administrator has taken these into account in his decision making regarding the protection from such effects that should be afforded by the secondary standard.

These commenters additionally claim that the USFS dataset indicates a clear relationship between the W126 metric and foliar injury. While we agree that the dataset provides some support for the conclusion of a greater incidence of nonzero BI scores and higher scores for the highest W126 bin, a change in response is not evident across the full range of W126 index levels (for records of similar soil moisture category), thus suggesting a limitation of the dataset in its ability to describe the E–R relationship of BI scores with W126 index. As discussed in the PA, limitations in the dataset (*e.g.,* with regard to assignment of W126 index estimates to biosite records and the approach for accounting for the role of soil moisture) may be contributing to the lack of a clearly delineated E–R relationship of injury occurrence and BI score with W126 index across a range of W126 index values, such that a clear shape for a relationship between these variables is not evident with this dataset, and may be contributing to uncertainties in this regard. It is with the increase in W126 for the last bin (>25 ppm-hrs) that the accompanying noticeable increase in response provides increased confidence in that response (BI scores) being related to a particular magnitude of the O_3 metric. It is this consideration which leads to the emphasis that EPA's conclusions from this analysis place on W126 index above 25 ppm-hrs, albeit with a recognition of some associated uncertainty.

Regarding the Administrator's judgment of the extent and severity of visible foliar injury that may be adverse to the public welfare, some commenters state that the EPA must, and has not, considered the full USFS dataset, including records for which the BI scores are below 5, and they express the view that the USFS data indicate injury (*i.e.,* a nonzero BI score) to be occurring at W126 index values as low as 3 ppm-hrs. In so doing, they note the occurrence of scores above 15 in the lowest bin (W126 index below 7 ppm-hrs). These commenters note that a third of all records with a BI above 15 are in the lowest W126 index bin (W126 <7 ppm-hrs) and more than 500 records with nonzero BI are in higher bins, seemingly intending this as support of their view that the EPA should identify a W126 of 7 ppm-hrs as a target level for visible foliar protection. However, this line of logic seems to ignore the fact that this bin also has over a third of the records with a BI above zero (PA, Table 4C–4), a fact which would seem contrary to these commenters' position that 7 ppm-hrs would protect against such scores. All three of these observations are likely due to the fact that this bin contains 42% of all records and the most records of any bin, by far (PA, Appendix 4C, Table 4C–4). Accordingly, the more important observation with regard to the extent of conclusions supported by the dataset on the role of W126 index in influencing BI scores is that the proportion of records in the lowest W126 bin that have scores above 15, 5 or 0 is appreciably less that in the highest W126 index bin (PA, Appendix 4C, Table 4C–6). The fact that there is not a clear pattern of increasing proportion across the intervening (and full set of) bins indicates there to be factors unaccounted-for in this dataset with regard to the O_3 exposure circumstances and the environmental circumstances that together elicit increased scores in vegetated areas.

In considering the PA analyses of the biosite dataset in light of these comments, we first note that, as described in the PA, the USFS dataset includes a broad assortment of BI scores, extending down to zero, occurring across the range of W126 estimates applied to the records (PA, Appendix 4C, Figure 4C–3). Contrary to the statement by these commenters, the EPA *has* considered the full dataset. The PA documents the various ways in which this is done, and the proposal discusses key observations from this dataset to inform the Administrator's judgment on adversity to public welfare (PA, section 4.3.3.2, 4.5.1.2 and Appendix 4C; 85 FR 49889–90, 49903, August 14, 2020). For example, the lack of clear BI score response to W126 across the range of lower values is consistent with findings of published studies of the USFS biomonitoring data which find that W126 index alone may not be sufficient to characterize the O_3 conditions contributing to injury levels that may be of interest (*e.g.,* Smith et al., 2012; Smith, 2012; 85 FR 49888–49889, August 14, 2020). Similar to the discussion above, these studies suggest a role for the occurrence of elevated hourly concentrations and a focus solely on W126 index may miss this. This consideration of the larger evidence base for visible foliar injury and associated USFS biomonitoring findings is important to judging the findings of analyses of the BI dataset and their informativeness to the Administrator's needs in judging public welfare adversity. Based on a detailed evaluation of the currently available record regarding such data, the EPA recognizes the need to consider factors beyond just W126 index in considering O_3 conditions most influential in the incidence and extent of visible foliar injury.

With regard to lower ''thresholds,'' the commenters simply cite a set of studies that describe visible foliar injury observations in bioindicator species and for which estimates of W126 index for a prior time period are below 25 ppm-hrs. The first group of these studies focus on naturally occurring plants in locations during which the current standard (with its level of 70 ppb) is not met.[226] As discussed above, the current standard limits the occurrence of elevated concentrations which, as discussed above, is suggested to be important in the occurrence of visible foliar injury in sites of the USFS biosite monitoring program, and such elevated concentrations are much more prevalent in areas that do not meet the current standard (*e.g.,* PA, Appendix 4A, section 2A.2; Wells [2020]). Thus, this group of studies do not provide sufficient information to characterize the O_3 exposure circumstances that may be eliciting the observed responses. Nor are they informative with regard to consideration of the incidence and extent or severity of injury that may occur under air quality conditions allowed by the current standard. Two other examples raised by commenters (but without complete study citations), appear to relate to leaf injury assessed in potted plants either outdoors but watered daily or maintained in greenhouse conditions. The injury assessed is at the individual plant level, making implications with regard to natural vegetation communities unclear, and the extent to which either finding in artificial conditions might represent such plant responses in natural environmental conditions is unknown. These commenters additionally note what they describe as ''threshold values'' reported in a National Park Service publication (Kohut, 2020). This publication includes three ''injury thresholds'' in terms of three assessment metrics, with one being a 3-month W126 index and a second in terms of

[226] For example, valid design values include: (1) 73 (2002) and 72 (2003) at monitoring site 450190046, (2) 91 (2002), 94 (2003), and 88 (2004) at 230090102; (3) 77 ppb (2004) at 261530001, and (4) 90 (2002 and 2003) at 340010005.

SUM06.[227] For each metric, three ranges of ''thresholds'' are presented (for different purposes). The ranges for SUM06 come from a 1996 workshop report (Heck and Cowling, 1997). The ranges for W126 index are based on a W126 index conversion of the SUM06 ranges. One of the ranges is labeled as pertaining to foliar injury as a response, yet, the publication cited does not provide data on foliar injury in relation to that range, nor do publications cited by the former publication. As we can best discern based on cited and related publications, it appears to at the lower end relate to a benchmark derived for growth effects (10% RBL) in the highly sensitive species, black cherry, rather than visible foliar injury (Kohut, 2007b; Lefohn et al., 1997; 80 FR 65378, October 26, 2015). Thus, contrary to the commenters' assertion, the range for W126 index (labeled as pertaining to foliar injury) does not appear to provide a threshold based on evidence for visible foliar injury.

Some commenters (citing page 4C–18 of the PA), express confusion over how EPA can state there to be an incomplete understanding of the relationships influencing severity of visible foliar injury while also using the USFS scores to inform the Administrator's judgments regarding conditions that may be adverse to the public welfare. We see no contradiction in this. Rather, it is this recognition of an incomplete understanding, including the recognition of uncertainty in ''specific aspects of [the influences of environmental/genetic factors] on the relationship between O_3 exposures, the most appropriate exposure metrics, and the occurrence or severity of visible foliar injury'' (PA, Appendix 4C, p. 4C–18), that leads the EPA to place greatest weight on the most clear findings from the USFS data. With regard to the PA presentation, with its recognized uncertainties and limitations, such a finding is the obviously increased prevalence and severity of visible foliar injury for records with W126 index estimates above 25 ppm-hrs.

Further, in considering public welfare implications of O_3 related visible foliar injury, the EPA continues to recognize that the occurrence of visible foliar injury has the potential to be adverse to the public welfare (*e.g.,* as summarized in section III.A.2.b above and section III.B.2 of the proposal). However, as noted in the proposal, the EPA does not find that any small discoloring on a single leaf of a plant (which might yield a quite low, nonzero BI score in the USFS system) is reasonably considered adverse to the public welfare. Thus, findings such as those raised by commenters of injury on individual plants in controlled conditions, while providing support to the conclusion of a causal relationship between O_3 exposure and visible foliar injury (ISA, Appendix 8, Table 8–3), are less informative to the Administrator's judgment on adequacy of the protection provided by the current standard from adverse effects to the public welfare. Rather, the USFS biosite monitoring data provide information that is more useful for such a judgment because this monitoring program, as summarized in section III.A.2.b above (and III.B.3.b of the proposal), and the scale of its objectives which focus on natural settings in the U.S. and forests as opposed to individual plants is better suited for the Administrator's consideration with regard to the public welfare protection afforded by the current standard. In this context, as described in section III.B.3 below, the Administrator judges that very low BI scores, such as those less than 5, described by the USFS scheme as ''little or no foliar injury'' do not pose concern for the public welfare.[228]

Lastly, we disagree with the comment that the Act requires the EPA to specify ''a level'' of injury that is adverse. The Court of Appeals for the D.C. Circuit has held that ''the Agency may sometimes need to articulate the level of threat to the population it considers tolerable; but there is no separate methodological requirement under § 109 that the Administrator establish a measure of the risk to safety it considers adequate to protect public health every time it establishes a standard pursuant to § 109.'' See *Nat. Res. Def. Council, Inc.* v. *EPA,* 902 F.2d 962, 973 (D.C. Cir. 1990), opinion vacated in part on other grounds, 921 F.2d 326 (D.C. Cir. 1991). The same principle applies for consideration of the protection of public welfare in the context of establishing or reviewing secondary standards. The court later confirmed that it ''expressly rejected the notion that the Agency must 'establish a measure of the risk to safety it considers adequate to protect public health every time it establishes a [NAAQS].'' See *ATA III,* 283 F.3d at 369 (D.C. Cir. 2002) (quoting *Natural Res. Def. Council, Inc.* v. *EPA,* 902 F.2d 962, 973 [D.C. Cir. 1990]). As is recognized by the courts and by EPA and CASAC across NAAQS reviews, the judgment of the Administrator, in addition to being based on the scientific evidence, depends on a variety of factors, including science policy judgments and public welfare policy judgments. As noted by the case law and also in section III.B.2.b(iv) below, the EPA is not required under the Act to identify individual levels of adversity or set separate standards for every type of effect that may be caused by a pollutant in ambient air, as long as it has engaged in reasoned decision making in determining that a particular standard provides the requisite protection. Thus, it is common for one NAAQS to provide protection for multiple effects, with the most sensitive effect influencing the stringency of the standard and accordingly leading to protection that is adequate for other, less sensitive effects. Given the significant uncertainties which are present in every NAAQS review, it is enough for the Administrator to set standards that specify a level of air quality that will be ''tolerable,'' (*NRDC,* 902 F.2d at 973), and ''qualitatively to describe the standard governing its selection of particular NAAQS'' (*ATA III,* 283 F.3d at 369). In reviewing each standard, the EPA gives due consideration to each of the effects that are relevant for that standard in considering whether the standard provides adequate protection from the type, magnitude or extent of such effects known or anticipated to be adverse to the public welfare. In the case of visible foliar injury, as discussed in section III.B.3 below, the Administrator has considered the available scientific evidence, with associated uncertainties and limitations, in reaching his decision that the current secondary standard provides adequate public welfare protection for this effect.

(iv) Crop Yield Effects

Some commenters object to the proposed conclusions with regard to the protection provided by the existing secondary standard from adverse effects on the public welfare related to O_3 effects on crop yield, expressing the view that the EPA must specify ''a level'' to protect the public welfare against crop yield reductions and that not doing so is unlawful and arbitrary. These commenters' additionally object to the Administrator's proposed judgment that a decision based on RBL as a proxy for other vegetation-related effects will also provide adequate protection against crop related effects, indicating their view that EPA does not

[227] We note that the third assessment approach utilizes a combination of a W126 index metric with the N100 metric, illustrating the consideration by the National Park Service of the role of peak concentrations in posing risk of visible foliar injury (Kohut, 2020).

[228] Studies that consider such data for purposes of identifying areas of potential impact to the forest resource suggest this category corresponds to ''none'' with regard to ''assumption of risk'' (Smith et al., 2007; Smith et al., 2012).

adequately explain the basis for this judgment. These commenters additionally claim that the prior CASAC described 5.1% RYL as constituting an adverse welfare effect and express the view that the EPA arbitrarily and unlawfully does not ''give effect to'' the prior CASAC's recommendation.

We disagree with the implication of these commenters that, in judging adequacy of protection provided by the current standard for a particular effect, it is *per se* unlawful to conclude that the air quality achieved by the current standard provides adequate protection for that particular effect, even if the greater attention in reviewing the current standard is on another effect. The EPA is not precluded from reaching such a conclusion as long as the Agency has engaged in reasoned decision-making in doing so.[229] In reaching his proposed conclusions regarding the extent to which the current standard provides appropriate protection from O_3 effects on crop yield that may be adverse to the public welfare, as in his conclusions described in section III.B.3 below, the Administrator recognizes the long-standing evidence of O_3 effects on crop yield and the established E–R functions for which RYL estimates for the median crop species are presented in the PA (PA, Appendix 3A). He also considers factors that might be important to his judgments related to the requisite protection for a secondary standard that protects against adverse effects to the public welfare. In this context he judges that the median RYL estimated for air quality that achieves his RBL-related objectives for the current standard does not constitute an adverse effect on public welfare and thus concludes that the current standard also provides adequate protection for crop yield-related effects. Given that the decision on adequacy of protection is a judgment of the Administrator and that the Clean Air Act does not require a particular approach for reaching such judgments, we disagree with the commenters to the extent that they suggest that it is *per se* unlawful for the Administrator to use such an approach. The circumstances for his use of this approach include particular aspects of the information available on O_3-related crop yield effects and other factors important to judgments on public welfare effects related to crop yield effects.

In reaching his decision in this review, as described in section III.B.3 below, the Administrator has also considered public comments on these issues, including that regarding a prior CASAC statement. The comment regarding the prior CASAC appears to draw on a judgment of the prior CASAC that a median RYL of 5% ''represents an adverse impact'' (Frey, 2014b, p. 14). The prior CASAC provided no clear scientific foundation for this judgment. While we infer this judgment to draw on discussion at a 1996 workshop,[230] neither the prior CASAC nor the workshop summary provides any explicit rationale for identification of 5% (with regard to RYL), or any description of a connection of an estimated 5% RYL to broader impacts of a specific magnitude or type, or to judgments on significance of a 5% RYL to the public welfare. Thus the EPA disagrees with the commenters regarding the weight to give the prior CASAC statement and, as described below, respectfully disagrees with the prior CASAC on this statement.

In reaching his judgment regarding whether the current standard provides the requisite public welfare protection, as described in section III.B.3 below, the Administrator considers the extent to which a specific estimate of RYL may be indicative of adverse effects to the public welfare. In so doing, he notes that the secondary standard is not intended to protect against all known or anticipated O_3-related effects, but rather those that are judged to be adverse to the public welfare, and that a bright-line determination of adversity is not required in judging what is requisite. In his decision described below, the Administrator also notes that the determination of the extent of RYL estimated from experimental O_3 exposures that should be judged adverse to the public welfare is not clear, in light of the extensive management of agricultural crops that occurs to elicit optimum yields (*e.g.,* through irrigation and usage of soil amendments, such as fertilizer). Further, in considering effects on the public welfare that may relate to agricultural markets, we note that detrimental impacts on crops, as well as beneficial impacts, can be unevenly distributed between producers and consumers, complicating conclusions with regard to relative adversity. In light of such considerations, the Administrator, while finding consideration of the RYL estimate for the median crop species informative to his judgment on the adequacy of the protection provided by the current standard for this effect, does not find such an RYL estimate of 5% to represent an adverse effect to the public welfare, as described more fully in section III.B.3 below. For these reasons, and for the reasons discussed earlier in this section, including those regarding advice from a prior CASAC, the EPA also disagrees with the commenters' assertion that the Administrator is arbitrarily and unlawfully failing to ''give effect to'' the prior CASAC's recommendation.

Further, we disagree with the comment that the Act requires the EPA to specify ''a level'' to protect the public welfare against crop yield reductions. As discussed in greater detail in section III.B.2.b(iii) above, the EPA is not required under the Act to set separate standards for every type of effect that may be caused by a pollutant in ambient air, as long as it has engaged in reasoned decision making in determining that a particular standard provides the requisite protection. Thus, it is common for one NAAQS to provide protection for multiple effects, with the most sensitive effect influencing the stringency of the standard and accordingly leading to protection that is adequate for other less sensitive effects. As discussed further in section III.B.2.b(iii) above, in reviewing each standard, the EPA gives due consideration to each effect relevant for that standard in considering whether the standard provides adequate protection from the type, magnitude or extent of such effects known or anticipated to be adverse to the public welfare. In the case of crop yield loss, as discussed in section III.B.3 below, the Administrator has considered the magnitude of RYL that may be

[229] Section 109(b)(2) of the CAA provides only that any secondary standard ''shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on [the air quality] criteria, 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.''

[230] The first reference to 5% RYL by the prior CASAC (in the 2015 O_3 NAAQS review) appears to be in its letter on the first draft PA (Frey and Samet, 2012). In that letter, the prior CASAC identifies 5% RYL as a factor on which levels for a W126 index secondary standard should be based, although no rationale is provided for this recommendation. In a letter attachment, comments from an individual member point to a 1996 workshop (2014 PA, pp. 6–15 through 6–17; Heck and Cowling, 1997). As summarized in the 2015 O_3 decision, the 1996 workshop participants (16 leading scientists, discussing their views for a secondary O_3 standard) indicated an interest in protecting against crop yield reductions of 5% yet noted uncertainties surrounding such a percentage which led them to identify 10% RYL (80 FR 65378, October 26, 2015). In their emphasis on 5%, the 2012 comments from the individual prior CASAC member expressed the view that the ability to estimate 5% RYL has improved (Frey and Samet, 2012, p. A–54). Neither the individual prior CASAC member nor the 1997 workshop report provide any explicit rationale for the percentages identified or any description of their connection to ecosystem impacts of a specific magnitude or type, or to judgments on significance of the identified effects for public welfare (80 FR 65378, October 26, 2015; Heck and Cowling, 1997).

associated with W126 index values that occur under the current standard and, based on the current information with regard to the RYL estimates, notes that these estimates are generally no higher than 5.1% and predominantly well below that. In so doing, he has also considered factors such as those raised above, and in light of all of these considerations, he judges that a RYL of 5.1% does not represent an adverse effect to the public welfare. Thus, the Administrator judges that the current standard provides adequate protection of the public welfare for crop yield loss related effects.

(v) RBL

In objecting to the EPA's proposed decision, some commenters disagree with the target level of protection identified based on use of RBL. In so doing, such commenters variously claim that a 3-year average of 17 ppm-hrs is ''ill-suited'' to protect against adverse impacts to the public welfare; that 6% RBL is too high to protect the public welfare; that use of a 3-year average instead of a single year W126 index is needed; and, that EPA must focus a target on exposures that would avoid 2% RBL, citing comments from the prior CASAC on the second draft PA in the 2015 review, and claiming that a focus on a W126 index of 7 ppm-hrs is needed for that. With regard to the EPA's use of 6% in considering the adequacy of protection related to RBL, these commenters recognize that *Murray Energy* rejected an argument that EPA's prior reliance on 6% (in the 2015 decision) was arbitrary based on the record in that case (*Murray Energy,* 936 F.3d at 615–16). In pressing their views, however, the commenters state that nothing in *Murray Energy* prevents EPA from revising its prior determination based on the scientific evidence and CASAC advice.

With respect to the latter point, the EPA agrees that the Administrator's decision in this review must take into account the currently available scientific evidence and advice from the CASAC, and that the Agency is not bound by the Administrator's conclusions in the prior review. As summarized in the proposal for the current review, in the proposal, the Administrator took the currently available scientific evidence and advice from the CASAC into account, while also choosing to consider the judgments and decision made by the prior Administrator in that Administrator's consideration of RBL related targets for cumulative seasonal exposure. He did so, in light of the welfare effects evidence and air quality information now available, as well as the advice from the current CASAC reflecting its concurrence that implementation of the prior Administrator's approach or framework is ''still effective'' in protecting the public welfare from vegetation effects of O_3 (Cox, 2020a, Consensus Responses to Charge Questions p. 21). As described in section III.B.3 below, after considering the public comments on this point, he is taking a similar approach in reaching his decision in this review.

With regard to the commenters' objection to the EPA's use of a 3-year average in assessing RBL, we note, as an initial matter, that the EPA's focus on a 3-year average of 17 ppm-hrs as a target level relates to an RBL estimate of 5.3%, a value that was also chosen in 2015 in recognition of the prior CASAC advice both with regard to 6% RBL and about considering a lower W126 index target for a 3-year average due to the prior CASAC's concern about ''unusually damaging years.'' In the current review, the CASAC has explicitly considered the EPA's interpretation of 6% in identifying a target of 17 ppm-hrs as a 3-year average, and expressed its view that this target ''is still effective in particularly protecting the public welfare in light of vegetation impacts from ozone'' (Cox, 2020a, Consensus Responses to Charge Questions p. 21). Accordingly, the EPA disagrees with the comments that 6% RBL and a 3-year average W126 index target of 17 ppm-hrs are too high to inform the Administrator's judgments on O_3 air quality that protects the public welfare; rather, the Administrator continues to find this useful in informing his judgments regarding the public welfare protection provided by the standard, together with a broader consideration of air quality patterns associated with meeting the current standard, such as control of peak hourly concentrations, as described in section III.B.3 below. Further, we refer to the discussion above of how the existing standard, with its current averaging time and form provides the protection from the occurrence of elevated hourly concentrations that may characterize what the prior CASAC described as ''unusually damaging years.'' As discussed above, the available air quality data demonstrate the strong protection provided by the current standard from elevated concentrations that may occur in some years. As noted above, these analyses indicate that while the current form and averaging time of the existing standard provides control of these concentrations and the associated peak exposures, reliance solely on a standard in the form of the W126 index based standard, as advocated by the commenters, even with a level as low as 7 ppm-hrs cannot be relied on to provide it.

In support of their view that the EPA must focus on avoiding 2% RBL with a W126 index of 7 ppm-hrs, these commenters provide little rationale beyond citing a comment by the prior CASAC made in the last review. In so doing, the commenters assert that because the prior CASAC had noted that 7 ppm-hrs was the only W126 index level for which the E–R functions yielded a RBL for the median tree species that was less than or equal to 2%, the EPA must protect against 2% RBL and adopt a W126 index level of 7 ppm-hrs. We disagree. As an initial matter, we note our discussion above regarding the EPA's consideration in this review of advice from a prior CASAC, including prior CASAC statements that are raised by commenters, such as those noted here. Further, in making the statement that the commenters' cite, the prior CASAC did not reach the same conclusion as the commenters with regard to the extent to which a revised secondary standard should limit cumulative exposures and associated estimates of RBL, such that the prior CASAC did not recommend that the EPA consider only W126 index levels associated with median RBL estimates at or below 2%.[231] See *Murray Energy,* 936 F.36 at 615–16 (noting that ''CASAC did not identify 2% growth loss as the only sufficiently protective level'' but merely recommended ''2% as the lower end of a range of permissible target levels'' to be considered). In fact, seven of the nine W126 index levels in the range recommended by the prior CASAC (7 to 15 ppm-hrs [Frey, 2014b]) are associated with RBL estimates higher than 2% (PA, Appendix 4A). As a basis for their assertion that the secondary standard should protect against a median RBL of 2%, these commenters additionally oddly declare that after three years, a 2% RBL per year ''becomes 6%.'' There is no evidence in the record, and the commenter provides no evidence, that would support their declaration that without a tripling in exposure, the O_3-attributable reduction in annual growth (the RBL) would triple.[232] Nor is there

[231] Additionally, an explicit scientific rationale for 2% is not provided by the former CASAC. Nor is it provided in the workshop report referenced by the prior CASAC in its discussion, as further discussed in the 2015 decision (80 FR 65394, October 26, 2015; Frey, 2014b, p. 14).

[232] It is unclear by what logic the commenters conclude that RBL, a metric describing the effect of

evidence that would support an alternative interpretation of the commenters' statement as a claim that a tree experiencing a 2% RBL per year is reduced in absolute biomass by 6% after three years.[233]

Some commenters who disagree with the proposed decision also express the view that the EPA has ''proposed'' to use RBL functions for trees as a proxy for all vegetation effects. Based on this view, these commenters variously assert that the EPA is failing to comply with its obligation under the Clean Air Act that a secondary standard protect the public welfare from ''any known or anticipated adverse effects''; that the EPA's approach is not the same as the prior CASAC's discussion of RBL as a surrogate; that the EPA is contravening its statutory obligation by using one adverse effect as a surrogate for another without showing that prevention of the former will prevent the latter; and that, based on the commenters' interpretation of a statement made by the prior CASAC, a standard that allows tree growth loss above 2% cannot protect against visible foliar injury. As an initial matter, we note that the citation provided by the commenters for their statement that the ''EPA proposes'' to use RBL functions as a proxy for the broad array of O_3 vegetation-related effects does not include such a ''proposal.'' Rather the commenters' citation points to the background section of the proposal which simply summarizes the concept of RBL as a proxy or surrogate which was employed in the last review and which was described by the prior CASAC (85 FR 49899, August 14, 2020). In describing use of RBL as a proxy or surrogate, the proposal (and the PA) use several phrases, ranging from ''for consideration of the broader array of vegetation-related effects of potential public welfare significance, that included effects on growth of individual sensitive species and extended to ecosystem-level effects, such as community composition in natural forests, particularly in protected public lands, as well as forest productivity'' (85 FR 49878, August 14, 2020), to shorter phrases, such as ''for the broad array of vegetation related effects that extend to the ecosystem scale'' (85 FR 49911, August 14, 2020).

We disagree with these commenters that the way the EPA uses RBL as a ''proxy'' or ''surrogate'' is contrary to law, and with their contention that the EPA uses one adverse effect as a surrogate for another without showing that prevention of the former will prevent the latter. As described in the Administrator's decision below, the most precise use of RBL as a surrogate or proxy is in the target level of protection for cumulative seasonal exposure (17 ppm-hrs as a 3-year average W126 index). This use relates specifically to public welfare effects related to O_3 effects on growth of individual sensitive species and related effects, including ecosystem-level effects, such as community composition in natural forests, particularly in protected public lands, as well as forest productivity (as discussed in the PA, section 4.5.1.2). In fact, the ISA describes (or relies on) conceptual relationships among such effects in considering causality determinations for ecosystem-scale effects such as altered terrestrial community composition and reduced productivity, as well as reduced carbon sequestration, in terrestrial ecosystems (ISA, Appendix 8, sections 8.8 and 8.10). Beyond these relationships of plant-level effects and ecosystem-level effects,[234] RBL can be appropriately described as a scientifically valid surrogate of a variety of welfare effects based on consideration of ecosystem services and the potential for adverse impacts on public welfare, as well as conceptual relationships between vegetation growth-related effects (including carbon allocation) and ecosystem-scale effects (PA, pp. 4–75 and 4–76). Both the prior CASAC and the current CASAC recognized this (Frey, 2014b, pp. iii, 9–10;[235] Cox, 2020a, Consensus Responses to Charge Questions pp. 18 and 21[236]). As was discussed in the proposal, the information available in this review provides continued support for the use of tree seedling RBL as a proxy for the broad array of vegetation-related effects conceptually related to growth effects, a conclusion with which the CASAC agreed (85 FR 49899,49906, August 14, 20202).[237]

As recognized in the proposal (and PA) there are two other vegetation effect categories with extensive evidence bases (which include analyses that assess the influence of cumulative seasonal exposure); these are crop yield loss and visible foliar injury. As discussed above, the consideration of protection provided by the current standard for the former goes beyond the target focused on RBL and includes aspects of the evidence specific to those effects. As described above and in section III.B.3 below, the EPA is concluding that the level of protection is adequate to protect the public welfare from effects related to crop yield loss. With regard to the latter, contrary to the commenter's assertion, the EPA is not claiming that protection focused on RBL provides protection for visible foliar injury. The EPA's consideration of visible foliar injury is described earlier in this section and in section III.B.3 below.

the O_3 exposure in a single year, can be modified by the RBL in a prior year.

[233] The fallacy of such interpretations can be seen in the presentation of above-ground biomass from a multiyear study of O_3 exposure of aspen that varies little over six years. Across the six years, the above-ground biomass of the trees receiving elevated O_3 exposure is 25%, 30%, 29%, 29%, 31% and 29% lower than the reference trees (2013 ISA, Table 9–14; 2020 ISA, Figure 8–17).

[234] As summarized in the ISA, O_3 can mediate changes in plant carbon budgets (affecting carbon allocation to leaves, stems, roots and other biomass pools) contributing to growth impacts, and altering ecosystem properties such as productivity, carbon sequestration and biogeochemical cycling. In this way, O_3 mediated changes in carbon allocation can ''scale up'' to population, community and ecosystem-level effects including changes in soil biogeochemical cycling, increased tree mortality, shifts in community composition, changes in species interactions, declines in ecosystem productivity and carbon sequestration and alteration of ecosystem water cycling (ISA, section 8.1.3).

[235] The prior CASAC 2014 letter on the second draft PA in that review stated the following (Frey, 2014b, p. 9–10):

For example, CASAC concurs that trees are important from a public welfare perspective because they provide valued services to humans, including aesthetic value, food, fiber, timber, other forest products, habitat, recreational opportunities, climate regulation, erosion control, air pollution removal, and hydrologic and fire regime stabilization. Damage effects to trees that are adverse to public welfare occur in such locations as national parks, national refuges, and other protected areas, as well as to timber for commercial use. The CASAC concurs that biomass loss in trees is a relevant surrogate for damage to tree growth that affects ecosystem services such as habitat provision for wildlife, carbon storage, provision of food and fiber, and pollution removal. Biomass loss may also have indirect process-related effects such as on nutrient and hydrologic cycles. Therefore, biomass loss is a scientifically valid surrogate of a variety of adverse effects to public welfare.

[236] The CASAC letter on the draft PA in the current review stated the following (Cox, 2020a, Consensus Responses to Charge Questions p. 18):

The RBL appears to be appropriately considered as a surrogate for an array of adverse welfare effects and based on consideration of ecosystem services and potential for impacts to the public as well as conceptual relationships between vegetation growth effects and ecosystem scale effects. Biomass loss is a scientifically sound surrogate of a variety of adverse effects that could be exerted to public welfare. . . . In the previous review, the Administrator used RBL as a surrogate for consideration of the broader array of vegetation related effects of potential welfare significance that included effects of growth of individual sensitive species and extended to ecosystem level effects such as community composition in natural forests, particularly in protected public lands (80 FR 65406, October 26, 2015). The EPA believes, and the CASAC concurs, that information available in the present review does not call into question this approach, indicating there continues to be support for the use of tree seedling RBL as a proxy for the broader array of vegetation-related effects, most particularly those related to growth.

[237] Further, the EPA lacks sufficient information in the air quality criteria to identify requisite air quality for these effects.

With regard to the two newly identified categories of insect-related effects, the Administrator finds there to be insufficient information to judge the current standard inadequate based on these effects, as discussed in section III.B.3 below. He does not claim that RBL provides a surrogate for these effects. However, he notes that the available information in the air quality criteria does not indicate a greater sensitivity of such effects as compared to O_3 effects on vegetation growth, and that he lacks sufficient information in the air quality criteria to identify requisite air quality for these effects.

(vi) W126 Index in Areas Meeting Current Standard

In objecting to the proposed decision, one group of commenters disagree with EPA's findings regarding the W126 index levels in areas that meet the current standard. In so doing, these commenters claim that the EPA is mistaken to claim that in virtually all design value periods and locations at which the current standard was met across the period covered by the historical dataset the 3-year W126 index was at or below 17 ppm-hrs because they variously assert there are either 25 or 21 such occurrences, and they further assert there to be either 50 occurrences of a single-year W126 index at or above 19 ppm-hrs or 52 occurrences of a single-year W126 index above 19 ppm-hrs. These counts are in disagreement with the air quality analyses documented in Appendix 4D of the PA. For example, out of 8,292 values across nearly 20 years for U.S. ambient air monitoring sites, distributed across all nine climate regions, with air quality that meets the current standard, there are just eight occurrences of a 3-year W126 index value above 17 ppm-hrs (PA, Appendix 4D, Tables 4D–10 and 4D–7). This means that 99.9% of the records (virtually all) were at or below 17 ppm-hrs. While the details of each step of the analyses in the PA are extensively documented, including data handling, rounding conventions and data acceptability criteria (PA, Appendix 4D, section4D.2), the lack of documentation provided by the commenters and their conflicting claims (indicated above) leave the EPA to hypothesize that the reason for the disagreements include differences with regard to these details, such as those regarding rounding conventions. As described in the PA, W126 values ''were rounded to the nearest unit ppm-hr for applications requiring direct comparison to a W126 level,'' a convention intended to provide consistency in the precision of the comparison as the W126 levels for comparison were also in whole numbers (PA, Appendix 4D, section 4D.2.2). With the rounding conventions applied in the PA, there are eight 3-year W126 index values greater than 17 ppm-hrs (*i.e.,* equal to 18 or 19). It may be that the commenters counted unrounded 3-year W126 index values as low as 17.01 as being greater than 17 ppm-hrs, although the reason for them providing two conflicting counts is unclear. Similarly with regard to the counts for single-year W126 index values above 19 ppm-hrs, the commenters may have counted unrounded single-year index values as low as 19.01 ppm-hrs as being greater than 19 ppm-hrs. Thus, we find the commenters criticism of the EPA's characterization of the findings of the air quality analyses, as well as the commenters' counts, to be unfounded.

Some commenters claim EPA pays inadequate attention to the relatively few occurrences of single-year W126 index values at or above 19 ppm-hrs that have occurred at sites meeting the current standard since 2002 and that the standard must be set to avoid such occurrences. The EPA disagrees with these commenters, as described below, after carefully considering the relatively few occurrences of W126 index values at or above 19 ppm-hrs, including single-year values. In so doing, we have given particular focus on Class I areas, recognizing the attention given to such areas by the Administrator in judging the potential for effects adverse to the public welfare, a focus recognized by the CASAC and with which the prior CASAC explicitly concurred (Cox, 2020a; Frey, 2014b, p. 9).

Among the nearly 500 values for monitoring sites in or near Federal Class I areas across the U.S., during periods from 2000 through 2018 when the current standard was met, there are no occurrences of a 3-year average W126 index above 19 ppm-hrs (PA, Table 4–1). Across this same period in the same Class I locations, there are just 15 occurrences of single-year W126 index values above 19 ppm-hrs, all of which date prior to 2013 (PA, Appendix 4D, section 4D.3.2.4). All of these occurrences are below 25 ppm-hrs. Thus, in addition to their being relatively few occurrences of a single-year W126 above 19 ppm-hrs in/near a Class I area in the 19-year dataset, none of them (the most recent of which was in 2012) is higher than 25 ppm-hrs; in fact, the highest is 23 ppm-hrs (PA, Appendix 4D, section 4D.3.2.4).

We have also considered the full 19-year dataset for locations beyond those in or near Class I areas, noting that, at other sites across the U.S., occurrences of single-year W126 index above 19 ppm-hrs (22) were predominantly in urban areas, including Los Angeles, and the highest values were just equal to 25 ppm-hrs, or, in one instance, just equal to 26 ppm-hrs, when rounded (85 FR 49895, 49904, August 14, 2020; PA, sections 4.4 and 4.5, Appendix 4D). In considering the potential risk posed by these scattered occurrences, largely in urban areas, with none since 2012 in or near a Class I areas, we additionally consider the data on peak hourly concentrations also discussed above (Wells, 2020). Together, these data indicate the control provided by the current standard in areas that are of particular focus in protecting the public welfare, on the extent and frequency of occurrence of cumulative exposures in terms of the W126 index (and of peak concentrations) of a magnitude of potential concern. As discussed in section III.B.3 below, the Administrator does not find the air quality patterns allowed by the current standard, as indicated by these analyses, to pose a risk of adverse effects to the public welfare.

In their criticism of the EPA's air quality analyses, one commenter claims that the analyses are difficult to evaluate for California and other West region states and suggest that California sites brought into compliance with the existing standard would still have elevated W126 index values, similar to sites in the Southwest region. We disagree with the commenter's claim that the air quality analyses suggest that compliance with the existing standard would not reduce the W126 index values at California sites. In making their claim, the commenters cite Figures 4D–4 and 4D–5 of the PA. These figures, however, simply document W126 index at sites with various design values at one point in time (2016–2018). They do not describe analyses of trends over time, with changes in air quality. Yet, that very issue was the subject of separate regression analyses in the PA (PA, Appendix 4D, section 4D.3.2.3). These analyses show that the Southwest region, which had highest W126 index values at sites meeting the current standard, also exhibited the greatest improvement in the W126 metric values per unit decrease in their design value (slope of 0.93) over the nearly 20 year period analyzed. The pattern is very similar for the West region (with a slope of 0.80), with the exception of three sites (in downtown LA); however, the design values for these sites are above 100 ppb, making such projections quite uncertain (PA, Appendix 4D, section 4D.3.2.3).

(vii) Climate Effects

In support of their disagreement with the EPA's proposed decision, some commenters claim that EPA needs to establish a standard to protect from radiative forcing and related climate effects. In so doing, they stated that EPA cannot rely on uncertainty by retaining the existing standard and instead, given the uncertainties recognized in the ISA, which they suggest could mean current information underestimates O_3 climate related impacts, the Administrator should strengthen the existing standard or establish an additional standard. Some commenters additionally assert that the EPA has failed to address a recommendation from CASAC regarding a quantitative analysis, while also criticizing EPA conclusions regarding a carbon storage analysis in the last review. The EPA disagrees with the commenters that the available information is sufficient to identify such a standard that could be judged to provide the requisite protection under the Act, and notes that the commenters do not submit or describe such information; nor do the commenters identify a standard that they claim would provide such protection.

With regard to the CASAC recommendation cited by some commenters, we note in its review of the draft PA, the CASAC recommended changes to the PA to ''more thoroughly address effects of ozone on climate change,'' that would include some quantitation, such as estimates of climate change related to a change in O_3 (Cox 2020a, Consensus Responses to Charge Questions p. 22). In consideration of this advice, the final PA included additional discussion on the available information and tools related to such estimates. As discussed below, we conclude that this information, as documented in the ISA, does not provide a foundation with which to derive such estimates as might pertain to O_3 and public health and welfare considerations relevant to decisions on the NAAQS.[238]

As recognized in the proposal and summarized in section III.A.2 above, there are a number of limitations and uncertainties that affect our ability to characterize the extent of any relationships between O_3 concentrations in ambient air in the U.S. and climate-related effects, thus precluding a quantitative characterization of climate responses to changes in O_3 concentrations in ambient air at regional (vs global) scales. While evidence supports a causal relationship between the global abundance of O_3 in the troposphere and radiative forcing, and a likely causal relationship between the global abundance of O_3 in the troposphere and effects on temperature, precipitation, and related climate variables (ISA, section IS.5.2 and Appendix 9; Myhre et al., 2013), the non-uniform distribution of O_3 (spatially and temporally) makes the development of quantitative relationships between the magnitude of such effects and differing O_3 concentrations in the U.S. challenging (ISA, Appendix 9). Additionally, ''the heterogeneous distribution of ozone in the troposphere complicates the direct attribution of spatial patterns of temperature change to ozone induced [radiative forcing]'' and there are ''ozone climate feedbacks that further alter the relationship between ozone [radiative forcing] and temperature (and other climate variables) in complex ways'' (ISA, Appendix 9, section 9.3.1, p. 9–19). Thus, various uncertainties ''render the precise magnitude of the overall effect of tropospheric ozone on climate more uncertain than that of the well-mixed GHGs'' and ''[c]urrent limitations in climate modeling tools, variation across models, and the need for more comprehensive observational data on these effects represent sources of uncertainty in quantifying the precise magnitude of climate responses to ozone changes, particularly at regional scales'' (ISA, section IS.6.2.2, Appendix 9, section 9.3.3, p. 9–22). For example, current limitations in modeling tools include ''uncertainties associated with simulating trends in upper tropospheric ozone concentrations'' (ISA, section 9.3.1, p. 9–19), and uncertainties such as ''the magnitude of [radiative forcing] estimated to be attributed to tropospheric ozone'' (ISA, section 9.3.3, p. 9–22). Further, ''precisely quantifying the change in surface temperature (and other climate variables) due to tropospheric ozone changes requires complex climate simulations that include all relevant feedbacks and interactions'' (ISA, section 9.3.3, p. 9–22). For example, an important limitation in current climate modeling capabilities for O_3 is representation of important urban- or regional-scale physical and chemical processes, such as O_3 enhancement in high-temperature urban situations or O_3 chemistry in city centers where NOx is abundant. Because of such limitations we cannot quantify or judge the impact of incremental changes in O_3 concentrations in the U.S. on radiative forcing and subsequent climate effects.

Thus, as discussed in section III.B.3 below, the significant limitations and uncertainties summarized here together preclude identification of an O_3 standard that could be judged to provide requisite protection of the public welfare from adverse effects linked to O_3 influence on radiative forcing, and related climate effects. Contrary to the commenters' charge that the lack of a quantitative analysis of climate-related effects due to recognition of such limitations and uncertainties is unlawful and arbitrary, the information available in this review is insufficient to judge the existing standard inadequate or to identify an appropriate revision based on O_3-related climate effects. In the face of insufficient evidence for such conclusions, it might, on the contrary, be judged unlawful and arbitrary for the Agency to perform guesswork to assert a particular new standard provided requisite protection for this category of effects. The EPA agrees with the commenters that ''perfect information'' is not required. However, information that provides for assessment of how the current and potential alternative or additional standards would affect O_3-related climate impacts is lacking. As noted in the ISA, few studies have even attempted to estimate ''climate response to changes in tropospheric ozone concentrations alone in the future atmosphere,'' and effects of O_3 on radiative forcing and climate depend on many factors other than tropospheric ozone concentrations, including ''changes in a suite of climate-sensitive

[238] In raising EPA's conclusions on a carbon storage analysis in the last review, some commenters repeat their comments in the last review that claimed that the relatively lesser weight the EPA placed on the 2014 WREA estimates of carbon storage (in terms of CO_2) was inconsistent with the emphasis the EPA placed on CO_2 emissions reductions estimated for another regulatory action. The commenters overlook, however, key distinctions between the two types of estimates in the two different analyses which appropriately led the EPA to recognize much greater uncertainty in the WREA estimates and accordingly give them less weight. While the WREA estimates were for amounts of CO_2 removed from the air and stored in vegetation as a result of plant photosynthesis occurring across the U.S., the estimates for the other action were for reductions in CO_2 produced and emitted from power plants (79 FR 34830, 34931–33). The potentially transient nature of carbon storage in vegetation makes a ton of additional carbon uptake by plants in the former arguably unequal to a ton of reduced emissions from fossil fuels. Further, there are appreciably larger uncertainties involved in attempting to quantify the additional carbon uptake by plants which requires complex modeling of biological and ecological processes and their associated sources of uncertainty, and there is no new information available in the current review that would reduce such uncertainties in quantitative estimates of carbon storage benefits to climate. In recognizing the public welfare value of ecosystem carbon storage, we additionally note, however, that protection provided by the current standard from vegetation effects (and RBL) also provides a degree of protection in terms of carbon storage.

factors, such as the water vapor content of the atmosphere'' (ISA, p. 9–20; Myhre et al., 2013). Thus, as discussed in section III.B.3 below, while the Administrator recognizes that the evidence supports a relationship of tropospheric O_3 with climate effects, he judges the quantitative uncertainties to be too great to support identification of a standard specific to such effects.

4. Administrator's Conclusions

Based on the large body of evidence concerning the welfare effects, and potential for public welfare impacts, of exposure to O_3 in ambient air, and taking into consideration the attendant uncertainties and limitations of the evidence, the Administrator concludes that the current secondary O_3 standard provides the requisite protection against known or anticipated adverse effects to the public welfare, and should therefore be retained, without revision. In reaching these conclusions, the Administrator has carefully considered the assessment of the available welfare effects evidence and conclusions contained in the ISA, with supporting details in the 2013 ISA and past AQCDs; the evaluation of policy-relevant aspects of the evidence and quantitative analyses in the PA (summarized in sections III.A.2 and III.A.3 above); the advice and recommendations from the CASAC (summarized in section III.B.1.b above); and public comments (as discussed in section III.B.2 above and the separate Response to Comments document), as well as the August 2019 decision of the D.C. Circuit remanding the secondary standard established in the last review to the EPA for further justification or reconsideration.

In considering the currently available information in this review of the O_3 secondary standard, the Administrator recognizes the longstanding evidence base for vegetation-related effects, augmented in some aspects since the last review, described in section III.A.2.a above. The currently available evidence describes an array of effects on vegetation and related ecosystem effects causally or likely to be causally related to O_3 in ambient air, as well as the causal relationship of tropospheric O_3 in radiative forcing and subsequent likely causally related effects on temperature, precipitation and related climate variables. The Administrator also takes note of the quantitative analyses and policy evaluations documented in the PA that, with CASAC advice and consideration of public comment, inform the judgments required of him in reaching his decision on a secondary standard that provides the requisite protection under the Act.

As an initial matter, the Administrator recognizes the continued support in the current evidence for O_3 as the indicator for photochemical oxidants (as recognized in section III.B.1.c above). In so doing, he notes that no newly available evidence has been identified in this review regarding the importance of photochemical oxidants other than O_3 with regard to abundance in ambient air, and potential for welfare effects, and that, as stated in the current ISA, ''the primary literature evaluating the health and ecological effects of photochemical oxidants includes ozone almost exclusively as an indicator of photochemical oxidants'' (ISA, section IS.1.1). Thus, the Administrator recognizes that, as was the case for previous reviews, the evidence base for welfare effects of photochemical oxidants does not indicate an importance of any other photochemical oxidants. For these reasons, described with more specificity in the ISA and PA, he proposes to conclude it is appropriate to retain O_3 as the indicator for the secondary NAAQS for photochemical oxidants (85 FR 49896, August 14, 2020).

In his review of the existing secondary O_3 standard, in light of the evidence base and quantitative analyses available today, the Administrator has given particular attention to consideration of the issues raised by the August 2019 court remand, and related issues raised in public comment, as well as analyses that were conducted or updated in this review in consideration of the remand and related public comment. In so doing, he has also given careful consideration of the form and averaging time of the current standard and its ability to control the patterns of O_3 concentrations that contribute to environmental exposures of potential concern to the public welfare. Further, he has considered what is indicated by the information currently available with regard to exposure metrics, supported by the current evidence, for assessing potential risks posed to vegetation, and protection provided from such exposures. Additionally, with regard to visible foliar injury, he has considered the current evidence in the ISA in combination with quantitative information and policy evaluations in the PA, advice from the CASAC and public comment, in making judgments regarding adequacy of the protection provided by the current standard from adverse effects to the public welfare related to this effect. Before turning to these issues, discussed, in turn, below in the context of the EPA's understanding of the information now available in the current review, he addresses two endpoints newly identified in this review, as well as tropospheric O_3 effects related to climate.

With regard to the two insect-related categories of effects with new ISA determinations in this review, the Administrator takes note of the conclusions that the current evidence is sufficient to infer likely causal relationships of O_3 with alterations of plant-insect signaling and insect herbivore growth and reproduction (as summarized in section III.A.2.a above). He additionally recognizes the PA finding that uncertainties in the current evidence, as summarized in section III.A.2 above, preclude a full understanding of such effects, the air quality conditions that might elicit them, the potential for impacts in a natural ecosystem. Accordingly, the Administrator notes a lack of clarity in the characterization of these effects, and a lack of important quantitative information to consider such effects in this context such that it is not feasible to relate different patterns of O_3 concentrations with specific risks of such alterations. As a result, the Administrator concludes there is insufficient information to judge how particular ambient air concentrations of O_3 relate to the degree of impacts on public welfare related to these effects. Thus, he concludes there is insufficient information to judge the current standard inadequate or to identify an appropriate revision based on these effects.

Before focusing further on the key vegetation-related effects identified above, the Administrator first considers the strong evidence documenting tropospheric O_3 as a greenhouse gas causally related to radiative forcing, and likely causally related to subsequent effects on variables such as temperature and precipitation. In so doing, he takes note of the limitations and uncertainties in the evidence base that affect characterization of the extent of any relationships between O_3 concentrations in ambient air in the U.S. and climate-related effects, and preclude quantitative characterization of climate responses to changes in O_3 concentrations in ambient air at regional or national (vs global) scales, as summarized in sections III.A.2 above. As a result, he recognizes the lack of important quantitative tools with which to consider such effects in this context such that it is not feasible to relate different patterns of O_3 concentrations at the regional (or national) scale in the U.S. with specific risks of alterations in temperature, precipitation and other climate-related variables. The Administrator finds that these significant limitations and uncertainties together preclude his identification of an O_3 standard reasonably judged to provide requisite protection of the public welfare from adverse effects linked to O_3 influence on radiative forcing, and related climate effects. Thus, the Administrator concludes that the information available in this review is insufficient to judge the existing standard inadequate or to identify an appropriate revision based on O_3-related climate effects.

The Administrator turns now to vegetation-related effects, the evidence for which as a whole is extensive, spans several decades, and supports the Agency's conclusions of causal or likely to be causal relationship for O_3 in ambient air with an array of effect categories. These categories include reduced vegetation growth, reproduction, crop yield, productivity and carbon sequestration in terrestrial systems; increased tree mortality; alteration of terrestrial community composition, belowground biogeochemical cycles and ecosystem water cycling; and visible foliar injury (ISA, Appendix 8). As an initial matter, the Administrator notes the new ISA determination that the current evidence is sufficient to infer likely causal relationships of O_3 with increased tree mortality. With regard to the current evidence for this effect, the Administrator notes that the evidence does not indicate a potential for O_3 concentrations that occur in locations that meet the current standard to cause increased tree mortality, as summarized in section III.A.2.a above (PA, section 4.3.1). Accordingly, he finds it appropriate to focus on more sensitive effects, such as tree seedling growth, in his review of the standard. Thus, in considering the adequacy of protection provided by the current standard from adverse effects to the public welfare related to these effects, the Administrator begins by considering vegetation growth and conceptually related effects with a focus on RBL (described in section III.B.2 above), then turns to a specific consideration of crop yield loss and lastly, to consideration of visible foliar injury.

With regard to vegetation growth and related effects, the Administrator has considered discussions in the PA and in response to public comments in section III.B.2 above, and finds it appropriate for identification of the requisite protection to extend beyond consideration of a magnitude of growth effects, *per se,* that he may judge adverse to the public welfare. Rather, the Administrator extends his consideration beyond that, judging it appropriate to consider reduced growth (*i.e.,* RBL) as a proxy for an array of other vegetation-related effects to the public welfare. As discussed in section III.B.2 above, these categories of effects include reduced vegetation growth, reproduction, productivity and carbon sequestration in terrestrial systems, and also alteration of terrestrial community composition, belowground biogeochemical cycles and ecosystem water cycling. In adopting RBL as a proxy for this array of effects, the Administrator notes that such a use is consistent with advice from CASAC, and that RBL was also adopted as a proxy for this array of effects by the prior Administrator, in consideration of advice from the prior CASAC.

In assessments of RBL estimated from O_3 exposure, the Administrator takes note of the PA consideration of the established E–R relationships for RBL in tree seedlings of 11 species with O_3 exposures in terms of W126 index (PA, Appendix 4A). In so doing, he agrees with the PA conclusion regarding 6% RBL, with which the CASAC concurred, as described in sections III.B.1.b and III.B.2 above), and judges that for his use of RBL as a proxy, maintaining O_3 concentrations such that associated estimates of RBL fall below 6%, as a median across the 11 species represented by the established E–R relationships would assure the appropriate protection. In making these judgments, he observes that they were also adopted by the prior Administrator, with consideration of advice from the prior CASAC.

Further, based on considerations discussed in the PA, advice from CASAC and discussion in section III.B.2 above, Administrator has considered the use of RBL in his judgment of the public welfare protection provided by the secondary standard. Based on those considerations, including uncertainties in the E–R relationships and their use in the way described here, the Administrator judges it appropriate for the standard to protect against W126 index values associated with a median RBL at or above 6% (while also controlling peak hourly concentrations, as discussed below). Based on this judgment, in addition to a recognition of uncertainty in these estimates (in light of the discussion in section III.B.2.b(ii) above regarding the appropriate duration or averaging for the W126 index metric) he concludes it appropriate for the standard to generally control exposures in terms of W126 index to a level of 17 ppm-hrs, recognizing that the RBL estimated for such a W126 index value is 5.3%, a value appreciably below 6%.

With regard to the appropriate O_3 exposure metric to employ in assessing adequacy of air quality control in protecting against RBL, the Administrator has considered the discussions in the PA, and in response to public comments in section III.B.2 above regarding the available evidence and air quality analyses. He has also considered this in the context of the court remand with regard to the EPA's use of a 3-year average W126 index to assess protection from RBL and the court's reference to advice from the prior CASAC on protection against ''unusually damaging years'' (described in section III.B.2 above). In so doing, the Administrator considers below the extent of conceptual similarities of the 3-year average W126 index with some aspects of the derivation approach for the established E–R functions, the context of RBL as a proxy (as recognized above), and limitations associated with a reliance solely on W126 index as a metric to control exposures that might be termed ''unusually damaging.''

With regard to the established E–R functions used to describe the relationship of RBL with O_3 in terms of a seasonal W126 index, the Administrator recognizes that the E–R functions were derived mathematically from studies of different exposure durations (varying from shorter than one to multiple growing seasons) by applying adjustments so that they would yield estimates normalized to the same period of time (season), such that the estimates may represent average impact for a season, as summarized in section III.A.1.c(ii) above (PA, section 4.5.1.2, Appendix 4A, Attachment 1). He notes the compatibility of W126 index averaged over multiple growing seasons or years with these adjustments. He also notes the exposure levels represented in the data underlying the E–R functions are somewhat limited with regard to the relatively lower cumulative exposure levels most commonly associated with the current standard (*e.g.,* at or below 17 ppm-hrs), indicating additional uncertainty for application to such levels. Further, he notes the PA observation that some of the underlying studies did not find statistically significant effects of O_3 at the lower exposure levels, indicating some uncertainty in predictions of an O_3-related RBL at those levels, as summarized in section III.A.1.c(ii) above (PA, section 4.5.1.2). He additionally notes the differing patterns of hourly concentrations of the elevated exposure levels in the datasets from which the E–R functions from the patterns in ambient air meeting the current standard across the U.S. today, as summarized in section III.B.2.b(ii). With these considerations regarding the E–R functions and their underlying datasets in mind, he also takes note of year-to-year variability of factors other than O_3 exposures that affect tree growth in the natural environment (*e.g.,* related to variability in soil moisture, meteorological, plant-related and other factors), that have the potential to affect O_3 E–R relationships (ISA, Appendix 8, section 3.12; 2013 ISA section 9.4.8.3; PA, sections 4.3 and 4.5). Based on these considerations, the Administrator finds there to be a consistency of his use of the W126 index averaged over multiple years with the approach used in deriving the E–R function, and with other factors that may affect growth in the natural environment.

In light of such considerations, the Administrator agrees with the PA finding that several factors contribute uncertainty and some resulting imprecision or inexactitude to RBL estimated from single-year seasonal W126 index values, as discussed in section III.D.1.b(ii) of the proposal (85 FR 49900–01, August 14, 2020; PA sections 4.5.1.2 and 4.5.3). The Administrator additionally recognizes the qualitative and conceptual nature of our understanding, in many cases, of relationships of O_3 effects on plant growth and productivity with larger-scale impacts, such as those on populations, communities and ecosystems. From these considerations, he judges that use of a seasonal RBL averaged over multiple years, such as a 3-year average, is reasonable, and provides a more stable and well-founded RBL estimate for his purposes as a proxy to represent the array of vegetation-related effects identified above. The Administrator additionally takes note of the CASAC advice agreeing with the EPA's focus on a 3-year average W126 for this purpose, concluding such a focus to be reasonable and scientifically sound, as summarized in section III.B.1.b above. In light of these considerations, the Administrator finds there to be support for use of an average seasonal W126 index derived from multiple years (with their representation of variability in environmental factors), concluding the use of such averaging to provide an appropriate representation of the evidence and attention to considerations summarized above. In so doing, he finds that sole reliance on single year W126 estimates for reaching judgments with regard to magnitude of O_3 related RBL and associated judgments of public welfare protection would ascribe a greater specificity and certainty to such estimates than supported by the current evidence. Rather, he finds it appropriate, for purposes of considering public welfare protection from effects for which RBL is used as a proxy, to primarily consider W126 index in terms of a 3-year average metric.

In his consideration of the appropriateness of using a 3-year average W126 metric, the Administrator additionally takes note of the discussion in section III.B.2 above with regard to protection against ''unusually damaging years,'' a caution raised by the prior CASAC in considering a secondary standard in terms of a 3-year average W126 index (and an issue raised in the court remand). With regard to this caution, the Administrator finds informative the discussion in section III.B.2 above regarding the extent to which a standard in terms of a W126 metric might be expected to control exposure circumstances of concern (*e.g.,* for growth effects, among others). This discussion and its focus on air quality analyses in the PA and additional analyses conducted in consideration of public comment investigate the annual occurrence of elevated hourly O_3 concentrations which may contribute to vegetation exposures of concern (PA, Appendix 2A, section 2A.2; Wells, 2020).[239]

These air quality analyses illustrate limitations of the W126 index for purposes of controlling peak concentrations, and also the strengths of the current standard in this regard. As discussed more fully in section III.B.2.b(ii) above, the W126 index cannot, by virtue of its definition, always differentiate between air quality patterns with high peak concentrations and those without such concentrations. This is demonstrated in the air quality analyses which show that the form and averaging time of the existing standard is much more effective than the W126 index in limiting peak concentrations (*e.g.,* hourly O_3 concentrations at or above 100 ppb) and in limiting number of days with any such hours (Wells, 2020, *e.g.,* Figures 4, 5, 8, 9 compared to Figures 6, 7, 10 and 11). A similar finding is evidence in the historical data extending back to 2000. These data show the appreciable reductions in peak concentrations that have been achieved in the U.S. as air quality has improved under O_3 standards of the existing form and averaging time (Wells, 2020, Figures 12 and 13). From these analyses, the Administrator concludes that the form and averaging time of the current standard is effective in controlling peak hourly concentrations and that a W126 index based standard would be much less effective in providing the needed protection against years with such elevated and potentially damaging hourly concentrations. Thus, in light of the current evidence and quantitative air quality analyses, the Administrator notes that the W126 index, by its very definition, does not provide specificity with regard to year-to-year variability in elevated hourly O_3 concentrations with the potential to contribute to the ''unusually damaging years'' that the prior CASAC identified for increased concern. In so doing, he disagrees with the statement of the prior CASAC that a single-year W126 index would necessarily provide protection from such years. Further, he judges that a standard based on either a 3-year or a single-year W126 index would not be expected to provide effective control of the peak concentrations that may contribute to ''unusually damaging years'' for vegetation.

Thus, in considering the extent of protection provided by the current standard, in addition to considering seasonal W126 averaged over a 3-year period to estimate median RBL using the established E–R functions, the Administrator finds it appropriate to also consider other metrics, including peak hourly concentrations. While he recognizes that the evidence does not indicate a particular threshold number of hours at or above 100 ppb (or another reference point for elevated concentrations), he takes particular note of the evidence of greater impacts from higher concentrations (particularly with increased frequency) and of the air quality analyses that document variability in such concentrations for the same W126 index value. In light of these considerations, he judges such a multipronged approach to be needed to ensure appropriate consideration of exposures of concern and the associated protection from them afforded by the secondary standard. Thus, the Administrator concludes that use of a seasonal W126 averaged over a 3-year period, which is the design value period for the current standard, to estimate median RBL using the established E–R functions, in combination with a

[239] The ISA references the longstanding recognition of the risk posed to vegetation of peak hourly O_3 concentrations (*e.g.,* ''[h]igher concentrations appear to be more important than lower concentrations in eliciting a response'' [ISA, p. 8–180]; ''higher hourly concentrations have greater effects on vegetation than lower concentrations'' [2013 ISA, p. 91–4] ''studies published since the 2006 O_3 AQCD do not change earlier conclusions, including the importance of peak concentrations, . . . in altering plant growth and yield'' [2013 ISA, p. 9–117]).

broader consideration of air quality patterns, such as peak hourly concentrations, is appropriate for considering the public welfare protection provided by the standard.

In the discussion above, the Administrator recognizes a number of public welfare policy judgments important to his review of the current standard that include the appropriateness of the W126 index, averaged across a 3-year period, for assessing the extent of protection afforded by the standard from cumulative seasonal O_3 exposures. In reflecting on these judgments, the current evidence presented in the ISA and the associated evaluations in the PA, the Administrator concludes that the currently available information supports such judgments, additionally noting the CASAC concurrence with regard to the scientific support for these judgments (Cox 2020a, Consensus Responses to Charge Questions p. 21). Accordingly, the Administrator concludes that the current evidence base and available information (qualitative and quantitative) continues to support consideration of the potential for O_3-related vegetation impacts in terms of the RBL estimates from established E–R functions as a quantitative tool within a larger framework of considerations pertaining to the public welfare significance of O_3 effects. Such consideration includes effects that are associated with effects on vegetation, and particularly those that conceptually relate to growth, and that are causally or likely causally related to O_3 in ambient air, yet for which there are greater uncertainties affecting estimates of impacts on public welfare. The Administrator additionally notes that this approach to weighing the available information in reaching judgments regarding the secondary standard additionally takes into account uncertainties regarding the magnitude of growth impact that might be expected in mature trees (*e.g.,* compared to seedlings), and of related, broader, ecosystem-level effects for which the available tools for quantitative estimates are more uncertain and those for which the policy foundation for consideration of public welfare impacts is less well established.

In his consideration of the adequacy of protection provided by the current standard, the Administrator does not consider every possible instance of an effect on vegetation growth from O_3 to be adverse to public welfare, although he recognizes that, depending on factors including extent and severity, such vegetation-related effects have the potential to be adverse to public welfare. Comments from the current CASAC, in the context of its review of the draft PA, expressed the view that the strategy described by the prior Administrator for the secondary standard established in 2015 with its focus on limiting 3-year average W126 index values somewhat below those associated with a 6% RBL in the median species and associated W126 index target of 17 ppm-hrs (in terms of a 3-year average), at or below which the 2015 standard was expected to generally restrict cumulative seasonal exposure, is ''still scientifically reasonable'' and ''still effective in particularly protecting the public welfare in light of vegetation impacts from ozone'' (Cox, 2020a, Consensus Responses to Charge Questions p. 21). In light of this advice and based on the current evidence as evaluated in the PA, the Administrator judges that this approach or framework, with its focus on controlling cumulative seasonal exposures associated with an RBL of 6% or greater, by limiting air quality in terms of a 3-year average W126 index, to or below a target of 17 ppm-hrs, in combination with a broader consideration of air quality patterns, such as control of peak hourly concentrations, associated with meeting the current standard, is appropriate for his use in this review. In so doing, he additional notes the isolated, rare occurrences in locations meeting the current standard of such exposures at 19 ppm-hrs. Based on the current information to inform consideration of vegetation effects and their potential adversity to public welfare, he additionally judges that the RBL estimates associated with such marginally higher exposures in isolated, rare instances are not indicative of effects that would be adverse to the public welfare, particularly in light of variability in the array of environmental factors that can influence O_3 effects in different systems and uncertainties associated with estimates of effects associated with this magnitude of cumulative exposure in the natural environment.

With regard to O_3 effects on crop yield, the Administrator, as an initial matter, takes note of the long-standing evidence, qualitative and quantitative, of the reducing effect of O_3 on the yield of many crops, as summarized in the PA and current ISA and characterized in detail in past reviews (*e.g.,* 2013 ISA, 2006 AQCD, 1997 AQCD, 2014 WREA). He additionally notes the established E–R functions for 10 crops and the estimates of RYL derived from them, as presented in the PA (PA, Appendix 4A, section 4A.1, Table 4A–4), and the potential public welfare significance of reductions in crop yield, as summarized in section III.A.2.b above. In so doing, however, he additionally recognizes that not every effect on crop yield will be adverse to public welfare. In the case of crops in particular there are a number of complexities related to the heavy management of many crops to obtain a particular output for commercial purposes, and related to other factors, that the Administrator takes into consideration in evaluating potential O_3-related public welfare impacts, as summarized in section III.B.2.b(iv) above (PA, sections 4.5.1.3 and 4.5.3).

Similarly, the Administrator concludes that the extensive management of agricultural crops that occurs to elicit optimum yields (*e.g.,* through irrigation and usage of soil amendments, such as fertilizer) is relevant in evaluating the extent of RYL estimated from experimental O_3 exposures that should be judged adverse to the public welfare. He considers these opportunities in crop management for market objectives, as well as complications in judging relative adversity that relate to market responses and their effects on producers and consumers in evaluating the potential impact on public welfare of estimated crop yield losses. Further, the Administrator takes note of the conclusion of the CASAC that the available evidence does not call into question the adequacy of the current secondary standard and that it should be retained (Cox 2020a, p.1).

The Administrator also considered the public comments, discussed in section III.B.2.b(iv) above, suggesting that the proposed decision was not giving adequate consideration to crop yield effects and that his decision should consider a statement by the prior CASAC, raised in public comments, that a 5% RYL estimate, as the median based on the 10 E–R functions, ''represents an adverse impact.'' With regard to the prior CASAC statement, he notes the discussion in section III.B.2.b(iv) above regarding the unclear basis for the prior CASAC judgment, both with regard to a connection of an estimated 5% RYL to broader impacts and to judgments on significance of a 5% RYL to the public welfare. In considering the adequacy of protection of the public welfare from effects related to crop yield loss, the Administrator considers the air quality analyses and the W126 index levels commonly occurring in areas that meet the current standard. In so doing, he notes that W126 index values (3-year average) were at or below 17 ppm-hrs in virtually all monitoring sites with air quality meeting the current standard.

Based on the established E–R functions, the median RYL estimate corresponding to 17 ppm-hrs is 5.1%. In considering single-year index values, as discussed in section III.B.2.b(vi), the vast majority are similarly low (with more than 99% less than or equal to 17 ppm-hrs), and the higher values predominantly occur in urban areas. The Administrator additionally takes note of the discussion in section III.B.2.b(ii) above regarding the role of elevated hourly concentrations in effects on vegetation growth and yield. In so doing, in addition to his consideration of W126 index occurring in areas that meet the current standard, he also takes note of the control of elevated hourly O_3 concentrations that is exerted by the current standard.

In light of all of the above, in reaching his judgment regarding public welfare implications of the W126 index values summarized here (and associated estimated RYL), including the isolated and rare occurrence of somewhat higher values, the Administrator notes that the secondary standard is not intended to protect against all known or anticipated O_3-related effects, but rather those that are judged to be adverse to the public welfare. He also takes into consideration the extensive management of agricultural crops, and the complexities associated with identifying adverse public welfare effects for market-traded goods (where producers and consumers may be impacted differently). Based on all of these factors, the Administrator disagrees with the prior CASAC statement that an estimated median RYL of 5% represents an adverse impact and further judges that an estimated median RYL of 5.1%, based on experimental exposures, would not constitute an adverse effect on public welfare. Accordingly, the Administrator notes that the current standard generally maintains air quality at a W126 index below 17 ppm-hrs, with few exceptions, and accordingly would limit the estimated RYL (based on experimental O_3 exposures) to this degree. Therefore, he concludes that the current standard provides adequate protection of public welfare related to crop yield loss and does not need to be revised to provide additional protection against this effect. In so doing, the Administrator notes the conclusions by the current CASAC that the evidence supports retaining the current standard, without revision.

Turning to consideration of visible foliar injury and protection afforded by the secondary standard from associated impacts to the public welfare, the Administrator takes note of the long-standing and well-established evidence base, updated in the ISA for this review, and of policy-relevant analyses presented in the PA to inform his judgments regarding a secondary standard that provides appropriate protection of the public welfare from this effect. In so doing, he has also taken into account issues raised by public comments, both with regard to our understanding of relationships between O_3 exposure circumstances and extent and severity of injury in natural areas across the U.S., and with regard to the extent of our understanding of the relationship of injury extent and severity to public welfare effects anticipated to be adverse, and the *Murray Energy* remand.

In considering public welfare implications of this effect, he notes the potential for this effect, when of a significant extent and severity, to reduce aesthetic and recreational values, such as the aesthetic value of scenic vistas in protected natural areas including national parks and wilderness areas, as well as other areas similarly protected by state and local governments for similar public uses. Based on these considerations, the Administrator recognizes that, depending on its severity and spatial extent, as well as the location(s) and the associated intended use, the impact of visible foliar injury on the physical appearance of plants has the potential to be significant to the public welfare. In this regard, he agrees with the PA statement that cases of widespread and relatively severe injury during the growing season (particularly when sustained across multiple years and accompanied by obvious impacts on the plant canopy) might reasonably be expected to have the potential to adversely impact the public welfare in scenic and/or recreational areas, particularly in areas with special protection, such as Class I areas (PA, sections 4.3.2 and 4.5.1). In so doing, the Administrator notes that the secondary standard is not meant to protect against all known or anticipated O_3-related welfare effects, but rather those that are judged to be adverse to the public welfare, and further notes that there are not established measures for when such welfare effects should be judged adverse to the public welfare. Rather, 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.

While recognizing there to be a paucity of established approaches for interpreting specific levels of severity and extent of foliar injury in natural areas with regard to impacts on the public welfare (*e.g.,* related to recreational services), the Administrator recognizes that injury to whole stands of trees of a severity apparent to the casual observer (*e.g.,* when viewed as a whole from a distance) would reasonably be expected to affect recreational values and thus pose a risk of adverse effects to the public welfare. He further notes that the available information does not provide for specific characterization of the incidence and severity that would not be expected to be apparent to the casual observer, nor for clear identification of the pattern of O_3 concentrations that would provide for such a situation.

In this context, the Administrator takes note of the system developed by the USFS for its monitoring program [240] to categorize BI scores of visible foliar injury at biosites (sites with O_3-sensitive vegetation assessed for visible foliar injury) in natural vegetated areas by severity levels (described in section III.A.2.c(ii) above). While recognizing that quantitative analyses and evidence are lacking that might support a more precise conclusion with regard to a magnitude of BI score coupled with an extent of occurrence that might be specifically identified as adverse to the public welfare, the Administrator also takes note of the D.C. Circuit's holding that substantial uncertainty about the level at which visible foliar injury may become adverse to public welfare does not necessarily provide a basis for declining to evaluate whether the existing standard provides requisite protection against such effects. See *Murray Energy Corp.* v. *EPA,* 936 F.3d 597, 619–20 (D.C. Cir. 2019). In this context, he considers the discussion in the PA and in sections III.A.2.b, III.A.2.c and III.B.2 above regarding the USFS biosite monitoring program. He finds the scale of this program's objectives, which focus on natural settings in the U.S. and forests as opposed to individual plants, to be suited for his consideration with regard to the public welfare protection afforded by the current standard, and consequently, he finds the data and analyses generated by the program informative in such considerations.

In this context, he takes note of the USFS system, including its descriptors for BI scores of differing magnitude intended for that Agency's consideration in identifying areas of potential impact to forest resources. As described in section III.A.2.b(iii) above, very low BI scores (at or below 5) are

[240] During the period from 1994 (beginning in eastern U.S.) through 2011, the USFS conducted surveys of the occurrence and severity of visible foliar injury on sensitive species at sites across most of the U.S. following a national protocol.

described by the USFS scheme as ''little or no foliar injury'' (Smith et al., 2007; Smith et al., 2012).[241] The Administrator notes that BI scores above 15 are categorized as moderate to severe (and scores above 25 as severe). In so doing, in light of considerations raised in the PA and consideration of public comment, he recognizes the lower categories of BI scores as indicative of injury of generally lesser risk to the natural area or to public enjoyment, which he judges unlikely to be indicative of injury of such a magnitude or extent as to pose risk of adverse effects to the public welfare. Thus, the Administrator reaches the conclusion that occurrence of the lower categories of BI scores does not pose concern for the public welfare, but that findings of BI scores categorized as ''moderate to severe'' injury by the USFS scheme would be an indication of visible foliar injury occurrence that, depending on extent and severity, may raise public welfare concerns. In this framework, the Administrator considers the PA evaluations of the currently available information and what it indicates with regard to patterns of air quality of concern for such an occurrence, and the extent to which they are expected to occur in areas that meet the current standard.

In so doing, the Administrator takes particular note of the USFS biosite monitoring program studies of the occurrence, extent and severity of visible foliar injury in indicator species in defined plots or biosites in natural areas across the U.S. These studies of data for USFS biosites (sites with O_3-sensitive vegetation assessed for visible foliar injury) have often summarized O_3 concentrations in terms of cumulative exposure metrics (*e.g.,* SUM06 or W126 index). Some of these studies, particularly those examining such data across multiple years and multiple regions of the U.S., have reported that variation in cumulative O_3 exposure, in terms of such metrics, does not completely explain the patterns of occurrence and severity of injury observed. Although the availability of detailed analyses that have explored multiple exposure metrics and other influential variables is limited, multiple studies have indicated a potential role for an additional metric, one related to the occurrence of days with relatively high concentrations (*e.g.,* number of days with a 1-hour concentration at or above 100 ppb), as summarized in section III.A.2.c above (PA, section 4.5.1.2). Thus, the Administrator takes note of this evidence indicating an influence of peak concentrations on BI scores (beyond an influence of cumulative exposure). He also finds noteworthy the extensive evidence of trends across the past nearly 20 years that indicate reductions in severity of visible foliar injury that parallel reductions in peak concentrations that have been suggested to be influential in the severity of visible foliar injury.[242]

Further, the Administrator considers the PA analysis of a dataset developed from USFS biosite index scores, combined with W126 estimates and soil moisture categories, summarized in section III.A.2.c above. In so doing, he takes note of the PA observation that important uncertainties remain in the understanding of the O_3 exposure conditions that will elicit visible foliar injury of varying severity and extent in natural areas, and particularly in light of the other environmental variables that influence its occurrence, and of the recognition by the CASAC that ''uncertainties continue to hamper efforts to quantitatively characterize the relationship of [visible foliar injury] occurrence and relative severity with ozone exposures'' (Cox 2020a, Consensus Responses to Charge Questions, p. 20). Notwithstanding, and while being mindful of, such uncertainties with regard to predictive O_3 metric or metrics and a quantitative function relating them to incidence and severity of visible foliar injury in natural areas (as also noted in the USFS studies referenced above), the Administrator takes note of the PA finding that the incidence of nonzero BI scores, and, particularly of relatively higher scores (such as scores above 15 which are indicative of ''moderate to severe'' injury in the USFS scheme) appears to markedly increase only with W126 index values above 25 ppm-hrs, as summarized in section III.B.2.b above (PA, section 4.3.3 and Appendix 4C).

In light of these observations, the Administrator finds the current evidence to be incomplete with regard to information to support a quantitative characterization of air quality that would be anticipated to result in visible foliar injury of an extent and severity to cause adverse effects to the public welfare. The Administrator also considers discussion in the court's remand of the 2015 standard with regard to visible foliar injury (*Murray Energy Corp.* v *EPA*, 936 F.3d at 619–20). The court concluded that the EPA had failed to offer a reasoned explanation for deciding not to specify a level of air quality to protect against adverse effects related to visible foliar injury. In particular, the court stated that the EPA had not explained why it was unable to choose such a level although the prior CASAC had provided advice with regard to a specific level. The EPA's disagreement with the prior CASAC on its identified level is explained in section III.B.2 above, as is the reason why the EPA did not find the analysis on which the prior CASAC based its advice to be appropriate for such a conclusion.[243] This and other associated issues raised by the court have been raised in public comments on the proposal for this action and are addressed in section III.B.2 above.

Based on the evidence and quantitative analyses available in the present review, and advice from the current CASAC, the Administrator considers the question of a level of air quality that would provide protection against visible foliar injury related effects known or anticipated to cause adverse effects to the public welfare. Based on the evidence and associated quantitative analyses in this review, the Administrator's judgment reflects his recognition of less confidence and greater uncertainty in the existence of adverse public welfare effects with lower O_3 exposures. In this context, the Administrator judges that W126 index values at or below 25 ppm-hrs, when in combination with infrequent occurrences of hourly concentrations at or above 100 ppb, would not be anticipated to pose risk of visible foliar injury of an extent and severity so as to be adverse to the public welfare.

With these conclusions in mind, the Administrator considers the air quality analyses presented in the PA and the additional analyses developed in response to public comment. In so doing, he notes that a W126 index above

[241] Studies that consider such data for purposes of identifying areas of potential impact to the forest resource suggest this category corresponds to ''none'' with regard to ''assumption of risk'' (Smith et al., 2007; Smith et al., 2012).

[242] For example, the PA describes findings from USFS studies that have concluded a ''declining risk of probable impact'' over the 16-year period of the program, especially after 2002 (*e.g.,* Smith, 2012), and the parallel national reductions in O_3 concentrations from 2000 through 2018 in terms of cumulative seasonal exposures, as well as in peak O_3 concentrations such as the annual fourth highest daily maximum 8-hour concentration and also the occurrence of 1-hour concentrations above 100 ppb (PA, Figure 2–11, Appendix 2A, Tables 2A–2 to 2A–4, and Appendix 4D, Figure 4D–9).

[243] As discussed in section III.B.2.b, the cumulative frequency graph relied on by the CASAC does not present biosite scores for comparison at different cumulative exposure levels. Accordingly, it does not provide the type of analysis that is needed for the EPA to reach a conclusion about the extent of protection that different patterns of O_3 concentrations would provide against visible foliar injury of an extent and severity as to pose risk of adverse effects to the public welfare.

25 ppm-hrs (either as a 3-year average or in a single year) is not seen to occur at monitoring locations (including in or near Class I areas) where the current standard is met, and that, in fact, values above 17 or 19 ppm-hrs are rare, as summarized in section III.A.3 above (PA, Appendix 4C, section 4C.3; Appendix 4D, section 4D.3.2.3). Further, the Administrator takes note of the PA consideration of the USFS publications that identify an influence of peak concentrations on BI scores (beyond an influence of cumulative exposure) and the PA observation of the appreciable control of peak concentrations exerted by the form and averaging time of the current standard, as evidenced by the air quality analyses which document reductions in 1-hour daily maximum concentrations with declining design values. He also notes, as discussed above, the uncommonness of days with any hours at or above 100 ppb at monitoring sites that meet the current standard, as well as the minimal number of hours on any such days (Wells, 2020). Based on these considerations, the Administrator concludes that the current standard provides control of air quality conditions that contribute to increased BI scores and to scores of a magnitude indicative of ''moderate to severe'' foliar injury.

The Administrator further takes note of the PA finding that the current information, particularly in locations meeting the current standard or with W126 index estimates likely to occur under the current standard, does not indicate a significant extent and degree of injury (*e.g.,* based on analyses of BI scores in the PA, Appendix 4C) or specific impacts on recreational or related services for areas, such as wilderness areas or national parks. Thus, he gives credence to the associated PA conclusion that the evidence indicates that areas that meet the current standard are unlikely to have BI scores reasonably considered to be impacts of public welfare significance. Based on all of the considerations raised here, the Administrator concludes that the current standard provides sufficient protection of natural areas, including particularly protected areas such as Class I areas, from O_3 concentrations in the ambient air that might be expected to elicit visible foliar injury of such an incidence and severity as would reasonably be judged adverse to the public welfare.

With a primary focus on RBL in its role as proxy, the Administrator further considers the analyses available in this review of recent air quality at sites across the U.S., particularly including those sites in or near Class I areas, and also the analyses of historical air quality. In so doing, the Administrator recognizes that these analyses are distributed across all nine NOAA climate regions and 50 states, although some geographic areas within specific regions and states may be more densely covered and represented by monitors than others, as summarized in section III.C of the proposal (PA, Appendix 4D). The Administrator notes that the findings from both the analysis of the air quality data from the most recent period and from the larger analysis of historical air quality data extending back to 2000, as presented in the PA and summarized in section III.A.3 above, are consistent with the air quality analyses available in the last review. That is, in virtually all design value periods and all locations at which the current standard was met across the 19 years and 17 design value periods (in more than 99.9% of such observations), the 3-year average W126 metric was at or below 17 ppm-hrs. Further, in all such design value periods and locations the 3-year average W126 index was at or below 19 ppm-hrs. The Administrator additionally considers the protection provided by the current standard from the occurrence of O_3 exposures within a single year with potentially damaging consequences, such as a significantly increased incidence of areas with visible foliar injury that might be judged moderate to severe, as discussed in section III.B.2 above. In so doing, he takes notes of the PA analyses, summarized in section III.A.2.c above, of USFS BI scores, giving particular focus to scores above 15, termed ''moderate to severe injury'' by the USFS categorization scheme, as described in section III.A.2.b above (PA, sections 4.3.3.2, 4.5.1.2 and Appendix 4C). He notes the PA finding that incidence of sites with BI scores above 15 markedly increases with W126 index estimates above 25 ppm-hrs. In this context, he additionally takes note of the air quality analysis finding of a scarcity of single-year W126 index values above 25 ppm-hrs at sites that meet the current standard, with just a single occurrence across all U.S. sites with design values meeting the current standard in the 19-year historical dataset dating back to 2000 (PA, section 4.4 and Appendix 4D). Further, in light of the evidence indicating that peak short-term concentrations (*e.g.,* of durations as short as one hour) may also play a role in the occurrence of visible foliar injury, the Administrator additionally takes note of the air quality analyses in the PA and in the additional analysis documented in Wells (2020). These analyses of data from the past 20 years show a declining trend in 1-hour daily maximum concentrations mirroring the declining trend in design values, supporting the PA conclusion that the form and averaging time of the current standard provides appreciable control of peak 1-hour concentrations. Furthermore, these analyses indicate there to be only a few days among sites meeting the current standard, with hourly concentrations at or above 100 ppb (just seven in the period from 2000 through 2018) (Wells, 2020). In light of these findings from the air quality analyses and considerations in the PA, both with regard to 3-year average W126 index values at sites meeting the current standard and the rarity of such values at or above 19 ppm-hrs, and with regard to single-year W126 index values at sites meeting the current standard, and the rarity of such values above 25 ppm-hrs, as well as with regard to the appreciable control of 1-hour daily maximum concentrations, the Administrator judges that the current standard provides adequate protection from air quality conditions with the potential to be adverse to the public welfare.

In reaching his conclusion on the current secondary O_3 standard, the Administrator recognizes, as is the case in NAAQS reviews in general, his decision depends on a variety of factors, including science policy judgments and public welfare policy judgments, as well as the currently available information. With regard to the current review, the Administrator gives primary attention to the principal effects of O_3 as recognized in the current ISA, the 2013 ISA and past AQCDs, and for which the evidence is strongest (*e.g.,* growth, reproduction, and related larger-scale effects, as well as, visible foliar injury). With regard to growth and the categories of effects identified above for which RBL has been identified for use as a proxy, based on all of the considerations above, including the discussion of air quality immediately above, the Administrator judges the current standard to provide adequate protection for air quality conditions with the potential to be adverse to the public welfare. Further, with regard to visible foliar injury, the Administrator concludes that the currently available information on visible foliar injury and with regard to air quality analyses that may be informative with regard to air quality conditions associated with appreciably increased incidence and severity of BI scores at USFS biomonitoring sites, and with particular attention to Class I and other areas afforded special protection, indicates the current standard to provide adequate protection from visible foliar injury of an extent or severity that might be anticipated to be adverse to the public welfare.

In summary, the Administrator has based his decision on the public welfare protection afforded by the secondary O_3 standard from identified O_3-related welfare effects, and from their potential to present adverse effects to the public welfare, on judgments regarding what the available evidence, quantitative information, and associated uncertainties and limitations (such as those identified above) indicate with regard to the protection provided from the array of O_3 welfare effects. He finds that, as a whole, this information, as summarized above, and presented in detail in the ISA and PA, does not indicate the current standard to allow air quality conditions with implications of concern for the public welfare. He has additionally considered the advice from the CASAC in this review, including its finding ''that the available evidence does not reasonably call into question the adequacy of the current secondary ozone standard and concurs that it should be retained'' (Cox, 2020a, p. 1), and well as public comment on the proposed decision. Based on all of the above considerations, including his consideration of the currently available evidence and quantitative exposure/risk information, the Administrator concludes that the current secondary standard is requisite to protect the public welfare from known or anticipated adverse effects of O_3 and related photochemical oxidants in ambient air, and thus that the current standard should be retained, without revision.

C. Decision on the Secondary 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 secondary O_3 standard is requisite to protect the public welfare from known or anticipated adverse effects, and is retaining the current standard without revision.

IV. 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) has determined that this action is a significant regulatory action and it was submitted to OMB for review. Any changes made in response to OMB recommendations have been documented in the docket. Because this action does not change the existing O_3 NAAQS, it does not impose costs or benefits relative to the baseline of continuing with the current NAAQS in effect. EPA has thus 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 quantified cost estimates 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 existing O_3 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 O_3 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), rev'd 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 O_3 NAAQS, without revision. Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health 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 and risk assessment information for this action, which focuses on children and people (of all ages) with asthma as key at-risk populations, is summarized in section II.A.2 and II.A.3 above and described in the ISA and PA, copies of which are in the public docket for this action.

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

This action is not a ''significant energy action'' for purposes of Executive Order 13211. The action is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This action retains the current O_3 NAAQS. This decision does not change existing requirements. The Administrator of the Office of Information and Regulatory Affairs has not otherwise designated this action as a significant energy action. Thus, this decision does not constitute a significant energy action as defined in Executive Order 13211.

J. National Technology Transfer and Advancement Act

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 O_3 NAAQS based on the Administrator's conclusions that the existing primary standard protects public health, including the health of sensitive groups, with an adequate margin of safety, and that the existing secondary standard protects public welfare from known or anticipated adverse effects. As discussed in section II above, 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

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

V. References

Adams, WC (2000). Ozone dose-response effects of varied equivalent minute ventilation rates. J Expo Anal Environ Epidemiol 10(3): 217–226.

Adams, WC (2002). Comparison of chamber and face-mask 6.6-hour exposures to ozone on pulmonary function and symptoms responses. Inhal Toxicol 14(7): 745–764.

Adams, WC (2003). Comparison of chamber and face mask 6.6-hour exposure to 0.08 ppm ozone via square-wave and triangular profiles on pulmonary responses. Inhal Toxicol 15(3): 265–281.

Adams, WC (2006). Comparison of chamber 6.6-h exposures to 0.04–0.08 PPM ozone via square-wave and triangular profiles on pulmonary responses. Inhal Toxicol 18(2): 127–136.

Adams, WC and Ollison, WM (1997). Effects of prolonged simulated ambient ozone dosing patterns on human pulmonary function and symptomatology. Air & Waste Management Association, Pittsburgh, PA.

Adhikari, A and Yin, J (2020). Short-Term Effects of Ambient Ozone, $PM_{2.5}$, and Meteorological Factors on COVID–19 Confirmed Cases and Deaths in Queens, New York. Int J Env Res Public Health 17(11): 4047.

Alexis, NE, Lay, JC, Hazucha, M, Harris, B, Hernandez, ML, Bromberg, PA, Kehrl, H, Diaz-Sanchez, D, Kim, C, Devlin, RB and Peden, DB (2010). Low-level ozone exposure induces airways inflammation and modifies cell surface phenotypes in healthy humans. Inhal Toxicol 22(7): 593–600.

Archer, CL. Brodie, JF and Rauscher, SA (2019). Global Warming Will Aggravate Ozone Pollution in the U.S. Mid-Atlantic. J Appl Meteorol Climatol 58(6): 1267–78.

ATS (1985). Guidelines as to what constitutes an adverse respiratory health effect, with special reference to epidemiologic studies of air pollution. Am Rev Respir Dis 131(4): 666–668.

ATS (2000). What constitutes an adverse health effect of air pollution? Am J Respir Crit Care Med 161(2): 665–673.

Bell, ML, Zanobetti, A and Dominici F (2014). Who Is More Affected by Ozone Pollution? A Systematic Review and Meta-Analysis. Am J Epi 180(1): 15–28.

Brown, JS, Bateson, TF and McDonnell, WF (2008). Effects of exposure to 0.06 ppm ozone on FEV1 in humans: a secondary analysis of existing data. Environ Health Perspect 116(8): 1023–1026.

Bureau of Labor Statistics (2017). U.S. Department of Labor, The Economics Daily, Over 90 percent of protective service and construction and extraction jobs require work outdoors. Available at: *https://www.bls.gov/opub/ted/2017/over-90-percent-of-protective-service-and-construction-and-extraction-jobs-require-work-outdoors.htm* (visited August 27, 2019).

Burra, TA, Moineddin, R, Agha, MM, and Glazier, RH (2009). Social disadvantage, air pollution, and asthma physician visits in Toronto, Canada. Environ Res 109(5):567–74.

Cakmak, S, Dales, RE and Judek, S (2006). Respiratory health effects of air pollution gases: Modification by education and income. Arch Environ Occup Health 61: 5–10.

Campbell, SJ, Wanek, R, and Coulston, JW (2007). Ozone injury in west coast forests: 6 years of monitoring—Introduction. U.S. Department of Agriculture. Portland, OR. Available at: *https://www.fs.usda.gov/treesearch/pubs/27926*

CDC (2019). National Health Interview Survey, 2017. National Center for Health Statistics, CDC. Washington, DC. Available at: *https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm* and *https://www.cdc.gov/asthma/nhis/2017/data.htm.* Accessed August 27, 2019.

Cleary, EG, Cifuentes, M, Grinstein, G, Brugge, D and Shea, TB (2018). Association of low-level ozone with cognitive decline in older adults. J Alzheimers Dis 61(1):67–78.

Cohen, AJ, Brauer, M, Burnett, R, Anderson, HR, Frostad, J, Estep, K, Balakrishnan, K, Brunekreef, B, Dandona, L, Dandona, R, Feigin, V, Freedman, G, Hubbell, B, Jobling, A, Kan, H, Knibbs, L, Liu, Y, Martin, Morawska, L, Pope, CA, Shin, H, Straif, K, Shaddick, G, Thomas, M, Van Dingenen, R, Van Dingenen, A, Vos, T, Murray, CJI and Forouzanfart, MH (2017). Estimates and 25 year trends of the global burden of disease Attributable to ambient air pollution: an analysis of data from the Global Burden of Diseases Study 2015. Lancet 389(10082): 1907–18.

Cordell, H, Betz, FM, Mou, S and Green, G (2008). How do Americans View Wilderness—A WILDERNESS Research Report in the internet Research Information Series. National Survey on Recreation and the Environment. This research is a collaborative effort between the U.S. Department of Agriculture Forest Service's Southern Research Station and its Forestry Sciences Laboratory in Athens, Georgia; the University of Georgia in Athens; and the University in Tennessee in Knoxville, Tennessee.

Costanza, R, De Groot, R, Braat, L, Kubiszewski, I, Fioramonti, L, Sutton, P, Farber, S and Grasso, M (2017). Twenty years of ecosystem services: How far have we come and how far do we still need to go? Ecosyst Serv 28: 1–16.

Coulston, JW, Smith, GC and Smith WD (2003). Regional assessment of ozone sensitive tree species using bioindicator plants. Environ Monito Assess 82(2): 113–127.

Cox, LA (2018). Letter from Dr. Louis Anthony Cox, Jr., Chair, Clean Air Scientific Advisory Committee, to Acting Administrator Andrew R. Wheeler, Re: Consultation on the EPA's *Integrated Review Plan for the Review of the Ozone.* December 10, 2018. EPA–CASAC–19–001. Office of the Administrator, Science Advisory Board U.S. EPA HQ, Washington DC. Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/A286A0F0151DC8238525835F007D348A/$File/EPA-CASAC-19-001.pdf.*

Cox, LA (2020a). Letter from Louis Anthony Cox, Jr., Chair, Clean Air Scientific Advisory Committee, to Administrator Andrew R. Wheeler. Re:CASAC Review of the EPA's *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft—October 2019).* February 19, 2020. EPA–CASAC–20–003. Office of the Adminstrator, Science Advisory Board Washington, DC. Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/4713D217BC07103485258515006359BA/$File/EPA-CASAC-20-003.pdf.*

Cox, LA (2020b). Letter from Louis Anthony Cox, Jr., Chair, Clean Air Scientific Advisory Committee, to Administrator Andrew R. Wheeler. Re:CASAC Review of the EPA's *Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft—September 2019).* February 19, 2020. EPA–CASAC–20–002. Office of the Adminstrator, Science Advisory Board Washington, DC. Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/*

264cb1227d55e02c85257402007446a4/F228E5D4D848BBED85258515006354D0/$File/EPA-CASAC-20-002.pdf.

Cromar, KR, Gladson, LA and Ewart, G (2019). Trends in Excess Morbidity and Mortality Associated with Air Pollution above American Thoracic Society-Recommended Standards, 2008–2017. Ann Am Thorac Soc 16(7): 836–845.

Davis, DD and Orendovici, T (2006). Incidence of ozone symptoms on vegetation within a National Wildlife Refuge in New Jersey, USA. Environ Pollut 143(3): 555–564.

Day, DB, Xiang, J, Mo, J, Li, F, Chung, M, Gong, J, Weschler, CJ, Ohman-Strickland, PA, Sundell, J, Weng, W, Zhang, Y and Zhang, JJ (2017). Association of ozone exposure with cardiorespiratory pathophysiologic mechanisms in healthy adults. JAMA Intern Med 177(9): 1344–1353.

Dedoussi, IC, Eastham, SD, Monier, E and Barrett, SRH (2020). Premature mortality related to United States cross-state air pollution. Nature 578: 261–265.

Devlin, RB, McDonnell, WF, Mann, R, Becker, S, House, DE, Schreinemachers, D and Koren, HS (1991). Exposure of humans to ambient levels of ozone for 6.6 hours causes cellular and biochemical changes in the lung. Am J Respir Cell Mol Biol 4(1): 72–81.

Di, Q, Dai, L, Wang, Y, Zanobetti, A, Choirat, C, Schwartz, JD and Dominici, F (2017a). Association of short-term exposure to air pollution with mortality in older adults. JAMA 318: 2446–2456.

Di, Q, Wang, Y, Zanobetti, A, Wang, Y, Koutrakis, P, Choirat, C, Dominici, F and Schwartz, J (2017b). Air Pollution and Mortality in the Medicare Population. N Engl J Med 376: 2513–2522.

Dominici, F, Schwartz, J, Di, Q, Braun, D, Choirat, C and Zanobetti, A (2019). Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution: Phase 1 Health Effects Institute. Boston, MA. Available at: *https://www.healtheffects.org/system/files/dominici-rr-200-report.pdf.*

Dryden, DM, Spooner, CH, Stickland, MK, Vandermeer, B, Tjosvold, L, Bialy, L, Wong, K and Rowe, BH (2010). Exercise-induced bronchoconstriction and asthma. (AHRQ Publication No. 10–E001). Rockville, MD: Agency for Healthcare Research and Quality.

Folinsbee, LJ and Hazucha, MJ (2000). Time course of response to ozone exposure in healthy adult females. Inhal Toxicol 12(3): 151–167.

Folinsbee, LJ, Horstman, DH, Kehrl, HR, Harder, S, Abdul-Salaam, S and Ives, PJ (1994). Respiratory responses to repeated prolonged exposure to 0.12 ppm ozone. Am J Respir Crit Care Med 149(1): 98–105.

Folinsbee, LJ, McDonnell, WF and Horstman, DH (1988). Pulmonary function and symptom responses after 6.6-hour exposure to 0.12 ppm ozone with moderate exercise. JAPCA 38(1): 28–35.

Frey, HC (2014a). Letter from Dr. H. Christopher Frey, Chair, Clean Air Scientific Advisory Committee, to Administrator Gina McCarthy. Re: *Health Risk and Exposure Assessment for Ozone (Second External Review Draft—February 2014)* EPA–CASAC–14–005. Office of the Administrator, Science Advisory Board Washington, DC. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100JR8I.txt.*

Frey, HC (2014b). Letter from Dr. H. Christopher Frey, Chair, Clean Air Scientific Advisory Committee to Honorable Gina McCarthy, Administrator, U.S. EPA. Re: CASAC Review of the EPA's *Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards.* June 26, 2014. EPA–CASAC–14–004. Office of the Administrator, Science Advisory Board Washington, DC. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100JR6F.txt.*

Frey, HC (2014c). Letter from Dr. H. Christopher Frey, Chair, Clean Air Scientific Advisory Committee, to Administrator Gina McCarthy. Re: CASAC Review of the EPA's *Welfare Risk and Exposure Assessment for Ozone (Second External Review Draft).* June 18, 2014. EPA–CASAC–14–003. Office of the Administrator, Science Advisory Board Washington, DC. Available at: *http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P100JMSY.PDF.*

Frey, HC and Samet, JM (2012). Letter from Dr. H. Christopher Frey, Chair, Clean Air Scientific Advisory Committee and Jonathan Samet, Immediate Past Chair, Clean Air Scientific Advisory Committee, to Administrator Lisa Jackson. Re: CASAC Review of the EPA's *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (First External Review Draft—August 2012).* November 26, 2012. EPA–CASAC–13–003. Office of the Administrator, Science Advisory Board Washington DC. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100J7PQ.txt.*

Gan, WQ, Allen, R W, Brauer, M, Davies, HW, Mancini, GB and Lear, SA (2014). Long-term exposure to traffic-related air pollution and progression of carotid artery atherosclerosis: a prospective cohort study. BMJ open, 4(4), e004743.

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

Garcia, E, Berhane, KT, Islam, T, McConnell, R, Urman, R, Chen, Z and Gilliland, FD (2019). Association of changes in air quality with incident asthma in children in California, 1993–2014. JAMA 321: 1906–1915.

Gharibi, H, Entwistle, MR, Ha, S, Gonzalez, M, Brown, P, Schweizer, D and Cisneros, R (2019). Ozone pollution and asthma emergency department visits in the Central Valley, California, USA, during June to September of 2015: a time-stratified case-crossover analysis. J Asthma 56(10):1037–1048.

Gold, JAW, Wong, KK, Szablewski, CM, Patel, PR, Rossow, J, da Silva, J, Natarajan, P, Morris, SB, Fanfair, RN, Rogers-Brown, J, Bruce, BB, Browning, SD, Hernandez-Romieu, AC, Furukawa, NW, Kang, M, Evans, ME, Oosmanally, N, Tobin-D'Angelo, M, Drenzek, C, Murphy, DJ, Hollberg, J, Blum, JM, Jansen, R, Wright, DW, Sewell, WM III, Owens, JD, Lefkove, B, Brown, FW, Burton, DC, Uyeki, TM, Bialek, SR and Jackson, BR (2020). Characteristics and Clinical Outcomes of Adult Patients Hospitalized with COVID–19—Georgia, March 2020. MMWR Morb Mortal Wkly Rep 2020;69:545–550.

Gong, H, Jr., Bradley, PW, Simmons, MS and Tashkin, DP (1986). Impaired exercise performance and pulmonary function in elite cyclists during low-level ozone exposure in a hot environment. Am J Respir Crit Care Med 134(4): 726–733.

Goodman, JE, Loftus, CT, Liu, X and Zu, K (2017). Impact of respiratory infections, outdoor pollen, and socioeconomic status on associations between air pollutants and pediatric asthma hospital admissions. PLoS One 12(7): e0180522.

Jerrett, M, Burnett, RT, Pope, CA, 3rd, Ito, K, Thurston, G, Krewski, D, Shi, Y, Calle, E and Thun, M (2009). Long-term ozone exposure and mortality. N Engl J Med 360(11): 1085–1095.

Heck, WW and Cowling, EB (1997). The need for a long term cumulative secondary ozone standard—An ecological perspective. EM: Environmental Manager January: 23–33.

Hildebrand, E, Skelly, JM and Fredericksen, TS (1996). Foliar response of ozone-sensitive hardwood tree species from 1991 to 1993 in the Shenandoah National Park, Virginia. Can J For Res 26(4): 658–669.

Hogsett, WE, Weber, JE, Tingey, D, Herstrom, A, Lee, EH and Laurence, JA (1997). Environmental auditing: An approach for characterizing tropospheric ozone risk to forests. J Environ Manage 21(1): 105–120.

Horstman, DH, Folinsbee, LJ, Ives, PJ, Abdul-Salaam, S and McDonnell, WF (1990). Ozone concentration and pulmonary response relationships for 6.6-hour exposures with five hours of moderate exercise to 0.08, 0.10, and 0.12 ppm. Am Rev Respir Dis 142(5): 1158–1163.

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

Killerby, ME, Link-Gelles, R, Haight, SC, Schrodt, CA, England, L, Gomes, DJ, Shamout, M, Pettrone, K, O'Laughlin, K, Kimball, A, Blau, EF, Burnett, E, Ladva, CN, Szablewski, CM, Tobin-D'Angelo, M, Oosmanally, N, Drenzek, C, Murphy, DJ, Blum, JM, Hollberg, J, Lefkove, B, Brown, FW, Shimabukuro, Tom, Midgley, CM and Tate, JE (2020). Characteristics Associated with Hospitalization Among Patients with COVID–19—Metropolitan Atlanta, Georgia, March–April 2020. MMWR Morb Mortal Wkly Rep 69:790–794.

Kim, CS, Alexis, NE, Rappold, AG, Kehrl, H, Hazucha, MJ, Lay, JC, Schmitt, MT, Case, M, Devlin, RB, Peden, DB and Diaz-Sanchez, D (2011). Lung function and inflammatory responses in healthy young adults exposed to 0.06 ppm ozone for 6.6 hours. Am J Respir Crit Care Med 183: 1215–1221.

King, JS, Kubiske, ME, Pregitzer, KS, Hendrey, GR, McDonald, EP, Giardina, CP, Quinn, VS and Karnosky, DF (2005). Tropospheric O3 compromises net primary production in young stands of trembling aspen, paper birch and sugar maple in response to elevated atmospheric CO_2. New Phytologist 168(3): 623–635.

Kohut, R (2007a). Assessing the risk of foliar injury from ozone on vegetation in parks in the US National Park Service's Vital Signs Network. Environ Pollut 149: 348–357.

Kohut, R (2007b). Handbook for Assessment of Foliar Ozone Injury on Vegetation in the National Parks: Revised Second Edition.

Kohut, R (2020). Field Surveys to Assess Foliar Ozone Injury on Plants in National Parks and Monuments on the Colorado Plateau. Natural Resource Report NPS/NRSS/ARD/NRR—2020/2112.

Kousha, T and Rowe, BH (2014). Ambient ozone and emergency department visits due to lower respiratory condition. Int J Occup Med Environ Health 27(1): 50–59.

Langstaff, J (2007). Memorandum to Ozone NAAQS Review Docket (EPA–HQ–OAR–2005–0172). Analysis of Uncertainty in Ozone Population Exposure Modeling. Docket ID No. EPA–HQ–OAR–2005–0172–0174.

Lavigne, E, Yasseen, AS 3rd, Stieb, DM, Hystad, P, van Donkelaar, A, Martin, RV, Brook, JR, Crouse, DL, Burnett, RT, Chen, H, Weichenthal, S, Johnson, M, Villeneuve, PJ and Walker M (2016). Ambient air pollution and adverse birth outcomes: Differences by maternal comorbidities. M Environ Res 148: 457–466.

Lee, EH and Hogsett, WE (1996). Methodology for calculating inputs for ozone secondary standard benefits analysis part II. Office of Air Quality Planning and Standards. Research Triangle Park, NC.

Lefohn, AS, Jackson, W, Shadwick, DS and Knudsen, HP (1997). Effect of surface ozone exposures on vegetation grown in the southern Appalachian Mountains: Identification of possible areas of concern. Atmospheric Environment 31(11): 1695–1708.

Lefohn, AS and Foley, JK (1992). NCLAN Results and their Application to the Standard-Setting Process: Protecting Vegetation from Surface Ozone Exposures, J Air Waste Manag Assoc 42(8): 1046–1052.

Lim, CC, Hayes, RB, Ahn, J, Shao, Y, Silverman, DT, Jones, RR, Garcia, C, Bell, ML and Thurston, GD (2019). Long-term exposure to ozone and cause-specific mortality risk in the United States. Am J Resp Crit Care Med 200:1022–1031.

Limaye, VS and Knowlton, K (2020). Shining New Light on Long-term Ozone Harms. JAMA Intern Med 180(1): 115–116.

Lin, S, Liu, X, Le, LH and Hwang, SA (2008). Chronic exposure to ambient ozone and asthma hospital admissions among children. Environ Health Perspect 116(12): 1725–30.

Luben, T (2020). Memorandum to the Integrated Science Assessment (ISA) for Ozone Docket, (EPA–HQ–ORD–2018–0274). Short-Term Cardiovascular Morbidity and Mortality Studies Excluded from the Draft Ozone ISA Based on Location and Considered for Final Ozone ISA. December 2020. Office of Air Quality Planning and Standards Research Triangle Park, NC.

Luben, T, Lassiter, M and Herrick, J (2020). Memorandum to Ozone NAAQS Review Docket (EPA–HQ–ORD–2018–0279). RE: List of Studies Identified by Public Commenters That Have Been Provisionally Considered in the Context of the Conclusions of the 2020 Integrated Science Assessment for Ozone and Related Photochemical Oxidants. December 2020. Docket ID No. EPA–HQ–OAR–2018–0279. Office of Air Quality Planning and Standards Research Triangle Park, NC.

Mar, TF and Koenig, JQ (2009). Relationship between visits to emergency departments for asthma and ozone exposure in greater Seattle, Washington. Ann Allergy, Asthma Immunol 103(6): 474–479.

McCurdy, T (2000). Conceptual basis for multi-route intake dose modeling using an energy expenditure approach. J Expo Anal Environ Epidemiol 10(1): 86–97.

McDonnell, WF, Kehrl, HR, Abdul-Salaam, S, Ives, PJ, Folinsbee, LJ, Devlin, RB, O'Neil, JJ and Horstman, DH (1991). Respiratory response of humans exposed to low levels of ozone for 6.6 hours. Arch Environ Health 46(3): 145–150.

McDonnell, WF, Horstman, DH, Hazucha, MJ, Seal, E Jr, Haak, ED, Salaam, SA and House, DE (1983). Pulmonary effects of ozone exposure during exercise: Dose-response characteristics. J Appl Physiol. 54(5): 1345–1352.

McDonnell, WF, Stewart, PW, Smith, MV, Kim, CS and Schelegle, ES (2012). Prediction of lung function response for populations exposed to a wide range of ozone conditions. Inhal Toxicol 24(10): 619–633.

McDonnell, WF, Stewart, PW and Smith, MV (2013). Ozone exposure-response model for lung function changes: an alternate variability structure. Inhal Toxicol 25(6): 348–353.

Medina-Ramón M and Schwartz J (2008). Who is more vulnerable to die from ozone air pollution? Epidemiology 19(5): 672–9.

Millett, GA, Jones, AT, Benkeser, D, Baral, S, Mercer, L, Beyrer, C, Honermann, B, Lankiewicz, E, Mena, L, Crowley, JS, Sherwood, J and Sullivan, PS (2020). Assessing differential impacts of COVID–19 on black communities. Ann Epidem 47: 37–44.

Moda, HM, Filho, WL and Minhas A (2019). Impacts of Climate Change on Outdoor Workers and Their Safety: Some Research Priorities. International Journal of Environmental Research and Public Health 16(18): 3458.

Morello-Frosch R, Jesdale BM, Sadd JL, Pastor M (2010). Ambient air pollution exposure and full-term birth weight in California. Environ Health 9: 44.

Myhre, G, Samset, BH, Schulz, M, Balkanski, Y, Bauer, S, Berntsen, TK, Bian, H, Bellouin, N, Chin, M, Diehl, T, Easter, RC, Feichter, J, Ghan, SJ, Hauglustaine, D, Iversen, T, Kinne, S, Kirkevag, A, Lamarque, JF, Lin, G, Liu, X, Lund, MT, Luo, G, Ma, X, van Noije, T, Penner, JE, Rasch, PJ, Ruiz, A, Seland, O, Skeie, RB, Stier, P, Takemura, T, Tsigaridis, K, Wang, P, Wang, Z, Xu, L, Yu, H, Yu, F, Yoon, JH, Zhang, K, Zhang, H, Zhou, C (2013). Radiative forcing of the direct aerosol effect from AeroCom Phase II simulations. Atmos Chem Phys 13: 1853–1877.

Nassikas, N, Spangler, K, Fann, N, Nolte, C, Dolwick, P, Spero, TL, Sheffield, P and Wellenius, GA (2020). Ozone-related asthma emergency department visits in the US in a warming climate. Env Red 183: 109206.

Neufeld, HS, Sullins, A, Sive, BC and Lefohn, AS (2019). Spatial and temporal patterns of ozone at Great Smoky Mountains National Park and implications for plant responses. Atmos Environ X 2: 100023.

Oksanen, E and Holopainen, T (2001). Responses of two birch (Betula pendula Roth) clones to different ozone profiles with similar AOT40 exposure. Atmos Environ 35(31): 5245–5254.

O'Lenick, CR, Winquist, A, Mulholland, JA, Friberg, MD, Chang, HH, Kramer, MR, Darrow, LA and Sarnat, SE (2017). Assessment of neighbourhood-level socioeconomic status as a modifier of air pollution-asthma associations among children in Atlanta. J Epidemiol Community Health 71(2): 129–136.

OTC (2020). Analysis of the potential health impacts of reducing ozone levels in the OTR using BenMAP—2020 edition.

Paulin, LM, Gassett, AJ, Alexis, N, Kirwa, K, Kanner, RE, Peters, S, Krishnan, JA, Paine, R, Adam A, Dransfield, M, Woodruff, EG, Cooper, C, Barr, RG, Comellas, AS, Pirozzi, CK, Han, B, Hoffman, David J, Martinez, F, Ana, V, Woo, Peng, Joel, D, Fawzy, R, Putcha, N, Breysse, PN, Kaufman, J, Hansel, NN, Anderson, WH, Arjomandi, M, Barjaktarevic, I, Bateman, LA, Bhatt, SP, Bleecker, ER, Boucher, RC, Bowler, RP, Christenson, SA, Couper, DJ, Criner, GJ, Crystal, RG, Curtis, JL, Doerschuk, CM, Dransfield, MT, Drummond, B, Freeman, CM, Galban, C, Han, MK, Hastie, AT, Huang, Y, Kaner, RJ, Kleerup, EC, Lavange, LM, Lazarus, SC, Meyers, DA, Moore, WC, Newell, JD, Jr, Paulin, L, Peters, SP, Pirozzi, C, Oelsner, EC, O'Neal, WK, Ortega, VE, Raman, S, Rennard, S, Tashkin, DP, Wells, JM, Wise, RA, Postow, L, and Viviano, L, for SPIROMICS Investigators (2020). Association of Long-term Ambient Ozone Exposure With Respiratory Morbidity in Smokers. JAMA Intern Med 180(1): 106–115.

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

Petroni, M, Hill, D, Younes, L, Barkman, L, Howard, S, Howell, IB, Mirowsky, J and Collins, MB (2020). Hazardous air pollutant exposure as a contributing factor to COVID–19 mortality in the United States. Environ Res Lett 15(9): 0940a9.

Price-Haywood, EG, Burton, J and Fort, D and Seoane, L (2020). Hospitalization and Mortality among Black Patients and White Patients with Covid-19. NEJM 382: 2534–2543.

Pruitt, E (2018). Memorandum from E. Scott Pruitt, Administrator, U.S. EPA to Assistant Administrators. Back-to-Basics Process for Reviewing National Ambient Air Quality Standards. May 9, 2018. Office of the Administrator U.S. EPA HQ, Washington DC. Available at: *https://www.epa.gov/criteria-air-pollutants/back-basics-process-reviewing-national-ambient-air-quality-standards.*

Rhee, J, Dominici, F, Zanobetti, A, Schwartz, J, Wang, Yun, Di, Q, Balmes, J and Christiani, DC (2019). Impact of Long-Term Exposures to Ambient $PM_{2.5}$ and Ozone on ARDS Risk for Older Adults in the United States. Chest 156(1): 71–79.

Salam, MT, Millstein, J, Li, YF, Lurmann, FW, Margolis, HG and Gilliland, FD (2005). Birth outcomes and prenatal exposure to ozone, carbon monoxide, and particulate matter: Results from the Children's Health Study. Environ Health Perspect 113: 1638–1644.

Samet, JM (2011). Letter from Jonathan Samet, Chair, Clean Air Scientific Advisory Committee, to Administrator Lisa Jackson. Re: CASAC Response to Charge Questions on the Reconsideration of the 2008 Ozone National Ambient Air Quality Standards. March 30, 2011. EPA–CASAC–11–004. Office of the Administrator, Science Advisory Board U.S. EPA HQ, Washington DC. Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/368203f97a15308a852574ba005bbd01/F08BEB48C1139E2A8525785E006909AC/$File/EPA-CASAC-11-004-unsigned+.pdf.*

Schelegle, ES, Morales, CA, Walby, WF, Marion, S and Allen, RP (2009). 6.6-hour inhalation of ozone concentrations from 60 to 87 parts per billion in healthy humans. Am J Respir Crit Care Med 180(3): 265–272.

Seltzer, KM, Shindell, DT, Kasibhatla, P and Malley, CS (2020). Magnitude, Trends, and Impacts of Ambient Long-Term Ozone Exposure in the United States from 2000 to 2015. Atmos Chem Phys 20(3): 1757–75.

Shin, S, Burnett, RT, Kwong, JC, Hystad, P, van Donkelaar, A, Brook, JR, Goldberg, MS, Tu, K, Copes, Ray, Martin, R, Lia, Y, Kopp, A and Chen, H (2019). Ambient Air Pollution and the Risk of Atrial Fibrillation and Stroke: A Population-Based Cohort Study. Environ Health Perspect 127(8): 87009.

Smith, G (2012). Ambient ozone injury to forest plants in Northeast and North Central USA: 16 years of biomonitoring. Environ Monit Assess(184): 4049–4065.

Smith, G, Coulston, J, Jepsen, E and Prichard, T (2003). A national ozone biomonitoring program: Results from field surveys of ozone sensitive plants in northeastern forests (1994–2000). Environ Monit Assess 87(3): 271–291.

Smith, GC, Smith, WD and Coulston, J (2007). Ozone bioindicator sampling and estimation. General Technical Report NRS–20. United States Department of Agriculture, US Forest Service, Northern Research Station.

Smith, GC, Morin, RS and McCaskill, GL (2012). Ozone injury to forests across the Northeast and North Central United States, 1994–2010. General Technical Report NRS–103. United States Department of Agriculture, US Forest Service, Northern Research Station.

Stieb, DM, Lavigne, E, Chen, L, Pinault, L, Gasparrini, A and Tjepkema, M (2019). Air pollution in the week prior to delivery and preterm birth in 24 Canadian cities: a time to event analysis. Environ Health 18(1): 1.

Stokes, EK, Zambrano, LD, Anderson, KN, Marder, EP, Raz, KM, Felix, SEB, Tie, Y and Fullerton, KE (2020). Coronavirus Disease 2019 Case Surveillance—United States, January 22–May 30, 2020. MMWR Morb Mortal Wkly Rep 2020,69:759–765.

Strosnider, HM, Chang, HH, Darrow, LA, Liu, Y, Vaidyanathan, A and Strickland, MJ (2019). Age-Specific Associations of Ozone and Fine Particulate Matter with Respiratory Emergency Department Visits in the United States. AM J Respi Crit Care Med 199(7): 882–890.

Thurston, GD, Kipen, H, Annesi-Maesano, I, Balmes, J, Brook, RD, Cromar, K, De Matteis, S, Forastiere, F, Forsberg, B, Frampton, MW, Grigg, J, Heederik, D, Kelly, FJ, Kuenzli, N, Laumbach, R, Peters, A, Rajagopalan, ST, Rich, D, Ritz, B, Samet, JM, Sandstrom, T, Sigsgaard, T, Sunyer, J and Brunekreef, B (2017). A joint ERS/ATS policy statement: what constitutes an adverse health effect of air pollution? An analytical framework. Eur Respir J 49(1): 1600419

U.S. Census Bureau (2019). Current Population Survey, Annual Social and Economic Supplement, 2018. Age and Sex Composition in the United States: 2018. Available at: *https://www.census.gov/data/tables/2018/demo/age-and-sex/2018-age-sex-composition.html* Accessed August 27, 2019.

U.S. DHEW (1970). Air Quality Criteria for Photochemical Oxidants. National Air Pollution Control Administration. Washington, DC. U.S. DHEW. publication no. AP–63. NTIS, Springfield, VA, PB–190262/BA.

U.S. EPA (1978). Air Quality Criteria for Ozone and Other Photochemical Oxidants Environmental Criteria and Assessment Office. Research Triangle Park, NC. EPA–600/8–78–004. April 1978. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=200089CW.txt.*

U.S. EPA (1986). Air Quality Criteria for Ozone and Other Photochemical Oxidants (Volumes I–V). Research Triangle Park, NC. U.S. EPA. EPA–600/8–84–020aF, EPA–600/8–84–020bF, EPA–600/8–84–020cF, EPA–600/8–84–020dF and EPA/600/8–84–020eF. *http://www.ntis.gov/search/product.aspx?ABBR=PB87142949.*

U.S. EPA (1989). Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information. OAQPS Staff Paper. Office of Air Quality Planning and Standards. Research Triangle Park, NC U.S. EPA.

U.S. EPA (1992). Summary of Selected New Information on Effects of Ozone on Health and Vegetation: Supplement to 1986 Air Quality Criteria for Ozone and Other Photochemical Oxidants. Office of Research and Development. Washington, DC. U.S. EPA. EPA/600/8–88/105F.

U.S. EPA (1996a). Air Quality Criteria for Ozone and Related Photochemical Oxidants. Volumes I to III. U.S. EPA. Research Triangle Park, NC. EPA/600/P–93/004aF, EPA/600/P–93/004bF, and EPA/600/P–93/004cF.

U.S. EPA (1996b). Review of national ambient air quality standards for ozone: Assessment of scientific and technical information: OAQPS staff paper. Office of Air Quality Planning and Standards. Research Triangle Park, NC. U.S. EPA. EPA–452/R–96–007. June 1996. Available at: *http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=2000DKJT.PDF.*

U.S. EPA (2006). Air Quality Criteria for Ozone and Related Photochemical Oxidants (Volumes I–III). EPA–600/R–05–004aF, EPA–600/R–05–004bF and EPA–600/R–05–004cF. U.S. Environmental Protection Agency. Washington, DC. Available at: *http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_cr_cd.html.*

U.S. EPA (2007). Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information: OAQPS Staff Paper. Office of Air Quality Planning and Standards. Research Triangle Park, NC. U.S. EPA. EPA–452/R–07–003. January 2007. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P10083VX.txt.*

U.S. EPA (2008). Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard. EPA–452/R–08–008a. Office of Air Quality Planning and Standards. Research Triangle Park, NC. Available at: *https://www3.epa.gov/ttn/naaqs/standards/nox/s_nox_cr_rea.html.*

U.S. EPA (2009). Risk and Exposure Assessment to Support the Review of the SO_2 Primary National Ambient Air Quality Standard. Office of Air Quality Planning and Standards. Research Triangle Park, NC. US EPA. EPA–452/R–09–007. Available at: *https://www3.epa.gov/ttn/naaqs/standards/so2/data/200908SO2REAFinalReport.pdf.*

U.S. EPA (2010). Quantitative Risk and Exposure Assessment for Carbon Monoxide—Amended. Office of Air Quality Planning and Standards. Research Triangle Park, NC. U.S. EPA. EPA–452/R–10–006. Available at: *https://www.epa.gov/naaqs/carbon-monoxide-co-standards-risk-and-exposure-assessments-current-review.*

U.S. EPA (2013). Integrated Science Assessment of Ozone and Related Photochemical Oxidants (Final Report). Office of Research and Development, National Center for Environmental Assessment. Research Triangle Park, NC. U.S. EPA. EPA–600/R–10–076F. February 2013. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100KETF.txt.*

U.S. EPA (2014a). Health Risk and Exposure Assessment for Ozone. (Final Report). Office of Air Quality Planning and Standards. Research Triangle Park, NC. U.S. EPA. EPA–452/R–14–004a. August 2014. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100KBUF.txt.*

U.S. EPA (2014b). Welfare Risk and Exposure Assessment for Ozone (Final). Office of Air Quality Planning and Standards. Research Triangle Park, NC. U.S. EPA. EPA–452/P–14–005a August 2014. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100KB9D.txt.*

U.S. EPA (2014c). Policy Assessment for the Review of National Ambient Air Quality Standards for Ozone (Final Report). Office of Air Quality Planning and Standards, Health and Environmental Impacts Divison. Research Triangle Park, NC. U.S. EPA. EPA–452/R–14–006 August 2014. Available at: *https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P100KCZ5.txt.*

U.S. EPA (2015). Responses to Significant Comments on the 2014 Proposed Rule on the National Ambient Air Quality Standards for Ozone (December 17, 2014, 79 FR 75234). Office of Air Quality Planning and Standards. Research Triangle Park, NC. U.S. EPA. Docket ID: EPA–HQ–OAR–2008–0699–4309. Available at: *https://www.epa.gov/naaqs/responses-significant-comments-2014-proposed-rule-national-ambient-air-quality-standards-ozone.*

U.S. EPA (2018). Risk and Exposure Assessment for the Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides. Office of Air Quality Planning and Standards. Research Triangle Park, NC. U.S. EPA. EPA–452/R–18–003. Available at: *https://www.epa.gov/sites/production/files/2018-05/documents/primary_so2_naaqs_-_final_rea_-_may_2018.pdf.*

U.S. EPA (2019a). The Consolidated Human Activity Database (CHAD). Documentation and User's Guide. Research Triangle Park, NC. US EPA. EPA–452/B–19–001. Available at: *https://www.epa.gov/sites/production/files/2019-11/documents/chadreport_october2019.pdf.*

U.S. EPA (2019b). Integrated Review Plan for the Ozone National Ambient Air Quality Standards. Office of Air Quality Planning and Standards. Research Triangle Park, NC. U.S. EPA. EPA–452/R–19–002. Available at: *https://www.epa.gov/sites/production/files/2019-08/documents/o3-irp-aug27-2019_final.pdf.*

U.S. EPA (2020a). Integrated Science Assessment for Ozone and Related Photochemical Oxidants. U.S. Environmental Protection Agency. Washington, DC. Office of Research and Development. EPA/600/R–20/012. Available at: *https://www.epa.gov/isa/integrated-science-assessment-isa-ozone-and-related-photochemical-oxidants.*

U.S. EPA (2020b). Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards. U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Heath and Environmental Impacts Division. Research Triangle Park, NC. U.S. EPA. EPA–452/R–20–001. 2020 Available at: *https://www.epa.gov/naaqs/ozone-o3-standards-policy-assessments-current-review.*

van Goethem, TM, Azevedo, LB, van Zelm, R, Hayes, F, Ashmore, MR and Huijbregts, MA (2013). Plant species sensitivity distributions for ozone exposure. Environ Pollut 178: 1–6.

Villeneuve, PJ, Chen, L, Rowe, BH and Coates, F (2007). Outdoor air pollution and emergency department visits for asthma among children and adults: A case-crossover study in northern Alberta, Canada. Environ Health 6: 40.

Wallace, ME, Grantz, KL, Liu, D, Zhu, Y, Kim, SS and Mendola P (2016). Exposure to Ambient Air Pollution and Premature Rupture of Membranes. Am J Epidemiol 183(12):1114–21.

Wang, M, Aaron, CP, Madrigano, J, Hoffman, EA, Angelini, E,Yang, Jie, Laine, A, Vetterli, TM, Kinney, PL, Sampson, PD, Sheppard, LE, Szpiro, AA, Adar, PD, Kirwa, K, Smith, MB, Lederer, AJ, Diez-Roux, FV, Vedal, S, Kaufman, DD and Barr, ARG (2019a). Association Between Long-term Exposure to Ambient Air Pollution and Change in Quantitatively Assessed Emphysema and Lung. JAMA 322(6): 546–556.

Wang, P, Baines, A, Lavine, M and Smith, G (2012). Modelling ozone injury to U.S. forests. Environ Ecol Stat 19(4): 461–472.

Wang, M, Sampson, PD, Sheppard, LE, Stein, JH, Vedal, S and Kaufman, JD (2019b). Long-Term Exposure to Ambient Ozone and Progression of Subclinical Arterial Disease: The Multi-Ethnic Study of Atherosclerosis and Air Pollution. Environ Health Perspect 127(5): 57001.

Ware, LB, Zhao, Z, Koyama, T, May, AK, Matthay, MA, Lurmann, FW, Balmes, JR and Calfee, CS (2016). Long-Term Ozone Exposure Increases the Risk of Developing the Acute Respiratory Distress Syndrome. Am J Respir Crit Care Med 193(10):1143–1150.

Wells, B (2020). Memorandum to Ozone NAAQS Review Docket (EPA–HQ–OAR–2018–0279). Additional Analyses of Ozone Metrics Related to Consideration of the Ozone Secondary Standard. December 2020. Docket ID No. EPA–HQ–OAR–2018–0279. Office of Air Quality Planning and Standards Research Triangle Park, NC.

Wells, B (2015). Memorandum to Ozone NAAQS Review Docket (EPA–HQ–OAR–2008–0699). Expanded Comparison of Ozone Metrics Considered in the Current NAAQS Review. September 28, 2015. Docket ID No. EPA–HQ–OAR–2008–0699. Office of Air Quality Planning and Standards Research Triangle Park, NC. Available at: *https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OAR-2008-0699-4325&contentType=pdf.*

Wells, BW, Wesson, K, Jenkins, S. (2012). Memorandum to Ozone NAAQS Review Docket (EPA–HQ–OAR–2008–0699). Analysis of Recent U.S. Ozone Air Quality Data to Support the 03 NAAQS Review and Quadratic Rollback Simulations to Support the First Draft of the Risk and Exposure Assessment. August 15, 2012. Docket ID No. EPA–HQ–OAR–2008–0699. Office of Air Quality Planning and Standards Research Triangle Park, NC. Available at: *https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OAR-2008-0699-4253&contentType=pdf.*

Wheeler, AR (2020). Letter from Andrew R. Wheeler, Administrator, to Dr. Louis Anthony Cox, Jr., Chair, Clean Air Scientific Advisory Committee. April 1, 2020. Office of the Administrator, U.S. EPA, Washington DC. Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/F228E5D4D848BBED85258515006354D0/$File/EPA-CASAC-20-002_Response.pdf*

Wendt, JK, Symanski, E, Stock, TH, Chan, W and Du, XL. (2014) Association of short-term increases in ambient air pollution and timing of initial asthma diagnosis among medicaid-enrolled children in a metropolitan area. Environ Res 131:50–58.

WHO (2008). Uncertainty and Data Quality in Exposure Assessment. The Internaltional Programme on Chemical Safety. Geneva. WHO. *https://www.who.int/ipcs/publications/methods/harmonization/exposure_assessment.pdf.*

Wu, X, Nethery, RC, Sabath, BM, Braun, D and Dominici F (2020). Exposure to air pollution and COVID–19 mortality in the United States: A nationwide cross-sectional study. medRxiv [Preprint] 2020 Apr 7: 2020.04.05.20054502.

Yun, S–C and Laurence, JA (1999). The response of clones of Populus tremuloides differing in sensitivity to ozone in the field. New Phytol 141(3): 411–421.

Zhu, Y, Xie, J, Huang, F and Cao, L (2020). Association between short-term exposure to air pollution and COVID–19 infection: Evidence from China. Sci Total Environ 727: 138704.

Zoran, MA, Savastru, RS, Savastru, DM and Tautan, MN (2020). Assessing the relationship between ground levels of ozone (O–3) and nitrogen dioxide (NO2) with coronavirus (COVID–19) in Milan. Sci Total Environ, 740: 140005.

List of Subjects in 40 CFR Part 50

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

Andrew Wheeler,
Administrator.

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BILLING CODE 6560–50–P

access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, and .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified deadline date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting, or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: February 26, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–04465 Filed 3–3–21; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–10020–31–ORD]

Ambient Air Monitoring Reference and Equivalent Methods; Designation of One New Reference Method and One New Equivalent Method

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of the designation of one new reference method and one new equivalent method for monitoring ambient air quality.

SUMMARY: Notice is hereby given that the Environmental Protection Agency (EPA) has designated one new reference method for measuring concentrations of sulfur dioxide (SO_2), and one new equivalent method for measuring concentrations of particulate matter (PM_{10}) in ambient air.

FOR FURTHER INFORMATION CONTACT: Robert Vanderpool, Air Methods and Characterization Division (MD–D205–03), Center for Environmental Measurements and Modeling, U.S. EPA, Research Triangle Park, North Carolina 27711. Phone: 919–541–7877. Email: *Vanderpool.Robert@epa.gov.*

SUPPLEMENTARY INFORMATION: In accordance with regulations at 40 CFR part 53, the EPA evaluates various methods for monitoring the concentrations of those ambient air pollutants for which EPA has established National Ambient Air Quality Standards (NAAQS) as set forth in 40 CFR part 50. Monitoring methods that are determined to meet specific requirements for adequacy are designated by the EPA as either reference or equivalent methods (as applicable), thereby permitting their use under 40 CFR part 58 by States and other agencies for determining compliance with the NAAQS. A list of all reference or equivalent methods that have been previously designated by EPA may be found at *http://www.epa.gov/ttn/amtic/criteria.html.*

The EPA hereby announces the designation of one new reference method for measuring concentrations of SO_2 in ambient air and one new equivalent method for measuring concentrations of PM_{10} in ambient air. These designations are made under the provisions of 40 CFR part 53, as amended on October 26, 2015 (80 FR 65291–65468).

The new reference method for SO_2 is an automated method (analyzer) utilizing the measurement principle based on UV fluorescence. This newly designated reference method is identified as follows:

RFSA–1120–257, ''KENTEK Inc. Model MEZUS 110 SO_2 Analyzer,'' UV fluorescence analyzer operated in a range of 0–0.5 ppm, with 0.5 μm, 47 mm diameter Teflon® filter installed, operated at temperatures between 20° C and 30° C, at a nominal sampling flow rate of 800 cc/min, using a 5 minute averaging time, with either 105VAC–125VAC or 200VAC–240VAC input power options installed, 280-watt power consumption, equipped with 7 inch LCD touch screen display, and operated according to the KENTEK Inc. Model Mezus 110 Sulfur Dioxide Analyzer User's Instruction Manual.

This application for a reference method determination for this SO_2 method was received by the Office of Research and Development on July 21, 2020. This analyzer is commercially available from the applicant, KENTEK Inc., Hanshin S. Meca Room #526, 65 Techno 3-ro, Yuseong-gu, Daejeon, Republic of Korea, 34016.

The new equivalent method for PM_{10} is an automated method (monitor) utilizing the measurement principle based on Beta Attenuation or β-ray monitoring. This newly designated equivalent method is identified as follows:

EQPM–0121–258, ''Focused Photonics Inc. BPM–200 PM_{10} Monitor,'' β-ray monitor operated in the following concentration ranges: 0–1 mg/m³, 0–2 mg/m³, 0–5 mg/m³, or 0–10 mg/m³, analyzing ambient conditions temperatures between −30° C to 50° C, while the monitor can operate in a conditioned space between 0° C to 50° C. The unit is operated for 24-hour average measurements, with the FPI P/N 6150138000X EPA PM_{10} inlet, glass fiber filter tape with axial inner diameter of 40mm (GCY00003900), the 220VAC 50Hz power supply, the FPI P/N 6150139000X Atmospheric Temperature Unit, the 6100050000X Air heating unit for maintaining moisture at about 35% and no ΔT control, the FPI P/N GCX00013700 filter, the FPI P/N 6102182000X internal calibration device, 290508D00A Main Board, and 2910510B00X Interface board display. Instrument must be operated in accordance with the appropriate instrument manual and with software (firmware) version AQMSPlus.P005.V01A.US001.

This application for an equivalent method determination for this PM_{10} method was received by the Office of Research and Development on October 13, 2020. This monitor is commercially available from the applicant, Focused Photonics Inc. (FPI), 760 Bin'an Road, Binjiang District, Hangzhou, Zhejiang, China.

Representative test analyzers have been tested in accordance with the applicable test procedures specified in 40 CFR part 53, as amended on October 26, 2015. After reviewing the results of those tests and other information submitted by the applicants, EPA has determined, in accordance with 40 CFR part 53, that these methods should be designated as a reference or equivalent method.

As a designated reference or equivalent method, these methods are acceptable for use by states and other air monitoring agencies under the requirements of 40 CFR part 58, Ambient Air Quality Surveillance. For such purposes, each method must be used in strict accordance with the operation or instruction manual associated with the method and subject to any specifications and limitations (*e.g.,* configuration or operational settings) specified in the designated method description (see the identification of the method above).

Use of the method also should be in general accordance with the guidance and recommendations of applicable sections of the ''Quality Assurance Handbook for Air Pollution Measurement Systems, Volume I,'' EPA/600/R–94/038a and ''Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Quality Monitoring Program,'' EPA–454/B–13–003, (both available at *http://www.epa.gov/ttn/amtic/qalist.html*). Provisions concerning modification of such methods by users are specified under Section 2.8 (Modifications of Methods by Users) of Appendix C to 40 CFR part 58.

Consistent or repeated noncompliance with any of these conditions should be reported to: Director, Air Methods and Characterization Division (MD–D205–03), Center for Environmental Measurements and Modeling, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

Designation of these reference and equivalent methods is intended to assist the States in establishing and operating their air quality surveillance systems under 40 CFR part 58. Questions concerning the commercial availability or technical aspects of the methods should be directed to the applicants.

Timothy Watkins,

Director, Center for Environmental Measurements and Modeling.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2021–0178; FRL–10021–15–OAR]

Clean Air Act Advisory Committee (CAAAC): Request for Nominations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Request for Nominations to the Clean Air Act Advisory Committee (CAAAC).

SUMMARY: The U.S. Environmental Protection Agency (EPA) invites nominations from a diverse range of qualified candidates to be considered for appointment to its Clean Air Act Advisory Committee (CAAAC). Vacancies are anticipated to be filled by August 2021 and applications are due by April 30, 2021. Sources in addition to this **Federal Register** Notice may also be utilized in the solicitation of nominees.

DATES: Applications are due by April 30, 2021.

ADDRESSES: Submit nominations in writing to: Shanika Whitehurst, Designated Federal Officer, Office of Air and Radiation, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460.

For further information or to email nominations, include in the subject line CAAAC Membership 2021 and send to *caaac@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Shanika Whitehurst, Designated Federal Officer, Office of Air and Radiation, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460, 202–564–8235, *whitehurst.shanika@epa.gov.*

SUPPLEMENTARY INFORMATION:

Background: Clean Air Act Advisory Committee provides advice, information and recommendations on policy and technical issues associated with implementation of the Clean Air Act (CAA) as requested by EPA. These issues include the development, implementation, and enforcement of programs required by the Act. The CAAAC will provide advice and recommendations on approaches for new and expanded programs including those using innovative technologies and policy mechanisms to achieve environmental improvements; the potential health, environmental and economic effects of CAA programs on the public, the regulated community, State and local governments, and other Federal agencies; the policy and technical contents of proposed major EPA rulemaking and guidance required by the Act in order to help effectively incorporate appropriate outside advice and information; and the integration of existing policies, regulations, standards, guidelines, and procedures into programs for implementing requirements of the Act.

The programs falling under the purview of the committee include, but are not limited to, those for meeting National Ambient Air Quality Standards, reducing emissions from vehicles and vehicle fuels, reducing air toxic emissions, permitting, carrying out compliance authorities, and CAA-related voluntary activities. Members are appointed by the EPA Administrator for two-year terms with the possibility of reappointment to additional term(s). The CAAAC usually meets approximately 2 times annually and the average workload for the members is approximately 5 to 10 hours per month.

Although EPA is unable to offer compensation or an honorarium for CAAAC members, they may receive travel and per diem allowances, according to applicable federal travel regulations. EPA is seeking nominations from academia, industry, non-governmental/environmental organizations, community organizations, state and local government agencies, tribal governments, unions, trade associations, utilities, and lawyers/consultants. EPA values and welcomes diversity. In an effort to obtain nominations of diverse candidates, EPA encourages nominations of women and men of all racial and ethnic groups.

Evaluation Criteria

The following criteria will be used to evaluate nominees:

- The background and experiences that would help members contribute to the diversity of perspectives on the committee (*e.g.,* geographic, economic, social, cultural, educational, and other considerations)
- Experience serving as an elected official;
- Experience serving as an appointed official for a state, county, city or tribe;
- Experience working on national level or on local government issues;
- Demonstrated experience with air quality policy issues;
- Executive management level experience with membership in broad-based networks;
- Excellent interpersonal, oral and written communication, and consensus-building skills.
- Ability to volunteer time to attend meetings 2–3 times a year, participate in teleconference meetings, attend listening sessions with the