ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[EPA–HQ–OAR–2018–0279; FRL–10012–49–OAR]

RIN 2060–AU40

Review of the Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed 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 proposing to retain the current standards, without revision.

DATES: Comments must be received on or before October 1, 2020.

Public hearings: The EPA will hold two virtual public hearings on Monday, August 31, 2020, and Tuesday, September 1, 2020. Please refer to the **SUPPLEMENTARY INFORMATION** section for additional information on the public hearings.

ADDRESSES: You may submit comments, identified by Docket ID No. EPA–HQ–OAR–2018–0279, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-Docket@epa.gov.* Include the Docket ID No. EPA–HQ–OAR–2018–0279 in the subject line of the message.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Air and Radiation Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery or Courier (by scheduled appointment only):* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this document. Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided. For detailed instructions on sending comments, see the **SUPPLEMENTARY INFORMATION** section of this document. 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. We encourage the public to submit comments via *https://www.regulations.gov/* or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

The two virtual public hearings will be held on Monday, August 31, 2020, and Tuesday, September 1, 2020. The EPA will announce further details on the virtual public hearing website at *https://www.epa.gov/ground-level-ozone-pollution/setting-and-reviewing-standards-control-ozone-pollution.* Refer to the **SUPPLEMENTARY INFORMATION** section below for additional information.

FOR FURTHER INFORMATION CONTACT: For information or questions about the public hearing, please contact Ms. Regina Chappell, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards (OAQPS) (Mail Code C304–03), Research Triangle Park, NC 27711; telephone: (919) 541–3650; email address: *chappell.regina@epa.gov.* For information or questions regarding the review of the O_3 NAAQS, please 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:

General Information

Participation in Virtual Public Hearings

Please note that the EPA is deviating from its typical approach because the President has declared a national emergency. Due to the current Centers for Disease Control and Prevention (CDC) recommendations, as well as state and local orders for social distancing to limit the spread of COVID–19, the EPA cannot hold in-person public meetings at this time. The EPA will begin pre-registering speakers for the hearings upon publication of this document in the **Federal Register**. To register to speak at a virtual hearing, please use the online registration form available at *https://www.epa.gov/ground-level-ozone-pollution/setting-and-reviewing-standards-control-ozone-pollution* or contact Ms. Regina Chappell at (919) 541–3650 or by email at *chappell.regina@epa.gov* to register to speak at the virtual hearing. The last day to pre-register to speak at one of the hearings will be August 27, 2020. On August 28, 2020, the EPA will post a general agenda for the hearings that will list preregistered speakers in approximate order at: *https://www.epa.gov/ground-level-ozone-pollution/setting-and-reviewing-standards-control-ozone-pollution.* The EPA will make every effort to follow the schedule as closely as possible on the day of each hearing; however, please plan for the hearing to run either ahead of schedule or behind schedule. Each commenter will have 5 minutes to provide oral testimony. The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically (via email) by emailing it to Dr. Deirdre Murphy and Ms. Regina Chappell. The EPA also recommends submitting the text of your oral testimony as written comments to the rulemaking docket. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing. Please note that any updates made to any aspect of the hearing will be posted online at *https://www.epa.gov/ground-level-ozone-pollution/setting-and-reviewing-standards-control-ozone-pollution.* While the EPA expects the hearings to go forward as set forth above, please monitor our website or contact Ms. Regina Chappell at (919) 541–3650 or *chappell.regina@epa.gov* to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates. If you require the services of a translator or a special accommodation such as audio description, please preregister for the hearing with Ms. Regina Chappell and describe your needs by August 21, 2020. The EPA may not be able to arrange accommodations without advance notice.

Preparing Comments for the EPA

Follow the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, the cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

When submitting comments, remember to:

• Identify the action by docket number and other identifying information (subject heading, **Federal Register** date and page number).

• Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.

• Describe any assumptions and provide any technical information and/or data that you used.

• Provide specific examples to illustrate your concerns and suggest alternatives.

• Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

• Make sure to submit your comments by the comment period deadline identified.

Availability of Information Related to This Action

All documents in the dockets pertaining to this action are listed on the *www.regulations.gov* website. This includes documents in the docket for the proposed decision (Docket ID No. EPA–HQ–OAR–2018–0279) and a separate docket, established for the Integrated Science Assessment (ISA) for this review (Docket ID No. EPA–HQ–ORD–2018–0274) that has been incorporated by reference into the docket for this proposed decision. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and may be viewed with prior arrangement with the EPA Docket Center. Additionally, a number of the documents that are relevant to this proposed decision 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 Review of the Ozone National Ambient Air Quality Standards (U.S. EPA, 2019b; hereafter IRP), available at *https://www.epa.gov/naaqs/ozone-o3-standards-planning-documents-current-review,* the Integrated Science Assessment for Ozone and Related Photochemical Oxidants (U.S. EPA, 2020a; hereafter ISA), available at *https://www.epa.gov/naaqs/ozone-o3-standards-integrated-science-assessments-current-review,* and the Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (U.S. EPA, 2020b; hereafter PA), available at *https://www.epa.gov/naaqs/ozone-o3-standards-policy-assessments-current-review.*

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The following topics are discussed in this preamble:

Executive Summary

This document presents the Administrator's proposed decisions in the current review of the primary (health-based) and secondary (welfare-based) O_3 NAAQS. In so doing, this document summarizes the background and rationale for the Administrator's proposed decisions to retain the current standards, without revision. In reaching his proposed decisions, the Administrator has considered the currently available scientific evidence in the ISA, quantitative and policy analyses presented in the PA, and advice from the Clean Air Scientific Advisory Committee (CASAC). The EPA solicits comment on the proposed decisions described here and on the array of issues associated with review of these standards, including judgments of public health, public welfare and science policy inherent in the proposed decisions, and requests commenters also provide the rationales upon which views articulated in submitted comments are based.

This review of the O_3 standards, required by the Clean Air Act (CAA) on a periodic basis, was initiated in 2018. The last review of the O_3 NAAQS, completed in 2015 established the current primary and secondary standards (80 FR 65291, October 26, 2015). In that review, the EPA significantly strengthened the primary and secondary standards by revising both standards from 75 ppb to 70 ppb and retaining their indicators (O_3), forms (fourth-highest daily maximum, averaged across three consecutive years) and averaging times (eight hours). These 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). In the decision on 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 proposed decision, and the associated proposed conclusions and judgments, described in this document.

In this review as in past reviews of the 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 precursor emissions of pollutants, such as nitrogen oxides and volatile organic compounds (VOCs), interact with solar radiation. Precursor 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, under more limited meteorological conditions and topographical characteristics, nearer the earth's surface.

The proposed decision to retain the current primary standard, without revision, has been informed by key aspects of the currently available health effects evidence and conclusions contained in the ISA, quantitative exposure/risk analyses and policy evaluations presented in the PA, advice from the CASAC and public input received as part of this ongoing review. The health effects evidence newly available in this review, in conjunction with the full body of evidence critically evaluated in the ISA, continues to support prior conclusions that short-term O_3 exposure causes and long-term O_3 exposure likely causes respiratory effects, with evidence newly available in this review also indicating a likely causal relationship of short-term O_3 with metabolic effects. The strongest evidence for health effects due to ozone exposure, however, continues to come from studies of short- and long-term ozone exposure and respiratory health, including effects related to asthma exacerbation in people with asthma, particularly children with asthma. The longstanding evidence base of respiratory effects, spanning several decades, documents the causal relationship between short-term exposure to O_3 and an array of respiratory effects. The clearest evidence for this conclusion 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 include associations between O_3 exposures and hospital admissions and emergency department visits, particularly for asthma exacerbation in children. People 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, also inform the proposed decision on the primary standard. The general approach and methodology for the exposure-based assessment used in this review is similar to that used in the last review. However, a number of updates and improvements have been implemented in this review which result in differences from the analyses in the prior review. 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. The analyses are summarized in this document and described in detail in the PA.

Based on the current evidence and quantitative information, as well as consideration of CASAC advice and public comment thus far in this review, the Administrator proposes to conclude that the current primary standard is requisite to protect public health, with an adequate margin of safety, from effects of O_3 in ambient air and should be retained, without revision. In its advice to the Administrator, the CASAC concurred with the draft PA that the currently available health effects evidence is generally similar to 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. The advice from the CASAC has been considered by the Administrator in proposing to conclude that the current standard, with its level of 70 ppb, provides the requisite public health protection, with an adequate margin of safety. The EPA solicits comment on the Administrator's proposed conclusion, and on the proposed decision to retain the standard, without revision. The EPA also solicits comment on the array of issues associated with review of this standard, including public health and science policy judgments inherent in the proposed decision.

The proposed decision to retain the current secondary standard, without revision, has been informed by key aspects of the currently available welfare effects evidence and conclusions contained in the ISA, quantitative exposure/risk analyses and policy evaluations presented in the PA, advice from the CASAC and public input received as part of this ongoing review. The welfare effects evidence newly available in this review, in conjunction with the full body of evidence critically evaluated in the ISA, supports, sharpens and expands somewhat on the conclusions reached in the last review. 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. Further, evidence newly available in this review augments more limited previously available evidence for some additional vegetation-related effects. As in the last review, the strongest evidence and the associated findings of causal or likely causal relationships with O_3 in ambient air, as well as the quantitative characterizations of relationships between O_3 exposure and occurrence and magnitude of effects, are 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 growth-related effects such as growth and yield. 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, reduced growth is considered as proxy or surrogate for the broader array of vegetation effects in reviewing the public welfare protection provided by the current standard.

Quantitative analyses of air quality and exposure, including use of the W126 index, as well as policy considerations in the PA, also inform the proposed decision on the secondary standard. For example, analyses of air quality monitoring data across the U.S., as well as in Class I areas, updated and expanded from analyses conducted in the last review, inform EPA's understanding of vegetation exposures in areas meeting the current standard. Based on the current evidence and quantitative information, as well as consideration of CASAC advice and public comment thus far in this review, the Administrator proposes to conclude that the current secondary standard is requisite to protect the public welfare from known or anticipated adverse effects of O_3 in ambient air, and should be retained, without revision. In its advice to the Administrator, the full CASAC concurred with the preliminary conclusions in the draft PA that the current evidence supports retaining the current standard without revision. The EPA solicits comment on the Administrator's proposed conclusion that the current standard is requisite to protect the public welfare, and on the proposed decision to retain the standard, without revision. The EPA also solicits comment on the array of issues associated with review of this standard, including public welfare and science policy judgments inherent in the proposed decision.

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), 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,

[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.''

revise the NAAQS, based on the revised air quality criteria.[3]

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.[4]

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. Review of the Air Quality Criteria and Standards for O_3

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 based on the scientific information in the 1970 air quality criteria document (AQCD). 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 AQCD (U.S. EPA, 1978), the EPA published proposed revisions to the original NAAQS in 1978 (43 FR 26962, June 22, 1978) and final 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. 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 photochemical oxidants began in 1982 and 1983, respectively (47 FR 11561, March 17, 1982; 48 FR 38009, August 22, 1983). The EPA subsequently published the 1986 AQCD, 1989 Staff Paper, and a supplement to the 1986 AQCD (U.S. EPA, 1986; U.S. EPA, 1989; U.S. EPA, 1992). 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 1992 decision in that review, the EPA announced its intention to proceed rapidly with the next review of the air quality criteria and standards for O_3 and other photochemical oxidants

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

[4] 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).

(57 FR 35542, August 10, 1992). The EPA subsequently published the AQCD and Staff Paper for that next review (U.S. EPA, 1996a; U.S. EPA, 1996b). In December 1996, 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 the primary and secondary 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, the D.C. Circuit remanded the 1997 O_3 NAAQS 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). Documents developed for the review included the 2006 AQCD (U.S. EPA, 2006) and 2007 Staff Paper (U.S. EPA, 2007) and related technical support documents. In 2007, the EPA proposed revisions to the primary and secondary standards (72 FR 37818, July 11, 2007). The EPA completed the review in March 2008 by revising the levels of both the primary and secondary standards from 0.08 ppm to 0.075 ppm while retaining 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,[5] 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 on September 29, 2008),[6] the EPA consolidated the reconsideration with its statutorily required periodic review.[7]

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 primary standard, the court rejected petitioners' arguments, upholding the EPA's decision. 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,[8] Risk and Exposure Assessments (REAs) for health and welfare, and PA.[9] In late 2014, the EPA proposed to revise the 2008 primary and secondary standards (79 FR 75234, December 17, 2014; Frey, 2014a, Frey, 2014b, Frey, 2014c, U.S. EPA, 2014a, U.S. EPA, 2014b, U.S. EPA, 2014c). The EPA's final decision in this review was published in October 2015, establishing the now-current standards (80 FR 65292, October 26, 2015). 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.[10] The other elements of the standard were retained. This decision on the secondary standard also incorporated the EPA's response to the D.C. Circuit's remand of the 2008 secondary standard in *Mississippi* v. *EPA,* 744 F.3d 1344 (D.C. Cir. 2013).[11]

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

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

[6] The ''Call for Information'' initiating the new review was announced in the **Federal Register** (73 FR 56581, September 29, 2008).

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

[8] The ISA serves the same purpose, in reviewing the air quality criteria, as the AQCD did in prior reviews.

[9] 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 review of the O_3 NAAQS.

[10] These standards, set in 2015, are specified at 40 CFR 50.19.

[11] 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).

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 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). 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 proposed decision, and associated proposed conclusions and judgments, described in section III.D.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 1.2 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.*).

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 current periodic review of the air quality criteria for photochemical oxidants and 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 is progressing on an accelerated schedule (Pruitt, 2018). The EPA is incorporating a number of efficiencies in various aspects of the review process, as summarized in the IRP, to support completion within the statutorily required period (Pruitt, 2018). As one example of such an efficiency, rather than produce two separate documents, the exposure and risk analyses for the primary standard are included as an appendix in the PA, along with a number of other technical appendices. 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).[12] 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 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 its document 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).[13] The CASAC discussed its

[12] 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 role under section 109(d)(2)(C) of the Act), as well as specific charge questions for review of each of the documents.

[13] 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

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 have informed completion of the final documents and further inform development of the Administrator's proposed decision in this review. Comments from the CASAC on the draft ISA have been considered by the EPA and led to a number of revisions in developing the final document. The CASAC review 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 Ozone 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). 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, which was completed in May 2020 (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.D.2 below and its advice on the secondary standard is summarized in section III.D.2.

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, 2020; 78 FR 938, January 7, 2013).

Materials upon which this proposed decision is based, including the documents described above, are available to the public in the docket for the review.[14] Following a public comment period on the proposed decision, a final decision in the review is projected for late in 2020.

D. Air Quality Information

Ground level ozone concentrations are a mix of mostly tropospheric ozone and some stratospheric ozone. Tropospheric ozone is formed due to chemical interactions involving solar radiation and precursor pollutants including volatile organic compounds (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 levels near the surface. 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).[15] 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 most recent 3-year period (2016–2018), the EPA identified 142 counties, in which together approximately 106 million Americans reside where O_3 design values[16] were above 0.070, the level of the existing NAAQS (PA, section 2.4.1). Across these areas, the highest design values are typically observed in California, Texas, and 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 daily peak O_3 concentrations generally 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 short-term 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 (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 U.S. background (USB). Findings from modeling analyses performed for this review to investigate

[14] The docket for the current O_3 NAAQS review is identified as EPA–HQ–OAR–2018–0279. This docket has incorporated the ISA docket (EPA–HQ–ORD–2018–0274) by reference. Both dockets are publicly accessible at *www.regulations.gov.*

[15] O_3 monitoring seasons vary by state from five months (May to September in Oregon and Washington) to all twelve months (in 11 states), with the most common season being March to October (in 27 states).

[16] 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.

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 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 a small area 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 episodic and 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 Proposed Decision on the Primary Standard

This section presents the rationale for the Administrator's proposed decision to retain the current primary O_3 standard. This rationale is 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 (ISA, section IS.1.2),[17] integrated with the information and conclusions from previous assessments and presented in the ISA, on human health effects associated with photochemical oxidants including O_3 and pertaining to their presence in ambient air. 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 received during the development of these documents.

In presenting the rationale for the Administrator's proposed decision and its foundations, section II.A provides background and introductory information for this review of the primary O_3 standard. It includes background on the establishment of the current standard in 2015 (section II.A.1) and also describes the general approach for the current review (section II.A.2). Section II.B summarizes the currently available health effects evidence, focusing on consideration of key policy-relevant aspects. Section II.C summarizes the exposure and risk information for this review, drawing on the quantitative analyses for O_3, presented in the PA. Section II.D presents the Administrator's proposed conclusions on the current standard (section II.D.3), drawing on both evidence-based and exposure/risk-based considerations (section II.D.1) and advice from the CASAC (section II.D.2).

A. General Approach

The past and current approaches described below are both based, most fundamentally, on using the EPA'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, all 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 evaluation of the current evidence in ISA and the quantitative exposure and risk analyses documented 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 with regard to the standard, the decision will draw 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

[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.*

health, including the health of sensitive groups.[18]

The subsections below provide background and introductory information. Background on the establishment of the current standard in 2015, including the rationale for that decision, is summarized in section II.A.1. This is followed, in section II.A.2, by an overview of the general approach for the current review of the 2015 standard. Following this introductory section and subsections, the subsequent sections summarize current information and analyses, including that newly available in this review. The Administrator's proposed conclusions on the standard set in 2015, based on the current information, are provided in section II.D.3.

1. Background on the Current Standard

The current primary standard was set in 2015 based on the scientific evidence and quantitative exposure and risk analyses available at that time, and on the Administrator's judgments regarding the available scientific 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). The 2015 decision revised the level of the primary standard from 0.075 to 0.070 ppm,[19] in conjunction with retaining the indicator (O_3), averaging time (eight hours), and form (annual fourth-highest daily maximum 8-hour average concentration, averaged across three consecutive years). This action provided increased protection for at-risk populations,[20] such as children and people with asthma, against an array of adverse health effects. The 2015 decision 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).

The health effects evidence base available in the 2015 review included extensive evidence from previous reviews as well as the evidence that had emerged since the prior review had been completed in 2008. This evidence base, spanning several decades, documents the causal relationship between exposure to O_3 and a broad range of respiratory effects (2013 ISA, p. 1–14). 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) to more serious health outcomes such as 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). In addition to extensive controlled human exposure and epidemiologic studies, the evidence base includes experimental animal studies that provide insight into potential modes of action for these effects, contributing to the coherence and robust nature of the evidence. Based on this evidence, the 2013 ISA concluded there to be a causal relationship between short-term O_3 exposures and respiratory effects, and also concluded that the relationship between longer-term exposure and respiratory effects was likely to be causal (2013 ISA, p. 1–14).[21]

With regard to the short-term respiratory effects that were the primary focus of the 2015 decision, the controlled human exposure studies were recognized to provide the most certain evidence indicating the occurrence of health effects in humans following specific O_3 exposures (80 FR 65343, October 26, 2015; 2014 PA, section 3.4). These studies additionally illustrate the role of ventilation rate[22] and exposure duration in eliciting responses to O_3 exposure at the lowest studied concentrations. The exposure concentrations eliciting a given level of response in subjects at rest are higher than those eliciting a response in subjects exposed while at elevated ventilation, such as while exercising (2013 ISA, section 6.2.1.1).[23]

The exposure and risk information available in the 2015 review included exposure and risk estimates for 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). Estimates were derived for two exposure-based analyses, as well as for an analysis based on epidemiologic study associations. The first of the exposure-based analyses involved comparison of population exposure estimates at elevated exertion to exposure benchmark concentrations (exposures of concern).[24] These benchmark concentrations are based on exposure concentrations from controlled human exposure studies in which lung function changes and other effects were measured in healthy, young adult volunteers exposed to O_3 while engaging in quasi-continuous moderate physical activity for a defined period (generally 6.6 hours).[25] The second

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

[19] 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 their use in the more recent literature. The level of the current primary standard, 0.070 ppm, is equivalent to 70 ppb.

[20] 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 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.

[21] The 2013 ISA also concluded there likely to be 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 O_3 exposures and total mortality, cardiovascular effects and reproductive and developmental effects, and between short-term and long-term O_3 exposure and nervous system effects (2013 ISA, section 2.5.2).

[22] Ventilation rate (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 V_E are usually liters (L) per minute (min). Another related term is equivalent ventilation rate (EVR), which refers to V_E normalized by a person's body surface area in square meters (m^2). Accordingly, the units for EVR are generally L/min-m^2. For different activities, a person will experience different levels of exertion and different ventilation rates.

[23] In the controlled human exposure studies, the magnitude or severity of the respiratory effects induced by O_3 is influenced by ventilation rate and exposure duration, as well as exposure concentration, with physical activity increasing ventilation and potential for effects. In studies of generally healthy adults exposed while at rest for 2 hours, 500 ppb is the lowest concentration eliciting a statistically significant O_3-induced reduction in group mean lung function measures, while a much lower concentration produces such result when the study subject ventilation rates are sufficiently increased with exercise (2013 ISA, section 6.2.1.1). The lowest exposure concentration found to elicit a statistically significant O_3-induced reduction in group mean lung function in an exposure of 2 hours or less was 120 ppb after a 1-hour exposure (continuous, very heavy exercise) of trained cyclists (2013 ISA, section 6.2.1.1; Gong et al., 1986) and after 2-hour exposure (intermittent heavy exercise) of young healthy adults (2013 ISA, section 6.2.1.1; McDonnell et al., 1983).

[24] The benchmark concentrations to which exposure concentrations experienced while at moderate or greater exertion were compared were 60, 70 and 80 ppb.

[25] The studies given primary focus were those for which O_3 exposures occurred over the course of 6.6

Continued

exposure-based analysis provided population risk estimates of the occurrence of days with O_3-attributable lung function reductions of varying magnitudes by using the exposure-response (E–R) information in the form of E–R functions or other quantitative descriptions of biological processes.[26] In the epidemiologic study-based analysis, risk estimates were also derived from ambient air concentrations using concentration-response (C–R) functions derived from epidemiologic studies. These latter estimates were given less weight by the Administrator in her decision on the standard in light of conclusions reached in the 2014 PA and the HREA, which reflected lower confidence in these estimates (80 FR 65316–17, October 26, 2015).

The 2014 HREA developed exposure-based estimates for several population groups including all children and all adults. The type of exposure-based estimates that involved comparison of exposures to benchmarks was also derived for children with asthma and adults with asthma. The estimates of percentages of all children with exposures at or above benchmarks were virtually indistinguishable from the corresponding estimates for children with asthma.[27] When considered in terms of the number of children (rather than percentages of the child populations), the estimates for all children were much higher than those for children with asthma, with the magnitude of the differences varying based on asthma prevalence in each study area (2014 HREA, sections 5.3.2, 5.4.1.5 and section 5F–1). 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 that children spend outdoors and engaged in activities at elevated exertion (2014 HREA, section 5.3.2). Thus, consideration of the exposure-based results in the 2015 decision focused on the results for all children and children with asthma.

In weighing the 2013 ISA conclusions with regard to 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 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,[28] 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 2015 decision, the Administrator first addressed the adequacy of protection provided by the then-existing primary standard and decided that the standard should be revised. Considerations related to that decision are summarized in section II.A.1.a below. The considerations and decisions on the revisions to the then-existing standard in order to provide the requisite protection under the Act, including an adequate margin of safety, are summarized in section II.A.1.b.

a. Considerations Regarding Adequacy of the Prior Standard

In the decision that the primary standard that existed at the time of the last review should be revised, the Administrator at that time gave primary consideration 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 65343, October 26, 2015). This emphasis was consistent with comments from the CASAC at that time on the strength of this evidence (Frey, 2014b, p. 5). In placing weight on these studies, the Administrator took note of the variety of respiratory effects reported from the studies of healthy adults engaged in six 50-minute periods of moderate exertion within a 6.6-hour exposure to O_3 concentrations of 60 ppb and higher. The lowest exposure concentration in such studies for which a combination of statistically significant reduction in lung function and increase in respiratory symptoms was reported was 72 ppb (during the exercise periods),[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] She additionally noted the CASAC comments on this point and also its caution that these study findings were for healthy adults and thus indicated the potential for such effects in some groups of people, such as people with asthma, at lower exposure concentrations (Frey, 2014b, pp. 5–6; 80 FR 65343, October 26, 2015).

The 2013 ISA indicated that the pattern of effects observed across the range of exposures assessed in the controlled human exposure studies, increasing with 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 (*e.g.,* respiratory-related hospital admissions, emergency department visits). With regard to the available epidemiologic studies, while analyses of O_3 air quality in the 2014 PA indicated that most O_3 epidemiologic studies reported health effect associations with O_3 concentrations in ambient air that violated the then-current (75 ppb) standard, the Administrator took particular note of a study that reported associations

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.

[26] The E–R information and quantitative models derived from it are based on controlled human exposure studies.

[27] This reflects use of the same time-location-activity diary pool to construct each simulated individual's time-activity series, which is based on the similarities observed in the available diary data with regard to time spent outdoors and exertion levels (2014 HREA, sections 5.3.2 and 5.4.1.5).

[28] In this regard, the 2014 PA considered statements issued by the ATS that had also been considered in prior reviews (ATS, 2000; ATS, 1985).

[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 measurements for the six exercise periods, 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).

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-current standard over the entire 5-year study period (80 FR 65344, October 26, 2015; Mar and Koenig, 2009).[31] While uncertainties limited the Administrator's conclusions on air quality in locations of multicity epidemiologic studies,[32] in looking across the body of epidemiologic evidence, the Administrator reached the conclusion that analyses of air quality in some study locations supported the occurrence of adverse O_3-associated effects at O_3 concentrations in ambient air that met, or are likely to have met, the then-current standard (80 FR 65344, October 26, 2016). 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 gave particular attention to the exposure-based comparison-to-benchmarks analysis, focusing on the estimates of exposures of concern for children, 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). In considering these estimates, she 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. In particular, she noted 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 based on the ISA conclusions regarding mode of action (80 FR 65343, 65345, October 26, 2015; 2013 ISA, section 6.2.3).[33] While generally placing the greatest weight on estimates of repeated exposures, 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). 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).

In considering the exposure estimates from the 2014 HREA with regard to public health implications, the Administrator concluded that the exposures and risks projected to remain upon meeting the then-current (75 ppb) standard could reasonably be judged to be important from a public health perspective. In particular, this conclusion was 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 the average percent of children estimated to experience two or more days with exposures at or above the 60 ppb benchmark approaches 10% in some urban study areas (on average across the analysis years), the Administrator concluded that the then-current 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). Further, although the Administrator recognized increased uncertainty in and placed less weight on the HREA estimates for lung function risk and for the epidemiologic-study-based risk analyses, she found them supportive of a conclusion that the O_3-associated health effects estimated to remain upon just meeting the then-current standard are an issue of public health importance on a broad national scale. Thus, she concluded that O_3 exposure and risk estimates, taken together, supported a conclusion that the exposures and health risks associated with just meeting the then-current standard could reasonably be judged to be of public health significance, such that the then-current 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),[34] 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 that it should be revised to provide increased public health protection. This decision was based on the Administrator's conclusions that the available evidence and exposure and risk information clearly called into question the adequacy of public health protection provided by the then-current primary standard such that it was "not appropriate, within the meaning of section 109(d)(1) of the CAA, to retain the current standard" (80 FR 65346, October 26, 2015).

b. Considerations for the Revised Standard

With regard to the most appropriate indicator for a revised standard, the Administrator considered findings and assessments in the 2013 ISA and 2014 PA, as well as advice from the CASAC and public comment. These include 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

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

[32] Compared to the single-city epidemiologic studies, the Administrator noted additional uncertainty that applied 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 (80 FR 65344; October 26, 2015).

[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] The Administrator also noted that CASAC for the prior, 2008, review likewise recommended revision of the standard to one with a level below 75 ppb. This earlier recommendation was based entirely on the evidence and information in the record for the 2008 decision, which had been expanded in the 2015 review (Samet, 2011; Frey and Samet, 2012).

65347, October 26, 2015). The CASAC indicated its view that O_3 is 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, 2014c, p. ii). Based on all of these considerations and public comments, the Administrator concluded that O_3 remained the most appropriate indicator for a standard meant to provide protection against photochemical oxidants in ambient air, and she retained O_3 as the indicator for the primary standard (80 FR 65347, October 26, 2015).

The 8-hour averaging time for the primary O_3 standard was established in 1997 with the decision to replace the then-existing 1-hour standard with an 8-hour standard (62 FR 38856, July 18, 1997). The decision in that review was based on evidence from numerous controlled human exposure studies of healthy adults of 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 advice from the CASAC (62 FR 38861, July 18, 1997; 61 FR 65727, December 13, 1996). The EPA reached similar conclusions in the subsequent 2008 review in which the 8-hour averaging time was retained (73 FR 16436, March 27, 2008). In the review completed in 2015, the Administrator concluded, in consideration of the then-available health effects information, that an 8-hour averaging time remained appropriate for addressing health effects associated with short-term exposures to ambient air O_3 and that it could effectively limit health effects attributable to both short- and long-term O_3 exposures (80 FR 65348, October 26, 2015). Thus, she found it appropriate to retain this averaging time (80 FR 65350, October 26, 2015).

While giving foremost consideration to the adequacy of public health protection provided by the combination of all elements of the standard, including the form, the Administrator additionally considered the appropriateness of retaining the *n*th-high metric as the form for the revised standard (80 FR 65350–65352, October 26, 2015). In so doing, she considered findings from prior reviews, including the 1997 review, in which 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, which had been the form of the standard prior to 1997.[35] Although the subsequent 2008 review considered the potential value of a percentile-based form, the EPA concluded at that time that, because of the differing lengths of the monitoring season for O_3 across the U.S., a percentile-based statistic would not be effective in ensuring the same degree of public health protection across the country (73 FR 16474–75, March 27, 2008). The 2008 review additionally 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). 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 2015 decision was to retain the existing form (the annual fourth-highest daily maximum 8-hour O_3 average concentration, averaged over three consecutive years), without revision (80 FR 65352, October 26, 2015).

The 2015 decision to set the level of the revised primary O_3 standard at 70 ppb built upon the Administrator's conclusion (summarized in section II.A.1.a above) that the overall body of scientific evidence and exposure/risk information called into question the adequacy of the public health protection afforded by the then-current standard, particularly for at-risk populations and lifestages (80 FR 65362, October 26, 2015). In her decision on level, the Administrator 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.[36] In so doing, the Administrator noted that controlled human exposure studies provide the most certain evidence indicating the occurrence of health effects in humans following specific O_3 exposures, noting 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). The Administrator's emphasis on the information from the controlled human exposure studies was consistent with the CASAC's advice and interpretation of the scientific evidence (80 FR 65362, October 26, 2015; Frey, 2014b). In this regard, the Administrator 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 considered both ATS recommendations and CASAC advice to inform her judgments on the potential adversity to public health associated with O_3 effects reported in controlled human exposure studies (80 FR 65363, October 26, 2015).[37]

In considering the degree of protection provided by a revised primary O_3 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 considered the exposure estimates from the HREA, focusing particularly on the estimates of two or more exposures of concern. In so doing,

[35] 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).

[36] The Administrator viewed the results of 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).

[37] In so doing, the Administrator recognized that a standard level of 70 ppb would be 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 to result in the adverse combination of lung function decrements and respiratory symptoms (80 FR 65363, October 26, 2015).

she placed the most emphasis on setting a standard that appropriately limits repeated occurrences of exposures at or above the 70 and 80 ppb benchmarks, while at elevated ventilation. She 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.[38] Given the considerable protection provided against repeated exposures of concern for all benchmarks evaluated in the HREA, the Administrator judged that a standard with a level of 70 ppb incorporated a margin of safety against the adverse O_3-induced effects shown to occur in the controlled human exposure studies (80 FR 65364, October 26, 2015).[39]

While she was less confident that adverse effects would occur following exposures to O_3 concentrations as low as 60 ppb,[40] as discussed above, the Administrator also considered estimates of exposures (while at moderate or greater exertion) for the 60 ppb benchmark (80 FR 65363–64, October 26, 2015). In so doing, she recognized that while CASAC advice regarding the potential adversity of effects observed in studies of 60 ppb was less definitive than for effects observed at the next higher concentration studied, the CASAC did clearly advise the EPA to consider the extent to which a revised standard is estimated to limit the effects observed in studies of 60 ppb exposures (80 FR 65364, October 26, 2015; Frey, 2014b). The Administrator's consideration of exposures at or above the 60 ppb benchmark, and particularly consideration of multiple occurrences of such exposures, 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 65464, 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). Compared to the estimates for the then-current standard (with its level of 75 ppb), this represented a reduction in repeated exposures of more than 60%. Given the considerable protection provided against repeated exposures of concern for all of the benchmarks evaluated, 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 following exposures (while at moderate or greater exertion) to a somewhat higher concentration. The Administrator also judged the HREA results for one or more exposures at or above 60 ppb to provide further 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]

In the context of considering a standard with a level of 70 ppb, the Administrator additionally considered the lung function risk estimates, epidemiologic evidence and quantitative estimates based on information from the epidemiologic studies. Although she placed less weight on these estimates and information in light of associated uncertainties,[42] she 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-current standard (80 FR 65364, October 26, 2015).

In summary, given her consideration of the evidence, exposure and risk information, advice from the CASAC, and public comments, the Administrator in 2015 judged a revised primary standard of 70 ppb, in terms of the 3-year average of annual fourth-highest daily maximum 8-hour average O_3 concentrations, to be requisite to protect public health, including the health of at-risk populations, with an adequate margin of safety (80 FR 65365, October 26, 2015).

2. Approach for the Current Review

To evaluate whether it is appropriate to consider retaining the current primary O_3 standard, or whether consideration of revision is appropriate, the EPA has adopted an approach in this review that builds upon the general approach used in the last review and reflects the body of evidence and information now available. Accordingly, the approach in this review takes into consideration the approach used in the last review, addressing key policy-relevant questions in light of currently available scientific and technical information. As summarized above, the Administrator's decisions in the prior review were based on an integration of O_3 health effects information with judgments on the adversity and public health significance of key health effects, policy judgments as to when the standard is requisite to protect public health with an adequate margin of safety, consideration of CASAC advice, and consideration of public comments.

Similarly, in this review, we draw on the current evidence and quantitative assessments of exposure pertaining to

[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] 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 is inclusive of 70 ppb) to be a policy judgment (80 FR 65355, October 26, 2015; Frey, 2014).

[40] 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 recommendation 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).

[41] While the Administrator was less concerned about single occurrences of O_3 exposures of concern, especially for the 60 ppb benchmark, she judged that estimates of one or more exposures of concern can provide further insight into the margin of safety provided by a revised standard. 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).

[42] The Administrator noted important uncertainties in using lung function risk estimates as a basis for considering the occurrence of adverse effects in the population (also recognized in the prior review) that limited her reliance on these estimates in reaching judgments on health protection of a standard level of 70 ppb versus lower levels. Additionally, with regard to epidemiologic studies, while the Administrator recognized there to be support for a standard level at least as low as 70 ppb from a single-epidemiologic study (Mar and Koenig, 2009) that reported health effect associations in a location that met the then-current standard over the entire study period but that would have violated a revised standard with a level of 70 ppb, she found these studies to be of more limited utility for distinguishing between the appropriateness of health protection estimated for a standard level of 70 ppb and that estimated for lower levels (80 FR 65364, October 26, 2015).

the public health risk of O_3 in ambient air. In considering the scientific and technical information here, we consider both the information available at the time of the last review and information newly available since the last review, including that which has been critically analyzed and characterized in the current ISA. The quantitative exposure and risk analyses provide a context for interpreting the evidence of respiratory effects in people breathing at elevated rates and the potential public health significance of exposures associated with air quality conditions that just meet the current standard. The overarching purpose of these analyses is to inform the Administrator's conclusions on the public health protection afforded by the current primary standard, with an important focus on the potential for exposures and risks beyond those indicated by the information available at the time the standard was established.

B. Health Effects Information

The information summarized here is based on our scientific assessment of the health effects evidence available in this review; this 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. Further, ''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 current health effects evidence and the Agency's review of the evidence, including the evidence newly available in this review, continues to focus on O_3.

More than 1600 studies are newly available and considered in the ISA, including more than 1000 health studies (ISA, Appendix 10, Figure 10–2). 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. Policy implications of the currently available evidence are discussed in the PA (as summarized in section II.D.1 below). The subsections below briefly summarize the following aspects of the evidence: The nature of O_3-related health effects (section II.B.1), the potential public health implications and populations at risk (section II.B.2), and exposure concentrations associated with health effects (section II.B.3).

1. 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 suggests the potential for relationships between O_3 exposure and other effects. As was established in prior reviews, the most commonly observed effects, and those 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 (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 lung function effects are also positively associated with ambient air O_3 concentrations in epidemiologic panel studies, available in past reviews, that describe these associations for outdoor workers and children attending summer camps in the 1980s and 1990s (2013 ISA, section 6.2.1.2; ISA, Appendix 3, section 3.1.4.1.3). The epidemiologic evidence base additionally documents associations of O_3 concentrations in ambient air 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 respiratory effects of short-term exposures (ISA, Appendix 3, section 3.1.11), and studies in animal models also provide evidence for effects of longer-term O_3 exposure on the developing lung (ISA, Appendix 3, section 3.2.6).

The current evidence continues to support our prior conclusion that short-term O_3 exposure causes respiratory effects. Specifically, the full body of evidence continues to support the conclusion of a causal relationship of respiratory effects with short-term O_3 exposures and the conclusion that the relationship of respiratory effects with longer-term exposures is likely to be causal (ISA, sections IS.4.3.1 and IS.4.3.2). The current evidence base for short-term O_3 exposure and metabolic effects,[44] which was not evaluated as a separate category of effects in the last review when less evidence was available, is expanded by evidence newly available in this review. The ISA determines the current evidence sufficient to conclude that the relationship between short-term O_3 exposure and metabolic effects is likely to be causal (ISA, section IS.4.3.3). The newly available evidence is primarily from experimental animal research. For other types of health effects, new evidence has led to different conclusions from those reached in the prior review. Specifically, the current evidence, particularly in light of the additional controlled human exposure studies, is less consistent than what was previously available and less indicative of O_3-induced cardiovascular effects. This evidence 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 is no longer concluded to indicate that the relationships are likely to be causal.[45] Thus, while conclusions have changed for some effects based on the new evidence, the conclusions reached in the last review on respiratory effects are supported by the current evidence, and conclusions are also newly reached for an additional category of health effects.

a. Respiratory Effects

As in the last review, the currently available evidence in this review supports the conclusion of a causal relationship between short-term O_3 exposure and respiratory effects (ISA, section IS.1.3.1). The strongest evidence for this comes from controlled human

[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 18–13 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 high blood pressure, elevated triglycerides and low high density lipoprotein cholesterol), diabetes, metabolic disease mortality, and indicators of metabolic syndrome that include alterations in glucose and insulin homeostasis, 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).

exposure studies, also available in the last review, demonstrating O_3-related respiratory effects in generally healthy adults.[46] Experimental studies in animals also document an array of respiratory effects resulting from short-term O_3 exposure and provide information related to underlying mechanisms (ISA, Appendix 3, section 3.1). 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, 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 reduced lung function,[47] respiratory symptoms, 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 in section II.B.3 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).[48]

The evidence is most well established with regard to the effects, reversible with the cessation of exposure, that are associated with short-term exposures of several hours. For example, the evidence indicates a rapid recovery from O_3-induced lung function decrements (*e.g.,* reduced FEV_1) and respiratory symptoms (2013 ISA, section 6.2.1.1). However, in some cases, such as after exposure to higher concentrations such as 300 ppb, the recovery phase may be slower and involve a longer time period (*e.g.,* at least 24 hours). Repeated daily exposure studies at such higher concentrations also have found FEV_1 response 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, 2013 ISA indicates that 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). 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 (ISA, Appendix 3, section 3.1.4.3.1).

The extensive evidence base for O_3 health effects, compiled over several decades, continues to indicate respiratory responses to short exposures as the most sensitive effects of O_3. Such

[46] The phrases ''healthy adults'' or ''healthy subjects'' are used to distinguish from subjects with asthma or other respiratory diseases, for which there are many fewer controlled human exposure studies. For studies of healthy subjects ''the study design generally precludes inclusion of subjects with serious health conditions,'' such as individuals with severe respiratory diseases (2013 ISA, p. lx).

[47] In summarizing FEV_1 responses from controlled human exposure studies, 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) and what is generally an improvement observed with filtered air (FA) exposure (post-exposure FEV_1 minus pre-exposure FEV_1). As explained in the 2013 ISA, ''[n]oting that some healthy individuals experience small improvements while others have small decrements in FEV_1 following FA exposure, investigators have used the randomized, crossover design with each subject serving as their own control (exposure to FA) to discern relatively small effects with certainty since alternative explanations for these effects are controlled for by the nature of the experimental design'' (2013 ISA, pp. 6–4 to 6–5).

[48] 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).

effects are well documented in controlled human exposure studies, most of which involve healthy adult study subjects. 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. Such effects 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, due to the latter characteristic, 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, p. IS–22; 2013 ISA, section 6.2.9; 2006 AQCD, section 8.4.2). Further, 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 (as recognized below in sections II.B.2 and II.C). The increased significance of effects in people with asthma and risk of increased exposure for children is illustrated by the epidemiologic findings of positive associations between O_3 exposure and asthma-related ED 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 for O_3 exposures to increase susceptibility to infectious diseases 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, the conclusion based on the current evidence base remains that the relationship for such exposure conditions with respiratory effects is likely to be causal (ISA, section IS.4.3.2). Most notably, 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, 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 evidence on biological mechanisms (ISA, Appendix 3, sections 3.2.3 and 3.2.4.1.2). Specifically, the animal evidence, including the nonhuman primate studies of early life O_3 exposure, indicates that such exposures can cause ''structural and functional changes that could potentially contribute to airway obstruction and increased airway responsiveness,'' which are hallmarks of asthma (ISA, Appendix 3, section 3.2.6, p. 3–113).

Overall, the respiratory effects evidence newly available in this review is generally consistent with the evidence base in the last review (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). Thus, our current understanding of the respiratory effects of O_3 is similar to that in the last review.

One aspect of the evidence that has been augmented concerns pulmonary function in adults older than 50 years of age. Previously available evidence in this age group indicated smaller O_3-related decrements in middle-aged adults (35 to 60 years) than in adults 35 years of age and younger (2006 AQCD, p. 6–23; 2013 ISA, p. 6–22; ISA, Appendix 3, section 3.1.4.1.1.2). A recent multicenter study of 55- to 70-year old subjects (average age of 60 years), conducted for a 3-hour duration involving alternating 15-minute rest and exercise periods and a 120 ppb exposure concentration, reported a statistically significant O_3 FEV_1 response (ISA, Appendix 3, section 3.1.4.1.1.2; Arjomandi et al., 2018). While there is not a study in younger adults of precisely comparable design, the mean response for the 55- to 70-year olds, 1.2% O_3-related FEV_1 decrement, is lower than results for somewhat comparable exposures in adults aged 18 to 35 years, suggesting somewhat reduced responses to O_3 exposure in this older age group (ISA, Appendix 3, section 3.1.4.1.1.2; Arjomandi et al., 2018; Adams, 2000; Adams, 2006b).[49] Such a reduced response in middle-aged and older adults compared to young adults is consistent with conclusions in previous reviews (2013 ISA, section 6.2.1.1; 2006 AQCD, section 6.4).

The strongest evidence of O_3-related health effects, as was the case in the last review, continues to be that for respiratory effects of O_3 (ISA, section ES.4.1). Among the newly available studies, there are several controlled human exposure studies that investigated lung function effects of higher exposure concentrations (*e.g.,* 100 to 300 ppb) in healthy individuals younger than 35 years old, with findings generally consistent with previous studies (ISA, Appendix 3, section 3.1.4.1.1.2, p. 3–17). No studies are newly available in this review of 6.6-hour controlled human exposures (with exercise) to O_3 concentrations below those previously studied.[50] The newly available animal toxicological studies augment the previously available information concerning mechanisms underlying the effects documented in experimental studies. 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 studies in the current epidemiologic evidence base continue to indicate the potential for O_3 exposures to contribute to such serious health outcomes, particularly for people with asthma.

[49] For the same exposure concentration of 120 ppb, Adams (2006b) observed an average 3.2%, statistically significant, O_3-related FEV_1 decrement in young adults (average age 23 years) at the end of the third hour of an 8-hour protocol that alternated 30 minutes of exercise and rest, with the equivalent ventilation rate (EVR) averaging 20 L/min-m² during the exercise periods (versus 15 to 17 L/min-m² in.Arjomandi et al.[2018]). For the same concentration with a lower EVR during exercise (17 L/min-m²), although with more exercise, Adams (2000) observed a 4%, statistically significant, O_3-related FEV_1 decrement in young adults (average age 22 years) after the third hour of a 6.6-hour protocol (alternating 50 minutes exercise and 10 minutes rest).

[50] The recent 3-hour study of 55- to 70-year old subjects included a target exposure of 70 ppb, as well as 120 ppb, with only the latter eliciting a statistically significant FEV_1 decrement in this age group of subjects (ISA, Appendix 3, section 3.1.4.1.1.2).

b. Other Effects

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. For some of these other categories of effects, the evidence now available has contributed to changes in conclusions reached in the last review. 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. Additionally, newly available evidence has also led to conclusions for another category, metabolic effects, for which formal causal determinations were previously not articulated.

The ISA finds the evidence for metabolic effects sufficient to conclude that the relationship with short-term O_3 exposures is likely to be causal (ISA, section IS.4.3.3). The evidence of metabolic effects of O_3 comes primarily from experimental animal study findings that short-term O_3 exposure can impair glucose tolerance, increase triglyceride levels and elicit fasting hyperglycemia, and increase hepatic gluconeogenesis (ISA, Appendix 5, section 5.1.8 and Table 5–3). The exposure conditions from these studies generally involve much higher O_3 concentrations than those commonly occurring in areas of the U.S. where the current standard is met. For example, the animal studies include 4-hour concentrations of 400 to 800 ppb (ISA, Appendix 5, Tables 5–8 and 5–10). The concentration in the available controlled human exposure study is similarly high, at 300 ppb; this study reported increases in two biochemicals suggestive of some liver biomarkers and no change in a number of other biochemicals associated with metabolic effects (ISA, sections 5.1.3, 5.1.5 and 5.1.8, Table 5–3). A limited number of epidemiologic studies is also available (ISA, section IS.4.3.3; Appendix 5, sections 5.1.3 and 5.1.8).

The ISA additionally concludes that the evidence is suggestive of, but not sufficient to infer, a causal relationship between long-term O_3 exposures and metabolic effects (ISA, section IS.4.3.6.2). As with metabolic effects and short-term O_3, the primary evidence is from experimental animal studies in which the exposure concentrations are appreciably higher than those commonly occurring in the U.S. For example, the animal studies include exposures over several weeks to concentrations of 250 ppb and higher (ISA, Appendix 5, section 5.2.3.1.1). The somewhat limited epidemiologic evidence related to long-term O_3 concentrations and metabolic effects includes studies reporting increased odds of being overweight or obese or having metabolic syndrome and increased hazard ratios for diabetes incidence with increased O_3 concentrations (ISA, Appendix 5, sections 5.2.3.4.1, 5.2.5 and 5.2.9, Tables 5–12 and 5–15).

With regard to cardiovascular effects and total (nonaccidental) mortality and short-term O_3 exposures, the conclusions regarding the potential for a causal relationship have changed from what they were in the last review after integrating the previously available evidence with newly available evidence. 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). This reflects several aspects of the current evidence base: (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) that still remain. Although there exists consistent or generally 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). Related to the updated evidence for cardiovascular effects, the evidence for short-term O_3 concentrations and mortality is also updated (ISA, section 4.3.5 and Appendix 6, section 6.1.8). While epidemiologic studies show positive associations between short-term O_3 concentrations and total (nonaccidental) and cardiovascular mortality (and there are some studies reporting associations that remain after controlling for PM_{10} and NO_2), the full evidence base does not describe a continuum of effects that could lead to cardiovascular mortality.[51] The category of total mortality includes all contributions to mortality, including both respiratory and cardiovascular mortality, as well as other causes of death, such as cancer or other chronic diseases. The evidence base supporting a continuum of effects of short-term O_3 concentrations that could potentially lead to respiratory mortality is more consistent and coherent as compared to that for cardiovascular mortality (ISA, sections 3.1.11 and 4.1.17; 2013 ISA, section 6.2.8). However, because cardiovascular mortality is the largest contributor to total mortality, the relatively limited biological plausibility and coherence within and across disciplines for cardiovascular effects (including mortality) is the dominant factor which contributes to a revised causality determination for total mortality (ISA, section IS.4.3.5). The ISA concludes that the currently available evidence for cardiovascular effects and total mortality is suggestive of, but not sufficient to infer, a causal relationship with short-term (as well as long-term) O_3 exposures (ISA, sections IS.4.3.4 and IS.4.3.5).

For other health effect categories, conclusions in this review are largely unchanged from those in the last review. 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, as was the case in the last review (ISA, section IS.4.3.6.5 and Table IS–1). Additionally, the evidence is inadequate to determine if a causal relationship exists between O_3 exposure and cancer (ISA, section IS.4.3.6.6 and Table IS–1).

2. Public Health Implications and At-Risk Populations

The public health implications of the evidence regarding O_3-related health

[51] Due to findings from controlled human exposure studies examining clinical endpoints (*e.g.,* blood pressure) that do not indicate an O_3 effect and from epidemiologic studies examining cardiovascular-related hospital admissions and ED visits that do not find positive associations, a continuum of effects that could lead to cardiovascular mortality is not apparent (ISA, Appendices 4 and 6).

effects, as for other effects, are dependent on the type and severity of the effects, as well as the size of the population affected. Such factors are discussed here in the context of our consideration of the health effects evidence related to O_3 in ambient air. Additionally, we summarize the currently available information related to judgments or interpretative statements developed by public health experts, particularly experts in respiratory health. This section also summarizes the current information on population groups at increased risk of the effects of O_3 in ambient air.

With regard to O_3 in ambient air, the potential public health impacts relate most importantly to the role of O_3 in eliciting respiratory effects, the category of effects that the ISA concludes to be causally related to O_3 exposure (short-term). 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.B.1 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 changes in pulmonary function, the severity of respiratory symptoms, and the duration of the response. With regard to pulmonary function, the greater impact of larger decrements on affected individuals can be described. For example, 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 for most healthy individuals, 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 for more of such individuals (*e.g.,* 2014 PA, p. 3–53; 2006 AQCD, Table 8–2).

In addition to the difference in severity or magnitude of specific effects in healthy people, the same reduction in FEV_1 or increase in inflammation or airway responsiveness in a healthy group and a group with asthma may increase the risk of a more severe effect in the group with asthma. For 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.,* 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. In summary, consideration of differences in magnitude or severity, and also the relative transience or persistence of such 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 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 ATS described the statement as not offering ''strict rules or numerical criteria,'' but rather proposing ''principles to be used in weighing the evidence and setting boundaries,'' and stated that ''the placement of dividing lines should be a societal judgment'' (ATS, 2000). Similarly, the most recent policy statement by the ATS, which once again broadens its discussion of effects, responses and biomarkers to reflect the expansion of scientific research in these areas, reiterates that concept, conveying that it does not offer ''strict rules or numerical criteria, but rather proposes considerations to be weighed in setting boundaries between adverse and nonadverse health effects,'' providing a general framework for interpreting evidence that proposes a ''set of considerations that can be applied in forming judgments'' for this context (Thurston et al., 2017).

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 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). More specifically, the recent ATS statement expresses the view that the occurrence of ''small lung function changes'' in individuals with pre-existing compromised function, such as asthma, ''should be considered adverse . . . even without accompanying respiratory symptoms'' (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 has not altered our understanding of human populations at particular risk of health effects from O_3 exposures (ISA, section IS.4.4). For example, as recognized in prior reviews, people with asthma are the key population at risk of O_3-related effects. The respiratory effects evidence, extending decades into the past and augmented by new studies in this review, supports this conclusion (ISA, sections IS.4.3.1). For example, numerous epidemiological studies document associations with 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).[52]

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 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). 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). [53] We additionally recognize that in these studies, the strongest associations (*e.g.,* highest effect estimates) or associations more likely to be statistically significant are those for childhood age groups, which are recognized in section II.C.1 as 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).[54] 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 ozone-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 (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 the summer 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 due to greater air volumes taken into the lungs (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 (ISA, section IS.4.4.4.1). Overall, the evidence available in the current review, while not increasing our knowledge about susceptibility of these population groups, is consistent with that in the last review.

Older adults have also been identified as being at increased risk. That identification, based on the assessment in the 2013 ISA, was based largely on studies of short-term O_3 exposure and mortality, which are part of the larger evidence base that is now concluded to be suggestive, but not sufficient to infer a causal relationship (ISA, sections IS.4.3.5 and IS.4.4.4.2, Appendix 4, section 4.1.16.1 and 4.1.17).[55] Other evidence available in the current review adds little to the evidence available at the time of the last review for older adults (ISA, sections IS.4.4.2 and IS.4.4.4.2).

The ISA in the last review concluded that the information available at the time for low socioeconomic status (SES) as a factor associated with the risk of O_3-related health effects, provided suggestive evidence of potentially increased risk (2013 ISA, section 8.3.3 and p. 8–37). The 2013 ISA concluded that ''[o]verall, evidence is suggestive of 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). 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 key 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). This is one of the principal populations that the primary O_3 NAAQS is designed to protect (80 FR 65294, October 26, 2015).

The age group for which the prevalence documented by these data is greatest is children aged five to 19 years old, with 9.7% of children aged five to

[52] 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.

[53] In addition to asthma exacerbation, the epidemiologic evidence also includes findings of positive associations of increased O_3 concentrations with hospital admissions or emergency department visits for COPD exacerbation and other respiratory diseases (ISA, Appendix 3, sections 3.1.6.1.3 and 3.1.8).

[54] There is limited data on activity patterns by health status. An analysis in the 2014 HREA indicated that asthma status had little to no impact on the percent of people participating in outdoor activities during afternoon hours, the amount of time spent, and whether they performed activities at elevated exertion levels (2014 HREA, section 5.4.1.5). Based on an updated evaluation of recent activity pattern data we found children, for days having some time spent outdoors 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 (see 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.

[55] As noted in the ISA, ''[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).

14 and 9.4% of children aged 15 to 19 years old having asthma (CDC, 2019, Tables 3–1 and 4–1; PA, Table 3–1). In 2012 (the most recent year for which such an evaluation is available), asthma was the leading chronic illness affecting children (Bloom et al., 2013). The prevalence is greater for boys than girls (for those less than 18 years of age). Among populations of different races or ethnicities, black non-Hispanic children aged five to 14 have the highest prevalence, at 16.1%. Asthma prevalence is also increased among populations in poverty. For example, 11.7% of people living in households below the poverty level have asthma compared to 7.3%, on average, of those living above it (CDC, 2019, Tables 3–1 and 4–1; PA, Table 3–1). Population groups with relatively greater asthma prevalence might be expected to have a relatively greater potential for O_3-related health impacts.[56]

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). Based on a prior analysis of data from the Consolidated Human Activity Database (CHAD) [57] in the 2014 HREA, children ages 4–18 years old, for days having some time spent outdoors, were found to more frequently spend time outdoors compared to other age groups (*e.g.,* adults aged 19–34) spending more than 2 hours outdoors, particularly during the afternoon and early evening (*e.g.,* 12:00 p.m. through 8:00 p.m.) (2014 HREA, section 5G–1.2). These results were confirmed by additional analyses of CHAD data reported in the ISA, noting greater participation in afternoon outdoor events for children ages 6–19 years old during the warm season months compared to other times of the day (ISA, Appendix 2, section 2.4.1, Table 2–1). The 2014 HREA also found that children ages 4–18 years old spent 79% of their outdoor time at moderate or greater exertion (2014 HREA, section 5G–1.4). Further analyses performed for this review using the most recent version of CHAD generated similar results (PA, Appendix 3D, section 3D.2.5.3 and Figure 3D–9). Each of these analyses indicate children participate more frequently and spend more afternoon time outdoors than all other age groups while at elevated exertion, and consistently do so when considering the most important influential factors such as day-of-week and outdoor temperature. Given that afternoon time outdoors and elevated exertion were determined most important in understanding the fraction of the population that might experience O_3 exposures of concern (*e.g.,* 2014 HREA, section 5.4.2), they may be at greater risk of effects due to increased exposure to O_3 in ambient air.

About one third of workers were required to perform outdoor work in 2018 (Bureau of Labor Statistics, 2019). Jobs in construction and extraction occupations and protective service occupations required more than 90% of workers to spend at least part of their workday outdoors (Bureau of Labor Statistics, 2017). Other employment sectors, including installation, maintenance and repair occupations and building and grounds cleaning and maintenance operations, also had a high percentage of employees who spent part of their workday outdoors (Bureau of Labor Statistics, 2017). These occupations often include physically demanding tasks and involve increased ventilation rates which when combined with exposure to O_3, may increase the risk of health effects.

3. Exposure Concentrations Associated With Effects

As at the time of the last review, the EPA's conclusions regarding exposure concentrations of O_3 associated with respiratory effects reflect the extensive longstanding evidence base of controlled human exposure studies of short-term O_3 exposures of people with and without asthma (ISA, Appendix 3). 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. 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). Factors influencing exposure include activity level or ventilation rate, exposure concentration, and exposure duration (ISA; 2013 ISA; 2006 AQCD). For example, evidence from studies with similar duration and exercise aspects (6.6-hour duration with six 50-minute exercise periods) demonstrates an exposure-response relationship for O_3-induced reduction in lung function (ISA, Appendix 3, Figure 3–3; PA, Figure 3–2).[58] [59]

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).[60]

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 of O_3. As summarized in section II.B.1 above, an array of respiratory effects is well documented in controlled human exposure studies of subjects exposed for 1 to 8 hours, primarily while exercising. 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.

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

[56] As summarized in section II.A.1 above, the current standard was set to protect at-risk populations, which include people with asthma. Accordingly, populations with asthma living in areas not meeting the standard would be expected to be at increased risk of effects than others in those areas.

[57] The CHAD provides time series data on human activities through a database system of collected human diaries, or daily time location activity logs.

[58] For a subset of the studies included in PA, Figure 3–2 (those with face mask rather than chamber exposures), there is no O_3 exposure during some of the 6.6-hour experiment (*e.g.,* during the lunch break). Thus, while the exposure concentration during the exercise periods is the same for the two types of studies, the time-weighted average (TWA) concentration across the full 6.6-hour period differs slightly. For example, in the facemask studies of 120 ppb, the TWA across the full 6.6-hour experiment is 109 ppb (PA, Appendix 3A, Table 3A–2).

[59] 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.

[60] No 6.6-hour studies are newly available in this review (ISA, Appendix 3, section 3.1.4.1.1). Rather, the newly available controlled human exposure studies are generally for exposures of three hours or less, and in nearly all instances involve exposure (while at elevated exertion) to concentrations above 100 ppb (ISA, Appendix 3, section 3.1.4).

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. 6–5 to 6–6). 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).

The exposure conditions (*e.g.,* duration and exercise) given primary focus in the past several 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. The 6.6 hours of exposure in these 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.[61] 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.[62] 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 70 ppb and 80 ppb (Table 1; PA, 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 (Schelegle et al., 2009).[63]

In the 6.6-hour studies, the group means of O_3-induced[64] FEV_1 reductions for exposure concentrations below 80 ppb are at or below 6% (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, 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 60 ppb target exposure, 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). This response increased to three of 31 subjects for the study with a 70 ppb target concentration (PA, Appendix 3D, Table 3D–19; 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).

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, 2006a.
			−7.8%	Schelegle et al., 2009.
		ND [E]	−3.5%	Kim et al., 2011.[F]
	70 ppb	Yes	−6.1%	Schelegle et al., 2009.

[61] 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).

[62] 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, 2006a), 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.

[63] Measurements are reported in this study for each of the six 50-minute exercise periods, for which the mean is 72 ppb (Schelegle et al., 2009). Based on these data, the time-weighted average concentration across the full 6.6-hour duration was 73 ppb (Schelegle et al., 2009). The study design includes a 35-minute lunch period following the third exposure hour during which the exposure concentration remains the same as in the third hour.

[64] 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).

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

Endpoint	O_3 target exposure concentration [A]	Statistically significant effect [B]	O_3-induced group mean response [B]	Study
	60 ppb	Yes [G]	−2.9%	Adams, 2006a; 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, 2006a.
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, 2006a.[H]
	100 ppb	Yes.		
	87 ppb	Yes.		
	80 ppb	Yes.		
	70 ppb	Yes.		
	60 ppb	No		Adams, 2006a; 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 at 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 (2006a) 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, ranging from one to two hours, 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; PA, Appendix 3A, Table 3A–3). In these studies, some exposure protocols have included heavy intermittent or very heavy continuous exercise, which results in 2–3 times greater ventilation rate than in the prolonged (6.6- or 8-hour) exposure studies, which only incorporate moderate quasi-continuous exercise.[65] Across these shorter-duration 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 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 duration at this concentration (120 ppb), as is illustrated by the 6.6-hour study results for this concentration (ISA, Appendix 3, Figure 33; 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, as summarized in section II.B.1 above,[66] 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 conditions that meet the current standard. 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. Further, the vast majority of these studies were conducted in locations and during time periods that would not have met the current standard.[67] While this does not

[65] A quasi-continuous exercise protocol is common to the prolonged 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).

[66] 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).

[67] Consistent with the evaluation of the epidemiologic evidence of associations between O_3

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.

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 (among this large group of studies) two single city studies conducted in western 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, Tables 3–14 and 3–39). Thus, the studies pose significant limitations with regard to informing conclusions regarding specific O_3 exposure concentrations and elicitation of such effects. There is also a handful of multicity studies conducted in the U.S. or Canada in which the O_3 concentrations in a subset of the study locations and for a portion of the study period appear to have met the current standard (PA, Appendix 3B). Concentrations in other portions of the study area or study period, however, do not meet the standard, or data were not available in some cities for the earlier years of the study period when design values for other cities in the study were well above 70 ppb. 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. Additionally, with regard to multicity studies, the reported associations were based on the combined dataset from all cities, complicating interpretations regarding the contribution of concentrations in the small subset of locations that would have met the current standard compared to that from the larger number of locations that would have violated the standard (Appendix 3B).[68] Further, given that populations in the single city or multicity studies may have also experienced longer-term, variable and uncharacterized exposure to O_3 (as well as to other ambient air pollutants), ''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'' (ISA, p. IS–87 [section IS.6.1]). While given the depth and breadth of the evidence base for O_3 respiratory effects, such uncertainties do not change our conclusions regarding the causal relationship between O_3 and respiratory effects, they affect the extent to which the two studies mentioned here (conducted in conditions that may have met the current standard) can inform our conclusions regarding the potential for O_3 concentrations allowed by the current standard to contribute to health effects.

With regard to the experimental animal evidence and exposure conditions associated with respiratory effects, concentrations are generally much greater than those examined in the controlled human exposure studies, summarized in section II.B.1 above, and higher than concentrations commonly occurring in ambient air in areas of the U.S. where the current standard is met. In addition to being true for the various rodent studies, 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. 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).

With regard to short-term O_3 and metabolic effects, the category of effects for which the ISA concludes there likely to be a causal relationship with O_3, the evidence base is comprised primarily of experimental animal studies, as summarized in section II.B.1 above (ISA, Appendix 5, section 5.1). The exposure conditions from these animal studies generally involve much higher O_3 concentrations 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). For example, the animal studies include 4-hour concentrations of 400 to 800 ppb (ISA, Appendix 5, Table 5–87).[69] The two epidemiologic studies reporting statistically significant positive associations of O_3 with metabolic effects (*e.g.,* changes in glucose, insulin, metabolic clearance) are based in Taiwan and South Korea, respectively.[70] Given the potential for appreciable differences in air quality patterns between Taiwan and South Korea and the U.S., as well as differences in other factors that might affect exposure (*e.g.,* activity patterns), those studies are of limited usefulness for informing our understanding of exposure concentrations and conditions eliciting such effects in the U.S. (ISA, Appendix 5, section 5.1).

C. Summary of Exposure and Risk Information

Our 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. Estimates from such analyses, particularly the comparison of daily maximum exposures to benchmark concentrations reflecting exposures at which respiratory effects have been observed in controlled human exposure studies, were most informative to the Administrator's decision in the last review (as summarized in section II.A.1 above). This largely reflected the conclusion that ''controlled human exposure studies provide the most certain evidence indicating the occurrence of health effects in humans following specific O_3 exposures,'' and recognition that ''effects reported in controlled human exposure studies are due solely to O_3 exposures, and interpretation of

exposure and respiratory health effects in the ISA, this summary focuses on those studies conducted in the U.S. and Canada to provide a focus on study populations and air quality characteristics that may be most relevant to circumstances in the U.S. (ISA, Appendix 3, section 3.1.2).

[68] As recognized in the last review, ''multicity studies do not provide a basis for considering the extent to which reported O_3 health effects associations are influenced by individual locations with ambient [air] O_3 concentrations low enough to meet the current O_3 standard versus locations with O_3 concentrations that violate this standard'' (80 FR 64344, October 26, 2015).

[69] Resting rats and resting human subjects exposed to the same concentration receive similar O_3 doses (ISA, section 3.1.4.1.2; Hatch et al., 2013). Further, the exposure concentration in the single controlled human exposure study of metabolic effects (*e.g.,* 300 ppb for two hours of intermittent moderate to heavy exercise [Miller et al., 2016]) is also well above exposures examined in the 6.6- to 8-hour respiratory effect studies (ISA, Appendix 5, Table 5–7).

[70] Of the epidemiologic studies discussed in the ISA that investigate associations between short-term O_3 exposure and metabolic effects, two are conducted in the U.S. and they report either a null or negative association of metabolic markers with O_3 concentration (ISA, Appendix 5, Tables 5–6 and 5–9).

study results is not complicated by the presence of co-occurring pollutants or pollutant mixtures (as is the case in epidemiologic studies)'' (80 FR 65343, October 26, 2015).[71] The focus in this review on exposure-based analyses reflects both the emphasis given to these types of analyses and the characterization of their uncertainties in the last review, and also the availability of new or updated information, models, and tools that address those uncertainties (IRP, Appendix 5A).

The longstanding evidence continues to demonstrate a causal relationship between short-term O_3 exposures and respiratory effects, with the current evidence base for respiratory effects is largely consistent with that for the last review, as summarized in section II.B above. Accordingly, the exposure-based analyses performed in this review, summarized below, are conceptually similar to those in the last review. Section II.C.1 summarizes key aspects of the assessment design, including the study areas, populations simulated, the conceptual approach, modeling tools, benchmark concentrations and exposure and risk metrics derived. Key limitations and uncertainties associated with the assessment are identified in section II.C.2 and the exposure and risk estimates are summarized in section II.C.3. An overarching focus of these analyses is whether the current exposure and risk information alters overall conclusions reached in the last review regarding health risk estimated to result from exposure to O_3 in ambient air, and particularly for air quality conditions that just meet the current standard.

1. Key Design Aspects

The analyses of O_3 exposures and risk summarized here inform our understanding of the protection provided by the current standard from effects that the health effects evidence indicates to be elicited in some portion of exercising people exposed for several hours to elevated O_3 concentrations. The analyses estimated population exposure and risk for simulated populations in eight urban study areas: Atlanta, Boston, Dallas, Detroit, Philadelphia, Phoenix, Sacramento and St. Louis. In addition to deriving exposure and risk estimates for air quality conditions just meeting the current primary O_3 standard, estimates were also derived for two additional scenarios reflecting conditions just meeting design values just lower and just higher than the level of the current standard (65 and 75 ppb).[72]

The eight study areas represent a variety of circumstances with regard to population exposure to short-term concentrations of O_3 in ambient air. The areas range in total population size from approximately two to eight million and are distributed across seven of the nine climate regions of the U.S.: Northeast, Southeast, Central, East North Central, South, Southwest and West (PA, Appendix 3D, Table 3D–1). The set of eight study areas is streamlined compared to the 15-area set in the last review and 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 (2014 HREA, section 3.5). Accordingly, while seven of the eight study areas were also included in the 2014 HREA, the eighth study area is newly added in the current assessment to insure representation of a large city in the southwest. Additionally, the years simulated reflect more recent emissions and atmospheric conditions subsequent to data used in the 2014 HREA, and therefore represent O_3 concentrations somewhat nearer the current standard than was the case for study areas included in the 2014 HREA (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. Study-area-specific characteristics contribute to variation in the estimated magnitude of exposure and associated risk across the urban study areas (*e.g.,* combined statistical areas that include urban and suburban populations) that reflect an array of air quality, meteorological, and population exposure conditions.

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 an air quality scenario 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 (that reflect the current standard scenario)[73] 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.B.1 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:[74] All children and children with asthma; two are populations of adults: All adults and adults with asthma. Asthma prevalence in each study area is estimated using regional, national, and state level prevalence information, as well as U.S. census tract-level population data and demographic information related to age, sex, and family income to represent expected spatial variability in asthma prevalence within and across the eight study areas. Asthma prevalence estimates for the full populations in the eight study areas

[71] In the last review, the Administrator placed relatively less weight on the air quality epidemiologic-based risk estimates, in recognition of an array of uncertainties, including, for example, those related to exposure measurement error (80 FR 65316, 65346, October 26, 2015; 79 FR 75277–75279, December 17, 2014; 2014 HREA, sections 3.2.3.2 and 9.6). Further, importantly in this review, the causal determinations for short-term O_3 with mortality in the current ISA differ from the 2013 ISA. The current determinations for both short-term and long-term O_3 exposure (as summarized in section II.B.1 above) are that the evidence is ''suggestive'' but not sufficient to infer causal relationships for O_3 with mortality (ISA, Table IS–1).

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

[73] 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.

[74] The child population group focuses on ages 5 to 18 in recognition of data limitations and uncertainties, including those related to accurately simulating activities performed and estimating physiological attributes, as well as challenges in asthma diagnoses for children younger than 5 years old.

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 using an approach that relies on a combination of ambient air monitoring data, atmospheric photochemical modeling, and statistical methods (PA, Appendix 3C). Population exposure and risk modeling is employed to estimate exposures and related lung function risk resulting from the estimated ambient air O_3 concentrations (PA, Appendix 3D). While the lung function risk analysis focuses only on the specific O_3 effect of FEV_1 reduction, the comparison-to-benchmark approach, 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.

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).[75] The final product 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 (just meeting the current standard, and the 65 ppb and 75 ppb scenarios).

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).[76] 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). 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).

The activity patterns of individuals are an important determinant of their exposure (2013 ISA, section 4.4.1). By incorporating individual activity patterns,[77] the model estimates physical exertion associated with each exposure event. This aspect of the exposure modeling is critical in estimating exposure, ventilation rate, O_3 intake (dose), and health risk resulting from ambient air concentrations of O_3.[78] Because of variation in O_3 concentrations among the different microenvironments in which individuals are active, the amount of time spent in each location, as well as the exertion level of the activity performed, will influence an individual's exposure to O_3 from ambient air and potential for adverse health effects. Activity patterns vary both among and within individuals, resulting in corresponding variations in exposure across a population and over time (2013 ISA, section 4.4.1; 2020 ISA, Appendix 2, section 2.4). For each exposure event, the APEX model tracks activity performed, ventilation rate, exposure concentration, and duration for all simulated individuals throughout the assessment period. The time-series of exposure events serves as the basis for calculating exposure and risk metrics of interest.

As in the last review, the quantitative analyses for this review uses the APEX model estimates of population exposures for simulated individuals breathing at elevated rates[79] to characterize health risk based on information from the controlled human exposure studies on the incidence of lung function decrements in study subjects who are exposed over multiple hours while intermittently or quasi-continuously exercising (PA, Appendix 3D, section 3D.2.8). In drawing on this evidence base for this purpose, the assessment has given primary focus to the well-documented controlled human exposure studies for 6.6-hour average exposure concentrations ranging from 40 ppb to 120 ppb (ISA, Appendix 3, Figure 3–3; PA, Figure 3–2 and Appendix 3A, Table 3A–1). Health risk is characterized in two ways, producing two types of risk metrics: One that compares population exposures involving elevated exertion to benchmark concentrations (that are specific to elevated exertion exposures), and the second that estimates population occurrences of ambient air O_3-related lung function decrements. The first risk metric is based on comparison of estimated daily maximum 7-hour average exposure concentrations for individuals breathing at elevated rates to 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% and 20%. Both of these metrics are 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).

[75] A similar approach was used to develop the air quality scenarios for the 2014 HREA.

[76] The APEX model estimates population exposure using a stochastic, event-based microenvironmental approach. This 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).

[77] 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 is comprised of data from several surveys that collected activity pattern data 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).

[78] Indoor sources are generally minor in comparison to O_3 from ambient air (ISA, Appendix 2, section 2.1) and are not accounted for by the exposure modeling in this assessment.

[79] Based on minute-by-minute activity levels, and physiological characteristics of the simulated person, APEX estimates an equivalent ventilation rate, by normalizing the simulated individuals' activity-specific ventilation rate to their body surface area (PA, Appendix 3D, section 3D.2.2.3.3).

The general approach and methodology for the exposure-based assessment used in this review is similar to that used in the last review. However, a number of updates and improvements, related to the air quality, exposure, and risk aspects of the assessment, have been implemented in this review which result in differences from the analyses in the prior review (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 CAMx model, 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 exposure-to-benchmark comparison 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 using 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 (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. At this concentration, there is evidence of a statistically significant decrease in lung function and increase in markers of airway inflammation (ISA, Appendix 3, section 3.1.4.1.1; Brown et al., 2008; Adams, 2006a). Exposure to approximately 70 ppb [80] averaged over 6.6 hours resulted in a larger group mean lung function decrement, as well as an increase in prevalence of respiratory symptoms over what was observed for 60 ppb (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 (Table 1; ISA, Appendix 3, sections 3.1.4.1 through 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.[81] The incidence of such exposures above the benchmark concentrations are summarized for each simulated population, study area, and air quality scenario as discussed in section II.C.3 below.

The lung function risk analysis provides estimates of the extent to which individuals in the populations could experience decrements in lung function. Estimates were derived for risk of experiencing a day with a lung function decrement at or above three different magnitudes, *i.e.,* FEV_1 reductions of at least 10%, 15%, and 20%. Lung function decrement risk was estimated by two different approaches, which utilize the evidence from the 6.6-hour controlled human exposure studies in different ways.[82] One, the population-based E–R function risk approach, uses quantitative descriptions of the E–R relationships for study group incidence of the different magnitudes of lung function decrements based on the individual study subject observations (PA, Appendix 3D, section 3D.2.8.2.1). The second, the individual-based McDonnell-Smith-Stewart model (MSS; McDonnell et al., 2013), uses quantitative descriptions 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). These two approaches involve different uses of the health effects evidence, with each accordingly, differing in their strengths, limitations and uncertainties.

The E–R functions used for estimating the risk of lung function decrements at or above three sizes were developed from the individual study subject measurements of O_3-related FEV_1 decrements from the 6.6-hour controlled human exposure studies targeting mean exposure concentrations from 120 ppb down to 40 ppb (PA, Appendix 3D, Table 3D–19; PA, Appendix 3A, Figure 3A–1). Functions were developed from the study results in terms of percent of study subjects experiencing O_3-related decrements equal to at least 10%, 15% or 20%.[83] The functions indicate the

[80] 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. 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 6.6-hour time weighted average 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, 2006a).

[81] For this assessment, the APEX model averages the ventilation rate ($\dot{V}_E$) and simultaneously occurring exposure concentration for every simulated individual (based on the activities performed) over 7-hour periods using their time-series of exposure events. To reasonably extrapolate the $\dot{V}_E$ of the controlled human study subjects (*i.e.,* adults having a specified body size and related lung capacity), who were engaging in quasi-continuous exercise during the study period, to individuals having varying body sizes (*e.g.,* children with smaller size and related lung capacity), an equivalent ventilation rate (EVR) was calculated by normalizing the $\dot{V}_E$ (L/min) by body surface area (m^2). Then, daily maximum 7-hour exposure concentrations associated with 7-hour average EVR at or above the target of 17.3 ± 1.2 L/min-m^2 (*i.e.,* the value corresponding to average EVR across the 6.6-hour study duration in the controlled human exposure studies) are compared to the benchmark concentrations (PA, Appendix 3D, section 3D.2.8.1).

[82] In so doing, the approaches also estimate responses associated with unstudied exposure circumstances and population groups in different ways.

[83] Across the exposure range from 40 to 120 ppb, the percentage of exercising study subjects with asthma estimated to have at least a 10% O_3 related FEV_1 decrement increases from 0 to 7% (a statistically non-significant response at exposures of 40 ppb) up to approximately 50 to 70% at

fraction of the population experiencing a particular decrement as a function of the exposure concentration experienced while at the target ventilation rate. This type of risk model, which has been used in risk assessments since the 1997 O_3 NAAQS review, was last updated with the recently available study data (PA, Appendix 3D, section 3D.2.8.2.1). In this review, the E–R functions are applied to the APEX estimates of daily maximum 7-hour average exposure concentrations concomitant with the target ventilation level estimated by APEX, with the results presented in terms of number of individuals in the simulated populations (and percent of the population) estimated to experience a day (or more) with a lung function decrement at or above 10%, 15% or 20%.

The MSS model, also used for estimating the risk of lung function decrements, was developed using the extensive database from controlled human exposure studies that has been compiled over the past several decades, and biological concepts based on that evidence (McDonnell et al., 2012; McDonnell et al., 2013). The model mathematically estimates the magnitude of FEV1 decrement as a function of inhaled O_3 dose (based on concentration & ventilation rate) over the time period of interest (PA, Appendix 3D, section 3D.2.8.2.2). The simulation of decrements is dynamic, based on a balance between predicted development of the decrement in response to inhaled dose and predicted recovery (using a decay factor). This model was first applied in combination with the APEX model to generate lung function risk estimates in the last review (80 FR 65314, October 26, 2015) and has been updated since then based on the most recent study by its developers (McDonnell et al., 2013). In this review, the model is applied to the APEX estimates of exposure concentration and ventilation for every exposure event experienced by each simulated individual. The model then utilizes its mathematical predictions of lung function response to inhaled dose and predicted recovery to estimate the magnitude of O_3 response across the sequence of exposure events in each individual's day. Each occurrence of decrements reaching magnitudes of interest (*e.g.,* 10%, 15% and 20%) is tallied. Thus, results are reported using the same metrics as for the E–R function, *i.e.,* number of individuals in the simulated populations (and percent of the population) estimated to experience a day (or more) per simulation period with a lung function decrement at or above 10%, 15% and 20%.

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 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 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 (*e.g.,* airway inflammation). Thus, the comparison-to-benchmark analysis provides for a broader risk characterization with consideration of the array of O_3-related respiratory effects. For this reason, as well as the uncertainties associated with the lung function risk estimates, as summarized below, the summary of estimates in section II.C.3 below focuses primarily on results for the comparison-to-benchmark analysis.

2. Key Limitations and Uncertainties

Uncertainty in the current exposure and risk analyses was characterized using a largely qualitative approach adapted from the World Health Organization (WHO) approach for characterizing uncertainty in exposure assessment (WHO, 2008) augmented by several quantitative sensitivity analyses for key aspects of the assessment approach (described in detail in Appendix 3D of the PA).[84] This characterization and associated analyses builds on information generated from a previously conducted quantitative uncertainty analysis of population-based O_3 exposure modeling (Langstaff, 2007). In so doing, the characterization considers the various types of data, algorithms, and models that together yield exposure and risk estimates for the eight study areas. In this way, the limitations and uncertainties underlying these data, algorithms, and models and the extent of their influence on the resultant exposure/risk estimates are considered. Consistent with the WHO (2008) uncertainty guidance, the overall impact of the uncertainty is scaled by qualitatively assessing the extent or magnitude of the impact of the uncertainty as implied by the relationship between the source of the uncertainty and the exposure and risk output. The characterization in the current assessment also evaluates the direction of influence, indicating how the source of uncertainty was judged to affect the exposure and risk estimates, *e.g.,* likely to over- or under-estimate (PA, Appendix 3D, section 3D.3.4.1).

Several areas of uncertainty are identified as particularly important to considering the exposure and risk estimates. There are also several areas where new or updated information have reduced uncertainties since the last review. Some of these areas pertain to estimates for both types of risk metrics, and some pertain more to one type of estimate *versus* the other. There are also differences in the uncertainties that pertain to each of the two approaches used for the lung function risk metric.

An overarching and important area of uncertainty, which remains from the last review, and is important to our consideration of the exposure and risk analysis results relates to the underlying health effects evidence base. This analysis focuses on the evidence base described as 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 (*e.g.,* lung function decrements, respiratory symptoms, increased airway responsiveness and inflammation). However, we recognize the lack of evidence from controlled human exposure studies at the lower concentrations of greatest interest (*e.g.,* 60, 70 and 80 ppb) for children and for people of any age with asthma. While the limited evidence that informs our understanding of potential risk to people with asthma is uncertain, it indicates some potential for them to have lesser reserve to protect against such effects than other population groups under similar exposure circumstances, as summarized in section II.B above. Thus, the health effects reported in controlled human exposure studies of healthy adults may be contribute to more severe outcomes in people with asthma. 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), as referenced in section II.B. above and presented in detail in the ISA. Further, with regard to lung function decrements, information is lacking on the factors contributing to increased

exposures of 120 ppb (PA, Appendix 3D, Section 3D.2.8.2.1, Table 3D–19).

[84] The approach used has been applied in REAs for past NAAQS reviews for O_3, NO_X, CO and sulfur oxides (U.S. EPA, 2008; U.S. EPA, 2010; U.S. EPA, 2014a; U.S. EPA, 2018).

susceptibility to O_3-induced lung function decrements among some people. Thus, there is uncertainty regarding the interpretation of the exposure and risk estimates and the extent to which they represent the populations at greatest risk of O_3-related respiratory effects.

Aspects of the analytical design that pertain to both exposure-based risk metrics include the estimation of ambient air O_3 concentrations for the assessed air quality scenarios, as well as the main components of the exposure modeling. Key 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 approach used has taken into account the currently available information and selected study areas having design values near the level of the current standard to minimize the size of the adjustment needed to meet a given air quality scenario. The approach also uses more recent data 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 in those areas for the air quality conditions simulated. 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), thus 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), which are ultimately 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 redevelopment of METs distributions, based on information newly available in this review, is expected to more realistically estimate activity-specific energy expenditure.

With regard to the aspects of the two risk metrics, there are some uncertainties that apply to the estimation of lung function risk and not to the comparison-to-benchmarks analysis. 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. This is the case in different ways and with differing impacts for the two approaches. One way in which both approaches extrapolate beyond the exposure studies concerns estimates of lung function risk derived for exposure concentrations below those represented in the evidence base. The approaches provide this in recognition of the potential for lung function decrements to be greater in unstudied at-risk population groups than is evident from the available 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.

There are differences between the two lung function risk approaches in how they extrapolate beyond the controlled human exposure study conditions and in the impact on the estimates (with somewhat smaller differences for multiple day estimates).[85] 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). The difference between the two models in the impact of the differing extents of extrapolation is illustrated by differences in the 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 (PA, Tables 3–6 and 3–7). For example, with the E–R model, 3 to 6% of the risk to children of experiencing at least one day with decrements greater than 20% (for single years in three study areas) is associated with exposure concentrations below 40 ppb (the lowest concentration studied in the controlled human exposure studies, and at which no decrements of this severity occurred in any study subjects). This is in comparison to 25% to nearly 40% of MSS model estimates of decrements greater than 20% deriving from exposures below 40 ppb. The MSS model also used ventilation rates lower than those used for the E–R function risk approach (which are based on the controlled human exposure study conditions), contributing to relatively greater risks estimated by the MSS model.[86]

Many of the uncertainties previously identified as part of the 2014 HREA as unique to the MSS model also remain as important uncertainties in the current assessment. For example, the extrapolation of the MSS model age parameter down to age 5 (from the age range of the 18- to 35-year old study subjects to which the model was fit) is an important uncertainty given that children are an at-risk population in this assessment. There is also uncertainty in estimating the frequency and magnitude of lung function decrements as a result of the statistical form and parameters used for the MSS model inter- and intra-individual variability terms (PA, Appendix 3D, section 3D.3.4). As a whole, the differences between the two lung function risk approaches and the estimates generated by these approaches indicate appreciably greater uncertainty for the MSS model estimates than the E–R function estimates (PA, section 3.4.4

[85] This is largely because the percent contribution to low-concentration risk for two or more decrement days predicted by the E–R approach is, by design, greater than the corresponding contribution to low-concentration risk for one or more days. This also occurs because the MSS model estimates risk from a larger variety of exposure and ventilation conditions (PA, Tables 3–6 and 3–7, Appendix 3D, sections 3D.3.4.2.3 and 3D.3.4.2.4).

[86] Limiting the MSS model results to estimates for individuals with at least the same exertion level achieved by study subjects (≥17.3 L/min-m^2), reduces the risks of experiencing at least one lung function decrement by an amount between 24 to 42%. (PA, Appendix 3D, Table 3D–69).

and Tables 3–6 and 3–7).[87] In light of the uncertainties summarized here for the MSS model (and discussed in detail in Appendix 3D, section 3D.3.4 of the PA), the lung function risk estimates summarized in section II.C.3 below are those derived using the E–R approach.

Two updates to the analysis approach since the 2014 HREA reduce uncertainty in the results. The first is related to the approach to identifying when simulated individuals may be at moderate or greater exertion. The approach used in the current review reduces the potential for overestimation of the number of people achieving the associated ventilation rate, an important uncertainty identified in the 2014 HREA. Additionally, the current analysis focuses on exposures of 7 hours duration to better represent 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).

In summary, among the multiple 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, several are particularly important, some of which are similar to those recognized in the last review. 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. Areas in which uncertainty has been reduced by new or updated information or methods include the use of more refined air quality modeling based on selection of study areas with design values near the current standard and a more recent model and model inputs, 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.

3. Summary of Exposure and Risk Estimates

Exposure and risk estimates for the eight urban study areas are summarized here, with a focus on the estimates for air quality conditions adjusted to just meet the current standard. The analyses in this review include two types of risk estimates for the 3-year simulation in each study area: (1) The number and percent of simulated people experiencing exposures at or above the particular benchmark concentrations of interest in a year, while breathing at elevated rates; and (2) the number and percent of people estimated to experience at least one O_3-related lung function decrement (specifically, FEV_1 reductions of a magnitude at or above 10%, 15% or 20%) in a year and the number and percent of people estimated to experience multiple lung function decrements associated with O_3 exposures.

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[88] 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). 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. Targeted analyses of outdoor workers in the 2014 HREA (single study area, single year) estimated an appreciably greater portion of this population to experience exposures at or above benchmark concentration than the full adult or child populations (2014 HREA, section 5.4.3.2) although there are a number of uncertainties associated with these estimates due to appreciable limitations in the data underlying the analyses. 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 the current analyses.[89]

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, we focus here on the estimates for children, including children with asthma. Under air quality conditions just meeting the current standard, approximately less than 0.1% of any 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 2). With regard to the 70 ppb benchmark, the study areas' estimates for children with asthma are as high as 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

[87] The E–R function risk approach conforms more closely to the circumstances of the 6.6-hour controlled human exposure studies, such that the 7-hour duration and moderate or greater exertion level are necessary for nonzero risk. This approach does, however, use a continuous function which predicts responses for exposure concentrations below those studied down to zero. As a result, exposures below those studied in the controlled human exposures will result in a fraction of the population being estimated by the E–R function to experience a lung function decrement (albeit to an increasingly small degree with decreasing exposures). The MSS model, which has been developed based on a conceptualization intended to reflect a broader set of controlled human exposure studies (*e.g.,* including studies of exposures to higher concentrations for shorter durations), does not require a 7-hour duration for estimation of a response, and lung function decrements are estimated for exertion below moderate or greater levels, as well as for exposure concentrations below those studied (PA, Appendix 3D, section 3D.3.4.2; 2014 HREA section 6.3.3). These differences in the models, accordingly, result in differences in the extent to which they reflect the particular conditions of the available controlled human exposure studies and the frequency and magnitude of the measured responses.

[88] 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).

[89] It is expected that if an approach similar to that used in the 2014 HREA were used for this assessment the distribution of exposures (single day and multiday) would be similar to that estimated in the 2014 HREA (*e.g.,* 2014 HREA, Figure 5–14), although with slightly lower overall percentages (and based on the comparison of current estimates with estimates from the 2014 HREA) (PA, Appendix 3D, section 3D.3.2.4).

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).

These estimates for the analyses in the current review, while based on conceptually similar approaches to those used in the 2014 HREA, also reflect the updates and revisions to those approaches that have been implemented since that time. The range of estimates across the study areas from the current assessment for air quality conditions simulated to just meet the current standard are similar, although the upper end of the ranges is slightly lower in some cases, to the estimates for these same populations in the 2014 HREA. For example, for air quality conditions just meeting the now-current standard, the 2014 HREA estimated 0.1 to 1.2% of all children across the study areas to experience, on average, at least one day with exposure at or above 70 ppb, while at elevated ventilation, compared to the comparable estimates of 0.2 to 0.6% from the current analyses (PA, Appendix 3D, section 3D.3.2.4, Table 3D–38). There are a number of differences between the quantitative modeling and analyses performed in the current assessment and the 2014 HREA that likely contribute to the small differences in estimates between the two assessments (*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).

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
Children With Asthma—Number of Individuals [A]						
≥80	0–67	202	0	0	0	0
≥70	93–1,145	1,616	3–39	118	0	0
≥60	1,517–8,544	11,776	282—2,609	3,977	23–637	1,033
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
All Children—Number of Individuals [A]						
≥80	0–464	1,211	0	0	0	0
≥70	727–8,305	11,923	16–341	660	0–5	14
≥60	14,928–69,794	96,261	2,601–24,952	36,643	158–5,997	9,554

[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).

In framing these same exposure estimates 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 2, above). 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. These estimates are of a magnitude roughly consistent with the level of protection that was described in establishing the current standard in 2015 (PA, section 3.1).

With regard to lung function risk estimated using the population-based E–R function approach, the estimates for children with asthma are similar to those for all children, but with the higher end of the ranges for the eight study areas being just slightly higher in some cases (Table 3). For example, on average between 0.5 to 0.9% (and at most 1.0%) of children with asthma are estimated to have at least one day per year with a 15% (or larger) FEV_1 decrement. When considering the same decrement for all children, on average the estimate is between 0.5 to 0.8% (and at most 0.9%). Somewhat larger differences are seen when comparing single-day occurrences of 10% (or larger) FEV_1 decrements for the two population groups, but again, differing by only a few tenths of a percent (*e.g.,* at most, 3.6% percent of children with asthma versus 3.3% of all children).

Regarding multi-day occurrences, the analyses find that very few children are estimated to experience 15% (or larger) FEV_1 decrements (*i.e.,* on the order of a few tenths of a percent). For example, at most 0.6% and 0.2% of all children (and children with asthma) are estimated to experience 15% (or larger) and 20% (or larger) FEV_1 decrements, respectively, for two or more days, and at most, about 2.5% of children are estimated to experience two or more days with a 10% FEV_1 decrement.

TABLE 3—PERCENT OF SIMULATED CHILDREN AND CHILDREN WITH ASTHMA ESTIMATED TO EXPERIENCE AT LEAST ONE OR MORE DAYS PER YEAR WITH A LUNG FUNCTION DECREMENT AT OR ABOVE 10, 15 OR 20% WHILE BREATHING AT AN ELEVATED RATE IN AREAS JUST MEETING THE CURRENT STANDARD

Lung function decrement [A]	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
E–R Function						
Percent of Simulated Children With Asthma [A]						
≥20%	0.2–0.3	0.4	0.1–0.2	0.2	<0.1 [B]–0.1	0.1
≥15%	0.5–0.9	1.0	0.3–0.6	0.6	0.2–0.4	0.4
≥10%	2.3–3.3	3.6	1.5–2.4	2.6	0.9–1.7	1.8
Percent of All Simulated Children [A]						
≥20%	0.2–0.3	0.4	0.1–0.2	0.2	<0.1–0.1	0.1
≥15%	0.5–0.8	0.9	0.3–0.5	0.6	0.2–0.4	0.4
≥10%	2.2–3.1	3.3	1.3–2.2	2.4	0.8–1.6	1.7

[A] Estimates for each urban case study area were averaged across the 3-year assessment period. Ranges reflect the ranges across urban study area averages.
[B] 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).

D. Proposed Conclusions on the Primary Standard

In reaching proposed conclusions on the current O_3 primary standard (presented in section II.D.3), the Administrator has taken into account the current evidence and associated conclusions in the ISA, in light of the policy-relevant evidence-based and exposure- and risk-based considerations discussed in the PA (summarized in section II.D.1), as well as advice from the CASAC, and public comment received on the standard thus far in the review (section II.D.2). In general, the role of the PA is to help ''bridge the gap'' between the Agency's assessment of the current evidence and quantitative analyses (of air quality, exposure and risk), and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the NAAQS. Evidence-based considerations draw upon the EPA's integrated assessment of the scientific evidence of health effects related to O_3 exposure presented in the ISA (summarized in section II.B above) to address key policy-relevant questions in the review. Similarly, the exposure- and risk-based considerations draw upon our assessment of population exposure and associated risk (summarized in section II.C above) in addressing policy-relevant questions focused on the potential for O_3 exposures associated with respiratory effects under air quality conditions meeting the current standard.

The approach to reviewing the primary standard is consistent with requirements of the provisions of the CAA related to the review of the NAAQS and with how the EPA and the courts have historically interpreted the CAA. As discussed in section I.A above, these provisions require the Administrator to establish primary standards that, in the Administrator's judgment, are requisite (*i.e.,* neither more nor less stringent than necessary) to protect public health with an adequate margin of safety. Consistent with the Agency's approach across all NAAQS reviews, the EPA's approach to informing these judgments is based on a recognition that the available health effects evidence generally reflects a continuum that includes ambient air exposures for which scientists generally agree that health effects are likely to occur through lower levels at which the likelihood and magnitude of response become increasingly uncertain. The CAA does not require the Administrator to establish a primary standard at a zero-risk level or at background concentration levels, but rather at a level that reduces risk sufficiently so as to protect public health, including the health of sensitive groups, with an adequate margin of safety.

The proposed decision on the adequacy of the current primary standard described below is a public health policy judgment by the Administrator that draws on the scientific evidence for health effects, quantitative analyses of population exposures and/or health risks, and judgments about how to consider the uncertainties and limitations that are inherent in the scientific evidence and quantitative analyses. The four basic elements of the NAAQS (*i.e.,* indicator, averaging time, form, and level) have been considered collectively in evaluating the health protection afforded by the current standard. The Administrator's final decision will additionally consider public comments received on this proposed decision.

1. Evidence- and Exposure/Risk-Based Considerations in the Policy Assessment

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 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).

With regard to the support in the current evidence for O_3 as the indicator for photochemical oxidants, 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.[90] As summarized in section 2.1 of the PA, O_3 is one of a group of photochemical oxidants formed by atmospheric photochemical reactions of hydrocarbons with NO_X in the presence of sunlight, with O_3 being the only photochemical oxidant other than nitrogen dioxide that is routinely monitored in ambient air. Data for other photochemical oxidants are generally derived from a few focused field studies such that national-scale data for these other oxidants are scarce (ISA, Appendix 1, section 1.1; 2013 ISA, sections 3.1 and 3.6). Moreover, few studies of the health impacts of other photochemical oxidants beyond O_3 have been identified by literature searches conducted for the 2013 ISA or 2006 AQCD (ISA, Appendix 1, section 1.1). As stated in the ISA, ''the primary literature evaluating the health . . . effects of photochemical oxidants includes ozone almost exclusively as an indicator of photochemical oxidants'' (ISA, section IS.1.1, p. IS–3). Thus, as was the case for previous reviews, the PA finds that the evidence base for health effects of photochemical oxidants does not indicate an importance of any other photochemical oxidants such that O_3 continues to be appropriately considered for the primary standard's indicator.

The currently available evidence on the health effects of O_3, including that newly available in this review, is largely consistent with the conclusions reached in the last review regarding health effects causally related to O_3 exposures (*i.e.,* respiratory effects). Specifically, as in the last review, respiratory effects are concluded to be causally related to short-term exposures to O_3. Also, as in the last review, the evidence is sufficient to conclude that the relationship between longer-term O_3 exposures and respiratory effects is likely to be causal (ISA, section IS.1.3.1, Appendix 3). Further, while a causal determination was not made in the last review regarding metabolic effects, the ISA for this review finds there to be sufficient evidence to conclude there to likely be a causal relationship of short-term O_3 exposures and metabolic effects and finds the evidence to be suggestive of, but not sufficient to infer, such a relationship between long-term O_3 exposure and metabolic effects (ISA, section IS.1.3.1). These new determinations are based on evidence on this category of effects, largely from experimental animal studies, that is newly available in this review (ISA, Appendix 5). Additionally, conclusions reached in the current review differ with regard to cardiovascular effects and mortality, based on newly available evidence in combination with uncertainties in the previously available evidence that had been identified in the last review (ISA, Appendix 4, section 4.1.17 and Appendix 6, section 6.1.8). The current evidence base is concluded to be suggestive of, but not sufficient to infer, causal relationships between O_3 exposures (short- and long-term) and cardiovascular effects, mortality, reproductive and developmental effects, and nervous system effects (ISA, section IS.1.3.1). As in the last review, the strongest evidence, including with regard to characterization of relationships between O_3 exposure and occurrence and magnitude of effects, is for respiratory effects, and particularly for effects such as lung function decrements, respiratory symptoms, airway responsiveness, and respiratory inflammation.

The current evidence does not alter our understanding of populations at increased risk from health effects of O_3 exposures. As in the last review, people with asthma, and particularly children, are the at-risk population groups for which the evidence is strongest. In addition to populations with asthma, groups with relatively greater exposures, particularly those who spend more time outdoors during times when ambient air concentrations of O_3 are highest and while engaged in activities that result in elevated ventilation, are recognized as at increased risk. Such groups include outdoor workers and children. Other groups identified as at risk, and for which the recent evidence is less clear, include older adults (in light of changes in causality determinations, as discussed in section II.B.2 above), and recent evidence regarding individuals with reduced intake of certain nutrients and individuals with certain genetic variants does not provide additional information for these groups beyond the evidence available at the time of the last review (ISA, section IS.4.4).

As in the last review, the most certain evidence of health effects in humans elicited by specific O_3 exposure concentrations is provided by controlled human exposure studies (largely with generally healthy adults). This category of short-term studies includes an extensive evidence base of 1- to 3-hour studies, conducted with continuous or intermittent exercise and generally involving relatively higher exposure concentrations, *e.g.,* greater than 120 ppb (as summarized in the PA, Appendix 3A, Table 3A–3, based on assessments of the studies in the 1996 and 2006 AQCDs, as well as the 2013 and current ISA). Given the lack of ambient air concentrations of this magnitude in areas meeting the current standard (as documented in section 2.4.1 of the PA), the focus in reviewing the current standard continues to primarily be on a second group of somewhat longer-duration studies of much lower exposure concentrations. These studies employ a 6.6-hour protocol that includes six 50-minute periods of exercise at moderate or greater exertion.

Respiratory effects continue to be the effects for which the experimental information regarding exposure concentrations eliciting effects is well established, as summarized here and in section II.B.3 above. Such information allows for characterization of potential population risk associated with O_3 in ambient air under conditions allowed by the current standard. The respiratory effects evidence includes support from a large number of epidemiologic studies that report positive associations of O_3 with severe respiratory health outcomes, such as asthma-related hospital admissions and emergency department visits, coherent with findings from the controlled human exposure and experimental animal studies. However, as summarized in section II.B.3 above, all but a few of these short- and long-term studies (and all U.S. studies) include areas and periods in which O_3 exceeds the current standard, making them less useful with regard to indication of effects of exposures that would occur with air quality allowed by the current standard.

[90] Close agreement between past O_3 measurements and photochemical oxidant measurements indicated the very minor contribution of other oxidant species in comparison to O_3 (U.S. DHEW, 1970).

Within the evidence base for the newly identified category of metabolic effects, the evidence derives largely from experimental animal studies of exposures appreciably higher than those for the 6.6-hour human exposure studies along with a small number of epidemiologic studies. The PA notes that, as discussed in section II.B.3 above, these studies do not prove to be informative to our consideration of exposure circumstances likely to elicit health effects.

Thus, the PA finds that the currently available evidence regarding O_3 exposures associated with health effects is largely similar to that available at the time of the last review and does not indicate effects attributable to exposures of shorter duration or lower concentrations than previously understood. 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. Based on these studies, the exposure concentrations investigated range from as low as approximately 40 ppb to 120 ppb. This information on concentrations that have been found to elicit effects for 6.6-hour exposures while exercising is unchanged from what was available in the last review. The lowest concentration for which lung function decrements have been found to be statistically significantly increased over responses to filtered air remains approximately 60 ppb [91] (target concentration, as average across exercise periods), at which group mean O_3-related FEV_1 decrements on the order of 2% to 3.5% have been reported (with decrements on the order of 2% to 3% of statistically significance), with associated individual study subject variability in decrement size; these results were not accompanied by a statistically significant increase in respiratory symptoms (Table 1).[92] In the single study assessing the next highest exposure concentration (73 ppb as the 6.6-hour average based on study-reported measurements), the group mean FEV_1 decrement was higher (6%) and was also statistically significant, as were respiratory symptom scores, as summarized in section II.B.3 above. At still higher exposure concentrations (80 ppb and above), the reported incidence of both respiratory symptom scores and O_3-related lung function decrements in the study subjects is increased and the incidence of decrements at or above 15% is larger. Other respiratory effects, such as inflammatory response and airway resistance, are also increased at higher exposures (ISA; 2013 ISA).

The PA concludes that important uncertainties identified in the health effects evidence at the time of the last review generally remain in the current evidence. Although 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. The PA additionally recognizes uncertainties associated with the epidemiologic studies concerning the potential influence of exposure history and co-exposure to other pollutants (including complications of prior population exposures) on the relationship between short-term O_3 exposure and respiratory effects. In so doing, however, the PA notes the appreciably greater strength in the epidemiologic evidence in its support for determination of a causal relationship for respiratory effects than that related to other categories, such as metabolic effects, for the current ISA newly determines there likely to be a causal relationship with short-term O_3 exposures (as summarized in section II.B.3 above), and recognizes the greater uncertainty with regard relationships between O_3 exposures and health effects other than respiratory effects. The array of important areas of uncertainty related to the current health evidence, including the evidence newly available in this review, is summarized below.

With regard to less well studied population groups, the PA notes that the majority of the available studies have generally involved healthy young adult subjects, although there are some studies involving subjects with asthma, and a limited number of studies, generally of very short durations (*i.e.,* less than four hours), involving adolescents and adults older than 50 years. For example, the only controlled human exposure study of 6.6- to 8-hour duration (7.6 hours with quasi-continuous light exercise) conducted in people with asthma was for an exposure concentration of 160 ppb (PA, Appendix 3A, Table 3A–2). Given a general lack of studies using subjects that have asthma, particularly those at exposure concentrations likely to occur under conditions meeting the current standard, uncertainties remain with regard to characterizing the response in people with asthma while at elevated ventilation to lower exposure concentrations, *e.g.,* below 80 ppb. The extent to which the epidemiologic evidence, including that newly available, can inform this specific area of uncertainty also may be limited.[93] As discussed in section II.B.2 above, given the effects of asthma on the respiratory system, exposures associated with significant respiratory responses in healthy people may pose an increased risk of more severe responses, including asthma exacerbation, in people with asthma. Thus, uncertainty remains with regard to the responses of the populations, such as children with asthma, that may be most at risk of O_3-related respiratory effects (*e.g.,* through an increased likelihood of severe responses, or greatest likelihood of response) to short-term (*e.g.,* 6.6 hr) exposures with exercise to concentrations at or below 80 ppb.

Other areas of uncertainty concerning the potential influence of O_3 exposure history and co-exposure to other pollutants on the relationship between O_3 exposures and respiratory effects in epidemiologic studies also remain from the last review. As in the epidemiologic evidence in the last review, there is a limited number of studies that include copollutant analyses for a small set of pollutants (*e.g.,* PM or NO_2). Recent studies with such analyses suggest that observed associations between O_3 concentrations and respiratory effects are independent of co-exposures to correlated pollutants or aeroallergens (ISA, sections IS.4.3.1 and IS.6.1; Appendix 3, sections 3.1.10.1 and 3.1.10.2). Despite the increased prevalence of copollutant modeling in recent epidemiologic studies, uncertainty still exists with regard to the independent effect of O_3 given the high correlations observed for some copollutants in some studies and the small fraction of all atmospheric

[91] Two studies have assessed exposure concentrations at the lower concentration of 40 ppb, with no statistically significant finding of O_3-related FEV_1 decrement for the group mean in either study, which is just above 1% in one study and well below 1% in the second (Table 1).

[92] A statistically significant, small increase in a marker of airway inflammation was observed in one controlled human exposure study following 6.6-hour exposures to 60 ppb (Table 1). An increase in respiratory symptoms has not been reported with this exposure level.

[93] Associations of health effects with O_3 that are reported in the epidemiologic analyses are based on air quality concentration metrics used as surrogates for the actual pattern of O_3 exposures experienced by study population individuals over the period of a particular study. Accordingly, the studies are limited in what they can convey regarding the specific patterns of exposure circumstances (*e.g.,* magnitude of concentrations over specific duration and frequency) that might be eliciting reported health outcomes.

pollutants included in these analyses (ISA, section IS.4.3.1; Appendix 2, section 2.5).

Further, although there remains uncertainty in the evidence with regard to the potential role of exposures to O_3 in eliciting health effects other than respiratory effects, the evidence has been strengthened since the last review with regard to metabolic effects. As noted in section II.B.1 above, the ISA newly identifies metabolic effects as likely to be causally related to short-term O_3 exposures. The evidence supporting this relationship is limited and not without its own uncertainties, such as the fact that the conclusion for this relationship is based primarily on animal toxicological studies conducted at much higher O_3 concentrations than those common in ambient air in the U.S. Only a handful of epidemiologic studies of short-term O_3 exposure and metabolic effects, with some inconsistencies, are available, ''many of these did not control for copollutant confounding,'' and the two U.S. studies in the group did not find a statistically significant association (ISA, p. 5–29 and Appendix 5, section 5.1; PA, section 3.3).

With regard to the evidence for other categories of health effects, its support for a causal relationship with O_3 in ambient air is appreciably more uncertain. For example, as noted in section II.B.1 above, the ISA has determined the evidence to be suggestive of, but not sufficient to infer, a causal relationship between long-term O_3 exposures and metabolic effects, and between O_3 exposures and several other categories of health effects, including effects on the cardiovascular, reproductive and nervous systems, and mortality (ISA, section IS.4.3).[94] Additionally, the ISA finds the evidence to be inadequate to determine if a causal relationship exists with O_3 and cancer (ISA, section IS.4.3).

As at the time of the last review, consideration of the scientific evidence in the current review is informed by results from a newly performed quantitative analysis of estimated population exposure and associated risk. The overarching PA consideration regarding these results is whether they alter the overall conclusions from the previous review regarding health risk associated with exposure to O_3 in ambient air and associated judgments on the adequacy of public health protection provided by the now-current standard. The quantitative exposure and risk analyses completed in this review update and in many ways improve upon analyses completed in the last review (as summarized in section II.C.1 above).

The exposure and risk analyses conducted for this review, as was true for those conducted for the last review, develop exposure and risk estimates for study area populations of children with asthma, as well as the populations of all children in each study area. The primary analyses focus on exposure and risk associated with air quality that might occur in an area under conditions that just meet the current standard. These study areas reflect different combinations of different types of sources of O_3 precursor emissions, and also illustrate different patterns of exposure to O_3 concentrations in a populated area in the U.S. (PA, Appendix 3C, section 3C.2). While the same conceptual air quality scenario is simulated in all eight study areas (*i.e.,* conditions that just meet the existing standard), variability in emissions patterns of O_3 precursors, meteorological conditions, and population characteristics in the study areas contribute to variability in the estimated magnitude of exposure and associated risk across study areas. In this way, the eight areas provide a variety of examples of exposure patterns that can be informative to the Administrator's consideration of potential exposures and risks that may be associated with air quality conditions occurring under the current O_3 standard.

In considering the exposure and risk analyses available in this review, the PA notes that there are a number of ways in which the current analyses update and improve upon those available in the last review. These include a number of improvements to input data and modeling approaches summarized in section II.C.1 above. As in prior reviews, exposure and risk are estimated from air quality scenarios designed to just meet an O_3 standard in all its elements. That is, the air quality scenarios are defined by the highest design value in the study area, which is the monitor location with the highest 3-year average of annual fourth highest daily maximum 8-hour O_3 concentrations (*e.g.,* equal to 70 ppb for the current standard scenario). The current risk and exposure analyses include air quality simulations based on more recent ambient air quality data that include O_3 concentrations closer to the current standard than was the case for the development of the air quality scenarios in the last review. As a result of this and the use of updated photochemical modeling, there is reduced uncertainty associated with the spatial and temporal patterns of O_3 concentrations that define these scenarios across all eight study areas. Additionally, the approach for deriving population exposure estimates, both for comparison to benchmark concentrations and for use in deriving lung function risk using the E–R function approach, has been modified to provide for a better match of the simulated population exposure estimates with the 6.6-hour duration of the controlled human exposure studies and with the study subject ventilation rates. Together, these differences, as well as a variety of updates to model inputs, are believed to reduce uncertainty associated with interpretation of the analysis results.

The PA also notes the array of air quality and exposure circumstances represented by the eight study areas. As summarized in section II.C.1 above, the areas fall into seven of the nine climate regions in the continental U.S. The population sizes of the associated metropolitan areas range in size from approximately 2.4 to 8 million and vary in population demographic characteristics. While there are uncertainties and limitations associated with the exposure and risk estimates, as noted in II.C.2, the PA considers the factors recognized here to contribute to their usefulness in informing the current review.

The PA gives primary attention to results for the comparison-to-benchmarks analysis in recognition of the relatively lesser uncertainty of these results (than the lung function risk estimates), and also of the broader characterization of respiratory effects that they can inform, as noted in section II.C above. Similarly, the results for this risk metric also received greater emphasis in the last review and were a focus in establishing the current standard in 2015. The estimates across all study areas from the current review are generally similar to those reported across all study areas assessed in the last review, particularly for estimates for two or more occurrences at or above a benchmark, and for the 80 ppb benchmark (Table 4). For consistency with the estimates highlighted in the 2015 review (*e.g.,* 80 FR 65313–65315, October 26, 2015), the PA comparison, summarized in Table 4 below, focuses on the simulated population of all children. We additionally note, however, the similarity of the estimates for all children to the estimates for the simulated population of children with asthma (Table 2). For example, for urban study areas with air quality that just meets the current standard, as many as 0.7% of children with asthma, on

[94] An evidence base determined to be ''suggestive of, but not sufficient to infer, a causal relationship'' is described as ''limited, and chance, confounding, and other biases cannot be ruled out'' (U.S. EPA, 2015, p. 23).

average across the 3-year period, and up to 1.0% in a single year might be expected to experience, while at elevated exertion, at least one day with a 7-hour average O_3 exposure concentration at or above 70 ppb (Table 2). The corresponding estimates for the simulated population of all children are as many as 0.6% of all children, on average across the 3-year period, and up to 0.9% in a single year (Table 2). For the benchmark concentration of 80 ppb (which reflects the potential for more severe effects), a much lower percentage (0.1%) of children with asthma, on average across the 3-year period or in any single year (compared to less than 0.1% on average and as many as 0.1% in a single year for all children), might be expected to experience, while at elevated exertion, at least one day with such a concentration (Table 2). Regarding estimates for multiple days, the percent of children with asthma (as well as the percent of all children) estimated to experience two or more days with an exposure at or above 70 ppb is less than 0.1%, on average across three years, and up to 0.1% in a single year period. There are no children estimated to experience more than a single day per year with a 7-hour average O_3 concentration at or above 80 ppb. With regard to the lowest benchmark concentration of 60 ppb, the percentages for the simulated population of children with asthma for more than a single day occurrence are 3%, on average across the three years, and just below 5% in a single year period, with just slightly lower percentages (2.9 and 4.3%) for the population of all children (Table 2).

The PA additionally compares the estimates derived in the current analyses with those from the 2014 HREA in the last review, finding them to be quite similar.[95] For example, with regard to the 80 ppb benchmark and air quality conditions just meeting the current standard, the percentage of children estimated to experience a day or more with such an exposure, ranges from zero (in both assessments) up to 0.1% (2014 HREA) and a nonzero value less than 0.1% (current assessment), on average across the three year period (Table 4). The estimates for the highest year (0.2 and 0.1%, for the 2014 and current assessments, respectively) are within 0.1% of each other. Both assessments estimate zero children to experience two or more days with an exposure at or above 80 ppb. The differences observed, which are particularly evident for the lower benchmarks and in the estimates for the highest year, are generally slight. Much larger differences are seen in comparing different air quality scenario results for the same benchmark. For example, for the 70 ppb benchmark, the differences between the 75 ppb scenario and the current standard (or between the 65 ppb scenario and the current standard) in either assessment are appreciably larger than are the slight differences observed between the two assessments for any air quality scenario. The factors likely contributing to the slight differences, *e.g.,* for the lowest benchmark, include greater variation in ambient air concentrations in some of the study areas in the 2014 HREA, as well as the lesser air quality adjustments required in study areas for the current assessment due to closer proximity of conditions to meeting the current standard (70 ppb).[96] Other important differences between the two assessments are the updates made to the ventilation rates used for identifying when a simulated individual is at moderate or greater exertion and the use of 7 hours for the exposure duration. Both of these changes were made to provide closer linkages to the conditions of the controlled human exposure studies which are the basis for the benchmark concentrations. Thus, the PA recognizes there to be reduced uncertainty associated with the current estimates.

TABLE 4—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, 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)

[95] In this comparison, the PA focuses on the full array of study areas assessed in each analysis given the purpose of each in providing estimates across a range of study areas to inform decision making with regard to the exposures and risks that may occur across the U.S. in areas that just meet the current standard.

[96] The 2014 HREA air quality scenarios involved adjusting 2006–2010 ambient air concentrations, and some study areas had design values in that time period that were well above the then-existing standard (and more so for the current standard). Study areas included the current exposure analysis had 2015–2017 design values close to the current standard, requiring less of an adjustment for the current standard (70 ppb) air quality scenario.

TABLE 4—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—Continued

Air quality scenario (DV, 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]
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".

Overall, the comparison-to-benchmarks estimates are generally similar to those which were the focus in the 2015 decision on establishing the current standard. For example, in the 2015 decision to set the standard level at 70 ppb, the Administrator took note of several findings for the air quality scenarios for this level, noting 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 results of the current assessment (Table 4). With regard to the 60 ppb benchmark, for which the 2015 decision placed relatively greater weight on 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 4).

In considering the public health implications of the estimated occurrence of exposures of different magnitudes, the PA considers the magnitude or severity of the effects associated with the estimated exposures as well as their adversity, the size of the population estimated to experience exposures associated with such effects, as well as consideration for such implications in previous NAAQS decisions and ATS policy statements (as summarized in section II.B.2 above). As an initial matter, the PA considers the severity of responses associated with the exposure and risk estimates, taking note of the health effects evidence for the different benchmark concentrations and judgments made with regard to the severity of these effects in the last review. As in the last review, the PA recognizes the greater prevalence of more severe lung function decrements among study subjects exposed to 80 ppb or higher concentrations compared to 60 or 70 ppb exposure concentrations, as well as the prevalence of other effects such as respiratory symptoms. In so doing, the PA notes that such exposures are appropriately considered to be associated with adverse respiratory effects consistent with past and recent ATS position statements. Studies of 6.6-hour controlled human exposures, with quasi-continuous exercise, to the lowest benchmark concentration of 60 ppb have found small but statistically significant O_3-related decrements in lung function (specifically reduced FEV_1) and airway inflammation. Somewhat above 70 ppb,[97] statistically significant increases in lung function decrements, of a somewhat greater magnitude (*e.g.,* approximately 6% increase, as study group average, versus 2 to 3% [Table 1]), and respiratory symptoms have been reported, which has led to characterization of these exposure conditions as also being associated with adverse responses, consistent with past ATS statements as summarized in section II.B.1 above (*e.g.,* 80 FR 65343, 65345, October 26, 2015).

The PA additionally takes note of the greater significance of estimates for multiple occurrences of exposures at or above these benchmarks consistent with the evidence, as has been recognized in multiple past O_3 NAAQS reviews. The role of such a consideration has also differed across the three benchmarks. More specifically, while estimates of one or more exposures at or above the higher benchmark concentrations (70 ppb and 80 ppb) was an important consideration in the decision on the current standard, estimates of multiple exposures at or above the lowest benchmark concentration of 60 ppb were given greater weight than estimates for one or more such exposures. More specifically, in the 2015 decision leading to establishment of the current standard, a greater emphasis on protection against multiple (*versus* single) occurrences of exposures at or above 60 ppb last was based in part on a recognition of the lesser severity of the effects at this exposure level in combination with the recognition that for effects such as inflammation (even when occurring to a small extent). This greater emphasis reflected a recognition that, while isolated occurrences can resolve entirely, repeated occurrences from repeated exposure could potentially result in more severe effects (2013 ISA, section 6.2.3 and p. 6–76). Additionally, while even multiple occurrences of such effects of lesser severity to otherwise healthy individuals may not result in severe effects, they may contribute to more important effects in individuals with compromised respiratory function, such as those with asthma. The ascribing of greater significance to repeated occurrences of exposures of potential concern is also consistent with public

[97] As noted in sections II.A.1 and II.B.3 above, the 70 ppb target exposure concentration comes from Schelegle et al. (2009). That study 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 measurements for the six exercise periods, the time weighted average concentration across the full 6.6-hour exposure was 73 ppb (Schelegle et al., 2009).

health judgments in NAAQS reviews for other pollutants, such as sulfur oxides and CO (84 FR 9900, March 18, 2019; 76 FR 54307, August 31, 2011).

As in the last review, while the exposure-based analyses include two types of metrics, the quantitative exposure and risk analyses results in which the PA expresses the greatest confidence are estimates from the comparison-to-benchmarks analysis, as discussed in section II.C above. In light of the conclusions that people with asthma and children are at-risk populations for O_3-related health effects (summarized in section II.B.2 above) and the exposure and risk analysis findings of higher exposures and risks for children (in terms of percent of that population), the PA focused its consideration of the analysis results on children (and also specifically children with asthma). The exposure and risk estimates indicate that in some areas of the U.S. where O_3 concentrations just meet the current standard, on average across the 3-year period simulated, less than 1%, and less than 0.1% of the simulated population of children with asthma might be expected to experience a single day per year with a maximum 7-hour exposure at or above 70 ppb and 80 ppb, respectively, while breathing at an elevated rate (Table 2). With regard to the lowest benchmark considered (60 ppb), the corresponding percentage is less than approximately 9%, on average across the 3-year period (Table 2). The corresponding estimates for the 75 ppb air quality scenario are notably higher, *e.g.,* 1.1 to 2.1% of children with asthma, on average across the 3-year design period, for the 70 ppb benchmark, with as many as 3.9% in a single year (PA, Table 3–5). The estimates for the 65 ppb scenario are appreciably lower (PA, Table 3–5).

While recognizing greater uncertainty and accordingly less confidence in the lung function risk estimates, the PA noted the results based on the E–R model that estimated 0.2 to 0.3% of children with asthma, on average across the 3-year design period are estimated to experience one or more days with a lung function decrement at or above 20%, and 0.5 to 0.9% to experience one or more days with a decrement at or above 15% (Table 3). In a single year, the highest estimate is 1.0% of this at-risk population expected to experience one or more days with a decrement at or above 15%. The corresponding estimate for two or more days is 0.6% (Table 3).

As summarized in section II.B.2 above, the size of the at-risk population (people with asthma, particularly children) in the U.S. is substantial. Nearly 8% of the total U.S. population and 8.4% of U.S. children have asthma.[98] The asthma prevalence in U.S. child populations (younger than 18 years) of different races or ethnicities ranges from 6.2% for Hispanic, Mexican or Mexican-American children to 12.6% for black non-Hispanic children (PA, Table 3–1). This is well reflected in the exposure and risk analysis study areas in which the asthma prevalence ranged from 7.7% to 11.2% of the total populations and 9.2% to 12.3% of the children. In each study area, the prevalence varies among census tracts, with the highest tract having a prevalence in boys of 25.5% and a prevalence in girls of 17.1% (PA, Appendix 3D, Table 3D–3).

The exposure and risk analyses inherently recognize that variability in human activity patterns (where people go and what they do) is key to understanding the magnitude, duration, pattern, and frequency of population exposures. For O_3 in particular, the amount and frequency of afternoon time outdoors at moderate or greater exertion is an important factor for understanding the fraction of the population that might experience O_3 exposures that have elicited respiratory effects in experimental studies (2014 HREA, section 5.4.2). In considering the available information regarding prevalence of behavior (time outdoors and exertion levels) and daily temporal pattern of O_3 concentrations, the PA notes the findings of evaluations of the data in the CHAD. Based on these evaluations of human activity pattern data, it appears that children and adults both, for days having some time spent outdoors spend, on average, about 2 hours of afternoon time outdoors per day, but differ substantially in their participation in these events at elevated exertion levels (rates of about 80% versus 60%, respectively) (2014 HREA, section 5.4.1.5), indicating children are more likely to experience exposures that may be of concern. This is one basis for their identification as an at-risk population for O_3-related health effects. The human activity pattern evaluations have also shown there is little to no difference in the amount or frequency of afternoon time outdoors at moderate or greater exertion for people with asthma compared with those who do not have asthma (2014 HREA, section 5.4.1.5). Further, recent CHAD analyses indicate that while 46–73% of people do not spend any afternoon time outdoors at moderate or greater exertion, a fraction of the population (*i.e.,* between 5.5–6.8% of children) spend more than 4 hours per day outdoors at moderate or greater exertion and may have greater potential to experience exposure events of concern than adults (PA, Appendix 3D, section 3D.2.5.3 and Figure 3D–9). It is this potential that contributes importance to consideration of the exposure and risk estimates.

In considering the public health implications of the exposure and risk estimates across the eight study areas, the PA notes that the purpose for the study areas is to illustrate exposure circumstances that may occur in areas that just meet the current standard, and not to estimate exposure and risk associated with conditions occurring in those specific locations today. To the extent that concentrations in the specific areas simulated may differ from others across the U.S., the exposure and risk estimates for these areas are informative to consideration of potential exposures and risks in areas existing across the U.S. that have air quality and population characteristics similar to the study areas assessed, and that have ambient concentrations of O_3 that just meet the current standard today or that will be reduced to do so at some period in the future. We note that numerous areas across the U.S. have air quality for O_3 that is near or above the existing standard.[99] Thus, the air quality and exposure circumstances assessed in the eight study areas are of particular importance in considering whether the currently available information calls into question the adequacy of public health protection afforded by the current standard.

The exposure and risk estimates for the study areas assessed for this review reflect differences in exposure circumstances among those areas and illustrate the exposures and risks that might be expected to occur in other areas with such circumstances under air quality conditions that just meet the current standard (or the alternate

[98] The number of people in the US with asthma is estimated to be about 25 million. As shown in the PA, Table 3–1 the estimated number of people with asthma was 25,191,000 in 2017. The updated estimate from the 2018 National Health Interview Survey is 24,753,000 (CDC, 2020). For children (younger than 18 years), the 2017 estimate is approximately 6,182,000, while the estimate for 2018 is slightly lower at 5,530,131 (PA, Table 3–1).

[99] Based on the most recently available data from 2016–2018, 142 counties have O_3 concentrations that exceed the current standard. Population size in these counties ranges from approximately 20,000 to more than ten million, with a total population of over 112 million living in counties that exceed the current standard. Air quality data are from Table 4. Monitor Status in the Excel file named ozone_designvalues_20162018_final_06_28_19.xlsx downloaded from *https://www.epa.gov/air-trends/air-quality-design-values.* Population sizes are based on 2017 estimates from the U.S. Census Bureau (*https://www.census.gov/programs-surveys/popest.html*).

conditions assessed). Thus, the exposure and risk estimates indicate the magnitude of exposure and risk that might be expected in many areas of the U.S. with O_3 concentrations at or near the current standard. Although the methodologies and data used to estimate population exposure and lung function risk in this review differ in several ways from what was used in the last review, the findings and considerations summarized here present a pattern of exposure and risk that is generally similar to that considered in the last review (as described above), and indicate a level of protection from respiratory effects that is generally consistent with that described in the 2015 decision.

Collectively, the PA finds that the evidence and exposure and risk-based considerations provide the basis for its conclusion that consideration should be given to retaining the current primary standard, without revision (PA, section 3.5.4). Accordingly, and in light of this conclusion that it is appropriate to consider the current primary standard to be adequate, the PA did not identify any potential alternative primary standards for consideration in this review (PA, section 3.5.4). In reaching these conclusions, the PA additionally notes that considerations raised in the PA are important to conclusions and judgments to be made by the Administrator concerning the public health significance of the evidence and of the exposure and risk estimates. Such judgments that are common to NAAQS decisions include those related to public health implications of effects of differing severity (75 FR 355260 and 35536, June 22, 2010; 76 FR 54308, August 31, 2011; 80 FR 65292, October 26, 2015). Such judgments also include those concerning the public health significance of effects at exposures for which evidence is limited or lacking, such as effects at the lower benchmark concentrations considered and lung function risk estimates associated with exposure concentrations lower than those tested or for population groups not included in the controlled exposure studies. The PA recognizes that such public health policy judgments will weigh in the Administrator's decision in this review with regard to the adequacy of protection afforded by the current standard.

2. CASAC Advice

The CASAC has provided advice on the adequacy of the current primary O_3 standard in the context of its review of the draft PA.[100] In this context, the CASAC agreed with the draft PA findings that the 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, p. 12 of the Consensus Responses). 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 of letter). 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 of letter and p. 12 of the enclosed Consensus Responses).[101] 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 in completing the PA and in presentations of the information in prior sections of this proposal document.

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, p. 14 of the Consensus Responses).

3. Administrator's Proposed Conclusions

Based on the large body of evidence concerning the health effects and potential public health impacts of exposure to O_3 in ambient air, and taking into consideration the attendant uncertainties and limitations of the evidence, the Administrator proposes to conclude that the current primary O_3 standard provides the requisite protection of public health, including an adequate margin of safety, and should therefore be retained, without revision. In reaching these proposed conclusions, 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 section II.D.1 above); the advice and recommendations from the CASAC (summarized in section II.D.2 above); and public comments received to date in this review.

In the discussion below, the Administrator considers first the evidence base on health effects associated with exposure to photochemical oxidants, including O_3, in ambient air. In so doing, he considers that health effects evidence newly available in this review, and the extent to which it alters key scientific conclusions in the last review. The Administrator 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 level of protection from adverse effects, associated with the current standard. Further, the Administrator considers the key aspects of the evidence and exposure/risk estimates emphasized in establishing 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, similar to the judgments made in establishing the current

[100] A limited number of public comments have also been received in this review to date, including comments focused on the draft IRP or draft PA. Of the public comment that addressed adequacy of the current primary O_3 standard, some expressed agreement with staff conclusions in the draft PA, while others expressed the view that the standard should be more restrictive. In support of this latter view, commenters largely cited advice from, and considerations raised by, the previous CASAC in the last review regarding adequacy of the margin of safety.

[101] 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, 2014, 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, 2014, 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, 2014, p. ii).

standard. Such judgments include public health policy judgments and judgments about 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. With attention to such factors as these, the Administrator considers the information currently available in this review with regard to the adequacy and appropriateness of the protection provided by the current standard.

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 above). He takes note of the PA conclusion 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, and of the ISA observation that ''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, he proposes to conclude 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. This array of effects, and the underlying evidence base, was integral to the basis for setting the current standard. The Administrator takes note of the ISA conclusion that this evidence base of studies on O_3 exposure and respiratory health is the ''strongest evidence for health effects due to ozone exposure'' (ISA p. IS–8). While the overall health effects evidence base has been augmented somewhat since the time of the last review, the Administrator notes that, as summarized in section II.B.1 above, the newly available evidence does not lead to different conclusions regarding the respiratory effects of O_3 in ambient air or regarding exposure concentrations associated with those effects; nor does it identify different populations at risk of O_3-related effects, than in the last review.

The Administrator recognizes that this strong evidence base continues to demonstrate a causal relationship between short-term O_3 exposures and respiratory effects, including in people with asthma. He also 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 notes 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. The Administrator also notes the ISA conclusion that the relationship between long-term exposures and respiratory effects is likely to be causal, a conclusion that is consistent with the conclusion in the last review and that reflects a general similarity in the underlying evidence base.

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.B.2 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 (2013 ISA, section 5.2.2.7). These factors and the strong evidence (briefly summarized in section II.B.2 above, and section 3.3.2 of the PA, based on evidence described in detail in the ISA), indicate people with asthma, including children, to be at increased risk of O_3 related respiratory effects, including specifically asthma exacerbation and associated health outcomes. Based on these considerations, the Administrator proposes to conclude 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 proposes to judge 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.

With regard to ISA conclusions 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.B.1 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 effects and mortality were likely to be causal, that conclusion is not supported by the now more expansive evidence base which the ISA now determines to be suggestive of, but not sufficient to infer, a causal relationship for these health effect categories. 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. 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.B.3 and II.D.1 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 proposes 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.

With regard to exposures of interest for respiratory effects, the Administrator notes the 6.6 hour controlled human exposure studies involving exposure, with quasi-continuous exercise,[102] to concentrations ranging from as low as approximately 40 ppb to 120 ppb (as considered in the PA, and summarized in sections II.B.3 and II.D.1 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 Administrator 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, the Administrator recognizes that while, 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.B.1 above), these studies 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. The Administrator takes note of the PA conclusions in this regard, including the scarcity of U.S. studies conducted in locations in which and during time periods when the current standard would have been met (as summarized in sections II.B.3 and II.D.1 above).[103] He also recognizes the additional considerations raised in the PA and summarized in section II.B.3 above regarding information on exposure concentrations in these studies during times and locations that would not have met the current standard, and also 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). While he notes that such considerations do not lessen their importance in the evidence base documenting the causal relationship between O_3 and respiratory effects, he concurs with the PA that these studies are less informative in considering O_3 exposure concentrations occurring under air quality conditions allowed by the current standard. Thus, the Administrator does not find the 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. In consideration of this evidence from controlled human exposure and epidemiologic studies, as assessed in the ISA and summarized in the PA, the Administrator notes 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 give particular focus to the studies of 6.6-hour exposures with quasi-continuous exercise to concentrations generally ranging from 60 to 80 ppb.

With regard to these 6.6-hour controlled human exposure studies, although two such studies have assessed exposures at the lower concentration of 40 ppb, statistically significant responses have not been reported from those exposures. Studies at the next highest concentration studied (a 60 ppb target) have reported decrements in lung function (assessed by FEV_1) that are statistically significantly increased over the decrements occurring with filtered air, with group mean O_3-related decrements on the order of 2 to 3% (and associated individual study subject variability in decrement size). A statistically significant, small increase in a marker of airway inflammation has also been reported in one of these 60 ppb studies. Exposure with the same study protocol to a concentration slightly above 70 ppb (73 ppb as the 6.6-hour average and 72 ppb as the exercise period average, based on study-reported measurements) has been reported to elicit statistically significant increases in both lung function decrements (group mean of 6%) and respiratory symptom scores, as summarized in section II.B.3 above. Further increases in O_3-related lung function decrements and respiratory symptom scores, as well as inflammatory response and airway responsiveness, are reported for exposure concentrations of 80 ppb and higher (ISA; 2013 ISA; 2006 AQCD).

In this review, as in the last review, 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, 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; 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.

In light of these uncertainties, as well as those associated with the exposure and risk analyses, the Administrator notes that, as is the case in NAAQS reviews in general, the extent to which the current primary O_3 standard is judged to be adequate will depend 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 the appropriate benchmark concentrations on which to place weight, 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. The factors relevant to judging the adequacy of the standards also include the interpretation of, and decisions as to the weight to place on, different aspects of the results of the exposure and risk assessment for the eight areas studied and the associated

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

[103] 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.B.3 above and in the PA.

uncertainties. Together, these and related factors will inform the Administrator's judgment about the degree of protection that is requisite to protect public health with an adequate margin of safety, and, accordingly, his conclusion regarding the adequacy of the current standard.

As at the time of the last review, 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. In considering the public health implications of estimated occurrences of exposures, while at increased exertion, to the three benchmark concentrations, the Administrator considers the effects reported in controlled human exposure studies of this range of concentrations during quasi-continuous exercise. In so doing, he notes the statements from the ATS, as well as judgments made by the EPA in considering similar effects in previous NAAQS reviews and the extent to which they may be adverse to health (80 FR 65343, October 26, 2015). In considering the ATS statements, including the most recent one which is newly available in the current review (Thurston et al., 2017), the Administrator recognizes the role of such statements, as described by the ATS, and as summarized in section II.B.2 above, as providing principles or considerations for weighing the evidence rather than offering ''strict rules or numerical criteria'' (ATS, 2000, Thurston et al., 2017). The more recent statement is generally consistent with the prior statement (that was considered in the last O_3 NAAQS review) and the attention of that statement 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, as summarized in section II.B.2 above. 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. In considering these statements, the Administrator notes that, in keeping with the intent of avoiding specific criteria, the statements do not provide specific descriptions of responses, such as with regard to magnitude, duration or frequency of small pollutant-related changes in lung function, and also takes note of the broader ATS emphasis on consideration of individuals with pre-existing compromised function, such as that resulting from asthma, recognizing such a focus to be important in his judgment on the adequacy of protection provided by the current standard for at-risk populations.

In this review of the 2015 standard, the Administrator takes note of several aspects of the rationale by which it was established. As summarized in section II.A.1 above, the decision in the last review 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 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).[104] The controlled human exposure study evidence as a whole provided context for consideration of the 2014 HREA results for the exposures of concern, *i.e.,* the comparison-to-benchmarks analysis (80 FR 65363, October 26, 2015). The Administrator proposes to similarly consider the exposure and risk analyses for this review.

As recognized above, people with asthma, and children, are key populations at increased risk of respiratory effects related to O_3 in ambient air. Children with asthma, which number approximately six million in the U.S., may be particularly at risk. While there are more adults in the U.S. with asthma than children with asthma, the exposure and risk analysis results in terms of percent of the simulated at-risk populations, indicate higher frequency of exposures of potential concern and risks for children as compared to adults. 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). In light of these factors and those recognized above, the Administrator is focusing his consideration of the exposure and risk analyses here on children and children with asthma.

In considering the exposure and risk analyses available in this review, the Administrator first notes that there are a number of ways in which the current analyses update and improve upon those available in the last review (as summarized in sections II.C.1 and II.D.1 above). For example, the Administrator notes that the air quality scenarios in the current assessment are based on the combination of updated photochemical modeling with more recent air quality data that include O_3 concentrations closer to the current standard than was the case for the development of the air quality scenarios in the last review. As a result of this and the use of updated photochemical modeling, there is reduced uncertainty with the resulting exposure and risk estimates. Additionally, two modifications have been made to the exposure and risk analysis in light of comments received in past reviews that provide for a better match of the exposure modeling estimates with the 6.6-hour duration of the controlled human exposure studies and with the study subject ventilation rates. The Administrator notes, as summarized in section II.C.2 above, that these and other updates have reduced the uncertainty associated with interpretation of the analysis results from that associated with results in the last review (PA, sections 3.4 through 3.6).

While the Administrator notes reduced uncertainty in several aspects

[104] 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 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. In one such consideration in 2015, the EPA noted that ''inflammation induced by a single exposure (or several exposures over the course of a summer) can resolve entirely. Thus, the inflammatory response observed following the single exposure to 60 ppb in the study by Kim et al. (2011) is not necessarily a concern. However, the EPA notes that it is also important to consider the potential for continued acute inflammatory responses to evolve into a chronic inflammatory state and to affect the structure and function of the lung'' (80 FR 65344, October 26, 2015; 2013 ISA, p. 6–76). The prior Administrator considered this information in judgments regarding the 2014 HREA estimates for the 60 ppb benchmark.

of the exposure and risk analysis approach as compared to the analyses in the last review, he recognizes the relatively greater uncertainty associated with the lung function risk estimates compared to the results of the comparison-to-benchmarks analysis. In so doing, he notes the PA analyses of uncertainty associated with the lung function risk estimates (and relatively greater uncertainty with estimates derived using the MSS model, versus the E–R models approach), as summarized in section II.C.2 above. 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 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 considering the exposure and risk estimates, the Administrator also notes that the eight study areas assessed represent an array of air quality and exposure circumstances reflecting such variation that occurs across the U.S. The areas fall into seven of the nine climate regions represented in the continental U.S., with populations of the associated metropolitan areas ranging in size from approximately 2.4 to 8 million and varying in demographic characteristics. The Administrator considers such factors as those identified here to contribute to their usefulness in informing the current review. As a result of such variation in exposure-related factors, the eight study areas represent an array of exposure circumstances, and accordingly, illustrate the magnitude of exposures and risks that may be expected in areas of the U.S. that just meet the current standard but that may differ in ways affecting population exposures of interest. The Administrator finds the estimates from these analyses to be informative to consideration of potential exposures and risks associated with the current standard and to his judgment on the adequacy of protection provided by the current standard.

Taking into consideration related information, limitations and uncertainties, such as those recognized above, the Administrator considers the exposure estimates across the eight study areas (with their array of exposure conditions) for air quality conditions just meeting the current standard. Given the greater severity of responses reported in controlled human exposures, with quasi-continuous exercise, at and above 73 ppb, the Administrator finds it appropriate to focus 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 so doing, he notes that across all eight study areas, less than 1% of children with asthma (and also of all children) are estimated to experience, while breathing at an elevated rate, a daily maximum 7-hour exposure per year at or above 70 ppb, on average across the 3-year period, with a maximum of about 1% for the study area with the highest estimates in the highest single year (Table 2). Further, the percentage (for both population groups) for at least one day with such an exposure at or above 80 ppb is less than 0.1%, as an average across the 3-year period (and 0.1% or less in each of the three years simulated across the eight study areas). No simulated children were estimated to experience more than a single such day with an exposure at or above the 80 ppb benchmark (Table 2). The Administrator recognizes these estimates to indicate a very high level of protection from exposures that been found in controlled human exposure studies to elicit lung function decrements of notable magnitude (*e.g.,* 6% at the study group mean for exposure to 73 ppb) accompanied by increases in respiratory symptom scores, as summarized in section II.B.3.

The Administrator additionally considers the estimated occurrences of days that include lower 7-hour exposures, while at elevated exertion (*i.e.,* daily maximum exposures at or above 60 ppb). In so doing, the Administrator takes note of the lesser severity of effects observed in controlled human exposure studies to 60 ppb (while at increased exertion) compared to the effects at the higher concentrations that have been studied (*e.g.,* statistically significant O_3-related decrements on the order of 2 to 3% at the study group mean compared to 6%). He notes the finding of statistically significant increased respiratory symptom scores with exposures targeted at an exposure concentration of 70 ppb (and averaging 73 ppb across the exposure period), and the lack of such finding for any lower exposure concentrations that have been studied. In light of these considerations, he finds occurrences of exposures at or above the lowest benchmark of 60 ppb to be of lesser concern than occurrences for the next higher benchmark of 70 ppb. As described above for the higher exposure concentrations, he additionally recognizes that the studies of 60 ppb were of generally healthy adults. While he notes the uncertainty regarding the risk that may be posed by this exposure concentration to at-risk populations, such as people with asthma, he additionally notes that the limited evidence available at higher exposure concentrations indicates lung function responses for this group that are similar to those for the generally healthy subjects, as well as the evidence of the transience of the responses in controlled human exposure studies. Further, he considers that due to the inherent characteristics of asthma as a disease, there is a potential, as summarized in section II.B.2 above, for O_3 exposures to trigger asthmatic responses, such as through causing an increase in airway responsiveness. In this context, he additionally recognizes 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. In recognizing that the finding for this exposure concentration is for generally healthy adults and does not directly relate to people with asthma, he finds it appropriate to give additional consideration to the two lower benchmarks. In so doing, he judges that a high level of protection is desirable against one or more occurrences of days with exposures while breathing at an elevated rate to concentrations at or above 70 ppb. Additionally, he takes note of the lesser severity of responses observed in studies of the lowest benchmark concentration of 60 ppb, while considering the exposure analysis estimates of occurrences of daily maximum exposures at or above this benchmark, while also recognizing there to be greater risk for occurrence of a more serious effect with greater frequency of such exposure occurrence. Thus, based on the considerations recognized here, including potential risks for at-risk populations, the Administrator considers it appropriate to give greater weight to the exposure analysis estimates of occurrences of two or more days (rather than one or more) with an exposure at or above the 60 ppb benchmark.

The exposure analysis estimates indicate fewer than 1% to just over 3% of children with asthma (just under 3% of all children), on average across the 3-year period to be expected to experience two or more days with an exposure at or above 60 ppb, while at elevated ventilation. The Administrator notes this to indicate that some 97% to more than 99% of children, on average, and more than 95% in the single highest year, are protected from experiencing two or more days with exposures at or above 60 ppb while at elevated exertion. He also considers this in combination with the high level of protection indicated by the exposure estimates for the higher benchmark concentration of 70 ppb, which is slightly below the exposure level at which increases in FEV_1 decrement (6% at the study group mean) accompanied by respiratory symptoms have been demonstrated. The current exposure analysis, with reduced uncertainty compared to the analysis available in the last review for air quality conditions in areas that just meet the current standard, indicates more than 99% of children with asthma (and of all children), on average per year, to be protected from a day or more with an exposure at or above 70 ppb. In light of all of the considerations summarized above, the Administrator proposes to judge that protection from these exposures, as described here, provides a strong degree of protection to at-risk populations such as children with asthma. In light of all of the above, the Administrator finds the updated exposure and risk analyses based on updated and improved information, including air quality concentrations closer to the current standard, to 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.

In reaching his proposed conclusion, the Administrator additionally takes 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 associated conclusion expressed by part of the CASAC, that the current evidence supports retaining the current standard. He also notes 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, 2020, p. 1). With regard to the latter view (that referenced 2014 comments from the prior CASAC), the Administrator additionally notes 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, 2014, p. ii). The Administrator considers these points to provide additional context for the comments of the prior CASAC that were cited by part of the current CASAC in its review of the draft PA in this review, as noted above.[105]

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.D.1 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 proposes to judge that a less stringent standard would not be appropriate to consider.

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, 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 (summarized in section II.D.1 above) 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 uncertainty in the estimates. 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. He considers this 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, and proposes to conclude, in light of all of the considerations raised here, that the current standard provides an adequate margin of safety, and that a more stringent standard is not needed.

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 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 proposes to judge that the current standard provides the requisite protection, including an adequate margin of safety, and thus should be retained, without revision.

As recognized above, 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

[105] 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).

concentration averaged across three years. The Administrator finds 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, as discussed above. In summary, the Administrator recognizes the newly available health effects evidence, critically assessed in the ISA as part of the full body of evidence, to reaffirm conclusions on the respiratory effects recognized for O_3 in the last review. He additionally notes 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 notes 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 above) provide the basis for the Administrator's 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 proposes 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. The Administrator solicits comment on these proposed conclusions.

Having reached the proposed decision described here based on interpretation of the health effects evidence, as assessed in the ISA, and the quantitative analyses presented in the PA; the evaluation of policy-relevant aspects of the evidence and quantitative analyses in the PA; the advice and recommendations from the CASAC; public comments received to date in this review; and the public health policy judgments described above, the Administrator recognizes that other interpretations, assessments and judgments might be possible. Therefore, the Administrator solicits comment on the array of issues associated with review of this standard, including public health and science policy judgments inherent in the proposed decision, as described above, and the rationales upon which such views are based.

III. Rationale for Proposed Decision on the Secondary Standard

This section presents the rationale for the Administrator's proposed decision to retain the current secondary O_3 standard. This rationale is 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 (ISA, section IS.1.2),[106] integrated with the information and conclusions from previous assessments and presented in the ISA on welfare effects associated with photochemical oxidants including O_3 and pertaining to their presence in ambient air. 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 received during the development of these documents; 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).

In presenting the rationale for the Administrator's proposed decision and its foundations, section III.A provides background and introductory information for this review of the secondary O_3 standard. It includes background on the establishment of the current standard in 2015 (section III.A.1) and also describes the general approach for its current review (section III.A.2). Section III.B summarizes the currently available welfare effects evidence, focusing on consideration of key policy-relevant aspects. Section III.C summarizes current air quality and environmental exposure information, drawing on the quantitative analyses presented in the PA. Section III.D presents the Administrator's proposed conclusions on the current standard (section III.D.3), drawing on both evidence-based and air quality, exposure and risk-based considerations (section III.D.1) and advice from the CASAC (section III.D.2).

A. General Approach

As is the case for all such reviews, this review of the current secondary O_3 standard is based, most fundamentally, on using the EPA's assessments of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgment regarding a secondary standard 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 determining whether the current standard provides the requisite public welfare protection, the PA evaluates policy implications of the evaluation 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 with regard to the standard, the decision will draw 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

[106] 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.*

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.

The subsections below provide background and introductory information. Background on the establishment of the current standard in 2015, including the rationale for that decision, is summarized in section III.A.1. This is followed, in section III.A.2, by an overview of the general approach for the current review of the 2015 standard. Following this introductory section and subsections, the subsequent sections summarize current information and analyses, including that newly available in this review. The Administrator's proposed conclusions on the standard set in 2015, based on the current information, are provided in section III.D.3

1. Background on the Current Standard

The current standard was set in 2015 based on the scientific and technical information 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). With the 2015 decision, the Administrator revised the level of the secondary standard for photochemical oxidants, including O_3, to 0.070 ppm, in conjunction with retaining the indicator (O_3), averaging time (8 hours) and form (fourth-highest annual daily maximum 8-hour average concentration, averaged across three years).

The welfare effects evidence base available in the 2015 review included 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, 1996, pp. 5–28 and 5–29). 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).[107] Such effects at the plant scale can also be linked to an array of effects at larger organizational (*e.g.,* population, community, system) and spatial scales, with the evidence available in the last review supporting conclusions of causal relationships between O_3 and alteration of below-ground biogeochemical cycles, in addition to 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). Further, 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).

The 2015 decision was a public welfare policy judgment made by the Administrator, which 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. The analyses utilized cumulative, concentration-weighted exposure indices for O_3. Use of this metric was based on conclusions in the 2013 ISA that exposure indices that cumulate hourly O_3 concentrations, giving greater weight to the higher concentrations (such as the W126 index), perform well in describing exposure-response relationships documented in crop and tree seedling studies (2013 ISA, section 9.5). 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.

The decision was based on a thorough review in the 2013 ISA of the scientific information on O_3-induced environmental effects. The decision also took into account: (1) 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[108] and potential alternative standard levels in combination with the form and averaging time of the then-current standard; (2) additional air quality analyses of the W126 index and design values based on the form and averaging time of the then-current standard; (3) CASAC advice and recommendations; and (4) public comments received during the development of these documents and on the proposal document. 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.

Consistent with the general approach routinely employed in NAAQS reviews, the initial consideration in the 2015 review of the secondary standard was

[107] Visible foliar injury includes leaf or needle changes such as small dots or bleaching (2013 ISA, p. 9–38).

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

with regard to the adequacy of protection provided by the existing standard, that was set in 2008 (0.075 ppm, as annual fourth-highest daily maximum 8-hour average concentration averaged over three consecutive years). In her decision making, 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 relative biomass loss (RBL), with the evidence base providing robust and established exposure-response (E–R) functions for seedlings of 11 tree species (80 FR 65391–92, October 26, 2015; 2014 PA, Appendix 5C).[109] The Administrator used this surrogate or proxy in making her judgments on O_3 effects to the public welfare. In this context, exposure was evaluated in terms of the W126 cumulative seasonal 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).

In considering the public welfare protection provided by the then-current standard, the Administrator gave primary consideration to an analysis of cumulative seasonal exposures in or near Class I areas[110] during periods when the then-current standard was met, and the associated estimates of growth effects in well-studied species of tree seedlings, in terms of the O_3 attributable reductions in RBL in the median species for which E–R functions have been established (80 FR 65385–65386, 65389–65390, October 26, 2015).[111] The Administrator noted the occurrence of exposures for which the associated median estimates of growth effects across the species with E–R functions extend above a magnitude considered to be ''unacceptably high'' by the CASAC.[112] This analysis estimated cumulative exposures, in terms of 3-year average W126 index values, at and above 19 ppm-hrs, occurring under the then-current standard for nearly a dozen areas, distributed across two NOAA climatic regions of the U.S. (80 FR 65385–86, October 26, 2015). The Administrator gave particular weight to this analysis because of its focus on exposures in Class I areas, 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. This emphasis on lands afforded special government protections, such as national parks and forests, wildlife refuges, and wilderness areas, some of which are designated Class I areas under the CAA, was consistent with a similar emphasis in the 2008 review of the standard (73 FR 16485, March 27, 2008). The Administrator 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).

As noted across past reviews of O_3 secondary standards, the Administrator's judgments regarding effects that are adverse to public welfare consider the intended use of the ecological receptors, resources and ecosystems affected (80 FR 65389, October 26, 2015; 73 FR 16496, March 27, 2008). Thus, in the 2015 review, the Administrator utilized the median RBL estimate for the studied species as a quantitative tool within a larger framework of considerations pertaining to the public welfare significance of O_3 effects. She recognized such considerations to include effects that are associated with effects on growth and that the 2013 ISA determined to be 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. These other effects included reduced productivity in terrestrial ecosystems, reduced carbon sequestration in terrestrial ecosystems, alteration of terrestrial community composition, alteration of below-ground biogeochemical cycles, and alteration of terrestrial ecosystem water cycles. Thus, in giving attention to the CASAC's characterization of a 6% estimate for tree seedling RBL in the median studied species as ''unacceptably high'', the Administrator, while mindful of uncertainties with regard to the magnitude of growth impact that might be expected in the field and in mature trees, was also mindful 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. As a result, the Administrator considered tree growth effects of O_3, in terms of RBL ''as a surrogate for the broader array of O_3 effects at the plant and ecosystem levels'' (80 FR 65389, October 26, 2015).

Based on all of these considerations, and taking into consideration CASAC advice and public comment, the Administrator concluded that the protection afforded by the then-current 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 for residents on those lands, as well as for visitors to those areas. 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 (80 FR 65390, October 26, 2015).

Consistent with the approach employed for considering the adequacy of the then-current secondary standard, the approach for considering revisions

[109] 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).

[110] 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.

[111] In specifically evaluating exposure levels in terms of the W126 index as to potential for impacts on vegetation, the Administrator focused on the median RBL estimate across the eleven tree species for which robust established E–R functions were available. The presentation of these E–R functions for growth effects on tree seedlings (and crops) included estimates of RBL (and relative yield loss [RYL]) at a range of W126-based exposure levels (2014 PA, Tables 5C–1 and 5C–2). The median tree species RBL or crop RYL was presented for each W126 level (2014 PA, Table 5C–3; 80 FR 65391 [Table 4], October 26, 2015). The Administrator focused on RBL as a surrogate or proxy for the broader array of vegetation-related effects of potential public welfare significance, which include effects on growth of individual sensitive species and extend to ecosystem-level effects, such as community composition in natural forests, particularly in protected public lands, as well as forest productivity (80 FR 65406, October 26, 2015).

[112] In the CASAC's consideration of RBL estimates presented in the 2014 draft PA, it characterized an estimate of 6% RBL in the median studied species as being ''unacceptably high,'' (Frey, 2014b).

that would result in a standard providing the requisite protection under the Act also focused on growth-related effects of O_3, using RBL as a surrogate for the broader array of vegetation-related effects and included judgments on the magnitude of such effects that would contribute to public welfare impacts of concern. In considering the adequacy of potential alternative standards to provide protection from such effects, the approach also focused on considering the cumulative seasonal O_3 exposures likely to occur with different alternative standards.

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 such a 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 for current and future generations, as well as areas similarly set aside by states, tribes and public interest groups with the intention of providing similar benefits to the public welfare. 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).

As mentioned above, the Administrator considered the use of a cumulative seasonal exposure index (the W126 index) for purposes of assessing potential public welfare risks, and similarly, for assessing potential protection achieved against such risks on a national scale. In consideration of conclusions of the 2013 ISA and 2014 PA, as well as advice from the CASAC and public comments, this W126 index was defined as a maximum, seasonal (3-month), 12-hour index (80 FR 65404, October 26, 2015).[113] While recognizing that no one definition of an exposure metric used for the assessment of protection for multiple effects at a national scale will be exactly tailored to every species or each vegetation type, ecosystem and region of the country, the Administrator judged that on balance, a W126 index derived in this way, and averaged over three years would be appropriate for such purposes (80 FR 65403, October 26, 2015).

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 (80 FR 65404, October 26, 2015). For example, the Administrator was mindful of both the strengths and limitations of the evidence and of the information on which to base her judgments with regard to adversity of effects on the public welfare.[114] While the Administrator recognized the scientific information and interpretations, as well as CASAC advice, with regard to a single-year exposure index, she also took note of uncertainties associated with judging the degree of vegetation impacts for single-year effects that would be adverse to public welfare. The Administrator was also mindful of the variability in ambient air O_3 concentrations from year to year, as well as year-to-year variability in environmental factors, including rainfall and other meteorological factors, that influence the occurrence and magnitude of O_3-related effects in any year, and contribute uncertainties to interpretation of the potential for harm to public welfare over the longer term (80 FR 65404, October 26, 2015).

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).[115]

With regard to the extensive evidence of welfare effects of O_3, including visible foliar injury and crop RYL, the information available for tree species was judged to be more useful in informing judgments regarding the nature and severity of effects associated with different air quality conditions and associated public welfare significance. Accordingly, the Administrator gave particular attention to the effects related to native tree growth and productivity, including forest and forest community composition, recognizing the relationship of tree growth and productivity to a range of ecosystem services, (80 FR 65405–06, October 26, 2015). In making this judgment, the Administrator recognized that among the broad array of O_3-induced vegetation effects were the occurrence of visible foliar injury and growth and/or yield loss in O_3-sensitive species, including crops and other commercial species (80 FR 65405, October 26, 2015). In regard to visible foliar injury, 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, with the significance of O_3-induced visible foliar injury depending on the extent and severity of the injury (80 FR 65407, October 26, 2015). In so doing, however, the Administrator also took note of limitations in the available visible foliar injury information, including the lack of established E–R functions that would allow prediction of

[113] As also described in section III.B.3.a below, this index is defined by the 3-consecutive-month period within the O_3 season with the maximum sum of W126-weighted hourly O_3 concentrations during the period from 8:00 a.m. to 8:00 p.m. each day.

[114] In this regard, 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. The Administrator 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).

[115] 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).

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 that might inform consideration of potential public welfare impacts related to this vegetation effect (80 FR 65407, October 26, 2015). 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).[116]

Thus, and in light of the extensive evidence base in this regard, the Administrator focused on trees and associated ecosystems in identifying the appropriate level of protection for the secondary standard. Accordingly, the Administrator found the estimates of tree seedling growth impacts (in terms of RBL) associated with a range of W126-based index values developed from the E–R functions for 11 tree species (referenced above) to be appropriate and useful for considering the appropriate public welfare protection objective for a revised standard (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 recognized she 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 and ecosystem effects of potential public welfare significance that include effects on growth of individual sensitive species and extend to ecosystem-level effects, such as community composition in natural forests, particularly in protected public lands, as well as forest productivity (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, and in consideration of CASAC advice; strengths, limitations and uncertainties in the evidence; and the linkages of growth effects to larger population, community and ecosystem impacts, the Administrator considered it appropriate to focus on a 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 focusing on cumulative exposures associated with a median RBL estimate somewhat below 6%, the Administrator considered the relationships between W126-based exposure and RBL in the studied species (presented in the final PA and proposal document), noting 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).[117] Given the information on median RBL at different W126 exposure levels, using a 3-year cumulative exposure index for assessing vegetation effects, 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 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 (80 FR 65407, October 26, 2015).

The Administrator's decisions regarding the revisions to the then-current standard that would appropriately achieve these public welfare protection objectives were based on extensive air quality analyses that extended from the then most recently available data (monitoring year 2013) 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, indicating reductions in cumulative exposures associated with air quality meeting lower levels of a standard of the existing form and averaging time. Based on these analyses, the Administrator judged that the desired level of public welfare protection could be achieved with a secondary standard having a revised level in combination with the existing form and averaging time (80 FR 65408, October 26, 2015).

The air quality analyses described the occurrences of 3-year W126 index values of various magnitudes at monitor locations where O_3 concentrations met potential alternative standards; the alternative standards were different levels for the current form and averaging time (annual fourth-highest daily maximum 8-hour average concentration, averaged over three consecutive years) (Wells, 2015). In the then-most recent period, 2011–2013, across the more than 800 monitor locations meeting the then-current standard (with a level of 75 ppb), the 3-year W126 index values were above 17 ppm-hrs in 25 sites distributed across different NOAA climatic regions, and above 19 ppm-hrs at nearly half of these sites, with some well above. In comparison, among sites meeting an alternative standard of 70 ppb, there were no occurrences of a W126 value above 17 ppm-hrs and fewer than a handful of occurrences that equaled 17 ppm-hrs.[118] For the longer

[116] With respect to commercial production of commodities, the Administrator noted that judgments about the extent to which O_3-related effects on commercially managed vegetation are adverse from a public welfare perspective are particularly difficult to reach, 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. The management practices used on such vegetation are highly variable and are designed to achieve optimal yields, taking into consideration various environmental conditions. In addition, changes in yield of commercial crops and commercial commodities, such as timber, may affect producers and consumers differently, further complicating the question of assessing overall public welfare impacts (80 FR 65405, October 26, 2015).

[117] 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).

[118] The more than 500 monitors that would meet an alternative standard of 70 ppb during the 2011–2013 period were distributed across all nine NOAA climatic regions and 46 of the 50 states (Wells, 2015

time period (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.

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).

and associated dataset in the docket [document identifier, EPA–HQ–OAR–2008–0699–4325]).

2. Approach for the Current Review

To evaluate whether it is appropriate to consider retaining the now current secondary O_3 standard, or whether consideration of revision is appropriate, the EPA has adopted an approach in this review that builds upon the general approach used in the last review and reflects the body of evidence and information now available. Accordingly the approach in this review takes into consideration the approach used in the last review, including the substantial assessments and evaluations performed over the course of that review, and also taking into account the more recent scientific information and air quality data now available to inform understanding of the key policy-relevant issues in the current review. As summarized above, the Administrator's decisions in the prior review were based on an integration of O_3 welfare effects information with judgments on the public welfare significance of key effects, policy judgments as to when the standard is requisite, consideration of CASAC advice, and consideration of public comments.

Similarly, in this review we draw on the current evidence and quantitative analyses of air quality and exposure pertaining to the welfare effects of O_3 in ambient air. In so doing, we consider both the information available at the time of the last review and information more recently available, including that which has been critically analyzed and characterized in the current ISA. The evaluations in the PA, of the potential implications of various aspects of the scientific evidence assessed in the ISA (building on prior such assessments), augmented by the quantitative air quality, exposure or risk-based information, are also considered along with the associated uncertainties and limitations.

This review of the secondary O_3 standard also considers the August 2019 decision by the D.C. Circuit on the secondary standard established in 2015 and issues raised by the court in its remand of that standard to the EPA such that the decision in this review will incorporate the EPA's response to this remand. The opinion issued by the court concluded, in relevant part, that EPA had not provided a sufficient rationale for aspects of its decision on the 2015 secondary standard. See *Murray Energy Corp.* v. *EPA,* 936 F.3d 597 (D.C. Cir. 2019). Accordingly, the court remanded the secondary 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, 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.[119] Thus, in addition to considering the currently available welfare effects evidence and quantitative air quality, exposure and risk information, this proposed decision on the secondary standard that was established in 2015, and the associated proposed conclusions and judgments, also consider the court's remand. In so doing, we have, for example, expanded certain analyses in this review compared with those conducted in the last review, included discussion on issues raised in the remand, and provided additional explanation of rationales for proposed conclusions on these points in this review. Together, the information, evaluations and considerations recognized here inform the Administrator's public welfare policy judgments and conclusions, including his decision as to whether to retain or revise this standard.

B. Welfare Effects Information

The information summarized here is based on our scientific assessment of the welfare effects evidence available in this review; this assessment is documented in the ISA [120] and its policy

[119] 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 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).

[120] 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 cited when providing further details not repeated in newer assessments.

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, p. IS–3). 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. Further, ''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 current welfare effects evidence and the Agency's review of the evidence, including the evidence newly available in this review, continues to focus on O_3.

More than 1600 studies are newly available and considered in the ISA, including more than 500 studies on welfare effects (ISA, Appendix 10, Figure 10–2). While expanding the evidence for some effect categories, studies on growth-related effects, a key group of effects from the last review, are largely consistent with the evidence that was previously available. Policy implications of the currently available evidence are discussed in the PA (as summarized in section III.D.1 below). The subsections below briefly summarize the following aspects of the evidence: The nature of O_3-related welfare effects (section III.B.1), the potential public welfare implications (section III.B.2), and exposure concentrations associated with effects (section III.B.3).

1. Nature of Effects

The welfare effects evidence base available in the current review includes 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 (1978 AQCD, 1986 AQCD, 1996 AQCD, 2006 AQCD, 2013 ISA, 2020 ISA). 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 (1996 AQCD, pp. 5–28 and 5–29). For seed-bearing plants, reproductive effects can include reduced seed or fruit production or yield. The strongest evidence for effects from O_3 exposure on vegetation was recognized at the time of the last review to be 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 evidence in the last review 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. Evidence newly available in this review augments more limited previously available evidence related to insect interactions with vegetation, contributing to conclusions regarding O_3 effects on plant-insect signaling (ISA, Appendix 8, section 8.7) and on insect herbivores (ISA, Appendix 8, section 8.6), as well as for ozone effects on tree mortality (Appendix 8, section 8.4). Thus, conclusions reached in the last review are supported by the current evidence base and conclusions are also reached in a few new areas based on the now expanded evidence.

The current evidence base, including a wealth of longstanding evidence, supports the conclusion of causal relationships between O_3 and visible foliar injury, reduced vegetation growth and reduced plant reproduction,[121] as well as reduced yield and quality of agricultural crops, reduced productivity in terrestrial ecosystems, alteration of terrestrial community composition,[122] and alteration of belowground biogeochemical cycles (ISA, section IS.5). Based on the current evidence base, the ISA also concluded 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). Additional evidence newly available in this review is concluded by the ISA to support conclusions on two additional plant-related effects: The body of evidence is concluded to be sufficient to infer that there is likely to be a causal relationship between O_3 exposure and alteration of plant-insect signaling, and to infer that there is likely to be a causal relationship between O_3 exposure and altered insect herbivore growth and reproduction (ISA, Table IS–12).

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. 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.B.2 below). The following summary addresses the identified vegetation-related effects of O_3 across these scales.

The current evidence, consistent with the decades of previously available evidence, documents and characterizes visible foliar injury in many tree, shrub, herbaceous, and crop species as an effect of exposure to O_3 (ISA, Appendix 8, section 8.2; 2013 ISA, section 9.4.2; 2006 AQCD, 1996 AQCD, 1986 AQCD, 1978 AQCD). As was also stated in the last scientific assessment, ''[r]ecent experimental evidence continues to show a consistent association between visible injury and ozone exposure'' (ISA, Appendix 8, section 8.2, p. 8–13; 2013 ISA, section 9.4.2, p. 9–41). Ozone-induced visible foliar injury symptoms on certain tree and herbaceous species, such as black cherry, yellow-poplar and common milkweed, have long been considered diagnostic of exposure to elevated O_3 based on the consistent association established with experimental evidence (ISA, Appendix 8, section 8.2; 2013 ISA, p. 1–10).[123]

[121] The 2013 ISA did not include a separate causality determination for reduced plant reproduction. Rather, it was included with the conclusion of a causal relationship with reduced vegetation growth (ISA, Table IS–12).

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

[123] As described in the ISA, ''[t]ypical types of visible injury to broadleaf plants include stippling, flecking, surface bleaching, bifacial necrosis,

The currently available evidence, consistent with that in past reviews, indicates 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). Further, the significance of O_3 injury at the leaf and whole plant levels also depends on an array of factors that include the amount of total leaf area affected, age of plant, size, developmental stage, and degree of functional redundancy among the existing leaf area (ISA, Appendix 8, section 8.2; 2013 ISA, section 9.4.2). In this review, as in the past, such modifying factors contribute to the difficulty in quantitatively relating visible foliar injury to other vegetation effects (*e.g.,* individual tree growth, or effects at population or ecosystem levels), such that visible foliar injury ''is not always a reliable indicator of other negative effects on vegetation'' (ISA, Appendix 8, section 8.2, p. 8–24; 2013 ISA, p. 9–39).[124]

Consistent with conclusions in past reviews, the evidence, extending back several decades, continues to document the detrimental effects of O_3 on plant growth and reproduction (ISA, Appendix 8, sections 8.3 and 8.4; 2013 ISA, p. 9–42). The available studies come from a variety of different study types that cover an array of different species, effects endpoints, and exposure methods and durations. In addition to studies on scores of plant species that have found O_3 to reduce plant growth, the evidence accumulated over the past several decades documents O_3 alteration of allocation of biomass within the plant and plant reproduction (ISA, Appendix 8, sections 8.3 and 8.4; 2013 ISA, p. 1–10). The biological mechanisms underlying the effect of O_3 on plant reproduction include ''both direct negative effects on reproductive tissues and indirect negative effects that result from decreased photosynthesis and other whole plant physiological changes'' (ISA, p. IS–71). A newly available meta-analysis of more than 100 studies published between 1968 and 2010 summarizes effects of O_3 on multiple measures of reproduction (ISA, Appendix 8, section 8.4.1).

Studies involving experimental field sites have also reported effects on measures of plant reproduction, such as effects on seeds (reduced weight, germination, and starch levels) that could lead to a negative impact on species regeneration in subsequent years, and bud size that might relate to a delay in spring leaf development (ISA, Appendix 8, section 8.4; 2013 ISA, section 9.4.3; Darbah et al., 2007, Darbah et al., 2008). A more recent laboratory study reported 6-hour daily O_3 exposures of flowering mustard plants to 100 ppb during different developmental stages to have mixed effects on reproductive metrics. While flowers exposed early *versus* later in development produced shorter fruits, the number of mature seeds per fruit was not significantly affected by flower developmental stage of exposure (ISA, Appendix 8, section 8.4.1; Black et al., 2012). Another study assessed seed viability for a flowering plant in laboratory and field conditions, finding effects on seed viability of O_3 exposures (90 and 120 ppb) under laboratory conditions but less clear effects under more field-like conditions (ISA, Appendix 8, section 8.4.1; Landesmann et al., 2013).

With regard to agricultural crops, the current evidence base, as in the last review, is sufficient to infer a causal relationship between O_3 exposure and reduced yield and quality (ISA, section IS.5.1.2). The current evidence is augmented by new research in a number of areas, including studies on soybean, wheat and other nonsoy legumes. The new information assessed in the ISA remains consistent with the conclusions reached in the 2013 ISA (ISA, section IS.5.1.2).

The evidence base for trees includes a number of studies conducted at the Aspen free-air carbon-dioxide and ozone enrichment (FACE) experiment site in Wisconsin (that operated from 1998 through 2011) and also available in the last review (ISA, IS.5.1 and Appendix 8, section 8.1.2.1; 2013 ISA, section 9.2.4). These studies, which occurred in a field setting (more similar to natural forest stands than open-top-chamber studies), reported reduced tree growth when grown in single or three species stands within 30-m diameter rings and exposed over one or more years to elevated O_3 concentrations (hourly concentrations 1.5 times concentrations in ambient air at the site) compared to unadjusted ambient air concentrations (2013 ISA, section 9.4.3; Kubiske et al., 2006, Kubiske et al., 2007).[125]

With regard to tree mortality, the 2013 ISA did not include a determination of causality (ISA, Appendix 8, section 8.4). While the then-available evidence included studies identifying ozone as a contributor to tree mortality, which contributed to the 2013 conclusion regarding O_3 and alteration of community composition (2013 ISA, section 9.4.7.4), a separate causality determination regarding O_3 and tree mortality was not assessed (ISA, Appendix 8, section 8.4; 2013 ISA, Table 9–19). The evidence assessed in the 2013 ISA (and 2006 AQCD) was largely observational, including studies that reported declines in conifer forests for which elevated O_3 was identified as contributor but in which a variety of environmental factors may have also played a role (2013 ISA, section 9.4.7.1; 2006 AQCD, sections AX9.6.2.1, AX9.6.2.2, AX9.6.2.6, AX9.6.4.1 and AX9.6.4.2). Since the last review, three additional studies are available (ISA, Appendix 8, Table 8–9). Two of these are analyses of field observations, one of which is set in the Spanish Pyrenees.[126] A second study is a large-scale empirical statistical analysis of factors potentially contributing to tree mortality in eastern and central U.S. forests during the 1971–2005 period, which reported O_3 (county-level 11-year [1996–2006] average 8 hour metric)[127] to be ninth among the 13 potential factors assessed[128] and to have a

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).

[124] Similar to the 2013 ISA, the ISA for the current review states the following (ISA, pp. 8–24).

Although visible injury is a valuable indicator of the presence of phytotoxic concentrations of ozone in ambient air, it is not always a reliable indicator of other negative effects on vegetation [*e.g.,* growth, reproduction; U.S. EPA (2013)]. 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 (U.S. EPA, 2013). Previous ozone AQCDs have noted the difficulty in relating visible foliar injury symptoms to other vegetation effects, such as individual plant growth, stand growth, or ecosystem characteristics (U.S. EPA, 2006, 1996). Thus, it is not presently possible to determine, with consistency across species and environments, what degree of injury at the leaf level has significance to the vigor of the whole plant.

[125] Seasonal (90-day) W126 index values for unadjusted O_3 concentrations over six years of the Aspen FACE experiments ranged from 2 to 3 ppm-hrs, while the elevated exposure concentrations (reflecting addition of O_3 to ambient air concentrations) ranged from somewhat above 20 to somewhat above 35 ppm-hrs (ISA, Appendix 8, Figure 8–17).

[126] The concentration gradient with altitude in the Spanish study, includes—at the highest site—annual average April-to-September O_3 concentrations for the 2004 to 2007 period that range up to 74 ppb (Diaz-de-Quijano et al., 2016).

[127] Annual fourth highest daily maximum 8-hour O_3 concentrations in these regions were above 80 ppb in the early 2000s and median design values at national trend sites were nearly 85 ppb (PA, Figures 2–11 and 2–12).

[128] This statistical analysis, which utilized datasets from within the 1971–2005 period,

Continued

significant positive correlation with tree mortality (ISA, section IS.5.1.2, Appendix 8, section 8.4.3; Dietze and Moorcroft, 2011). A newly available experimental study also reported increased mortality in two of five aspen genotypes grown in mixed stands under elevated O_3 concentrations (ISA, section IS.5.1.2; Moran and Kubiske, 2013). Coupled with the plant-level evidence of phytotoxicity discussed above, as well as consideration of community composition effects, this evidence was concluded to indicate the potential for elevated O_3 concentrations to contribute to tree mortality (ISA, section IS.5.1.2 and Appendix 8, sections 8.4.3 and 8.4.4). Based on the current evidence, the ISA concludes there is likely to be a causal relationship between O_3 and increased tree mortality (ISA, Table IS–2, Appendix 8, section 8.4.4). A variety of factors in natural environments can either mitigate or exacerbate predicted O_3-plant interactions and are recognized sources of uncertainty and variability. Such factors at the plant level include multiple genetically influenced determinants of O_3 sensitivity, changing sensitivity to O_3 across vegetative growth stages, co-occurring stressors and/or modifying environmental factors (ISA, Appendix 8, section 8.12).

Ozone-induced effects at the scale of the whole plant have the potential to translate to effects at the ecosystem scale, such as 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. For example, under the relevant exposure conditions, O_3-related reduced tree growth and reproduction, as well as increased mortality, could lead to reduced ecosystem productivity. Recent studies from the Aspen FACE experiment and modeling simulations indicate that O_3-related negative effects on ecosystem productivity may be temporary or may be limited in some systems (ISA, Appendix 8, section 8.8.1). Previously available studies had reported impacts on productivity in some forest types and locations, such as ponderosa pine in southern California and other forest types in the mid-Atlantic region (2013 ISA, section 9.4.3.4). Through reductions in sensitive species growth, and related ecosystem productivity, O_3 could lead to reduced ecosystem carbon storage (ISA, IS.5.1.4; 2013 ISA, section 9.4.3). With regard to forest community composition, available studies have reported changes in tree communities composed of species with relatively greater and relatively lesser sensitivity to O_3 (ISA, section IS.5.1.8.1, Appendix 8, section 8.10; 2013 ISA, section 9.4.3; Kubiske et al., 2007). As the ISA concludes, ''[t]he extent to which ozone affects terrestrial productivity will depend on more than just community composition, but other factors, which both directly influence [net primary productivity] (*i.e.,* availability of N and water) and modify the effect of ozone on plant growth'' (ISA, Appendix 8, section 8.8.1). Thus, the magnitude of O_3 impact on ecosystem productivity, as on forest composition, can vary among plant communities based on several factors, including the type of stand or community in which the sensitive species occurs (*e.g.,* single species *versus* mixed canopy), the role or position of the species in the stand (*e.g.,* dominant, sub-dominant, canopy, understory), and the sensitivity of co-occurring species and environmental factors (*e.g.,* drought and other factors).

The effects of O_3 on plants and plant populations have implications for ecosystem functions. Two such functions, effects with which O_3 is concluded to be likely causally or causally related, are ecosystem water cycling and belowground biogeochemical cycles, respectively (ISA, Appendix 8, sections 8.11 and 8.9). With regard to the former, the effects of O_3 on plants (*e.g., via* stomatal control, as well as leaf and root growth and changes in wood anatomy associated with water transport) can affect ecosystem water cycling through impacts on root uptake of soil moisture and groundwater as well as transpiration through leaf stomata to the atmosphere (ISA, Appendix 8, section 8.11.1). These ''impacts may in turn affect the amount of water moving through the soil, running over land or through groundwater and flowing through streams'' (ISA, Appendix 8, p. 8–161). Evidence newly available in this review is supportive of previously available evidence in this regard (ISA, Appendix 8, section 8.11.6). The current evidence, including that newly available, indicates the extent to which the effects of O_3 on plant leaves and roots (*e.g.,* through effects on chemical composition and biomass) can impact belowground biogeochemical cycles involving root growth, soil food web structure, soil decomposer activities, soil microbial respiration, soil carbon turnover, soil water cycling and soil nutrient cycling (ISA, Appendix 8, section 8.9).

Additional vegetation-related effects with implications beyond individual plants include the effects of O_3 on insect herbivore growth and reproduction and plant-insect signaling (ISA, Table IS–12, Appendix 8, sections 8.6 and 8.7). With regard to insect herbivore growth and reproduction, the evidence includes multiple effects in an array of insect species, although without a consistent pattern of response for most endpoints (ISA, Appendix 8, Table 8–11). As was also the case with the studies available at the time of the last review,[129] in the newly available studies individual-level responses are highly context- and species-specific and not all species tested showed a response (ISA, section IS.5.1.3 and Appendix 8, section 8.6). Evidence on plant-insect signaling that is newly available in this review comes from laboratory, greenhouse, open top chambers (OTC) and FACE experiments (ISA, section IS.5.1.3 and Appendix 8, section 8.7). The available evidence indicates a role for elevated O_3 in altering and degrading emissions of chemical signals from plants and reducing detection of volatile plant signaling compounds (VPSCs) by insects, including pollinators. Elevated O_3 concentrations degrade some VPSCs released by plants, potentially affecting ecological processes including pollination and plant defenses against herbivory. Further, the available studies report elevated O_3 conditions to be associated with plant VPSC emissions that may make a plant either more attractive or more repellant to herbivorous insects, and to predators and parasitoids that target phytophagous (plant-eating) insects (ISA, section IS.5.1.3 and Appendix 8, section 8.7).

Ozone welfare effects also extend beyond effects on vegetation and associated biota due to it being a major greenhouse gas and radiative forcing agent.[130] As in the last review, the

included an examination of the sensitivity of predicted mortality rate to 13 different covariates. On average across the predictions for 10 groups of trees (based on functional type and major representative species), the order of mortality rate sensitivity to the covariates, from highest to lowest, was: Sulfate deposition, tree diameter, nitrate deposition, summer temperature, tree age, elevation, winter temperature, precipitation, O_3 concentration, tree basal area, topographic moisture index, slope and topographic radiation index (Dietze and Moorcroft, 2011).

[129] During the last review, the 2013 ISA stated with regard to O_3 effects on insects and other wildlife that ''there is no consensus on how these organisms respond to elevated O_3'' (2013 ISA, section 9.4.9.4, p. 9–98).

[130] 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. The ISA describes it more specifically as ''a perturbation in net radiative flux at the tropopause (or top of the atmosphere) caused by a change in radiatively active forcing agent(s) after stratospheric

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 [131] (ISA, section IS.5.2 and Appendix 9; Myhre et al., 2013). As was also true at the time of the last review, tropospheric O_3 has been ranked third in importance for global radiative forcing, after carbon dioxide and methane, with the radiative forcing of O_3 since pre-industrial times estimated to be about 25 to 40% of the total warming effects of anthropogenic carbon dioxide and about 75% of the effects of anthropogenic methane (ISA, Appendix 9, section 9.1.3.3). Uncertainty in the magnitude of radiative forcing estimated to be attributed to tropospheric O_3 is a contributor 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).

2. 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, 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). 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 each review, the Administrator's judgment regarding the currently available information and adequacy of protection provided by the current standard is generally informed by considerations in prior reviews and associated conclusions.

The categories of effects identified in the CAA to be included among welfare effects are quite diverse,[132] and among these categories, any single category includes many different types of effects that are of broadly varying specificity and level of resolution. For example, effects on vegetation, is a category identified in CAA section 302(h), and the ISA recognizes numerous vegetation-related effects of O_3 at the organism, population, community and ecosystem level, as summarized in section III.B.1 above (ISA, Appendix 8). The significance of each type of vegetation-related 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 are generally considered in light of judgments and conclusions made in prior reviews regarding effects on the public welfare. For example, a key consideration with regard to public welfare implications in prior reviews of the O_3 secondary standard was the intended use of the affected or sensitive vegetation and the significance of the vegetation to the public welfare (73 FR 16496, March 27, 2008; 80 FR 65292, October 26, 2015).

More specifically, 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, 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). For example, in the decision to revise the secondary standard in the 2008 review, the Administrator took note of ''a number of actions taken by Congress to establish public lands that are set aside for specific uses that are 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'' (73 FR 16496, March 27, 2008).[133] Such areas include Class I areas [134] which are federally mandated to preserve certain air quality related values. Additionally, as the Administrator recognized, ''States, Tribes and public interest groups also set aside areas that are intended to provide similar benefits to the public welfare, for residents on State and Tribal lands, as well as for visitors to those areas'' (73 FR 16496, March 27, 2008). The Administrator took note of 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). Similarly, in the 2015 review, the Administrator indicated particular concern for O_3-related effects on plant function and productivity and associated ecosystem effects in natural ecosystems ''such as those in areas with protection designated by Congress for current and future generations, as well

temperatures have readjusted to radiative equilibrium (stratospherically adjusted RF)'' (ISA, Appendix 9, section 9.1.3.3).

[131] 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).

[132] Section 302(h) of the CAA states that language referring to ''effects on welfare'' in the CAA ''includes, but is 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.''

[133] 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)).

[134] 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 (as described in the PA, Appendix 4D, section 4D.2.4).

as areas similarly set aside by states, tribes and public interest groups with the intention of providing similar benefits to the public welfare'' (80 FR 65403, October 26, 2015).

The 2008 and 2015 decisions recognized that the degree to which effects on vegetation in specially protected areas, such as those identified above, may be judged adverse involves considerations from the species level to the ecosystem level, such that judgments can depend on the intended use for, or service (and value) of, the affected vegetation, ecological receptors, ecosystems and resources and the significance 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. For example, ecosystem services are the ''benefits that people derive from functioning ecosystems'' (Costanza et al., 2017; ISA, section IS.5.1).[135] 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). Aesthetic value and outdoor recreation depend, at least in part, on the perceived scenic beauty of the environment. Further, there have been analyses that report the American public values—in monetary as well as nonmonetary ways—the protection of forests from air pollution damage (Haefele et al., 1991). In fact, 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 spatial, temporal and social dimensions of public welfare impacts are also influenced by the type of service affected. For example, a national park can provide direct recreational services to the thousands of visitors that come each year, but also provide an indirect value to the millions who may not visit but receive satisfaction from knowing that it exists and is preserved for the future (80 FR 65377, October 26, 2015).

The different types of effects on vegetation discussed in section III.B.1 above differ with regard to aspects important to judging their public welfare significance. In the case of crop yield loss, such judgments depend on considerations related to the heavy management of agriculture in the U.S. Judgments for other categories of effects may generally relate to considerations regarding forested areas, including specifically those forested areas that are not managed for harvest. For example, effects on tree growth and reproduction, and also visible foliar injury, have the potential to be significant to the public welfare through impacts in Class I and other areas given special protection in their natural/existing state, although they differ in how they might be significant. Additionally, as described in section III.B.1 above, 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, forest or forest 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.

Depending on the type and location of the affected ecosystem, however, a broader array of services benefitting the public can be affected in a broader array of areas as well. For example, other services valued by people that can be affected by reduced tree growth, productivity and associated forest effects include aesthetic value, food, fiber, timber, other forest products, habitat, 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.

Depending on its severity and spatial extent, visible foliar injury, which affects the physical appearance of the plant, also has the potential to be significant to the public welfare through impacts in Class I and other similarly protected areas. In cases of widespread and severe injury during the growing season (particularly when sustained across multiple years, and accompanied by obvious impacts on the plant canopy), O_3-induced visible foliar injury might be expected to have the potential to impact the public welfare in scenic and/or recreational areas, particularly in areas with special protection, such as Class I areas.[136] The ecosystem services most likely to be affected by O_3-induced visible foliar injury (some of which are also recognized above for tree growth-related effects) are cultural services, including aesthetic value and outdoor recreation.

The geographic extent of protected areas that may be vulnerable to public welfare effects of O_3, such as impacts to outdoor recreation, is potentially appreciable. For example, biomonitoring surveys that were routinely administered by the U.S.

[135] Ecosystem services analyses were one of the tools used in the last review of the secondary standards for oxides of nitrogen and sulfur to inform the decisions made with regard to adequacy of protection provided by the standards and as such, were used in conjunction with other considerations in the discussion of adversity to public welfare (77 FR 20241, April 3, 2012).

[136] For example, although analyses specific to visible foliar injury are of limited availability, there have been analyses developing estimates of recreation value damages of severe impacts related to other types of forest effects, such as tree mortality due to bark beetle outbreaks (*e.g.,* Rosenberger et al., 2013). Such analyses estimate reductions in recreational use when the damage is severe (*e.g.,* reductions in the density of live, robust trees). Such damage would reasonably be expected to also reflect damage indicative of injury with which a relationship with other plant effects (*e.g.,* growth and reproduction) would be also expected. Similarly, a couple of likelihood for reduced recreational use in areas with stands of pine in which moderate to severe injury was apparent from 30 or 40 feet (PA, section 4.3.2).

Forest Service (USFS) as far back as 1994 in the eastern U.S. and 1998 in the western U.S. include many field sites at which there are plants sensitive to O_3-related visible foliar injury; there are 450 field sites across 24 states in the North East and North Central regions (Smith, 2012).[137] Since visible foliar injury is a visible indication of O_3 exposure in species sensitive to this effect, a number of such species have been established as bioindicator species, and such surveys have been used by federal land managers as tools in assessing potential air quality impacts in Class I areas (U.S. Forest Service, 2010). Additionally, the USFS has developed categories for the scoring system that it uses for purposes of describing and comparing injury severity at biomonitoring sites. The sites are termed biosites and the scoring system involves deriving biosite index (BI) scores that 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).[138] As noted in section III.B.1 above, there is not an established quantitative relationship between visible foliar injury and other effects, such as reduced growth and productivity as visible foliar injury ''is not always a reliable indicator of other negative effects'' (ISA, Appendix 8, section 8.2).

Public welfare implications associated with visible foliar injury might further be considered to relate largely to effects on scenic and aesthetic values. 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, such as Class I areas, where the public can be expected to place value (*e.g.,* for recreational uses), might reasonably be concluded to impact the public welfare. Accordingly, key considerations for public welfare significance of this endpoint would relate to qualitative consideration of the potential for such effects to affect the aesthetic value of plants in protected areas, such as Class I areas (73 FR 16490, March 27, 2008).

While, as noted above, public welfare benefits of forested lands can be particular to the type of area in which the forest occurs, some of the potential public welfare benefits associated with forest ecosystems are not location dependent. A potentially extremely valuable 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).[139] As noted above, the EPA has concluded that effects on this ecosystem service are likely causally related to O_3 in ambient air (ISA, Table IS–12). The importance of carbon sequestration to the public welfare relates to its role in counteracting the impact of greenhouse gases on radiative forcing and related climate effects. As summarized in section III.B.1 above, O_3 is also a greenhouse gas and O_3 abundance in the troposphere is causally related to radiative forcing and likely causally related to subsequent effects on temperature, precipitation and related climate variables (ISA, section IS.6.2.2). Accordingly, such effects 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). The service of carbon storage is 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). In other words, the benefit exists as long as the trees are growing, regardless of what additional functions and services it provides.

With regard to agriculture-related effects, the EPA has recognized other complexities related to areas and plant species that are heavily managed to obtain a particular output (such as commodity crops or commercial timber production). For example, the EPA has recognized that the degree to which O_3 impacts on vegetation that could occur in such areas and on such species 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. 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). When agricultural impacts or vegetation effects in other areas are contrasted with the emphasis on ecosystem effects in Class I and similarly protected areas, the EPA most recently has judged the significance to the public welfare of O_3-induced effects on sensitive vegetation growing within the U.S. to differ depending on the nature of the effect, the intended use of the sensitive plants or ecosystems, and the types of environments in which the sensitive vegetation and ecosystems are located, with greater significance ascribed to areas identified for specific uses and benefits to the public welfare, such as Class I areas, than to areas for which such uses have not been established (80 FR 65292, October 26, 2015; FR 73 16496–16497, March 27, 2008).

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. For example, given the role of plant-insect signaling in such important ecological processes as insect herbivore growth and reproduction. The potential to contribute to adverse effects to the public welfare, *e.g.,* given the role of the plant-insect signaling process in pollination and seed dispersal, as well as natural plant defenses against predation and parasitism, particular effects on particular signaling processes can be seen to have the potential for adverse effects on the public welfare (ISA, section IS.5.1.3). However, uncertainties and limitations in the current evidence (*e.g.,* summarized in sections III.B.3 and III.D.1 below) preclude an assessment of the extent

[137] This aspect of the USFS biomonitoring surveys has apparently been suspended, with the most recent surveys conducted in 2011 (USFS, 2013, USFS, 2017).

[138] Studies presenting USFS biomonitoring program data have suggested what might be ''assumptions of risk'' 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).

[139] 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.

and magnitude of O_3 effects on these endpoints, which thus also precludes an evaluation of the potential for associated public welfare implications, particularly under exposure conditions expected to occur in areas meeting the current standard.

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. There are uncertainties and limitations associated with the consideration of the magnitude of key welfare effects that might be concluded to be adverse to ecosystems and associated services. There are numerous locations where the presence of O_3-sensitive tree species may contribute to a vulnerability to impacts from O_3 on tree growth, productivity and carbon storage and their associated ecosystems and services. Exposures that may elicit effects and the significance of the effects in specific situations can vary due to differences in exposed species sensitivity, 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.

3. Exposures Associated With Effects

The welfare effects identified in section III.B.1 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 them. As recognized in the 2013 ISA and in the ISA for this review, such information is most advanced for growth-related effects such as growth and yield. For example, the information on exposure metric and E–R relationships for these effects is long-standing, having been first described in the 1997 review. The current information regarding exposure metrics and relationships between exposure and the occurrence and severity of visible foliar injury, summarized in section III.B.3.b below, is much less advanced or well established. The evidence base for other categories of effects is still more lacking in information that might support characterization of potential impacts related to these effects of changes in O_3 concentrations.

a. Growth-Related Effects

(i) Exposure Metric

The long-standing body of vegetation effects evidence includes a wealth of information on aspects of O_3 exposure that are important in influencing effects on plant growth and yield 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, including ''concentration, time of day, respite time, frequency of peak occurrence, plant phenology, predisposition, etc.'' (2013 ISA, section 9.5.2), and the importance of the duration of the exposure as well as the relatively greater importance of higher concentrations over lower concentrations have been consistently well documented (2013 ISA, section 9.5.3). Based on the associated improved understanding of the biological basis for plant response to O_3 exposure, a number of mathematical approaches have been developed for summarizing O_3 exposure for the purpose of assessing effects on vegetation, including those that cumulate exposures over some specified period while weighting higher concentrations more than lower (2013 ISA, sections 9.5.2 and 9.5.3; ISA, Appendix 8, section 8.2.2.2).

In the last several reviews, based on the then-available evidence, as well as advice from the CASAC, the EPA's scientific assessments have focused on the use of a cumulative, seasonal [140] concentration-weighted index for considering the growth-related effects evidence and in quantitative exposure analyses for purposes of reaching conclusions on the secondary standard. More specifically, the Agency used the W126-based cumulative, seasonal metric (80 FR 65404, October 26, 2015; ISA, section IS.3.2, Appendix 8, section 8.13). This metric, commonly called the W126 index, is a non-threshold approach described as the sigmoidally weighted sum of all hourly O_3 concentrations observed during a specified daily and seasonal time window, where each hourly O_3 concentration is given a weight that increases from zero to one with increasing concentration (2013 ISA, pp. 9–101, 9–104).

Across the last several decades, several different exposure metrics have been evaluated, primarily for their ability to summarize ambient air O_3 concentrations into a metric that best describes quantitatively the relationship of O_3 in ambient air with the occurrence and/or extent of effects on vegetation, particularly growth-related effects. More specifically, an important objective has been to identify the metric that summarizes O_3 exposure in a way that is most predictive of the effect of interest (*e.g.,* reduced growth). Along with the continuous weighted, W126 index, the two other cumulative indices that have received greatest attention across the past several O_3 NAAQS reviews are the threshold weighted indices, AOT60 [141] and SUM06.[142] Accordingly, some studies of O_3 vegetation effects have reported exposures using these metrics. Alternative methods for characterizing O_3 exposure to predict various plant responses (particularly those related to photosynthesis, growth and productivity) have, in recent years, also included flux models (models that are based on the amount of O_3 that enters the leaf). However, as was the case in the last review, there remain a variety of complications, limitations and uncertainties associated with this approach. For example, ''[w]hile some efforts have been made in the U.S. to calculate ozone flux into leaves and canopies, little information has been published relating these fluxes to effects on vegetation'' (ISA, section IS.3.2). Further, as flux of O_3 into the plant under different conditions of O_3 in ambient air is affected by several factors including temperature, vapor pressure deficit, light, soil moisture, and plant growth stage, use of this approach to quantify the vegetation impact of O_3 would require information on these various types of factors (ISA, section IS.3.2). In addition to these data requirements, each species has different amounts of internal detoxification potential that may protect species to differing degrees. The lack of detailed species- and site-specific data required for flux modeling in the U.S. and the lack of understanding of detoxification

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

[141] The AOT60 index is the seasonal sum of the difference between an hourly concentration above 60 ppb, minus 60 ppb (2006 AQCD, p. AX9–161). More recently, some studies have also reported O_3 exposures in terms of AOT40, which is conceptually similar but with 40 substituted for 60 in its derivation (ISA, Appendix 8, section 8.13.1).

[142] The SUM06 index 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). This may sometimes be referred to as SUM60, *e.g.,* when concentrations are in terms of ppb. There are also variations on this metric that utilize alternative reference points above which hourly concentrations are summed. For example, SUM08 is the seasonal sum of hourly concentrations at or above 0.08 ppm and SUM0 is the seasonal sum of all hourly concentrations.

processes continues to make this technique less viable for use in risk assessments in the U.S. (ISA, section IS.3.2).

Based on extensive review of the published literature on different types of E–R metrics, including comparisons between metrics, the EPA has generally focused on cumulative, concentration-weighted indices of exposure, recognizing them as the most appropriate biologically based metrics to consider in this context (1996 AQCD; 2006 AQCD; 2013 ISA). Quantifying exposure in this way 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 (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 and one for 10 crops, described further in section III.B.3.a(ii) below (*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 (termed relative biomass loss or RBL) in seedlings of the tree species and E–R functions for RYL for a set of common crops (ISA, Appendix 8, section 8.13.2; 2013 ISA, section 9.6.2).

Among the studies newly available in this review, no new exposure indices for assessing effects on vegetation growth or other physiological process parameters have been identified. The SUM06, AOTx (*e.g.,* AOT60) and W126 exposure metrics remain the cumulative metrics that are most commonly discussed (ISA, Appendix 8, section 8.13.1). The ISA notes that ''[c]umulative indices of exposure that differentially weight hourly concentrations [which would include the W126 index] have been found to be best suited to characterize vegetation exposure to ozone with regard to reductions in vegetation growth and yield'' (ISA, section ES.3). Accordingly, in this review, as in the last two reviews, the seasonal W126-based cumulative, concentration-weighted metric receives primary attention in considering the effects evidence and exposure analyses, particularly related to growth effects (*e.g.,* in sections III.C and III.D below).

The first step in calculating the seasonal W126 index for a specific year, as described and considered in this review, is to sum the weighted hourly O_3 concentrations in ambient air during daylight hours (defined as 8:00 a.m. to 8:00 p.m. local standard time) within each calendar month, resulting in monthly index values. The monthly W126 index values are calculated from hourly O_3 concentrations as follows.[143]

$$\textit{Monthly}\ \mathbf{W126} = \sum_{d=1}^{N} \sum_{h=8}^{19} \frac{C_{dh}}{1+4403*\exp(-126*C_{dh})}$$

where,

N is the number of days in the month
d is the day of the month (d = 1, 2, . . ., N)
h is the hour of the day (h = 0, 1, . . ., 23)
C_{dh} is the hourly O_3 concentration observed on day d, hour h, in parts per million

The W126 index value for a specific year is the maximum sum of the monthly index values for three consecutive months within a calendar year (*i.e.,* January to March, February to April, . . . October to December). Three-year average W126 index values are calculated by taking the average of seasonal W126 index values for three consecutive years (*e.g.,* as described in the PA, Appendix 4D, section 4D.2.2).

(ii) Relationships Between Exposure Levels and Effects

Across the array of O_3-related welfare effects, consistent and systematically evaluated information on E–R relationships across multiple exposure levels is limited. Most prominent is the information on E–R relationships for growth effects on tree seedlings and crops,[144] which has been available for the past several reviews. The information on which these functions are based comes primarily from the U.S. EPA's National Crop Loss Assessment Network (NCLAN)[145] project for crops and the NHEERL–WED project for tree seedlings, projects implemented primarily to define E–R relationships for major agricultural crops and tree species, thus advancing understanding of responses to O_3 exposures (ISA, Appendix 8, section 8.13.2). These projects included a series of 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). These experiments have produced multiple studies that document O_3 effects on tree seedling growth and crop yield across multiple levels of exposure. Importantly, the information on exposure includes hourly concentrations across the season-long (or longer) exposure period which can then be summarized in terms of the various seasonal metrics.[146] In the initial analyses of these data, exposure was characterized in terms of several metrics, including seasonal SUM06 and W126 indices (Lee and Hogsett, 1996; 1997 Staff Paper, sections IV.D.2 and IV.D.3; 2007 Staff Paper, section 7.6), while use of these functions more recently has focused on their implementation in terms of seasonal W126 index (2013 ISA, section 9.6; 80 FR 65391–92, October 26, 2015).

The 11 tree species for which robust and well-established E–R functions for RBL are available are black cherry, Douglas fir, loblolly pine, ponderosa pine, quaking aspen, red alder, red maple, sugar maple, tulip poplar, Virginia pine, and white pine (PA, Appendix 4A; 2013 ISA, section 9.6).[147] While these 11 species represent only a small fraction of the total number of native tree species in the contiguous U.S., this small subset includes eastern and western species, deciduous and coniferous species, and species that

[143] In situations where data are missing, an adjustment is factored into the monthly index (PA, Appendix 4D, section 4D.2.2).

[144] The E–R functions estimate O_3-related reduction in a year's tree seedling growth or crop yield as a percentage of that expected in the absence of O_3 (ISA, Appendix 8, section 8.13.2).

[145] The NCLAN program, which was undertaken in the early to mid-1980s, assessed multiple U.S. crops, locations, and O_3 exposure levels, using consistent methods, to provide the largest, most uniform database on the effects of O_3 on agricultural crop yields (1996 AQCD, 2006 AQCD, 2013 ISA, sections 9.2, 9.4, and 9.6; ISA, Appendix 8, section 8.13.2).

[146] This underlying database for the exposure is a key characteristic that sets this set of studies (and their associated E–R analyses) apart from other available studies.

[147] A quantitative analysis of E–R information for an additional species was considered in the 2014 WREA. But the underlying study, rather than being a controlled exposure study, involves exposure to ambient air along an existing gradient of O_3 concentrations in the New York City metropolitan area, such that O_3 and climate conditions were not controlled (2013 ISA, section 9.6.3.3). Based on recognition that this dataset is not as strong as those for the 11 species for which E–R functions are based on controlled ozone exposure, this study is not included with the established E–R functions for the 11 species (PA, section 4.3.3).

grow in a variety of ecosystems and represent a range of tolerance to O_3 (PA, Appendix 4B; 2013 ISA, section 9.6.2). The established E–R functions for most of the 11 species were derived using data from multiple studies or experiments involving a wide range of exposure and/or growing conditions. From the available data, separate E–R functions were developed for each combination of species and experiment (2013 ISA, section 9.6.1; Lee and Hogsett, 1996). From these separate species-experiment-specific E–R functions, species-specific composite E–R functions were developed (PA, Appendix 4A).

In total, the 11 species-specific composite E–R functions are based on 51 tree seedling studies or experiments (PA, Appendix 4A, section 4A.1.1). For six of the 11 species, this function is based on just one or two studies (*e.g.,* red maple and black cherry), while for other species there were as many as 11 studies available (*e.g.,* ponderosa pine). A stochastic analysis drawing on the experiment-specific functions provides a sense of the variability and uncertainty associated with the estimated E–R relationships among and within species (PA, Appendix 4A, section 4A.1.1, Figure 4A–13). Based on the species-specific E–R functions, growth of the studied tree species at the seedling stage appears to vary widely in sensitivity to O_3 exposure (PA, Appendix 4A, section 4A.1.1). Since the initial set of 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 many of the earlier OTC studies (ISA, Appendix 8, section 8.13.2).

With regard to crops, established E–R functions are available for 10 crops: Barley, field corn, cotton, kidney bean, lettuce, peanut, potato, grain sorghum, soybean and winter wheat (PA, Appendix 4A, section 4A.1; ISA, Appendix 8, section 8.13.2). Studies available since the last review for seven soybean cultivars support conclusions from prior studies that of similarity of current soybean cultivar sensitivity compared to the earlier genotypes from which the soybean E–R functions were (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 trees, have been assessed (ISA, section IS.5.1.2). These include a compilation of previously available studies on plant biomass response to O_3 (in terms of AOT40); the compilation reports linear regressions conducted on the associated varying datasets (ISA, Appendix 8, section 8.13.2; van Goethem et al., 2013). Based on these regressions, this study describes distributions of sensitivity to O_3 effects on biomass across nearly 100 plant species (trees and grasslands) including 17 species native to the U.S. and 65 additional species that have been introduced to the U.S. (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.[148]

b. Visible Foliar Injury

With regard to visible foliar injury, as with the evidence available in the last review, the 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 current ISA, in concluding that the newly available information is consistent with conclusions of the 2013 ISA, also summarizes several recently available studies that continue to document that O_3 elicits visible foliar injury in many plant species. These include a synthesis of previously published studies that categorizes studied species (and their associated taxonomic classifications) as to whether or not O_3-related foliar injury has been reported to occur in the presence of elevated O_3,[149] while not providing quantitative information regarding specific exposure conditions or analyses of E–R relationships (ISA, Appendix 8, section 8.2). The evidence in the current review, as was the case in the last 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),[150] does not include a quantitative description of the relationship of incidence or severity of visible foliar injury in sensitive species in natural locations in the U.S. with specific metrics of O_3 exposure.

Several studies of the extensive USFS field-based dataset of visible foliar injury incidence in forests across the U.S.[151] illustrate the extent to which our current understanding of this relationship is limited. For example, a study that was available in the last review presents a trend analysis of these data for sites located in 24 states of the northeast and north central U.S. for the 16-year period from 1994 through 2009 that provides some insight into the influence of changes in air quality and soil moisture on visible foliar injury and the difficulty inherent in predicting foliar injury response under different air quality and soil moisture scenarios (Smith, 2012, Smith et al., 2012; ISA, Appendix 8, section 8.2). This study, like prior analyses of such data, shows the dependence of foliar injury incidence and severity on local site conditions for soil moisture availability and O_3 exposure. For example, while the authors characterize the ambient air O_3 concentrations to be the ''driving force'' behind incidence of injury and its severity, they state that ''site moisture conditions are also a very strong influence on the biomonitoring data'' (Smith et al., 2003). In general, the USFS data analyses have found foliar injury prevalence and severity to be higher during seasons and sites that have experienced the highest O_3 than during other periods (*e.g.,* Campbell et al., 2007; Smith, 2012).

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). For example, a

[148] The set of studies included in this compilation were described as meeting a set of criteria, such as: Including O_3 only exposures in conditions described as ''close to field'' exposures (which were expressed as AOT40); including at least 21 days exposure above 40 ppb O_3; and having a maximum hourly concentration that was no higher than 100 ppb (van Goethem et al., 2013). The publication does not report exposure duration for each study or details of biomass response measurements, making it less useful for the purpose of describing E–R relationships that might provide for estimation of specific impacts associated with air quality conditions meeting the current standard (*e.g.,* 2013 ISA, p. 9–118).

[149] The publication identifies 245 species across 28 plant genera, many native to the U.S., in which O_3-related visible foliar injury has been reported (ISA, Appendix 8, Table 8–3).

[150] As noted in the 2013 ISA and the ISA for the current review, visible foliar injury usually occurs when sensitive plants are exposed to elevated ozone concentrations in a predisposing environment, with a major modifying factor being the amount of soil moisture available to a plant. Accordingly, dry periods are concluded to 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).

[151] These data were collected as part of the U.S. Forest Service Forest Health Monitoring/Forest Inventory and Analysis (USFS FHM/FIA) biomonitoring network program (2013 ISA, section 9.4.2.1; Campbell et al., 2007, Smith et al., 2012).

study of six years of USFS biosite[152] data (2000–2006) for three western states found that the biosites with the highest O_3 exposure (SUM06 at or above 25 ppm-hrs) had the highest percentage of biosites with injury and the highest mean BI, with little discernable difference among the lower exposure categories; this study also identified ''better linkage between air levels and visible injury'' as an O_3 research need (Campbell et al., 2007).[153] More recent studies of the complete 16 years of data in 24 northeast and north central states have suggested that a cumulative exposure index alone may not completely describe the O_3-related risk of this effect at USFS sites (Smith et al., 2012; Smith, 2012). For example, Smith (2012) observed there to be a declining trend in the 16-year dataset, ''especially after 2002 when peak ozone concentrations declined across the entire region'' thus suggesting a role for peak concentrations.

Some studies of visible foliar injury incidence data have investigated the role of 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 1-hour concentration of 100 ppb, N100 (*e.g.,* Smith, 2012; Smith et al., 2012). For example, the study by Smith (2012) discussed injury patterns at biosites in 24 states in the Northeast and North Central regions in the context of the SUM06 index and N100 metrics (although not via a statistical model).[154] That study of 16 years of biomonitoring data from these sites suggested that there may be a threshold exposure needed for injury to occur, and 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).[155] The study's authors noted this finding to be consistent with findings reported by a study of statistical analyses of seven years of visible foliar injury data from a wildlife refuge in the mid-Atlantic (Davis and Orendovici, 2006, Smith et al., 2012). The latter study investigated the fit of multiple models that included various metrics of cumulative O_3 (SUM06, SUM0, SUM08), alone and in combination with some other variables (Davis and Orendovici, 2006). Among the statistical models investigated (which did not include one with either W126 index or N100 alone), the model with the best fit to the visible foliar injury incidence data was found to be one that included the cumulative metric, W126, and the N100 index, as well as drought index (Davis and Orendovici, 2006).[156]

The established significant role of higher or peak O_3 concentrations, as well as pattern of their occurrence, in plant responses has been noted in prior ISAs or AQCDs. In identifying support 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). For example, a study of European white birch saplings reported that peak concentrations and the duration of the exposure event were important determinants of foliar injury (2013 ISA, section 9.5.3.1; Oksanen and Holopainen, 2001). This study also evaluated tree growth, which was found to be more related to cumulative exposure (2013 ISA, p. 9–105).[157] A second study that was cited by both assessments that focused on aspen, reported that ''the variable peak exposures were important in causing injury, and that the different exposure treatments, although having the same SUM06, resulted in very different patterns of foliar injury'' (2013 ISA, p. 9–105; 2006 AQCD, p. AX9–169; Yun and Laurence, 1999). As noted in the 2006 AQCD, the cumulative exposure indices (*e.g.,* SUM06, W126) were ''originally developed and tested using only growth/yield data, not foliar injury'' and ''[t]his distinction is critical in comparing the efficacy of one index to another'' (2006 AQCD, p. AX9–173). It is also recognized that where cumulative indices are highly correlated with the frequency or occurrence of higher hourly average concentrations, they could be good predictors of such effects (2006 AQCD, section AX9.4.4.3).

In a more recent study (by Wang et al. [2012]) that is cited in the current ISA, a statistical modeling analysis was performed on a subset of the years of data that were described in Smith (2012). This analysis, which involved 5,940 data records from 1997 through 2007 from the 24 northeast and north central states, 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 combination 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 environmental conditions.

The available information related to O_3 exposures associated with visible foliar injury of varying severity also includes the dataset developed by the EPA in the last review from 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[158] and estimates of seasonal cumulative O_3 exposure in terms of

[152] As described in section III.B.2 above, biosites are biomonitoring sites where the USFS applies a scoring system for purposes of categorizing areas with regard to severity of visible foliar injury occurrence (U.S. Forest Service, 2010).

[153] 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).

[154] The current ISA, 2013 ISA and prior AQCDs have not described extensive evaluation of specific peak-concentration metrics such as the N100 that might assist in identifying the one best suited for such purposes.

[155] 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 O_3 concentrations declined'' (2013 ISA, p. 9–40).

[156] The models evaluated included several with cumulative exposure indices alone. These included SUM60, SUM0, and SUM80, 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).

[157] The study authors concluded that ''high peak concentrations were important for visible injuries and stomatal conductance, but less important for determining growth responses'' (Oksanen and Holopainen, 2001).

[158] Soil moisture categories (dry, wet or normal) were assigned to each biosite record based on the NOAA Palmer Z drought index values obtained from the NCDC website for the April-through-August periods, averaged for the relevant year; details are provided in the PA, Appendix 4C, section 4C.2. There are inherent uncertainties in this assignment, including the substantial spatial variation in soil moisture and large size of NOAA climate divisions (hundreds of miles). This dataset, including associated uncertainties and limitations, is described in the PA, Appendix 4C, section 4C.5.

W126 index [159] (Smith and Murphy, 2015; 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) [160] are at sites with W126 index estimates below 7 ppm-hrs.

In an extension of analyses of this dataset developed in the last review, the presentation in the PA [161] describes the BI scores for the records in the 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. The lowest USFS category encompasses BI scores from zero to just below 5; scores of this magnitude are described as ''little or no foliar injury'' (Smith et al., 2012). The next highest category encompasses scores from five to just below 15 and is described as ''light to moderate foliar injury,'' BI scores of 15 up to 25 are described as ''moderate'' and above 25 is described as ''severe'' (Smith et al., 2012). The PA 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).

While recognizing limitations in the dataset,[162] the PA makes several observations, focusing particularly on records in the normal soil category (PA, section 4.5.1). For records categorized as wet soil moisture, the sample size for the W126 bins above 13 ppm-hrs is quite small (including only 18 of the 1,189 records in that soil moisture category), precluding meaningful interpretation.[163] For the normal soil category, the percentages of records in the greater than 25 ppm-hrs bin that have BI scores above 15 (''moderate'' and ''severe'' injury) or above 5 (''little,'' ''moderate'' and ''severe'' injury) are both more than three times greater than such percentages in any of the lower W126 bins.[164] For example, the proportion of records with BI above five fluctuates between 5% and 13% across all but the highest W126 bin (>25 ppm-hrs) for which the proportion is 41% (PA, Appendix 4C, Table 4C–6). The same pattern is observed for BI scores above 15 at sites with normal and dry soil moisture conditions, albeit with lower incidences. For example, the incidence of normal soil moisture records with BI score above 15 in the bin for W126 index values above 25 ppm-hrs was 20% but fluctuates between 1% and 4% in the bin for W126 index values at or below 25 ppm-hrs (PA, Appendix 4C, Table 4C–6). The average BI of 7.9 in the greater-then-25-ppm-hrs bin is more than three times the next highest W126 bin average. The average BI in each of the next two lower W126 bins is just slightly higher than average BIs for the rest of the bins, and the average BI for all bins at or below 25 ppm-hrs are well below 5 (PA, Appendix 4C).

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 studies of detailed quantitative analyses, 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 others, 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 soil moisture conditions, with regard to their influence on extent and/or severity of injury in sensitive species in natural areas (Davis and Orendovici, 2006, Smith et al., 2012; Wang et al., 2012).

Dose modeling or flux models (referenced in section III.B.3.a(i) above, have also been considered for quantifying O_3 dose that may be related to plant leaf injury. Among the newly available evidence is a study examining relationships between short-term flux and leaf injury on cotton plants that described a sensitivity parameter that might characterize the influence on the flux-injury relationship of diel and seasonal variability in plant defenses (among other factors) and suggested additional research might provide for such a sensitivity parameter to ''function well in combination with a sigmoidal weighting of flux, analogous to the W126 weighting of concentration'', and perhaps an additional parameter (Grantz et al., 2013, p. 1710; ISA, Appendix 8, section 8.13.1). However, the ISA recognizes there is ''much unknown'' with regard to the relationship between O_3 uptake and leaf injury, and relationships with detoxification processes (ISA, Appendix 8, section 8.13.1 and p. 8–184). These uncertainties have made this technique less viable for assessments in the U.S., precluding use of a flux-based approach at this time (ISA, Appendix 8, section 8.13.1 and p. 8–184).

c. 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

[159] The W126 index values assigned to the biosite locations are estimates developed for 12 kilometer (km) by 12 km cells in a national-scale spatial grid for each year. The grid cell estimates were derived from applying a spatial interpolation technique to annual W126 values derived from O_3 measurements at ambient air monitoring locations for the years corresponding to the biosite surveys (details in the PA, Appendix 4C, sections 4.C.2 and 4C.5).

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

[161] 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).

[162] For example, the majority of records have W126 index estimates at or below 9 ppm-hrs, and fewer than 10% have W126 estimates above 15 ppm-hrs. Further, the BI scores are quite variable across the range of W126 bins, with even the lowest W126 bin (estimates below 7 ppm-hrs) including BI scores well above 15 (PA, Appendix 4C, section 4C.4.2). The records for the wet soil moisture category in the higher W126 bins are more limited that 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). Accordingly, the PA observations focused primarily on the records for the normal or dry soil moisture categories, for which W126 index above 13 ppm-hrs is better represented.

[163] The full database includes only 18 records at sites in the wet soil moisture category with estimated W126 index above 13 ppm-hrs, with 9 or fewer (less than 1%) in each of the W126 bins above 13 ppm-hrs (PA, Appendix 4C, Table 4C–3). Among the bins for W126 at or below 13 ppm-hrs, the average BI score is less than 2 (PA, Appendix 4C, Table 4C–5).

[164] When scores characterized as ''little injury'' by the USFS classification scheme are also included (*i.e.,* when considering all scores above zero), there is a suggestion of increased frequency of records for the W126 bins above 19 or 17 ppm-hrs, although difference from lower bins is less than a factor of two (PA, Appendix 4C).

regarding O_3 concentrations at the national scale. For example, tropospheric O_3 continues to be recognized as having a causal relationship with radiative forcing, although ''uncertainty in the magnitude of radiative forcing estimated to be attributed to tropospheric ozone is a contributor to the relatively greater uncertainty associated with climate effects of tropospheric ozone compared to such effects of the well mixed greenhouse gases (*e.g.,* carbon dioxide and methane)'' (ISA, section IS.6.2.2).

While tropospheric O_3 also continues to be recognized as having a likely causal relationship with subsequent effects on temperature, precipitation and related climate variables, the non-uniform distribution of O_3 within the troposphere (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. 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 for which the 2013 ISA did not assess with regard to its support for inference of a causal relationship with O_3 exposure), 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, section 9.4.7.1). Although three newly available studies contribute to the ISA conclusion of sufficient evidence to infer a likely causal relationship for O_3 with tree mortality (ISA, Appendix 8, section 8.4), there is only limited experimental evidence that isolates the effect of O_3 on tree mortality and might be informative regarding O_3 concentrations of interest in the review. This evidence, primarily from an Aspen FACE study of aspen survival, involves cumulative seasonal exposure to W126 index levels above 30 ppm-hrs during the first half of the 11-year study period (ISA, Appendix 8, Tables 8–8 and 8–9). Evidence is lacking regarding exposure conditions closer to those occurring under the current standard and any contribution to tree mortality.

With regard to the two categories of welfare effects involving insects (for which there are new causal determinations in this review), there are multiple limitations and uncertainties regarding characterization of exposure conditions that might elicit effects and the comprehensive characterization of the effects (ISA, p. IS–91, Appendix 8, section 8.6.3). For example, 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 ISA also notes the variation in study designs and endpoints used to assess O_3 response (ISA, IS.6.2.1 and Appendix 8, section 8.6). Thus, while the evidence describes changes in nutrient content and leaf chemistry following O_3 exposure (ISA, p. IS–73), the effect of these changes on herbivores consuming the leaves is not well characterized, and factors such as identified here preclude broader characterization, as well as quantitative analysis related to air quality conditions meeting the O_3 standard.

The evidence for the second category, alteration of plant-insect signaling, draws on new research that has provided clear evidence of O_3 modification of VPSCs and behavioral responses of insects to these modified chemical signals (ISA, section IS.6.2.1). The available evidence involves a relatively small number of plant species and plant-insect associations. While the evidence documents effects on plant production of signaling chemicals and on the atmospheric persistence of signaling chemicals, as well as on the behaviors of signal-responsive insects, it is limited with regard to characterization of mechanisms and the consequences of any modification of VPSCs by O_3 (ISA, p. ES–18; sections ES.5.1.3 and IS.6.2.1). Further, the available studies vary with regard to the experimental exposure circumstances in which the different types of effects have been reported (most of the studies have been carried out in laboratory conditions rather than in natural environments), and many of the studies involve quite short controlled exposures (hours to days) to elevated concentrations, posing limitations for our purposes of considering the potential for impacts associated with the studied effects to be elicited by air quality conditions that meet the current standard (ISA, section IS.6.2.1 and Appendix 8, section 8.7).

With regard to previously recognized categories of vegetation-related effects, other than growth and visible foliar injury, such as 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, as identified in the ISA (ISA, Appendix 8, sections 8.4, 8.8 and 8.10). Across the studies, a variety of metrics (including AOT40, 4- to 12-hour mean concentrations, and others) are used to quantify exposure over varying durations and various countries. The ISA additionally describes publications that summarize previously published studies in several ways. 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 to reach conclusions regarding the presence of an O_3-related effect (ISA, Appendix 8, section 8.4.1). While such studies continue to support conclusions of the ecological hazards of O_3, they do not improve capabilities for characterizing the likelihood of such effects under varying patterns of environmental O_3 concentrations that occur with air quality conditions that meet the current standard.

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. Thus, as was the case in the decision for 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.

C. Summary 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). As summarized in the IRP, we identified these analyses to be updated in this review in recognition of the relatively reduced 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 lesser uncertainty of these air quality monitoring-based analyses contributes to their value in informing the current review. The sections below present findings of the updated analyses that have been performed in the current review using recently available information.

As in the last review, the analyses focus on both the most recent 3-year period (2016 to 2018) for which data were available when the analyses were performed, and also across the full historical period back to 2000, which is now expanded from that available in the last review.[165] Design values (3-year average annual fourth-highest 8-hour daily maximum concentration, also termed ''4th max metric'' in this analysis) and W126 index values (in terms of the 3-year average) were calculated at each site where sufficient data were available.[166] 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. The specific monitoring sites differed somewhat across the 19 years. There were 1,557 sites with sufficient data for calculation of valid design values and W126 index values for at least one 3-year period between 2000 and 2018, and 543 sites had such data for all seventeen 3-year periods. Analyses in the current review are based on the expanded set of air monitoring data now available[167] (PA, Appendix 4D, section 4D.2.2).

These analyses are based primarily on the hourly air monitoring data that were reported to EPA from O_3 monitoring sites nationwide. In the recent and historical datasets, the O_3 monitors (more than 1000 in the most recent period) are distributed across the U.S., covering all nine NOAA climate regions and all 50 states (PA, Figure 4–6 and Appendix 4D, Table 4D–1). Some geographical areas within these regions and states are more densely covered and well represented by monitoring sites, while others may have sparse or no data. Given that there has been a longstanding emphasis on urban areas in the EPA's monitoring regulations, urban areas are generally well represented in the U.S. dataset, with the effect being that the current dataset is more representative of locations where people live than of complete spatial coverage for all areas in the U.S., (*i.e.,* the current dataset is more population weighted than geographically weighted). As O_3 precursor sources are also generally more associated with urban areas, one impact of this may be a greater representation of relatively higher concentration sites (PA, section 4.4.3 and Appendix 4D, section 4D.4).

With regard to Class I areas, of the 158 mandated federal Class I areas, 65 (just over 40%) have or have had O_3 monitors within 15 km with valid design values, thus allowing inclusion in the Class I area analysis. Even so, the Class I areas dataset includes monitoring sites in 27 states distributed across all nine NOAA climatic regions across the contiguous U.S, as well as Hawaii and Alaska. Some NOAA regions have far fewer numbers of Class I areas with monitors than others. For instance, the Central, Northeast, East North Central, and South regions all have three or fewer Class I areas in the dataset. However, these areas also have appreciably fewer Class I areas in general when compared to the Southwest, Southeast, West, and West North Central regions, which are more well represented in the dataset. The West and Southwest regions are identified as having the largest number of Class I areas, and they have approximately one third of those areas represented with monitors, which include locations where W126 index values are generally higher, thus playing a prominent role in the analysis (PA, section 4.4.3 and Appendix 4D, section 4D.4).

These updated air quality analyses, and what they indicate regarding environmental exposures of interest in this review, are summarized in the following two subsections which differ in their areas of focus. The first subsection (section III.C.1) summarizes information regarding 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. The second subsection (section III.C.2) summarizes findings of the analyses of the currently available monitoring data with regard to the magnitude of environmental exposures, in terms of the W126 index, in areas across the U.S., and particularly in Class I areas, during periods in which air quality met the current standard.

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

In revising the standard in 2015 to the now-current standard, 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). The focus on cumulative seasonal exposure as the type of exposure metric of interest primarily reflects the

[165] In the last review, the dataset analyzed included data from 2000 through 2013, with the most recent period being 2011 to 2013 (Wells, 2015).

[166] Data adequacy requirements and methods for these calculations are described in Appendix 4D, section 4D.2 of the PA.

[167] In addition to being expanded with regard to data for more recent time periods than were available during the last review, the current dataset also includes a small amount of newly available older data for some rural monitoring sites that are now available in the AQS.

evidence on E–R relationships for plant growth (summarized in section III.B.3 above). The 2015 conclusion was based on the air quality data analyzed at that time (80 FR 65408, October 26, 2015). Analyses in the current review of the now expanded set of air monitoring data, which now span 19 years and 17 3-year periods, document similar findings as from the analysis of data from 2000–2013 described in the last review (PA, Appendix 4D, section 4D.2.2).

Among the analyses performed is an evaluation of the variability in the annual W126 index values across a 3-year period (PA, Appendix 4D, section 4D.3.1.2). This evaluation was performed for all U.S. monitoring sites with sufficient data available in the most recent 3-year period, 2016 to 2018. This analysis 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). Focusing on the approximately 850 sites meeting the current standard (*i.e.,* sites with a design value at or below 70 ppb), over 99% of single-year W126 index values in this subset 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).

Another air quality analysis performed for the current review documents the positive nonlinear relationship that is observed between cumulative seasonal exposure, quantified using the W126 index, and design values, based on the form and averaging time of the current standard. This 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). From this presentation, it is clear that cumulative seasonal exposures, assessed in terms of W126 index (in a year or averaged across years), are lower at monitoring sites with lower design values. This is seen both for design values above the level of the current standard (70 ppb), where the slope is steeper (due to the sigmoidal weighting of higher concentrations by the W126 index function), as well as for lower design values that meet the current standard (PA, Figure 4–7). This presentation also indicates some regional differences in the relationship. For example, for the 2016–2018 period, at sites meeting the current standard in the regions outside of the West and Southwest regions, all 3-year average W126 index values are at or below 12 ppm-hrs and all single-year values are at or below 16 ppm-hrs (PA, Figures 4–6 and 4–7). The W126 index values are generally higher in the West and Southwest regions. However, the positive relationship between the W126 index and the design value is evident in all nine regions (PA, Figure 4–7).

An additional analysis assesses the relationship between long-term changes in design value and long-term changes in the W126 index. This analysis is presented in detail in the PA and focuses on the relationship between changes (at each monitoring site) in the 3-year design value across the 16 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).[168] This analysis, performed using either the 3-year average W126 index or values for individual years, shows there to be a positive, linear relationship between the changes in the W126 index and the changes in the design value at monitoring sites across the U.S. (PA, Appendix 4D, Figure 4D–11). 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. Nationally, the W126 index (in terms of 3-year average) decreased by approximately 0.62 ppm-hrs per ppb decrease in design value over the full period from 2000 to 2018 (PA, Appendix 4D, Table 4D–12). This relationship varies across the NOAA climate regions, with the greatest change in the W126 index per unit change in design value observed in the Southwest and West regions. Thus, the regions which had the highest W126 index values at sites meeting the current standard (PA, Figure 4D–6) also showed the greatest improvement in the W126 index per unit decrease in their design values over the past 19 years (PA, Appendix 4D, Table 4D–12 and Figure 4D–14).

The trends analyses indicate 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 (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). This similarity is consistent with the strong positive relationship that exists between the W126 index and the design value metric for the current standard summarized above.

With regard to the control of the current form and averaging time on vegetation exposures of potential concern, the PA also describes air quality information pertinent to the evidence discussed in section III.B.3 above regarding the potential for days with particularly high O_3 concentrations to play a contributing role in visible foliar injury. In so doing, the PA notes that the current standard's form and averaging time, by their very definition, limit occurrences of such concentrations. For example, the peak 8-hour average concentrations are lower at sites with lower design values, as illustrated by the declining trends in annual fourth highest MDA8 concentrations that accompany the declining trend in design values (PA, Figure 2–11). Additionally, the frequency of elevated 1-hour concentrations, including concentrations at or above 100 ppb, decrease with decreasing design values (PA, Appendix 2A, section 2A.2). For example, in the most recent design value period (2016–2018) across all sites with adequate data to derive design values, the mean number of daily maximum 1-hour observations per site at or above 100 ppb was well below one (0.19) for sites that meet the current standard, compared to well above one (8.09) for sites not meeting the current (PA, Appendix 2A, Table 2A–2).

In summary, monitoring sites with lower O_3 concentrations as measured by the design value metric (based on the current form and averaging time of the secondary standard) have lower cumulative seasonal exposures, as quantified by the W126 index, as well as lower short-term peak concentrations. 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 with reductions in the standard level (*i.e.,* from 0.08 ppm in 1997 to 0.075 ppm in 2008 to 0.070 ppm in 2015) on

[168] At each site, the trend in values of a metric (W126 or design value), in terms of a per-year change in metric value, is calculated using the Theil-Sen estimator, a type of linear regression method that chooses the median slope among all lines through pairs of sample points. For example, if applying this method to a dataset with metric values for four consecutive years (*e.g.,* $W126_1$, $W126_2$, $W126_3$, $W126_4$), the trend would be the median of the different per-year changes observed in the six possible pairs of values ($[W126_4–W126_3]/1$, $[W126_3–W126_2]/1$, $[W126_2–W126_1]/1$, $[W126_4–W126_2]/2$, $[W126_3–W126_1]/2$, $[W126_4–W126_1]/3$).

cumulative seasonal exposures in terms of W126 index (and on the magnitude of short-term peak concentrations). The analyses have found that the long-term reductions in the design values, presumably associated with implementation of the revised standards, have been accompanied by reductions in cumulative seasonal exposures in terms of W126 index, as well as reductions in short-term peak concentrations.

2. Environmental Exposures in Terms of W126 Index

The following presentation is framed by the question: What are 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, and what do they indicate regarding the potential for O_3-related vegetation impacts? 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.B above), exposure is quantified using the W126 metric. The potential for impacts of interest is assessed through considering the magnitude of estimated exposure, in light of current information and, in comparison to levels given particular focus in the 2015 decision on the current standard (80 FR 65292; October 26, 2015). The updated analyses summarized here, while including assessment of all monitoring sites nationally, include a particular focus on monitoring sites in or near Class I areas [169], in light of the greater public welfare significance of many O_3 related impacts in such areas, as described in section III.B.2 above.

The analyses summarized here consider both recent air quality (2016–2018) and air quality since 2000 (PA, Appendix 4D). These air quality analyses of cumulative seasonal exposures associated with conditions meeting the current standard nationally provide conclusions generally similar to those based on the data available at the time of the last review when the current standard was set, when the most recent data were available for 2011 to 2013 (Wells, 2015). Such conclusions are with regard to regional differences as well as the rarity of W126 index values at or above 19 ppm-hrs in areas with air quality meeting the current standard.[170]

Cumulative exposures vary across the U.S. with the highest W126 index values for sites that met the current standard being located exclusively in Southwest and West climate regions (PA, Figure 4–6). At sites meeting the current standard in all other NOAA climate regions, W126 index values, averaged over the 3-year design value period are at or below 13 ppm-hrs (PA, Figure 4–6 and Appendix 4D, Figure 4D–2). At Southwest and West region sites that met the current standard, W126 index values, averaged across the 3-year design value period, are at or below 17 ppm-hrs in virtually all cases in the most recent 3-year period and across all of the seventeen 3-year periods in the full dataset evaluated (*i.e.,* all but one site out of 147 for recent period and all but eight out of over 1,800 cases across full dataset). Across all U.S. sites with valid design values at or below 70 ppb in the full 2000 to 2018 dataset, the W126 index, averaged over three years, was at or below 17 ppm-hrs on 99.9% of all occasions, and at or below 13 ppm-hrs on 97% of all occasions. All but one of the eight occasions when the 3-year W126 index was above 17 ppm-hrs (including the highest occasion at 19 ppm-hrs) occurred in the Southwest region during a period before 2011. The most recent occasion occurred in 2018 at a site in the West region when the 3-year average W126 index value was 18 ppm-hrs (PA, Appendix 4D, section 4D.3.2).

In summary, among sites meeting the current standard in the most 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 5). 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, with the highest such occurrence just equaling 19 ppm-hrs (Table 5; PA, Appendix 4D, section 4D.3.2.1).

With regard to Class I areas, the updated air quality analyses include data at 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. 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 (as average over design value period) above 17 ppm-hrs (Table 5). 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 5).

The W126 exposures at sites with design values above 70 ppb range up to approximately 60 ppm-hrs (Table 5). 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 5). A similar situation exists for Class I area sites (Table 5). Thus, 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.

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

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

TABLE 5—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.

As summarized above, the information available in this review continues to indicate that average cumulative seasonal exposure levels at virtually all sites and 3-year periods with air quality meeting the current standard fall at or below the level of 17 ppm-hrs that was identified when the current standard was established (80 FR 65393; October 26, 2015). Additionally, the full dataset indicates that at sites meeting the current standard, annual W126 index values were less than or equal to 19 ppm-hrs well over 99% of the time (PA, Appendix 4D, section 4D.3.2.1). Additionally, the average W126 index in Class I areas that meet the current standard for the most recent 3-year period is below 17 ppm-hrs at all areas which have a monitor within or near their borders (PA, Appendix 4D, Table 4D–16). Further, with the exception of seven values that occurred prior to 2011, cumulative seasonal exposures, in terms of average 3-year W126, in all Class I areas during periods that met the current standard were no higher than 17 ppm-hrs. This contrasts with the occurrence of much higher W126 index values at sites when the current standard was not met. 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 (ranging up to 47 ppm-hrs) and for nine, it was above 17 ppm-hrs (Table 5; PA, Appendix 4D, Table 4D–17).

D. Proposed Conclusions on the Secondary Standard

In reaching proposed conclusions on the current secondary O_3 standard (presented in section III.D.3), the Administrator has taken into account policy-relevant evidence-based and air quality-, exposure- and risk-based considerations discussed in the PA (summarized in section III.D.1), as well as advice from the CASAC, and public comment on the standard received thus far in the review (section III.D.2). In general, the role of the PA is to help ''bridge the gap'' between the Agency's assessment of the current evidence and quantitative analyses (of air quality, exposure and risk), and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the NAAQS. Evidence-based considerations draw upon the EPA's integrated assessment of the scientific evidence of welfare effects related to O_3 exposure presented in the ISA (summarized in section III.B above) to address key policy-relevant questions in the review. Similarly, the air quality-, exposure- and risk-based considerations draw upon our assessment of air quality, exposure and associated risk (summarized in section III.C above) in addressing policy-relevant questions focused on the potential for O_3 exposures associated with welfare effects under air quality conditions meeting the current standard.

This approach to reviewing the secondary standard is consistent with requirements of the provisions of the CAA related to the review of the NAAQS and with how the EPA and the courts have historically interpreted the CAA. As discussed in section I.A above, these provisions require the Administrator to establish secondary standards that, in the Administrator's judgment, are requisite (*i.e.,* neither more nor less stringent than necessary) to protect the public welfare from known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. Consistent with the Agency's approach across all NAAQS reviews, the EPA's approach to informing these judgments is based on a recognition that the available welfare effects evidence generally reflects a continuum that includes ambient air exposures for which scientists generally agree that effects are likely to occur through lower levels at which the likelihood and magnitude of response become increasingly uncertain. The CAA does not require the Administrator to establish a secondary standard 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.

The proposed decision on the adequacy of the current secondary standard described below is a public welfare policy judgment by the Administrator that draws upon the scientific evidence for welfare effects, quantitative analyses of air quality, exposure and risks, as available, and judgments about how to consider the uncertainties and limitations that are inherent in the scientific evidence and quantitative analyses. This proposed decision has additionally considered the August 2019 remand of the secondary standard. The four basic elements of the NAAQS (*i.e.,* indicator, averaging time, form, and level) have been considered collectively in evaluating the public welfare protection afforded by the current standard. The Administrator's final decision will additionally consider public comments received on this proposed decision.

1. Evidence- and Exposure/Risk-Based Considerations in the Policy Assessment

Based on its evaluation of the evidence and quantitative analyses of air quality, exposure and potential risk, the PA for this review reaches the conclusion that consideration should be given to retaining the current secondary standard, without revision (PA, section 4.5.3). Accordingly, and in light of this conclusion that it is appropriate to consider the current secondary standard to be adequate, the PA did not identify any potential alternative secondary standards for consideration in this review (PA, section 4.5.3). The PA additionally 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. These factors include public welfare policy judgments concerning the appropriate benchmarks on which to place weight, as well as judgments on the public welfare significance of the effects that have been observed at the exposures evaluated in the welfare effects evidence. The factors relevant to judging the adequacy of the standard also include the interpretation of, and decisions as to the weight to place on, different aspects of the quantitative analyses of air quality and cumulative O_3 exposure and any associated uncertainties. Thus, the Administrator's conclusions regarding the adequacy of the current standard will depend in part on public welfare policy judgments, science policy judgments regarding aspects of the evidence and exposure/risk estimates, as well as judgments about the level of public welfare protection that is requisite under the Clean Air Act.

The subsections below summarize key considerations and conclusions from the PA. The main focus of the policy-relevant considerations in the PA is 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 secondary O_3 standard? In addressing this overarching question, the PA focuses first on consideration of the evidence, as evaluated in the ISA (and supported by the prior ISA and AQCDs), including that newly available in this review, and the extent to which it alters the EPA's overall conclusions regarding welfare effects associated with photochemical oxidants, including O_3, in ambient air. The PA also considers questions related to the general approach or framework in which to evaluate public welfare protection of the standard. Additionally, the PA considers the currently available quantitative information regarding environmental exposures likely to occur in areas of the U.S. where the standard is met, including associated limitations and uncertainties, and the significance of these exposures with regard to the potential for O_3-related vegetation effects, their potential severity and any associated public welfare implications and judgments about the uncertainties inherent in the scientific evidence and quantitative analyses that are integral to consideration of whether the currently available information supports or calls into question the adequacy of the current secondary O_3 standard.

a. Welfare Effects Evidence

With regard to the support in the current evidence for O_3 as the indicator for photochemical oxidants, 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.[171] Data for photochemical oxidants other than O_3 are generally derived from a few special field studies; such that national-scale data for these other oxidants are scarce (ISA, Appendix 1, section 1.1; 2013 ISA, sections 3.1 and 3.6). Moreover, few studies of the welfare effects of other photochemical oxidants beyond O_3 have been identified by literature searches conducted for the 2013 ISA and prior AQCDs, such that ''the primary literature evaluating the . . . ecological effects of photochemical oxidants includes ozone almost exclusively as an indicator of photochemical oxidants'' (ISA, section IS.1.1, Appendix 1, section 1.1). Thus, as was the case for previous reviews, the PA finds that the evidence base for welfare effects of photochemical oxidants does not indicate an importance of any other photochemical oxidants such that O_3 continues to be appropriately considered for the secondary standard's indicator.

(i) Nature of Effects

Across the full array of welfare effects, summarized in section III.B.1 above, the evidence newly available in this review strengthens previous conclusions, provides further mechanistic insights and augments current understanding of varying effects of O_3 among species, communities and ecosystems (ISA, sections IS.1.3.2, IS.5 and IS.6.2, and Appendices 8 and 9). The current evidence, including the wealth of long-standing evidence, continues to support conclusions of causal relationships between O_3 and visible foliar injury, reduced yield and quality of agricultural crops, reduced vegetation growth and plant reproduction, reduced productivity in terrestrial ecosystems, and alteration of belowground biogeochemical cycles. The current evidence additionally continues to support conclusions of likely causal relationships between O_3 and reduced carbon sequestration in terrestrial systems, and alteration of terrestrial ecosystem water cycling (ISA, section IS.I.3.2). Also as in the last review, the current ISA determines there to be a causal relationship between tropospheric O_3 and radiative forcing and a likely causal relationship between tropospheric O_3 and temperature, precipitation and related climate variables (ISA, section IS.1.3.3). The current evidence has led to an updated conclusion on the relationship of O_3 with alteration of terrestrial community composition to causal (ISA, sections IS.I.3.2). Lastly, the current ISA concludes the current evidence sufficient to infer likely causal relationships of O_3 with three additional categories of effects (ISA, sections IS.I.3.2). For example, while previous recognition of O_3 as a contributor to tree mortality in a number of field studies was a factor in the 2013 conclusion of a likely causal relationship between O_3 and alterations in community composition, tree mortality has been separately assessed in this review. Additionally, newly available evidence on two additional plant related effects augments more limited previously available evidence related to insect interactions with vegetation, contributing to additional conclusions that the body of evidence is sufficient to infer likely causal relationships between O_3 and alterations of plant-insect signaling and insect herbivore growth and reproduction (ISA, Appendix 8, sections 8.6 and 8.7).[172]

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 quantitative characterizations of relationships between O_3 exposure and occurrence and magnitude of effects are for vegetation-related effects. With regard to uncertainties and limitations associated with the current welfare effects

[171] Close agreement between past ozone measurements and the photochemical oxidant measurements upon which the early NAAQS (for photochemical oxidants including O_3) was based indicated the very minor contribution of other oxidant species in comparison to O_3 (U.S. DHEW, 1970).

[172] As in the last review, the ISA again concludes that the evidence is inadequate to determine if a causal relationship exists between changes in tropospheric ozone concentrations and UV–B effects (ISA, Appendix 9, section 9.1.3.4; 2013 ISA, section 10.5.2).

evidence, the PA recognized that the type of uncertainties for each category of effects tends to vary, generally in relation to the maturity of the associated evidence base, from those associated with overarching characterizations of the effects to those associated with quantification of the cause and effect relationships. For example, given the longstanding nature of the evidence for many of the vegetation effects identified in the ISA as causally or likely causally related to O_3 in ambient air, the key uncertainties and limitations in our understanding of these effects relate largely to the implications or specific aspects of the evidence, as well as to current understanding of the quantitative relationships between O_3 concentrations in the environment and the occurrence and severity (or relative magnitude) of such effects or understanding of key influences on these relationships. For more newly identified categories of effects, the evidence may be less extensive, and accordingly, the areas of uncertainty greater, thus precluding consideration of quantitative details related to risk of such effects under varying air quality conditions that would inform review of the current standard.

The evidence bases for the three newly identified categories provide examples of such gaps in relevant information. For example, the evidence for increased tree mortality includes previously available studies with field observations from locations and periods of O_3 concentrations higher than are common today and three more recently available publications assessing O_3 exposures not expected under conditions meeting the current standard, as summarized in section III.B.1 above. The information available regarding the newly identified categories of plant-insect signaling and insect herbivore growth and reproduction additionally does not provide for a clear understanding of the specific environmental effects that may occur in the natural environment under specific exposure conditions, as summarized in sections III.B.1 and III.B.3 above (PA, section 4.5.1.1). Accordingly, the PA does not find the current evidence for these newly identified categories to call into question the adequacy of the current standard.

With regard to tropospheric O_3 as a greenhouse gas at the global scale, and associated effects on climate, the PA notes that while additional characterizations of tropospheric O_3 and climate have been completed since the last review, uncertainties and limitations in the evidence that were also recognized in the last review remain (PA, section 4.5.1.1). As summarized in section III.B.3 above, there is appreciable uncertainty associated with understanding quantitative relationships involving regional O_3 concentrations near the earth's surface and climate effects of tropospheric O_3 on a global scale. Further, there are limitations in our modeling tools and associated uncertainties in interpretations related to capabilities for quantitatively estimating effects of regional-scale lower tropospheric O_3 concentrations on climate. These uncertainties and limitations affect our ability to make a quantitative characterization of the potential magnitude of climate response to changes in O_3 concentrations in ambient air, particularly at regional (*vs* global) scales, and thus our ability to assess the impact of changes in ambient air O_3 concentrations in regions of the U.S. on global radiative forcing or temperature, precipitation and related climate variables. Consequently, the PA finds that current evidence in this area is not informative to consideration of the adequacy of public welfare protection of the current standard (PA, section 4.5.1.1).

(ii) E–R Information

The category of O_3 welfare effects for which current understanding of quantitative relationships is strongest continues to be reduced plant growth. While the ISA describes studies of welfare effects associated with O_3 exposures newly identified since the last review, the established E–R functions for tree seedling growth and crop yield that have been available in the last several reviews continue to be the most robust descriptions of E–R relationships for welfare effects. These well-established E–R functions for seedling growth reduction in 11 tree species and yield loss in 10 crop species are based on response information across multiple levels of cumulative seasonal exposure (estimated from extensive records of hourly O_3 concentrations across the exposure periods). Studies of some of the same species, conducted since the derivation of these functions, provide supporting information (ISA, Appendix 8, section 8.13.2; 2013 ISA, sections 9.6.3.1 and 9.6.3.2). The E–R functions provide for estimation of the growth-related effect, RBL, for a range of cumulative seasonal exposures.

The evidence newly available in this review does not include studies that assessed reductions in tree growth or crop yield responses across multiple O_3 exposures and for which sufficient data are available for analyses of the shape of the E–R relationship across a range of cumulative exposure levels (*e.g.,* in terms of W126 index) relevant to conditions associated with the current standard. While there are several newly available studies that summarize previously available studies or draw from them, such as for linear regression analyses, these do not provide robust E–R functions or cumulative seasonal exposure levels associated with important vegetation effects, such as reduced growth, that define the associated exposure circumstances in a consistent manner (as summarized in section III.B.3 above).[173] This limits their usefulness for considering the potential for occurrence of welfare effects in air quality conditions that meet the current standard. Thus, the PA concludes that robust E–R functions are not available for growth or yield effects on any additional tree species or crops in this review.

In considering the E–R functions and their use in informing judgments regarding such effects in areas with air quality of interest, the PA additionally recognized a number of limitations, and associated uncertainties, that remain in the current evidence base, and that affect characterization of the magnitude of cumulative exposure conditions eliciting growth reductions in U.S. forests (PA, section 4.3.4). For example, there are uncertainties in the extent to which the 11 tree species for which there are established E–R functions encompass the range of O_3 sensitive species in the U.S., and also the extent to which they represent U.S. vegetation as a whole. These 11 species include both deciduous and coniferous trees with a wide range of sensitivities and species native to every NOAA climate region across the U.S. and in most cases are resident across multiple states and regions. Thus, they may provide a range that encompasses species without E–R

[173] For example, among the newly available publications cited in the ISA is a study that compiles EC_{10} values (estimated concentration at which 10% lower biomass [compared to zero O_3] is predicted) derived for trees and grassland species (including 17 native to the U.S. [ISA, Table 8–26]) using linear regression of previously published data on plant growth response and O_3 concentration quantified as AOT40. The data were from studies of various experimental designs, that involved various durations ranging up from 21 days, and involving various concentrations no higher than 100 ppb as a daily maximum hourly concentration. More detailed analyses of exposure and response information across a relevant range of seasonal exposure levels (*e.g.,* accompanied by detailed records of O_3 concentrations) that would support derivation of robust E–R functions for purposes discussed here are not available.

functions.[174] The PA additionally recognizes important uncertainties in the extent to which the E–R functions for reduced growth in tree seedlings are also descriptive of such relationships during later lifestages, for which there is a paucity of established E–R relationships. Although such information is limited with regard to mature trees, analyses in the 2013 ISA indicated that reported growth response of young aspen over six years was similar to the reported growth response of seedlings (ISA, Appendix 8, section 8.13.2; 2013 ISA, section 9.6.3.2). Additionally, there are uncertainties with regard to the extent to which various factors in natural environments can either mitigate or exacerbate predicted O_3-plant interactions and contribute variability in vegetation-related effects, including reduced growth. Such factors include multiple genetically influenced determinants of O_3 sensitivity, changing sensitivity to O_3 across vegetative growth stages, co-occurring stressors and/or modifying environmental factors (PA, section 4.3.4).

The PA additionally considered the quantitative information for other long-recognized effects of O_3 (PA, section 4.3.4). For example, with regard to crop yield effects, as at the time of the last review, the PA recognized the potential for greater uncertainty in estimating the impacts of O_3 exposure on agricultural crop production than that associated with O_3 impacts on vegetation in natural forests. This relates to uncertainty in the extent to which agricultural management methods influence potential for O_3-related effects and accordingly, the applicability of the established E–R functions for RYL in current agricultural areas (PA, section 4.3.4).

With regard to visible foliar injury, the PA finds that, as in the last review, there remains a lack of established E–R functions that would quantitatively describe relationships between the occurrence and severity of visible foliar injury and O_3 exposure, as well as factors influential in those relationships, such as soil moisture conditions (PA, section 4.5.1.1). While the currently available information continues to include studies that document foliar injury in sensitive plant species in response to specific O_3 exposures, investigations of a quantitative relationship between environmental O_3 exposures and visible foliar injury occurrence/severity have not yielded a predictive result. In addition to experimental studies, the evidence includes multiple studies that have analyzed data collected as part of the USFS biosite biomonitoring program (*e.g.,* Smith, 2012). These analyses continue to indicate the limitations in capabilities for predicting the exposure circumstances under which visible foliar injury would be expected to occur, as well as the circumstances contributing to increased injury severity. As noted in section III.B.3.b above, expanded summaries of the dataset compiled in the 2015 review from several years of USFS biosite records also does not clearly and consistently describe a relationship between incidence of foliar injury or severity (based on individual site scores) and W126 index estimates across the range of exposures. Overall, however, the dataset indicates that the proportion of records having different levels of severity score is generally highest in the records at sites with the highest W126 index (*e.g.,* greater than 25 ppm-hrs for the normal and dry soil moisture categories). This analysis does not provide for identification of air quality conditions, in terms of O_3 concentrations associated with the relatively lower environmental exposures most common in the USFS dataset that would correspond to a specific magnitude of injury incidence or severity scores across locations.

As discussed in section III.B.3 above, a number of analyses of the USFS biosite data (as well as several experimental studies), while often using cumulative exposure metrics to quantify O_3 exposures have additionally reported there to be a role for a metric that quantifies the incidence of ''high'' O_3 days (2013 ISA, p. 9–10; Smith, 2012; Wang et al., 2012). Such analyses have not, however, established specific air quality metrics and associated quantitative functions for describing the influence of ambient air O_3 on incidence and severity of visible foliar injury. As a result, the PA concludes that limitations recognized in the last review remain in our ability to quantitatively estimate incidence and severity of visible foliar injury likely to occur in areas across the U.S. under different air quality conditions over a year, or over a multi-year period.

In looking across the full array of O_3 welfare effects, the PA recognizes that the E–R functions for growth-related effects that were available in the last review continue to be the most robust E–R information available. The currently available evidence for growth-related effects, including that newly available in this review, does not indicate the occurrence of growth-related responses attributable to cumulative O_3 exposures lower than was established at the time of the last review. With regard to visible foliar injury, the available information that would support estimates of occurrence and severity across a range of air quality conditions continues to be limited, affecting the nature of conclusions that may be reached related to potential occurrence and/or severity for conditions. The quantitative information for other effects is more limited, as recognized earlier in this section and in section III.B.3 above. Thus, the PA concludes that the newly available evidence does not appreciably address key limitations or uncertainties as would be needed to expand capabilities for estimating welfare impacts that might be expected as a result of differing patterns of O_3 concentrations in the U.S.

(iii) W126 Index as Exposure Metric

With regard to exposure metric the currently available evidence continues to support a cumulative, seasonal exposure index as a biologically relevant and appropriate metric for assessment of the evidence of exposure/risk information for vegetation, most particularly for growth-related effects. The most commonly used such metrics are the SUM06, AOT40 (or AOT60) and W126 indices (ISA, section IS.3.2).[175] The evidence for growth-related effects continues to support important roles for cumulative exposure and for weighting higher concentrations over lower concentrations. Thus, among the various such indices considered in the literature, the cumulative, concentration-weighted metric, defined by the W126 function, continues to be best supported for purposes of relating O_3 air quality to growth-related effects. Accordingly, the PA continues to find the W126 index appropriate for consideration of the potential for vegetation-related effects to occur under air quality conditions (PA, section 4.5.1.1). The PA also recognizes, as recognized in the past, the lack of support for E–R functions for incidence and severity of visible foliar injury with W126 index as the descriptor of exposure, particularly in environmental settings where exposures are below a

[174] This was the view of the CASAC in the 2015 review (Frey, 2014b, p. 11).

[175] The evidence includes some studies reporting O_3-reduced soybean yield and perennial plant biomass loss using AOT40 (as well as W126) as the exposure metric, however, no newly available analyses are available that compare AOT40 to W126 in terms of the strength of association with such responses. Nor are studies available that provide analyses of E–R relationships for AOT with reduced growth or RBL with such extensiveness as the analyses supporting the established E–R functions for W126 with RBL and RYL.

W126 index of 25 ppm-hrs. While the PA analysis of the dataset of USFS biosite scores indicates appreciable increases in incidence and severity at and above 25 ppm-hrs, a pattern is unclear at lower W126 index estimates across which the dataset does not support a predictive relationship. As summarized in section III.3.b above, while the overall evidence also indicates an important role for peak concentrations (*e.g.,* N100) in influencing the occurrence and severity of visible foliar injury, the current evidence does not include an established predictive relationship based on such an additional metric (PA, section 4.5.1.1).

b. General Approach for Considering Public Welfare Protection

This section summarizes PA consideration of the current evidence and air quality information with regard to key aspects of the general approach and risk management framework for making judgments and reaching conclusions regarding the adequacy of public welfare protection provided by the secondary standard that was applied in 2015 (summarized in section III.A.1 above). Key aspects of the approach include the use of RBL as a proxy for the broad array of O_3 vegetation-related effects, E–R relationships for this endpoint with the W126 index, and the focus on this index averaged across a 3-year period.

(i) RBL as Proxy or Surrogate

In the last review, the Administrator used RBL as a proxy or surrogate for an array of adverse welfare effects 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. Such a use was supported by the CASAC at that time (80 FR 65406, October 26, 2015; Frey, 2014b, pp. iii, 9–10).[176] In consideration of the broader evidence base and public welfare implications, including associated strengths, limitations and uncertainties, the Administrator focused on RBL, not simply in making judgments specific to a magnitude of growth effect in seedlings that would be acceptable or unacceptable in the natural environment, but as a surrogate or proxy 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 (80 FR 65406, October 26, 2015).

The currently available evidence related to conceptual relationships between plant growth impacts and the broader array of vegetation effects (*e.g.,* that supported the use of RBL as a surrogate or proxy) is largely consistent with that available in the last review. In fact, the ISA for the current review describes (or relies on) such relationships 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). Thus, the PA concludes that the current evidence does not call into question conceptual relationships between plant growth impacts and the broader array of vegetation effects. Rather, the current evidence continues to support the use of tree seedling RBL as a proxy for the broad array of vegetation-related effects, most particularly those conceptually related to growth (PA, sections 4.5.1.2 and 4.5.3).

Beyond tree seedling growth, on which RBL is specifically based, two other vegetation effect categories with extensive evidence bases, crop yield and visible foliar injury, were also given attention in considering the public welfare protection provided by the standard in 2015. Based on the available information for these endpoints, along with associated limitations and uncertainties, the Administrator at that time concluded there was not support for giving a primary focus, in selecting a revised secondary standard, to these two types of effects. With regard to crop yield, the Administrator recognized the significant role of agricultural management practices in agricultural productivity, as well as market variability, concluding that, in describing her public welfare protection objectives, additional attention to this endpoint was not necessary. The rough similarities in estimated W126 levels of median crops and tree species are also noteworthy. With regard to foliar injury, the lack of clear quantitative relationships that would support predictive E–R functions was recognized. In light of such considerations, the Administrator focused on RBL estimates in identifying the requisite standard, and judged that a standard set based on public welfare protection objectives described in terms of cumulative exposures and relationships with tree seedling RBL was an appropriate means to, and would, provide appropriate protection for the array of vegetation-related effects. With regard to the information available in the current review, the PA concludes it does not call into question the basis for such judgments and continues to be supportive of the use of tree seedling RBL as a proxy for the broad array of vegetation-related effects (PA, section 4.5.1.2).

In considering the magnitude of estimated RBL on which to focus in its role as a surrogate or proxy for the full array of vegetation effects in the last review, the Administrator endeavored to identify a secondary standard that would limit 3-year average O_3 exposures somewhat below W126 index values associated with a 6% RBL median estimate from the established species-specific E–R functions. This led to identification of a seasonal W126 index value of 17 ppm-hrs that the Administrator concluded appropriate as a target at or below which the new standard would generally restrict cumulative seasonal exposures (80 FR 65407, October 26, 2015). In identifying this exposure level as a target, the Administrator, recognizing limitations and uncertainties in the evidence and variability in biota and ecosystems in the natural environment, additionally judged that RBL estimates associated with isolated rare instances of marginally higher cumulative exposures (in terms of a 3-year average W126 index), *e.g.,* those that round to 19 ppm-hrs (which corresponds to 6% RBL as median from 11 established E–R functions), were not indicative of adverse effects to the public welfare (80 FR 65409, October 26, 2015).

The PA concludes that the information newly available in this review does not differ from that available in the last review with regard to a magnitude of RBL in the median species appropriately considered a reference for judgments concerning

[176] The CASAC 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.

potential vegetation-related impacts to the public welfare (PA, section 4.5.1.2). The currently available evidence continues to indicate conceptual relationships between reduced growth and the broader array of vegetation-related effects, and limitations and uncertainties remain with regard to quantitation. The PA notes that consideration of the magnitude of tree growth effects that might cause or contribute to adverse effects for trees, forests, forested ecosystems or the public welfare is complicated by various uncertainties or limitations in the evidence base, including those associated with relating magnitude of tree seedling growth reduction to larger-scale forest ecosystem impacts. Further, other factors can influence the degree to which O_3-induced growth effects in a sensitive species affect forest and forest community composition and other ecosystem service flows (*e.g.,* productivity, belowground biogeochemical cycles and terrestrial ecosystem water cycling) from forested ecosystems. These include (1) the type of stand or community in which the sensitive species is found (*i.e.,* single species versus mixed canopy); (2) the role or position the species has in the stand (*i.e.,* dominant, sub-dominant, canopy, understory); (3) the O_3 sensitivity of the other co-occurring species (O_3 sensitive or tolerant); and (4) environmental factors, such as soil moisture and others. The lack of such established relationships with O_3 complicates consideration of the extent to which different estimates of impacts on tree seedling growth would indicate significance to the public welfare. Further, efforts to estimate O_3 effects on carbon sequestration are handicapped by the large uncertainties involved in attempting to quantify the additional carbon uptake by plants as a result of avoided O_3-related growth reductions. Such analyses require complex modeling of biological and ecological processes with their associated sources of uncertainty.

Quantitative representations of such relationships have been used to study potential impacts of tree growth effects on such larger-scale effects as community composition and productivity with the results indicating the array of complexities involved (*e.g.,* ISA, Appendix 8, section 8.8.4). Given their purpose in exploring complex ecological relationships and their responses to environmental variables, as well as limitations of the information available for such work, these analyses commonly utilize somewhat general representations. The PA notes that this work indicates how established the existence of such relationships is, while also identifying complexities inherent in quantitative aspects of such relationships and interpretation of estimated responses. Thus, the PA finds the currently available evidence to be little changed from the last review with regard to informing identification of an RBL reference point reflecting ecosystem-scale effects with public welfare impacts elicited through such linkages (PA, section 4.5.1.2).

(ii) Focus on 3-Year Average W126 Index

In setting the current standard, as described in section III.A.1 above, the Administrator focused on control of seasonal cumulative exposures in terms of a 3-year average W126 index. The evaluations in the PA for that review recognized there to be limited information to discern differences in the level of protection afforded for cumulative growth-related effects by a standard focused on a single-year W126 index as compared to a 3-year W126 index (80 FR 65390, October 26, 2015). Accordingly, 3-year average was identified for considering the seasonal W126 index based on the recognition that there was year-to-year variability not just in O_3 concentrations, but also in environmental factors, including rainfall and other meteorological factors, that influence the occurrence and magnitude of O_3-related effects in any year (*e.g.,* through changes in soil moisture), contributing uncertainties to projections of the potential for harm to public welfare (80 FR 65404 October 26, 2015). Given this recognition, as well as other considerations, the Administrator expressed greater confidence in judgments related to projections of public welfare impacts based on seasonal W126 index estimated by a 3-year average and accordingly, relied on that metric.

A general area of uncertainty that remains in the current evidence continues to affect interpretation of the potential for harm to public welfare over multi-year periods of air quality that meet the current standard (PA, section 4.3.4). As recognized in the last review, there is variability in ambient air O_3 concentrations from year to year, as well as year-to-year variability in environmental factors, including rainfall and other meteorological factors that affect plant growth and reproduction, such as through changes in soil moisture. Accordingly, these variabilities contribute uncertainties to estimates of the occurrence and magnitude of O_3-related effects in any year, and to such estimates over multi-year periods. The PA recognizes that limitations in our ability to estimate the effects on growth over tree lifetimes of year-to-year variation in O_3 concentrations, particularly those associated with conditions meeting the current standard, contribute uncertainty to estimates of cumulative growth (biomass) effects over multi-year periods in the life of individual trees and associated populations, as well as related effects in associated communities and ecosystems (PA, section 4.3.4).

As summarized in section III.B.3 above, the longstanding evidence on O_3 effects on plant growth includes the established and robust E–R functions for 11 species of tree seedlings (ISA, Appendix 8, Table 8–24; PA, Appendix 4A, Table 4A–1,). The PA recognized the strength of these functions in describing tree seedling response across a broad range of W126 index values, concluding that the evidence continues to support their use in estimating the median RBL across species in this review. In considering the appropriate representation of seasonal W126 for use of these functions with air quality data, the PA additionally considered the available information underlying the E–R functions and the extent to which the information is specific to a single seasonal exposure, *e.g.,* as compared to providing representation for an average W126 index across multiple seasons (PA, section 4.5.1.2). In so doing, the PA took note of aspects of the evidence that reflect variability in organism response under different experimental conditions and the extent to which this variability is represented in the available data. This might indicate an appropriateness of assessing environmental conditions using a mean across seasons in recognition of the existence of such year-to-year variability in conditions and responses. An additional aspect of the information underlying the E–R functions that was identified as relevant to consider is the extent to which the exposure conditions represented include those associated with O_3 concentrations that meet the current standard, and the extent to which tree seedling growth responses to such conditions may have been found to not be significantly different from responses to the control (*e.g.,* zero O_3) conditions. The extent to which E–R predictions are extrapolated beyond the tested exposure conditions also contributes to uncertainty which the PA indicated may argue for a less precise interpretation, such as an average across multiple seasons.

The experiments from which the functions were derived vary in duration from periods of 82 to 140 days over a single year to periods of 180 to 555 days across two years, and in whether measurements were made immediately following exposure period or in the subsequent season (PA, section 4.5.1.2, Appendix 4A, Table 4A–5; 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 and then normalized to 3-month (seasonal) periods (see Lee and Hogsett, 1996, section I.3; PA, Appendix 4A). 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. 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).

The PA additionally recognizes that the experiment-specific E–R functions for both aspen and ponderosa pine illustrate appreciable variability in response across experiments (PA, Appendix 4A, Figure 4A–10). The PA suggested that reasons for this variability may relate to a number of factors, including variability in seasonal response related to variability in non-O_3 related environmental influences on growth, such as rainfall, temperature and other meteorological variables, as well as biological variability across individual seedlings, in addition to potentially variability in the pattern of O_3 concentrations contributing to similar cumulative exposures (PA, section 4.5.1.2). In recognition of some of the variability in both seasonal environmental conditions in the studies and the associated experimental data, the 11 species-specific E–R functions are based on median responses (derived from experiment-specific functions) across an array of W126 index values (PA, Appendix 4A; Lee and Hogsett, 1996).[177] The number of experiments used in deriving the E–R functions for each species varies. For example, there are 7 experimental studies for wild aspen and 11 for ponderosa pine (PA, Appendix 4A, Table 4A–5), and only two or three for the three species (black cherry, sugar maple and tulip poplar) that exhibit greater sensitivity than aspen and ponderosa pine (PA, Appendix 4A, section 4A–2, Table 4A–5; 1996 AQCD, Table 5–28; Lee and Hogsett, 1996). Regarding the extent or strength of the database underlying the E–R functions for cumulative exposure levels of interest in the current review, the PA also notes that the data generally appear to be more extensive for relatively higher (*e.g.,* at/above a SUM06 of 30 ppm-hrs), *versus* lower, seasonal exposures (PA, Appendix 4A, Table 4A–6). Additionally, while the evidence is long-standing and robust for growth effects of O_3, the studies available for some species appear to be somewhat limited in the extent to which they include cumulative O_3 exposures commonly occuring with air quality conditions that meet the current standard (*e.g.,* W126 index values below 20 ppm-hrs).[178] The PA concludes the factors identified here to contribute to uncertainty or inexactitude in estimates based on the E–R functions.

The PA recognizes that the evidence that allows for specific evaluation of the predictability of growth impacts from single-year versus multiple-year average exposure estimates is quite limited. Such evidence would include multi-year studies reporting results for each year of the study, which are the most informative to the question of plant annual and cumulative responses to individual years (high and low) over multiple-year periods. The evidence is quite limited with regard to studies of O_3 effects that report seasonal observations across multi-year periods and that also include detailed hourly O_3 concentration records (to allow for derivation of exposure index values). Such a limitation contributes uncertainty and accordingly a lack of precision to our understanding of the quantitative impacts of seasonal O_3 exposure, including its year-to-year variability on tree growth and annual biomass accumulation (PA, section 4.3.4). The PA finds this uncertainty to limit our understanding of the extent to which tree biomass would be expected to appreciably differ at the end of multi-year exposures for which the overall average exposure is the same, yet for which the individual year exposures varied in different ways (*e.g.,* as analyzed in Appendix 4D of the PA). Thus, the PA notes that the extent of any differences in tree biomass for two multi-year scenarios with the same 3-year average W126 index but differing single-year indices is not clear, including for exposures associated with O_3 concentrations that would meet the current standard (PA, section 4.3.4).[179]

One such study, which tracked exposures across six years, is available for aspen (King et al., 2005; 2013 ISA, section 9.6.3.2; ISA, Appendix 8, section 8.13.2).[180] This study was used in a presentation of the 2013 ISA that compared the observed growth response to that predicted from the E–R function for aspen. Specifically, the observed aboveground biomass (and RBL) after each of the six growing seasons was compared to estimates derived from the aspen E–R function based on the cumulative multiple-year average seasonal W126 index values for each year[181] (2013 ISA, section 9.6.3.2). The conclusions reached were that the agreement between the set of predictions and the Aspen FACE observations were ''very close'' and that ''the function based on one year of growth was shown to be applicable to subsequent years'' (2013 ISA, p. 9–135). The PA observes that such results indicate that when considering O_3 impacts on growing trees across multiple years, a multi-year average index yields predictions close to observed measurements across the multi-year time period (2013 ISA, section 9.6.3.2 and Figure 9–20; PA, Appendix 4A, section 4.A.3). The PA also includes example analyses that use biomass measurements from the multi-year study (King et al., 2005) to estimate aboveground aspen biomass over a multi-year period using the established

[177] This median-based approach is expected to guard against statistical bias in parameter values.

[178] The evidence is unclear on the extent to which six of the 11 species include exposure treatments likely to correspond to W126 index values at or below 20 ppm-hrs (PA, Appendix 4A, Table 4A–5). For five of the species in Table 4A–5 in Appendix 4A, SUM06 index values below 25 ppm-hrs range from 12 to 21.7. In considering these values, we note that an approach used in the 2007 Staff Paper on specific temporal patterns of O_3 concentrations concluded that a SUM06 index value of 25 ppm-hrs would be estimated to correspond to a W126 index value of approximately 21 ppm-hrs (U.S. EPA, 2007, Appendix 7B, p. 7B–2). Accordingly, a SUM06 value of 21 ppm-hrs might be expected to correspond to a W126 index value below 20 ppm-hrs. The PA further notes that for one of the species for which lower exposures were studied, black cherry, the findings for at least one study reported statistical significance only for effects observed for higher exposures (PA, section 4.3.4, Appendix 4A, Table 4A–6).

[179] Variation in annual W126 index values indicates that for the period, 2016–2018, the amount by which annual W126 index values at a site differ from the 3-year average varies is generally below 10 ppm-hrs across all sites and generally below 5 ppm-hrs at sites with design values at or below 70 ppb (PA, Appendix 4D, Figure 4D–7).

[180] A similar comparison is presented in the current ISA (ISA, Appendix 8).

[181] Although not emphasized or explained in detail in the 2013 ISA, the W126 estimates used to generate the predicted growth response were cumulative average. To clarify, the cumulative average W126 for year 1 is simply the W126 index for that year (*e.g.,* based on highest 3 months). For year 2, it is the average of the year 1 seasonal W126 and year 2 seasonal W126, and so on. For year 6, it is the average of each of the six year's seasonal W126 index values.

E–R function for aspen with a constant single-year W126 index, *e.g.,* of 17 ppm-hrs, or with varying annual W126 index values (10, 17 and 24 ppm-hrs) for which the 3-year average is 17 ppm-hrs, and that yield somewhat similar total biomass estimates after multiple years (PA, Appendix 4A, section 4A.3).[182]

Thus, the PA finds that, while the E–R functions are based on strong evidence of seasonal and cumulative seasonal O_3 exposure reducing tree growth, and while they provide for quantitative characterization of the extent of such effects across O_3 exposure levels of appreciable magnitude, there is uncertainty associated with the resulting RBL predictions. Further, the current evidence does not indicate single-year seasonal exposure in combination with the established E–R functions to be a better predictor of RBL than a seasonal exposure based on a multi-year average, or *vice versa* (Appendix 4A, section 4A.3.1). Rather, associated uncertainty contributes or implies an imprecision or inexactitude in the resulting predictions, particularly for the lower W126 index estimates of interest in this review. In light of this, the current evidence does not support concluding there to be an appreciable difference in the effect of three years of exposure held at 17 ppm-hrs compared to a 3-year exposure that averaged 17 ppm-hrs yet varied by 5 to 10 ppm (*e.g.,* 7 ppm-hrs) from 17 ppm-hrs in any of the three years for tree RBL over such multiple-year periods. The PA considered all of the factors identified here, the currently available evidence and recognized limitations, variability and uncertainties, to contribute uncertainty and resulting imprecision or inexactitude to RBL estimates of single-year seasonal W126 index values. The PA found these considerations to indicate there to be no lesser support for use of an average seasonal W126 index derived from multiple years (with their representation of variability in environmental factors), such as for a 3-year period, for estimating median RBL using the established E–R functions than for use of a single-year index.

(iii) Visible Foliar Injury

In considering a public welfare protection approach related to visible foliar injury, the PA first notes that some level of visible foliar injury can impact public welfare and thus might reasonably be judged adverse to public welfare.[183] As summarized in section III.B.2 above, depending on its spatial extent and severity, there are many situations or locations in which visible foliar injury can adversely affect the public welfare. For example, significant, readily perceivable and widespread injury in national parks and wilderness areas can adversely affect the perceived scenic beauty of these areas, harming the aesthetic experience for both outdoor enthusiasts and the occasional park visitor. Such considerations have also been recognized by the Agency in past reviews, in which decisions to revise the O_3 secondary standard emphasized protection of Class I areas, which are areas such as national wilderness areas and national parks given special protections by the Congress (*e.g.,* 73 FR 16496, March 27, 2008, ‘‘the Administrator concludes it is appropriate to revise the secondary standard, in part, to provide increased protection against O_3-caused impairment to such protected vegetation and ecosystems’’).[184]

In establishing the current secondary standard and describing its underlying public welfare protection objectives (as summarized in section III.A.1, above), the Administrator at that time focused primarily on RBL in tree seedlings as a proxy or surrogate for the full array of vegetation related effects of O_3, while additionally concluding that the then-available information on visible foliar injury provided some support for establishing a strengthened standard. In so doing, she took note of the indication of the evidence of the association between O_3 and visible foliar injury, as well as in the declines generally observed in USFS BI scores with reductions in W126 index from well above 20 ppm-hrs to lower levels (80 FR 65407–65408, October 26, 2015). She recognized, however, that the evidence was not conducive to use in identifying a quantitative public welfare protection objective focused specifically on visible foliar injury (based on judgment of the specific extent and severity at which such effects should be considered adverse to the public welfare) due to uncertainties and complexities associated with the available information. In related manner, she specifically recognized significant challenges posed by the lack of clear quantitative relationships (including robust exposure-response functions that addressed the variability observed in the available data, likely associated with the variables creating a predisposing environment), that would allow prediction of visible foliar injury severity and incidence under varying air quality and environmental conditions, as well as the lack of established criteria or objectives that might inform consideration of potential public welfare impacts related to this vegetation effect (80 FR 65407, October 26, 2015).

The PA finds that these challenges are not addressed by the information available in the current review. Beyond the lack of established descriptive quantitative relationships for O_3 concentrations or exposure metrics with incidence or severity of visible foliar injury, summarized in sections III.D.1.a and III.B.3 above, there is a paucity of information clearly relating differing levels of severity and extent of location affected to scenic or aesthetic values (*e.g.,* reflective of visitor enjoyment and likelihood of frequenting such areas) that might inform judgments of public welfare protection from adversity (PA, section 4.5.1). Thus, there remain appreciable limitations of the current information for the purpose of providing a foundation for judgments on public

[182] This example, while simplistic in nature, and with inherent uncertainties, including with regard to broad interpretation given the reliance on data available for the single study, quantitatively illustrates potential differences in growth impacts of W126 index, as a 3-year average, for which individual year values vary while still meeting the value specified for the average, from such impacts from exposure controlled to the same W126 index value annually. The PA suggests that this example indicates based on the magnitude of variation documented for annual W126 index values occurring under the current standard, a quite small magnitude of differences in tree biomass between single-year and multi-year average approaches to controlling cumulative exposure (PA, Appendix 4A, section 4A.3).

[183] As stated in the 2015 decision notice: ‘‘both tree growth-related effects and visible foliar injury have the potential to be significant to the public welfare’’ (80 FR 65377, October 26, 2015); ‘‘O_3-induced visible foliar injury also has the potential to be significant to the public welfare through impacts in Class I and other similarly protected areas’’ (80 FR 65378, October 26, 2015); ‘‘[d]epending on the extent and severity, O_3-induced visible foliar injury might be expected to have the potential to impact the public welfare in scenic and/or recreational areas during the growing season, particularly in areas with special protection, such as Class I areas. (80 FR 65379, October 26, 2015); ‘‘[t]he Administrator also recognizes the potential for this effect to affect the public welfare in the context of affecting values pertaining to natural forests, particularly those afforded special government protection (80 FR 65407, October 26, 2015).

[184] In the discussion of the need for revision of the 1997 secondary standard, the 2008 decision noted that ‘‘[i]n considering what constitutes a vegetation effect that is adverse from a public welfare perspective, . . . the Administrator has taken note of a number of actions taken by Congress to establish public lands that are set aside for specific uses that are 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’’ (73 FR 16496, March 27, 2008). This passage of the 2008 decision notice clarified that ‘‘[s]uch public lands that are protected areas of national interest include national parks and forests, wildlife refuges, and wilderness areas’’ (73 FR 16496, March 27, 2008).

welfare protection objectives specific to visible foliar injury.

Notwithstanding these limitations with regard to a detailed approach or framework for judging public welfare protection related to impacts of visible foliar injury, the current evidence and analyses are informative to such considerations. For example, the published studies and EPA analyses of the USFS biosite data indicate that incidence and severity of injury are increased at the highest exposures. With regard to the dataset analyzed in the PA, while clear trends in incidence and severity related to increasing W126 index are not evident across the W126 bins below 25 ppm-hrs, the incidence of sites with the more severe classification of injury (*e.g.,* BI score above 15 [''moderate'' or ''severe''] or 5 [''light,'' ''moderate,'' or ''severe'']) is appreciably lower at sites with W126 index values below 25 ppm-hrs than at sites with higher values (*e.g.,* PA, Appendix 4C, Figures 4C–5 and 4C–6 and Table 4C–5). This observation is based primarily on records for the normal soil moisture category, for which is sufficient sample size across the full range of W126 and the largest differences in incidence and average score are observed.[185] Based on these observations and the full analysis, the PA concludes that the currently available information does not support precise conclusions as to the severity and extent of such injury associated with the lower values of W126 index most common at USFS sites during the years of the dataset, 2006–2010.[186] Based on the general pattern observed, however, the PA suggests a reduced severity (average BI score below 5) and incidence of visible foliar injury, as quantified by BI scores, to be expected under conditions that maintain W126 index values below 25 ppm-hrs, (PA, section 4.5.1.3).

Given the evidence regarding the role of peak O_3 concentrations as an influence on occurrence of visible foliar injury separate from that of the cumulative, concentration-weighted, W126 index (summarized in section III.B.3.b above), the PA additionally finds that the conditions associated with visible foliar injury in locations with sensitive species appear to relate to peak concentration as well as cumulative exposure to generally higher concentrations over the growing season (PA. section 4.5.1.2). Accordingly, the PA also considered the current information with regard to peak concentration metrics. Such information includes the 2007 Staff Paper comparison based on the less extensive USFS dataset of counties grouped by fourth highest annual daily maximum 8-hour concentration. This analysis found a smaller incidence of nonzero BI biosites in counties with a fourth-high metric at or below 74 ppb as compared to counties limited to metric values at or below 84 ppb (U.S. EPA 2007, pp. 7–63 to 7–64). The indication of this finding that the averaging time and form of the current standard, which emphasizes peak concentrations through a short (8-hour) averaging time and a rare-occurrence form (annual fourth highest daily maximum), exert some control on the incidence of sites with visible foliar injury has a conceptual similarity to the finding of the most extensive study of USFS data (1994–2009) that reductions in peak 1-hour concentrations have influenced the declining trend observed in visible foliar injury since 2002 (Smith, 2012).

(iv) Climate Effects

In considering the currently available information for the effects of the global tropospheric abundance of O_3 on radiative forcing, and temperature, precipitation and related climate variables, the PA recognized there to be limitations and uncertainties in the associated evidence bases with regard to assessing potential for occurrence of climate-related effects as a result of varying O_3 concentrations in ambient air of locations in the U.S (as summarized in III.B.3 above). The current evidence is limited with regard to support for such quantitative analyses that might inform considerations related to the current standard. For example, as stated 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 9.3.1). These are ''in addition to the key sources of uncertainty in quantifying ozone RF changes, such as emissions over the time period of interest and baseline ozone concentrations during preindustrial times'' (ISA, section IS.9.3.1). Together such uncertainties limit development of quantitative estimates of climate-related effects in response to earth surface O_3 concentrations at the regional scale, such as in the U.S. While these complexities inhibit our ability to consider tropospheric O_3 effects, such as radiative forcing, we note that our consideration of O_3 growth-related impacts on trees inherently encompasses consideration of the potential for O_3 to reduce carbon sequestration in terrestrial ecosystems (*e.g.,* through reduced tree biomass as a result of reduced growth). That is, limiting the extent of O_3-related effects on growth would be expected to also limit reductions in carbon sequestration, a process that can reduce the tropospheric abundance of CO_2, the greenhouse gas ranked highest in importance as a greenhouse gas and radiative forcing agent (section III.B.3 above; ISA, section 9.1.1).

c. Public Welfare Implications of Air Quality Under the Current Standard

In considering the potential for effects and related public welfare implications of air quality conditions and associated exposures indicated to occur under the current standard, the PA first looked to the air quality analyses particular to cumulative O_3 exposures, in terms of the W126 index, given its established relationship with growth-related effects and specifically RBL as the identified proxy or surrogate for the full array of such effects (PA, section 4.5.1.3, Appendix 4D). In that context, the PA gave relatively greater emphasis to air quality in Class I areas in recognition of the increased significance of effects in such areas that have been accorded special protection, as discussed in section III.B.2 above. In evaluating the extent and magnitude of O_3 exposures, in terms of W126, in such areas that meet the current standard, the PA also considered year to year variability in the index, while recognizing that, with regard to W126 index relationships with RBL, there was uncertainty associated with RBL predictions from a single year W126 estimate (PA, sections 4.3.4 and 4.5.1, Appendix 4A). As discussed in section III.D.1.b above, the evidence does not indicate estimates based on an average of seasonal W126 across three years to be less, or more, predictive of RBL or resulting total plant biomass (PA, sections 4.3.4 and 4.5.1.2). The PA considered the magnitude of W126 index occurring in areas nationwide, and particularly in Class I areas, that meet the current standard, as well as the frequency of the relatively higher index values. Further, the PA evaluated the extent of control of such index values exerted by the current standard, as

[185] Across W126 bins in which at least 1% of the wet soil moisture records are represented, differences of highest bin from lower bins for injury incidence or average score is less than a factor of two (PA, section 4.3.3).

[186] Factors that may contribute to the observed variability in BI scores and lack of a clear pattern with W126 index bin 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 potential role of other aspects of O_3 air quality not captured by the W126 index.

evidence by comparisons of sites with design values at or below the current standard level and sites with higher design values (PA, section 4.4). Lastly, the PA also considered what the currently available information indicated with regard to the incidence and severity of visible foliar injury that might be expected to occur under air quality conditions that meet the current standard, and the potential for impacts on public welfare (PA, sections 4.5.1.2, 4.5.1.3 and 4.5.3).

The air quality analyses of monitoring data at sites across the U.S. that meet the current standard in the most recent 3-year period find that the seasonal W126 index, as assessed by the 3-year average, is at or below 17 ppm-hrs, with just one exception, among 849 locations, where it equaled 18 ppm-hrs. No 3-year average W126 index values exceeded 17 ppm-hrs in or near Class I areas. Further, such W126 exposures are generally well below 17 ppm-hrs across most of the U.S. These findings for sites meeting the current standard, differ dramatically from sites with higher design values. For example, a third of all U.S. sites with design values above 70 ppb in the recent period, and more than 80% of Class I area sites with design values above 70 ppb, have average W126 index values above 17 ppm-hrs. Looking back across the 19 years covered by the full historical dataset, the cumulative exposure estimates, averaged over the design value periods, were virtually all at or below 17 ppm-hrs, with most of the W126 index values below 13 ppm-hrs (PA, Appendix 4D, Table 4D–9).[187]

The PA also considered the general occurrence and distribution of relatively higher single-year W126 index values, finding a generally similar pattern to that for averages over the design value period. For example, fewer than two dozen of the 849 sites meeting the current standard in the recent period had a single-year index above 17 ppm-hrs; about a dozen of these sites fall above 19 ppm- hrs, the highest of which just reaches 25 ppm-hrs in downtown Denver, CO.[188] The frequency of such occurrences is still lower for the Class I area monitors. For example, during the most recent three years, when the average seasonal W126 index is at or below 17 ppm-hrs in all Class I areas meeting the current standard, there were just three single-year W126 index values above 17 ppm-hrs and none above 19 ppm-hrs (PA, Appendix 4D, Table 4D–15).[189] The PA additionally notes that single-year W126 index values in Class I areas over the 19-year dataset evaluated were generally at or below 19 ppm-hrs, particularly in the more recent years (PA, Appendix 4D, section 4D.3.2.3).

In reflecting on the air quality analysis findings summarized here, the PA additionally recognized limitations and uncertainties of the underlying database, noting there to be inherent limitations in any air monitoring network. The monitors for O_3 are distributed across the U.S., covering all NOAA regions and all states although some geographical areas are more densely covered than others, which may have sparse or no data. For example, only about 40% of all Federal Class I Areas have or have had O_3 monitors (with valid design values) within 15 km, thus allowing inclusion in the Class I area analysis. Even so, the dataset for that analysis includes sites in 27 states distributed across all nine NOAA climatic regions across the contiguous U.S, as well as Hawaii and Alaska. While some NOAA regions have far fewer numbers of Class I areas with monitors than others (*e.g.,* the Central, North East, East North Central, and South regions versus other regions), these areas also have appreciably fewer Class 1 areas in general. Thus, the regions with relatively more Class I area are also more well represented in the dataset. For example, the West and Southwest regions (with the largest number of Class I areas) have approximately a third of those areas represented with monitors, which include locations where W126 index values are generally higher, thus playing a prominent role in the analysis.

Another inherent uncertainty is with regard to the extent to which the results will prove to reflect conditions far out into the future as air quality and patterns of O_3 concentrations in ambient air continue to change in response to changing circumstances, such as changes in precursor emissions to meet the current standard across the U.S. However, findings from these analyses in the current review are largely consistent with those from analyses of the data available in the last review. Further, the analysis of how changes in O_3 patterns in the past have affected the relationship between W126 index and the averaging time and form of the current standard finds a positive, linear relationship between trends in design values and trends in the W126 index (both in terms of single-year W126 index and averages over 3-year design value period), as was also the case for similar analyses conducted for the data available at the time of the last review (Wells, 2015). While this relationship varied across NOAA regions, the regions showing the greatest potential for exceeding W126 index values of interest (*e.g.,* with 3-year average values above 17 and/or 19 ppm-hrs) also showed the greatest improvement in the W126 index per unit decrease in design value over the historical period assessed (PA, Appendix 4D, section 4D.3.2.3). Thus, the available data and this analysis appear to indicate that as design values are reduced to meet the current standard in areas that presently do not, W126 values in those areas would also be expected to decline (PA, Appendix 4D, section 4D.4).

In the last review, the Administrator focused on cumulative exposure estimates derived as the average W126 index over the 3-year design value period, concluding variations of single-year W126 index from the average to be of little significance in assessing public welfare protection. This focus generally reflected the judgment that estimates based on the average adequately, and appropriately reflected the precision of current understanding of O_3-related growth reductions, given the various limitations and uncertainties in such predictions, that have been further evaluated in the current review (as summarized in section III.D.1.b above). Based on the information available in the current review, the PA concludes that, with the year-to-year variation observed in areas meeting the current standard,[190] differences in year-to-year tree growth in response to each year's seasonal exposure from the tree growth estimated from the 3-year average of the single-year values would, given the offsetting impacts of seasonal exposures above and below the average, reasonably be expected to generally be small over

[187] Based on the established E–R functions for tree seedlings of 11 species, the median RBL estimates for such W126 index values are 3.8% or less (PA, Appendix 4A).

[188] These highest W126 index values occur in the South West and West regions in which there are nearly 150 monitor locations meeting the current standard (PA, Figure 4–6, Appendix 4D, Figure 4D–5, Table 4D–1). Across the full 19-year dataset, the downtown Denver site value is just one of six instances in the more than 8,000 design value periods meeting the current standard of a single-year W126 index value at or above 25 ppm-hrs. All but one of these instances were equal to 25 ppm-hrs; the single higher occurrence was equal to 26 ppm-hrs.

[189] Across the full 19-year dataset for Class I area monitors meeting the current standard (58 monitors with at least one such occurrence and approximately 500 total occurrences), there are no more than 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).

[190] The current air quality data indicates single-year W126 index values generally to vary by less than 5 ppm-hrs from the 3-year average when the 3-year average is below 20 ppm-hrs, which is the case for locations meeting the current standard (PA, Appendix 4D).

tree lifetimes (PA, section 4.5.1.2). In so doing, the PA takes note of limitations in aspects of the data underlying the E–R functions that contribute to imprecision or inexactitude to estimates of growth impacts associated with multi-year exposures in the relatively lower W126 index values pertinent to air quality under the current standard. The information newly available in the current review does not appreciably address such limitations and uncertainties or improve the certainty or precision in RBL estimates for such exposures (PA, sections 4.3.4, 4.5.1).

Combining the findings of W126 index values (averaged over design value period) likely under the current standard with the established E–R functions for reduced growth in 11 tree seedling species yields a median species RBL for tree seedlings at or below 5.3% for the recent period, with very few exceptions, with the highest estimates occurring in areas not near or within Class I areas. This general pattern is confirmed over the longer time period (2000–2018) for the vast majority of the data, with virtually all RBL estimates below 6%.[191] Further, given the variability and uncertainty associated with the data underlying the E–R functions (as summarized in section III.D.1.a above), the few higher single-year occurrences are reasonably considered to be of less significance than 3-year average values. Judgments in the last review (in the context of the framework summarized in section III.D.1.b above) concluded isolated rare occurrences of exposures for which median RBL estimates might be at or just above 6% to not be indicative of conditions adverse to the public welfare, particularly considering the variability in the array of environmental factors that can influence O_3 effects in different systems, and the uncertainties associated with estimates of effects in the natural environment.

With regard to visible foliar injury, the PA observes that the available evidence does not include an approach for characterizing natural areas experiencing some severity or extent injury (*e.g.,* via USFS BI score) with regard to public perception and potential impacts on public enjoyment; nor does it address this in combination with information on whether air quality conditions in sites with scores of a particular severity level do or do not meet the current standard (PA, section 4.5.1). As summarized in section III.B.2 above, public welfare implications relate largely to effects on scenic and aesthetic values. Accordingly, key considerations of this endpoint in past reviews have generally related to qualitative consideration of potential impacts related to the plant's aesthetic value in protected forested areas and the somewhat general, nonspecific judgment that a more restrictive standard is likely to provide increased protection. The currently available information does not yet address or describe the relationships expected to exist for some level of visible foliar injury severity (below that at which broader physiological effects on plant growth and survival might also be expected) and/or extent of location or site injury (*e.g.,* BI) scores with values held by the public and associated impacts on public uses of the locations.[192] Additionally, no criteria have been established regarding a level or prevalence of visible foliar injury considered to be adverse to the affected vegetation as the current evidence does not provide for determination of a degree of leaf injury that would have significance to the vigor of the whole plant (ISA, Appendix 8, p. 8–24). Nevertheless, while minor spotting on a few leaves of a plant may easily be concluded to be of little public welfare significance, it is reasonable to conclude 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) would likely impact the public welfare in scenic and/or recreational areas, particularly in areas with special protection, such as Class I areas. However, the gaps in our information and tools, as summarized in prior sections, restrict our ability to identify air quality conditions that might be expected to provide a specific level of protection from public welfare effects of this endpoint.

Assessment of any public welfare implications of air quality occurring under the current standard with regard to visible foliar injury is further hampered by the lack of an established quantitative description of the relationship between O_3 concentrations (or exposure metrics) and injury extent or incidence, as well as severity, that would support estimates of potential injury for varying air quality and environmental conditions (*e.g.,* moisture), most particularly for situations that meet the current standard. Although no such relationship or pertinent metrics for describing exposure are established, the available information, indicates a role for both a cumulative metric of exposure as well as the occurrence of relatively higher concentrations. More specifically, the PA notes the information indicating potential for increased incidence and severity of injury in locations with W126 index above 25 ppm-hrs and with increased occurrence of peak (1-hour) concentrations such as above 100 ppb (PA, section 4.5.1).

The analyses of recent and historical air quality at monitoring sites where the current standard is met do not indicate a tendency for such occurrence of cumulative exposures or peak concentrations (PA, sections 2.4.5 and 4.4, Appendices 2A and 4D). In these analyses, all 3-year average W126 index values are below 25 ppm-hrs, and values above 17 ppm-hrs are rare. In addition, all single-year, W126 index values at Class I area locations meeting the current standard (and virtually all sites across the U.S.) are at or below 25 ppm-hr; even, and values above 19 ppm-hrs are rare, and mores so in more recent years (PA, section 4.4.2, Appendix 4D). Accordingly, while the current evidence is limited for the purposes of identifying public welfare protection objectives related to visible foliar injury in terms of specific air quality metrics, the PA notes that the current information indicates that the occurrence of injury categorized as more severe than ''little'' by the USFS categorization (*i.e.,* a BI scores above 5 or above 15) would be expected to be infrequent in areas that meet the current standard.

In light of the evidence regarding a role for peak concentrations, the PA additionally took note of the control of peak concentrations exerted by the form and averaging time of the current standard. For example, daily maximum 1-hour, as well as 8-hour average O_3 concentrations have declined over the past 15 years, a period in which there have been two revisions of the level of the secondary standard, each providing greater stringency, while retaining the same averaging time and form as the current standard (*e.g.,* PA, Figures 2–10, 2–12 and 2–17). Further, during periods when the current standard is met, there is less than one day per site, on average

[191] Although potential for effects on crop yield was not given particular emphasis in the last review (for reasons similar to those summarized earlier), we additionally note that combining the exposure levels summarized for areas across the U.S. where the current standard is met with the E–R functions established for 10 crop species indicates a median RYL across crops to be at or below 5.1%, on average, with very few exceptions. Further, estimates based on W126 index at the great majority of the areas are below 5% (PA, Appendices 4A and 4D).

[192] Information with some broadly conceptual similarity to this has been used for judging public welfare implications of visibility effects of PM in setting the PM secondary standard (78 FR 3086, January 15, 2012).

with a maximum hourly concentration at or above 100 ppb. This compares with roughly 40 times as many such days, on average, for sites with design values above the current standard level (PA, Appendix 2A, section 2A.2). The currently available information indicates that the current standard provides appreciable control of peak 1-hour concentrations, as well as W126 index values, and thus, to the extent that such metrics play a role in the occurrence and severity of visible foliar injury, the current standard also provides appreciable control of these.

Thus, although the current information does not establish a metric or combination of metrics that well describes the relationship between occurrence and severity of visible foliar injury across a broad range of O_3 concentration patterns from those more common in the past to those in areas recently meeting the current standard, the PA concludes that the currently available information does not indicate that a situation of widespread and relatively severe visible foliar injury, with apparent implications for the public welfare, is likely associated with air quality that meets the current standard. Based on the USFS dataset presentations as well as the air quality analyses of W126 index values and frequency of 1-hour observations at or above 100 ppb, the prevalence of injury scores categorized as severe, or even moderate, which, depending on spatial extent, might reasonably be concluded to have potential to be adverse to the public welfare do not appear likely to occur under air quality conditions that meet the current standard. Thus, the PA finds, based on the current evidence and currently available air quality information, that the exposure conditions associated with air quality meeting the current standard are not those that might reasonably be concluded to result in the occurrence of significant foliar injury (with regard to severity and extent).

With regard to other vegetation-related effects, including those at the ecosystem scale, such as alteration in community composition or reduced productivity in terrestrial ecosystems, as recognized in section III.D.1.a above, the available evidence is not clear with regard to the risk of such impacts (and their magnitude or severity) associated with the environmental O_3 exposures estimated to occur under air quality conditions meeting the current standard, which primarily include W126 index at or below 17 ppm-hrs. In considering effects on crop yield, the air quality analyses at monitoring locations that meet the current standard indicate estimates of RYL for such conditions to be at and below 5.1%, based on the median estimate derived from the established E–R functions for 10 crops (PA, Appendix 4A, Table 4A–5). We additionally recognize there to be complexities involved in interpreting the significance of such small RYL estimates in light of the factors also recognized in the last review. These included the extensive management of crops in agricultural areas that may to some degree mitigate potential O_3-related effects, as well as the use of variable management practices to achieve optimal yields, while taking into consideration various environmental conditions. We also recognize that changes in yield of commercial crops and commercial commodities may affect producers and consumers differently, further complicating the question of assessing overall public welfare impacts for such RYL estimates (80 FR 65405, October 26, 2015).

2. CASAC Advice

The CASAC provided its advice regarding the current secondary standard in the context of its review of the draft PA (Cox, 2020a).[193] In so doing, 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, 2020, 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, pp. 2, 22).[194] 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, 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 sound'' (Cox, 2020, 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, 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, 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, p. 21), it described there to be a solid

[193] A limited number of public comments have been received in this review to date, including comments focused on the draft IRP, draft ISA or draft PA. Of the commenters that addressed adequacy of the current secondary O_3 standard, most expressed agreement with staff conclusions in the draft PA, while some expressed the view that the standard should be revised to a W126-based form or that articulation of its rationale should more explicitly address the protection the standard provides for public welfare effects.

[194] 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.

scientific foundation for the current secondary standard and also commented on areas related to the remand. With regard to the focus on the 3-year average W126 index, in addition to the comments summarized above, the CASAC concluded, as noted above, that the EPA Administrator's focus on the 3-year average and her judgments in doing so ''appears of reasonable thought and scientifically sound'' (Cox, 2020a, 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, 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, p. 22).

3. Administrator's Proposed 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 proposes to conclude 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 proposed 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 section III.D.1 above); the advice and recommendations from the CASAC (summarized in section III.D.2 above); and public comments received to date in this review, 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 the discussion below, the Administrator considers first the evidence base on welfare effects associated with exposure to photochemical oxidants, including O_3, in ambient air. In so doing, he considers the welfare effects evidence newly available in this review, and the extent to which it alters key scientific conclusions. The Administrator additionally considers the quantitative analyses available in this review, including associated limitations and uncertainties, and the extent to which they indicate differing conclusions regarding level of protection indicated to be provided by the current standard from adverse effects to the public welfare. Further, the Administrator considers the key aspects of the evidence and air quality and exposure information emphasized in establishing the now-current standard. He additionally considers uncertainties in the evidence and quantitative information, as part of public welfare policy judgments that are essential and integral to his decision on the adequacy of protection provided by the standard. The Administrator draws on the considerations and conclusions in the PA, taking note of key aspects of the rationale presented for those conclusions. In so doing, he notes the CASAC characterization of the ''thorough discussion and rationale for the secondary standard'' presented in the PA (Cox, 2020a, p. 2). Further, the Administrator considers the advice of the CASAC regarding the secondary standard, including particularly its 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). With attention to all of the above, the Administrator considers the information currently available in this review with regard to the appropriateness of the protection provided by the current standard.

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.D.1 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 the O_3 as the indicator for the secondary NAAQS for photochemical oxidants.

In considering the currently available welfare effects evidence for O_3, the Administrator recognizes the longstanding evidence base for vegetation-related effects, augmented in some aspects since the last review, described in section III.B.1 above. 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 Administrator also notes the Agency conclusions on three categories of effects with new ISA determinations that the current evidence is sufficient to infer likely causal relationships of O_3 with increased tree mortality, alteration of plant-insect signaling and alteration of insect herbivore growth and reproduction (as summarized in section III.B.1 above). With regard to the current evidence for increased tree mortality, the Administrator notes the PA finding 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. Accordingly, consistent with the approach in the PA, he finds 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 in this review, the Administrator takes note of the PA finding that uncertainties in the current evidence, as summarized in section III.B and III.D.1 above, preclude a full understanding of such effects, the air quality conditions that might elicit them, the potential for impacts in a natural ecosystem and, consequently, the potential for such impacts under air quality conditions associated with meeting the current standard; thus, there is insufficient information to judge the current standard inadequate based on these effects.

In considering the evidence with regard to support for quantitative description of relationships between air quality conditions and response to inform his judgments on the current standard, the Administrator recognizes the supporting evidence for plant growth and yield. The evidence base continues to indicate growth-related effects as sensitive welfare effects, with the potential for ecosystem-scale ramifications. For this category of effects, there are 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 (in terms of RYL). Many decades of research also recognize visible foliar injury as an effect of O_3, although uncertainties continue to hamper efforts to quantitatively characterize the relationship of its occurrence and relative severity with O_3 exposures, as discussed further below (and summarized in sections III.B.3.b and III.D.1.b above).

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 (vs global) scales, as summarized in sections III.D.1 and II.B.3 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 scale in the U.S. with specific risks of alterations in temperature, precipitation and other climate-related variables. The resulting uncertainty leads the Administrator to conclude that, with respect to radiative forcing and related effects, there is insufficient information available in the current review to judge the existing standard inadequate or to identify an appropriate revision.

The Administrator turns next to consideration of visible foliar injury. In so doing, he considers both the conclusions of the ISA and the examination and analysis in the PA of the currently available information as to what it indicates and supports with regard to adequacy of protection provided by the current standard, as summarized in section III.D.1 above. As an initial matter, he takes note of the long-standing documentation of visible foliar injury as an effect of O_3 in ambient air under certain conditions. Further, as summarized in section III.B.2 above, the public welfare significance of visible foliar injury of vegetation in areas not closely managed for harvest, particularly specially protected natural areas, has generally been considered in the context of potential effects on aesthetic and recreational values, such as the aesthetic value of scenic vistas in protected natural areas such as national parks and wilderness areas (*e.g.,* 73 FR 16496, March 27, 2008). 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 notes 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, summarized in section III.D.1 above (PA, sections 4.3.2 and 4.5.1). Thus, he considers the PA evaluation of the currently available information with regard to the potential for such an occurrence with air quality conditions that meet the current standard.

In considering the PA evaluations, the Administrator 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, as summarized in sections III.B.3 and III.D.1 above. In so doing, he notes 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,'' as summarized in section III.D.2 above.

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 well as interpretation of such incidence and severity in the context of considering protection from such impacts that might reasonably be considered adverse to the public welfare, the Administrator takes note of several findings of the PA. First, he notes that the evidence for visible foliar injury, as well as analyses of data for USFS biosites (sites with O_3-sensitive vegetation assessed for visible foliar injury) indicate there to be associations with cumulative exposure metrics (*e.g.,* SUM06 or W126 index), such metrics do not completely explain the occurrence and severity of injury. Although the availability of detailed analyses that have explored multiple exposure metrics and other influential variables is limited, multiple studies also have indicated a potential role for an additional metric 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.B.3 above (PA, section 4.5.1.2).

The Administrator also notes the PA observation that publications related to the evidence base for the USFS biosite monitoring program document reductions in the incidence of the higher BI scores over the 16-year period of the program (1994 through 2010), especially after 2002, leading to researcher conclusions of a ''declining risk of probable impact'' on the monitored forests over this period (*e.g.,* Smith, 2012). The PA observes that these reductions parallel the O_3 concentration trend information nationwide that shows clear reductions in cumulative seasonal exposures, as well as in peak O_3 concentrations such as the annual fourth highest daily maximum 8-hour concentration, from 2000 through 2018 (PA, Figure 2–11 and Appendix 4D, Figure 4D–9). These USFS BI score reductions also parallel reductions in the occurrence of 1-hour concentrations above 100 ppb (PA, Appendix 2A, Tables 2A–2 to 2A–4). Thus, the extensive evidence of trends across the past nearly 20 years indicate reductions in severity of visible foliar injury in addition to reductions in peak concentrations that some studies have suggested to be influential in the severity of visible foliar injury, as summarized in section III.D.1 above (PA, section 4.5.1).

The Administrator additionally takes note of the PA recognition of a paucity of established approaches for interpreting specific levels of severity and extent of foliar injury in protected forests with regard to impacts on public welfare effects, *e.g.,* related to recreational services. The PA notes 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. However, the available information does not provide for specific characterization of the incidence and severity that would not be expected to have such an impact, nor for clear identification of the pattern of O_3 concentrations that would provide for such a situation. In this context, the Administrator notes the PA description of the scheme developed by the USFS to categorize biosite scores of injury in natural vegetated areas by severity levels (as summarized in section III.B.2 above). He notes the USFS description of scores above 15 as ''moderate to severe,'' as well as the USFS categorization of lower scores, such as those from zero to just below 5, which are described as ''little to no foliar injury'' and 5 to just below 10 as ''light to moderate.'' In so doing, he recognizes the PA consideration of such lower scores as being unlikely to be indicative of injury of such a magnitude or extent that would reasonably be considered significant risks to the public welfare. In light of these considerations, the Administrator takes note of the PA finding 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, but that the lower categories of BI scores are indicative of injury of generally lesser risk to the natural area or to public enjoyment. 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). Consequently, he proposes 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 extent and severity, may raise public welfare concerns.

With regard to the PA presentations of the USFS data combined with W126 estimates and soil moisture categories, summarized in section III.B.3 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.3.b above (PA, section 4.3.3 and Appendix 4C). In so doing, he notes 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 (including in or near Class I areas) where the current standard is met, and that values above 17 or 19 ppm-hrs are rare, as summarized in section III.D.1.c 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. For example, the PA finds the average number of 1-hour daily maximum concentrations across monitored sites to be some 40 times lower for sites meeting the current standards compared to sites that do not, as summarized in section III.D.1 above. Based on these considerations, the Administrator agrees 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.

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 proposes 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.

In turning to consideration of the remaining array of vegetation-related effects, the Administrator first takes note of uncertainties in the details and quantitative aspects of relationships between plant-level effects such as growth and reproduction, and ecosystem impacts, the occurrence of which are influenced by many other ecosystem characteristics and processes. These examples illustrate the role of public welfare policy judgments, both with regard to the extent of protection that is requisite and concerning the weighing of uncertainties and limitations of the underlying evidence base and associated quantitative analyses. The Administrator notes that such judgments will inform his decision in the current review, as is common in NAAQS reviews. Public welfare policy judgments play an important role in each review of a secondary standard, just as public health policy judgments have important roles in primary standard reviews. One type of public welfare policy judgment focuses on how to consider the nature and magnitude of the array of uncertainties that are inherent in the scientific evidence and analyses. These judgments are traditionally made with a recognition that current understanding of the relationships between the presence of a pollutant in ambient air and associated welfare effects is based on a broad body of information encompassing not only more established aspects of the evidence but also aspects in which there may be substantial uncertainty. This may be true even of the most robust aspect of the evidence base. In the case of the secondary O_3 standard review, as an example, while recognizing the strength of the established and well-founded E–R functions in predicting the relationship of O_3 in terms of the W126 index cumulative exposure metric across a wide array of exposure levels, the Administrator additionally recognizes increased uncertainty, and associated imprecision or inexactitude in application of the E–R functions with lower cumulative exposures, and in the current understanding of aspects of relationships of such estimated effects with larger-scale impacts, such as those on populations, communities and ecosystems, as discussed in the PA and summarized in sections III.D.1 above.

The Administrator now turns to the welfare effects of reduced plant growth or yield. In so doing, he takes note of the well-established E–R functions for seedlings of 11 tree species that relate cumulative seasonal O_3 exposures of varying magnitudes to various incremental reductions in expected tree seedling growth (in terms of RBL) and in expected crop yield, that have been recognized across multiple O_3 NAAQS reviews. In so doing, he additionally takes note of uncertainties recognized in the PA, as summarized in section III.D.1.a above, that include the limited information that can address the extent to which the E–R functions for tree seedlings reflect growth impacts in mature trees, and the fact that the 11 species represent a very small portion of the tree species across the U.S. (PA, sections 4.3.4 and 4.5.3). While recognizing these and other uncertainties, RBL estimates based on the median of the 11 species were used as a surrogate in the last review for comparable information on other species and lifestages, as well as a proxy or surrogate for other vegetation-related effects, including larger-scale effects. The Administrator takes note of the PA conclusion and CASAC advice that use of this approach continues to appear to be a reasonable judgment in this review (PA, section 4.5.3). More specifically, the PA concludes that the currently available information continues to support (and does not call into question) the use of RBL as a useful and evidence-based approach for consideration of the extent of protection from the broad array of vegetation-related effects associated with O_3 in ambient air, as summarized in section III.D.1.b above. The Administrator also takes note of the PA conclusions that the currently available evidence, while somewhat expanded since the last review does not indicate an alternative metric for such a use; nor is an alternative approach evident. He further notes the CASAC concurrence that the current evidence continues to support this approach, as summarized in section III.D.2 above. Thus, he finds it appropriate to adopt this approach in the current review.

With regard to the use of RBL and the median RBL estimate based on the established E–R functions for 11 species of tree seedlings, the Administrator takes note of considerations in the PA. For example, while the E–R functions for the 11 species have been derived in terms of a seasonal W126 index, the experiments from which they were derived vary in duration from less than three months to many more, such that, the adjustment to a 3-month season duration, with its underlying simplifying assumptions of uniform W126 distribution over the exposure period and relationship between duration and response, contributes some imprecision or inexactitude to the resulting functions and estimates derived using it, as discussed in section III.D.1.b above. Additionally, there is greater uncertainty with regard to estimated RBL at lower cumulative exposure levels, as the exposure levels represented in the data underlying the E–R functions are somewhat limited with regard to the relatively lower cumulative exposure levels, such as those most commonly associated with the current standard (*e.g.,* at or below 17 ppm-hrs). 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. With these considerations regarding the E–R functions and their underlying datasets in mind, he also takes note of 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, as summarized in section III.D.1 above. The Administrator also considers the issues discussed in the court's remand of the 2015 secondary standard with respect to use of a 3-year average. See *Murray Energy Corp.* v. *EPA,* 936 F.3d at 617–18. In light of these considerations, the Administrator considers whether aspects of this evidence support making judgments using the E–R functions with W126 index derived as an average across multiple years. The Administrator notes 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). Such averaging, 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 more suitably paired with the E–R functions. The Administrator additionally takes note of the PA summary of comparisons performed in the 2013 ISA and current ISA of RBL estimates based on either cumulative average multi-year W126 index or single-year W126 with estimates derived from information in a multi-year O_3 exposure study, summarized in section III.D.1.b(ii) above (PA, section 4.5.1 and Appendix 4A, section 4A.3.1). He notes the PA finding that these 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, while also providing general agreement of predictions (based on either metric) with observations. The Administrator finds these considerations particularly informative in considering the evidence with regard to the appropriateness of a focus on a multi-year (*e.g.,* 3-year) average seasonal W126 index in assessing protection using RBL as a proxy or surrogate of the broader array of effects to obscure cumulative seasonal exposures of concern, a point discussed by the court in its 2019 remand of the 2015 secondary standard to EPA (*Murray Energy Corp.* v. *EPA,* 936 F.3d at 617–18).

In light of the above considerations, the Administrator agrees with the PA finding that such factors as those identified here (also summarized in section III.D.1.b(ii) above), and discussed in the PA (PA, sections 4.5.1.2 and 4.5.3), including the currently available evidence and its recognized limitations, variability and uncertainties, contribute uncertainty and resulting imprecision or inexactitude to RBL estimates of single-year seasonal W126 index values, thus supporting a conclusion that it is reasonable to use a seasonal RBL averaged over multiple years, such as a 3-year average. The Administrator additionally takes 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, as summarized in section III.D.2 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 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, the Administrator proposes 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.

Thus, the Administrator recognizes a number of public welfare policy judgments important to his review of the current standard. Those judgments include adoption of the median tree seedling RBL estimate for the studied species as a surrogate for the broad array of vegetation related effects that extend to the ecosystem scale, and identification of cumulative seasonal exposures (in terms of the average W126 index across the 3-year design period for the standard) for assessing O_3 concentrations in areas that meet the standard with regard to the extent of protection afforded by the standard. In reflecting on these judgments, the current evidence presented in the ISA and the associated evaluations in the PA, the Administrator proposes to conclude that the currently available information supports such judgments, additionally noting the CASAC concurrence with regard to the scientific support for these judgments (Cox 2020, p. 21). Accordingly, the Administrator proposes to conclude 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, 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 also notes 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. As with visible foliar injury, 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. In this context, the Administrator notes that the 2015 decision set the standard with an ''underlying objective of a revised secondary standard that would limit cumulative exposures in nearly all instances to those for which the median RBL estimate would be somewhat lower than 6%'' (80 FR 65407, October 26, 2015). With this objective, the prior Administrator did not additionally find that a cumulative seasonal exposure, for which such a magnitude of median species RBL was estimated, represented conditions that were adverse to the public welfare. Rather, the 2015 decision noted that ''the Administrator does not judge RBL estimates associated with marginal higher exposures [at or above 19 ppm-hrs] in isolated, rare instances to be indicative of adverse effects to the public welfare'' (80 FR 65407, October 26, 2015). 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 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 effective in particularly protecting the public welfare in light of vegetation impacts form ozone'' (Cox, 2020, p. 21). In light of this advice and based on the current evidence as evaluated in the PA, the Administrator proposes to conclude that this approach or framework, 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 proposes to use such an approach in this review.

With this approach and protection target in mind, 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 above. 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.C 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. In so doing, he takes notes of the PA analyses, summarized in section III.D.1 above, of USFS BI scores, giving particular focus to scores above 15 (termed ''moderate to severe injury'' by the USFS categorization scheme). 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 PA presentation of air quality data over the past 20 years, as summarized in section III.D.1 above, that shows a declining trend in 1-hour daily maximum concentrations mirroring the declining trend in design values, and the associated PA conclusion that the form and averaging time of the current standard provides appreciable control of peak 1-hour concentrations. As further evidence of the level of control exerted, the PA notes there to be less than one day per site, on average (among sites meeting the current standard), with a maximum hourly concentration at or above 100 ppb, compared to roughly 40 times as many such days, on average, for sites with design values above the current standard level (PA, Appendix 2A, section 2A.2). In light of these findings from the air quality analyses and considerations in the PA, summarized in section III.D.1 above, 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 proposes to judge that the current standard provides adequate protection from air quality conditions with the potential to be adverse to the public welfare.

In reaching his proposed 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). As discussed above, the Administrator notes 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 indicates a sufficient degree of protection from such conditions. Further, the currently available evidence for natural areas across the U.S., such as studies of USFS biosites, does not indicate widespread incidence of significant visible foliar injury, and analyses of USFS biosite scores in the PA do not indicate marked increases in scores categorized by the USFS as ''moderate'' or ''severe'' for W126 index values generally occurring at sites that meet the current standard. The Administrator finds 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 above, and with particular attention to Class I and other areas afforded special protection, the Administrator proposes 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 considers O_3 effects on crop yield. In so doing, he 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.B.2 above. However, he additionally recognizes that not every effect on crop yield will be adverse to public welfare and 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 contribute uncertainty to predictions of potential O_3-related public welfare impacts, as summarized in sections III.B.2 and III.D.1 above (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 recognizes the potential for a much larger influence of extensive management of such crops, and also considers other factors recognized in the PA and summarized in section III.D.1 above, including similarities in median estimates of RYL and RBL (PA, sections 4.5.1.3 and 4.5.3). With this in mind, the Administrator does not find that the information for crop yield effects leads him 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 proposes 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 above, the Administrator further proposes 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.

In reaching his proposed conclusion on the current standard, the Administrator also considers the extent to which the current information may provide support for an alternative standard. In so doing, he notes the longstanding evidence documenting the array of welfare effects associated with O_3 in ambient air, as summarized in section III.B.1 above. He additionally recognizes the robust quantitative evidence for growth-related effects and the E–R functions for RBL, which he considers as a proxy for the broader array of effects in reaching his proposed decision. He takes note of the air quality analyses that show an 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, as summarized in section III.C above for areas with design values above 70 ppb. He proposes to conclude that such occurrences contribute to air quality conditions that would not provide the appropriate protection of public welfare in light of the potential for adverse effects on the public welfare.

Further, the Administrator recognizes that public comments thus far in this review have suggested that an alternative standard, such as one based solely on the W126 metric, is required to provide adequate protection of the public welfare. Such a point was raised in the litigation challenging the 2015 secondary standard, although the court did not resolve this issue in its decision. In considering this issue, the Administrator recognizes that, as summarized in section III.B.3.a above, concentration-weighted, cumulative exposure metrics, including the W126 index, have been identified as quantifying exposure in a way that relates to reduced plant growth (ISA, Appendix 8, section 8.13.1). The W126 index is the metric used with the 11 established E–R functions discussed above, which provide estimates of RBL that the Administrator considers appropriately used as a proxy or surrogate for the broader array of vegetation-related effects. The Administrator additionally notes, however, that the evidence indicates there to be aspects of O_3 air quality not captured by measures of cumulative exposure, such as W126 index, that may pose a risk of harm to the public welfare. For example, as discussed above, the current evidence indicates a role for peak concentrations in the occurrence of visible foliar injury. With this in mind, the Administrator notes that an ambient air quality standard established in terms of the W126 index, while giving greater weight to generally higher concentrations, would not explicitly limit the occurrence of hourly concentrations at or above specific magnitudes. For example, two records of air quality may have the same W126 index while differing appreciably in patterns of hourly concentrations, including in the frequency of occurrence of peak concentrations (*e.g.,* number of hours above 100 ppb). The Administrator notes, however, as discussed above, that the current standard, with its 8-hour averaging time and fourth-highest daily maximum form (averaged over three years), can provide control of both peak concentrations and concentration-weighted cumulative exposures, as illustrated by the substantially limited occurrence of hourly concentrations of magnitudes at or above 100 ppb and of cumulative exposures at or above 19 ppm-hrs in areas that meet the current standard (PA, section 2.4.5, Appendix 2A, section 2A.2 and Appendix 4D). Thus, in light of the information available in this review, summarized in the sections above and including that related to a role of peak concentrations in posing risk of visible foliar injury to sensitive vegetation, the Administrator proposes 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. As indicated above, he proposes to judge that the current information indicates that the requisite control of such aspects of air quality is provided by the current standard.

In summary, the Administrator recognizes that his proposed 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, is based in part on judgments regarding uncertainties and limitations in the available information, such as those identified above. In this context, he has considered what the available evidence and quantitative information indicate with regard to the protection provided from the array of O_3 welfare effects. He finds that the 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 additionally takes note of 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). Based on all of the above considerations, including his consideration of the currently available evidence and quantitative exposure/risk information, the Administrator proposes 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. The Administrator solicits comment on this proposed conclusion.

Having reached the proposed decision described here based on interpretation of the welfare effects evidence, as assessed in the ISA, and the quantitative analyses presented in the PA; the evaluation of policy-relevant aspects of the evidence and quantitative analyses in the PA; the advice and recommendations from the CASAC; public comments received to date in this review; and the public welfare policy judgments described above, the Administrator recognizes that other interpretations, assessments and judgments might be possible. Therefore, the Administrator solicits comment on the array of issues associated with review of this standard, including public welfare and science policy judgments inherent in the proposed decision, as described above, and the rationales upon which such views are based.

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 propose to change the existing NAAQS for O_3, 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 expected to be an Executive Order 13771 regulatory action. There are no quantified cost estimates for this proposed action because EPA is proposing to retain 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 proposes to retain the current 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 proposes to retain, 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 proposes to retain the current 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 sections II.B and II.C 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 subject to Executive Order 13211, because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this document is to propose to retain the current O_3 NAAQS. This proposal does not change existing requirements. Thus, the EPA concludes that this proposal 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 proposed in this document is to retain without revision the existing O_3 NAAQS based on the Administrator's proposed 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 proposed 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).

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 (2006a). 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 (2006b). Human pulmonary responses with 30-minute time intervals of exercise and rest when exposed for 8 hours to 0.12 ppm ozone via square-wave and acute triangular profiles. Inhal Toxicol 18(6): 413–422.

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.

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.

Arjomandi, M, Balmes, JR, Frampton, MW, Bromberg, P, Rich, DQ, Stark, P, Alexis, NE, Costantini, M, Hollenbeck-Pringle, D, Dagincourt, N and Hazucha, MJ (2018). Respiratory Responses to Ozone Exposure. MOSES (The Multicenter Ozone Study in Older Subjects). Am J Respir Crit Care Med 197(10): 1319–1327.

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.

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 on the internet 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).

Bureau of Labor Statistics (2019). U.S. Department of Labor. Occupational Requirements Survey—Accessed August 27, 2019. *https://www.bls.gov/ors/home.htm.*

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.

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.

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.

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 Availbale at: *https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/F228E5D4D848BBED85258515006354D0/$File/EPA-CASAC-20-002.pdf.*

Darbah, JNT, Kubiske, ME, Neilson, N, Oksanen, E, Vaapavuori, E and Karnosky, DF (2007). Impacts of elevated atmospheric CO_2 and O_3 on paper birch (Betula papyrifera): Reproductive fitness. ScientificWorldJournal 7: 240–246.

Darbah, JNT, Kubiske, ME, Nelson, N, Oksanen, E, Vapaavuori, E and Kamosky, DF (2008). Effects of decadal exposure to interacting elevated CO_2 and/or O_3 on paper birch (Betula papyrifera) reproduction. Environ Pollut 155(3): 446–452.

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.

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.

Diaz-de-Quijano, M, Kefauver, S, Ogaya, R, Vollenweider, P, Ribas, À and Peñuelas, J (2016). Visible ozone-like injury, defoliation, and mortality in two Pinus uncinata stands in the Catalan Pyrenees (NE Spain). Eur J Forest Res 135(4): 687–696.

Dietze, MC and Moorcroft, PR (2011). Tree mortality in the eastern and central United States: Patterns and drivers. Global Change Biol 17(11): 3312–3326.

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, US 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 Ambient Air Monitoring & Methods 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.*

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.

Haefele, M, Kramer, RA and Holmes, TP (1991). Estimating the Total Value of a Forest Quality in High-Elevation Spruce-Fir Forests. The Economic Value of Wilderness: Proceedings of the Conference, Southeastern For Exper. Station. Asheville, NC, USDA Forest Service.

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.

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(9): 1215–1221.

Kubiske, ME, Quinn, VS, Heilman, WE, McDonald, EP, Marquardt, PE, Teclaw, RM, Friend, AL and Karnoskey, DF (2006). Interannual climatic variation mediates elevated CO_2 and O_3 effects on forest growth. Global Change Biol 12(6): 1054–1068.

Kubiske, ME, Quinn, VS, Marquardt, PE and Karnosky, DF (2007). Effects of elevated atmospheric CO_2 and/or O_3 on intra- and interspecific competitive ability of aspen. Plant Biol 9(2): 342–355.

Landesmann, JB, Gundel, PE, Martínez-Ghersa, MA and Ghersa, CM (2013). Ozone exposure of a weed community produces adaptive changes in seed populations of Spergula arvensis. PLoS ONE 8(9): e75820.

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.

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.

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, Stewart, PW and Smith, MV (2013). Ozone exposure-response model for lung function changes: An alternate variability structure. Inhal Toxicol 25(6): 348–353.

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.

Miller, DB, Ghio, AJ, Karoly, ED, Bell, LN, Snow, SJ, Madden, MC, Soukup, J, Cascio, WE, Gilmour, MI, and Kodavanti, UP (2016). Ozone Exposure Increases Circulating Stress Hormones and Lipid Metabolites in Humans Am J Resp Crit Care Med 193(12): 1382–1391 and Online Supplement.

Moran, EV and Kubiske, ME (2013). Can elevated CO2 and ozone shift the genetic composition of aspen (Populus tremuloides) stands? New Phytol 198(2): 466–475.

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.

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.*

Rosenberger, RS, Bell, LA, Champ, PA and White, EM (2013). Estimating the economic value of recreation losses in Rocky Mountain National Park due to a mountain pine beetle outbreak. Western Economics Forum 12(1): 31–39.

Samet, JM. (2010). Letter from Jonathan Samet, Chair, Clean Air Scientific Advisory Committee, to Administrator Lisa Jackson. Re: CASAC Review of EPA's *Proposed Ozone National Ambient Air Quality Standard* (**Federal Register**, Vol. 75, Nov. 11, January 19, 2010) February 19, 2010. EPA–CASAC–10–007. Office of the Administrator, Science Advisory Board U.S. EPA HQ, Washington DC. Available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P10072T1.txt.*

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.

Silverman, RA and Ito, K (2010). Age-related association of fine particles and ozone with severe acute asthma in New York City. J Allergy Clin Immunol 125(2): 367–373.

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.

Smith, JT and Murphy, D. (2015). Memorandum to Ozone NAAQS Review Docket (EPA–HQ–OAR–2008–0699). Additional Observations from WREA Datasets for Visible Foliar Injury. September 24, 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-2008-0699-4250&contentType=pdf.*

Stieb, DM, Szyszkowicz, M, Rowe, BH and Leech, JA (2009). Air pollution and emergency department visits for cardiac and respiratory conditions: A multi-city time-series analysis. Environ Health 8(25): 25.

Strickland, MJ, Darrow, LA, Klein, M, Flanders, WD, Sarnat, JA, Waller, LA, Sarnat, SE, Mulholland, JA and Tolbert, PE (2010). Short-term associations between ambient air pollutants and pediatric asthma emergency department visits. Am J Respir Crit Care Med 182(3): 307–316.

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).

U.S. Census Bureau (2019). Current Population Survey, Annual Social and Economic Supplement, 2018. Age and Sex Composition in the United States: 2018. *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 (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). Preamble to the integrated science assessments. U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, RTP Division. Research Triangle Park, NC. 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 (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.*

U.S. Forest Service, NPS, and U.S. Fish and Wildlife Service (2010). Federal land managers' air quality related values work group (FLAG): Phase I report—revised (2010). National Park Service, Denver, CO.

USFS (2013). Forest Inventory and Analysis: Fiscal Year 2012 Business Report. United States Department of Agriculture. *http://www.fia.fs.fed.us/library/bus-org-documents/docs/FIA_Annual_Report_2013.pdf.*

USFS (2017). Forest Inventory and Analysis: Fiscal Year 2016 Business Report. United State Department of Agriculutre. *https://www.fs.fed.us/sites/default/files/fs_media/fs_document/publication-15817-usda-forest-service-fia-annual-report-508.pdf.*

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.

Wang, P, Baines, A, Lavine, M and Smith, G (2012). Modelling ozone injury to U.S. forests. Environ Ecol Stat 19(4): 461–472.

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, 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.*

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.*

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.

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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