Integrated Review Plan for the National Ambient Air Quality Standards for Ozone and Related Photochemical Oxidants

Volume 1: Background Document

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Integrated Review Plan for the National Ambient Air Quality Standards for Ozone and Related Photochemical Oxidants.

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U.S. Environmental Protection Agency
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This document serves as a public information document and as a management tool for the U.S. Environmental Protection Agency's (EPA’s) Center for Public Health and Environmental Assessment and the Office of Air Quality Planning and Standards in conducting the review of air quality criteria and the primary national ambient air quality standards for ozone and related photochemical oxidants. It does not represent and should not be construed to represent an Agency determination or policy. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

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PREFACE

The planning phase of the U.S. Environmental Protection Agency's (EPA's) reviews of the air quality criteria and the national ambient air quality standards (NAAQS) includes development of an integrated review plan (IRP), which is composed of three volumes. Volume 1 (this document) provides background information and serves as a reference for the public and the Clean Air Scientific Advisory Committee (CASAC). Volume 2 addresses the general approach for the review, identifies policy-relevant issues in the review and describes key considerations in the EPA's development of the ISA. This document is the subject of CASAC consultation and public comment. Volume 3 describes key considerations in the EPA's planning with regard to any quantitative risk and exposure analyses to be considered for the review. In order that consideration of the availability of new scientific evidence in the review inform these plans, the development and public release of Volume 3 will generally coincide with the availability of the draft ISA. At that time, Volume 3 is the subject of CASAC consultation and public comment.

1 BACKGROUND ON THE OZONE NAAQS

1.1 HISTORY OF AIR QUALITY CRITERIA AND STANDARDS FOR PHOTOCHEMICAL OXIDANTS INCLUDING OZONE

Air quality criteria were developed for photochemical oxidants in 1970 (U.S. DHEW, 1970; 35 FR 4768, March 19, 1970), and primary and secondary NAAQS were first established in 1971 (36 FR 8186, April 30, 1971). Based on the scientific information in the 1970 air quality criteria document (AQCD), 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.

The EPA initiated the first periodic review of the NAAQS for photochemical oxidants in 1977, and proposed revisions in 1979, based on the 1978 AQCD (U.S. EPA, 1978; 43 FR 26962, June 22, 1978). In 1979, the EPA published its final decision in the review (44 FR 8202, February 8, 1979). With this decision, 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).

Following the EPA's decision in the 1979 review, several petitioners sought judicial review. Among those, the city of Houston challenged the Administrator's decision arguing that the standard was arbitrary and capricious because natural O_3 concentrations and other physical phenomena in the Houston area made the standard unattainable in that area. The U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) rejected this argument, holding 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 this difficulty 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 (U.S. EPA, 1986) and the 1989 Staff Paper (U.S. EPA, 1989). A 1992 supplement to the 1986 AQCD described additional important scientific studies on potential health and welfare effects (U.S. EPA, 1992). In August 1992, the EPA proposed to retain the existing primary and secondary standards based on the health and welfare effects information contained in the 1986 AQCD and its 1992 Supplement (57 FR 35542, August 10, 1992). In March 1993, the EPA announced its decision to conclude this review by affirming its proposed decision to retain the standards, without revision (58 FR 13008, March 9, 1993).

In the 1992 notice of its proposed decision in that review, the EPA announced its intention to proceed as rapidly as possible with the next review of the air quality criteria and standards for O_3 and other photochemical oxidants in light of emerging evidence of health effects related to 6- to 8-hour O_3 exposures (57 FR 35542, August 10, 1992). The EPA subsequently published the AQCD and Staff Paper for that next review (U.S. EPA, 1996a, b). In December 1996, the EPA proposed revisions to both the primary and secondary standards (61 FR 65716, December 13, 1996). With regard to the primary standard, the EPA proposed to replace the then-existing 1-hour primary standard with an 8-hour standard set at a level of 0.08 ppm (equivalent to 0.084 ppm based on the proposed data handling convention) as a 3-year average of the annual third-highest daily maximum 8-hour concentration. The EPA proposed to revise the secondary standard either by setting it identical to the proposed new primary standard or by setting it as a new seasonal standard using a cumulative form. The EPA completed this review in 1997 by setting the primary standard at a level of 0.08 ppm, based on the annual fourth-highest daily maximum 8-hour average concentration, averaged over three years, and setting the secondary standard identical to the revised primary standard (62 FR 38856, July 18, 1997).

On May 14, 1999, in response to challenges by industry and others to the EPA's 1997 decision, the D.C. Circuit remanded the 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 (*American Trucking Assoc. v. EPA*, 175 F.3d 1027, 1034-1040 [D.C. Cir. 1999]). In addition, the court 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). In 1999, the EPA petitioned for rehearing *en banc* on several issues related to that decision. The court granted the request for rehearing in part and denied it in part, but declined to review its ruling with regard to the potential beneficial effects of O_3 pollution (*American Trucking Assoc. v. EPA*,195 F.3d 4, 10 [D.C Cir., 1999]). On January 27, 2000, the EPA petitioned the U.S. Supreme Court for *certiorari* on the constitutional issue (and two other issues), but did not request review of the ruling regarding the potential beneficial health effects of O_3. On February 27, 2001, the U.S. Supreme Court unanimously reversed the judgment of the D.C. Circuit on the constitutional issue. *Whitman v. American Trucking Assoc*., 531 U. S. 457, 472-74 (2001) (holding that section 109 of the CAA does not delegate legislative power to the EPA in contravention of the Constitution). The Court remanded the case to the D.C. Circuit to consider challenges to the O_3 NAAQS that had not been addressed by that court's earlier decisions. On March 26, 2002, the D.C. Circuit issued its final decision on the remand, finding the 1997 O_3 NAAQS to be "neither arbitrary nor capricious," and so denying the remaining petitions for review. See *ATA III*, 283 F.3d at 379.

Specifically, in *ATA III*, the D.C. Circuit upheld the EPA's decision on the 1997 O_3 standard as the product of reasoned decision making. With regard to the primary standard, the court made clear that the most important support for the EPA's decision to revise the standard was the health evidence of insufficient protection afforded by the then-existing standard ("the record [is] replete with references to studies demonstrating the inadequacies of the old one-hour standard"), as well as extensive information supporting the change to an 8-hour averaging time (*id.* at 378). The court further upheld the EPA's decision not to select a more stringent level for the primary standard noting "the absence of *any* human clinical studies at ozone concentrations below 0.08 [ppm]" which supported the EPA's conclusion that "the most serious health effects of ozone are 'less certain' at low concentrations, providing an eminently rational reason to set the primary standard at a somewhat higher level, at least until additional studies become available" (*id.* at 379, emphasis in original, internal citations omitted). The court also pointed to the significant weight that the EPA properly placed on the advice it received from the CASAC (*id.* at 379). In addition, the court noted that "although relative proximity to peak background O_3 concentrations did not, in itself, necessitate a level of 0.08 [ppm], EPA could consider that factor when choosing among the three alternative levels" (*id.* 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). The EPA provisionally determined that the information linking changes in patterns of ground-level O_3 concentrations to changes in relevant patterns of exposures to UV radiation of concern to public health was too uncertain, at that time, to warrant any relaxation in 1997 O_3 NAAQS. The EPA also expressed the view that any plausible changes in UV-B radiation exposures from changes in patterns of ground-level O_3 concentrations would likely be very small from a public health perspective. In view of these findings, the EPA proposed to leave the 1997 primary standard unchanged (66 FR 57268, Nov. 14, 2001). After considering public comment on the proposed decision, the EPA published its final response to this remand in 2003, re-affirming the 8-hour primary standard set in 1997 (68 FR 614, January 6, 2003).

The EPA initiated the fourth periodic review of the air quality criteria and standards for O_3 and other photochemical oxidants with a call for information in September 2000 (65 FR 57810, September 26, 2000). In 2007, the EPA proposed to revise the level of the primary standard within a range of 0.075 to 0.070 ppm (72 FR 37818, July 11, 2007). The EPA proposed to revise the secondary standard either by setting it identical to the proposed new primary standard or by setting it as a new seasonal standard using a cumulative form. Documents supporting these proposed decisions included the 2006 AQCD (U.S. EPA, 2006) and 2007 Staff Paper (U.S EPA, 2007) and related technical support documents. 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).

In May 2008, state, public health, environmental, and industry petitioners filed suit challenging the EPA's final decision on the 2008 O_3 standards. On September 16, 2009, the EPA announced its intention to reconsider the 2008 O_3 standards[1] 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). In that notice, the EPA proposed that further revisions of the primary and secondary standards were necessary to provide a requisite level of protection to public health and welfare. The EPA proposed to revise the level of the primary standard from 0.075 ppm to a level within the range of 0.060 to 0.070 ppm, and to revise the secondary standard to one with a cumulative, seasonal form. At the EPA's request, the CASAC reviewed the proposed rule at a public teleconference on January 25, 2010 and provided additional advice in early 2011 (Samet, 2010, 2011). 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), the EPA decided to consolidate the reconsideration with its statutorily required periodic review.[2]

In light of the EPA's decision to consolidate the reconsideration with the next review, the D.C. Circuit proceeded with the litigation on the 2008 final decision. On July 23, 2013, the court upheld the EPA's 2008 primary O_3 standard, but remanded the 2008 secondary standard to the EPA (*Mississippi v. EPA*, 744 F. 3d 1334 [D.C. Cir. 2013]). With respect to the primary standard, the court first rejected arguments that the EPA should not have lowered the level of the existing primary standard, holding that the EPA reasonably determined that the existing primary standard was not requisite to protect

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

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

public health with an adequate margin of safety, and consequently required revision. The court went on to reject arguments that the EPA should have adopted a more stringent primary standard. 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. This review had been formally initiated in 2008 with a call for information in the *Federal Register* (73 FR 56581, September 29, 2008). In late 2014, based on the Integrated Science Assessment (ISA), Risk and Exposure Assessments (REAs) for health and welfare, and PA[3] developed for this review, the EPA proposed to revise the 2008 primary and secondary standards by reducing the level of both standards to within the range of 0.070 to 0.065 ppm (79 FR 75234, December 17, 2014).

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 the 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.[4] The other elements of the standard were retained. This decision on the secondary standard also incorporated the

[3] The final versions of these documents, released in August 2014, were developed with consideration of the comments and recommendations from the CASAC, as well as comments from the public on the draft documents (U.S. EPA 2014a; U.S. EPA, 2014b; U.S. EPA, 2014c; Frey, 2014a; Frey, 2014b; Frey, 2014c).

[4] The standards set in 2015 (generally referred to as the current standards herein) are specified at 40 CFR 50.19.

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). The 2015 revisions to the NAAQS were accompanied by revisions to the data handling procedures, and the ambient air monitoring requirements[5] (80 FR 65292, October 26, 2015).[6] The Appendix to this volume summarizes the current ambient air monitoring and data handling requirements.

After publication of the final rule, a number of industry groups, environmental and public health organizations, and certain states filed petitions for judicial review in the D.C. Circuit. The industry and state petitioners filed briefs arguing that the revised standards are too stringent, while the environmental and health petitioners' brief argued that the revised standards are 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 (*Murray Energy v. EPA*, 936 F.3d 597 (D.C. Cir. 2019)).

The EPA announced its initiation of the fifth periodic review of the air quality criteria for photochemical oxidants and the O_3 NAAQS in June 2018, issuing a call for information in the *Federal Register* (83 FR 29785, June 26, 2018). Under the plan outlined in the final IRP (U.S. EPA 2019) and as directed by the Administrator in initiating the review, this O_3 NAAQS review progressed on an accelerated schedule (Pruitt, 2018). In a divergence from past practice in recent history, a pollutant-specific O_3 review panel was not assembled to assist the CASAC in its review. Rather, the CASAC was assisted in its review by a pool of consultants with expertise in a number of fields (84 FR 38625,

[5] The current federal regulatory measurement methods for O_3 are specified in 40 CFR 50, Appendix D and 40 CFR Part 53. Consideration of ambient air measurements with regard to judging attainment of the standards is specified in 40 CFR 50, Appendix U. The O_3 monitoring network requirements are specified in 40 CFR 58.

[6] This decision additionally announced revisions to the exceptional events scheduling provisions, as well as changes to the air quality index and the regulations for the prevention of significant deterioration permitting program.

August 7, 2019).[7] On August 14, 2020, based on the current evidence in the 2020 ISA, the PA, with associated air quality, risk and exposure analyses, and CASAC advice, the EPA proposed to retain both the primary and secondary O_3 standards, without revision (85 FR 49830, August 14, 2020). In December 2020, the EPA issued its final decision to retain the existing standards without revision (85 FR 87256, December 31, 2020).[8]

Following publication of the 2020 decision, three petitions were filed seeking review in the D.C. Circuit and the court consolidated the cases. The EPA also received two petitions for reconsideration of the 2020 decision. On October 29, 2021, the Agency announced its decision to reconsider the 2020 decision and filed a motion with the court which explained that decision.[9] The consolidated cases were put in abeyance.

The EPA's approach for the reconsideration included establishment of an O_3 Review Panel to assist the CASAC in its role. In a series of public meetings from 2021 to 2023, the EPA briefed the Panel on the 2020 ISA, and a small set of more recent provisionally considered health studies (2020 ISA; Luben et al., 2020; Duffney et al., 2022; 87 FR 41309, July 12, 2022), and also engaged the Panel in review of two versions of a draft PA for the reconsideration (U.S. EPA, 2022; 87 FR 19501, April 4, 2022; U.S. EPA 2023; 88 FR 9275, February 13, 2023; 88 FR 17840, March 24, 2023). During this period, the O_3 Review Panel and CASAC also held discussions in consideration of the ISA and more recent studies (87 FR 41309, July 12, 2022; 87 FR 60394, October 5, 2022; Sheppard, 2022a, b). Based on these discussions, the CASAC determined "that the existing scientific evidence summarized in the 2020 ISA provides a scientifically sound foundation for the Agency's reconsideration of the 2020 Ozone NAAQS decision" and stated "that the CASAC was not recommending that the 2020 ISA be reopened or

[7] Rather than join with some or all of the CASAC members in a pollutant specific review panel as had been common in previous NAAQS reviews, 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, as a means of obtaining subject matter expertise for its document review.

[8] The decision on the secondary standard also considered and addressed the 2019 remand of the secondary standard by the D.C. Circuit such that the 2020 decision incorporated the EPA's response to that remand.

[9] The Agency's October 29, 2021 announcement is available at https://www.epa.gov/ground-level-ozone-pollution/epa-reconsider-previous-administrations-decision-retain-2015-ozone.

revised" (Sheppard, 2022c).[10] In June 2023, based on its additional consideration of the second version of the draft PA for the reconsideration (U.S. EPA, 2023), the CASAC conveyed its comments on the draft document, and its recommendations on the standards (Sheppard, 2023). Relying in part on several new studies published subsequent to the 2020 ISA, the majority of the CASAC recommended that the primary and secondary O_3 NAAQS be revised (Sheppard, 2023). On August 21, 2023, after consideration of the advice received from the CASAC, the EPA announced its decision to initiate a new, full statutory review of the O_3 NAAQS and the underlying air quality criteria and to incorporate the ongoing reconsideration of the 2020 O_3 NAAQS decision into the new review (Regan, 2023). [11]

With regard to the consolidated cases before the D.C. Circuit seeking review of EPA's 2020 decision, on January 3, 2024, the EPA filed an unopposed motion for voluntary remand without vacatur. The court granted the motion on February 2, 2024. See *New York et al. v. EPA*, No. 21-1028, Order (Doc. No. 2038660, D.C. Cir. Feb. 2, 2024).

1.2 THE PRIMARY STANDARD

The current primary O_3 standard of 0.070 ppm,[12] as the annual fourth-highest daily maximum 8-hour average concentration, averaged across three consecutive years, was set in 2015 and retained without revision in 2020 (80 FR 65292, October 26, 2015; 85 FR 87256, December 31, 2020). Establishment of this standard, and its retention in 2020, were based on the extensive body of evidence most prominently documenting the causal relationship between O_3 exposure and a broad range of respiratory effects, as well as the Administrator's judgments regarding the appropriate degree of public health

[10] The CASAC additionally noted that "[r]egarding the Agency's judgments, in some instances the CASAC does have differing opinions," and also offered comments and advice on several issues and areas for improvement in future O_3 ISAs (Sheppard, 2022c).

[11] The Agency's August 21, 2023, announcement is available at https://www.epa.gov/newsreleases/epa-initiates-new-review-ozone-national-ambient-air-quality-standards-reflect-latest. As noted in this announcement and in the Administrator's response letter to CASAC, the new review will also consider the advice and recommendations of the CASAC (Regan, 2023)).

[12] Although ppm are the units in which the level of the standard is defined, the units, ppb, are more commonly used throughout this IRP 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.

protection for the 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; 85 FR 87263, December 31, 2020). The respiratory effects associated with O_3 exposure range from small, reversible changes in lung 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 asthma-related emergency department visits and hospital admissions, which have been associated with ambient air concentrations of O_3 in epidemiologic studies (2020 ISA, section 3.1; 2013 ISA, section 6.2). [13] The EPA's establishment of the standard in 2015, and its retention in 2020, focused particularly on implications of the effects evidence to ensure protection of at-risk populations,[14] such as people with asthma, and particularly children with asthma (80 FR 65343, October 26, 2015; 85 FR 87305, December 31, 2020). Key aspects of the decisions in 2015 and 2020, are summarized below for each of the four basic elements of the NAAQS (indicator, averaging time, form, and level), in turn.

1.2.1 Indicator

In 1979, O_3 was established as the indicator for a standard meant to provide protection against photochemical oxidants in ambient air (44 FR 8202, February 8, 1979). In setting the current standard in 2015 and reviewing it in 2020, the Administrator considered the available information presented in the ISA and PA, along with advice from the CASAC and public comment. Both the 2013 and 2020 ISAs specifically noted that O_3 is the only photochemical oxidant (other than nitrogen dioxide) that is routinely monitored and for which a comprehensive database exists (2013 ISA, section 3.6; 80 FR 65347, October 26, 2015; 2020 ISA, p. IS-3; 85 FR 87301, December 31, 2020). The 2020

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

[14] 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 O_3 as well as extrinsic, nonbiological factors, such as those related to socioeconomic status, reduced access to health care, or exposure.

ISA further noted that "the primary literature evaluating the health and ecological effects of photochemical oxidants includes ozone almost exclusively as an indicator of photochemical oxidants" (2020 ISA, p. IS-3). In both reviews, the CASAC indicated its support for O_3 as the appropriate indicator. Based on these considerations and public comments, the Administrators in both reviews concluded that O_3 remains the most appropriate indicator for a standard meant to provide protection against photochemical oxidants in ambient air, and they retained O_3 as the indicator for the primary standard (80 FR 65347, October 26, 2015; 85 FR 87306; December 31, 2020).

1.2.2 Averaging Time

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). This decision was based on the then newly available evidence from numerous controlled human exposure studies in healthy adults of adverse respiratory effects resulting from 6- to 8-hour exposures, as well as quantitative analyses indicating the air quality 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, 1996). In the establishment of the existing standard in 2015 and its review in 2020, the averaging time was retained in light of both the strong evidence for O_3-associated respiratory effects following short-term exposures and the available evidence related to effects following longer-term exposures (80 FR 65347-50, October 26, 2015). Based on the health effects evidence and quantitative exposure/risk information in the 2015 review, along with CASAC advice and public comments, the Administrator concluded that a standard with an 8-hour averaging time (and the newly revised level) could effectively limit health effects attributable to both short- and long-term O_3 exposures and that it was appropriate to retain the 8-hour averaging time (80 FR 65350, October 26, 2015). The EPA reached similar conclusions in the 2020 review and retained the 8-hour averaging time (85 FR 87306; December 31, 2020).

1.2.3 Form

The concentration-based form (e.g., the *n*th-high metric) of the existing standard was established in the 1997 review when it was recognized that such a form better reflects the continuum of health effects associated with increasing O_3 concentrations than an expected exceedance form.[15] Unlike an expected exceedance form, a concentration-based form gives proportionally more weight to years when 8-hour O_3 concentrations are well above the level of the standard than years when 8-hour O_3 concentrations are just above the level of the standard. 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 not a basis identified for selection of a more restrictive form (62 FR 38856, July 18, 1997). In subsequent reviews, while the potential value of a percentile-based form[16] was considered, the EPA concluded that, because of the differing lengths of the monitoring season for O_3 across the U.S., such a statistic would not be effective in ensuring the same degree of public health protection across the country (73 FR 16474-75, March 27, 2008).[17] The form includes averaging across three years in recognition of the importance of a form that provides stability to ongoing control programs.[18] In establishing the

[15] The first O_3 standard, set in 1979 as an hourly standard, had an expected exceedance form, such that attainment was defined as when the expected number of days per calendar year, with maximum hourly average concentration greater than 0.12 ppm, was equal to or less than 1 (44 FR 8202, February 8, 1979).

[16] It is noted that such statistic allows comparison among datasets of varying length because it samples approximately the same place in the distribution of air quality values, whether the dataset is several months or several years long.

[17] Specifically, a percentile-based form would allow more days with higher air quality values (i.e., higher O_3 concentrations) in locations with longer O_3 seasons relative to locations with shorter O_3 seasons.

[18] For example, it was noted that it was important to have a form that provides stability and insulation from the impacts of extreme meteorological events that are conducive to O_3 occurrence. Such events could have the effect of reducing public health protection, to the extent they result in frequent shifts in and out of attainment due to meteorological conditions because such frequent shifting could disrupt an area's ongoing implementation plans and associated control programs (73 FR 16475, March 27, 2008). Advice from the CASAC in the 2015 review supported this, stating that this concentration-based form that is averaged over three years "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, 2014, p. 6; 80 FR 65352, October 26, 2015).

existing standard in 2015 and in retaining it in 2020, the fourth-high form (i.e., the annual fourth-highest daily maximum 8-hour O_3 average concentration, averaged over 3 years) was retained (80 FR 65352, October 26, 2015; 85 FR 87306; December 31, 2020).

1.2.4 Level

In establishing the level of the standard in 2015 and in the decision to retain it in 2020, the Administrator at each time carefully considered: (1) the assessment of the health effects evidence and conclusions reached in the ISA; (2) the available quantitative exposure/risk analyses, including associated limitations and uncertainties, described in detail in the Health Risk and Exposure Assessment (HREA, in the 2015 review or appendices of the 2020 PA in the 2020 review); (3) considerations and staff conclusions and associated rationales in the PA; (4) advice and comments from the CASAC; and (5) public comments (80 FR 65362, October 26, 2015; 85 FR 37300, December 31, 2020).

In weighing the health effects evidence and making judgments regarding the public health significance of the quantitative estimates of exposures and risks allowed by the existing standard and potential alternative standards considered, as well as judgments regarding margin of safety, both of the decisions, in 2015 and 2020, considered the currently available information, including EPA judgments in prior reviews, advice from the CASAC, statements of the American Thoracic Society (ATS, an organization of respiratory disease specialists), and public comments. Such statements from the ATS (ATS, 2000; Thurston et al., 2017), as well as judgments made by the EPA in considering similar health effects in previous NAAQS reviews, were considered when the standard was set in 2015 and reviewed in 2020 (85 FR 87270-72, 87302-87305, December 31, 2020; 80 FR 65343, October 26, 2015). The 2020 review included a newly available ATS statement (Thurston et al., 2017), which is generally consistent with the prior statement (ATS, 2000) including the attention that it gives to at-risk or vulnerable population groups, while also broadening the discussion of effects, responses, and biomarkers to reflect the expansion of scientific research in these areas. In 2020, the Administrator recognized the role of such statements, as described by the ATS, as proposing principles or considerations for weighing the evidence rather than offering ‘‘strict rules or numerical criteria’’ (ATS, 2000, Thurston et al., 2017).

In keeping with this intent of the ATS statements (to avoid specific criteria), the statements, in discussing what constitutes an adverse health effect, do not comprehensively describe all the biological responses raised, e.g., with regard to magnitude, duration or frequency of small pollutant-related changes in pulmonary function. While recognizing the limitations in the available evidence base with regard to our understanding of these aspects of such changes that may be associated with exposure concentrations of interest (e.g., as estimated in the exposure analysis), the Administrator, in both reviews, considered individuals with preexisting compromised function, such as that resulting from asthma, important to judgments on the adequacy of protection provided for at-risk populations. The Administrator in each review also recognized that the controlled human exposure studies, primarily conducted in healthy adults, on which the depth of our understanding of O_3-related health effects is based, in combination with the larger evidence base, informs our conceptual understanding of O_3 responses in people with asthma and in children (85 FR 87303, December 31, 2020). In so doing, each decision 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, in both the 2015 and 2020 decisions, the Administrator took into account the need for an adequate margin of safety as an integral part of their decision-making.

The evidence base available in the 2020 review included decades of extensive evidence that clearly describes the role of O_3 in eliciting an array of respiratory effects and more recent evidence indicating the potential for relationships between O_3 exposure and metabolic effects. As was established in prior reviews, the effects for which the evidence is strongest are transient decrements in lung function and respiratory symptoms as a result of short-term exposures particularly when breathing at elevated rates (2020 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[19] (1978 AQCD, 1986 AQCD, 1996 AQCD, 2006 AQCD, 2013 ISA, 2020 ISA). The epidemiologic evidence base documents consistent, positive associations of O_3 concentrations in ambient air with lung function effects in panel studies (2013 ISA, section 6.2.1.2; 2020 ISA, Appendix 3, section 3.1.4.1.3), and with more severe health outcomes, including asthma-related emergency department visits and hospital admissions (2013 ISA, section 6.2.7; 2020 ISA, Appendix 3, sections 3.1.5.1 and 3.1.5.2). Extensive experimental animal evidence informs a detailed understanding of mechanisms underlying the short-term respiratory effects, and studies in animal models describe effects of longer-term O_3 exposure on the developing lung (2020 ISA, Appendix 3, sections 3.1.11 and 3.2.6).

Although less influential to considering the standard than the respiratory effects evidence, the available evidence when the standard was set and when it was reviewed in 2020 also included evidence for effects other than respiratory effects. Most prominent was evidence regarding O_3 exposure and cardiovascular effects and associated mortality, conclusions regarding which changed across the two reviews (2013 ISA, Table 1-1; 2020 ISA, Table ES–1). For example, while the evidence available in the 2015 review was sufficient to conclude that the relationships for short-term O_3 exposure with cardiovascular health effects and mortality were likely to be causal, that conclusion was no longer supported by the more expansive evidence base which the 2020 ISA determined to be suggestive of, but not sufficient to infer, a causal relationship for these health effect categories (2020 ISA, Appendix 4, section 4.1.17; Appendix 6, section 6.1.8). Further, newly available evidence in the 2020 review, largely experimental animal studies, with exposure concentrations well above those at which respiratory effects occur, was judged sufficient to conclude there to be a causal relationship between short-term O_3 exposure and metabolic effects (2020 ISA, section IS.4.3.3; 85 FR 87270, December 31, 2020).

[19] The vast majority of the controlled human exposure studies (and all of the studies conducted at the lowest exposures) involved young healthy adults (typically 18-35 years old) as study subjects (2013 ISA, section 6.2.1.1). There are also some controlled human exposure studies of one to eight hours duration in older adults and adults with asthma, and there are still fewer controlled human exposure studies in healthy children (i.e., individuals aged younger than 18 years) or children with asthma (See, for example, 2020 PA, Appendix 3A, Table 3A-3).

The 2015 decision to set the level of the revised primary O_3 standard at 70 ppb and the 2020 decision to retain this standard, without revision, placed the greatest weight on the results of controlled human exposure studies and on quantitative analyses based on information from these studies, particularly the comparison-to-benchmarks analysis comparing exposure estimates for study area populations of children at elevated exertion[20] to exposure benchmark concentrations (exposures of concern) under air quality conditions just meeting the current standard (80 FR 65362, October 26, 2015; 85 FR 87284, December 31, 2020).[21] In considering the epidemiologic studies in the 2015 review, the Administrator concluded that a revised standard with a level of 70 ppb would result in improvements in public health, beyond the protection provided by the current standard, against the clearly adverse effects reported in epidemiologic studies.[22] In further evaluating information from epidemiologic studies, the Administrator considered the epidemiologic-based risk estimates for O_3-associated morbidity or mortality and noted relatively less confidence in these estimates than in the estimates of exposures of concern and lung function risks (80 FR 65364-65365, October 26, 2015). This weighting reflected the recognition that controlled human exposure studies provide the most certain evidence indicating the occurrence of health effects in humans following specific O_3 exposures, and, in particular, that the effects reported in the controlled human exposure studies are due solely to O_3 exposures, and are not

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

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

[22] This included consideration of single-city epidemiologic studies reporting significant positive associations of O_3 with health effects in areas where the existing standard of 75 ppb was met, as well as the epidemiology-based risk estimates of reductions in mean premature mortality associated with ozone levels lower than the current standard (80 FR 65364-65365, October 26, 2015).

complicated by the presence of co-occurring pollutants or pollutant mixtures, as is the case in epidemiologic studies (80 FR 65362-65363, October 26, 2015).[23]

The Administrator's judgment in establishing the standard in 2015, and in retaining it in 2020, included a focus on the public health implications of the exposure and risk analyses conducted in each review. The comparison-to-benchmarks analysis, which included a focus on the at-risk populations of children and children with asthma, 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. The analysis conducted for the 2020 review reflected a number of updates and improvements and provided estimates with reduced uncertainty compared to those from the 2015 review. The results for analyses in both reviews are characterized through comparison of exposure concentration estimates to three benchmark concentrations of O_3: 60, 70, and 80 ppb. These are based on the three lowest concentrations targeted in studies of 6- to 6.6-hour exposures of generally healthy adults engaging in quasi-continuous exercise (at a moderate level of exertion), and that yielded different occurrences of statistical significance and severity of respiratory effects (80 FR 65312, October 26, 2015; 85 FR 87277; December 31, 2020; 2020 PA, section 3.3.3).[24] Such study data were further recognized to be lacking at these exposure levels for children and people with asthma, and the evidence indicates that such responses, if repeated or sustained, particularly in people with asthma, pose risks

[23] Other quantitative exposure/risk analyses (e.g., the lung function risk assessment, analyses of O3 air quality in locations of epidemiologic studies, and epidemiologic-study-based quantitative health risk assessment) were viewed as providing information in support of the 2015 decision to revise the then-current standard level of 75 ppb, but of less utility for selecting a particular standard level among a range of options (80 FR 65362, October 26, 2015). For example, with regard to the epidemiologic studies, the Administrator noted that most of the studies were conducted in locations likely to have violated the then current standard during all or part of the study period.

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

of effects of greater concern, including asthma exacerbation, as cautioned by the CASAC (85 FR 87302, December 31, 2020).[25]

The three benchmark concentrations (60, 70 and 80 ppb) were recognized to represent exposure conditions (during quasi-continuous exercise) associated with different levels of respiratory response (both with regard to the array of effects and severity of individual effects) in the subjects studied, and also to inform the Administrators' judgments in both reviews regarding different levels of risk that might be posed to unstudied members of at-risk populations. The highest benchmark concentration (80 ppb) represented an exposure where multiple controlled human exposure studies involving 6.6-hour exposures during quasi-continuous exercise demonstrate a range of O_3-related respiratory effects including inflammation and airway responsiveness, as well as respiratory symptoms and lung function decrements in healthy adult subjects. The second benchmark (70 ppb) represented an exposure level below the lowest exposures that have reported both statistically significant lung function decrements and increased respiratory symptoms (reported at 73 ppb,[26] Schelegle et al., 2009) or statistically significant increases in airway resistance and responsiveness (reported at 80 ppb, Horstman et al., 1990).[27] The lowest benchmark (60 ppb) represents still lower exposure, and a level for which findings from controlled human exposure studies of largely healthy subjects have included: statistically significant

[25] In the 2020 review, the CASAC noted that ''[a]rguably the most important potential adverse effect of acute ozone exposure in a child with asthma is not whether it causes a transient decrement in lung function, but whether it causes an asthma exacerbation'' and that O_3 "has respiratory effects beyond its well-described effects on lung function," including increases in airway inflammation which also have the potential to increase the risk for an asthma exacerbation. (Cox, 2020, Consensus Responses to Charge Questions pp. 7–8).

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

[27] The study group mean lung function decrement for the 73 ppb exposure was 6%, with individual decrements of 15% or greater (moderate or greater) in about 10% of subjects and decrements of 10% or greater in 19% of subjects. Decrements of 20% or greater were reported in 6.5% of subjects (Schelegle et al., 2009; 2020 PA, Table 3–2 and Appendix 3D, Table 3D–20). In studies of 80 ppb exposure, the percent of study subjects with individual FEV_1 decrements of this size ranged up to nearly double this (2020 PA, Appendix 3D, Table 3D–20).

decrements in lung function (with mean decrements ranging from 1.7% to 3.5% across the four studies with average exposures of 60 to 63 ppb), but not respiratory symptoms; and a statistically significant increase in a biomarker of airway inflammatory response relative to filtered air exposures in one study (Kim et al., 2011).

In placing greater weight and giving primary attention to the comparison-to-benchmarks analysis, the Administrators in both reviews recognized that this analysis provides for characterization of risk for the broad array of respiratory effects documented in the controlled human exposure studies, facilitating consideration of an array of respiratory effects, including but not limited to lung function decrements (80 FR 65363, October 26, 2015; 85 FR 87303, December 31, 2020). As in the 2015 decision, the Administrator in 2020 noted that due to differences among individuals in responsiveness, not all people experiencing exposures (e.g., to 73 ppb), experience a response, such as a lung function decrement, and among those experiencing a response, not all will experience an adverse effect (85 FR 87304, December 31, 2020). Accordingly, the Administrators in the two reviews noted that not all people estimated to experience an exposure of 7-hour duration while at elevated exertion above even the highest benchmark would be expected to experience an adverse effect, even members of at-risk populations (80 FR 65345, October 26, 2015; 85 FR 87304, December 31, 2020). With these considerations in mind, the Administrators in the two reviews noted that while single occurrences could be adverse for some people, particularly for the higher benchmark concentration where the evidence base is stronger, the potential for adverse response and greater severity increased with repeated occurrences (as cautioned by the CASAC) (80 FR 65345, October 26, 2015; 85 FR 87305, December 31, 2020). The Administrators also noted that while the exposure/risk analyses provide estimates of exposures of the at-risk population to concentrations of potential concern, they do not provide information on how many of such populations will have an adverse health outcome. Accordingly, in considering the exposure/risk analysis results, while giving due consideration to occurrences of one or more days with an exposure at or above a benchmark, particularly the higher benchmarks, both Administrators judged multiple occurrences to be of greater concern than single occurrences (80 FR 65364, October 26, 2015; 85 FR 87304, December 31, 2020).

The Administrators' judgments in considering the exposure analysis results for each of the three benchmarks are briefly summarized below, first in the context of setting the standard level of 70 ppb in 2015, and then in the context of the decision to retain this standard in 2020.

2015 Decision: In the 2015 considerations of the degree of protection to be provided by a revised standard, and the extent to which that standard would be expected to limit population exposures to the broad range of O_3 exposures shown to result in health effects, the Administrator focused particularly on the exposure analysis estimates of two or more exposures of concern. Placing the most emphasis on a standard that limits repeated occurrences of exposures at or above the 70 and 80 ppb benchmarks, while at elevated ventilation, the Administrator noted that a standard of the existing form and averaging time with a revised level of 70 ppb was estimated to eliminate the occurrence of two or more days with exposures at or above 80 ppb and to virtually eliminate the occurrence of two or more days with exposures at or above 70 ppb for all children and children with asthma, even in the worst-case year and location evaluated (80 FR 65363-65364, October 26, 2015).[28] The Administrator's consideration of exposure estimates at or above the 60 ppb benchmark, an estimated exposure to which the Administrator was less confident would result in adverse effects,[29] focused most particularly on multiple occurrences and was primarily in the context of considering the extent to which the health protection provided by a revised standard included a margin of safety against the occurrence of adverse O_3-induced effects (80 FR 65364, October 26, 2015). In this context, the Administrator noted that a revised standard with a level of 70 ppb was estimated to protect the vast majority of children in urban study areas (i.e., about 96% to more than 99% of children in individual areas) from

[28] 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).

[29] The 2015 decision noted that "the Administrator is 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," citing, among other considerations, "uncertainty in the extent to which short-term, transient population-level decrease in FEV_1 would increase the risk of other, more serious respiratory effects in that population" (80 FR 54363, October 26, 2015). Note: FEV_1 (a measure of lung function response) is the forced expiratory volume in one second.

experiencing two or more days with exposures at or above 60 ppb (while at moderate or greater exertion).[30]

Given the considerable protection provided against repeated exposures of concern for all three benchmarks, including the 60 ppb benchmark, the Administrator in 2015 judged that a standard with a level of 70 ppb would incorporate a margin of safety against the adverse O_3-induced effects shown to occur in the controlled human exposure studies following exposures (while at moderate or greater exertion) to a concentration somewhat higher than 70 ppb (80 FR 65364, October 26, 2015).[31] The Administrator also judged the estimates of one or more exposures (while at moderate or greater exertion) at or above 60 ppb to also provide support for her somewhat broader conclusion that "a standard with a level of 70 ppb would incorporate an adequate margin of safety against the occurrence of O_3 exposures that can result in effects that are adverse to public health" (80 FR 65364, October 26, 2015).[32]

[30] The 2015 decision also noted the Administrator's consideration of the extent to which she judged that adverse effects could occur following specific O_3 exposures related to each of the three benchmarks. The Administrator recognized the interindividual variability in responsiveness in her interpretation of the exposure analysis results noting noted "that not everyone who experiences an exposure of concern, including for the 70 ppb benchmark, is expected to experience an adverse response," further judging "that the likelihood of adverse effects increases as the number of occurrences of O_3 exposures of concern increases." And "[i]n making this judgment, she note[d] that the types of respiratory effects that can occur following exposures of concern, particularly if experienced repeatedly, provide a plausible mode of action by which O_3 may cause other more serious effects. Therefore, her decisions on the primary standard emphasize[d] the public health importance of limiting the occurrence of repeated exposures to O_3 concentrations at or above those shown to cause adverse effects in controlled human exposure studies" (80 FR 65331, October 26, 2015).

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

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

2020 Decision: The 2020 review of the standard established in 2015 also focused on the exposure-based comparison-to-benchmark analyses in the context of results from the controlled human exposure studies of exposures from 60 to 80 ppb, recognizing this information on exposure concentrations found to elicit respiratory effects in exercising study subjects to be unchanged from what was available in the 2015 review (2020 PA, section 3.3.1; 85 FR 87302, December 31, 2020).[33]

The Administrator in 2020, similar to Administrators in prior reviews, judged the array of effects associated with exposure at or above the highest benchmark concentration (80 ppb), in combination and severity, to represent adverse effects for individuals in the population group studied, and to pose a risk of adverse effects for individuals in at-risk populations, most particularly people with asthma. With this in mind, he considered the exposure/risk estimates for this benchmark, particularly the results for children and children with asthma,[34] and found them to indicate strong protection against exposures of at-risk populations that have been demonstrated to elicit a wide array of respiratory responses in multiple studies (85 FR 87304, December 31, 2020).

With regard to the second benchmark concentration (70 ppb), the Administrator recognized it to be just below the lowest exposure concentration (73 ppb) for which a study has reported a combination of a statistically significant increase in respiratory

[33] With regard to the epidemiologic studies of respiratory effects, the Administrator recognized that, as a whole, these investigations of associations between O_3 and respiratory effects and health outcomes (e.g., asthma-related hospital admission and emergency department visits) provided strong support for the conclusions of causality but the studies were less informative regarding exposure concentrations associated with O_3 air quality conditions that meet the current standard. He noted that the evidence base in the 2020 review did not include new evidence of respiratory effects associated with appreciably different exposure circumstances than the evidence available in the 2015 review, including particularly any circumstances that would also be expected to be associated with air quality conditions likely to occur under the current standard.

[34] For the current standard, the exposure/risk estimates indicated more than 99.9% to 100% of children and children with asthma, on average across the three years, to be protected from one or more occasions of exposure at or above 80 ppb; the estimate is 99.9% of children with asthma and of all children for the highest year and study area (85 FR 87279, Table 2, December 31, 2020). Further, no children in the simulated populations (zero percent) were estimated to be exposed more than once (two or more occasions) in the 3-year simulation to 7-hr concentrations, while at elevated exertion, at or above 80 ppb (85 FR 87279, Table 2, December 31, 2020).

symptoms and statistically significant lung function decrements in sensitive individuals in a study group of largely healthy adult subjects, exposed while at elevated exertion (Schelegle et al., 2009). However, in light of the lack of evidence for people with asthma from studies at 80 ppb and 73 ppb, as well as the emphasis in the ATS statement on the vulnerability of people with compromised respiratory function, such as people with asthma, the Administrator judged it appropriate that the standard protect against exposure, particularly multiple occurrences of exposure, to levels somewhat below 73 ppb. In this context, the Administrator considered the exposure/risk estimates, finding them to indicate more than 99% of all children, including all children with asthma, to be protected from one or more occasions in a year, on average, of 7-hour exposures to concentrations at or above 70 ppb, while at elevated exertion; 99.9% of both groups to be protected from two or more such occasions; and 100% from still more occasions (85 FR 87279, Table 2, December 31, 2020). Accordingly, he judged these estimates to also indicate strong protection of at-risk populations against exposures similar to those demonstrated to elicit lung function decrements and increased respiratory symptoms in healthy subjects, a response described as adverse by the ATS (85 FR 87304, December 31, 2020).

As in 2015, the Administrator in 2020 considered the exposure/risk estimates for the third benchmark of 60 ppb to be informative most particularly to his judgments on an adequate margin of safety. In so doing, he noted that the lung function decrements in controlled human exposure studies of largely healthy adult subjects exposed while at elevated exertion to concentrations of 60 ppb, although statistically significant, were much reduced from that observed in the next higher studied concentration (73 ppb), both at the mean and individual level, and were not reported to be associated with increased respiratory symptoms in healthy subjects (85 FR 87274, Table 1, December 31, 2020. [35] While the Administrator did not judge these responses to represent adverse effects for generally healthy individuals, he recognized that such data are lacking for at-risk groups, such as people with asthma, and in consideration of comments from the

[35] The response for the 60 ppb studies is also somewhat lower than that for a 63 ppb study (Table 1; 2020 PA, Appendix 3D, Table 3D–20).

CASAC (and the ATS statement), he judged it important for the standard to provide protection that reduces the potential risk of asthma exacerbation in this at-risk group. Further, in consideration of the potential risk of inflammatory response in this group, he noted evidence indicating the role of repeated occurrences of inflammation in contributing to severity of response. In consideration of these factors, he placed greater weight on exposure/risk estimates for multiple occurrences (85 FR 87304-87305, December 31, 2020). The Administrator found the 2020 estimates of children with asthma protected from 7-hour exposures to concentrations at or above this level (60 ppb), while at elevated exertion (more than 96% to more than 99% for multiple occasions and more than 90% for one or more exposures on average across the 3-year assessment period), to indicate an appropriate degree of protection from such exposures (85 FR 87305, December 31, 2020).

In the 2020 review, the Administrator additionally considered the slight differences of the 2020 exposure and risk estimates from the corresponding estimates in the 2015 review for the 60 ppb benchmark (85 FR 87280, Table 3, December 31, 2020). The Administrator recognized that the factors contributing to these differences, which includes the use of air quality data reflecting concentrations much closer to the existing standard than was the case in the 2015 review, also contribute to a reduced uncertainty in the current estimates (85 FR 87275-87279, December 31, 2020; 2020 PA, sections 3.4 and 3.5). Thus, he noted that the exposure analysis estimates in the 2020 review indicate the current standard to provide appreciable protection against multiple days with a maximum exposure at or above 60 ppb. Therefore, based on his consideration of the evidence and exposure/risk information, including that related to the lowest exposures studied in controlled human exposure studies, and the associated uncertainties, the Administrator judged that the current standard provides the requisite protection of public health, including an adequate margin of safety, and thus should be retained, without revision. Accordingly, he also concluded that a more stringent standard was not needed to provide requisite protection and that the current standard provides the requisite protection of public health under the Act (85 FR 87306, December 31, 2020).

1.3 THE SECONDARY STANDARD

The current secondary O_3 standard is 0.070 ppm,[36] as the annual fourth-highest daily maximum 8-hour average concentration, averaged across three consecutive years. The establishment of this standard in 2015, and its retention in 2020, is based primarily on consideration of the extensive welfare effects evidence base compiled from more than fifty years of 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, 2020). Key considerations when the standard was established in 2015, and when it was retained in 2020, were the scientific evidence and technical analyses available at that time, as well as the Administrator's judgments regarding the available welfare effects evidence, the appropriate degree of public welfare protection for the revised standard, and available air quality information on seasonal cumulative exposures (in terms of the W126 exposure index[37]) that may be allowed by such a standard (80 FR 65292, October 26, 2015; 85 FR 87256, December 31, 2020).

The 2020 decision to retain the standard, without revision, additionally took into account updates to the evidence base since the 2015 review, and associated conclusions regarding welfare effects; updated and expanded quantitative analyses of air quality data, including the frequency of cumulative exposures of potential concern and of elevated hourly concentrations in areas with air quality meeting the standard; and also the August 2019 decision of the D.C. Circuit remanding the 2015 secondary standard to the EPA for further justification or reconsideration, as mentioned earlier in Section 1.1 (*Murray Energy Corp. v. EPA*, 936 F.3d 597 [D.C. Cir. 2019]). In the August 2019 decision, the court held that the EPA had not adequately explained its decision to focus on a 3-

[36] Although ppm are the units in which the level of the standard is defined, the units, ppb, are more commonly used throughout this IRP 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.

[37] The W126 index is a cumulative seasonal metric described as the sigmoidally weighted sum of all hourly O_3 concentrations during a specified daily and seasonal time window, with each hourly O_3 concentration given a weight that increases from zero to one with increasing concentration (80 FR 65373-74, October 26, 2015). The units for W126 index values are ppm-hours (ppm-hrs). More detail is provided in section 4.3.3.1.1 below.

year average for consideration of the cumulative exposure, in terms of W126, identified as providing requisite public welfare protection, or its decision to not identify a specific level of air quality related to visible foliar injury. The EPA's decision not to use a seasonal W126 index as the form and averaging time of the secondary standard was also challenged, but the court did not reach a decision on that issue, concluding that it lacked a basis to assess the EPA's rationale because the EPA had not yet fully explained its focus on a 3-year average W126 in its consideration of the standard. Accordingly, the 2020 decision included discussion of these areas to address these aspects of the court's decision.

The extensive evidence base considered in the 2015 and 2020 decisions documents an array of vegetation and vegetation-related effects, ranging from the organism scale to larger-scale impacts, such as those on populations, communities, and ecosystems. These categories of effects which the 2013 and 2020 ISAs identified as causally or likely causally related to O_3 in ambient air include: reduced vegetation growth, reproduction, crop yield, productivity and carbon sequestration in terrestrial systems; alteration of terrestrial community composition, belowground biogeochemical cycles and ecosystem water cycling; and visible foliar injury (2013 ISA, Appendix 9; 2020 ISA, Appendix 8).[38] Across the different types of studies, the strongest quantitative evidence available at the times of both the 2015 and 2020 decisions for effects from O_3 exposure on vegetation comes from controlled exposure studies of growth effects in a number of species (2013 ISA, p. 1-15). Of primary importance in considering the appropriate level of protection for the standard, both in the 2015 decision establishing it and in its 2020 retention, were the studies of O_3 exposures that reduced growth in tree seedlings from which E-R functions of seasonal relative biomass loss (RBL)[39] have been

[38] The 2020 ISA also newly determined the evidence sufficient to infer likely causal relationships of O_3 with increased tree mortality, which was not causally assessed in 2013, although it does not indicate a potential for O_3 concentrations that occur in locations that meet the current standard to cause this effect (85 FR 87319, December 31, 2020; 2020 PA, section 4.3.1).

[39] These functions were developed to quantify O_3-related reduced growth in tree seedlings relative to control treatments (without O_3). In this way, RBL is the percentage by which the O_3 treatment growth in a growing season differs from the control seedlings over the same period, and the functions provide a quantitative estimate of 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; 2020 PA, Appendix 4A).

established (80 FR 65385-86, 65389-90, October 26, 2015, 85 FR 87256, December 31, 2020). Consistent with advice from the CASAC in both reviews, the Administrators considered the effects of O_3 on tree seedling growth 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; 85 FR 87319, 87399, December 31, 2020).

In their consideration of O_3 effects on tree seedling growth, the Administrators in both the 2015 and 2020 decisions ascribed importance to the intended use of the natural resources and ecosystems potentially affected. For example, the 2015 decision considered the available evidence and quantitative analyses in the context of an approach for considering and identifying public welfare objectives for the revised standard (80 FR 65403-65408, October 26, 2015). In light of the extensive evidence base of O_3 effects on vegetation and associated terrestrial ecosystems, the Administrator, in both decisions, focused on protection against adverse public welfare effects of O_3-related effects on vegetation, giving particular attention to such effects in natural ecosystems, such as those in areas with protection designated by Congress, and areas similarly set aside by states, tribes and public interest groups, with the intention of providing benefits to the public welfare for current and future generations (80 FR 65405, October 26, 2015; 85 FR 87344, December 31, 2020).

Another category of effects considered in both reviews is climate-related effects (2013 ISA, Appendix 10, Section 10.3; 2020 ISA, Appendix 9, Section 9.2 and 9.3). In 2020, as was the case when the standard was set in 2015, the evidence documented 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 2020, as in 2015, limitations and uncertainties in the evidence base affected characterization of the extent of any relationships between ground-level O_3 concentrations in ambient air in the U.S. and climate-related effects and precluded quantitative characterization of climate responses to changes in ground-level O_3 concentrations in ambient air at regional or national (vs global) scales (80 FR 65405, October 26, 2015; 80 FR 65370, October 26, 2015; 85 FR 87337-87339, December 31, 2020). The 2020 review also identified two other types of effects – alterations in plant-insect signaling and insect herbivore growth and reproduction – as likely causally related to O_3, although uncertainties in the evidence for the effects precluded a full understanding of the effects, the air quality conditions that might elicit them and the potential for impacts in a natural system (2020 ISA, sections 8.6 and 8.7). Thus, as for climate-related effects (in 2015 and 2020), the evidence for insect-related effects was not a primary consideration in the 2020 decision to retain the existing standard (80 FR 65292, October 26, 2015; 85 FR 87256, December 31, 2020).

In both 2015 and 2020, effects on tree seedling growth, quantified in terms of RBL, were used as a surrogate or proxy for a broader array of vegetation-related effects and were quantified using the RBL metric and a set of established E-R functions for seedlings of 11 tree species (80 FR 65391-92, October 26, 2015; 2014 PA, Appendix 5C; 85 FR 87307-9, 87313-4, December 31, 2020; 2020 PA, Appendix 4A). Cumulative O_3 exposure was evaluated in terms of the W126 cumulative seasonal exposure index, an index supported by the evidence in the 2013 and 2020 ISAs for this purpose and consistent with advice from the CASAC in both reviews (2013 ISA, section 9.5.3, p. 9-99; 80 FR 65375, October 26, 2015; 2020 ISA, section 8.13; 85 FR 87307-8, December 31, 2020). In judgments regarding effects that are adverse to the public welfare, the decision setting the standard in 2015, and the decision retaining it in 2020, both utilized the RBL as a quantitative tool within a larger framework of considerations pertaining to the public welfare significance of O_3 effects (80 FR 65389, October 26, 2015; 73 FR 16496, March 27, 2008; 85 FR 87339-41, December 31, 2020).

Accordingly, in both the 2015 and 2020 decisions, consideration of the appropriate public welfare protection objective for the secondary standard gave prominence to the estimates of tree seedling growth impacts (in terms of RBL) for a range of W126 index values, developed from the E-R functions for 11 tree species (80 FR 65391-92, Table 4, October 26, 2015; 85 FR 87339-41, December 31, 2020). The Administrators also incorporated into their 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 Administrators noted they were not simply making judgments about a specific magnitude of growth effect in seedlings that would be acceptable or unacceptable in the natural environment. Rather, mindful of associated uncertainties, the RBL estimates were used as a surrogate or proxy for consideration of the broader array of related vegetation-related effects of potential public welfare significance, which included effects on individual species and extending to ecosystem-level effects (80 FR 65406, October 26, 2015; 85 FR 87304, December 31, 2020). 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 the 2015 decision to revise the standard level to 70 ppb and the 2020 decision to retain that standard, without revision, air quality analyses played an important role in the Administrators' judgments. Such judgments of the Administrator in setting the revised standard in 2015 are briefly summarized below. These are followed by a summary of additional key aspects of the considerations and judgments associated with the decision to retain this standard in 2020.

2015 Review: In using the RBL estimates as a proxy, the Administrator in 2015 focused her attention on a revised standard that would generally limit cumulative exposures to those for which the median RBL estimate for seedlings of the 11 species with established E-R functions would be somewhat below 6% (80 FR 65406-07, October 26, 2015).[40] She noted that the median RBL estimate was 6% for a cumulative seasonal W126 exposure index of 19 ppm-hrs (80 FR 65391-92, Table 4, October 26, 2015). Given the information on median RBL at different W126 exposure levels, using a 3-year cumulative exposure index for assessing vegetation effects,[41] the potential for single-

[40] In her focus on 6%, the Administrator noted the CASAC view regarding 6%, most particularly the CASAC's characterization of this level of effect in the median studied species as ''unacceptably high'' (Frey, 2014b, pp. iii, 13, 14). These comments were provided in the context of CASAC's considering the significance of effects associated with a range of alternatives for the secondary standard (80 FR 65406, October 26, 2015).

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

season effects of concern, and CASAC comments on the appropriateness of a lower value for a 3-year average W126 index, the Administrator judged it appropriate to identify a standard that would restrict cumulative seasonal exposures to 17 ppm-hrs or lower, in terms of a 3-year W126 index, in nearly all instances (80 FR 65407, October 26, 2015). Based on such information, available at that time, to inform consideration of vegetation effects and their potential adversity to public welfare, the Administrator additionally judged that the RBL estimates associated with marginally higher exposures in isolated, rare instances were not indicative of effects that would be adverse to the public welfare, particularly in light of variability in the array of environmental factors that can influence O_3 effects in different systems and uncertainties associated with estimates of effects associated with this magnitude of cumulative exposure in the natural environment (80 FR 65407, October 26, 2015).

Using these objectives, the 2015 decision regarding a standard revised from the then-existing (2008) standard was based on extensive air quality analyses that included the most recently available data as well as air monitoring data that extended back more than a decade (80 FR 65408, October 26, 2015; Wells, 2015). These analyses evaluated the cumulative seasonal exposure levels in locations meeting different alternative levels for a standard of the existing form and averaging time. These analyses supported the Administrator's judgment that a standard with a revised level in combination with the existing form and averaging time could achieve the desired level of public welfare protection, considered in terms of cumulative exposure, quantified as the W126 index (80 FR 65408, October 26, 2015). Based on the extensive air quality analyses and consideration of the W126 index value associated with a median RBL of 6%, and the W126 index values at monitoring sites that met different levels for a revised standard of the existing form and averaging time, the Administrator additionally judged that a standard level of 70 ppb would provide the requisite protection. The Administrator noted that such a standard 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

potential for adverse effects to public welfare that may relate to shorter exposure periods, including a single year (80 FR 65404, October 26, 2015).

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).

The 2015 decision also took note of the well-recognized evidence for visible foliar injury and crop yield effects. However, the RBL information available for seedlings of a set of 11 tree species was judged to be more useful (particularly in a role as surrogate for the broader array of vegetation-related effects) in informing judgments regarding the nature and severity of effects associated with different air quality conditions and associated public welfare significance than the available information on visible foliar injury and crop yield effects (80 FR 65405-06, October 26, 2015). With regard to visible foliar injury, while the Administrator recognized the potential for this effect to affect the public welfare in the context of affecting value ascribed to natural forests, particularly those afforded special government protection, she also recognized limitations in the available information that might inform consideration of potential public welfare impacts related to this vegetation effect noting the significant challenges in judging the specific extent and severity at which such effects should be considered adverse to public welfare (80 FR 65407, October 26, 2015).[42] 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 judgments regarding an appropriate level of public welfare protection (80 FR 65405, October 26, 2015).[43]

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

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

In summary, the 2015 decision focused primarily on the information related to trees and growth impacts in identifying the public welfare objectives for the revised secondary standard (80 FR 65409-65410, October 26, 2015). In this context, the Administrator in 2015 judged that the 70 ppb 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. She additionally judged that the new standard would be sufficient to protect public welfare from known or anticipated adverse effects. These judgments by the Administrator at that time 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.

As noted in Section 1.1 above and earlier in this section, the D.C. Circuit remanded the 2015 secondary standard to the EPA for further justification or reconsideration (*Murray Energy Corp. v. EPA*, 936 F.3d 597 [D.C. Cir. 2019]), and the 2020 review incorporated EPA's response to that remand, as discussed further below.

2020 Review: Regarding the appropriate O_3 exposure metric to employ in assessing adequacy of air quality control in protecting against RBL, in addition to finding it appropriate to continue to consider the seasonal W126 index averaged over a 3-year period to estimate median RBL (as was concluded in 2015), the Administrator in 2020 judged it appropriate to also consider other metrics including peak hourly concentrations[44] (85 FR 87344, December 2020). With regard to his consideration of the W126 index averaged over three years (as described below), he recognized conceptual

[44] Both the 2020 and 2013 ISAs reference the longstanding recognition of the risk posed to vegetation of peak hourly O_3 concentrations (e.g., "[h]igher concentrations appear to be more important than lower concentrations in eliciting a response" [2020 ISA, p. 8-180]; "higher hourly concentrations have greater effects on vegetation than lower concentrations" [2013 ISA, p. 91-4] "studies published since the 2006 O_3 AQCD do not change earlier conclusions, including the importance of peak concentrations, ... in altering plant growth and yield" [2013 ISA, p. 9-117]). While the evidence does not indicate a particular threshold number of hours at or above 100 ppb (or another reference point for elevated concentrations), the evidence of greater impacts from higher concentrations (particularly with increased frequency) and the air quality analyses that document variability in such concentrations for the same W126 index value led the Administrator to judge such a multipronged approach to be needed to ensure appropriate consideration of exposures of concern and the associated protection from them afforded by the secondary standard (85 FR 87340, December 31, 2020).

similarities of the 3-year average W126 index to some aspects of the derivation approach for the established E-R functions, and his use of the RBL as a proxy for other effects (as recognized above). His consideration of peak hourly concentration metrics (described below) related to his recognition of limitations associated with a reliance solely on W126 index as a metric to control exposures that might be termed "unusually damaging"[45] (85 FR 877339-40, December 31, 2020).

In describing the focus on a 3-year average W126 index , the 2020 review recognized that several factors associated with the derivation and application of the established E-R functions contributed uncertainty and some resulting imprecision or inexactitude to RBL estimated from single-year seasonal W126 index values, and that our understanding, in many cases, of relationships of O_3 effects on plant growth and productivity with larger-scale impacts, such as those on populations, communities and ecosystems is largely of a qualitative and conceptual nature (85 FR 49900-01, August 14, 2020; 2020 PA sections 4.5.1.2 and 4.5.3).[46] Accordingly, the Administrator judged that

[45] In its discussion regarding the EPA's use of a 3-year average W126 index, the 2019 court decision remanding the 2015 standard back to the EPA referenced advice from the CASAC in the 2015 review on protection against "unusually damaging years." Use of this term occurs in the 2014 CASAC letter on the second draft PA (Frey, 2014b). Most prominently, the CASAC defined as damage "injury effects that reach sufficient magnitude as to reduce or impair the intended use or value of the plant to the public, and thus are adverse to public welfare" (Frey, 2014b, p. 9). We also note that the context for the CASAC's use of the phrase "unusually damaging years" in the 2015 review is in considering the form and averaging time for a revised secondary standard in terms of a W126 index (Frey, 2014b, p. 13), which as discussed below is relatively less controlling of high-concentration years (whether as a single year index or averaged over three years) than the current secondary standard and its fourth highest daily maximum 8-hour metric (85 FR 87327, December 31, 2020).

[46] The E-R functions were derived mathematically from studies of different exposure durations (varying from shorter than one to multiple growing seasons) by applying adjustments so that they would yield estimates normalized to the same period of time (season). Accordingly, the estimates may represent average impact for a season, and have compatibility with W126 index averaged over multiple growing seasons or years (85 FR 87326, December 31, 2020; 2020 PA, section 4.5.1.2, Appendix 4A, Attachment 1). The available information also indicated that the patterns of hourly concentrations (and frequency of peak concentrations, e.g., at/above 100 ppb) in O_3 treatments on which the E-R functions are based differ from the patterns in ambient air meeting the current standard across the U.S. today (85 FR 87327, December 31, 2020). Additionally noted was the year-to-year variability of factors other than O_3 exposures that affect tree growth in the natural environment (e.g., related to variability in soil moisture, meteorological, plant-related and other factors), that have the potential to affect O_3 E-R relationships (2020 ISA, Appendix 8, section 3.12; 2013 ISA section 9.4.8.3; PA, sections 4.3 and 4.5). All of these considerations contributed to the finding of a consistency of the use of W126 index averaged over

use of a seasonal RBL averaged over multiple years (e.g., 3-year average) is reasonable, and provides a more stable and well-founded RBL estimate for its use as a proxy for the array of vegetation-related effects identified above. More specifically, the Administrator concluded that the use of an average seasonal W126 index derived from multiple years (with their representation of variability in environmental factors) provides an appropriate representation of the evidence and attention to the identified considerations, and that a sole reliance on single year W126 estimates for reaching judgments with regard to magnitude of O_3 related RBL and associated judgments of public welfare protection would ascribe a greater specificity and certainty to such estimates than supported by the evidence. Thus, the Administrator in 2020 found it appropriate, for purposes of considering public welfare protection from effects for which RBL is used as a proxy, to primarily consider W126 index in terms of a 3-year average metric (85 FR 87339-87340, December 31, 2020).

In the context of his primary focus on RBL in its role as proxy for the broader array of vegetation-related effects of O_3, the Administrator further considered the available analyses of air quality data at sites across the U.S., particularly including those sites in or near Class I areas, which were consistent with the air quality analyses available in the 2015 review.[47] In virtually all design value periods between 2000 and 2018 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 (85 FR 87344, December 31, 2020).

In using a 3-year average W126 index to assess protection from RBL, the 2020 decision additionally took into account the 2019 court remand on this issue, including the remand's reference to protection against "unusually damaging years" (85 FR 87325-

multiple years with the approach used in deriving the E-R function, and with other factors that may affect growth in the natural environment (85 FR 87340, December 31, 2020).

[47] These data 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 (2020 PA, Appendix 4D).

87328, December 31, 2020). In this context, the 2020 decision also relied on consideration of air quality analyses of peak hourly concentrations in the context of controlling exposure circumstances of concern (e.g., for growth effects, among others). More specifically, the EPA considered air quality analyses that investigated the annual occurrence of elevated hourly O_3 concentrations which may contribute to vegetation exposures of concern (2020 PA, Appendix 2A, section 2A.2; Wells, 2020). In illustrating limitations of the W126 index (whether in terms of a 3-year average or a single year) for the purpose of controlling peak concentrations,[48] and also the strengths of the current standard in this regard, the air quality analyses show that the form and averaging time of the existing standard controls cumulative exposures in terms of W126 and also is much more effective than the W126 index in limiting peak concentrations (e.g., hourly O_3 concentrations at or above 100 ppb)[49] and in limiting number of days with any such hours (Wells, 2020, e.g., Figures 4, 5, 8, 9 compared to Figures 6, 7, 10 and 11).[50] Thus, the 2020 review found that the W126 index, by its very definition, and as illustrated by the air quality data analyses, does not provide specificity with regard to year-to-year variability in elevated hourly O_3 concentrations with the potential to contribute to the "unusually damaging years" that the CASAC had identified for increased concern in the 2015 review. As a result, the 2020 decision found that a standard based on a W126 index (either a 3-year or a single-year index) would not be expected to provide effective control of the peak concentrations that may contribute to "unusually damaging years" for vegetation, while control of such years is a characteristic of the existing standard.[51] In

[48] The W126 index cannot, by virtue of its definition, always differentiate between air quality patterns with high peak concentrations and those without such concentrations.

[49] As described in section 4.3.3 below, the occurrence of high concentrations (including those at or above 100 ppb [e.g., Smith, 2012; Smith et al., 2012]), as well as cumulative exposures influence the effects of O_3 on plants.

[50] With regard to the existing standard, historical air quality data extending back to 2000 additionally show the appreciable reductions in peak concentrations that have been achieved in the U.S. as air quality has improved under O_3 standards of the existing form and averaging time (Wells, 2020, Figures 12 and 13).

[51] From these analyses, the Administrator concluded that the form and averaging time of the current standard is effective in controlling peak hourly concentrations and that a W126 index based standard would be much less effective in providing the needed protection against years with such elevated and potentially damaging hourly concentrations.

light of the air quality analyses and evidence of short-term risks to vegetation, the 2020 decision concluded that for considering the public welfare protection provided by the standard, it is appropriate to consider use of a seasonal W126 averaged over a 3-year period to estimate median RBL using the established E-R functions, in combination with a broader consideration of the air quality pattern of peak hourly concentrations (85 FR 87340-87341, December 31, 2020).

Additionally, the Administrator concluded that the 0.07 ppm standard provides adequate protection of the public welfare related to crop yield loss (85 FR 87342, December 31, 2020). Key considerations in this conclusion included the established E-R functions for 10 crops and the estimates of RYL derived from them (2020 ISA, 2020 PA, Appendix 4A, section 4A.1, Table 4A-5), as well as the existence of 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 (85 FR 87341-87342, December 31, 2020). With regard to RYL estimates for the 10 crops with established E-R functions, the air quality analysis indicated that the current standard generally maintains air quality at a W126 index below 17 ppm-hrs, with few exceptions, which would accordingly limit the associated estimates of median RYL below 5.1% (based on experimental O_3 exposures), a level which the Administrator judged would not constitute an adverse effect on public welfare. Therefore, the Administrator concluded that the current standard provides adequate protection of public welfare related to crop yield loss and did not need to be revised to provide additional protection against this effect (85 FR 87342, December 31, 2020).

With regard to visible foliar injury and the question of a level of air quality that would provide protection against visible foliar injury related effects known or anticipated to cause adverse effects to the public welfare, the Administrator recognized that there was a paucity of established approaches for interpreting specific levels of severity and extent of foliar injury in natural areas with regard to impacts on the public welfare (e.g., related to recreational services). The Administrator recognized that the available information did not provide for specific characterization of the incidence and severity that would not be expected to be apparent to the casual observer, nor for clear identification of the pattern of O_3 concentrations that would provide for such a situation. In 2020, the Administrator further considered the USFS system for interpreting visible foliar injury impacts in its surveys across the U.S. More specifically, he concluded that scores in the USFS system categorized as “moderate to severe” injury would be an indication of visible foliar injury occurrence that, depending on extent and severity, may raise public welfare concerns. In this framework, the Administrator noted the findings of the 2020 PA evaluations that, the incidence of USFS scores classified as indicative of ”moderate to severe “injury in the USFS scheme appear to markedly increase only with W126 index values above 25 ppm-hrs. He further took note of the multiple published studies analyzing the USFS data across multiple years and multiple U.S. regions with regard to metrics intended to quantify influential aspects of O_3 air quality, which indicated a potential role for an additional metric related to the occurrence of days with relatively high hourly concentrations (e.g., number of days with a 1-hour concentration at or above 100 ppb [2020 PA, section 4.5.1.2]). In light of this evidence and the 2020 PA analyses of these data, the Administrator judged that W126 index values at or below 25 ppm-hrs, when in combination with infrequent occurrences of hourly concentrations at or above 100 ppb, would not be anticipated to pose risk of visible foliar injury of an extent and severity so as to be adverse to the public welfare (85 FR 87343, December 31, 2020).

The Administrator further noted that the available air quality analyses that a W126 index above 25 ppm-hrs (either as a 3-year average or in a single year) was not seen to occur at monitoring locations where the current standard is met (including in or near Class I areas), and that, in fact, values above 17 or 19 ppm-hrs are rare and that days with any hourly concentrations at or above 100 ppb at monitoring sites that meet the current standard are uncommon (85 FR 87316-18, December 31, 2020; 2020 PA, Appendix 4C, section 4C.3; Appendix 4D; Wells, 2020). Based on these findings, the Administrator concluded that the current standard provides control of air quality conditions that contribute to USFS scores of a magnitude indicative of “moderate to severe” foliar injury. In so doing, he also noted the 2020 PA finding that the information from the USFS monitoring program, 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 or specific impacts on recreational or related services for areas, such as wilderness areas or national parks, such that, as concluded by the 2020 PA the evidence indicates that areas that meet the current standard are unlikely to have scores reasonably considered to be impacts of public welfare significance (85 FR 87344, December 31, 2020).

With regard to the protection provided by the current standard from the occurrence of O_3 exposures within a single year with potentially damaging consequences, including a significantly increased incidence of areas with visible foliar injury that might be judged moderate to severe, the Administrator gave particular focus to USFS scores termed "moderate to severe injury" (85 FR 87344, December 31, 2020; 2020 PA, sections 4.3.3.2, 4.5.1.2 and Appendix 4C). As discussed above, the incidence of USFS sites with scores above 15 markedly increases with W126 index estimates above 25 ppm-hrs, a magnitude of W126 index indicated by the air quality analysis to be scarce 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 (2020 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 took note of the air quality analyses of hourly concentrations (2020 PA, Appendix 2A; Wells 2020). These analyses of data from the past 20 years show a declining trend in 1-hour daily maximum concentrations mirroring the declining trend in design values, and indicate that sites meeting the current standard had few days with hourly concentrations at or above 100 ppb, supporting the 2020 PA conclusion that the form and averaging time of the current standard provides appreciable control of peak 1-hour concentrations. In light of these findings from the air quality analyses and considerations in the 2020 PA, both with regard to 3-year average W126 index values at sites meeting the current standard and the rarity of such values at or above 19 ppm-hrs, and with regard to single-year W126 index values at sites meeting the current standard, and the rarity of such values above 25 ppm-hrs, as well as with regard to the appreciable control of 1-hour daily maximum concentrations, the Administrator judged that the current standard provides adequate protection from air quality conditions with the potential to be adverse to the public welfare (85 FR 87344, December 31, 2020).

2 THE CURRENT OZONE NAAQS REVIEW: MILESTONES AND TIMELINE

In August 2023, EPA announced the initiation of the current periodic review of the air quality criteria for O_3 and related photochemical oxidants, and the O_3 NAAQS and issued a call for information in the *Federal Register* (88 FR 58264). The current review of the O_3 standards builds on the substantial body of work done during the course of prior reviews, represented both in comprehensive science assessments (ISAs) and past quantitative exposure and risk analyses. These different types of information, evaluated in past policy assessments, provided the basis for decisions on the existing O_3 NAAQS.

A wide range of external experts, as well as EPA staff representing a variety of areas of expertise (e.g., epidemiology, controlled human exposure studies, animal toxicology, ecology, statistics, biological, environmental, and physical sciences, atmospheric and climate science, human exposure science, and risk analysis), participated in a virtual workshop held by the EPA on May 13-16, 2024. The workshop provided an opportunity for a public discussion of the key policy-relevant issues associated with the review of the O_3 NAAQS and the new science available to inform our understanding of these issues[52].

The timeline projected for the remainder of the current review is presented in Table 4-1. Concurrent with the release of this background document (Volume 1 of the IRP),[53] the EPA is releasing the planning document for the review and the ISA, as Volume 2 of the IRP (U.S. EPA, 2024). Volume 2 identifies policy-relevant science issues important to guiding the evaluation of the air quality criteria for O_3 and the reviews of the primary and secondary O_3 NAAQS. It will be subject of a consultation with CASAC. Based on consideration of input received during this consultation, the EPA will develop a draft ISA for external review.

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[52] The proceedings document from the workshop are available at: https://assessments.epa.gov/risk/document/&deid%3D362873.

[53] In addition to providing an overview of the history of the criteria and standards for ozone and related photochemical oxidants (chapter 1), this document also includes a summary of the monitoring and data handling regulations, as well an overview of recent air quality and trends in the Appendix.

With consideration of the newly available evidence identified in the draft ISA, the EPA will develop the planning document for quantitative analyses, including exposure/risk analyses, that might be warranted to inform decisions in the current review. This planning document for quantitative analyses will comprise the third volume of the IRP. With consideration of the CASAC review of the draft ISA and consultation discussion on Volume 3 of the IRP, the EPA will develop a draft of the PA (with associated policy evaluations and quantitative analyses) for public and CASAC review. The timeline projects completion of the final ISA in 2027 and the final PA in 2028, followed by proposed and final decisions in 2029.

Table 2-1. Projected timeline for the review of ambient air quality criteria and NAAQS for Ozone.

Stage of Review	Major Milestone	Target Dates*
Planning	Federal Register Call for Information	August 25, 2023
	Workshop To Inform Review of the O_3 NAAQS	May 13-16, 2024
	Integrated Review Plan (IRP), volumes 1 and 2	December 2024
	CASAC consultation on IRP, volume 2	February/March 2025
	IRP, volume 3	Spring 2027
	CASAC consultation on IRP, volume 3	Spring 2027
Science Assessment	External review draft of ISA	Early 2027
	CASAC public meeting for review of draft ISA	Spring 2027
	Final ISA	Late 2027
Quantitative Exposure/Risk Analyses and Policy Assessment	External draft of PA (including quantitative air quality, exposure and/or risk analyses, as warranted)	Summer 2028
	CASAC public meeting for review of draft PA	Summer 2028
	Final PA	Early 2029
Regulatory Process	Notice of proposed decision	2029
	Notice of final decision	2030

* Exact dates are given for milestones that have already occurred.

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APPENDIX AMBIENT AIR MONITORING AND DATA HANDLING

Ozone is a gas composed of three oxygen atoms (O_3). It is naturally present in the Earth's atmosphere, both in the stratospheric layer occurring roughly 10 to 30 miles above the Earth's surface as well as in the closer tropospheric layer. The stratosphere contains a large reservoir of O_3 (i.e. the "ozone layer") that results naturally from photochemical reactions between ultraviolet light (UV) and molecular oxygen (O_2).[1] Under specific meteorological conditions, this reservoir can contribute to O_3 concentrations at the Earth's surface (Langford et al., 2017). Ozone is also produced near the earth's surface due to chemical interactions involving solar radiation and pollution resulting from human activity. These chemical reactions involve specific O_3 precursors, such as nitrogen oxides (NO_X), volatile organic compounds (VOCs), carbon monoxide (CO) and methane (CH_4), which can be emitted from both natural and anthropogenic sources.[2]

The EPA established O_3 as the indicator for the NAAQS for photochemical oxidants in 1979. Prior to 1979, the indicator for the NAAQS for photochemical oxidants was total photochemical oxidants. Early ambient air monitoring indicated similarities between O_3 measurements and the photochemical oxidant measurements, as well as reduced precision and accuracy of the latter. Ozone is currently the only photochemical oxidant other than nitrogen dioxide that is routinely monitored in a national ambient air monitoring network.

The EPA and State and local agencies have been measuring O_3 in the atmosphere for decades. Ambient air O_3 concentrations are measured in several national networks. These include the state and local air monitoring stations (SLAMS network) intended for O_3 NAAQS surveillance, the photochemical assessment monitoring stations (PAMs),

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[1] This layer of O_3 in the upper atmosphere helps to protect the earth's populations and ecosystems from the damaging effects of UV radiation (Norval et al., 2011; Bais et al., 2017).

[2] Impacts from methane emissions on O_3 formation are generally observed at the global scale over longer time periods (e.g., decadal scale) while impacts from NOx and VOCs may occur over shorter temporal timescales (days to weeks) and over a variety of spatial scales (urban up to global).

national core (NCore) monitoring sites, the clean air status and trends network (CASTNET) monitors, and special purpose monitoring. The data from these networks are accessible via EPA's Air Quality System (AQS): http://www.epa.gov/ttn/airs/airsaqs/.

There were 1,287 monitoring sites reporting hourly O_3 concentration data to the EPA during the 2021-2023 period (Figure A-1). Nearly 80% of this network are SLAMS monitors operated by state and local governments to meet regulatory requirements and provide air quality information to public health agencies; these sites are largely focused on urban and suburban areas.

Federal regulations specify requirements for the data collection and calculations performed to assess whether the O_3 NAAQS are met. This appendix describes the ambient air O_3 measurement methods, the sites and networks where these measurements are made, and the data handling conventions and computations.

A.1. STATE AND LOCAL AIR MONITORING STATIONS NETWORK

This section describes the monitoring O_3 monitoring requirements for the SLAMS network, the main purpose of which is surveillance for the O_3 NAAQS. The EPA regulates how this monitoring is conducted to ensure accurate and comparable data for determining compliance with the NAAQS. The code of federal regulations (CFR) at parts 50, 53, and 58 specifies required aspects of the ambient air monitoring program for NAAQS pollutants. [3]

A.1.1. Sampling and Analysis Methods

In order to be used in NAAQS attainment designations, ambient air O_3 concentration data must be obtained using either the Federal Reference Method (FRM) or a Federal Equivalent Method (FEM). In recent years, about 99% of the state, local, and tribal air monitoring stations that report data to the EPA use ultraviolet FEMs. The FRM was revised in 2015 to include a new chemiluminescence by nitric oxide (NO-CL) method (40 CFR Part 50, Appendix D). The previous ethylene (ET-CL) method, while still

[3] The Federal Reference Methods (FRMs) for sample collection and analysis are specified in 40 CFR Part 50, the procedures for approval of FRMs and Federal Equivalent Methods (FEMs) are specified in 40 CFR Part 53, and the rules specifying requirements for the planning and operations of the ambient monitoring network are specified in 40 CFR Part 58.

included in the CFR as an acceptable method, is no longer used due to lack of availability and safety concerns with ethylene.

In 2023, the EPA updated a standard parameter used to measure concentrations of O_3 in ambient air (40 CFR Part 50, Appendix D). This parameter, called the absorption cross-section value, is used in ultraviolet-based O_3 analyzers and Standard Reference Photometers (SRPs). The new value reflects advances in science and measurement technology and is more accurate and precise than the value established in 1961. An international group reviewed absorption cross-section measurements in 2019 and reached consensus on an updated value, which will be implemented worldwide beginning in 2025. The new absorption cross-section value will improve the accuracy of surface O_3 monitoring measurements and reduce the uncertainty in measured O_3 concentrations.

A.1.2. Network Requirements

The requirements for the SLAMS network depend on the population and most recent O_3 design values[4] in an area. The minimum number of O_3 monitors required in a metropolitan statistical area (MSA) ranges from zero for areas with a population less than 350,000 and no recent history of an O_3 design value greater than 85 percent of the level of the standard, to four monitors for areas with a population greater than 10 million and an O_3 design value greater than 85 percent of the standard level.[5] At least one monitoring site for each MSA must be situated to record the maximum concentration for that particular metropolitan area.

Siting criteria for SLAMS includes horizontal and vertical inlet probe placement; spacing from minor sources, obstructions, trees, and roadways; inlet probe material; and

[4] A design value is a statistic that summarizes the air quality status of a given area relative to the level of the standard, taking the averaging time and form into account, as well as any data handling requirements (e.g., for the 2015 O_3 NAAQS, these requirements are specified in Appendix U to 40 CFR Part 50). Design values are typically used to classify nonattainment areas as meeting or not meeting the standard, to assess progress towards meeting the NAAQS, and to develop control strategies.

[5] The SLAMS minimum monitoring requirements to meet the O_3 design criteria are specified in 40 CFR Part 58, Appendix D. The minimum O_3 monitoring network requirements for urban areas are listed in Table D-2 of Appendix D to 40 CFR Part 58 (accessible at https://www.ecfr.gov).

sample residence times.[6] Adherence to these criteria ensures uniform collection and comparability of O_3 data. Since the highest O_3 concentrations tend to be associated with a particular season for various locations, the EPA requires O_3 monitoring during specific O_3 monitoring seasons (shown in Figure A-2) which 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).[7]

Ambient air quality data and associated quality assurance (QA) data are reported to the EPA via the AQS, as required by 40 CFR 58.16 and summarized here. Data are reported quarterly and must be submitted to AQS within 90 days after the end of the quarterly reporting period. Each monitoring agency is required to certify data that is submitted to AQS from the previous year. The data are certified, taking into consideration any QA findings, and a data certification letter is sent to the EPA Regional Administrator. Data must be certified by May 1st of the following year. Data collected by FRM or FEM monitors that meet the QA requirements must be certified as meeting the QA criteria for use in assessing NAAQS attainment (40 CFR 58.15). The estimates of both precision and bias are derived from quality control (QC) checks using calibration gas, performed at each site by the monitoring agency. The data quality goal for precision and bias is 7 percent.[8]

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[6] The probe and monitoring path siting criteria for ambient air quality monitoring are specified in 40 CFR, Part 58, Appendix E.

[7] The required O_3 monitoring seasons for each state are listed in 40 CFR Part 58, Appendix D, Table D-3.

[8] Quality assurance requirements for monitors used in evaluations of the NAAQS are provided in 40 CFR Part 58, Appendix A. Annual summary reports of precision and bias can be obtained for each monitoring site at the EPA's Air Data website: https://www.epa.gov/outdoor-air-quality-data/single-point-precision-and-bias-report.

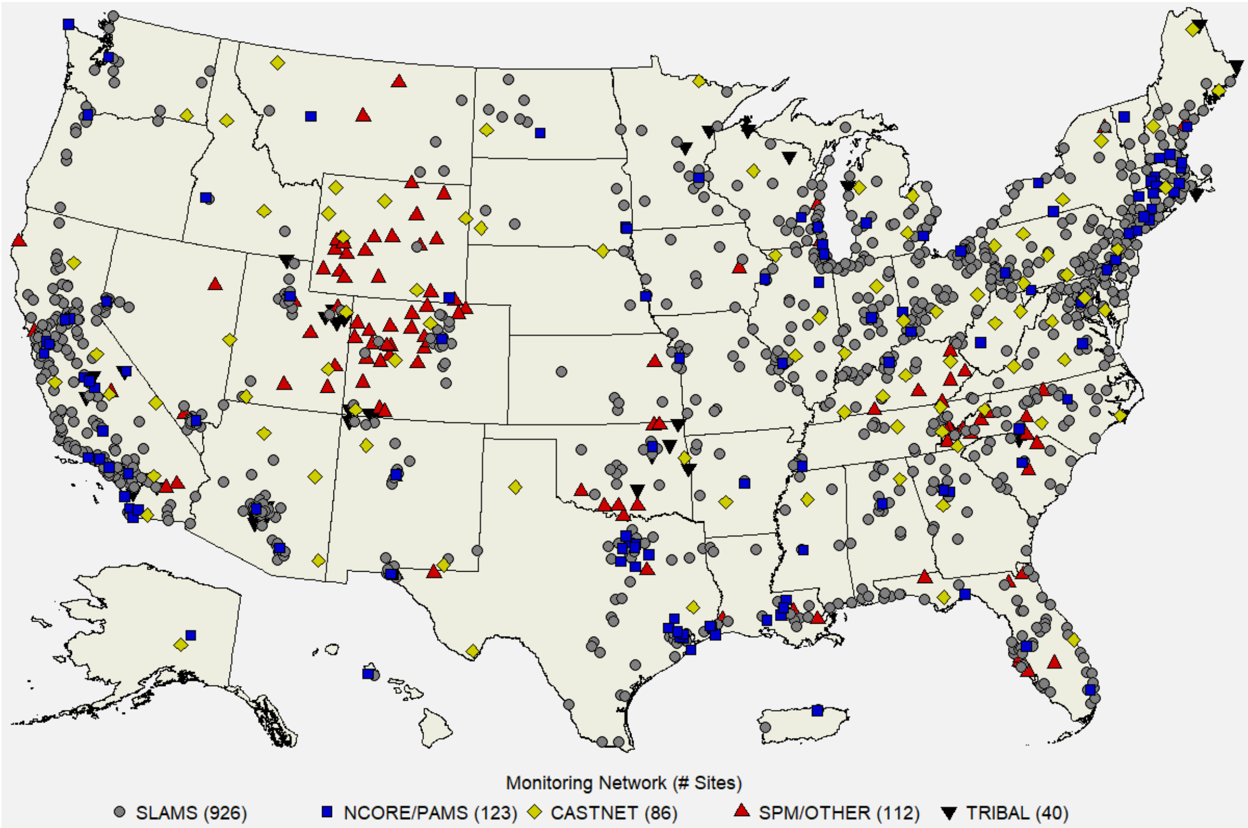

Figure A-1. Map of U.S. O_3 monitoring sites reporting data to the EPA during the 2021-2023 period. Source: AQS**.**

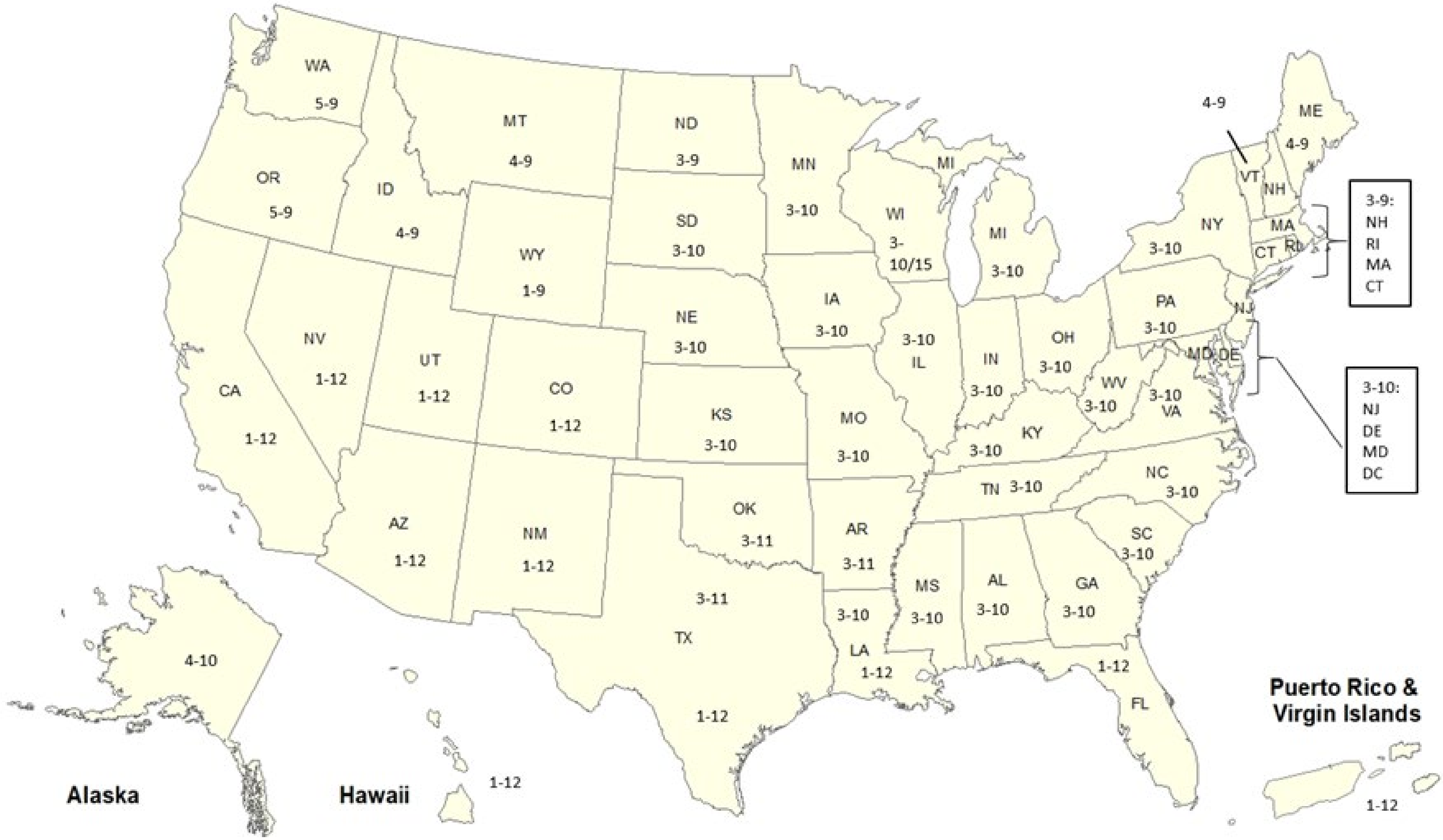

Figure A-2. Current O_3 monitoring seasons in the U.S. Numbers in each state indicate the months of the year the state is required to monitor for O_3 (e.g., 3-10 means O_3 monitoring is required from March through October).

Two important subsets of SLAMS are the NCore stations and PAMS. The NCore sites feature co-located measurements of chemical species such as nitrogen oxide (NO_X) and total reactive nitrogen (NO_Y), along with meteorological measurements. The additional data collected at the PAMS sites include measurements of NO_X, a target set of VOCs, and meteorological measurements. The enhanced monitoring at sites in these two networks informs our understanding of local O_3 formation.

A.2. OTHER NETWORKS MONITORING O_3

While the SLAMS network has a largely urban and population-based focus, there are monitoring sites in other networks that can be used to track compliance with the NAAQS in rural areas. For example, the Clean Air Status and Trends Network (CASTNET) monitors are located in rural areas. There were 86 CASTNET monitors operating during the 2021-2023 period, with most of the sites in the eastern U.S. being operated by the EPA, and most of the sites in the western U.S. being operated by the National Park Service (NPS).

Additionally, there are also a number of Special Purpose Monitoring Stations (SPMs), which are not required but are often operated by air agencies for short periods of time (less than 3 years) to collect data for human health and welfare studies, as well as other types of monitoring sites, including monitors operated by tribes and industrial sources. The SPMs are typically not used to assess compliance with the NAAQS.[62]

A.3. DATA HANDLING CONVENTIONS AND COMPUTATIONS FOR DETERMINING WHETHER STANDARDS ARE MET

To assess whether a monitoring site or geographic area (usually a county or urban area) meets or exceeds a NAAQS, the monitoring data are analyzed consistent with the established regulatory requirements for the handling of monitoring data for the purposes of deriving a design value. A design value summarizes ambient air concentrations for an area in terms of the indicator, averaging time, and form for a

[62] However, SPMs that use FEMs or FRMs, meet all applicable requirements in 40 CFR Part 58, and operate continuously for more than 24 months may be used to assess compliance with the NAAQS (40 CFR 58.20(c)). If an SPM using an FRM or FEM is discontinued within 24 months of start-up, a NAAQS violation determination for O_3 NAAQS will not be based solely on data from the SPM (40 CFR 58.20(d)).

given standard, such that its comparison to the level of the standard indicates whether the area meets or exceeds the standard. The procedures for calculating design values for the current O_3 NAAQS (established in 2015) are detailed in Appendix U to 40 CFR Part 50 and are summarized below.

Hourly average O_3 concentrations at the monitoring sites used for assessing whether an area meets or exceeds the NAAQS are required to be reported in ppm to the third decimal place, with additional digits truncated, consistent with the typical measurement precision associated with most O_3 monitoring instruments. The hourly concentrations are used to compute moving 8-hour averages, which are stored in the first hour of each 8-hour period (e.g., the 8-hour average for the 7:00 AM to 3:00 PM period is stored in the 7:00 AM hour), and digits to the right of the third decimal place are truncated. Each 8-hour average is considered valid if 6 or more hourly concentrations are available for the 8-hour period.

Next, the daily maximum 8-hour average (MDA8) concentration for each day is identified as the highest of the 17 consecutive, valid 8-hour average concentrations beginning at 7:00 AM and ending at 11:00 PM (which includes hourly O_3 concentrations from the subsequent day). MDA8 values are considered valid if at least 13 valid 8-hour averages are available for the day, or if the MDA8 value is greater than the level of the NAAQS. Finally, the O_3 design value is calculated as the annual fourth highest MDA8 value averaged over three consecutive years[63]. An O_3 design value less than or equal to the level of the NAAQS is considered to be valid if valid MDA8 values are available for at least 90% of the days in the O_3 monitoring season (as defined for each state and shown in Figure A-1) on average over the 3 years, with a minimum of 75% data completeness in any individual year. Design values greater than the level of the NAAQS are always considered to be valid.

An O_3 monitoring site meets the NAAQS if it has a valid design value less than or equal to the level of the standard, and it exceeds the NAAQS if it has a design value greater than the level of the standard. A geographic area meets the NAAQS if all

[63] Design values are reported in ppm to the third decimal place, with additional digits truncated. This truncation step also applies to the initially calculated 8-hour average concentrations (2020 PA, Appendix 2A, section 2A.1).

ambient air monitoring sites in the area have valid design values meeting the standard. Conversely, if one or more monitoring sites has a design value exceeding the standard, then the area exceeds the NAAQS.

As discussion in section A.1, to assess O_3 concentrations across the U.S., state and local environmental agencies submit the monitoring data to the EPA for analyses. Each year EPA calculates and makes available the air quality design values to the public (available here: https://www.epa.gov/air-trends/air-quality-design-values).[64] Figure A-3 is a map of the most recent O_3 design values at U.S. ambient air monitoring sites based on data from the 2021-2023 period, that shows many monitoring sites with design values exceeding the current NAAQS, with most of these located in or near urban areas. Overall, concentrations of O_3 in the U.S. have trended downward over the past several decades. The U.S. median design value decreased by 23% from 2000 (86 ppb) to 2023 (66 ppb) (Figure A-4).

[64] EPA also publishes an overview of O_3 air quality in the U.S. with up-to-date graphical summaries of air quality information that supports the review of the NAAQS for O_3 (available here: https://www.epa.gov/air-quality-analysis/ozone-naaqs-review-analyses-and-data-sets).

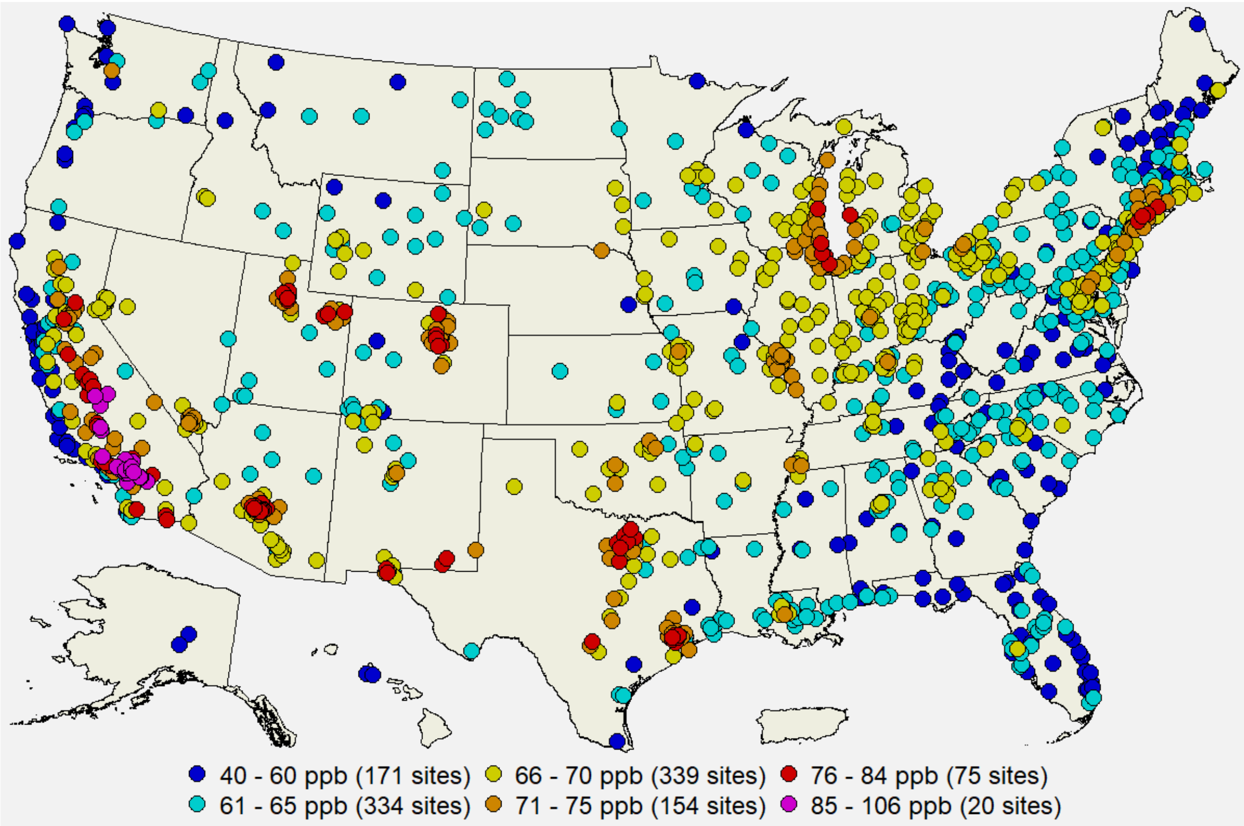

Figure A-3. O_3 design values in ppb for the 2021-2023 period. Source: AQS.

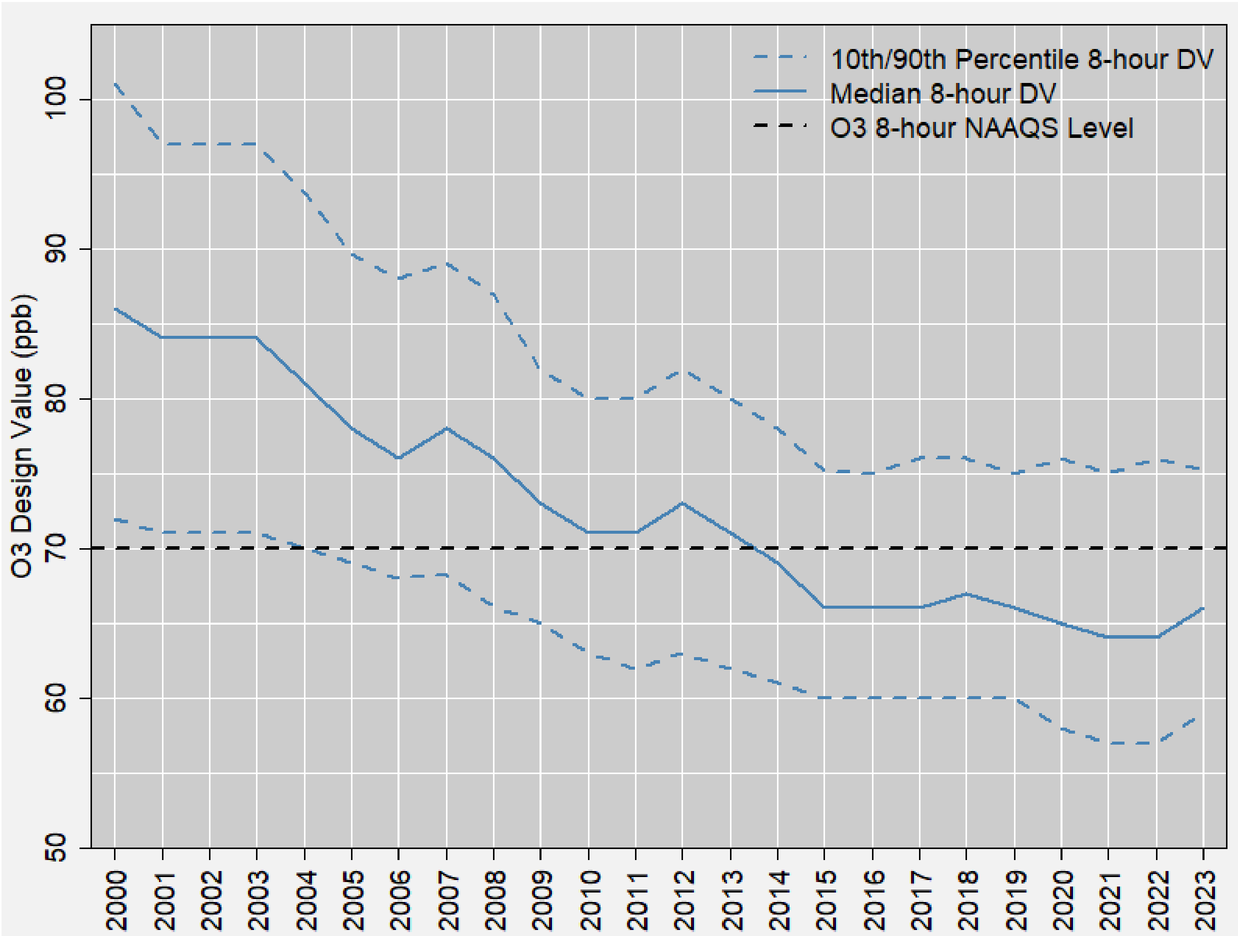

Figure A-4. National trend in O_3 design values in ppb, 2000 to 2023. Source: AQS.

A.4. REFERENCES

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