ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50 and 58

[EPA-HQ-OAR-2005-0172; FRL-]

RIN 2060-AP98

National Ambient Air Quality Standards for Ozone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA has reconsidered the primary and secondary national ambient air quality standards (NAAQS) for ozone (O_3) set in March 2008, and has determined that different standards than those set in 2008 are necessary to provide requisite protection of public health and welfare, respectively. With regard to the primary standard for O_3, EPA is setting the level of the 8-hour standard at 0.070 parts per million (ppm). With regard to the secondary standard for O_3, EPA is setting a new cumulative, seasonal standard to replace the standard set in 2008. This new secondary standard is set at a level of 13 ppm-hours. This secondary standard is defined in terms of a concentration-weighted index, which is used to sum weighted hourly O_3 concentrations over 12 hours per day (8:00 am to 8:00 pm) and over 3-month periods within each calendar year. This standard is based on the 3-year average of the maximum 3-month index values for each year. EPA is also making conforming changes to the Air Quality Index (AQI) for O_3, setting an AQI value of 100 equal to 0.070 ppm, 8-hour average. In addition, EPA is revising and adopting data interpretation procedures for the primary and secondary O_3 NAAQS, respectively; setting deadlines for optional state demonstrations that O_3 concentrations have been affected by exceptional events; and establishing the schedule for initial area designations for the O_3 NAAQS set by this action.

DATES: This final rule is effective on **[insert date 60 days after date of publication in the Federal Register]**.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2005-0172. All documents in the docket are listed on the www.regulations.gov website. Although listed in the index, some information is not publicly available, e.g. confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is 202-566-1742. The telephone number for the Public Reading Room is 202-566-1744.

FOR FURTHER INFORMATION CONTACT: Ms. Susan Lyon Stone, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C504-06, Research Triangle Park, NC 27711; telephone: 919-541-1146; fax: 919-541-0237; email: stone.susan@epa.gov.

SUPPLEMENTARY INFORMATION:

Children's Environmental Health

Consideration of children's environmental health played a central role in the reconsideration of the 2008 O_3 primary NAAQS and EPA's decision to set the 8-hour primary O_3 standard at 0.070 ppm. Technical information that pertains to children, including the evaluation of scientific evidence, policy considerations, and exposure and risk assessments, is discussed in the following documents: the 2006 Air Quality Criteria for Ozone and Other Related Photochemical Oxidants (2006 Criteria Document,

EPA/600/R-05/004aB-cB); the Review of the National Ambient Air Quality Standards for Ozone: Assessment of Scientific and Technical Information. OAQPS Staff Paper. (2007 Staff Paper, EPA-452/R-07-007); the 2007 Ozone Population Exposure Analysis for Selected Urban Areas (EPA-452/R-07-010); the 2007 Ozone Health Risk Assessment for Selected Urban Areas (EPA-452/R-07-009); the Responses to Significant Comments on the 2007 Proposed Rule on the National Ambient Air Quality Standards for Ozone (July 11, 2007; 72 FR 37818; henceforth "2008 Response to Comments"); and the Responses to Significant Comments on the 2010 Proposed Rule on the National Ambient Air Quality Standards for Ozone (January 19, 2010; 75 FR 2938; henceforth "2011 Response to Comments"). All of these documents are available on the TTN NAAQS Web site, at:

http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_index.html

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The following topics are discussed in this preamble:

I. Background

The decisions presented in this final rule are based on a reconsideration of the O_3 NAAQS set in 2008 (73 FR 16436, March 27, 2008), as discussed in the 2010 proposed rule (75 FR 2938, Jan 19, 2010). This reconsideration is based on the scientific and technical information and analyses on which the March 2008 O_3 NAAQS rulemaking was based. Therefore, much of the information included in this final rule is drawn directly from information included in the 2007 proposed rule (72 FR 37818, July 11, 2007) and the 2008 final rule (73 FR 16436, March 27, 2008), as well as the 2010 proposed rule (75 FR 2938, Jan 19, 2010).

A. Summary of the Final O_3 NAAQS

Based on its review of the air quality criteria for O_3 and related photochemical oxidants and NAAQS for O_3, EPA has reconsidered the 2008 final rule on the primary and secondary NAAQS for O_3

to provide protection of public health and welfare, respectively, that is required under section 109, and is making corresponding revisions in data handling conventions for O_3.

With regard to the primary standard for O_3, EPA is setting the level of the 8-hour standard at 0.070 parts per million (ppm), to provide requisite protection for children and other "at risk" populations against an array of O_3-related adverse health effects that range from decreased lung function and increased respiratory symptoms to serious indicators of respiratory morbidity including emergency department visits and hospital admissions for respiratory causes, and possibly cardiovascular-related morbidity as well as total nonaccidental and cardiorespiratory mortality. EPA is also making conforming changes to the Air Quality Index (AQI) for O_3, setting an AQI value of 100 equal to 0.070 ppm, 8-hour average.

With regard to the secondary standard for O_3, EPA is setting a new cumulative, seasonal standard[1] to replace the standard set in 2008. This new secondary standard is set at a level of 13 ppm-hours, to provide requisite protection against O_3-related adverse impacts on vegetation and forested ecosystems. This secondary standard is defined in terms of a concentration-weighted index, which is used to sum weighted hourly O_3 concentrations over 12 hours per day (8:00 am to 8:00 pm) and over 3-month periods within each calendar year. This standard is based on the 3-year average of the maximum 3-month index values for each year.

With regard to Appendix P, EPA is revising the data requirements for interpreting the primary NAAQS for O_3, and adopting data interpretation procedures for the new secondary O_3 NAAQS. In addition, EPA is setting deadlines for optional state demonstrations that O_3 concentrations have been

[1]In describing the secondary standard as a "seasonal" standard, EPA is referring generally to the growing season of O_3-sensitive vegetation, not to the seasons of the year (i.e., spring, summer, fall, winter), as discussed most fully below in section IV.C.2.

affected by exceptional events and establishing the schedule for initial area designations for the O_3 NAAQS set by this action.

B. Legislative Requirements

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

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants for which air quality criteria are issued. Section 109(b)(1) defines a primary standard as one "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health."[2] A secondary standard, as defined in section 109(b)(2), must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such

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

criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air."[3]

The requirement that primary standards include an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir 1980), *cert. denied*, 449 U.S. 1042 (1980); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186 (D.C. Cir. 1981), *cert. denied*, 455 U.S. 1034 (1982); *American Farm Bureau Federation v. EPA,* 559 F. 3d 512, 533 (D.C. Cir. 2009); *Association of Battery Recyclers v. EPA*, 604 F. 3d 613, 617-18 (D.C. Cir. 2010). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels, *see Lead Industries Association v. EPA*, 647 F.2d at 1156 n. 51, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, EPA considers such factors as the nature and severity of the health effects involved, the size of the population(s) at risk, and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to

[3]Welfare effects as defined in section 302(h) (42 U.S.C. 7602(h)) include, but are not limited to, "effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being."

providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *Lead Industries Association v. EPA*, 647 F.2d at 1161-62; *Whitman v. American Trucking Associations*, 531 U.S. 457, 495 (2001).

In setting standards that are "requisite" to protect public health and welfare, as provided in section 109(b), EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes. In so doing, EPA may not consider the costs of implementing the standards. See generally, *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001). Likewise, "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards." *American Petroleum Institute v. Costle*, 665 F. 2d at 1185.

Section 109(d)(1) of the CAA requires that "not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards . . . and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate . . . ." Section 109(d)(2) requires that an independent scientific review committee "shall complete a review of the criteria . . . and the national primary and secondary ambient air quality standards . . . and shall recommend to the Administrator any new . . . standards and revisions of existing criteria and standards as may be appropriate . . . ." Since the early 1980's, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC).[4] .

C. Federal Partnership with State, Tribal and Local Air Quality Agencies

[4] Lists of CASAC members and of members of the CASAC Ozone Review Panel for the Reconsideration of the 2008 NAAQS (CASAC Ozone Reconsideration Panel, or CASAC Panel) are available at:
http://yosemite.epa.gov/sab/sabpeople.nsf/WebExternalSubCommitteeRosters?OpenView&committee=CASAC&subcommittee=Ozone%20Review%20Panel%20for%20the%20Reconsideration%20of%20the%202008%20NAAQS

States have primary responsibility for ensuring attainment and maintenance of ambient air quality standards once EPA has established them. Under section 110 of the CAA (42 U.S.C. 7410) and related provisions, States are to submit, for EPA approval, State implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to emission sources.

The EPA recognizes that any time a national ambient air quality standard is revised, it creates a set of implementation challenges for States, Tribes and local areas. The primary O_3 standard we are setting today presents challenges, as well, particularly in those areas with more severe O_3 problems and those areas that will have to address nonattainment for the first time. But the tremendous public health benefits this standard will yield – and, in fact, the requirements of the Clean Air Act itself – make this a challenge we must meet. Our history of implementing ambient air quality standards under the Act, especially since the 1990 Amendments, is proof of our ability to meet such challenges: By working together across all levels of government, we have made steady progress in public health protection without jeopardizing the country's economic progress.

Reducing pollution to meet national air quality standards always has been a shared task, one involving the Federal government, States, Tribes and local air quality agencies. EPA develops regulations and strategies to reduce pollution on a broad scale, while States and Tribes are responsible for implementation planning and any additional emission reduction measures necessary to bring areas into attainment. The Agency supports implementation planning with technical resources, while States and local agencies bring their knowledge of local needs and opportunities to bear on designing emission-reduction strategies that will work best for their industries and communities.

This partnership has proved effective since EPA first issued O_3 standards more than three decades ago. For example, 101 areas were designated as nonattainment for the 1-hour O_3 standards

issued in 1979. Today, air quality in 94 of those areas meets the 1-hour standards. EPA strengthened the O_3 standards in 1997, shifting to an 8-hour standard to improve protection to the public, especially children, against effects such as reduced lung function and respiratory symptoms, hospital and emergency room visits for asthma, and possible irreversible damage to the lungs. The 1997 standards drew significant public attention when they were proposed, with numerous people voicing concerns about States' ability to comply. But as we did with the 1-hour standard, we worked closely with States, Tribes and local areas to reduce O_3-forming pollutants, and our nation has made tremendous progress toward clean air as a result. Air quality in nearly 80% of the 113 areas designated as nonattainment now meets the 1997 standards. And 10 of the areas that have not yet met the standard still have some time to do so, with attainment dates ranging from 2013 to 2024. We have seen similar, consistent progress in reducing the other pollutants for which EPA has set national ambient air quality standards.

As we look to the future, EPA believes we can make this kind of progress again – progress that will help prevent damage to children's developing lungs, cut the frequency and severity of asthma attacks, and reduce medication use, doctors' visits and trips to the hospital, and the risk of premature death now understood to be associated with O_3 exposure.

The EPA is prepared to shoulder its share of the workload needed to bring about these important public health benefits, through federal rules, planning assistance for State, Tribal and local air agencies, and by providing flexibility where appropriate and allowed by law. Indeed, the Agency already has rules in place or proposed that will make important reductions in O_3-forming nitrogen oxides (NOx) and volatile organic compounds (VOCs) in the coming years. Many of these, including a number of mobile source requirements and the proposed Transport Rule, are specifically designed to reduce pollutants that form O_3. Others, such as air toxics standards for stationary reciprocating internal combustion engines, Portland cement manufacturing and petroleum refineries, will yield NOx reductions as a co-benefit of

reducing hazardous air pollutant emissions. And standards for industries such gasoline distribution will reduce O_3-forming VOCs.

For example, four existing mobile source rules – the light-duty Tier 2 rule for new cars, trucks SUVs and vans, the heavy duty truck and bus rule, the nonroad diesel Tier 4 rule, and the locomotive and marine diesels rule – will reduce NOx emissions across the country by more than 6.9 million tons when they are fully phased in in 2030. VOC emissions would drop by more than half a million tons from these regulations over the same period. We expect even more NOx reductions from mobile source rules to be completed over the next several years, including light duty vehicle greenhouse gas (GHG) emissions standards for 2017 and beyond, and GHG emissions standards for heavy duty vehicles.

The EPA's proposed Transport Rule is expected to ensure reductions in O_3-forming NOx emissions in the eastern U.S. by requiring power plant emission controls in 31 States and the District of Columbia. NOx reductions would begin by 2012 -- within just one year after the rule is final – dropping 52 percent over 2005 levels by 2014. In addition, EPA intends to issue a second transport rule designed to achieve further NOx reductions specifically targeted to provide States additional assistance in meeting the revised ozone standards. We expect to propose that rule in the summer of 2011.

A number of EPA's rules for reducing air toxics also will result in both VOC and NOx reductions. EPA's proposed regulations for commercial, industrial and solid waste incinerators would set standards for NOx and several air toxics for all commercial incinerators, as required under Section 129 of the Act. Proposed air toxics rules for industrial boilers would yield co-benefit NOx reductions as a result of tune-ups and energy efficiency measures, especially from boilers that burn coal. We intend to issue these rules in late 2010. Affected facilities would need to comply within three years, well within the implementation planning window for ozone nonattainment areas. And several new source performance standards and air toxics standards now in the development phase are expected to make

further cuts to NOx and VOC emissions from new and existing sources of pollution. These include upcoming proposals for gas turbines and municipal waste combustors, along with rules for the petroleum refining industry.

While EPA uses its regulatory opportunities to reduce NOx and VOCs, the Agency also is aggressively pursuing non-regulatory efforts as we strive toward cleaner air. Energy Star, a joint program of EPA and the U.S. Department of Energy, protects the environment and saves money through energy efficient products and practices. Improving energy efficiency in homes, buildings and industry helps reduce all emissions from the power sector – including NOx – while reducing compliance costs for electricity providers.

The EPA recognizes that a number of areas of the country have been working to reduce O_3 precursors for many years and now may need to turn to newer, more innovative approaches for reducing emissions as they develop their implementation plans. These approaches, such as smart growth policies and renewable energy portfolios, hold great promise for improved air quality and health, and EPA is working with air quality agencies and stakeholders to identify ways to include these types of programs in implementation plans. This step will allow States and Tribes to pursue effective strategies that address some of the more challenging issues affecting air quality, such as land use planning, ever-increasing motor vehicle use, and planning for long-term energy needs.

The Agency also is active in work to reduce the international transport of O_3 and other pollutants, which can contribute to "background" O_3 levels in the U.S. Much of this work is being conducted under the Convention on Long-range Transboundary Air Pollution (LRTAP) of the United Nations Economic Commission for Europe. One example of the LRTAP work is the Protocol to Abate Acidification, Eutrophication, and Ground-level Ozone (known as Gothenburg Protocol), is expected to make significant cuts to NOx and VOC emissions once all of the participating countries have achieved

their emission reduction goals. Parties to the protocol are negotiating further NOx and VOC emission reduction measures, which are expected to be fully implemented by 2020. EPA also continues to work with rapidly growing countries such as China to address emissions of O_3-forming pollutants. This work includes supporting China's efforts to rapidly deploy power plant pollution controls that can achieve NOx reductions of at least 80 to 90%.

Reducing pollution, while the ultimate requirement of our national air quality standards, is not the only challenge States, Tribes and local agencies face as they work to bring areas into attainment. We know that developing the implementation plans that outline the steps a nonattainment area will take to meet an air quality standard requires a significant amount of work on the part of State, Tribal or local air agencies. EPA is looking at options for easing this workload, including assisting with air quality modeling by providing inputs such as emissions, meteorological and boundary conditions; and providing national-scale model results that States could incorporate into their attainment demonstrations. At the same time, we are looking for opportunities to provide implementation flexibility to the extent allowed by law. These include options for a nonattainment area classification system, and minimizing planning requirements in areas where most of the O_3 problem is caused by transport. Both of these options are outlined in the proposed implementation rule that the Agency also issued today. In addition, EPA will work with States that are required to implement vehicle inspection and maintenance programs to help them do so in the most effective and least burdensome way possible. We discuss these options in more detail in the preamble to the proposed O_3 implementation rule.

D. Review of Air Quality Criteria and Standards for O_3

The last review of the O_3 NAAQS was initiated in September 2000 with a call for information (65 FR 57810; September 26, 2000) for the development of a revised Air Quality Criteria Document for O_3 and Other Photochemical Oxidants (henceforth the "2006 Criteria Document"). A project work plan

(EPA, 2002) for the preparation of the 2006 Criteria Document was released in November 2002 for CASAC and public review. EPA held a series of workshops in mid-2003 on several draft chapters of the Criteria Document to obtain broad input from the relevant scientific communities. These workshops helped to inform the preparation of the first draft Criteria Document (EPA, 2005a), which was released for CASAC and public review on January 31, 2005; a CASAC meeting was held on May 4-5, 2005 to review the first draft Criteria Document. A second draft Criteria Document (EPA, 2005b) was released for CASAC and public review on August 31, 2005, and was discussed along with a first draft Staff Paper (EPA, 2005c) at a CASAC meeting held on December 6-8, 2005. In a February 16, 2006 letter to the Administrator, CASAC provided comments on the second draft Criteria Document (Henderson, 2006a), and the final 2006 Criteria Document (EPA, 2006a) was released on March 21, 2006. In a June 8, 2006 letter to the Administrator (Henderson, 2006b), CASAC provided additional advice to the Agency concerning chapter 8 of the final 2006 Criteria Document (Integrative Synthesis) to help inform the second draft Staff Paper.

A second draft Staff Paper (EPA, 2006b) was released on July 17, 2006 and reviewed by CASAC on August 24-25, 2006. In an October 24, 2006 letter to the Administrator, CASAC provided advice and recommendations to the Agency concerning the second draft Staff Paper (Henderson, 2006c). The final 2007 Staff Paper (EPA, 2007a) was released on January 31, 2007. In a March 26, 2007 letter (Henderson, 2007), CASAC offered additional advice to the Administrator with regard to recommendations and revisions to the primary and secondary O_3 NAAQS.

The schedule for completion of the 2008 rulemaking was governed by a consent decree resolving a lawsuit filed in March 2003 by a group of plaintiffs representing national environmental and public health organizations, alleging that EPA had failed to complete the review within the period provided by

statute.[5] The modified consent decree that governed the 2008 rulemaking, entered by the court on December 16, 2004, provided that EPA sign a proposal and final rule concerning its review of the O_3 NAAQS no later than March 28, 2007 and December 19, 2007, respectively. That consent decree was further modified in October 2006 to change these proposed and final rulemaking dates to no later than May 30, 2007 and February 20, 2008, respectively. These dates for signing the proposal and final rule were further extended to no later than June 20, 2007 and March 12, 2008, respectively. The proposed decision was signed on June 20, 2007 and published in the Federal Register on July 11, 2007 (72 FR 37818).

Five public hearings on the 2007 proposed decision were held across the U.S. A large number of comments were received from various commenters on the 2007 proposed revisions to the O_3 NAAQS. A comprehensive summary of all significant comments, along with EPA's responses, can be found in the docket for the 2008 rulemaking, which is also the docket for this reconsideration rulemaking.

The EPA's 2008 final decision on the O_3 NAAAQS was published in the Federal Register on March 27, 2008 (73 FR 16436). In the 2008 rulemaking, EPA revised the level of the 8-hour primary standard for O_3 to 0.075 parts per million (ppm), expressed to three decimal places. With regard to the secondary standard for O_3, EPA revised the 8-hour standard by making it identical to the revised primary standard. EPA also made conforming changes to the Air Quality Index (AQI) for O_3, setting an AQI value of 100 equal to 0.075 ppm, 8-hour average, and making proportional changes to the AQI values of 50, 150 and 200.

E. Reconsideration of the 2008 O_3 NAAQS Final Rule

Consistent with a directive of the new Administration regarding the review of new and pending regulations (Emanuel memorandum, 74 FR 4435; January 26, 2009), the Administrator reviewed a

[5] *American Lung Association v. Whitman* (No. 1:03CV00778, D.D.C. 2003).

number of actions that were taken in the last year by the previous Administration. The 2008 final rule was included in this review in recognition of the central role that the NAAQS play in enabling EPA to fulfill its mission to protect the nation's public health and welfare. In her review, the Administrator was mindful of the need for judgments concerning the NAAQS to be based on a strong scientific foundation which is developed through a transparent and credible NAAQS review process, consistent with the core values highlighted in President Obama's memorandum on scientific integrity (March 9, 2009).

1. Decision to Initiate a Rulemaking to Reconsider

In her review of the 2008 final rule, several aspects of the final rule related to the primary and secondary standards stood out to the Administrator. As an initial matter, the Administrator noted that the 2008 final rule concluded that the 1997 primary and secondary O_3 standards were not adequate to protect public health and public welfare, and that revisions were necessary to provide increased protection. With respect to revision of the primary standard, the Administrator noted that the revised level established in the 2008 final rule was above the range that had been unanimously recommended by CASAC.[6] She also noted that EPA received comments from a large number of commenters from the medical and public health communities, including EPA's Children's Health Protection Advisory Committee, all of which endorsed levels within CASAC's recommended range.

With respect to revision of the secondary O_3 standard, the Administrator noted that the 2008 final rule differed substantially from CASAC's recommendations that EPA adopt a new secondary O_3 standard based on a cumulative, seasonal measure of exposure. The 2008 final rule revised the secondary standard to be identical to the revised primary standard, which is based on an 8-hour daily maximum measure of exposure. She also noted that EPA received comments from a number of

[6]The level of the 8-hour primary ozone standard was set at 0.075 ppm, while CASAC unanimously recommended a range between 0.060 and 0.070 ppm.

commenters representing environmental interests, all of which endorsed CASAC's recommendation for a new cumulative, seasonal secondary standard.[7]

Subsequent to issuance of the 2008 final rule, in April 2008, CASAC took the unusual step of sending EPA a letter expressing strong, unanimous disagreement with EPA's decisions on both the primary and secondary standards (Henderson, 2008). The CASAC explained that it did not endorse the revised primary O_3 standard as being sufficiently protective of public health because it failed to satisfy the explicit stipulation of the CAA to provide an adequate margin of safety. The CASAC also expressed the view that failing to revise the secondary standard to a cumulative, seasonal form was not supported by the available science. In addition to CASAC's letter, the Administrator noted a recent adverse ruling issued by the U.S. Court of Appeals for the District of Columbia Circuit on another NAAQS decision. In February 2009, the DC Circuit remanded the Agency's decisions on the primary annual and secondary standards for fine particles ($PM_{2.5}$). In so doing, the Court found that EPA had not adequately explained the basis for its decisions, including why CASAC's recommendations for a more health-protective primary annual standard and for secondary standards different from the primary standards were not accepted. *American Farm Bureau v. EPA*, 559 F.3d. 512 (D.C. Cir. 2009).

Based on her review of the information described above, the Administrator had serious cause for concern regarding whether the revisions to the primary and secondary O_3 standards adopted in the 2008 final rule satisfy the requirements of the CAA, in light of the body of scientific evidence before the Agency. In addition, the importance of the O_3 NAAQS to public health and welfare weighed heavily in favor of reconsidering parts of the 2008 final rule as soon as possible, based on the scientific and technical information upon which the 2008 final rule was based. Therefore, the Administrator initiated a

[7]The Administrator also noted the exchange that had occurred between EPA and the Office of Management and Budget (OMB) with regard to the final decision on the secondary standard, as discussed in the 2008 final rule (73 FR 16497).

rulemaking to reconsider parts of the 2008 final rule. Specifically, the Administrator reconsidered the level of the primary standard to ensure that it is sufficiently protective of public health, as discussed in section II below, and reconsidered all aspects of the secondary standard to ensure that it appropriately reflects the available science and is sufficiently protective of public welfare, as discussed in section IV below.

Also, EPA conducted a provisional assessment of "new"[8] scientific papers (EPA, 2009) evaluating health and ecological effects of O_3 exposure published since the close of the 2006 Criteria Document upon which the 2008 O_3 NAAQS were based. The Administrator noted that the 2009 Provisional Assessment of "new" science found that such studies did not materially change the conclusions in the Criteria Document. This Provisional Assessment supported the Administrator's decision to reconsider parts of the 2008 final rule, based on the scientific and technical information available for the 2008 final rule, as compared to foregoing such reconsideration and taking appropriate action in the future as part of the next periodic review of the air quality criteria and NAAQS, which will include such scientific and technical information.

As a result of the reconsideration, the Administrator determined that different primary and secondary NAAQS for O_3 were necessary to provide requisite protection of public health and welfare, respectively. The proposed decision was signed on January 6, 2010 and published in the Federal Register on January 19, 2010 (75 FR 2938).

Public hearings on the 2010 proposed decision were held on Tuesday, February 2, 2010 in Arlington, VA and Houston, TX. On Thursday, February 4, 2010, a hearing was held in Sacramento,

[8] For ease of reference, these studies will be referred to as "new" studies, using quotation marks around the word *new*. Referring to studies that were published too recently to have been included in the 2006 Criteria Document as "new" studies is intended to clearly differentiate such studies from those that have been published since the 1997 review and were included in the 2006 Criteria Document, and thus were newly available for the 2008 review.

CA. A large number of comments were received from various commenters on the 2010 proposed revisions to the O_3 NAAQS. A comprehensive summary of all significant comments, along with EPA's 2011 Response to Comments document, can be found in the docket for the 2008 rulemaking, which is also the docket for this reconsideration rulemaking.

The reconsideration of parts of the 2008 final rule discussed in the 2010 proposal and this final rule are based on the scientific and technical record from the 2008 rulemaking, including public comments and CASAC advice and recommendations. The information that was assessed during the 2008 rulemaking includes information in the 2006 Criteria Document (EPA, 2006a), the 2007 Policy Assessment of Scientific and Technical Information, referred to as the 2007 Staff Paper (EPA, 2007a), and related technical support documents (U.S. EPA, 2007c; Abt Associates, 2007a,b). Scientific and technical information developed since the 2006 Criteria Document will be considered in the next periodic review, instead of this reconsideration rulemaking, allowing the "new" information to receive careful and comprehensive review by CASAC and the public before it is used as a basis in a rulemaking that determines whether to revise the NAAQS.

2. Comments on the Reconsideration

Several commenters argued that EPA's reconsideration of the 2008 final rule was unlawful. These commenters argued that Sections 108 and 109 set forth the specific and exclusive process that EPA must follow in revising a NAAQS. They argued that EPA's 2010 proposed rule was unlawful because it did not follow this process. The commenters noted that the CAA requires EPA to issue air quality criteria documents every five years and then promulgate new standards as appropriate. They argued that the CAA requires preparation of a Criteria Document as a first step. This document must be reviewed by CASAC, which in turn provides recommendations to the Administrator. Commenters argued EPA could not revise a NAAQS until all these steps are followed and that EPA disregarded these

steps prior to issuing the 2010 proposed rule. They argued EPA could only revise a NAAQS pursuant to this 5-year schedule, recognizing that EPA could expedite this review process if desired. Since EPA did not go through the required process to review and update the air quality criteria, EPA could not propose to revise the NAAQS. They also argued EPA's only authority to reconsider past actions is found in section 307(d), which does not apply in this case.

The EPA's authority to reconsider the 2008 final rule is based on its authority under section 109, and the reconsideration action fully complies with the CAA requirements. Section 108(a)(2) requires EPA to prepare air quality criteria that "accurately reflect[s] the latest scientific knowledge" regarding a pollutant's effects on public health and welfare. Section 109(d) requires CASAC to provide EPA with its advice and recommendations on appropriate revisions to the air quality criteria for the Administrator's consideration. EPA must revise the air quality criteria at least every five years and must revise the corresponding NAAQS as appropriate. Revisions to the NAAQS are based on the air quality criteria.

The EPA's reconsideration complies with all CAA requirements. The reconsideration is based on the current air quality criteria. As required under section 108, the then-latest scientific knowledge on the health and welfare effects of O_3 was reflected in the 2006 Criteria Document. As noted in Section I.D above, drafts of the Criteria Document were reviewed by CASAC and CASAC provided comments on the first and second draft Criteria Documents to EPA in February and June 2006, respectively. The first and second drafts of the Criteria Document were also made available for public review and comment. CASAC also provided advice and recommendations to EPA regarding revisions to the primary and secondary standard in October 2006 and March 2007.

It is important to recognize that EPA's reconsideration is not a new periodic review of the O_3 NAAQS pursuant to the five-year-interval review required by CAA § 109(d).[9] The reconsideration is a review of the 2008 final rule to ensure that the O_3 primary and secondary standards meet the legal requirements of CAA §109(b)(1) and (2). The Administrator is basing this reconsideration on the same air quality criteria as Administrator Johnson considered when issuing the 2008 final rule. The reconsideration is a revisiting of this prior decision, and it complies with the requirements of section 109 as well as the various procedural requirements in section 307.

The EPA disagrees with comments that argued that the Agency lacks the authority to reconsider the 2008 final rule, and that section 109(d) precludes any revisions other than those conducted during a periodic review that includes a review and issuance of updated air quality criteria as well as a review of the NAAQS. It is well established that agencies may, on their own initiative, reconsider prior decisions whether or not a statute expressly provides for such review. Mazaleski v. Treusdell, 562 F. 2d 701, 720 (D.C. Cir. 1977). This authority is critical if an agency is to effectuate a fundamental tenant of administrative law that, "[a]n initial agency interpretation is not carved instantly in stone. On the contrary, the agency . . . must consider varying interpretations and the wisdom of its policy on a continuing basis . . . ." National Cable & Tel. v. Brand X Internet, 545 U.S. 967, 981 (2005). As noted in section I.E.1 above, after reviewing the entire record, including the scientific evidence, the advice and recommendations from CASAC, and subsequent D.C. Circuit case law, the Administrator had cause for concern whether the revisions to the primary and secondary O_3 standards adopted in the 2008 final rule satisfied the requirements of the CAA. The Administrator's reconsideration of the 2008 final rule, to

[9] In 2008, EPA initiated a separate process to review and revise the NAAQS pursuant to the five-year-interval requirement of CAA § 109(d). More information on that process can be found at http://www.epa.gov/ttn/naaqs/review.html.

ensure the standards meet the requirements of the CAA, falls squarely within the Agency's inherent authority to review past actions.

The EPA disagrees with the suggestion that because sections 108 and 109 set forth a mandatory minimum time period for EPA to review and revise both the air quality criteria and the NAAQS, EPA is precluded from revisiting a prior NAAQS decision. Commenters cited to two cases, American Methyl Corp. v. EPA, 749 F.2d 826 (D.C. Cir. 1984) and New Jersey v. EPA, 517 F.3d 574 (D.C. Cir. 2008), to argue that Congress has already provided a method for revising a NAAQS, namely the process set forth in 108 and 109, thereby stripping EPA of any inherent authority to reconsider the 2008 final rule. The New Jersey case involved a challenge to an EPA rule removing coal- and oil-fired EGUs from the list of HAP sources prepared pursuant to section 112(c)(1) of the CAA. EPA had previously listed coal- and oil-fired EGUs under this provision after finding such action was "appropriate and necessary." EPA's rule to delete coal- and oil-fired EGUs (the "delisting rule") was based on a conclusion that the Agency's prior "appropriate and necessary" determination was, in essence, in error and therefore the listing was an error. EPA's "delisting rule" did not follow the requirements in section 112(c)(9), which specifically set forth the process and the substantive findings required to delist or delete a source from the HAPs list. The D. C. Circuit vacated the "delisting rule" because EPA did not follow the specific requirements in 112(c)(9) for deleting a source from the HAPs source list. The court disagreed with EPA's assertion that it had inherent authority to reverse its earlier determination via the "delisting rule." The court found instead that Congress had unambiguously limited EPA's authority to delete sources by setting forth specific delisting requirements in 112(c)(9) that applied to "any" delisting. The court found that Congress had provided EPA with a specific mechanism "capable of rectifying mistaken actions" and EPA could not circumvent it. New Jersey, 517 F.3d at 583.

In the American Methyl case, EPA granted a company a waiver under section 211(f) of the CAA to market a fuel called Petrocoal. After granting the waiver, EPA received information indicating Petrocoal caused cars to exceed limits on evaporative emissions of hydrocarbons. EPA proposed to revoke the waiver previously granted to Petrocoal primarily on this new information. The court ruled that under the facts presented, EPA did not have the inherent authority to reconsider and revoke the waiver under section 211(f). Instead, Congress had specified in a different provision, section 211(c) of the CAA, the Agency's authority to regulate fuels that were already in commerce. The court held a contrary interpretation would allow EPA to circumvent the limitations Congress provided in section 211(c) on EPA's authority to regulate fuels already in commerce. The court noted the reconsideration was not based on the record as it existed at the time of the initial waiver decision. Instead, EPA's concern was based on new information that had been developed since the granting of the waiver. The court found that Congress had addressed this scenario in section 211(c) by giving EPA the authority to regulate fuel already in commerce.

The reconsideration of the 2008 O_3 NAAQS is consistent with these cases as well as with sections 108 and 109. In both cases, the court found that Congress had explicitly provided for the exact action EPA sought to take in its reconsideration. In New Jersey, EPA asserted it had inherent authority to reconsider its initial listing decision and remove coal- and oil-fired EGUs from the HAPs list. The result of EPA's reconsideration was a delisting action. However, the court found Congress had already provided a procedure for delisting sources in section 112(c)(9). As noted, the court held the section 112(c)(9) process unambiguously applied to "any" delisting. Similarly, in the American Methyl decision, EPA sought in its reconsideration to prohibit the sale in commerce of a fuel based on new information. The court found Congress had already provided EPA with such a mechanism in section

211(c). Thus, in both cases, the statute explicitly set forth a process to achieve directly what EPA had attempted to circumvent and do indirectly via reconsideration.

That is not the case with the NAAQS. There is no mechanism specified in section 109 that addresses the revisiting of a previously issued NAAQS decision, based on the existing scientific and technical record, to ensure it meets the requirements of the CAA. The process set forth in sections 108 and 109 requires EPA to regularly review scientific information regarding a pollutant and to revise the NAAQS as appropriate. This process ensures that the primary and secondary standards are updated, and continue to meet the statutory requirements, in light of advances in the science since the last review. This process addresses when to update the NAAQS to take into account future or changed circumstances that may make the past decision no longer appropriate. The periodic review and revision required by sections 108 and 109 does not speak to EPA's authority to reconsider decisions made in a periodic review and revision process for the purpose of ensuring compliance with the CAA's requirements; nor does it provide a mechanism reasonably capable of reaching different decisions, as appropriate, based on the same air quality criteria as the prior NAAQS decision. The periodic review process to address advances in the science and reconsideration based on existing science are fundamentally different actions.

Specifying a periodic review process that requires EPA to review and consider advances in the science over time does not infer a prohibition on EPA reconsidering a past decision to ensure the appropriate NAAQS has been set, where subsequent advances in the science are not at issue. The periodic review process in section 109 does not address a reconsideration that is based on the same air quality criteria as the prior NAAQS decision. The inherent authority to reconsider and set different standards than those set in 2008 to comply with the CAA's requirements, based on the same air quality criteria, is not specifically addressed by section 109(d) and is not precluded by it.

Another important aspect of New Jersey and American Methyl is absent here. In both cases, EPA's reconsideration applied a different decision making standard than what Congress specified. In New Jersey, EPA reconsidered whether its initial "appropriate and necessary" finding was correct. Based on the conclusion that it was not, EPA delisted coal- and oil-fired EGUs. Under section 112(c)(9), however, EPA can only delist a source category for the kind of HAPs at issue in New Jersey if it found that "emissions from no source in the category . . . exceed a level which is adequate to protect public health with an ample margin of safety and no adverse environmental effect will result from emissions from any source." Section 112(c)(9)(B)(ii). The court concluded that EPA's reconsideration effectively nullified the standard Congress had established. Similarly, in American Methyl, the result of EPA's reconsideration would have been the removal of Petrocoal from the market. EPA had proposed to apply the waiver standard in section 211(f), with the burden of proof on the fuel manufacturer. In contrast, section 211(c) places the burden on EPA to make a different set of findings before taking action to regulate or prohibit the sale of a fuel in commerce. As in the New Jersey decision, the American Methyl court found EPA's reconsideration would effectively nullify a standard established by Congress, the section 211(c) criteria. In contrast, EPA's reconsideration of the 2008 O_3 NAAQS does not supplant or nullify the standard established by Congress. EPA reconsidered the O_3 NAAQS to ensure that the primary and secondary standards meet the substantive criteria established by Congress in section 109(b). Rather than nullify or circumvent the standard specified in section 109(b), EPA is utilizing the reconsideration process to make certain that Congress' directive in section 109(b) is met.

The EPA also disagrees with commenters who suggested EPA's only authority to reconsider past actions is found in section 307(d). That section provides the public with an opportunity to present to EPA an objection to an action that could have not have been raised during the public comment period. The Administrator must reconsider the action if the objection is of central relevance to the outcome of

the action. Section 307(d) provides a vehicle by which the public may require reconsideration of an action, based on new information. Providing this avenue for the public is not a limitation on the Agency's recognized inherent authority to reconsider past actions on its own initiative. Such an interpretation would frustrate the purpose of the CAA. Section 307(d) compels reconsideration when a person presents information or an objection of "central relevance" that could not have been raised during the comment period. It would be an anomalous result if any person could compel reconsideration by presenting appropriate information but the Administrator could not reconsider an action on her own initiative, even if it was based on that same information. Section 307(d) provides the public an additional procedural right; it does not speak to or remove the Agency's inherent reconsideration authority. Thus, the reconsideration process outlined in section 307(d) does not limit the Agency's authority on its own initiative to reconsider the 2008 O_3 NAAQS. The public health and welfare protection goals of the CAA would be seriously undermined if EPA does not have the ability to independently reconsider a past decision and put in place an appropriate standard.

Several commenters also argued the reconsideration is unlawful because it is not based on the most current science since the 2006 Criteria Document is now four years old. They argued the 2009 Provisional Assessment does not cure this flaw. As noted, this reconsideration is based on the air quality criteria developed for the 2008 review. The commenter misinterprets the legal requirements applicable under section 108 and 109 to a review of the NAAQS. Under section 108, the air quality criteria is required to reflect the then-latest scientific information. The air quality criteria developed for the 2008 review fully satisfied the requirements of section 108. The NAAQS decision is required to be based on the air quality criteria, under section 109(b), and under section 307 EPA is required to employ notice and comment rulemaking. As such, the statute envisions that the final decision in the NAAQS rulemaking will always follow the issuance of the air quality criteria by some amount of time. Hence

there is always a gap of some time period between the issuance of the air quality criteria and the final NAAQS decision. EPA is required to base the NAAQS decision on the air quality criteria, however, which is not the same as a requirement to base the NAAQS decision on whatever is the latest scientific information as of the date of issuance of the NAAQS, even if that is not reflected in the air quality criteria. If that were the case, EPA would have to base the NAAQS on the air quality criteria and on whatever changes in the science had occurred between issuance of the air quality criteria and issuance of the NAAQS. EPA has consistently rejected such an interpretation of section 109. See, e.g., EPA's discussion in the 2008 final rule of "new studies" published since the issuance of the 2006 Criteria Document. 73 FR 16436, 16438 (March 27, 2008).

Thus, the issue before EPA is not whether the 2006 Criteria Document reflects the current scientific studies that have been published since it was issued, as by definition it will not. In light of EPA's interpretation of section 109, the issue before EPA is whether or not to proceed with this reconsideration, based on the same science as the 2008 final rule. To inform this decision, EPA conducted a provisional assessment of studies that were completed after the 2006 Criteria Document. The 2009 Provisional Assessment concluded that these "new" studies did not materially change the conclusions reached in the Criteria Document. Based on that, EPA has determined to proceed with this reconsideration rulemaking, based on the current air quality criteria. EPA will address the "new" scientific studies and other scientific evidence in the next periodic review of the air quality criteria and the NAAQS. This exercise of discretion under section 109 on the timing of this rulemaking is both reasonable and lawful.

It is important to note that this means EPA is not relying on these "new" studies in this reconsideration of the NAAQS. They were considered only for the limited purpose of deciding whether or not to proceed with the reconsideration at this time, based on the current air quality criteria. It

appears many commenters viewed the 2009 Provisional Assessment as an attempted replacement for a criteria document. As discussed above, that is not the purpose of the Provisional Assessment. EPA's preparation of a provisional assessment is not uncommon in the NAAQS revision process. In other reviews, EPA has prepared assessments of "new" studies that were submitted during the public comment period but were not available at the time the criteria documents were finalized. As is the case with the 2009 Provisional Assessment prepared for the O_3 reconsideration, the purpose of those assessments was to inform EPA's decision on whether to proceed with the NAAQS rulemaking at that time, and base the NAAQS decision on the then current air quality criteria, or to delay the rulemaking until after EPA had completed a review and issued a new, updated air quality criteria. EPA does not use provisional assessments as a replacement for a criteria document. *See*, 73 FR at 16438-9.

Several commenters argued that EPA's reconsideration did not follow the review and revision process the Administrator announced in 2009. *See*, "Process for Reviewing National Ambient Air Quality Standards" (May 21, 2009). These commenters assume that this reconsideration is a new periodic review of the O_3 NAAQS. That is not the case. The reconsideration is a review of the 2008 final rule, to ensure that the primary and secondary standards meet the requirements of the CAA in light of the body of evidence available in the 2008 periodic review. Since the reconsideration is not a new periodic review, the procedures outlined in the May 2009 memorandum do not apply. EPA will be following the procedures in the May 2009 memorandum for the next periodic review of the O_3 NAAQS, which was initiated in 2008.

3. Ongoing Litigation

In May 2008, following publication of the 2008 final rule, numerous groups, including state, public health, environmental, and industry petitioners, challenged EPA's decisions in federal court. The challenges were consolidated as *State of Mississippi, et al. v. EPA* (No. 08-1200, D.C. Cir. 2008). On

March 10, 2009, EPA filed an unopposed motion requesting that the Court vacate the briefing schedule and hold the consolidated cases in abeyance. The Agency stated its desire to allow time for appropriate officials from the new Administration to review the O_3 standards to determine whether they should be maintained, modified or otherwise reconsidered. EPA further requested that it be directed to notify the Court and all the parties of any actions it has taken or intends to take, if any, within 180 days of the Court vacating the briefing schedule. On March 19, 2009, the Court granted EPA's motion. Pursuant to the Court's order, on September 16, 2009 EPA notified the Court and the parties of its decision to initiate a rulemaking to reconsider the primary and secondary O_3 standards set in March 2008 to ensure they satisfy the requirements of the CAA In its notice to the Court, EPA stated that a proposal would be signed by December 21, 2009, and that this final rule would be signed by August 31, 2010.[10] On August 20, 2010, EPA filed a status report with the court indicating that the review of public comments and other steps necessary to reach a final decision would take approximately two months longer than initially expected. EPA thus noted that it intended to sign a final rule on the reconsideration of the 2008 final rule on or about the end of October 2010. On November 1, 2010, EPA filed a motion stating that completing the rulemaking had taken longer than anticipated and thus, EPA was committed to signing a final rule on the reconsideration of the 2008 O_3 standards by December 31, 2010. As discussed in section I.E.4 below, in a revised Motion filed in December 2010, EPA stated that in the process of evaluating this information and determining how to exercise her judgment concerning the appropriate revisions to the O_3 standard, the EPA Administrator had recently determined that additional advice from the CASAC Panel may prove useful and important in evaluating the scientific and other information before her. In the revised Motion EPA outlined the process for receiving and considering such

[10]The proposal was signed on January 6, 2010.

additional advice, and stated EPA's expectation that this process would require just over an additional seven months, until July 29, 2011.

4. Additional CASAC Advice

In January, 2011 EPA asked the CASAC Ozone Reconsideration Panel that reviewed the evidence, risk and exposure assessments, and staff paper for the 2008 standards to provide further advice about the strengths and limitations of the scientific evidence and the results of the exposure and health risk assessments. EPA was in the process of reaching final decisions on the reconsideration of the 2008 O_3 NAAQS, which requires the deliberative evaluation of the extensive body of scientific and technical information available in the 2008 review and the many comments received on the proposed reconsideration. In the process of evaluating this information and determining how to exercise her judgment concerning the appropriate O_3 NAAQS to set, the EPA Administrator determined that additional advice from CASAC would be useful and important in evaluating the scientific and technical information from the 2008 review upon which the reconsideration of the primary (health-based) standard is based. To ensure that a final decision on the reconsideration of the 2008 O_3 primary standard is based on the most appropriate interpretation of the scientific evidence and exposure/risk information that was available in the 2008 review, the Administrator asked the CASAC Ozone Reconsideration Panel to provide further advice about the strengths and limitations of the scientific evidence and the results of the exposure and health risk assessments to aid in her interpretation of this information. It was expected that CASAC's advice would help the Administrator in most appropriately weighing the strengths and limitations of the scientific evidence and other information before her, and thus aid her in the exercise of judgment as to the appropriate primary standard for O_3. The Panel was requested to consider only the information available in the record for the 2008 O_3 NAAQS review. The EPA's Office of Air Quality Planning and Standards (OAQPS) prepared charge questions (Wegman, 2011) to

solicit this advice from the CASAC Ozone Reconsideration Panel. The Panel met on February 18, March 3, and March 23, 2011, and provided its response to these charge questions in a letter to the Administrator dated March 30, 2011 (Samet, 2011).[11]

F. Summary of Proposed Reconsideration of the O_3 NAAQS

With regard to the primary O_3 standard, the Administrator proposed to set the level of the 8-hour O_3 standard at a level within the range of 0.060 ppm to 0.070 ppm.[12] The range for the primary standard level was proposed to provide increased protection for children and other "at risk" populations against an array of O_3-related adverse health effects that range from decreased lung function and increased respiratory symptoms to serious indicators of respiratory morbidity, including emergency department visits and hospital admissions for respiratory causes, and possibly cardiovascular-related morbidity, as well as total nonaccidental and cardiorespiratory mortality. EPA solicited comment on the proposed range and on the appropriate weight to place on the various types of available evidence, the exposure and risk assessment results, and the uncertainties and limitations related to this information, as well as on the benefits to public health associated with a standard set within this range relative to the benefits associated with the standard set in 2008.

With regard to the secondary standard for O_3, EPA proposed to revise the current 8-hour standard to provide increased protection against O_3-related adverse impacts on vegetation and forested ecosystems by replacing the 2008 standard with a cumulative, seasonal standard expressed as an index of the annual sum of weighted hourly concentrations (i.e., the W126 form), cumulated over 12 hours per

[11] Public comments submitted to the Panel as part of the Panel's consideration of the charge questions were included in the docket and responded to as part of the 2011 Response to Comments document or in the preamble to the final rule.

[12] The indicator (O_3), averaging time (8 hours) and form (the fourth highest 8-hour average concentrations averaged over 3 years) of the standard were not reconsidered and are thus retained.

day (8:00 am to 8:00 pm) during the consecutive 3-month period within the O_3 season with the maximum index value, averaged over 3 years, set at a level within the range of 7 to 15 ppm-hours.

With regard to Appendix P, EPA proposed to revise and adopt data interpretation procedures for the primary and secondary O_3 NAAQS, respectively. In addition; EPA proposed deadlines for optional state demonstrations that O_3 concentrations have been affected by exceptional events and proposed the schedule for initial area designations for the O_3 NAAQS to be set by this final action.

G. Organization and Approach to Final O_3 NAAQS Decisions

This action presents the Administrator's final decisions regarding her reconsideration of the level of the primary O_3 standard set in 2008 and of all aspects of the secondary O_3 standard set in 2008. The final decision on the level of the primary standard for O_3 is presented below in section II, and a discussion of the communication of public health information through a revised AQI for O_3 is presented in section III. The final decision on the secondary O_3 standard is presented below in section IV. Related data completeness and data handling and rounding conventions, including the schedule for flagging data for exceptional events, are addressed in section V. The designation schedule is discussed in section VI. A discussion of the O_3 monitoring rule, including the schedule for final revisions, is provided in section VII, and a discussion of statutory and executive order reviews is provided in section VIII. Also published today in the Federal Register is the related implementation proposal and guidance. The implementation proposal describes EPA's proposed approach to classifying nonattainment areas, SIP submittal deadlines, attainment deadlines, and required SIP elements. It also describes EPA's planned efforts to address some of the specific implementation challenges and to minimize the burden on states of implementing the O_3 standards.

Today's final decisions are based on a thorough review in the 2006 Criteria Document of scientific information on known and potential human health and welfare effects associated with the

presence of O_3 in the ambient air. These final decisions also take into account: (1) staff assessments in the 2007 Staff Paper of the most policy-relevant information in the Criteria Document as well as air quality analyses and quantitative exposure and risk assessments based on that information; (2) CASAC Panel advice and recommendations, as reflected in its letters to the Administrator on its reviews of drafts of the Criteria Document, exposure and risk assessment documents, and Staff Paper at public meetings, its letters on the 2008 final rule and the 2010 proposed rule, and separate written comments prepared by individual members of the CASAC Panel; (3) public comments received during the development of these Agency documents, either in connection with CASAC Panel meetings or separately; (4) the 2007 proposed rule, public comments on that proposal, and the 2008 final rule; and, (5) the 2010 proposed rule and public comments received on that proposal.

II. Rationale for Final Decision on the Primary O_3 Standard

As an initial matter, in the 2010 proposal the Administrator noted that the 2008 final rule concluded that the 1997 primary O_3 standard was "not sufficient and thus not requisite to protect public health with an adequate margin of safety, and that revision is needed to provide increased public health protection" (73 FR 16472). The Administrator did not reconsider this aspect of the 2008 decision, which is based on the reasons discussed in section II.B of the 2008 final rule (73 FR 16443-16472). The Administrator also noted in the 2010 proposal that the 2008 final rule concluded that it was appropriate to retain the O_3 indicator, the 8-hour averaging time, and form of the primary O_3 standard (specified as the annual fourth-highest daily maximum 8-hour concentration, averaged over 3 years), while concluding that revision of the standard level was appropriate.[13] The Administrator did not reconsider

[13]The use of O_3 as the indicator for photochemical oxidants was adopted in the 1979 final rule and retained in subsequent rulemaking. An 8-hour averaging time and a form based on the annual fourth-highest daily maximum 8-hour concentration, averaged over 3 years, were adopted in the 1997

these aspects of the 2008 decision, which are based on the reasons discussed in sections II.C.1-3 of the 2008 final rule, which address the indicator, averaging time, and form, respectively, of the primary O_3 standard (73 FR 16472-16475). For these reasons, the Administrator did not reopen the 2008 decision with regard to the need to revise the 1997 primary O_3 standard nor with regard to the indicator, averaging time, and form of the 2008 primary O_3 standard. Thus, the information that follows in this section specifically focuses on a reconsideration of level of the primary O_3 standard.[14]

This section presents the rationale for the Administrator's final decision that the O_3 primary standard, which was set at a level of 0.075 ppm in the 2008 final rule, should instead be set at 0.070 ppm. In developing this rationale, the Administrator recognizes that the CAA requires her to reach a public health policy judgment as to what standard would be requisite to protect public health with an adequate margin of safety, based on scientific evidence and technical assessments that have inherent uncertainties and limitations. This judgment requires making reasoned decisions as to what weight to place on various types of evidence and assessments, and on the related uncertainties and limitations. Thus, in selecting a final level, the Administrator is seeking not only to prevent O_3 levels that have been demonstrated to be harmful but also to prevent lower O_3 levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

In this final rule, EPA has drawn upon an integrative synthesis of the entire body of evidence, published through early 2006, on human health effects associated with the presence of O_3 in the ambient air. As discussed in section II.A.1 below, this body of evidence addresses a broad range of health

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final rule and retained in the 2008 rulemaking.

[14] EPA recognizes that some commenters argue that EPA should not revise the standard adopted in the 1997 rule, and that the evidence supports a standard of 0.08 ppm as requisite to protect public health with an adequate margin of safety. EPA treated these comments as objections to EPA's proposal that a standard within a range of 0.060 to 0.070 ppm is requisite to protect public health with an adequate margin of safety, and has responded to them as part of responding to comments and explaining its reasons for adopting a standard of 0.070 ppm.

endpoints associated with exposure to ambient levels of O_3 (EPA, 2006a, chapter 8), and includes over one hundred epidemiological studies conducted in the U.S., Canada, and many countries around the world.[15] In reconsidering this evidence, EPA has focused on those health endpoints that have been demonstrated to be caused by exposure to O_3, or for which the 2006 Criteria Document judges associations with O_3 to be causal, likely causal, or for which the evidence is highly suggestive that O_3 contributes to the reported effects. This rationale also draws upon the results of quantitative exposure and risk assessments, discussed in section II.A.2 below. The rationale for the 2008 final rule on the level of the primary standard and CASAC advice, given both prior to the development of the 2007 proposed rule and following the 2008 final rule, are summarized in section II.B below. Section II.C below describes the Administrator's reconsideration of the 2008 decision, including the rationale for the 2010 proposed range for the level of the primary standard (section II.C.1), comments on the 2010 proposed decision (section II.C.2), and the Administrator's final conclusions on the level of the primary standard (section II.C.3). Section II.D summarizes the final decision on the level of the primary O_3 standard.

A. Evidence and Exposure/Risk-Based Considerations

This section summarizes the information presented in sections II.A and B of the 2010 proposal (75 FR 2946-29785) on the known or potential effects on public health that may be expected from the presence of O_3 in ambient air. The approach used in the 2007 Staff Paper as a basis for staff recommendations on standard levels builds upon and broadens the general approach used by EPA in the 1997 review. This approach reflects the more extensive and stronger body of evidence available for the 2008 rulemaking on a broader range of health effects associated with exposure to O_3, including: (1)

[15]In its assessment of the epidemiological evidence judged to be most relevant to making decisions on the level of the O_3 primary standard, EPA has placed greater weight on U.S. and Canadian epidemiologic studies, since studies conducted in other countries may well reflect different demographic and air pollution characteristics.

additional respiratory-related endpoints; (2) new information about the mechanisms underlying respiratory morbidity effects supporting a judgment that the link between O_3 exposure and these effects is causal; (3) newly identified cardiovascular-related health endpoints from animal toxicology and controlled human exposures studies that are highly suggestive that O_3 can directly or indirectly contribute to cardiovascular morbidity, and (4) new U.S. multicity time series studies, single city studies, and several meta-analyses of these studies that provide relatively strong evidence for associations between short-term O_3 exposures and all-cause (nonaccidental) mortality, at levels below the current primary standard: as well as (5) a substantial body of new evidence of increased susceptibility in people with asthma and other lung diseases. In evaluating evidence-based and exposure/risk-based considerations, the Staff Paper considered: (1) the ranges of levels of alternative standards that are supported by the evidence, and the uncertainties and limitations in that evidence and (2) the extent to which specific levels of alternative standards reduce the estimated exposures of concern and risks attributable to O_3 and other photochemical oxidants, and the uncertainties associated with the estimated exposure and risk reductions.

1. Evidence-based Considerations

Evidence-based considerations are summarized below and presented more fully in section II.A of the 2010 proposal (75 FR 2946-2974). In taking into account evidence-based considerations, the 2007 Staff Paper evaluated available evidence from controlled human exposure studies and epidemiological studies, as well as the uncertainties and limitations in that evidence. In particular, it focused on the extent to which controlled human exposure studies provide evidence of lowest-observed-effects levels and the extent to which epidemiological studies provide evidence of associations that extend down to the lower levels of O_3 concentrations observed in the studies or some indication of potential effect thresholds in terms of 8-hour average O_3 concentrations.

The most certain evidence of adverse health effects from exposure to O_3 comes from the controlled human exposure studies, as discussed in the 2010 proposal in section II.A.2, and the large bulk of this evidence derives from studies of exposures at levels of 0.080 ppm and above. At those levels, there is consistent evidence of lung function decrements and respiratory symptoms in healthy young adults, as well as evidence of inflammation and other medically significant airway responses.

There is also limited but important evidence, newly available for consideration in the 2008 rulemaking, from controlled human exposure studies at lower levels. Two studies by Adams (2002, 2006) are the only available controlled human exposure studies that examine respiratory effects associated with prolonged O_3 exposures at levels below 0.080 ppm, which was the lowest exposure level that had been examined in the 1997 review. As discussed in section II.A.2.a.i.(a)(i) of the 2010 proposal, the Adams (2006) study investigated a range of exposure levels, including 0.060 and 0.080 ppm O_3, and analyzed hour-by-hour changes in responses, including lung function (measured in term of decrements in FEV_1) and respiratory symptoms, to investigate the effects of different patterns of exposure. At the 0.060 ppm exposure level, the author reported no statistically significant differences for lung function decrements; statistically significant responses were reported for total subjective respiratory symptoms toward the end of the exposure period for one exposure pattern.

In 2007, EPA conducted a separate analysis of the data from the Adams (2006) study to address a more fundamental question. EPA's analysis (Brown, 2007) addressed the fundamental question of whether there were statistically significant changes in lung function from a 6.6-hour exposure to 0.060 ppm O_3 versus filtered air. EPA's analysis used a standard statistical method appropriate for a simple paired comparison. This analysis found small group mean lung function decrements in healthy adults at the 0.060 ppm exposure level to be statistically significantly different from responses associated with filtered air exposure.

Moreover, 7 to 20% of the subjects in the Adams studies experienced lung function decrements ($\geq$ 10%) at the 0.060 ppm exposure level. Although the evidence from this study is limited, this result is a concern because, for active healthy people, moderate levels of functional responses (e.g., FEV_1 decrements of $\geq$ 10% but < 20%) and/or moderate respiratory symptom responses would likely interfere with normal activity for relatively few responsive individuals. However, for people with lung disease, even moderate functional or symptomatic responses would likely interfere with normal activity for many individuals, and would likely result in more frequent use of medication. In the context of standard setting, the CASAC indicated (Henderson, 2006c) that a focus on the lower end of the range of moderate levels of functional responses (e.g., FEV_1 decrements $\geq$ 10%) is most appropriate for estimating potentially adverse lung function decrements in people with lung disease. Therefore, the results of the Adams studies, which indicate that a percentage of healthy, non-asthmatic subjects are likely to experience FEV_1 decrements $\geq$ 10% when exposed to 0.060 ppm O_3, have implications for setting a standard that protects public health, including the health of sensitive populations such as asthmatics, with an adequate margin of safety.

In considering these most recent controlled human exposure studies, the 2007 Staff Paper concluded that these studies provide evidence of a lowest-observed-effects level of 0.060 ppm for potentially adverse lung function decrements and respiratory symptoms in some healthy adults while at prolonged moderate exertion. It further concluded that since people with asthma, particularly children, have been found to be more sensitive to O_3 and to experience larger decrements in lung function in response to O_3 exposures than would healthy adults, the 0.060 ppm exposure level also can be interpreted as representing a level likely to cause adverse lung function decrements and respiratory symptoms in children with asthma and more generally in people with respiratory disease.

In considering controlled human exposure studies of pulmonary inflammation, airway responsiveness, and impaired host defense capabilities, discussed in the 2010 proposal in section II.A.2.a.i, the 2007 Staff Paper noted that these studies provide evidence of a lowest-observed-effects level for such effects in healthy adults at prolonged moderate exertion of 0.080 ppm, the lowest level tested. Moreover there is no evidence that the 0.080 ppm level is a threshold for these effects. Studies reporting inflammatory responses and markers of lung injury have clearly demonstrated that there is significant variation in response of subjects exposed, even to O_3 exposures at 0.080 ppm. One study showed notable inter-individual variability in young healthy adult subjects in most of the inflammatory and cellular injury indicators analyzed at 0.080 ppm. This inter-individual variability suggests that some portion of the population would likely experience such effects at exposure levels extending well below 0.080 ppm.

These physiological effects have been linked to aggravation of asthma and increased susceptibility to respiratory infection, potentially leading to increased medication use, increased school and work absences, increased visits to doctors' offices and emergency departments, and increased hospital admissions. Further, pulmonary inflammation is related to increased cellular permeability in the lung, which may be a mechanism by which O_3 exposure can lead to cardiovascular system effects, and to potential chronic effects such as chronic bronchitis or long-term damage to the lungs that can lead to reduced quality of life. These are all indicators of adverse O_3-related morbidity effects, which are consistent with and lend plausibility to the adverse morbidity effects and mortality effects observed in epidemiological studies.

Significant associations between ambient O_3 exposures and a wide variety of respiratory symptoms and other morbidity outcomes (e.g., asthma medication use, school absences, emergency department visits, and hospital admissions) have been reported in epidemiological studies, as discussed

in the 2010 proposal in section II.A.2.a.i. Overall, the 2006 Criteria Document concludes that positive and robust associations were found between ambient O_3 concentrations and various respiratory disease hospitalization outcomes, when focusing particularly on results of warm-season analyses. Recent studies also generally indicate a positive association between O_3 concentrations and emergency department visits for asthma during the warm season. These positive and robust associations are supported by the controlled human exposure, animal toxicological, and epidemiological evidence for lung function decrements, increased respiratory symptoms, airway inflammation, and increased airway responsiveness. Taken together, the overall evidence supports a causal relationship between acute ambient O_3 exposures and increased respiratory morbidity outcomes resulting in increased emergency department visits and hospitalizations during the warm season (EPA, 2006a, p. 8-77).

Moreover, many single- and multicity epidemiological studies observed positive associations of ambient O_3 concentrations with total nonaccidental and cardiopulmonary mortality. As discussed in the 2010 proposal in section II.A.2.b.i, the 2006 Criteria Document finds that the results from U.S. multicity time-series studies provide the strongest evidence to date for O_3 effects on acute mortality. Recent meta-analyses also indicate positive risk estimates that are unlikely to be confounded by PM; however, future work is needed to better understand the influence of model specifications on the magnitude of risk. The Criteria Document concludes that the "positive O_3 effects estimates, along with the sensitivity analyses in these three meta-analyses, provide evidence of a robust association between ambient O_3 and mortality" (EPA, 2006a, p. 7-97). In summary, the Criteria Document (p. 8-78) concludes that these findings are highly suggestive that short-term O_3 exposure directly or indirectly contribute to non-accidental and cardiopulmonary-related mortality, but additional research is needed to more fully establish underlying mechanisms by which such effects occur.

The 2007 Staff Paper considered the epidemiological studies to evaluate evidence related to potential effects thresholds at the population level for morbidity and mortality effects. As discussed in the 2010 proposal in section II.A.3.a (and more fully in the Staff Paper in chapter 3 and the 2006 Criteria Document in chapter 7), a number of time-series studies have used statistical modeling approaches to evaluate potential thresholds at the population level. A few such studies reported some suggestive evidence of possible thresholds for morbidity and mortality outcomes in terms of 24-hour, 8-hour, and 1-hour averaging times. These results, taken together, provide some indication of possible 8-hour average threshold levels from below about 0.025 to 0.035 ppm (within the range of background concentrations) up to approximately 0.050 ppm. Other studies, however, observe linear concentration-response functions suggesting no effect threshold. The Staff Paper (p.6-60) concluded that the statistically significant associations between ambient O_3 concentrations and lung function decrements, respiratory symptoms, indicators of respiratory morbidity including increase emergency department visits and hospital admissions, and possibly mortality reported in a large number of studies likely extend down to ambient O_3 concentrations that are well below the level of the then current standard (0.084 ppm). These associations also extend well below the level of the standard set in 2008 (0.075 ppm) in that the highest level at which there is any indication of a threshold is approximately 0.050 ppm. Toward the lower end of the range of O_3 concentrations observed in such studies, ranging down to background levels (i.e., 0.035 to 0.015 ppm), however, the 2007 Staff Paper stated that there is increasing uncertainty as to whether the observed associations remain plausibly related to exposures to ambient O_3, rather than to the broader mix of air pollutants present in the ambient atmosphere.

The 2007 Staff Paper also considered studies that did subset analyses, which included only days with ambient O_3 concentrations below the level of the 1997 standard, or below even lower O_3 concentrations, and continue to report statistically significant associations. Notably, as discussed in

section II.A.3.a (75 FR 2960) of the 2010 proposal, Bell et al. (2006) conducted a subset analysis that continued to show statistically significant mortality associations even when only days with a maximum 8-hour average O_3 concentration below a value of approximately 0.061 ppm were included.[16] Also of note is the large multicity NCICAS (Mortimer et al., 2002) that reported statistically significant associations between ambient O_3 concentrations and lung function decrements even when days with 8-hour average O_3 levels greater than 0.080 ppm were excluded (which consisted of less than 5% of the days in the eight urban areas in the study).

Further, as discussed in the 2010 proposal in section II.A.3.a, there are limitations in epidemiological studies that make discerning thresholds in populations difficult, including low data density in the lower concentration ranges, the possible influence of exposure measurement error, and inter-individual differences in susceptibility to O_3-related effects in populations. There is the possibility that thresholds for individuals may exist in reported associations at fairly low levels within the range of air quality observed in the studies but not be detectable as population thresholds in epidemiological analyses.

Based on the above considerations, the 2007 Staff Paper recognized that the available evidence neither supports nor refutes the existence of effect thresholds at the population level for morbidity and mortality effects, and that if a population threshold level does exist, it would likely be well below the level of the then current standard and possibly within the range of background levels. Taken together, these considerations also support the conclusion that if a population threshold level does exist, it would likely be well below the level of the 0.075 ppm, 8-hour average, standard set in 2008.

[16]Bell et al. (2006) referred to this level as being approximately equivalent to 120 $\mu g/m^3$, daily 8-hour maximum, the World Health Organization guideline and European Commission target value for O_3.

In looking more broadly at evidence from animal toxicological, controlled human exposure, and epidemiological studies, the 2006 Criteria Document found substantial evidence, newly available in the 2008 rulemaking, that people with asthma and other preexisting pulmonary diseases are among those at increased risk from O_3 exposure. Altered physiological, morphological, and biochemical states typical of respiratory diseases like asthma, COPD, and chronic bronchitis may render people sensitive to additional oxidative burden induced by O_3 exposure (EPA, 2006a, section 8.7). Children and adults with asthma are the groups that have been studied most extensively. Evidence from controlled human exposure studies indicates that asthmatics may exhibit larger lung function decrements in response to O_3 exposure than healthy controls. As discussed more fully in section II.A.4 in the 2010 proposal, asthmatics present a different response profile for cellular, molecular, and biochemical parameters (EPA, 2006a, Figure 8-1) that are altered in response to acute O_3 exposure. They can have larger inflammatory responses, as manifested by larger increases in markers of inflammation such as white bloods cells (e.g., PMNs) or inflammatory cytokines. Asthmatics, and people with allergic rhinitis, are more likely to have an allergic-type response upon exposure to O_3, as manifested by increases in white blood cells associated with allergy (i.e., eosinophils) and related molecules, which increase inflammation in the airways. The increased inflammatory and allergic responses also may be associated with the larger late-phase responses that asthmatics can experience, which can include increased bronchoconstrictor responses to irritant substances or allergens and additional inflammation.

In addition to the experimental evidence of lung function decrements, respiratory symptoms, and other respiratory effects in asthmatic populations, two large U.S. epidemiological studies as well as several smaller U.S. and international studies, have reported fairly robust associations between ambient O_3 concentrations and measures of lung function and daily respiratory symptoms (e.g., chest tightness, wheeze, shortness of breath) in children with moderate to severe asthma and between O_3 and increased

asthma medication use (EPA, 2007a, chapter 6). These more serious responses in asthmatics and others with lung disease provide biological plausibility for the respiratory morbidity effects observed in epidemiological studies, such as emergency department visits and hospital admissions.

The body of evidence from controlled human exposure and epidemiological studies, which includes asthmatic as well as non-asthmatic subjects, indicates that controlled human exposure studies of lung function decrements and respiratory symptoms that evaluate only healthy, non-asthmatic subjects likely underestimate the effects of O_3 exposure on asthmatics and other susceptible populations. Therefore, relative to the healthy, non-asthmatic subjects used in most controlled human exposure studies, including the Adams (2002, 2006) studies, a greater proportion of people with asthma may be affected, and those who are affected may have as large or larger lung function and symptomatic responses at ambient exposures to 0.060 ppm O_3. This indicates that the lowest-observed-effects levels demonstrated in controlled human exposure studies that use only healthy subjects may not reflect the lowest levels at which people with asthma or other lung diseases may respond.

As discussed above, children and adults with asthma and other preexisting pulmonary diseases are at increased risk to the effects of O_3 exposures. Other population groups have also been identified as having increased susceptibility (referring to innate factors, such as genetic or developmental factors) or vulnerability (referring to acquired factors, such as increased likelihood of exposure while active outdoors) to the effects of O_3 exposures, as discussed in section II.A.4.b of the 2010 proposal. These population groups include the lifestages of children and older adults, people who have larger than normal lung function responses that may be due to genetic susceptibility, as well as healthy children and adults who are active outdoors, such as outdoor workers and joggers. Of particular note are children, including not only children with asthma or other pulmonary diseases but also healthy children, who are among the populations most susceptible to many air pollutants, including O_3. This is in part because

their lungs are still developing through adolescence, they generally have higher ventilation rates than adults, and they are likely to spend more time outdoors while at high levels of physical activity, which results in increased exposures and higher inhaled doses of O_3 relative to adults. For these reasons, children have been an important focus of studies on the effects of O_3, and, as discussed below, children were a primary focus of EPA's quantitative exposure and risk assessments.

2. Exposure- and Risk-Based Considerations

Exposure- and risk-based considerations are summarized below and presented more fully in section II.B of the 2010 proposal (75 FR 2974-85). To put judgments about health effects that are adverse for individuals into a broader public health context, EPA developed and applied models to estimate human exposures and health risks. This broader public health context included consideration of the size of particular population groups at risk for various effects, the likelihood that exposures of concern would occur for individuals in such groups under varying air quality scenarios, estimates of the number of people likely to experience O_3-related effects, the variability in estimated exposures and risks, and the kind and degree of uncertainties inherent in assessing the exposures and risks involved.

While there are a number of important uncertainties that affect the exposure and health risk estimates, it is also important to note that there have been significant improvements since the 1997 review in both the exposure and health risk models. The CASAC Panel expressed the view that the exposure analysis represents a state-of-the-art modeling approach and that the health risk assessment was "well done, balanced and reasonably communicated" (Henderson, 2006c). While recognizing and considering the kind and degree of uncertainties in both the exposure and health risk estimates, the 2007 Staff Paper (pp. 6-20 to 6-21) judged that the quality of the estimates is such that they are suitable to be used as an input to the Administrator's decisions on the O_3 primary standard.

The 2007 Staff Paper evaluated quantitative exposures and health risks estimated to occur upon just meeting the then-current 0.084 ppm standard and alternative standards.[17] In so doing, it presented the important uncertainties and limitations associated with these exposure and risk assessments (discussed more fully in section II.B of the 2010 proposal, 75 FR 2974-2985, and chapters 2, 4, and 5 of the 2007 Staff Paper).

With regard to the exposure assessment, the most important uncertainties are related to the modeling of human activity patterns over an O_3 season, the modeling of variations in ambient concentrations near roadways, the modeling of air exchange rates that affect the amount of O_3 that penetrates indoors, and the characterization of energy expenditure for children engaged in various activities. The uncertainties in the exposure model inputs and the estimated exposures have been assessed using quantitative uncertainty and sensitivity analyses.

With regard to the risk assessment, there are many sources of uncertainty and variability in the inputs to the assessment and in the resulting O_3 risk estimates. For example, there is significant year-to-year and city-to-city variability related to the air quality data that affects both the controlled human exposure studies-based and epidemiological studies-based parts of the risk assessment. With respect to uncertainties about estimated background concentrations, alternative assumptions about background levels have a variable impact depending on the location, standard, and health endpoint analyzed. With respect to the lung function part of the health risk assessment, key uncertainties include uncertainties in the exposure estimates, discussed above, and uncertainties associated with the shape of the exposure-response relationship, especially at levels below 0.08 ppm, 8-hour average, where only very limited data

[17] As described in the 2007 Staff Paper (section 4.5.8) and section II.B of the 2010 proposal, recent O_3 air quality distributions have been statistically adjusted to simulate just meeting the then current 0.084 ppm standard and selected alternative standards. These simulations do not represent predictions of when, whether, or how areas might meet the specified standards. Modeling that projects whether and how areas might attain alternative standards in a future year is presented in the Regulatory Impact Analysis prepared in connection with this rulemaking.

are available down to 0.04 ppm and there is an absence of data below 0.04 ppm (EPA, 2007a, pp.6-20 to 6-21). Concerning the part of the risk assessment based on effects reported in epidemiological studies, important uncertainties include the following: (1) estimates of the O_3 coefficients for concentration-response relationships used in the assessment; (2) the shape of the concentration-response relationship and whether or not a population threshold or non-linear relationship exists within the range of concentrations examined in the studies, (3) the extent to which concentration-response relationships derived from studies in a given location and time when O_3 levels were higher or behavior and /or housing conditions were different provide accurate representations of the concentration-response relationships for those same locations when there are lower air quality distributions and/or different behavior and/or housing conditions, and (4) the possible role of co-pollutants which also may have varied between the time of the studies and the current assessment period. An important additional uncertainty for the mortality risk estimates is the extent to which the associations reported between O_3 and non-accidental and cardiorespiratory mortality actually reflect causal relationships. Some of these uncertainties have been addressed quantitatively in the form of estimated confidence ranges around central risk estimates; others are addressed through separate sensitivity analyses (e.g., the influence of alternative estimates for policy-relevant background levels) or are characterized qualitatively. For both parts of the health risk assessment, statistical uncertainty due to sampling error has been characterized and is expressed in terms of 95% credible intervals. The EPA recognizes that these credible intervals do not reflect all of the uncertainties noted above.

The 2007 Staff Paper (and the CASAC) also recognized that the exposure and risk analyses could not provide a full picture of the O_3 exposures and O_3-related health risks posed nationally. EPA did not have sufficient information to evaluate all relevant susceptible populations (e.g., outdoor workers) or all O_3-related health outcomes (e.g., increased medication use, school absences, and

emergency department visits that are part of the broader pyramid of effects discussed in section II.A.4.d of the 2010 proposal), and the scope of the Staff Paper analyses was generally limited to estimating exposures and risks in 12 urban areas across the U.S., and to only five or just one area for some health effects included in the risk assessment. Thus, national-scale public health impacts of ambient O_3 exposures are clearly much larger than the quantitative estimates of O_3-related incidences of adverse health effects and the numbers of children likely to experience exposures of concern associated with meeting the 0.084 ppm standard or alternative standards as analyzed in the risk assessment. On the other hand, inter-individual variability in responsiveness means that only a subset of individuals in each group estimated to experience exposures exceeding a given benchmark exposure of concern level would actually be expected to experience such adverse health effects.

The 2007 Staff Paper focused on alternative standards with the same form as the 1997 0.084 ppm O_3 standard (i.e. the 0.074/4, 0.070/4 and 0.064/4 scenarios).[18] Having concluded in the Staff Paper that it was appropriate to consider a range of standard levels from somewhat below 0.080 ppm down to as low as 0.060 ppm, the Staff Paper looked to results of the analyses of exposure and risk for the 0.074/4 scenario to represent the public health impacts of selecting a standard in the upper part of the range, the results of analyses of the 0.070/4 scenario to represent the impacts in the middle part of the range, and the results of the analyses of the 0.064/4 scenario to represent the lower part of the range.

As discussed in section II.B.1 of the 2010 proposal, the exposure estimates presented in the 2007 Staff Paper are for the number and percent of all children and asthmatic children exposed, and the number of person-days (occurrences) of exposures, with daily 8-hour maximum exposures at or above several benchmark levels while at intermittent moderate or greater exertion. Exposures above selected

[18]The abbreviated notation used to identify the then current 0.084 ppm standard and alternative standards in this section and in the risk assessment section of the Staff Paper is in terms of ppm and the nth highest daily maximum 8-hour average. For example, the 8-hour standard established in 1997 is identified as "0.084/4."

benchmark levels provide some perspective on the public health impacts of health effects that cannot currently be evaluated in quantitative risk assessments but that may occur at existing air quality levels, and the extent to which such impacts might be reduced by meeting alternative standard levels. As described in section II.B.1.c in the 2010 proposal, the Staff Paper refers to exposures at and above these benchmark levels as "exposures of concern." The Staff Paper notes that exposures of concern, and the health outcomes they represent, likely occur across a range of O_3 exposure levels, such that there is no one exposure level that addresses all public health concerns. As noted in section II.B of the 2010 proposal, EPA also has acknowledged that the concept is more appropriately viewed as a continuum with greater confidence and less uncertainty about the existence of health effects at the upper end and less confidence and greater uncertainty as one considers increasingly lower O_3 exposure levels.

Consistent with advice from CASAC, the 2007 Staff Paper estimates exposures of concern not only at and above a benchmark level of 0.080 ppm O_3, a level at which there are clearly demonstrated effects, but also at benchmark levels of 0.070 and 0.060 ppm O_3, levels where there is some evidence that health effects are likely to occur in some individuals. The 2007 Staff Paper recognizes that there will be varying degrees of concern about exposures at each of these levels, based in part on the population groups experiencing them. While there is clear evidence of inflammation, increased airway responsiveness, and changes in host defenses in healthy people exposed to 0.080 ppm, and reason to infer that such effects will continue at lower exposure levels, there is increasing uncertainty about the extent to which such effects occur at lower O_3 concentrations. Based on this evidence, the Staff Paper focuses on exposures of concern at or above benchmark levels of 0.070 and 0.060 ppm O_3 for purposes of evaluating alternative standards. The focus on these two benchmark levels reflects the following evidence-based considerations, discussed above in section II.A.2, that raise concerns about adverse health effects likely occurring at levels below 0.080 ppm: (1) limited, but important, new evidence from

controlled human exposure studies showing lung function decrements and respiratory symptoms in some healthy subjects at 0.060 ppm; (2) asthmatics are likely to have more serious responses than healthy individuals; (3) lung function is not likely to be as sensitive a marker for O_3 effects as lung inflammation; and (4) there is epidemiological evidence which reports associations with O_3 levels that extend well below 0.080 ppm.

Table 1 below (Table 3 in the 2010 proposal) summarizes the exposure estimates for all children and asthmatic children at and above the 0.060 and 0.070 ppm health effect benchmark levels associated with O_3 levels adjusted to just meet 0.074/4, 0.070/4, and 0.064/4 alternative 8-hour standards based on a generally poorer year of air quality (2002) and based on a generally better year of air quality (2004). This table includes exposure estimates reflecting the aggregate estimate for the 12 urban areas as well as the range across these same 12 areas. As shown in Table 1 the percent of population exposed over the selected benchmark levels is very similar for all and asthmatic school age children. Thus, the following discussion focuses primarily on the exposure estimates for asthmatic children, recognizing that the pattern of exposure estimates is similar for all children when expressed in terms of percentage of the population.

Table 1. Number and Percent of All and Asthmatic School Age Children in 12 Urban Areas Estimated to Experience 8-Hour Ozone Exposures At and Above 0.060 and 0.070 ppm While at Moderate or Greater Exertion, One or More Times Per Season Associated with Just Meeting Alternative 8-Hour Standards Based on Adjusting 2002 and 2004 Air Quality Data[1,2]

Benchmark Levels of Exposures of Concern (ppm)	8-Hour Air Quality Standards[3] (ppm)	All Children, ages 5-18 Aggregate for 12 urban areas Number of Children Exposed (% of all children) [Range across 12 cities, % of all children]		Asthmatic Children, ages 5-18 Aggregate for 12 urban areas Number of Children Exposed (% of group) [Range across 12 cities, % of group]	
		2002	2004	2002	2004
0.070	0.074	770,000 (4%) [0 – 13%]	20,000 (0%) [0 - 1%]	120,000 (5%) [0 - 14%]	0 (0%) [0 - 1%]
	0.070	270,000 (1%) [0 - 5%]	0 (0%) [0%]	50,000 (2%) [0 - 6%]	0 (0%) [0%]
	0.064	30,000 (0.2%)	0 (0%)	10,000 (0.2%)	0 (0%)

		[0 - 1%]	[0%]	[0 - 1%]	[0%]
0.060	0.074	4,550,000 (25%) [1 - 48%]	350,000 (2%) [0 - 9%]	700,000 (27%) [1 -51%]	50,000 (2%) [0 - 9%]
	0.070	3,000,000 (16%) [1 - 36%]	110,000 (1%) [0 - 4%]	460,000 (18%) [0 - 41%]	10,000 (1%) [0 - 3%]
	0.064	950,000 (5%) [0 - 17%]	10,000 (0%) [0 - 1%]	150,000 (6%) [0 - 16%]	0 (0%) [0 - 1%]

[1] Moderate or greater exertion is defined as having an 8-hour average equivalent ventilation rate $\geq$ 13 l-min/m^2.

[2] Estimates are the aggregate results based on 12 combined statistical areas (Atlanta, Boston, Chicago, Cleveland, Detroit, Houston, Los Angeles, New York, Philadelphia, Sacramento, St. Louis, and Washington, D.C.). Estimates are for the ozone season which is all year in Houston, Los Angeles and Sacramento and March or April to September or October for the remaining urban areas.

[3] All standards summarized here have the same form as the 8-hour standard established in 1997 which is specified as the 3-year average of the annual 4th highest daily maximum 8-hour average concentrations must be at or below the concentration level specified. As described in the 2007 Staff Paper (EPA, 2007a, section 4.5.8), recent O_3 air quality distributions have been statistically adjusted to simulate just meeting the 0.084 ppm standard and selected alternative standards. These simulations do not represent predictions of when, whether, or how areas might meet the specified standards

As shown in Table 1, aggregate estimates of exposures of concern for the 12 urban areas included in the assessment are considerably larger for the benchmark level of 0.060 ppm O_3, compared to the 0.070 ppm benchmark level. Substantial year-to-year variability is observed in the number of children estimated to experience exposures of concern at and above both the 0.060 and 0.070 ppm benchmark levels.

As shown in Table 1, aggregate estimates of exposures of concern at and above a 0.060 ppm benchmark level vary considerably among the three alternative standards, particularly for the 2002 simulations (a year with generally poorer air quality in most, but not all areas). For air quality just meeting a 0.074/4 standard, approximately 27% of asthmatic children, based on the 2002 simulation, and approximately 2% of asthmatic children based on the 2004 simulation (a year with better air quality in most but not all areas), are estimated to experience one or more exposures of concern at and above the benchmark level of 0.060 ppm O_3. Considering a 0.070/4 standard using the same benchmark level (0.060 ppm), about 18% of asthmatic children are estimated to experience one or more exposures of concern in a year with poorer air quality (2002), and only about 1% in a year with better air quality

(2004). For the lowest standard level examined (a 0.064/4 standard), about 6% of asthmatic children are estimated to experience one or more exposures of concern in the simulation based on the year with poorer air quality (2002), and exposures of concern at and above the 0.060 ppm benchmark level are essentially eliminated based on a year with better air quality (2004).

Table 1 also provides aggregate exposure estimates for the 12 urban areas where a benchmark level of 0.070 ppm is used. Based on the year with poorer air quality (2002), the estimate of the percent of asthmatic children exposed one or more times is about 5% when a 0.074/4 standard is just met; based on a year with better air quality (2004), exposures of concern are essentially eliminated. For this same benchmark (0.070 ppm) level, when a 0.070/4 standard is just met, estimates range from about 2% of asthmatic children exposed one or more times at and above this benchmark level based on a year with poorer air quality (2002), and exposures of concern are essentially eliminated based on a year with better air quality (2004). At the 0.070 ppm benchmark level, just meeting a 0.064/4 standard essentially eliminates exposures of concern regardless of the year that is used as the basis for the analysis.

The 2007 Staff Paper also notes that there is substantial city-to-city variability in these estimates, and notes that it is appropriate to consider not just the aggregate estimates across all cities, but also to consider the public health impacts in cities that receive relatively less protection from the alternative standards. As shown in Table 1, in considering the benchmark level of 0.060 ppm, while the aggregate percentage of asthmatic children estimated to experience one or more exposures of concern at and above this benchmark level across all 12 cities for a 0.074/4 standard is about 27% based on the year with poorer air quality (2002), it ranges up to approximately 51% for asthmatic children in the city with the least degree of protection from that alternative standard. Similarly, for air quality just meeting a 0.070/4 standard, the aggregate percentage of asthmatic children estimated to experience one or more exposures of concern at and above the 0.060 ppm benchmark level across all 12 cities is 18% based on the year

with poorer air quality, but it ranges up to about 41% in the city with the least degree of protection associated with just meeting that alternative standard. For just meeting a 0.064/4 standard, the aggregate estimate of asthmatic children experiencing one or more exposures of concern at and above the 0.060 ppm benchmark is about 6% based on the year with poorer air quality and ranges up to 16% in the city with the least degree of protection.

This pattern of city-to-city variability also occurs at the benchmark level of 0.070 ppm associated with air quality just meeting these same three alternative standards (i.e., 0.074/4, 0.070/4, and 0.064/4). While the aggregate percentage of asthmatic children estimated to experience exposures of concern at and above this benchmark level across all 12 cities is about 5% based on the year with poorer air quality for just meeting the 0.074/4 standard, it ranges up to 14% in the city with the least degree of protection associated with that alternative standard. For just meeting a 0.070/4 standard the aggregate estimate is 2% of asthmatic children experiencing one or more exposures of concern for at and above the 0.070 ppm benchmark based on the year with poorer air quality and ranges up to 6% in the city with the least degree of protection. The aggregate estimate for exposures of concern is further reduced to 0.2% of asthmatic children at and above this same benchmark level for air quality just meeting a 0.064/4 standard based on the year with poorer air quality and ranges up to 1% in the city with the least degree of protection.

In addition to observing the fraction of the population estimated to experience exposures of concern associated with just meeting alternative standards, EPA also took into consideration in the 2007 Staff Paper the percent reduction in exposures of concern and health risks associated with alternative standards relative to just meeting the then-current 0.084/4 standards. For reconsideration of the 2008 final rule, it is also informative to consider the incremental reductions in exposures of concern associated with alternative lower standard levels relative to the 0.075 ppm standard set in 2008. As

shown in Table 1 of the 2010 proposal, at and above the 0.060 ppm benchmark level based on a year with poorer air quality, the reduction in exposures of concern for asthmatic children in going from the 0.074/4 standard (which approximates the 0.075 ppm standard set in 2008) down to a 0.064/4 standard is very similar to the reduction estimated to occur in going from then-current 0.084/4 standard down to a 0.074/4 standard. More specifically, the estimates for asthmatic children are reduced from 47% (about 1.2 million children) associated with meeting a 0.084/4 standard down to 27% (about 700,000 children) for just meeting a 0.074/4 standard and the estimates are reduced further to about 6% (about 150,000 children) associated with just meeting a 0.064/4 standard in the 12 urban areas included in the assessment. In a year with better air quality (2004), exposures estimated to exceed the 0.060 ppm benchmark in asthmatic children one or more times in a year are reduced from 11% associated with just meeting a 0.084/4 standard down to about 2% for a 0.074/4 standard and are essentially eliminated when a 0.064/4 standard is just met.

Turning to consideration of the risk assessment estimates, Table 2 in the 2010 proposal summarizes the risk estimates for moderate lung function decrements in both all school-age children and asthmatic school-age children associated with just meeting several alternative standards based on simulations involving a year with relatively poorer air quality (2002) and a year with relatively better air quality (2004). For the 2002 simulation the reduction in the number of asthmatic children estimated to experience one or more moderate lung function decrements going from a 0.074/4 standard down to a 0.064/4 standard is roughly equivalent to the additional health protection afforded associated with just meeting a 0.074/4 standard relative to then-current 0.084/4 standard. More specifically, for just 5 urban areas, it is estimated that nearly 8% of asthmatic children (130,000 children) would experience one or more occurrences of moderate lung function decrements per year at a 0.084/4 standard, which would be reduced to about 5% (90,000 children) at a 0.074/4 standard, and further reduced to about 3% (50,000

children) at a 0.064/4 standard. Based on the 2002 simulations, the percent reduction associated with just meeting a 0.064/4 standard relative to then-current 0.084/4 standard is about 62%, which is about twice the reduction in risk compared to the estimated 31% reduction associated with just meeting a 0.074/4 standard. Similar patterns were observed in reductions in lung function risk for all school age children in 12 urban areas associated with these alternative standards.

With regard to mortality risk, Figures 6-5 and 6-6 in the 2007 Staff Paper show the percent reduction in non-accidental mortality risk estimates associated with just meeting the same alternative standards discussed above relative to just meeting the then-current 0.084/4 standard for 12 urban areas, based on adjusting 2002 and 2004 air quality data. These figures also provide perspective on the extent to which the estimated risks in these years (i.e., 2002 and 2004) are greater than those estimated to occur upon meeting the then-current 0.084/4 standard (in terms of a negative percent reduction relative to a 0.084/4 standard). Based on the 2002 simulations (EPA, 2007a, Figure 6-5), the estimated reduction in non-accidental mortality is about 30 to 70% across the 12 urban areas for just meeting a 0.064/4 standard relative to the then-current 0.084/4 standard. This reduction is roughly twice the 15 to 30% estimated reduction across the 12 urban areas associated with just meeting a 0.074/4 standard relative to a 0.084/4 standard. While the estimated incidence is lower based on the 2004 simulations (EPA, 2007a, Figure 6-6), the pattern of risk reductions among alternative standards is roughly similar to that observed for the 2002 simulations.

In addition to the risk estimates for lung function decrements in all school age children and non-accidental mortality that were estimated for 12 urban areas and lung function decrements in asthmatic children for 5 urban areas, a similar pattern of incremental reductions in health risks was shown for two health outcomes where risks were compared for alternative standards in one city for each of these outcomes. These included reductions in respiratory symptoms in asthmatic children (EPA, 2007a;

Boston, Table 6-9) and respiratory-related hospital admissions (EPA, 2007a; New York City, Table 6-10) associated with just meeting alternative 8-hour standards set at 0.074 ppm, 0.070 ppm, and 0.064 ppm relative to just meeting the then current 0.084 ppm standard. Using the 2002 simulation, a standard set at 0.074/4 is estimated to reduce the incidence of symptom days in children with moderate to severe asthma in the Boston area by about 15 percent relative to a 0.084/4 standard. With this reduction, it is estimated that about 1 respiratory symptom day in 8 during the O_3 season would be attributable to O_3 exposure. A standard set at 0.064/4 is estimated, based on the 2002 simulation, to reduce the incidence of symptom days in children with moderate to severe asthma in the Boston area by about a 25 to 30% reduction relative to a 0.084 ppm standard, which is roughly twice the reduction compared to that provided by a 0.074/4 standard. But even with this reduction, it is estimated that 1 respiratory symptom day in 10 during the O_3 season is attributable to O_3 exposure

As shown in Table 6-10 (EPA, 2007a), estimated incidence of respiratory-related hospital admissions in one urban area (New York City) was reduced by 14 to 17% by a standard set at 0.074/4 relative to then-current 0.084/4 standard, in the years with relatively high and relatively low O_3 air quality levels, respectively. Similar to the pattern observed for the other health outcomes discussed above, the reduction in incidence of respiratory-related hospital admissions for a 0.064/4 standard relative to a 0.084/4 standard is about twice that associated with a 0.074/4 standard relative to a 0.084/4 standard.

B. 2008 Decision on the Level of the Primary Standard

This section presents the rationale for the 2008 final decision on the primary O_3 standard as presented in the 2008 final rule (73 FR 16475). EPA's conclusions on the level of the standard began by noting that, having carefully considered the public comments on the appropriate level of the O_3 standard, EPA concluded that the fundamental scientific conclusions on the effects of O_3 reached in the 2006

Criteria Document and 2007 Staff Paper remained valid. In considering the level at which the primary O_3 standard should be set, EPA placed primary consideration on the body of scientific evidence available in the 2008 final rulemaking on the health effects associated with O_3 exposure, while viewing the results of exposure and risk assessments as providing information in support of the decision. In considering the available scientific evidence, EPA concluded that a focus on the proposed range of 0.070 to 0.075 ppm was appropriate in light of the large body of controlled human exposure and epidemiological and other scientific evidence. The 2008 final rule stated that this body of evidence did not support retaining the then current 0.084 ppm 8-hour O_3 standard, as suggested by some commenters, nor did it support setting a level just below 0.080 ppm, because, based on the entire body of evidence, such a level would not provide a significant increase in protection compared to the 0.084 ppm standard. Further, such a level would not be appreciably below the level in controlled human exposure studies at which adverse effects have been demonstrated (i.e., 0.080 ppm). The 2008 final rule also stated that the body of evidence did not support setting a level of 0.060 ppm or below, as suggested by other commenters. In evaluating the information from the exposure assessment and the risk assessment, EPA judged that this information did not provide a clear enough basis for choosing a specific level within the range of 0.075 to 0.070 ppm.

In making a final judgment about the level of the primary O_3 standard, EPA noted that the level of 0.075 ppm is above the range unanimously recommended by the CASAC (i.e., 0.070 to 0.060 ppm). The 2008 final rule stated that in placing great weight on the views of CASAC, careful consideration had been given to CASAC's stated views and the scientific basis and policy views for the range it recommended. In so doing, EPA fully agreed that the scientific evidence supports the conclusion that the current standard was not adequate and must be revised.

With respect to CASAC's recommended range of standard levels, EPA observed that the basis for CASAC's recommendation appeared to be a mixture of scientific and policy considerations. While in general agreement with CASAC's views concerning the interpretation of the scientific evidence, EPA noted that there was no bright line clearly directing the choice of level, and the choice of what was appropriate was clearly a public health policy judgment entrusted to the EPA Administrator. This judgment must include consideration of the strengths and limitations of the evidence and the appropriate inferences to be drawn from the evidence and the exposure and risk assessments. In reviewing the basis for the CASAC Panel's recommendation for the range of the O_3 standard, EPA observed that it reached a different policy judgment than the CASAC Panel based on apparently placing different weight in two areas: the role of the evidence from the Adams studies and the relative weight placed on the results from the exposure and risk assessments. While EPA found the evidence reporting effects at the 0.060 ppm level from the Adams studies to be too limited to support a primary focus at this level, EPA observed that the CASAC Panel appeared to place greater weight on this evidence, as indicated by its recommendation of a range down to 0.060 ppm. It was noted that while the CASAC Panel supported a level of 0.060 ppm, they also supported a level above 0.060, which indicated that they did not believe that the results of Adams studies meant that the level of the standard had to be set at 0.060 ppm. EPA also observed that the CASAC Panel appeared to place greater weight on the results of the risk assessment as a basis for its recommended range. In referring to the risk assessment results for lung function, respiratory symptoms, hospital admissions and mortality, the CASAC Panel concluded that: "beneficial effects in terms of reduction of adverse health effects were calculated to occur at the lowest concentration considered (i.e., 0.064 ppm)" (Henderson, 2006c, p.4). However, EPA more heavily weighed the implications of the uncertainties associated with the Agency's quantitative human exposure and health risk assessments. Given these uncertainties, EPA did not agree that these assessment results

appropriately served as a primary basis for concluding that levels at or below 0.070 ppm were required for the 8-hour O_3 standard.

The 2008 final rule stated that after carefully taking the above comments and considerations into account, and fully considering the scientific and policy views of the CASAC, EPA decided to revise the level of the primary 8-hour O_3 standard to 0.075 ppm. EPA judged, based on the available evidence, that a standard set at this level would be requisite to protect public health with an adequate margin of safety, including the health of sensitive subpopulations, from serious health effects including respiratory morbidity, that were judged to be causally associated with short-term and prolonged exposures to O_3, and premature mortality. EPA also judged that a standard set at this level provides a significant increase in protection compared to the 0.084 ppm standard, and is appreciably below 0.080 ppm, the level in controlled human exposure studies at which adverse effects have been demonstrated. At a level of 0.075 ppm, exposures at and above the benchmark of 0.080 ppm are essentially eliminated, and exposures at and above the benchmark of 0.070 are substantially reduced or eliminated for the vast majority of people in susceptible populations. A standard set at a level lower than 0.075 would only result in significant further public health protection if, in fact, there is a continuum of health risks in areas with 8-hour average O_3 concentrations that are well below the concentrations observed in the key controlled human exposure studies and if the reported associations observed in epidemiological studies are, in fact, causally related to O_3 at those lower levels. Based on the available evidence, EPA was not prepared to make these assumptions. Taking into account the uncertainties that remained in interpreting the evidence from available controlled human exposure and epidemiological studies at very low levels, EPA noted that the likelihood of obtaining benefits to public health decreased with a standard set below 0.075 ppm O_3, while the likelihood of requiring reductions in ambient concentrations that go beyond those that are needed to protect public health increased. EPA judged that the appropriate balance to be drawn,

based on the entire body of evidence and information available in the 2008 final rulemaking, was to set the 8-hour primary standard at 0.075 ppm. EPA expressed the view that a standard set at 0.075 ppm would be sufficient to protect public health with an adequate margin of safety, and did not believe that a lower standard was needed to provide this degree of protection. EPA further asserted that this judgment appropriately considered the requirement for a standard that was neither more nor less stringent than necessary for this purpose and recognized that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

C. Reconsideration of the Level of the Primary Standard

This section presents the Administrator's final decision in the reconsideration of the level of the 8-hour primary O_3 standard set in 2008. The following discussion includes a summary of the 2010 proposed decision on the level of the primary O_3 standard (section II.C.1), significant comments on the 2010 proposed decision and EPA's responses to those comments (section II.C.2), and the Administrator's final conclusions on the level of the primary O_3 standard (section II.C.3).

1. 2010 Proposed Decision

In January 2010, the Administrator proposed to set a new level for the 8-hour primary O_3 within the range from 0.060 to 0.070 ppm.[19] In reaching this proposed decision, the Administrator considered: the evidence-based considerations from the 2006 Criteria Document and the 2007 Staff Paper; the results of the exposure and risk assessments discussed above and in the Staff Paper; CASAC advice and recommendations provided in CASAC's letters to the Administrator both during and following the 2008 rulemaking; EPA staff recommendations; and public comments received in conjunction with review of

[19]As discussed above at the beginning of section II, the Administrator has focused her reconsideration of the primary O_3 standard set in the 2008 final rule on the level of the standard, having decided not to reopen the 2008 final rule with regard to the need to revise the 1997 primary O_3 standard to provide increased public health protection nor with regard to the indicator, averaging period, and form of the 2008 standard.

drafts of these documents and on the 2007 proposed rule. In considering what level of an 8-hour O_3 standard is requisite to protect public health with an adequate margin of safety, the Administrator was mindful that this choice required judgments based on an interpretation of the evidence and other information that neither overstates nor understates the strength and limitations of the evidence and information.

The Administrator noted that the most certain evidence of adverse health effects from exposure to O_3 comes from the controlled human exposure studies, and that the large bulk of this evidence derives from studies of exposures at levels of 0.080 ppm and above. At those levels, there is consistent evidence of lung function decrements and respiratory symptoms in healthy young adults, as well as evidence of O_3-induced pulmonary inflammation, airway responsiveness, impaired host defense capabilities, and other medically significant airway responses. Moreover, there is no evidence that the 0.080 ppm exposure level is a threshold for any of these types of respiratory effects. Indeed, there is now controlled human exposure evidence, including studies of lung function decrements and respiratory symptoms at the 0.060 ppm exposure level, that strengthens our previous understanding that this array of respiratory responses is likely to occur in some healthy adults at such lower levels.

In particular, the Administrator noted two studies by Adams (2002, 2006), newly available in the 2008 rulemaking, that examined lung function and respiratory symptom effects associated with prolonged O_3 exposures at levels below 0.080 ppm, as well as EPA's analysis of the data from the Adams (2006) study at a 0.060 ppm exposure level. As discussed above, the author's analysis focused on hour-by-hour comparisons of effects for the purpose of exploring responses associated with different patterns of exposure, EPA's analysis evaluated the studies' data to try to answer a different, more fundamental question of whether the pre- to post-exposure change in lung function differed between a 6.6-hour exposure to 0.060 ppm O_3 versus a 6.6 hour exposure to clean filtered air. The Administrator

noted that this analysis found small, but statistically significant group mean differences in lung function decrements in healthy adults at the 0.060 ppm exposure level, which is now the lowest-observed-effects level for these effects. Moreover, these studies also report a percentage of subjects (7 to 20%) experienced moderate lung function decrements ($\geq$ 10%) at the 0.060 ppm exposure level. While for active healthy people, moderate levels of functional responses (e.g., FEV_1 decrements of $\geq$ 10% but < 20%) and/or moderate respiratory symptom responses would likely interfere with normal activity for relatively few responsive individuals, the Administrator noted that for people with lung disease, even moderate functional or symptomatic responses would likely interfere with normal activity for many individuals, and would likely result in more frequent use of medication. Further, she noted that CASAC indicated that a focus on the lower end of the range of moderate levels of functional responses (e.g., FEV_1 decrements $\geq$ 10%) is most appropriate for estimating potentially adverse lung function decrements in people with lung disease (Henderson, 2006c).

The Administrator also noted that many public commenters on the 2007 proposed rule raised a number of questions about the weight that should be placed on the Adams studies and EPA's analysis of data from the Adams (2006) study. Some commenters expressed the view that the results of these studies and EPA's analysis provided support for setting a standard level below the proposed range, while others raised questions about EPA's analysis and generally expressed the view that the study results were not robust enough to reach conclusions about respiratory effects at the 0.060 ppm exposure level.[20]

Based on all the above considerations, the Administrator concluded that the Adams studies add limited but important evidence to the overall body of evidence that informed her proposed decision on the range of levels within which a standard could be set that would be requisite to protect public health

[20]The EPA responded to these comments in the 2008 final rule (73 FR 16454-5).

with an adequate margin of safety, including the health of susceptible populations such as people with lung disease.

In considering controlled human exposure studies reporting O_3-induced pulmonary inflammation, airway responsiveness, and impaired host defense capabilities at exposure levels down to 0.080 ppm, the lowest level at which these effects have been tested, the Administrator noted that these physiological effects have been linked to aggravation of asthma and increased susceptibility to respiratory infection, potentially leading to increased medication use, increased school and work absences, increased visits to doctors' offices and emergency departments, and increased hospital admissions, especially in people with lung disease. These physiological effects are all indicators of potential adverse O_3-related morbidity effects, which are consistent with and lend plausibility to the associations observed between O_3 and adverse morbidity effects and mortality effects in epidemiological studies.

With regard to epidemiological studies, the Administrator observed that statistically significant associations between ambient O_3 levels and a wide array of respiratory symptoms and other morbidity outcomes including school absences, emergency department visits, and hospital admissions have been reported in a large number of studies. More specifically, positive and robust associations were found between ambient O_3 concentrations and respiratory hospital admissions and emergency department visits, when focusing particularly on the results of warm season analyses. Taken together, the overall body of evidence from controlled human exposure, toxicological, and epidemiological studies supports the inference of a causal relationship between acute ambient O_3 exposures and increased respiratory morbidity outcomes resulting in increased emergency department visits and hospitalizations during the warm season. Further, the Administrator noted that recent epidemiological evidence is highly

suggestive that O_3 directly or indirectly contributes to non-accidental and cardiopulmonary-related mortality.

The Administrator also considered the epidemiological evidence with regard to considering potential effects thresholds at the population level for morbidity and mortality effects. As discussed above, while some studies provide some indication of possible 8-hour average threshold levels from below about 0.025 to 0.035 ppm (within the range of background concentrations) up to approximately 0.050 ppm, other studies observe linear concentration-response functions suggesting that there may be no effects thresholds at the population level above background concentrations. In addition, other studies conducted subset analyses that included only days with ambient O_3 concentrations below the level of the then current standard, or below even lower O_3 concentrations, including a level as low as 0.061 ppm, and continue to report statistically significant associations. The Administrator noted that the relationships between ambient O_3 concentrations and lung function decrements, respiratory symptoms, indicators of respiratory morbidity including increased respiratory-related emergency department visits and hospital admissions, and possibly mortality reported in a large number of studies likely extend down to ambient O_3 concentrations well below the level of the standard set in 2008 (0.075 ppm), in that the highest level at which there is any indication of a threshold is approximately 0.050 ppm. The Administrator noted as well that toward the lower end of the range of O_3 concentrations observed in such studies, ranging down to background levels (i.e., 0.035 to 0.015 ppm), there is increasing uncertainty as to whether the observed associations remain plausibly related to exposures to ambient O_3, rather than to the broader mix of air pollutants present in the ambient atmosphere. She also noted that there are limitations in epidemiological studies that make discerning population thresholds difficult, as discussed above, such that there is the possibility that thresholds for individuals may exist in reported

associations at fairly low levels within the range of air quality observed in the studies but not be detectable as population thresholds in epidemiological analyses.

In looking more broadly at evidence from animal toxicological, controlled human exposure, and epidemiological studies, the Administrator found substantial evidence, newly available for consideration in the 2008 rulemaking, that people with asthma and other preexisting pulmonary diseases are among those at increased risk from O_3 exposure. As discussed above, altered physiological, morphological, and biochemical states typical of respiratory diseases like asthma, COPD, and chronic bronchitis may render people sensitive to additional oxidative burden induced by O_3 exposure. Children and adults with asthma are the group that has been studied most extensively. Evidence from controlled human exposure studies indicates that asthmatics and people with allergic rhinitis generally exhibit larger lung function decrements in response to O_3 exposure than healthy subjects and that they can have larger inflammatory responses. The Administrator also noted that two large U.S. epidemiological studies, as well as several smaller U.S. and international studies, have reported fairly robust associations between ambient O_3 concentrations and measures of lung function and daily symptoms (e.g., chest tightness, wheeze, shortness of breath) in children with moderate to severe asthma and between O_3 and increased asthma medication use. These more serious responses in asthmatics and others with lung disease provide biological plausibility for the respiratory morbidity effects observed in epidemiological studies, such as respiratory-related emergency department visits and hospital admissions.

The Administrator also observed that a substantial body of evidence from controlled human exposure and epidemiological studies indicates that relative to the healthy, non-asthmatic subjects used in most controlled human exposure studies, a greater proportion of people with asthma may be affected, and those who are affected may have as large or larger lung function and symptomatic responses to O_3 exposures. Thus, the Administrator concluded that controlled human exposure studies of lung function

decrements and respiratory symptoms that evaluate only healthy, non-asthmatic subjects likely underestimate the effects of O_3 exposure on asthmatics and other susceptible populations.

In addition to the evidence-based considerations discussed above, the Administrator also considered quantitative exposures and health risks estimated to occur associated with air quality simulated to just meet various standard levels to help inform judgments about a range of standard levels for consideration that could provide an appropriate degree of public health protection. In so doing, she was mindful of the important uncertainties and limitations that are associated with the exposure and risk assessments, as discussed in the 2007 Staff Paper and in sections II.B and II.C.1.b of the 2010 proposal, and as summarized above in section II.A.2. Beyond these uncertainties, the Administrator also recognized important limitations related to the exposure and risk analyses. For example, EPA did not have sufficient information to evaluate all relevant susceptible populations (e.g., outdoor workers) or all O_3-related health outcomes (e.g., increased medication use, school absences, emergency department visits), and the scope of the analyses was generally limited to estimating exposures and risks in 12 urban areas across the U.S., and to only five or just one area for some health effects. Thus, it is clear that national-scale public health impacts of ambient O_3 exposures are much larger than the quantitative estimates of O_3-related incidences of adverse health effects and the numbers of children likely to experience exposures of concern associated with meeting the then current standard or alternative standards. Taking these limitations into account, the CASAC advised EPA not to rely solely on the results of the exposure and risk assessments in considering alternative standards, but also to place significant weight on the body of evidence of O_3-related health effects in drawing conclusions about an appropriate range of levels for consideration. The Administrator agreed with this advice.

Turning first to the results of the exposure assessment, the Administrator focused on the extent to which alternative standard levels, approximately at and below the 0.075 ppm O_3 standard set in the 2008

final rule, are estimated to reduce exposures over the 0.060 and 0.070 ppm health effects benchmark levels, for all and asthmatic school age children in the 12 urban areas included in the assessment.[21] The Administrator also noted that the lowest standard level included in the exposure and health risk assessments was 0.064 ppm and that additional reductions in exposures over the selected health benchmark levels would be anticipated for just meeting a 0.060 ppm standard.

As an initial matter, the Administrator recognized that the concept of "exposures of concern" is more appropriately viewed as a continuum, with greater confidence and less uncertainty about the existence of health effects at the upper end and less confidence and greater uncertainty as one considers increasingly lower O_3 exposure levels. In considering the concept of exposures of concern, the Administrator also noted that it is important to balance concerns about the potential for health effects and their severity with the increasing uncertainty associated with our understanding of the likelihood of such effects at lower O_3 levels. Within the context of this continuum, estimates of exposures of concern at and above discrete benchmark levels provide some perspective on the public health impacts of O_3-related physiological effects that have been demonstrated in controlled human exposure and toxicological studies but cannot be evaluated in quantitative risk assessments, such as lung inflammation, increased airway responsiveness, and changes in host defenses. They also help in understanding the extent to which such impacts have the potential to be reduced by meeting alternative standards. As discussed in II.C.1.a of the 2010 proposal and II.A.3 above, these O_3-related physiological effects are plausibly linked to the increased morbidity seen in epidemiological studies (e.g., as indicated by increased medication use in asthmatics, school absences in all children, and emergency department visits and hospital admissions in people with lung disease).

[21] As noted in section II.C.1.b.above, the Administrator focused on alternative standards with different levels but the same form and averaging time as the primary standard set in 2008.

Estimates of the number of people likely to experience exposures of concern cannot be directly translated into quantitative estimates of the number of people likely to experience specific health effects, since sufficient information to draw such comparisons is not available -- if such information were available, these health outcomes would have been included in the quantitative risk assessment. Due to individual variability in responsiveness, only a subset of individuals who have exposures at and above a specific benchmark level is expected to experience such adverse health effects, and susceptible populations such as those with asthma are expected to be affected more by such exposures than healthy individuals.

For the reasons discussed in section II.C.1.b in the 2010 proposal and summarized above, the Administrator concluded that it is appropriate to focus on both the 0.060 and 0.070 ppm health effect benchmarks for her decision on the primary standard. In summary, the focus on these two benchmark levels reflects the following evidence-based considerations that raise concerns about adverse health effects likely occurring at levels below 0.080 ppm: (1) there is limited, but important, new evidence from controlled human exposure studies showing lung function decrements and respiratory symptoms in some healthy subjects at 0.060 ppm; (2) asthmatics are likely to have more serious responses than healthy individuals; (3) lung function is not likely to be as sensitive a marker for O_3 effects as lung inflammation; and (4) there is epidemiological evidence which reports associations between ambient O_3 concentrations and respiratory symptoms, emergency department visits, hospital admissions, and premature mortality in areas with O_3 levels that extend well below 0.080 ppm.

Based on the exposure and risk considerations discussed in detail in the 2007 Staff Paper and summarized above in section II.A.2, the Administrator noted the following important observations from these assessments: 1) there is a similar pattern for all children and asthmatic school age children in terms of exposures of concern at and above selected benchmark levels when estimates are expressed in

terms of percentage of the population; 2) the aggregate estimates of exposures of concern reflecting estimates for the 12 urban areas included in the assessment are considerably larger at and above the benchmark level of 0.060 ppm compared to the 0.070 ppm benchmark; 3) there is notable year-to-year variability in exposure and risk estimates with higher exposure and risk estimates occurring in simulations involving a year with generally poorer air quality in most areas (2002) compared to a year with generally better air quality (2004); and 4) there is significant city-to-city variability in exposure and risk estimates, with some cities receiving considerably less protection associated with air quality just meeting the same standard. As discussed above, the Administrator believed that it is appropriate to consider not just the aggregate estimates across all cities, but also to consider the public health impacts in cities that receive relatively less protection from alternative standards under consideration. Similarly, the Administrator believed that year-to-year variability should also be considered in making judgments about which standards will protect public health with an adequate margin of safety.

In addition, significant reductions in exposures of concern and risk have been estimated to occur across standard levels analyzed. The magnitudes of exposure and risk reductions estimated to occur in going from a 0.074 ppm standard to a 0.064 ppm standard are as large as those estimated to occur in going from the then current 0.084 ppm standard to a 0.074 ppm standard. Consequently, the reduction in risk that can be achieved by going from a standard of 0.074 ppm to a standard of 0.064 ppm is comparable to the risk reduction that can be achieved by moving from the 1997 O_3 standard, effectively a 0.084 ppm standard, to a standard very close to the 2008 standard of 0.075 ppm.

The Administrator also observed that estimates of exposures of concern associated with air quality just meeting the alternative standards below 0.080 ppm (i.e., 0.074, 0.070, and 0.064 ppm, the levels included in the assessment) are notably lower than estimates for alternative standards set at and above 0.080 ppm. As shown in Table 6-8 in the 2007 Staff Paper, just meeting a 0.080 ppm standard is

associated with an aggregate estimate of exposures of concern of about 13% of asthmatic children at and above the 0.070 ppm benchmark level, ranging up to 31% in the city with the least degree of protection in a year with generally poorer air quality, and an aggregate estimate of exposures of concern of about 40% of asthmatic children, ranging up to 63% in the city with the least degree of protection at and above the 0.060 ppm benchmark level. Based on the exposure estimates presented in Table 3 in the 2010 proposal (included above in this document as Table 1), she observed that standards included in the assessment below 0.080 ppm (i.e., 0.074, 0.070, and 0.064 ppm), are estimated to have substantially lower estimates of exposures of concern at and above the 0.070 ppm benchmark level. Similarly, she noted that exposures of concern at and above the 0.060 ppm benchmark associated with alternative standards below 0.080 ppm are appreciably lower than exposures associated with standards at or above 0.080 ppm, especially for standards set at 0.064 and 0.070 ppm.

As noted previously, the Administrator also recognized that the risk estimates for health outcomes included in the risk assessment are limited and that the overall health effects evidence is indicative of a much broader array of O_3-related health effects that are part of a "pyramid of effects" that include various indicators of morbidity that could not be included in the risk assessment (e.g., school absences, increased medication use, doctor's visits, and emergency department visits), some of which have a greater impact on susceptible populations. Consideration of such unquantified risks for this array of health effects, taken together with the estimates of exposures of concern and the quantified health risks discussed above, supported the Administrator's evidence-based conclusion that revising the standard level to a level well below 0.080 ppm will provide important increased public health protection, especially for susceptible populations such as people with asthma or other lung disease, as well as children and older adults, particularly those active outdoors, and outdoor workers

Based on the evidence- and exposure/risk-based considerations discussed above, the Administrator concluded that it is appropriate to set the level of the primary O_3 standard to a level well below 0.080 ppm, a level at which the evidence provides a high degree of certainty about the adverse effects of O_3 exposure in healthy people, to provide an adequate margin of safety for susceptible populations. In selecting a proposed range of levels, the Administrator believed it was appropriate to consider the following information: (1) the strong body of evidence from controlled human exposure studies evaluating healthy people at exposure levels of 0.080 ppm and above that demonstrated lung function decrements, respiratory symptoms, pulmonary inflammation, and other medically significant airway responses, as well as limited but important evidence of lung function decrements and respiratory symptoms in healthy people down to O_3 exposure levels of 0.060 ppm; (2) the substantial body of evidence from controlled human exposure and epidemiological studies indicating that people with asthma are likely to experience larger and more serious effects than healthy people; (3) the body of epidemiological evidence indicating associations are observed for a wide range of serious health effects, including respiratory-related emergency department visits and hospital admissions and premature mortality, across distributions of ambient O_3 concentrations that extend below the current standard level of 0.075 ppm, as well as questions of biological plausibility in attributing the observed effects to O_3 alone at the lower end of the concentration ranges extending down to background levels; and (4) the estimates of exposures of concern and risks for a range of health effects that indicate that important improvements in public health are very likely associated with O_3 levels just meeting alternative standards, especially for standards set at 0.070 and 0.064 ppm (the lowest levels included in the assessment), relative to standards set at and above 0.080 ppm.

The Administrator next considered what standard level well below 0.080 ppm would be requisite to protect public health, including the health of susceptible populations, with an adequate margin of

safety that is sufficient but not more than necessary to achieve that result. The assessment of a standard level calls for consideration of both the degree of risk to public health at alternative levels of the standard as well as the certainty that such risk will occur at any specific level. Based on the information available in the 2008 rulemaking, there is no evidence-based bright line that indicates a single appropriate level. Instead there is a combination of scientific evidence and other information that needs to be considered as a whole in making this public health policy judgment, and selecting a standard level from a range of potentially reasonable values.

As an initial matter, the Administrator considered whether the standard level of 0.075 ppm set in the 2008 final rule is sufficiently below 0.080 ppm to be requisite to protect public health with an adequate margin of safety. In considering this standard level, the Administrator looked to the rationale for selecting this level presented in the 2008 final rule, as summarized in section II.B above. In that rationale, EPA observed that a level of 0.075 ppm is above the range of 0.060 to 0.070 ppm recommended by CASAC, and that the CASAC Panel appeared to place greater weight on the evidence from the Adams studies and on the results of the exposure and risk assessments, whereas EPA placed greater weight on the limitations and uncertainties associated with that evidence and the quantitative exposure and risk assessments. Additionally, EPA's rationale did not discuss and thus placed no weight on exposures of concern relative to the 0.060 ppm benchmark. Further, EPA concluded that "[a] standard set at a lower level than 0.075 ppm would only result in significant further public health protection if, in fact, there is a continuum of health risks in areas with 8-hour average O_3 concentrations that are well below the concentrations observed in the key controlled human exposure studies and if the reported associations observed in epidemiological studies are, in fact, causally related to O_3 at those lower levels. Based on the available evidence, [EPA] is not prepared to make these assumptions" (73 FR 16483).

In reconsidering the entire body of evidence available in the 2008 rulemaking, including the Agency's own assessment of the epidemiological evidence in the 2006 Criteria Document, and placing significant weight on the views of CASAC, the Administrator concluded that important and significant risks to public health are likely to occur at a standard level of 0.075 ppm. She judged that a standard level of 0.075 ppm is not sufficient to provide protection with an adequate margin of safety. In support of this conclusion, the Administrator found that setting a standard that would protect public health, including the health of susceptible populations, with an adequate margin of safety should reasonably depend upon giving some weight to the results of the Adams studies and EPA's analysis of the Adams data, and to how effectively alternative standard levels would serve to limit exposures of concern relative to the 0.060 ppm benchmark level as well as to the 0.070 ppm benchmark level. The Administrator noted that EPA's risk assessment estimates comparable risk reductions in going from a 0.074 ppm standard to a 0.064 ppm standard as were estimated in going from the then current 0.084 ppm standard down to a 0.074 ppm standard for an array of health effects analyzed. These estimates include reductions in risk for lung function decrements in all and asthmatic school age children, respiratory symptoms in asthmatic children, respiratory-related hospital admissions, and non-accidental mortality.

Further, based on the exposure assessment estimates discussed above, the Administrator noted that for air quality just meeting a 0.074 ppm standard, approximately 27% of asthmatic school age children and 25% of all school age children are estimated to experience one or more exposures of concern at and above the 0.060 ppm benchmark level based on simulations for a year with generally poorer air quality; this estimate increases to about 50% of asthmatic and all children in the city with the least degree of protection. The Administrator judged that these estimates are large and strongly suggest significant public health impacts would likely remain in many areas with air quality just meeting a 0.075 ppm O_3 standard.

In light of these estimates and the available evidence, the Administrator agreed with CASAC's conclusion that important public health protections can be achieved by a standard set below 0.075 ppm, within the range of 0.060 to 0.070 ppm. In addition, based on both the evidence- and exposure/risk-based considerations summarized above, the Administrator concluded that a standard set as high as 0.075 would not be considered requisite to protect public health with an adequate margin of safety, and that consideration of lower levels is warranted. In considering such lower levels, the Administrator recognized that the CAA requires her to reach a public health policy judgment as to what standard would be requisite to protect public health with an adequate margin of safety, based on scientific evidence and technical assessments that have inherent uncertainties and limitations. This judgment requires making reasoned decisions as to what weight to place on various types of evidence and assessments and on the related uncertainties and limitations.

In reaching her proposed decision, the Administrator also considered the public comments that were received on the 2007 proposed rule (72 FR 37818). The Administrator noted that there were sharply divergent views expressed by two general sets of commenters with regard to considering the health effects evidence, results of exposure and risk assessments, and the advice of the CASAC panel. On one hand, medical groups, health effects researchers, public health organizations, environmental groups, and some state, tribal and local air pollution control agencies strongly supported a standard set within the range recommended by the CASAC. These commenters generally placed significant weight on the more recent evidence from controlled human exposure studies, down to the 0.060 ppm exposure level, as well as on the epidemiological studies and the results of the exposure and risk assessment conducted for the 2008 rulemaking. Many of these commenters took a more precautionary view and supported a standard set at 0.060 ppm O_3, the lower end of the CASAC recommended range. The Administrator noted that these views are generally consistent with her proposed conclusions. On the

other hand, another group of commenters primarily representing industry associations and businesses and some state environmental agencies, primarily expressed the view that the more recent evidence from controlled human exposure, the epidemiological studies, and the results of exposure and human health risk assessments were so uncertain that they did not provide a basis for making any changes to the then current 0.084 ppm O_3 standard set in 1997. This group of commenters generally argued that the health effects evidence newly available in the 2008 rulemaking, the results of the exposure and health risk assessments, and the advice of the CASAC were flawed. For the reasons discussed above, the Administrator did not agree with the latter group of commenters that essentially no weight should be placed on any of the new evidence or assessments that were available for consideration in the 2008 rulemaking.

Based on consideration of the entire body of evidence and information available in the 2008 rulemaking, including exposure and risk estimates, as well as the recommendations of CASAC, the Administrator proposed to set the level of the primary 8-hour O_3 standard to a level within the range of 0.060 to 0.070 ppm. A standard level within this range would reduce the risk of a variety of health effects associated with exposure to O_3, including the respiratory symptoms and lung function effects demonstrated in the controlled human exposure studies, and the respiratory-related emergency department visits, hospital admissions and mortality effects observed in the epidemiological studies. All of these effects are indicative of a much broader array of O_3-related health endpoints, such as school absences and increased medication use, that are plausibly linked to these observed effects. Depending on the weight placed on the evidence and information available in the 2008 rulemaking, as well as the uncertainties and limitations in the evidence and information, a standard could be set within this range at a level that would be requisite to protect public health with an adequate margin of safety.

In reaching this proposed decision, as discussed above, the Administrator focused on the nature of the increased public health protection that would be afforded by a standard set within the proposed range of levels relative to the protection afforded by the standard set in 2008. Having considered the public comments received on the 2007 proposed rule in reaching this proposed decision that reconsiders the 2008 final rule, the Administrator expressed interest in again receiving public comment on the benefits to public health associated with a standard set at specific levels within the proposed range relative to the benefits associated with the standard set in 2008.

At the request of EPA, the CASAC Ozone Review Panel for the Reconsideration of the 2008 NAAQS met to review the 2010 proposed decision on the level of the primary standard. The CASAC again fully supported the proposed range of 0.060 – 0.070 parts per million (ppm) for the 8-hour primary O_3 standard, noting that the range was justified by the scientific evidence as presented in the Air Quality Criteria for Ozone and Related Photochemical Oxidants (March 2006) and Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper (July 2007). The letter further stated the following strong, unanimous view:

> As stated in our letters of October 24, 2006, March 26, 2007 and April 7, 2008 to former Administrator Stephen L. Johnson,[22] CASAC unanimously recommended selection of an 8-hour average ozone NAAQS within the range proposed by EPA (0.060 to 0.070 ppm). In proposing this range, EPA has recognized the large body of data and risk analyses demonstrating that retention of the 2008 standard would leave large numbers of individuals at risk for respiratory effects and/or other significant health impacts including asthma exacerbations, emergency room visits, hospital admissions and mortality. (Samet, 2010)

2. Comments on the Proposed Decision

Section II.A above outlines the health effects evidence and exposure and risk assessments that were the basis for both the 2008 decision on the level of the primary standard, discussed above in

[22]See Letters from CASAC Chair Rogene Henderson, EPA-CASAC-07-001 (October 24, 2006), EPA-CASAC-07-002 (March 26, 2007) and EPA-CASAC-08-000 (April 7, 2008) respectively.

section II.B, and the 2010 proposed reconsideration of the 2008 decision, discussed above in section II.C.1. Significant comments received on the 2010 proposal with regard to the level of the primary standard are addressed in this section.

As an initial matter, in the 2010 proposal the Administrator noted that the 2008 final rule concluded that the 1997 primary O_3 standard was "not sufficient and thus not requisite to protect public health with an adequate margin of safety, and that revision is needed to provide increased public health protection" (73 FR 16472). Since the Administrator did not reopen the 2008 decision with regard to this issue, and comments on revising the 1997 primary O_3 standard were responded to in the 2008 rulemaking, EPA is not providing any further response to comments on the need to revise the 1997 primary O_3 standard in this rulemaking.

Significant or expanded new comments on the proposed level of the primary O_3 standard were received in a number of areas, and are responded to in this section and more fully in the 2011 Response to Comments document. EPA notes that many commenters essentially reiterated the scientific and technical comments on the evidence and the exposure and risk assessments that they had made in the 2008 rulemaking. These comments are addressed briefly here and more fully in the 2011 Response to Comments document.

Some commenters generally asserted that it was not appropriate for EPA to reach a different decision now based on the same information that was the basis for the 2008 decision, whereas other commenters asserted that the 2008 decision did not appropriately weigh the available information and that a different decision was supported by that information. Comments about the appropriateness of the reconsideration are discussed in section a below. Some commenters provided new comments on the evidence and assessments upon which the 2010 proposed decision on the level of the primary standard

was based as part of rationales supporting specific levels of the standard.[23] Comments about the evidence and exposure and risk assessments are discussed in sections b and c, respectively, below. Some commenters addressed the technical merits and conclusions of the 2009 Provisional Assessment. In addition, some commenters cited specific "new" scientific studies that were published too late to be included in the 2006 Criteria Document, including some that were not addressed in the Provisional Assessment, as a basis for their comments on the level of the standard. With regard to comments citing "new" studies, EPA notes, as discussed above in section I, that as in past NAAQS reviews, it is basing the final decision in this reconsideration on the studies and related information included in the Criteria Document that have undergone CASAC and public review and will consider newly published studies for the purposes of decision making in the next O_3 NAAQS review. Nonetheless, as discussed below in section d, EPA has provisionally evaluated these studies in the Provisional Assessment and/or in the 2011 Response to Comments document, and EPA finds that such studies do not materially change the conclusions reached in the Criteria Document.

a. Appropriateness of the Reconsideration

Section II.A.1 above provides a summary overview of the health effects evidence used by the Administrator to inform judgments about the degree of health protection that would be requisite for setting the final primary O_3 standard. With regard to the health effects evidence, new comments were received on whether it is appropriate or lawful to reconsider the 2008 decision on the primary O_3 standard based on the scientific and technical record from the 2008 rulemaking. More extensive comments, although not entirely new, were received on the role of the CASAC and its advice in the

[23]With respect to comments that expressed support for a specific standard level without a specific rationale, this final rule and the 2011 Response to Comments document provide EPA's response to those comments.

standard-setting process. Comments on the legality of the reconsideration are addressed in section I.E.2 above.

With regard to the scientific and policy bases for reconsidering the 2008 decision on the primary O_3 standard based on the scientific record of that review, sharply divergent comments were received from two general sets of commenters. Many public comments received on the 2010 proposal asserted that the O_3 standard set in 2008 is not adequate to protect public health, especially the health of sensitive groups, with an adequate margin of safety and that reconsideration of the 2008 decision based on the scientific record of that decision is appropriate. Other public comments received on the 2010 proposal asserted that the O_3 standard set in 2008 is adequate to protect public health, including the health of sensitive groups, with an adequate margin of safety and that reconsideration of the 2008 decision based on the same scientific record is not warranted.

Among those supporting the reconsideration of the 2008 decision were medical, public health, and disease and patient advocacy groups, including for example, the American Academy of Pediatrics, the American Medical Association, the American Thoracic Society (ATS), and the American College of Chest Physicians, American Public Health Association and the American Heart Association, as well as other similar organizations who, in a joint comment, supported the decision to reconsider the 2008 decision on the O_3 standard. In support of this position, the commenters made the point that the scientific and medical understanding of the mechanisms by which exposure to ambient O_3 pollution impacts human health grew considerably stronger between 1997 and 2007, and that extensive reviews of the body of evidence confirmed that the primary standard set in 2008 is not sufficient to protect public health with an adequate margin of safety. These commenters expressed the view that the scientific evidence in the record of the 2008 decision supports setting a primary standard more protective than 0.075 ppm, and included a discussion of individual clinical and epidemiological studies of respiratory

and cardiovascular morbidity effects, and mortality effects occurring below this level as well as a discussion of the size of the sensitive populations in support of this view.

Similar conclusions were also expressed in a joint comment (ALA et al., 2010) by the American Lung Association (ALA), Earthjustice, Environmental Defense Fund, Sierra Club and Natural Resources Defense Council. These groups all supported the reconsideration of the 2008 decision on the basis of the scientific record for that decision. They expressed the view that reconsideration of the 2008 standards is warranted by the law and science for four reasons: (1) the extensive evidence in the record for the 2008 review shows that a 0.075 ppm standard allows adverse health effects affecting many thousands of Americans each year - including premature death and serious morbidity effects such as asthma hospitalizations and asthma attacks; (2) in 2008, EPA failed to provide a rational justification for adopting a standard well above the level recommended by CASAC and above levels shown by science to be associated with adverse effects; (3) CASAC's objections warrant EPA's reconsideration of the primary standard; and, (4) in an intervening decision of the U.S. Court of Appeals for the District of Columbia Circuit in American Farm Bureau Federation v. EPA, 559 F.3d 512 (D.C. Cir. 2009), the Court rejected EPA's rationales for refusing to adopt stronger NAAQS for particulate matter, rationales that were similar to those relied upon in the 2008 O_3 final rule.

With regard to the first point, these commenters note that numerous peer-reviewed studies show adverse health effects at 8-hour O_3 levels down to and below 0.060 ppm, including controlled human exposure studies showing adverse effects in healthy individuals as low as 0.060 ppm and numerous epidemiological studies showing morbidity and mortality effects at levels below 0.060 ppm. Therefore, these commenters assert, the 0.075 ppm standard adopted in 2008 which allows these documented adverse effects to occur is not requisite to protect public health and cannot provide a margin of safety as the CAA requires. These commenters also point out that this extensive record led CASAC to

unanimously recommend a standard in the range of 0.060 to 0.070 ppm, finding "overwhelming" scientific evidence for their recommendation.

With regard to the second point, that in 2008 EPA failed to provide a rational justification for adopting a standard well above the level recommended by CASAC and above levels shown by science to be associated with adverse effects, these commenters expressed the view that the CAA requires EPA to set standards at a level at which there is "an absence of adverse effect" on sensitive individuals. Therefore, these commenters conclude that the 2008 rationale, which they contend is based upon substantially reducing what they assert are "arbitrarily" selected exposures of concern, and the discretion claimed by EPA to set the standard at 0.075 ppm "because there is no bright line clearly directing the choice of level" is not a rational basis for allowing adverse health effects to occur at lower levels. They assert that EPA failed to provide a rational explanation as to why the evidence was too limited below 0.075 ppm in the face of peer-reviewed studies showing health effects at those levels, or why it concluded that whatever uncertainty existed at 0.064 ppm or lower was so great as to render such health effects improbable. Finally these commenters note that EPA in 2008 did not explain how a standard set at 0.075 ppm included a margin of safety as required by the CAA. For these reasons, commenters found that EPA's stated justifications for rejecting CASAC's recommendations were arbitrary and unlawful.

With respect to the third point, commenters noted that CASAC took the unusual step of writing to EPA to protest the Agency's final decision on the O_3 primary standard as being contrary to its unanimous recommendation and not sufficiently protective of public health, and also to state that it failed to ensure an adequate margin of safety.

Finally, these commenters took note of an intervening decision of the U.S. Court of Appeals for the District of Columbia Circuit in *American Farm Bureau Federation v. EPA*, 559 F.3d 512 (D.C. Cir. 2009) in which the Court rejected similar Agency rationales for refusing to adopt stronger NAAQS for

particulate matter. They expressed the view that in that final decision, EPA rejected CASAC's recommendation on the level of the standard on the ground that EPA found it more "appropriate" to discount evidence supporting a more protective standard. The Court found such assertions did not amount to an adequate explanation of why the standard chosen was requisite to prevent adverse health effects, and that EPA's approach was unreasonable, in light of the Agency's obligation to explain how the standard it set would protect not only average healthy individuals, but also sensitive citizens. These commenters assert that in the 2008 O_3 final rule, the Agency rejected as too limited the evidence from the Adams study showing statistically significant lung decrements in healthy people at O_3 levels as low as 0.060 ppm, without explaining why this evidence was too limited, and without explaining why even more serious health effects would not be expected at 0.060 ppm in more sensitive people. These commenters expressed the view that the 2008 O_3 decision was particularly deficient in that it failed to incorporate impacts on some susceptible populations, such as outdoor workers, into the analyses supporting the rulemaking. The *Farm Bureau* Court further held that EPA had failed to show that its chosen standard would provide an adequate margin of safety because, among other things, the Agency provided no explanation of how the standard would adequately reduce risks to sensitive people. In the 2008 final O_3 rule, these commenters asserted that there was no reasoned explanation of how a 0.075 ppm primary O_3 standard would provide an adequate margin of safety. In conclusion, these commenters noted that the *Farm Bureau* decision establishes that EPA cannot rely on the sorts of conclusory assertions and generalizations it provided in the 2008 O_3 NAAQS decision to reject more protective standards recommended by CASAC and supported by peer-reviewed evidence. These commenters expressed the view that reconsideration of the 2008 action to ensure that EPA's O_3 NAAQS decision conforms with the ruling in *Farm Bureau* is plainly warranted.

The medical, public health, disease and patient advocacy groups, and environmental group commenters discussed above also cited the role and advice of CASAC in their support of reconsidering the 2008 decision on the primary O_3 standard. In their comments these groups noted that CASAC is the Congressionally-chartered advisory committee specifically charged by the CAA to advise the EPA Administrator on the review of the official limits on the NAAQS. They also noted that Section 109 of the CAA requires CASAC to recommend to the EPA Administrator any new NAAQS and revision of existing criteria and standards as may be appropriate, and that revisions of the standards must by law be based solely on the science.

These commenters also noted that EPA's CASAC O_3 Review Panel consists of 23 distinguished scientists representing a broad range of disciplines and perspectives. The panel included some of the nation's leading experts in O_3 air pollution science and health, who conducted a very thorough review of the adequacy of EPA's scientific assessments. They expressed the view that it is remarkable for such a diverse group of scientists to agree upon anything, but in this case they achieved consensus on several key issues in the review - one of them being that EPA should set the 8-hour O_3 standard much lower - in the range of 0.060 to 0.070 ppm - to adequately protect public health. They also expressed the view that it is highly unusual - perhaps unprecedented - for the CASAC to make such strong and unanimous recommendations.

Commenters from the medical, public health, disease and patient advocacy and environmental groups cited above all supported a primary standard set at the level of 0.060 ppm O_3. These commenters asserted that the primary standard should be set at 0.060 ppm O_3 to protect against all known and anticipated adverse health effects and to provide a margin of safety as required by the CAA.

The EPA agrees with these commenters' conclusions regarding the need to reconsider the 2008 decision on the primary O_3 standard. The scientific evidence relating health effects to O_3 exposure and

the conclusions reached about this evidence, noted by these commenters, were similar to that assessed in the 2006 Criteria Document, 2007 Staff Paper, and the 2010 proposal. EPA agrees that this information provides a basis for concluding that the 8-hour primary O_3 standard of 0.075 ppm is not adequately protective of public health, that the 2008 decision should be reconsidered, and that the primary O_3 standard should be set at a more protective level. As discussed in section I.E.1 above, the Administrator took note of the April 2008 CASAC letter expressing strong, unanimous disagreement with EPA's 2008 decision on the primary O_3 standard. Moreover, the Administrator also noted the adverse ruling by the U.S. Court of Appeals for the District of Columbia Circuit on the PM NAAQS decision cited by these commenters. Based on her review of the information discussed in section I.E.1, which includes the points raised by these commenters, in January 2010 the Administrator initiated a rulemaking to reconsider the level of the primary O_3 standard.

However, for reasons discussed below in more detail in the comments on the strength of the evidence from controlled human exposure and epidemiology studies, the uncertainties related to these types of studies, the rationale for the final decision in section II.C.3, and in the 2011 Response to Comments document, EPA disagrees with these commenters' views that the evidence and assessments that served as the basis for the 2008 decision clearly demonstrate adverse health effects in a significant fraction of the susceptible population so as to require EPA to set the O_3 standard at 0.060 ppm or below.

The majority of State and local air pollution control authorities, and multi-agency air pollution control organizations, who commented on the 2010 reconsideration proposal, supported the reconsideration of the 2008 decision on the primary O_3 standard, as did the National Tribal Air Association (NTAA). State environmental agencies that supported the reconsideration of the 2008 rulemaking include agencies from: California; Colorado; Connecticut; Iowa; Illinois; Kentucky; Michigan; Minnesota, Mississippi; Nebraska; New Hampshire; New Mexico; New York; Oklahoma;

Oregon; Pennsylvania; Utah; Washington and Wisconsin. State organizations, including the National Association of Clean Air Agencies (NACAA), Northeast States for Coordinated Air Use Management (NESCAUM), Ozone Transport Commission (OTC), and the Western States Air Resources Council (WESTAR) also supported reconsideration of the O_3 standard set in 2008. All of these commenters supported revisions to the 0.075 ppm standard, with most commenters supporting the proposed range (0.060 to 0.070 ppm O_3), and almost all of the others supporting either a "health-science based standard setting process," or the upper end of the proposed range (0.070 ppm O_3).[24] The American Association of State Highway and Transportation Officials, Association of Metropolitan Planning Organizations, and National Association of Development Organizations also supported setting the primary O_3 standard at the upper end of the proposed range (0.070 ppm O_3). One State, California, supported the lower end of the proposed range (0.060 ppm O_3), indicating that a national standard set at that level would be comparable in protectiveness to the California State O_3 standard, which was developed through an open public review process that included independent scientific peer review.

Many of these agencies and organizations cited the advice of CASAC in support of their position. The Virginia Department of Environmental Quality (VA DEQ) notes that "…the CASAC findings do clearly indicate that the upper end of the proposed range (0.070 parts per million) is fully protective of public health with an adequate margin of safety as required by the Clean Air Act" as part of the rationale for recommending that if a more stringent standard within the proposed range is going to be adopted, it should be set at 0.070 ppm O_3 (VA DEQ, 2010, pp.1 and 3). The Washington Department

[24]Almost all State agencies, including some that did not express a view on reconsideration of the 2008 decision or the level of the primary standard, did express views on the designation schedule and other implementation-related issues. Comments on Appendix P and exceptional events were considered and addressed in section V below, and the designations schedule in section VI below, and all of these comments are addressed more fully in the 2011 Response to Comments document. Comments on ambient monitoring are discussed in section VII below, but these comments are addressed in the O_3 monitoring rulemaking. Comments on other implementation-related issues were considered in the development of the implementation rule.

of Ecology (WA Ecology), which concurred with WESTAR and supported the use of a science-based process for setting the standards, stated that "…we would like to emphasize our strong support for a primary ozone standard that is protective of public health. We note that the Clean Air Scientific Advisory Committee has reaffirmed its support for the range for the primary standard being considered by EPA" (WA Ecology, 2010, p.1 and p.3). The Iowa Department of Natural Resources (IDNR) and Department of Public Health (IDPH), which supported the proposed range, expressed the view that:

> This level is the range recommended by CASAC and appears to be protective of human health. There is some uncertainty in the level that would be protective of the health of sensitive individuals, such as asthmatics. Because of this, the IDNR and the IDPH recommend that EPA begin to collect additional data to better determine if there is a level of short-term exposure to ozone that would not significantly impact the health of sensitive individuals. This additional data will help EPA to determine if any adjustment in the 8-hour primary ozone standard will be needed in the future (IDNR, IDPH, 2010, p.3).

The EPA agrees with the majority of State and local air pollution control authorities, and multi-agency air pollution control organizations, who commented that the scientific evidence and technical assessments provide a basis for finding that the 8-hour primary O_3 standard of 0.075 ppm is not adequately protective of public health, that the 2008 decision should be reconsidered, and that the primary O_3 standard should be set at a more protective level.

Another group of commenters, mainly representing industry associations and businesses, opposed the reconsideration of the 2008 decision on the primary O_3 standard. These views were extensively presented in comments from the American Petroleum Institute (API), the National Association of Manufacturers (NAM), and in comments from other industry and business associations including, for example: Exxon Mobil Corporation; the American Electric Power Service Corporation (AEPSC); the American Forest & Paper Association (AF&PA) and American Wood Council (AWC);

the American Chemistry Council (ACC); the Alliance of Automobile Manufacturers (AAM); and the Utility Air Regulatory Group (UARG).

Most of these commenters expressed strong views that EPA's reconsideration of the 2008 O_3 rule was unlawful, that the Agency lacks the authority to reconsider the 2008 rule, and that section 109(d) precludes any revisions other than those conducted during a periodic review that includes a review and issuance of updated air quality criteria as well as a review of the NAAQS. These commenters also argued the reconsideration is unlawful because it is not based on the most current science since the 2006 Criteria Document is now four years old, and that the 2009 Provisional Assessment does not cure this flaw. We respond to these comments in section I.E.2 above. Some of these commenters also provided extensive comments that were critical of the Provisional Assessment, comparing the Provisional Assessment unfavorably to a Criteria Document or Integrated Science Assessment in terms of comprehensiveness, external peer-review, and its role in the reconsideration of the 2008 decision on the O_3 primary standard. With regard to the scientific and technical merit of the Provisional Assessment, several commenters state that the assessment is flawed. They also expressed the view that the Provisional Assessment does not accurately reflect the latest science since it overlooks several significant "new" scientific studies, does not thoroughly assess the studies it does summarize, and omits consideration of new information concerning a key issue in the 2008 review, background O_3 concentrations. We address all of these comments in section II.C.2.d below. These commenters also commented on whether reconsideration of the 2008 decision on the primary O_3 standard based on the scientific record from the 2008 rulemaking is warranted, and raised concerns about the role of the CASAC and its advice in the standard-setting process. These comments are addressed below. The entire body of comments is addressed more fully in the 2011 Response to Comments document.

Industry commenters asserted that the scientific evidence the Administrator relied on in 2008 when the 0.075 ppm primary O_3 NAAQS was promulgated -- human clinical studies, epidemiological studies, studies regarding sensitive subpopulations, and the risk and exposure assessments -- do not support revising the primary NAAQS to make it more stringent at this time. These commenters asserted that the Agency should maintain the primary O_3 standard at 0.075 ppm, set in the 2008 rule, because EPA does not have a strong justification for changing the 2008 standard so soon, and it relied on the same record.[25] In support of this view, these commenters focused on issues and concerns that were raised in 2007, stating that the Agency has: inappropriately based its decision on two clinical studies of respiratory effects at 0.060 ppm O_3 by Adams which yielded lung function decrements that were not statistically significant, reported respiratory symptoms among subjects that were not adverse, and which were the subject of a controversial analysis conducted by Agency staff; relied on the results of epidemiological studies that were inconsistent and unrepresentative of the populations studied; cited studies that focused on asthmatics as a sensitive subpopulation which did not show that asthmatics were more susceptible to O_3 exposure than the Agency believed in 1997 during the previous NAAQS review; and relied upon risk and exposure assessments that were severely flawed and overestimated risk that would remain upon attainment of the 1997 O_3 NAAQS. Some commenters expressed the view that the reconsideration of the 2008 O_3 NAAQS decision is not based on judgments about the scientific evidence, but reflects a different policy conclusion. The API argues that "[u]se of reconsideration to reach a politically-driven judgment to lower the NAAQS would set an unfortunate precedent for future EPA Administrators to conduct an endless and arbitrary series of reconsiderations" (API, 2010, p.2).

[25]Some of these commenters reiterated their position that the scientific record on which the 2008 final rule and the 2010 reconsideration proposal rely fails to support any revision of the 1997 primary and secondary O_3 NAAQS that made those standards more stringent. As noted above, since the Administrator did not reopen the 2008 decision with regard to this issue, and comments on revising the 1997 primary O_3 standard were responded to in the 2008 rulemaking, EPA is not providing any further response to comments on the need to revise the 1997 primary O_3 standard in this rulemaking.

Several State and local air pollution control authorities and an organization of counties did not support the reconsideration of the 2008 decision on the primary O_3 standard in their comments on the proposal. These commenters included agencies from: Indiana, Ohio, South Dakota, Texas, and West Virginia, the National Association of Regional Councils and the National Association of Counties. These commenters generally supported retaining the 2008 primary O_3 standard and waiting for the next periodic O_3 NAAQS review to consider revision the 2008 standard. Many of these commenters argued that the primary O_3 standard set in 2008 will provide improvements in air quality until the next review. The Indiana Department of Environmental Management (IDEM) expressed the view that: "Over the next three years, continuing to implement the current standard will lead to continuing improvements in air quality focused on the areas with the highest levels of pollution and thus provide the maximum public health and welfare improvements" (IDEM, 2010, p. 1). While most of these commenters also focused on implementation and economic issues to support their position, some expressed concerns about health evidence, including the weight placed on the Adams studies and uncertainties associated with the epidemiological studies, including exposure measurement error, and the uncertainties associated with the human exposure and health risk assessments.

The EPA strongly disagrees with these commenters' conclusions regarding the need to reconsider the 2008 decision on the primary O_3 standard. EPA notes here that most of the issues and concerns raised by these commenters on the 2010 proposed rule concerning the strength of the evidence from controlled human exposure and epidemiology studies, the uncertainties related to these types of studies, and the consistency and coherence in the overall body of evidence are essentially restatements of issues and concerns raised during the development and review of the 2006 Criteria Document, the 2007 Staff Paper and associated analyses, and in comments on the 2007 Proposed Rule. Most of these issues and concerns were presented to the CASAC Panel and were the subject of CASAC deliberation

during its review of the Criteria Document, Staff Paper, and technical assessments. EPA presented and the CASAC Panel reviewed in detail the health effects evidence, the methods used and estimates provided by the exposure and health risk assessments, and the conclusions and policy judgments drawn from the evidence and exposure and health risk assessments discussed in these documents. For the reasons discussed in section I.E above, in the 2010 reconsideration proposal discussed in section II.C.1 above, and in the rationale for the final decision in section II.C.3 of this final rule, EPA continues to believe that this information provides a basis for concluding that the 8-hour primary O_3 standard of 0.075 ppm is not adequately protective of public health, that the 2008 decision should be reconsidered, and that the primary O_3 standard should be set at a more protective level. In addition, EPA continues to conclude that the importance of the O_3 NAAQS to public health weighs heavily in favor of reconsidering parts of the 2008 final rule now, based on the scientific and technical information upon which the 2008 final rule was based.

Several industry commenters argued that CASAC had gone beyond its statutory role by providing policy advice to the Administrator. The commenters asserted that determining the requisite level of the NAAQS needed to protect public health with an adequate margin of safety is a policy judgment that is in the hands of the Administrator. By repeatedly providing input on the appropriate level of the standard, commenters argued that CASAC was attempting to transform its role from an advisory body providing scientific and technical advice to one that also provides policy advice.

The EPA disagrees with this comment. The plain language of the CAA provides that CASAC shall review air quality criteria and then "shall recommend to the Administrator any . . . revisions of existing criteria and standards as may be appropriate" under the CAA. The CAA unambiguously states that CASAC shall make recommendations regarding revisions to standards. CASAC was clearly acting within the scope of its duties when it made recommendations to the Administrator regarding the

appropriate level of the O_3 NAAQS. Even if CASAC's recommendations regarding the level of the standard are characterized as policy advice, the statutory language quoted above expressly states that CASAC is required by the CAA to provide such advice regarding revisions to the standards. CASAC did not transform its role in the NAAQS process but was instead acting pursuant to its statutory directive. We also note that the scope of CASAC's advice here is consistent with the scope of its advice in other NAAQS rulemakings.

Several commenters argued that CASAC overstepped its role in sending the Administrator an unsolicited letter following the March 2008 decision. Commenters argued the statue does not provide for such post-decision advice and that EPA could not rely on the letter.

The Administrator considered CASAC's post-decision letter in deciding whether to reconsider the March 2008 final rule. The Administrator did not consider the post-decision letter in determining whether the March 2008 final rule met the requirements of CAA § 109. The decision on the revisions to the NAAQS necessary to meet the requirements of the CAA was based on the scientific and technical record that existed at the time of the March 2008 decision. EPA notes also that the statute is silent on the specific timing of CASAC advice and does not prohibit post-decision advice from CASAC. It is appropriate and reasonable to consider input from CASAC regardless of when it is received.

Several commenters argued that the Administrator cannot simply defer to CASAC in reaching a decision about the NAAQS. They argued the Administrator must make her own judgment about the NAAQS. In their view, the Administrator has simply adopted CASAC's recommendations without exercising her own policy judgment.

While the Administrator considered the advice of CASAC in reaching her decision, as explained in detail in this final rule, the Administrator independently considered the scientific and technical information in the record. The fact that the Administrator's judgments are consistent with the advice

CASAC has provided does not mean the Administrator has simply deferred to CASAC. The final decisions in this rule are the Administrator's judgments of what is necessary to meet the requirements of the CAA.

b. Consideration of Health Effects Evidence

More specific comments on the evidence and EPA's responses are discussed in this section. Section II.C.2.b.i contains comments on evidence from controlled human exposure studies; section II.C.2.b.ii contains comments on evidence from epidemiological studies, including interpretation of the evidence and specific methodological issues. Comments on evidence pertaining to susceptible populations for O_3-related effects can be found in section II.C.2.b.iii below. EPA notes here that most of the issues and concerns raised by commenters concerning the health effects evidence, including both the interpretation of the evidence and specific technical or methodological issues, were essentially restatements of issues raised during the review of the 2006 Criteria Document and the 2007 Staff Paper. Most of these issues were highlighted and thoroughly discussed during the review of these documents by the CASAC. Moreover these issues were considered in the development of the 2010 reconsideration proposal and thus are concisely summarized in the following sections. More detailed responses related to the interpretation of the health effects evidence and its role in the decision on the level of the primary O_3 NAAQS are contained in the 2011 Response to Comments document.

i. Evidence from Controlled Human Exposure Studies

As noted in the overview of health effects evidence, section II.A.1 above, two new controlled human-exposure studies (Adams, 2002, 2006) were available for the 2008 review that examined respiratory effects associated with prolonged O_3 exposures at levels at and below 0.080 ppm, which was the lowest exposure level that had been examined in the last review. One group of commenters that included national environmental and public health organizations (e.g., ALA et al., 2010) that supported

the reconsideration of the 2008 final decision, agreed with EPA's analysis and interpretation of the Adams data. These commenters expressed the view that the Adams studies provide evidence of effects at lower concentrations than had previously been reported. They note that Adams, while finding small group mean changes at 0.060 ppm, reported total subjective symptom scores that reached statistical significance (relative to pre-exposure) at 5.6 and 6.6 hours, with the triangular exposure scenario, and that pain on deep inspiration values followed a similar pattern to total subjective symptoms scores. In addition, Adams (2002) reports that "some sensitive subjects experience notable effects at 0.060 ppm," based on a greater than 10% reduction in FEV_1. These commenters asserted that the responses of more responsive individuals are more important than group mean responses and that when the Adams (2002, 2006) study data are corrected for the effects of exercise in clean air, 7 percent of subjects experience FEV_1 decrements greater than 10% at the 0.040 and 0.060 ppm exposure levels. They expressed the view that while 2 of 30 tested subjects responding at the 0.060 ppm level may seem like a small number, a 7% response rate is far from trivial. Seven percent of the U.S. population is 21 million people (ALA et al., 2010, p.38). Noting that the subjects in the Adams studies were all healthy adults, these groups expressed concern that "larger decrements in FEV_1 would be expected in more susceptible populations" (ALA et al., 2010, p.38). These commenters generally supported EPA's analysis of the Adams data, stating that EPA has undertaken a careful analysis of the underlying data in the Adams studies to assess the change in FEV_1 following exposure to 0.060 ppm O_3 and filtered air, and concluding that the EPA analysis "…employs the standard approach used by other researchers, and supported by CASAC" (ALA et al., 2010, p.36). These commenters conclude by asserting that the chamber studies provide "powerful evidence of the need to lower the 8-hour ozone standard to 60 ppb or below" (ALA et al., 2010, p.40).

The EPA generally agrees with the comments summarized above, while placing more emphasis on the limited nature of the evidence addressing O_3-related lung function and respiratory symptom

responses at the 0.060 ppm exposure level. As characterized in the 2010 reconsideration proposal, EPA's analysis of the data from the most recent Adams study (Adams, 2006) shows small group mean decrements in lung function responses to be statistically significant at the 0.060 ppm exposure level, while acknowledging that the author's analysis did not yield statistically significant lung function responses. The Adams studies (2002, 2006) report a percentage of subjects experiencing lung function decrements (≥ 10%) at the 0.060 ppm exposure level. While EPA uses the combined results of numerous studies to estimate the fraction of individuals expected to be affected by O_3-related lung function decrements, EPA disagrees with these commenters that the percent of subjects experiencing FEV_1 decrements greater than 10% in a single study of 30 subjects is by itself generalizable to the U.S. population. Because there are only two studies available from one investigator (Adams 2002, 2006), and the health effects at the 0.060 ppm exposure level have not been replicated by other investigators in other studies, EPA concluded that these studies provide limited evidence of O_3-related lung function decrements and respiratory symptoms at this lower exposure level.

The second group of commenters, including industry commenters or industry organization commenters who opposed reconsideration of the 2008 standard, raised many concerns about the role of the Adams studies, EPA's analysis of the Adams (Adams 2002, 2006) data, and the new weight placed on the Adams data in the 2010 proposal. Many of these comments were restatements of issues or concerns raised in the 2008 review. With regard to the results reported by Adams (2002, 2006), these commenters expressed the view that results of these studies do not support the presence of health effects below 0.080 ppm and that the group mean FEV_1 decrement measured at 0.060 ppm was small, less than 3%. With respect to the larger decrements in FEV_1 (≥10%) experienced by some subjects in the Adams studies, these commenters stated the view that such decrements would not be considered adverse in healthy individuals, and that:

> EPA's new adversity criterion indicates that a small transient change in pulmonary function such as a 10% or greater decrease in FEV_1 alone, in the absences of corresponding symptoms, is adverse. This definition contrasts with the guidance from the American Thoracic Society which does not consider small changes in pulmonary function, alone, as adverse (ATS, 2002) (NAM, 2010a, Attachment 2, p.5)

They stated that the data from Adams (2002, 2006) on O_3 levels below 0.080 ppm were too limited to support a revised standard, and noted that responses reported in the Adams studies at 0.080 ppm were similar to responses reported previously (Horstmann et al., 1990 and McDonnell et al., 1991), and therefore, provided no new information on O_3 that was not known at the time of EPA's 1997 review (Exxon Mobil, 2010, Detailed Comment, pp.5 - 6). These commenters further noted that the Agency extensively reviewed both the studies and the public comments filed with respect to the Adams studies during the review of the standards completed in 2008. These commenters asserted that:

> In this reconsideration, however, EPA attempts to draw expansive new conclusions based on the Adams studies, suggesting that they support both the presence of a "smooth response curve" for exposures below 0.080 ppm and that the studies, in an unqualified manner, "lower the lowest observed effects level found in controlled human exposure studies." (ACC, 2010, p.14)

These commenters disagreed with EPA's conclusion that there is a statistically significant group mean decrease in FEV_1 at 0.060 ppm O_3, which was based on an EPA analysis of the data at the 6 hour time point using a t-test. They raised one or more of the following concerns about EPA's analysis of the Adams data: (1) EPA's analysis was not published or peer-reviewed, and therefore neither the scientific community nor the public was afforded opportunity to appropriately review the analysis (Exxon Mobil, 2010, Detailed Comment, p.6); (2) EPA has misinterpreted the studies of Dr. Adams, and over his objections used a different analytical methodology to reach a different conclusion; and, (3) EPA's analysis did not employ an appropriate statistical test; the ANOVA statistical test employed by Adams was preferred over the statistical test used in EPA's analysis (paired t-test).

First, EPA agrees that the group mean lung function decrement observed in the Adams study at the 0.060 ppm exposure level is relatively small. However, as EPA noted in the 2007 Staff Paper, "the CASAC Panel felt that more emphasis should be placed on numbers of subjects in controlled human exposure studies with FEV_1 decrements greater than 10%, which can be clinically significant, rather than on relatively small average decrements" (Staff Paper, p.6-43). The magnitude of changes in the group mean do not address whether a subset of the population is at risk of health effects. The clinical evidence to date makes it clear that there is significant variability in responses across individuals, so it is important to look beyond the group mean to the response of subsets of the group to evaluate the potential impact for sensitive or susceptible parts of the population. The CASAC Panel shared this view stating that "… the evidence suggests that prolonged exposure to 60 ppb ozone causes a general shift in the distribution of FEV_1 towards lower values. Although the mean decrement is less than 3% and would not be considered clinically important, the shift to the right in the distribution pushes a fraction of the subjects (7%) into the region of clinical importance (>10%) decrement)." (Samet, 2011, p.7) As discussed below, EPA agrees with the views of both EPA staff and the CASAC panel that this level of response may not represent an adverse health effect in healthy individuals but does represent a level that should be considered adverse for asthmatic individuals.

The EPA strongly rejects commenter's assertions that it has used "new adversity criterion" in this reconsideration review. The ATS guidelines have been consistently applied throughout the 2008 review and, thus, in the reconsideration of the 2008 decision. While recognizing that perceptions of "medical significance" and "normal activity" may differ among physicians, lung physiologists and experimental subjects, the ATS (1985) defined adverse respiratory health effects as "medically significant physiologic changes generally evidenced by one or more of the following: (1) interference with the normal activity of the affected person or persons, (2) episodic respiratory illness, (3)

incapacitating illness, (4) permanent respiratory injury, and/or (5) progressive respiratory dysfunction.'' During the 1997 review, it was concluded that there was evidence of causal associations from controlled human exposure studies for effects in the first of these five ATS-defined categories, evidence of statistically significant associations from epidemiological studies for effects in the second and third categories, and evidence from animal toxicology studies, which could be extrapolated to humans only with a significant degree of uncertainty, for the last two categories.

While O_3 has been associated with effects that are clearly adverse, such as emergency department visits, hospital admissions, and premature mortality, application of these guidelines, in particular to the least serious category of effects related to ambient O_3 exposures, involves judgments about which medical experts on the CASAC panel and public commenters have expressed diverse views in the past. It is these effects that are the focus of this comment, and have been an important focus in the 2008 review and the 1997 review of the primary O_3 standard. To help frame such judgments, EPA staff have defined specific ranges of functional responses (e.g., decrements in FEV_1 and airway responsiveness) and symptomatic responses (e.g., cough, chest pain, wheeze), together with judgments as to the potential impact on individuals experiencing varying degrees of severity of these responses, that have been used in previous NAAQS reviews. These ranges of pulmonary responses and their associated potential impacts are summarized in Tables 3-2 and 3-3 of the Staff Paper (EPA, 2007).

In the context of standard setting, CASAC indicated that a focus on the mid- to upper-end of the range of moderate levels of functional responses (e.g., FEV_1 decrements $\geq$ 15% but < 20%) is appropriate for estimating potentially adverse lung function decrements in active healthy people. However, for people with lung disease, CASAC indicated that even moderate functional (e.g., FEV_1 decrements $\geq$ 10% but < 20%, lasting up to 24 hours) or symptomatic responses (e.g., frequent spontaneous cough, marked discomfort on exercise or with deep breath, wheeze accompanied by

shortness of breath, lasting up to 24 hours) would likely interfere with normal activity for many individuals, and would likely result in more frequent use of medication.

For people with lung disease, large functional responses (e.g., FEV_1 decrements $\geq$ 20%, lasting longer than 24 hours) and/or severe symptomatic responses (e.g., persistent uncontrollable cough, severe discomfort on exercise or deep breath, persistent wheeze accompanied by shortness of breath, lasting longer than 24 hours) would likely interfere with normal activity for most individuals and would increase the likelihood that these individuals would seek medical treatment. In the context of standard setting, the CASAC indicated (Henderson, 2006c) that a focus on the lower end of the range of moderate levels of functional responses (e.g., FEV_1 decrements $\geq$ 10%) is most appropriate for estimating potentially adverse lung function decrements in people with lung disease.

In judging the extent to which these impacts represent effects that should be regarded as adverse to the health status of individuals, an additional factor that has been considered in previous NAAQS reviews as well as the 2008 review is whether such effects are experienced repeatedly during the course of a year or only on a single occasion. While some experts would judge single occurrences of moderate responses to be a "nuisance," especially for healthy individuals, a more general consensus view of the adversity of such moderate responses emerges as the frequency of occurrence increases. This is the reason that EPA estimates and focuses not only on the risk of single, but also on repeated occurrences of moderate lung function decrements in all and asthmatic school-age children.

Second, EPA notes that its analysis of the Adams (2006) study was prepared in response to the issues and analysis raised by a public commenter who made a presentation to the CASAC Panel at its March 5, 2007 teleconference. EPA replicated the analysis and addressed issues raised in these public comments concerning the statistical significance of 0.060 ppm O_3 exposure on lung function response in the Adams (2006) publication. EPA documented its response in a technical memorandum (Brown,

2007), which was placed in the rulemaking docket prior to publication of the 2007 proposal. EPA has clearly stated that the additional statistical analyses conducted by both the public commenter and by EPA staff do not contradict or undercut the statistical analysis presented by Dr. Adams in his published study, as EPA and the author were addressing different questions. While the author of the original study was focused on determining whether the changes observed on an hour by hour basis were statistically significant for different exposure protocols, EPA's analysis was focused on the important policy question of whether there was a statistically significant difference in lung function decrement before and after the entire 6.6 hour exposure period between the 0.060 ppm exposure protocol and filtered air.

Third, EPA disagrees with concerns raised by Dr. Adams and other commenters asserting that EPA used an inappropriate statistical approach to analyze lung function responses at 0.060 ppm. In the Adams (2006) study, lung function response data for each subject were available for exposure to filtered air and exposure to 0.060 ppm O_3. The distribution of lung function responses was generally symmetrical. For normally distributed data, a paired t-test is an appropriate and commonly applied statistical test of the null hypothesis that the difference between two responses (e.g., due to exposure to filtered air and O_3) measured in the same individuals has mean value of zero. Members of the CASAC Panel on the March 5, 2007 teleconference supported the use of this statistical approach (i.e., paired *t* test) in the analysis prepared by the public commenter, which was the same approach later used in EPA's analysis, as the preferred method for analyzing the pre- minus post-exposure lung function responses reported in this study. These same CASAC Panel members also noted the very conservative nature (i.e., prone to type II error, falsely accepting the null hypothesis) of the approach used by Adams to evaluate the research questions posed by the author. Moreover, as discussed in the 2010 proposal, finding effects at 0.060 ppm was not unexpected because the previously observed group mean FEV_1 responses to 0.08 ppm were in the range of 6–9% suggesting that exposure to lower concentrations of O_3

would result in smaller, but real group mean FEV_1 decrements, i.e., the responses to 0.060 ppm O_3 are consistent with the presence of a smooth exposure-response curve with responses that do not end abruptly below 0.080 ppm (75 FR 2950). In its March 2011 consensus letter the CASAC Panel stated that, "The results of the Adams et al. study also have been carefully reanalyzed by EPA investigators (Brown et al., 2007), and this reanalysis showed a statistically significant group effect on FEV_1 after 60 ppb ozone exposure." (Samet, 2011, p.6)

ii Evidence from Epidemiological Studies

This section contains major comments on EPA's assessment of epidemiological studies in the 2010 proposal and the Agency's general responses to those comments. Comments on EPA's interpretation and assessment of the body of epidemiological evidence are briefly discussed first and then comments on methodological issues and particular study designs are discussed. EPA notes here that most of the issues and concerns raised by commenters on the interpretation of the epidemiological evidence and methodological issues are essentially restatements of issues raised during the review of the 2006 Criteria Document and 2007 Staff Paper. EPA presented and the CASAC Panel reviewed the interpretation of the epidemiological evidence in the Criteria Document and the integration of the evidence with policy considerations in the development of the policy options presented in the Staff Paper for consideration by the Administrator. CASAC reviewed both the Criteria Document and Staff Paper and commented favorably on the scientific content and accuracy of both documents. The CASAC chairman sent to the Administrator one letter (Henderson, 2006a) for the Criteria Document and another letter for the Staff Paper (Henderson, 2006c) indicating that these documents provided an appropriate basis for use in regulatory decision making regarding the O_3 NAAQS. To the extent that these same issues and concerns were raised again in comments on the 2010 rulemaking, they are briefly

summarized and responded to in this section. Many of the issues discussed below are addressed in more detail in the 2011 Response to Comments document.

As with evidence from controlled human exposure studies, sharply divergent comments were received on the evidence from epidemiological studies, including EPA's interpretation of the evidence. One group of commenters from medical, public health and environmental organizations, in general, supported EPA's interpretation of the epidemiological evidence (75 FR 2960, II.A.3.a) with regard to whether the evidence for associations is consistent and coherent and whether there is biological plausibility for judging whether exposure to O_3 is causally related to respiratory and cardiovascular morbidity and mortality effects. Commenters representing public health and environmental groups, including a joint set of comments from ALA and several environmental groups, note that more than 250 new epidemiological studies, published from 1996 to 2005, were included in the 2006 Criteria Document and point to a figure from the 2007 Staff Paper and 2010 proposal (75 FR 2965, Figure 1) of short-term O_3 exposures and respiratory health outcomes showing consistency in an array of positive effects estimates and health endpoints observed in multiple locations in Canada and the U.S. Medical commenters, including ATS and AMA, stated that epidemiological studies support the findings of chamber studies that show adverse respiratory health effects occurring at levels below the 0.075 ppm 8-hour O_3 standard. These commenters generally expressed agreement with the weight of evidence approach taken in the Criteria Document and the conclusions reached, which were reviewed by CASAC, that the associations between O_3 exposures and a variety of effects including respiratory symptoms, lung function changes, emergency department visits for respiratory and cardiovascular effects, and hospital admissions should be considered causal.

The EPA agrees with this interpretation of the epidemiological evidence. The 2006 Criteria Document concludes that positive and robust associations were found between ambient O_3

concentrations and various respiratory disease hospitalization outcomes and emergency department visits for asthma, when focusing particularly on results of warm-season analyses. These positive and robust associations are supported by the human clinical, animal toxicological, and epidemiological evidence for lung function decrements, increased respiratory symptoms, airway inflammation, and increased airway responsiveness. Taken together, the overall evidence supports a causal relationship between acute ambient O_3 exposures and increased respiratory morbidity outcomes resulting in increased emergency department visits and hospitalizations during the warm season (EPA, 2006a, p.8-77).

However, in contrast to EPA's interpretation, these commenters from ALA and other environmental, medical and public health groups asserted that the causal associations extend down to the lowest ambient O_3 concentrations reported in these studies. These commenters also expressed the view that the respiratory morbidity effects are well-supported by the Hill criteria[26] of judging causality: strength of association, consistency between studies, coherence among studies, and biological plausibility (ALA et al., 2010, p.40). They also noted that evidence is beginning to emerge about the potential cardiovascular effects of O_3.

> Numerous recent studies point to adverse associations between ozone exposure and various cardiovascular health endpoints, including alterations in heart rate variability in older adults, cardiac arrhythmias, strokes, heart attacks, and hospital admissions or cardiovascular diseases. (ATS et al., 2010, p.3).

The EPA disagrees with the assertion of these commenters that the causal associations have been demonstrated to extend down to the lowest ambient O_3 concentrations reported in these studies (i.e., 0.060 ppm and lower). The biological plausibility of the epidemiological associations is generally supported by controlled human exposure evidence of respiratory morbidity effects for levels at and

[26]The Hill criteria, published by Sir Bradford Hill (1965), are commonly used criteria for reaching judgments about causality from observed associations, and these criteria were the basis for the critical assessment of the epidemiological evidence presented in the Criteria Document (pp.7-3 – 7-4).

below 0.080 ppm, potentially down to 0.060 ppm, but that biological plausibility becomes increasingly uncertain at lower levels. Further, at much lower levels, it becomes increasingly uncertain as to whether the reported associations are related to O_3 alone rather than to the broader mix of air pollutants present in the ambient air. With regard to cardiovascular health outcomes, the 2006 Criteria Document concludes that the generally limited body of evidence from animal toxicology, human controlled exposure, and epidemiologic studies is suggestive that O_3 can directly and/or indirectly contribute to cardiovascular-related morbidity, and that for cardiovascular mortality the Criteria Document suggests that effects estimates are more consistently positive and statistically significant in warm season analyses but that additional research is needed to more fully establish the underlying mechanisms by which such mortality effects occur (EPA, 2006a, pp.8-77 - 78).

The second group of commenters, mostly representing industry associations and some businesses opposed to revising the primary O_3 standard, disagreed with EPA's interpretation of the epidemiological evidence. These commenters expressed the view that while many epidemiological studies have been published since the 1997 primary O_3 standard was promulgated, the inconsistencies and uncertainties inherent in these studies as a whole should preclude any reliance on them as justification for a more stringent primary O_3 NAAQS. They contend that the purported consistency is the result of inappropriate selectivity in focusing on specific studies and specific results within those studies (Exxon Mobil, 2010, p.15). With regard to daily mortality, the 2010 proposal emphasizes the multi-city studies, suggesting that they have greater statistical power to allow the authors to reliably distinguish even weak relationships from the null hypothesis with statistical confidence. However, these commenters note that these studies are not consistent, with regard to the findings concerning individual cities analyzed in the multi-city analyses. One commenter asserted that each of the multi-city studies and meta-analyses cited by EPA involves cities for which the city-specific estimates of O_3 effects have been observed to vary

over a wide range that includes negative [i.e., beneficial] effects (Gradient, 2010, for API, pp.8 - 12). To illustrate this point, many commenters point to EPA's use of the study by Bell et al., 2004. They note that in focusing on the national estimate from Bell of the association between 24-hour average O_3 levels and daily mortality, the Administrator overlooks the very significant and heterogeneous information from the individual analyses of the 95 cities used to produce the national estimate and, based on this inconsistency, question whether what is being seen is actually an O_3 mortality association at all.

In the 2008 review and in the 2010 proposal, EPA has accurately characterized the inconsistencies and uncertainties in the epidemiological evidence and strongly disagrees that it has inappropriately focused on specific positive studies or specific positive results within those studies. EPA's assessment of the health effects evidence in the 2006 Criteria Document has been reviewed by the CASAC Panel. EPA has appropriately characterized the heterogeneity in O_3 health effects in assessing the results of the single-city and multi-city studies and the meta-analyses, as discussed in section 7.6.6 of the Criteria Document.

More specifically, the Bell et al. (2004) study observed a statistically significant, positive association between short-term O_3 concentrations (24-hour average) and all-cause mortality using data from 95 U.S. National Morbidity, Mortality, and Air Pollution Study (NMMAPS) communities. The objective of the NMMAPS was to develop an overall national effect estimate using multi-city time-series analyses, by drawing on information from all of the individual cities. The strength of this approach is the use of a uniform analytic methodology, avoidance of selection bias, and greater statistical power increasing the ability of this study to detect an effect. Significant intercity heterogeneity was noted in the Bell et al. and other multi-city studies, probably due to many factors, including city-specific differences in pollution characteristics, the use of air conditioning, time spent

indoors versus outdoors, and socioeconomic factors. Levy et al. (2005) found suggestive evidence that air conditioning prevalence was a predictor of heterogeneity in O_3 risk estimates in their meta-analysis.

Several commenters argued that EPA overstates the probability of causal links between health effects and exposure to O_3, especially at the lower concentrations examined, and that the statistical associations found in the cited epidemiological studies do not automatically imply that a causal relationship exists. These commenters expressed the view that the correlation between health effects and O_3 exposure must be rigorously evaluated according to a standard set of criteria before concluding that there is a causal link and that EPA fails to articulate and follow the weight of the evidence or established causality criteria for evaluating epidemiological studies in drawing conclusion regarding causality (Exxon Mobil, 2010, Detailed Comment, pp.10 - 11).

In the 2010 proposal, EPA explicitly stated that epidemiological studies are not themselves direct evidence of a causal link between exposure to O_3 and the occurrence of effects (75 FR 37879). Throughout the O_3 review, a standard set of criteria has been used to evaluate evidence of a causal link. The critical assessment of epidemiological evidence presented in the 2006 Criteria Document was conceptually based upon consideration of salient aspects of the evidence of associations so as to reach fundamental judgments as to the likely causal significance of the observed associations in accordance with the Hill criteria (EPA, 2006, pp.7-3 - 7-4). Moreover, consistent with the 2010 proposal, the Administrator has specifically considered evidence from epidemiological studies in the context of all the other available evidence in evaluating the degree of certainty that O_3-related adverse health effects occur at various levels at and below 0.080 ppm, including the strong evidence of lung function decrements, respiratory symptoms, airway inflammation and increased airway responsiveness from controlled human exposure studies at and above 0.080 ppm O_3, and limited but important evidence of lung function decrements and respiratory symptoms at 0.060 ppm O_3, evidence from controlled human exposures

studies showing more serious effects in people with asthma and other lung diseases, and the evidence from toxicological studies that demonstrate biological plausibility and mechanisms for effects found in epidemiological studies.

In addition, based on all of the evidence, the Administrator judged that evidence of a causal relationship between adverse health outcomes and O_3 exposures became increasingly uncertain at lower levels of O_3 exposure. At the lower end of the range of O_3 concentrations observed in such studies, ranging down to background levels (i.e., 0.035 to 0.015 ppm), there is increasing uncertainty as to whether the observed associations remain plausibly related to exposures to ambient O_3, rather than to the broader mix of air pollutants present in the ambient atmosphere. More detailed discussion of the criteria used to evaluate evidence with regard to judgments about causality can be found in the 2011 Response to Comments document.

Several commenters made the point that the results of the epidemiological studies included in the 2008 review are not coherent. They state that although EPA notes that estimates of risk from cardiovascular mortality are higher than those for total mortality and indicate that these findings are highly suggestive that short-term O_3 exposure directly or indirectly contributes to cardiovascular mortality, the Agency fails to contrast the mortality studies to studies of hospital admissions and other cardiovascular morbidity outcomes. These commenters charge that some epidemiological studies of cardiovascular morbidity outcomes have not found statistically significant associations with O_3 exposures and that some others that have found associations either used a single pollutant model or are of questionable clinical significance (Gradient, 2010, for API, pp.21 - 24).

The EPA strongly disagrees that it has failed to characterize appropriately the association between O_3 exposure and potential cardiovascular morbidity and mortality effects. As noted above, the 2006 Criteria Document characterizes the overall body of evidence as limited, but highly suggestive, and

concludes that much needs to be done to more fully integrate links between ambient O_3 exposures and adverse cardiovascular outcomes (EPA, 2006a, p.8-77). Some field and panel studies that examined associations between O_3 and various cardiac physiologic endpoints have yielded limited epidemiological evidence suggestive of a potential association between acute O_3 exposure and altered heart rate variability, ventricular arrhythmias, and incidence of myocardial infarction (Criteria Document, section 7.2.7). In addition, there were approximately 20 single-city studies of emergency department visits and hospital admissions for all cardiovascular diseases or specific diseases (i.e., myocardial infarction, congestive heart failure, ischemic heart disease, dysrhythmias). In the studies using all year data, many showed positive results but few were statistically significant. Given the strong seasonal variations in O_3 concentrations and the changing relationship between O_3 and other copollutants by season, inadequate adjustment for seasonal effects might have masked or underestimated the associations. In the limited number of studies that analyzed data by season (6 studies), statistically significant associations were observed in all but one study (Criteria Document, section 7.3.4). Newly available animal toxicology data, including evidence of O_3-induced effects on heart rate, vascular tone, and platelet activating factor release, provide some plausibility for the observed associations between O_3 and cardiovascular outcomes (Criteria Document, section 5.3.3). EPA believes that its characterization of the evidence for O_3-related cardiovascular system effects is appropriate (Criteria Document, section 8.8.1).

Many commenters who did not support revising the current O_3 primary standard also submitted comments on specific methodological issues related to the epidemiological evidence, including: (1) the adequacy of exposure data; (2) confounding by copollutants; (3) model selection; (4) evidence of mortality; and (5) "new" studies not included in the 2006 Criteria Document. Major comments on methodological issues raised by these commenters are briefly discussed below. The 2011 Response to

Comments document contains more detailed responses to many of these comments, as well as responses to other comments not addressed here.

(1) Adequacy of exposure data. Many commenters expressed concern about the adequacy of exposure data both for time-series and panel studies. These commenters argued that almost all of the epidemiological studies on which EPA relies in recommending a more stringent O_3 standard are based on data from ambient monitors for which there is a poor correlation with the actual personal exposure subjects receive during their daily activities. They questioned EPA's conclusion that in the absence of available data on personal O_3 exposure, the use of routinely monitored ambient O_3 concentrations as a surrogate for personal exposures is not generally expected to change the principal conclusions from epidemiological studies. Commenters (NAM, 2010a?, p.21) cited studies that show a lack of correlation between personal exposures and ambient concentrations (e.g., Sarnat et al., 2001; Sarnat et al., 2005) and other additional studies that have found that the ability of ambient gas monitors to represent personal exposure to such gases is quite limited (Sarnat et al., 2001, 2005, and 2006; and Koutrakis et al., 2005). These studies report that most personal exposures are so low as to be not detectable at a level of 5 parts per billion (ppb), resulting in very low correlation between concentrations reported from central ambient monitors and personal monitors. These commenters contend that with such a low correlation between concentrations reported from central ambient monitors and personal monitors, there is no legitimate way for EPA to conclude that O_3 exposure has caused the reported health effects, or to conclude that use of routinely monitored ambient O_3 concentrations as a surrogate for personal exposures is adequate. The commenters also contend that populations expected to be potentially susceptible to O_3, including children, the elderly, and those with COPD, are at the low end of the population exposure distribution -- that is, less likely to be exposed (Exxon Mobil, 2010, Detailed Comment, pp.15 - 16). Additionally, some of these commenters also contended that EPA incorrectly

concludes that the exposure error in epidemiological studies results in an underestimate of risk (Exxon Mobil, 2010, Detailed Comment, p.20).

The EPA agrees that exposure measurement error may result from the use of stationary ambient monitoring data as an indicator of personal exposures in population studies. There is a full discussion of measurement error and its effect on the estimates of relative risk in section 7.1.3.1 of the 2006 Criteria Document. However, the possibility of measurement error does not preclude the use of ambient monitoring data as a surrogate for personal exposure to O_3 of ambient origin in time-series or panel studies. It simply means that in some situations where the likelihood of measurement error is greatest, effect estimates must be evaluated carefully and that caution must be used in interpreting the results from these studies. Throughout the 2008 review, EPA recognized this concern. The Criteria Document states that there is supportive evidence that ambient O_3 concentrations from central monitors may serve as valid surrogate measures for *mean* personal O_3 exposures of ambient origin experienced by the population, which is of most relevance to time-series studies, in which individual variations in factors affecting exposure tend to average out across the study population. This is especially true for respiratory hospital admission studies for which much of the response is attributable to O_3 effects on asthmatics. In children, for whom asthma is more prevalent than for adults, ambient monitors are more likely to correlate reasonably well with personal exposure to O_3 of ambient origin because children tend to spend more time outdoors than adults in the warm season. EPA does not agree that the correlation between personal exposures of ambient origin and ambient monitoring data is necessarily poor, especially in healthy and asthmatic children. Moreover, the CASAC Panel supported this view as they noted that "[p]ersonal exposures most likely correlate better with central site values for those subpopulations that spend a good

deal of time outdoors, which coincides, for example, with children actively engaged in outdoor activities, and which happens to be a group that the ozone risk assessment focuses upon." (Henderson, 2006c, p.10). Of concern in interpreting results from mortality and hospitalization time-series studies is the extent to which the ambient O_3 concentrations are representative of personal O_3 exposures in a particularly susceptible group of individuals, the debilitated elderly, as the correlation between the two measurements have not been examined in this population. However, until more data on O_3 exposure become available, the use of monitored ambient O_3 concentrations as a surrogate for exposures is not expected to change the principal conclusions from O_3 epidemiological studies (Criteria Document, pp.3-75 - 3-76).

With regard to the specific comments that reference the findings of studies by Sarnat et al. (2001, 2005, 2006) and Koutrakis et al. (2005), the fact that personal exposure monitors cannot detect O_3 levels of 5 ppb and below may in part explain why there was a poor correlation between personal exposure measurements and ambient monitoring data in the winter relative to the correlation in the warm season, along with differences in activity patterns and building ventilation. In Baltimore, Sarnat et al. (2001) observed that ambient O_3 concentrations showed stronger associations with personal exposure to $PM_{2.5}$ than to O_3; however, in a later study conducted in Boston (Sarnat et al., 2005), ambient O_3 concentrations and personal O_3 exposures were found to be significantly associated in the summer. Another study cited by the commenter, but not included in the 2006 Criteria Document, conducted in Steubenville (Sarnat et al., 2006), also observed significant associations between ambient O_3 concentrations and personal O_3 exposures. The authors noted that the city-specific discrepancy in the results may be attributable to differences in ventilation. Though the studies by Sarnat et al. (2001, 2005, and 2006) included senior citizens, the study selection criteria required them to be nonsmoking and physically healthy.

As discussed in the 2006 Criteria Document, existing epidemiological models may not fully take into consideration all the biologically relevant exposure history or reflect the complexities of all the underlying biological processes. Moreover, results from studies examining relationships between measured ambient O_3 concentrations from fixed monitoring sites and personal O_3 exposure (Avol et al., 1998b; Brauer and Brook, 1995, 1997; Chang et al., 2000; Delfino et al., 1996; Lee et al., 2004; Liard et al., 1999; Linn et al., 1996; Liu et al., 1995, 1997; O'Neill et al., 2003; Sarnat et al., 2001) indicate that the relationship between ambient O_3 concentrations and personal exposure will vary depending on individual- or city-specific factors such as time activity patterns, indoor air exchange rates, and housing conditions, creating potential exposure measurement errors. Using ambient concentrations to determine exposure generally overestimates true personal O_3 exposures (by approximately 2- to 4-fold in the various studies described in the 2006 Criteria Document, section 3.9), which assuming the relationship is causal, would result in biased descriptions of underlying concentration-response relationships (i.e., in attenuated effect estimates). From this perspective, the implication is that the effects being estimated in relationship to ambient levels occur at fairly low personal exposures and the potency of O_3 is greater than these effect estimates indicate. On the other hand, as very few studies evaluating O_3 health effects with personal O_3 exposure measurements exist in the literature, effect estimates determined from ambient O_3 concentrations must be evaluated and used with caution to assess the health risks of O_3 (Criteria Document, pp.7-8 - 7-10). Nonetheless, as noted in section II.C.1 of the 2010 proposal, the use of routinely monitored ambient O_3 concentrations as a surrogate for personal exposures to O_3 of ambient origin is not generally expected to change the principal conclusions from O_3 epidemiologic studies. Therefore, population risk estimates derived using ambient O_3 concentrations from currently

available observational studies, with appropriate caveats about personal exposure considerations, remain useful (75 FR 2985-2988).

(2) Confounding by copollutants. Many commenters argued that known confounders are inadequately controlled in the epidemiological studies of O_3 and various health outcomes and that the health effects of O_3 are often not statistically significant when epidemiological studies consider the effects of confounding air pollutants (e.g., $PM_{2.5}$, CO, nitrogen dioxide [NO_2]) in multi-pollutant models. For example, Mortimer et al. (2002), a large multi-city asthma panel study, found that when other pollutants, i.e., sulfur dioxide [SO_2], NO_2), and particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM_{10}), were placed in a multi-pollutant model with O_3, the O_3-related associations with respiratory symptoms became non-significant (Gradient, for API, 2010, pp.13 - 14).

The National Cooperative Inner-City Asthma Study (Mortimer et al., 2002) evaluated air pollution health effects in 846 asthmatic children in 8 urban areas. The pollutants evaluated included O_3, PM_{10}, SO_2, and NO_2. Three effects were evaluated: (1) daily percent change in lung function, measured as peak expiratory flow rate (PEFR); (2) incidence of ≥ 10% reduction in lung function (PEFR); and, (3) incidence of symptoms (i.e., cough, chest tightness, and wheeze). EPA notes that in this study, O_3 was the only pollutant associated with reduction in lung function. Nitrogen dioxide had the strongest effect on morning symptoms, and the authors concluded it "…may be a better marker for the summer-pollutant mix in these cities" but had no association with morning lung function. In a two-pollutant model with NO_2, the O_3 effect on morning symptoms remained relatively unchanged. Sulfur dioxide had statistically significant effects on morning symptoms but no association with morning lung function. Particulate matter (PM_{10}), which was measured daily in 3 cities, had no statistically significant effect on morning lung function. In a two-pollutant model with O_3, the PM_{10} estimate for morning

symptoms was slightly reduced and there was a larger reduction in the O_3 estimate, which remained positive but not statistically significant.

(3) Model selection. Commenters who did not support revision of the primary O_3 standard raised issues regarding the adequacy of model specification including control of temporal and weather variables in the time-series epidemiological studies that EPA has claimed support the finding of O_3-related morbidity and mortality health outcomes. Specifically, commenters expressed concern regarding the important effects of model selection in the results of the time-series studies, including the choice of models to address weather and the degree of smoothing, in direct contradiction of the 2007 Staff Paper's conclusion on the robustness of the models used in the O_3 time-series studies (Exxon Mobil, 2010, Detailed Comment, p.41); and commenters contended that there were no criteria for how confounders such as temperature or other factors were to be addressed, resulting in arbitrary model selection potentially impacting the resulting effect estimates.

In response to the first issue, EPA agrees that the results of the meta-analyses do support the conclusion that there are important effects of model selection and that, for example, alternative models to address weather might make a difference of a factor of two in the effect estimates. However, as noted in the 2006 Criteria Document, one of the meta-analyses (Ito et al., 2005) suggested that the stringent weather model used in the Bell et al. (2004) NMMAPS study may tend to yield smaller effect estimates than those used in other studies (Criteria Document, p.7-96), and, thus concerns about appropriate choice of models could result in either higher or lower effect estimates than reported. In addressing this issue, the Criteria Document concluded,

> Considering the wide variability in possible study designs and statistical model specification choices, the reported O_3 risk estimates for the various health outcomes are in reasonably good agreement. In the case of O_3-mortality time-series studies, combinations of choices in model specifications … alone may explain the extent of difference in O_3 risk estimates across studies. (Criteria Document, p.7-174)

Second, the issues surrounding sensitivity to model specifications were thoroughly discussed in the 2006 Criteria Document (see section 7.1.3.6) and evaluated in some of the meta-analyses reviewed in the Criteria Document and 2007 Staff Paper. As stated in the Criteria Document, O_3 effect estimates "were generally more sensitive to alternative weather models than to varying degrees of freedom for temporal trend adjustment" (Criteria Document, p.7-176). The Criteria Document also concluded that "although there is some concern regarding the use of multipollutant models … results generally suggest that the inclusion of copollutants into the models do not substantially affect O_3 risk estimates" and the results of the time-series studies are "robust and independent of the effects of other copollutants" (Criteria Document, p.7-177). Overall, EPA continues to believe that based on its integrated assessment, the time-series studies provide strong support for concluding there are O_3-related morbidity effects, including respiratory-related hospital admissions and emergency department visits during the warm season, and that the time-series studies provide findings that are highly suggestive that short-term O_3 exposure directly or indirectly contributes to non-accidental and cardiorespiratory-related mortality.

The EPA acknowledges that uncertainties concerning appropriate model selection are an important source of uncertainty affecting the specific risk estimates included in EPA's risk assessment and that these quantitative risk estimates must be used with appropriate caution, keeping in mind these important uncertainties, as discussed above in section II.A.2. As discussed below in section II.C.3 in this final rule, the Administrator is considering the effect estimates from the time-series studies and the risk estimates based on the time-series studies as providing supporting information, keeping in mind the uncertainties and limitations associated with these studies, in reaching her judgment about the level of the 8-hour primary O_3 standard.

(4) Evidence of mortality. Many commenters, including those that supported the reconsideration of the level of the 2008 O_3 standard as well as those that argued against reconsideration, focused on the

new evidence from multi-city time-series analyses and meta-analyses linking O_3 exposure with mortality. Again, the comments were highly polarized. One set of commenters, including medical, public health, and environmental organizations argued that recent published research has provided more robust, consistent evidence linking O_3 to cardiovascular and respiratory mortality. The ATS, AMA, and others stated that data from single-city studies, multi-city studies, and meta-analyses show a consistent relationship between O_3 exposure and mortality from respiratory and cardiovascular causes. These commenters noted that this effect was observed after controlling for co-pollutants and seasonal impacts. These commenters stated that research has demonstrated that exposure to O_3 pollution is causing premature deaths, and has also provided clues on the possible mechanisms that lead to premature mortality (ALA et al., 2010, p.44). These commenters noted that people may die from O_3 exposure even when the concentrations are well below 0.075 ppm. They pointed to a study (Bell et al., 2006) in which the authors followed up on their 2004 multi-city study to estimate the exposure-response curve for O_3 and the risk of mortality and to evaluate whether a threshold exists below which there is no effect. Bell et al. (2006) applied several statistical models to data on air pollution, weather, and mortality for 98 U.S. urban communities for the period 1987 to 2000. The study reported that O_3 and mortality results did not appear to be confounded by temperature or PM and showed that any threshold, if it existed, would have to be at very low concentrations, far below the current standard (ALA et al., 2010, p.62). These commenters also cited a case-crossover study (Schwartz, 2005) of over one million deaths in 14 U.S. cities, designed to control for the effect of temperature on daily deaths attributable to O_3, which found that the association between O_3 and mortality risk reported in the multi-city studies is unlikely to be due to confounding by temperature (ALA et al., 2010, p.65). These commenters argue that meta-analyses also provide compelling evidence that the O_3-mortality findings are consistent. They point to three independent meta-analyses conducted by separate research groups at Johns Hopkins University, Harvard

University and New York University, using their own methods and study criteria, which reported a remarkably consistent link between daily O_3 levels and total mortality.

In response, EPA notes that the 2006 Criteria Document states that the results from the U.S. multi-city time-series studies provide the strongest evidence to date for O_3 effects on acute mortality. Meta-analyses also indicate positive risk estimates that are unlikely to be confounded by PM; however, the Criteria Document notes that future work is needed to better understand the influence of model specifications on the risk coefficient (EPA, 2006a, p.7-175). EPA's view of the evidence is expressed in the Criteria Document which concludes that these findings are highly suggestive that short-term O_3 exposure directly or indirectly contributes to non-accidental and cardiorespiratory-related mortality but that additional research is needed to more fully establish the underlying mechanisms by which such effects occur (75 FR 2957). In addition, it must be noted that the Administrator did not focus on mortality as a basis for proposing to reconsider the level of the 2008 O_3 NAAQS. In the 2010 proposal, the Administrator focused on the very strong evidence of respiratory morbidity effects in healthy people at the 0.080 ppm exposure level, the limited evidence of lung function decrements at 0.060 ppm, and new evidence that people with asthma are likely to experience larger and more serious effects than healthy people at the same level of exposure (75 FR 2992). With regard to the ambient concentrations at which O_3-related mortality effects may be occurring, EPA recognized in the 2010 proposal, and continues to believe, that evidence of a causal relationship between adverse health effects and O_3 exposures becomes increasingly uncertain at lower levels of exposure (75 FR 2992).

Several industry organizations argued against placing any reliance on the time-series epidemiological studies, especially those studies related to mortality effects. Because of the importance of the O_3 mortality multi-city studies in EPA's analysis of this issue, several of these commenters focused on them in particular, arguing that, although these studies have the statistical power to

distinguish weak relationships between daily O_3 and mortality, they do not provide reliable or consistent evidence implicating O_3 exposures as a cause of mortality. Several reasons were given, including: (a) the multi-city studies cited by EPA involve a wide range of city-specific effects estimates (Bell et al., 2004), thus causing several commenters to question the relevance of a "national" effect of O_3 on mortality and argue that results were inappropriately combined across cities and summarized as an overall national average relative risk, which is of limited value in light of the substantial heterogeneity across cities and regions (Gradient, for API, 2010, pp.8 - 9); (b) the multi-city mortality studies did not sufficiently account for other pollutants, for example, Bell et al. (2004) adjusted for PM_{10} but did not have the daily air quality data to adequately adjust for $PM_{2.5}$, which EPA has concluded also causes mortality and is correlated with O_3, especially in the summer months (Exxon Mobil, 2010, Detailed Comments, p.21), thus failing to capture the daily and seasonal fluctuations in both $PM_{2.5}$ and O_3 levels that tend to occur in a parallel fashion; and (c) these studies contain several findings that are inconsistent or implausible, such as premature mortality reported at such low levels as to imply that O_3-related mortality is occurring at levels well within natural background, which is not biologically plausible; leading one of these commenters to assert that there is no scientific evidence to extrapolate mortality below the range of 0.060 to 0.080 ppm (Exxon Mobil, 2010, Detailed Comments, p.46).

The EPA does not agree with the characterization of the evidence relating O_3 exposures to mortality provided in industry and business group comments. Evidence supporting an association between short-term O_3 exposure and premature mortality is not limited to multi-city time-series studies. Most single-city studies also show elevated risk of total, non-accidental mortality, cardiorespiratory, and respiratory mortality (> 20 studies), including one study in an area that would have met the 0.075 ppm primary O_3 standard (Vedal et al., 2003). A study in Seoul, Korea used several different modeling approaches and reported a potential threshold level of < 0.035 ppm, 8-hour average, for an association

between mortality and short-term O_3 exposure during the summer months (Kim et al., 2004; EPA, 2006a, p.8-43).

The EPA notes that three large meta-analyses, which pool data from many single-city studies to increase statistical power, reported statistically significant associations and examined sources of heterogeneity in those associations (Bell et al., 2005; Ito et al., 2005; Levy et al., 2005). These studies found: (1) larger and more significant effects in the warm season than in the cool season or all year; (2) no strong evidence of confounding by PM; and (3) suggestive evidence of publication bias, but significant associations remain even after adjustment for the publication bias.

Moreover, EPA notes that the biological plausibility of the epidemiological mortality associations is generally supported by controlled human exposure and toxicological evidence of respiratory morbidity effects for levels at and below 0.080 ppm, but that biological plausibility becomes increasingly uncertain especially below 0.060 ppm, the lowest level at which effects were observed in controlled human exposure studies. Further, at lower levels, it becomes increasingly uncertain as to whether the reported associations are related to O_3 alone rather than to the broader mix of air pollutants present in the ambient air. EPA agrees that the multi-city times series studies evaluated in this review do not completely resolve this issue. It also becomes increasingly uncertain as to whether an effects threshold exists but it cannot be clearly discerned by statistical analyses. Thus, when considering the epidemiological evidence in light of the other available information, it is reasonable to judge that at some point the epidemiological associations cannot be interpreted with confidence as providing evidence that the observed health effects can be attributed to O_3 alone.

With regard to the specific issues raised in the comments as to why the times-series mortality studies do not provide reliable or consistent evidence implicating O_3 exposure as a cause of mortality, EPA has the following responses:

(a) The purpose of the NMMAPS approach is not to single out individual city results but rather to estimate the overall effect from the 95 communities. It was designed to provide a general, nationwide estimate. With regard to the very slight or negligible effects estimates for some large cities (e.g., Los Angeles), an important factor to consider is that the Bell et al. (2004) study used all available data in their analyses. Bell et al. reported that the effect estimate for all available (including 55 cities with all year data) and warm season (April-October) analyses for the 95 U.S. cities were similar in magnitude; however, in most other studies, larger excess mortality risks were reported in the summer season (generally June-August when O_3 concentrations are the highest) compared to all year or the cold season. Though the effect estimate for Los Angeles is small compared to some of the other communities, it should be noted that all year data (combined warm and cool seasons) was used in the analyses for this city, which likely resulted in a smaller effect estimate. Because all year data were used for Los Angeles, the median O_3 concentration for Los Angeles is fairly low compared to the other communities, ranked 23rd from the top out of 95 communities. The median 24-hour average O_3 concentration for Los Angeles in this dataset was 22 ppb, with a 10th percentile of 8 ppb to a 90th percentile of 38 ppb. The importance of seasonal differences in O_3-related health outcomes has been well documented in the O_3 Criteria Document (section 7.6.3.2).

(b) In section 7.4.6, O_3 mortality risk estimates adjusting for PM exposure, the 2006 Criteria Document states that the main confounders of interest for O_3, especially for the northeast U.S., are "summer haze-type" pollutants such as acid aerosols and sulfates. Since very few studies included these chemical measurements, PM (especially $PM_{2.5}$) data may serve as surrogates. However, due to the expected high correlation among the constituents of the "summer haze mix," multipollutant models including these pollutants may result in unstable coefficients; and, therefore, interpretation of such results requires some caution. In this section of the 2006

Criteria Document, Figure 7-22 shows the O_3 risk estimates with and without adjustment for PM indices using all-year data in studies that conducted two-pollutant analyses. Approximately half of the O_3 risk estimates increased slightly, whereas the other half decreased slightly with the inclusion of PM in the models. In general, the O_3 mortality risk estimates were robust to adjustment for PM in the models.

The U.S. 95 communities study by Bell et al. (2004) examined the sensitivity of acute O_3-mortality effects to potential confounding by PM_{10}. Restricting analysis to days when both O_3 and PM_{10} data were available, the community-specific O_3-mortality effect estimates as well as the national average results indicated that O_3 was robust to adjustment for PM_{10} (Bell et al., 2004). As commenters noted, there were insufficient data available to examine potential confounding by $PM_{2.5}$. One study (Lipfert et al., 2000) reported O_3 risk estimates with and without adjustment for sulfate, a component of $PM_{2.5}$. Lipfert et al. (2000a) calculated O_3 risk estimates based on mean (45 ppb) less background (not stated) levels of 1-hour maximum O_3 in seven counties in Pennsylvania and New Jersey. The O_3 risk estimate was not substantially affected by the addition of sulfate in the model (3.2% versus 3.0% with sulfate) and remained statistically significant.

Several O_3 mortality studies examined the effect of confounding by PM indices in different seasons (Figure 7-23, section 7.4.6, Criteria Document). In analyses using all-year data and warm-season only data, O_3 risk estimates were once again fairly robust to adjustment for PM indices, with values showing both slight increases and decreases with the inclusion of PM in the model. In the analyses using cool season data only, the O_3 risk estimates all increased slightly with the adjustment of PM indices, although none reached statistical significance.

The three recent meta-analyses (Bell et al., 2005; Ito et al., 2005; Levy et al. 2005) all examined the influence of PM on O_3 risk estimates. No substantial influence was observed in any of these studies. In the analysis by Bell et al. (2005), the combined estimate without PM adjustment was 1.75% (95% PI: 1.10, 2.37) from 41 estimates, and the combined estimate with PM adjustment was 1.95% (95% PI: -0.06, 4.00) from 11 estimates per 20 ppb increase in 24-hour average O_3. In the meta-analysis of 15 cities by Ito et al. (2005), the combined estimate was 1.6% (95% CI: 1.1, 2.2) and 1.5% (95% CI: 0.8, 2.2) per 20 ppb in 24-hour average O_3 without and with PM adjustment, respectively. The additional time-series analysis of six cities by Ito et al. (2005) found that the influence of PM by season varied across alternative weather models but was never substantial. Levy et al. (2005) examined the regression relationships between O_3 and PM indices (PM_{10} and $PM_{2.5}$) with O_3-mortality effect estimates for all year and by season. Positive slopes, which might indicate potential confounding, were observed for $PM_{2.5}$ on O_3 risk estimates in the summer and all-year periods, but the relationships were weak. The effect of one causal variable (i.e., O_3) is expected to be overestimated when a second causal variable (e.g., PM) is excluded from the analysis, if the two variables are positively correlated and act in the same direction. However, EPA notes that the results from these meta-analyses, as well as several single- and multiple-city studies, indicate that associations with O_3 are independent of the effects of copollutants, including PM.

(c) With regard to the biological plausibility of O_3-related mortality occurring at levels well within natural background, EPA concluded in the 2010 proposal that additional research is needed to more fully establish underlying mechanisms by which mortality effects occur (72 FR 37836). Such research would likely also help determine whether it is plausible that mortality would occur at such low levels. As noted above, the multi-city times series studies evaluated in this review cannot resolve the

issue of whether the reported associations at such low levels are related to O_3 alone rather than to the broader mix of air pollutants present in the ambient air.

iii. Evidence Pertaining to Susceptible Populations for O_3-Related Effects

This section contains major comments on EPA's assessment of the body of evidence, including controlled human exposure and epidemiological studies, related to the effects of O_3 exposure on susceptible populations. Information available since the 1997 review about the increased responsiveness of people with lung disease, especially children and adults with asthma, was an important consideration in the Administrator's proposed decision that the current O_3 standard is not adequate, and many of the comments focused on this information and the conclusions drawn from it. There were also comments on other susceptible populations identified by EPA, as well as comments suggesting that additional populations should be considered at increased risk from O_3 exposure. Many of the issues discussed below, as well as other related issues, are addressed in more detail in the 2011 Response to Comments document.

As with the comments on controlled human exposure and epidemiological studies, upon which judgments about susceptible populations were based, the comments about EPA's delineation of these groups were highly polarized. In general, one group of commenters who supported revising the current O_3 primary standard, including medical associations, public health and environmental groups, agreed in part with EPA's assessment of the populations that are at increased risk from O_3 exposure, but commented that there are additional populations that need to be considered. A comment from ATS, AMA and other medical associations noted:

> Children are acutely vulnerable to the hazardous effects of air pollution. … Several other groups have shown above-average susceptibility. Based upon a number of recent studies investigating age-related differences in the mortality effect of ozone, the Criteria Document concludes that the elderly are at increased risk of ozone-related mortality. Individuals with preexisting lung disease comprise another susceptible population group, and studies show that low level ozone exposure exacerbates respiratory symptoms in

> child asthmatics and increases hospitalization among adults suffering from chronic obstructive pulmonary disease. Outdoor workers as well as active adults who exercise outdoors are particularly vulnerable to ozone exposure due to greater levels of exposure (ATS et al., 2010, pp.3 - 4).

These commenters agreed with EPA, that based on evidence from controlled human exposure and epidemiology studies, people with asthma, especially children, are likely to have greater lung function decrements and respiratory symptoms in response to O_3 exposure than people who do not have asthma, and are likely to respond at lower levels. Because of this, these commenters make the point that controlled human exposure studies that employ healthy subjects will underestimate the effects of O_3 exposures in people with asthma. These commenters agreed with EPA's assessment that epidemiological studies provide evidence of increased morbidity effects, including lung function decrements, respiratory symptoms, emergency department visits and hospital admissions, in people with asthma and that controlled human exposure studies provide biological plausibility for these morbidity outcomes.

Commenters also identified infants as one potentially susceptible population that EPA did not focus on in the 2010 proposal. Commenters from medical associations, and environmental and public health groups expressed the view that O_3 exposure can have important effects on infants, including reduced birth weight, pre-term birth, and increased respiratory morbidity effects in infants. Ozone exposure can impact prenatal health, with recent research finding that in-utero exposure to O_3 is associated with lower birth weight and intrauterine growth retardation (ATS et al., 2010, p.5). Other commenters cited new studies showing increased respiratory symptoms and respiratory hospital admissions in newborns and infants (ALA et al., 2010, pp.47 - 49).

EPA agrees with comments that there is very strong evidence from controlled human exposure and epidemiological studies that people with lung disease, especially children and adults with asthma, are susceptible to O_3 exposure and are likely to experience more serious effects than those people who

do not have lung disease. This means that controlled human exposure studies that employ subjects who do not have lung disease will likely underestimate effects in those people that do have asthma or other lung diseases.

In summarizing the epidemiological evidence related to birth-related health outcomes, the 2006 Criteria Document (p.7-133) concludes that O_3 was not an important predictor of several birth-related outcomes including premature births and low birth weight. Birth-related outcomes generally appeared to be associated with air pollutants that tend to peak in the winter and are possibly traffic-related. However, given that most of these studies did not analyze the data by season, seasonal confounding may have influenced the reported associations. One study reported some results suggestive of associations between exposures to O_3 in the second month of pregnancy and birth defects, but further evaluation of such potential associations is needed. With regard to comments about effect in infants, EPA notes that some of the studies cited by commenters were not considered in the Criteria Document. More detailed responses to studies submitted by commenters but not considered in the Criteria Document can be found in the 2011 Response to Comments document.

The second group of commenters, mostly representing industry associations and some businesses opposed to revising the primary O_3 standard, asserted that EPA is wrong to claim that new evidence indicates that the current standard does not provide adequate health public health protection for people with asthma. In support of this position, these commenters asserted that EPA recognized asthmatics as a susceptible population in 1997, and new information does not suggest greater susceptibility than was previously believed.

In section II.A.4.b.ii of the 2010 proposal (75 FR 2969 - 2971), EPA describes the evidence indicating that people with asthma are as sensitive as, if not more sensitive than, normal subjects in manifesting O_3-induced pulmonary function decrements. Controlled human exposure studies show that

asthmatics present a differential response profile for cellular, molecular, and biochemical parameters that are altered in response to acute O_3 exposure. Asthmatics have greater O_3-induced inflammatory responses and increased O_3-induced airway responsiveness (both incidence and duration) that could have important clinical implications. EPA did not base its increased concern for asthmatics solely on the results of the controlled human exposure studies, but has appropriately used a weight of evidence approach, integrating evidence from animal toxicological, controlled human exposure and epidemiological studies as a basis for this concern. The 2006 Criteria Document concludes that the positive and robust epidemiological associations between O_3 exposure and emergency department visits and hospitalizations in the warm season are supported by the human clinical, animal toxicological and epidemiological evidence for lung function decrements, increased respiratory symptoms, airway inflammation, and increased airway responsiveness (72 FR 37832). The CASAC Panel itself expressed the view that people with asthma, especially children, have been found to be more sensitive to O_3 exposure, and indicated that EPA should place more weight on inflammatory responses and serious morbidity effects, such as increased respiratory-related emergency department visits and hospitalizations (Henderson, 2006c, p.4). Therefore, EPA continues to assert that there is strong evidence that asthmatics are likely to have more serious responses to O_3 exposure than people without asthma, and that these responses have the potential to lead to exacerbation of asthma as indicated by the serious morbidity effects, such as increased respiratory-related emergency department visits and hospitalizations found in epidemiological studies.

With regard to the second point, industry and business group commenters expressed the view that there is no significant new evidence establishing greater risk to asthmatics than was accepted in 1997, when EPA concluded that the existing NAAQS was sufficiently stringent to protect public health – including asthmatics – with an adequate margin of safety.

> "….the evidence does not demonstrate greater risk to asthmatics (or others with preexisting pulmonary disease) from ozone. ….. As early as 1997, however, EPA *assumed* that individuals with preexisting pulmonary diseases, including asthma, were at greater risk from ozone than was the general population, 62 Fed. Reg. at 38859/3, and the 0.08 ppm 8-hour NAAQS adopted at that time therefore took that assumption into account (UARG, 2010, p.20).

At the time of the 1997 review, EPA concluded that people with asthma were at greater risk because the impact of O_3-induced responses on already-compromised respiratory systems would noticeably impair an individual's ability to engage in normal activity or would be more likely to result in increased self-medication or medical treatment. At that time there was little evidence that people with pre-existing disease were more responsive than healthy individuals in terms of the magnitude of pulmonary function decrements or symptomatic responses.

Based on a substantial body of evidence from animal, controlled human exposure and epidemiological studies, the 2006 Criteria Document concludes that people with asthma and other preexisting pulmonary diseases are likely to be among those at increased risk from O_3 exposure. Altered physiological, morphological and biochemical states typical of respiratory diseases like asthma, COPD and chronic bronchitis may render people sensitive to additional oxidative burden induced by O_3 exposure (EPA 2006a, section 8.7). Children and adults with asthma are the group that has been studied most extensively. Evidence from controlled human exposure studies indicates that asthmatics may exhibit larger lung function decrements in response to O_3 exposure than healthy controls. As discussed more fully in section II.A.4.b.ii of the 2010 proposal (75 FR 2969 - 2971), asthmatics present a differential response profile for cellular, molecular, and biochemical parameters (EPA, 2006a, section 8.7.1) that are altered in response to acute O_3 exposure. They can have larger inflammatory responses, as manifested by larger increases in markers of inflammation such as white bloods cells (e.g., PMNs) or inflammatory cytokines. Asthmatics, and people with allergic rhinitis, are more likely to mount an allergic-type response upon exposure to O_3, as manifested by increases in white blood cells associated

with allergy (i.e., eosinophils) and related molecules, which increase inflammation in the airways. The increased inflammatory and allergic responses also may be associated with the larger late-phase responses that asthmatics can experience, which can include increased bronchoconstrictor responses to irritant substances or allergens and additional inflammation. In addition to the experimental evidence of lung function decrements, respiratory symptoms, and other respiratory effects in asthmatic populations, two large U.S. epidemiological studies (Mortimer et al., 2002; Gent et al., 2003) as well as several smaller U.S. and international studies, have reported fairly robust associations between ambient O_3 concentrations and measures of lung function and daily symptoms (e.g., chest tightness, wheeze, shortness of breath) in children with moderate to severe asthma and between O_3 and increased asthma medication use (EPA, 2007a, chapter 6). These responses in asthmatics and others with lung disease provide biological plausibility for the more serious respiratory morbidity effects observed in epidemiological studies, such as emergency department visits and hospital admissions. These results from controlled exposure and epidemiological studies indicate that individuals with preexisting lung disease, especially people with asthma, are likely to have more serious responses than people who do not have lung disease and therefore are at greater risk for O_3 health effects than previously judged in the 1997 review.

c. Consideration of Human Exposure and Health Risk Assessments

Section II.A.2 above provides a summary overview of the exposure and risk assessment information used by the Administrator to inform judgments about exposure and health risk estimates associated with just meeting the 0.084 ppm standard set in 1997, the 0.075 ppm standard promulgated in 2008, and alternative standards. EPA notes here that most of the issues and concerns raised by commenters on the 2010 proposed rule concerning the methods used in the exposure and risk assessments are essentially restatements of concerns raised during the review of the 2007 proposed rule

and during the review of the 2006 Criteria Document and the development and review of these quantitative assessments as part of the preparation and review of the 2007 Staff Paper and the associated analyses. EPA presented and the CASAC Panel reviewed in detail the approaches used to assess exposure and health risk, the studies and health effect categories selected for which exposure-response and concentration-response relationships were estimated, and the presentation of the exposure and risk results summarized in the Staff Paper. As stated in the 2010 proposal, EPA believes and the CASAC Panel concurred, that the model selected to estimate exposure represents the state of the art, the risk assessment was "well done, balanced and reasonably communicated," and the selection of health endpoints for inclusion in the quantitative risk assessment was appropriate (Henderson, 2006c). To the extent that the same issues and concerns were raised again in comments on the 2010 rulemaking, they are briefly summarized and responded to in this section. Many of the issues discussed below are addressed in more detail in the 2011 Response to Comments document.

Comments received after the 2010 proposal related to the development of exposure and health risk assessments, interpretation of exposure and risk results, and the role of the quantitative human exposure and health risk assessments in considering whether or not to set a more stringent 8-hour O_3 standard than announced in 2008 generally fell into two groups. One group of commenters that included national environmental and public health organizations (e.g., joint set of comments by ALA and several environmental groups including Environmental Defense and Sierra Club) argued that consideration of exposure estimates is not permitted or is somehow inappropriate in decisions concerning the primary standard. These same commenters joined by NESCAUM and some State and local health and air pollution agencies expressed the view that if exposure and risk assessments were to be considered, that they supported setting the 8-hour standard at 0.070 ppm or below. They also argued that the exposure and health risk assessments underestimated exposure and risks for several reasons including: (1) the

geographic scope was limited to at most only 12 urban areas and thus underestimates national public health impacts due to exposures to O_3; (2) the assessments did not include all relevant at risk population groups and excluded populations such as pre-school children, outdoor workers, and adults who exercise outdoors; (3) the risk assessment did not include all of the health effect endpoints for which there is evidence that there are O_3-related health effects (e.g., increased medicine use by asthmatics, lung function decrements and respiratory symptoms in adults, increased doctors' visits, emergency department visits, school absences, inflammation, and decreased resistance to infection among children and adults); and (4) EPA's exposure assessment underestimates exposures since it considers average children, not active children who spend more time outdoors, and repeated exposures are underestimated. The joint set of comments from ALA and several environmental groups contended that while EPA's risk assessment showed the most stringent standard analyzed (0.064 ppm) would reduce the number of school-age children estimated to experience moderate lung function decrements relative to the prior standard of 0.084 ppm, a standard set at 0.064 ppm would still leave 20 percent of those school-age children who were estimated to experience this health effect unprotected. Therefore, they argued that EPA must adopt a more stringent standard of 0.060 ppm or below to reduce the considerable residual risk associated with a 0.064 ppm standard. This same set of commenters also stated that EPA should have estimated and considered total risk without excluding risks associated with PRB levels because there is no rational basis for excluding natural and anthropogenic sources from outside North America and that the NAAQS must protect against total exposure. While disagreeing with EPA's approach of estimating risks only above PRB, this same set of commenters supported the use of the GEOS-CHEM model as the "best tool available to derive background concentrations" should EPA continue to pursue this approach. These comments are briefly discussed in turn below and are discussed in more detail in the 2011 Response to Comments document.

The EPA does not agree that consideration of exposure estimates is not permitted or is somehow inappropriate in decisions concerning the primary standard. EPA has considered population exposure estimates as a consideration in prior NAAQS review decisions, including the 1997 revision of the O_3 primary standard and the 1994 decision on the carbon monoxide (CO) standard. As indicated in the 2010 proposal, estimating exposures of concern is important because it provides some indication of potential public health impacts of a range of O_3-related health outcomes, such as lung inflammation, increased airway responsiveness, and changes in host defenses. These particular health effects have been demonstrated to occur in some individuals in controlled human exposure studies at levels as low as 0.080 ppm O_3 but have not been evaluated at lower levels. While there is very limited evidence addressing lung function and respiratory symptom responses at 0.060 ppm, this evidence does not address these other health effects.

The EPA agrees that the exposure and health risk assessments are limited to certain urban areas and do not capture all of the populations at risk for O_3-related effects, and that the risk assessment does not include all potential O_3-related health effects. The criteria and rationale for selecting the populations and health outcomes included in the quantitative assessments were presented in the Health Assessment Plan, 2007 Staff Paper, and technical support documents for the exposure and health risk assessments that were reviewed by the CASAC Panel and the public. The CASAC Panel indicated in its letter that the health outcomes included in the quantitative risk assessment were appropriate, while recognizing that other health outcomes such as emergency department visits and increased doctors' visits should be addressed qualitatively (Henderson, 2006c). The Staff Paper (and the CASAC Panel) clearly recognized that the exposure and risk analyses could not provide a full picture of the O_3 exposures and O_3-related health risks posed nationally. The 2010 proposal made note of this important point and stated that "national-scale public health impacts of ambient O_3 exposures are much larger than the quantitative

estimates of O_3-related incidences of adverse health effects and the numbers of children likely to experience exposures of concern associated with meeting the then current standard or alternative standards" (75 FR 2994).

However, as stated in the 2010 proposal, EPA also recognizes that inter-individual variability in responsiveness to O_3 shown in controlled human exposure studies for a variety of effects means that only a subset of individuals in any population group estimated to experience exposures exceeding a given benchmark exposure of concern level would actually be expected to experience such adverse health effects (75 FR 2995). As discussed below in section II.C.3, the Administrator continues to recognize that there is a broader array of O_3-related adverse health outcomes for which risk estimates could not be quantified (that are part of a broader "pyramid of effects") and that the scope of the assessment was limited to just a sample of urban areas and to some but not all susceptible populations, leading to an incomplete estimation of public health impacts associated with O_3 exposures across the country. The Administrator is fully mindful of these limitations, along with the uncertainties in these estimates, in reaching her conclusion that observations from the exposure and health risk assessments provide additional support for her judgment that the 0.075 ppm 8-hour standard set in the 2008 final rule does not protect public health with an adequate margin of safety and that decision must be reconsidered. For reasons discussed below in section II.C.3, however, the Administrator disagrees with aspects of these commenters' views on the level of the standard that is appropriate and supported by the available health effects evidence and quantitative assessments associated with just meeting alternative standards.

As noted in the 2010 proposal, EPA emphasized that although the analysis of "exposures of concern" was conducted using three discrete benchmark levels (0.080, 0.070, 0.060 ppm), the concept was more appropriately viewed as a continuum, with greater confidence and less uncertainty about the existence of health effects at the upper end and less confidence and greater uncertainty as one considers

increasingly lower O_3 exposure levels. For the reasons discussed in section II.C.1.b of the 2010 proposed rule, the Administrator continues to conclude that it is appropriate to focus on both the 0.060 and 0.070 ppm health benchmarks for her decision on the primary standard. In summary, the focus on these two benchmark levels reflects the following evidence-based considerations, discussed above in section II.A.1, that raise concerns about adverse health effects likely occurring at levels below 0.080 ppm: (1) there is limited, but important, new evidence from controlled human exposure studies showing lung function decrements and respiratory symptoms in some healthy subjects at 0.060 ppm; (2) asthmatics are likely to have more serious responses than healthy individuals; (3) lung function is not likely to be as sensitive a marker for O_3 effects as lung inflammation; and (4) there is epidemiological evidence which reports associations between ambient O_3 concentrations and respiratory symptoms, emergency department visits, hospital admissions, and premature mortality in areas with O_3 levels that extend well below 0.080 ppm.

The EPA does not agree that it is inappropriate or impermissible to assess risks that are in excess of PRB or that EPA must focus on total risks when using a risk assessment to inform decisions on the primary standard. Consistent with the approach used in the risk assessment for the prior O_3 standard review and consistent with the approach used in risk assessments for other prior NAAQS reviews, estimating risks in excess of PRB is judged to be more relevant to policy decisions regarding the ambient air quality standard than risk estimates that include effects potentially attributable to uncontrollable background O_3 concentrations. EPA also notes that, with respect to the adequacy of the 0.075 ppm standard, taking total risks into account would not affect the Administrator's decision, since she judges that the 0.075 ppm standard is not adequate even when risks in excess of current PRB estimates are considered. In addition, EPA notes that consideration of the evidence itself, as well as

exposures at and above benchmark levels in the range of 0.060 to 0.080 ppm, are not affected by consideration of current PRB estimates.

The EPA does agree with the ALA and environmental groups comment that the GEOS-CHEM model represents the best tool currently available to estimate PRB as recognized in the 2006 Criteria Document evaluation of this issue and the CASAC Panel support expressed during the review of the Criteria Document.

The second group of commenters mostly representing industry associations, businesses, and some State and local officials opposed either revising the then current 8-hour standard or reconsidering the 0.075 ppm standard set in the March 2008 final rule. These views are most extensively presented in comments from UARG, API, Exxon-Mobil, AAM, and NAM, which raised one or more of the following concerns: (1) exposures of concern and health risk estimates have not changed significantly since the prior review in 1997; (2) uncertainties and limitations underlying the exposure and risk assessments make them too speculative to be used in supporting a decision to revise the standard; (3) EPA should have defined PRB differently and EPA underestimated PRB levels which results in health risk reductions associated with more stringent standards being overestimated; (4) exposures are overestimated based on specific methodological choices made by EPA including, for example, use of O_3 measurements at fixed-site monitors which can be higher than other locations where individuals are exposed, the failure of exposure estimates to account for O_3 avoidance behaviors, and overestimation of elevated breathing rates in the exposure model; and (5) health risks are overestimated based on specific methodological choices made by EPA including, for example, selection of inappropriate effect estimates from health effect studies, EPA's approach to addressing the shape of exposure-response relationships, and whether to incorporate thresholds into its models for the various health effects analyzed. These comments are briefly discussed in turn below and are addressed in more detail in the 2011 Response to

Comments document. Additional detailed comments related to the development, presentation, and interpretation of EPA's exposure and health risk assessments, along with EPA's responses to the specific issues raised by these commenters also can be found in the 2011 Response to Comments document.

(1) In asserting that the estimated exposures and risks associated with air quality just meeting the then current 0.084 ppm standard have not appreciably changed since the prior review, comments from Exxon Mobil and others have compared results of EPA's lung function risk assessment done in the 1997 review with those from the Agency's risk assessment done as part of the 2008 review and have concluded that lung function risks upon attainment of the then current O_3 standard are below those that were predicted in 1997 and that uncertainties about other health effects based on epidemiological studies remain the same. These commenters used this conclusion as the basis for a claim that there is no reason to depart from the Administrator's 1997 decision that the then current 8-hour standard is requisite to protect public health.

The EPA believes that this claim is fundamentally flawed for two reasons, as discussed in turn below: (i) it is factually inappropriate to compare the quantitative risks estimated in 1997 with those estimated in the current rulemaking; and (ii) it fails to take into account that with similar risks, increased certainty in the risks presented by O_3 implies greater concern than in the 1997 review. With respect to the first point, the 1997 risk estimates, or any comparison of the 1997 risk estimates to the current estimates, are irrelevant for the purpose of judging the adequacy of the then current 8-hour standard, as the 1997 estimates reflect outdated analyses that have been updated in the 2008 review to reflect the current science. Just comparing the results for lung function decrements ignores these differences. In particular, as discussed in section 4.6.1 of the 2007 Staff Paper, there have been significant improvements to the exposure model, which is a key component of the lung function risk assessment,

since the last review that make comparisons inappropriate between the prior and current review. For example, the geographic areas modeled are larger than in the previous review. When modeling a larger area, extending well beyond the urban core, there will be more people exposed, but a smaller percentage of the modeled population will be exposed at high levels, if O_3 concentrations are lower in the extended areas. In the 1997 review, only typical years, in terms of O_3 air quality, were modeled, while the current review used the most recent three year period (i.e., 2002-2004). Also, the 1997 review estimated exposures for children who spent more time outdoors, while the assessment for the current review included all school age and all asthmatic school age children. Therefore, the population groups examined in the exposure assessment, which is a key component of the lung function risk assessment, are different between those considered in the 1997 and 2008 review, making comparison of the resulting estimates inappropriate.

Another important difference making comparison between the 1997 health risk assessment and the 2008 assessment inappropriate is that a number of additional health effects were included in the 2008 review (e.g., respiratory symptoms in moderate/severe asthmatic children, non-accidental and cardiorespiratory mortality) based on health effects observed in epidemiological studies that were not included in the risk assessment for the prior review. These commenters only compare the risk estimates with respect to lung function decrement, and fail to account for differences in additional and more severe health endpoints not covered in the 1997 assessment, as well as the fact that there are somewhat different and more urban areas included in the 2008 assessment.

Second, it is important to take into account EPA's increased level of confidence in the associations between short-term O_3 exposures and morbidity and mortality effects. In comparing the scientific understanding of the risk presented by exposure to O_3 between the 1997 and 2008 reviews, one must examine not only the quantitative estimate of risk from those exposures (e.g. the numbers of

increased hospital admissions at various levels) but also the degree of confidence that the Agency has that the observed health effects are causally linked to O_3 exposure at those levels. As documented in the 2006 Criteria Document and the recommendations and conclusions of CASAC, EPA recognizes significant advances in our understanding of the health effects of O_3 based on new epidemiological studies, new controlled human exposure and animal studies that support biological plausibility of O_3 effects (See Staff Paper, section 3.5, pp.3-50 - 3-62), and new studies addressing the utility of using ambient monitors to assess population exposures to ambient O_3 (See Staff Paper, section 3.4.2.1, pp.3-39 - 3-42). As a result of these advances, EPA is now more certain that ambient O_3 presents a significant risk to public health at levels at or below the range of levels that the Agency had considered for these standards in 1997. From this more comprehensive perspective, since the risks presented by O_3 are more certain and the current quantitative risk estimates include additional important health effects, O_3-related risks for a wider range of health effects are now of greater concern at both the 0.084 ppm and 0.075 ppm standard levels than in the 1997 review.

(2) In asserting that uncertainties and limitations associated with the exposure and health risk assessments make them too speculative to be used in supporting a decision to revise the 0.084 ppm standard or to reconsider the 0.075 ppm standard announced in March 2008, comments from industry associations and others cited a number of issues including: (i) uncertainties about the air quality adjustment approach used to simulate just meeting various alternative standards; (ii) uncertainties about whether the respiratory symptoms, hospital admissions, and non-accidental and cardiorespiratory mortality effects included in the health risk assessment are actually causally related to ambient O_3 concentrations, particularly at levels well below the 0.075 ppm standard; and (iii) uncertainties about the shape of the exposure-response relationships for lung function responses and concentration-response

relationships for the health effects based on findings from epidemiological studies and the assumption of a linear non-threshold relationship for these responses.

Many of the industry groups (e.g., API, AAM, NAHB, NAM) and individual business commenters (e.g., Exxon Mobil, Dow) placed increased emphasis in their comments on issues related to PRB, contending that uncertainties and limitations associated with the definition and estimation of PRB concentrations were responsible for overestimation of the risk reductions that would be achieved by meeting alternative standards. These commenters also argued that EPA should not set a standard in the range of 0.60-0.070 ppm because this would be below peak PRB levels in rural areas and portions of the Western U.S.

In summary, many of these commenters contend that the substantial uncertainties present in the exposure and risk assessments preclude the Administrator from using any of the results to support a conclusion that the 2008 decision on the 8-hour standard does not adequately protect public health.

Several of the issues raised, including whether EPA's judgments about causality for the effects included in the risk assessment are appropriate, the shape of concentration-response relationships, and use of a linear non-threshold relationship for the health outcomes based on the epidemiological evidence, have been discussed in the previous section on health effects evidence. Concerns expressed about the definition and estimation of PRB levels for O_3 and the role of PRB in the risk assessment are addressed as a separate item below. These issues also are addressed in more detail in the 2011 Response to Comments document.

With respect to the air quality adjustment approach used in the current review to simulate air quality just meeting the then current and alternative O_3 standards, as discussed in the 2007 Staff Paper (section 4.5.6) and in more detail in a staff memorandum (Rizzo, 2006), EPA concluded that the quadratic air quality adjustment approach generally best represented the pattern of reductions across the

O_3 air quality distribution observed over the last decade in areas implementing control programs designed to attain the O_3 NAAQS. While EPA recognizes that future changes in air quality distributions are area-specific, and will be affected by whatever specific control strategies are implemented in the future to attain a revised NAAQS, there is no empirical evidence to suggest that future reductions in ambient O_3 will be significantly different from past reductions with respect to impacting the overall shape of the O_3 distribution.

As discussed in the 2010 proposal, EPA recognizes that the exposure and health risk assessments necessarily contain many sources of uncertainty including those noted by these commenters, and EPA has accounted for such uncertainties to the extent possible. EPA developed and presented an uncertainty analysis addressing the most significant uncertainties affecting the exposure estimates. With respect to the health risk assessment, EPA conducted and presented sensitivity analyses addressing the impact on risk estimates of different assumptions about the shape of the exposure-response relationship for lung function decrements and alternative assumptions about PRB levels. EPA notes that most of the comments summarized above concerning limitations and uncertainties in these assessments are essentially restatements of concerns raised during the development and review of these quantitative assessments as part of the preparation and review of the 2007 Staff Paper and assessments. The CASAC Panel reviewed in detail the approaches used to assess exposure and health risks and the presentation of the results in the Staff Paper. EPA believes, and the CASAC Panel concurred, that the model used to estimate exposures represents a state-of-the-art approach and that “there is an explicit discussion of the limitations of the APEX model in terms of variability and quality of the input data, which is appropriate and fine” (Henderson, 2006c, p. 11). The CASAC O_3 Panel recently stated that, "Based on earlier uncertainty and sensitivity analyses carried out by EPA, and relative to the uncertainty in health effect estimates, the extent of uncertainty in these exposure estimates is acceptable" (Samet, 2011, p.12). The

CASAC Panel also found the risk chapter in the Staff Paper and the risk assessment "to be well done, balanced, and reasonably communicated" (Henderson, 2006c, p. 12). Although EPA agrees that important limitations and uncertainties remain, and that future research directed toward addressing these uncertainties is warranted, EPA believes that overall uncertainties about population exposure and possible health risks associated with short-term O_3 exposure have diminished since the 1997 review. As discussed below in section II.C.3, the Administrator has carefully considered the limitations and uncertainties associated with these quantitative assessments but continues to believe that they provide general support for concluding that (i) exposures and health risks associated with meeting the 0.075 ppm, 8-hour standard are important from a public health perspective and that the 8-hour standard needs to be set below this level in order to protect public health with an adequate margin of safety and (ii) that there are important reductions in exposure and health risks associated with alternative 8-hour standards set at and below 0.070 ppm that should be considered in selecting the level of the standard that is judged to protect public health with an adequate margin of safety.

(3) Comments from several industry organizations, businesses, and others related to PRB included the following: (i) EPA should have defined PRB differently so as to include anthropogenic emissions from Canada and Mexico; (ii) EPA underestimated PRB levels by relying on a range of O_3 PRB values predicted by the GEOS-CHEM model, 0.015 to 0.035 ppm, which they asserted underestimates PRB, and advocated that EPA use monitoring data at remote monitoring locations rather than modeling to estimate PRB levels; (iii) several "new" studies published subsequent to the 2006 Criteria Document raise issues relevant to EPA's estimated PRB levels; (iv) the use of underestimated PRB levels in the risk assessment results in overestimated health risks associated with air quality just meeting the then current standard; (v) EPA neglected to estimate the extreme values of PRB even though the statistical form of the O_3 standard is an extreme value and that EPA only calculated monthly

mean background values in the risk assessment; and (vi) concerns expressed by the CASAC Panel that "the Final Ozone Staff Paper does not provide a sufficient base of evidence from the peer-reviewed literature to suggest that the current approach to determining a PRB is the best method to make this estimation" (Henderson, 2007, p.2). Each of these concerns is addressed briefly below and in more detail in the 2011 Response to Comments document.

First, the U.S. government has influence over emissions at our borders that affect ambient O_3 concentrations entering the U.S. from Canada and Mexico through either regulations or international agreements, and therefore EPA does not agree that these emissions are uncontrollable. PRB is designed to identify O_3 levels that result from emissions that are considered uncontrollable because the U.S. has little if any influence on their control, and in that context anthropogenic emissions from Mexico or Canada should be excluded from PRB. EPA has consistently defined PRB as excluding anthropogenic emissions from Canada and Mexico in NAAQS reviews over more than two decades and sees no basis in the comments to alter this definition.

Second, the criticisms raised concerning the use of a modeling approach (GEOS-CHEM using 2001 meteorology) and the alternative approach of using remote monitoring data to estimate PRB were considered by EPA's scientific staff and the CASAC Panel during the course of reviewing the 2006 Criteria Document. Both EPA's experts and CASAC experts endorsed the use of the peer-reviewed, thoroughly evaluated modeling approach (GEOS-CHEM) described in the Criteria Document as the best current approach for estimating PRB levels. The Criteria Document reviewed detailed evaluations of GEOS-CHEM with O_3 observations at U.S. surface sites (Fiore et al., 2002, 2003) and comparisons of GEOS-CHEM predictions with observations at Trinidad Head, CA (Goldstein et al., 2004) and found no significant differences between the model predictions and observations for all conditions, including those given in the current PRB definition. The Criteria Document states that the current model estimates

indicate that PRB in the U.S. is generally 0.015 to 0.035 ppm, declines from spring to summer and is generally < 0.025 ppm under conditions conducive to high O_3 episodes. EPA recognizes that the range of PRB values cited by commenters is not all inclusive but represents only about 70% of values. The Criteria Document acknowledges that O_3 PRB values tend to be higher in the West during spring and can be lower in the East during conditions conducive to the formation of O_3 episodes in the summer. The Criteria Document also noted that it is impossible to determine sources of O_3 without ancillary data that could be used as tracers of sources or to calculate photochemical production and loss rates. Given the lack of the necessary ancillary data in most areas, EPA continues to believe that the use of global chemical transport models, like GEOS-CHEM, is the best approach for estimating O_3 PRB. In addition, EPA notes that unusually high springtime O_3 episodes tied to stratospheric intrusion are rare, generally occur at elevated locations, and can be readily identified and excluded under EPA's Exceptional Events Rule (72 FR 13560) to avoid any impact on attainment/non-attainment status of an area. It is important to note that EPA's risk assessments require spatially and temporally resolved estimates of PRB which can only be provided through modeling.

Third, issues related to "new" studies not included in the 2006 Criteria Document that were cited by commenters as supporting arguments that EPA underestimated PRB levels, particularly in the springtime in western and rural locations, and buttressing concerns that there is still substantial uncertainty in modeling estimates of PRB are addressed in section II.C.2.d. of this final rule and in more detail in the 2011 Response to Comments document.

Fourth, many of the commenters who raised the concern that EPA's estimates of PRB were too low and had the impact of exaggerating the risks associated with the then current standard ignored the fact that the risk assessment included a sensitivity analysis which showed the potential impact of both lower and higher estimates of PRB or only focused on the impact of higher estimates of PRB. The

choices of lower and higher estimates of PRB included in the risk assessment sensitivity analyses were based on the peer-reviewed evaluation of the accuracy of GEOS-CHEM model. The 2006 Criteria Document states "in conclusion, we estimate that the PRB O_3 values reported by Fiore et al. (2003) for afternoon surface air over the United States are likely 10 parts per billion by volume (ppbv) too high in the southeast in summer, and accurate within 5 ppbv in other regions and seasons." These error estimates are based on comparison of model output with observations for conditions which most nearly reflect those given in the PRB definition, i.e., at the lower end of the probability distribution. As discussed in the 2006 Criteria Document and 2007 Staff Paper, it can be seen that GEOS-CHEM overestimates O_3 for the southeast and underestimates it by a small amount for the northeast. These commenters generally ignored the scientific conclusion presented in the Criteria Document that for some regions of the country the evidence suggests that the model actually overestimates PRB. Thus, the influence of alternative estimates of PRB on risks in excess of PRB associated with meeting the then current standard, or any of the alternative standards included in the assessment, can be to lower or increase the risk estimates. While the choice of estimates for PRB contributes to the uncertainty in the risk estimates, EPA does not agree that the approach used is biased since peer-reviewed evaluations of the model have shown relatively good agreement (i.e., generally within 5 ppb for most regions of the country).

Fifth, concerns raised about EPA's failure to estimate an extreme value (i.e., the fourth highest daily maximum 8-hour average in the year) for PRB ignores the fact that EPA's risk assessment takes into account the entire distribution of daily 8-hour concentrations over the warm O_3 season. Considering that the state-of-the-science for global atmospheric chemistry modeling for the current review was not at the point where the fourth highest 8-hour PRB value in a year could be reliably estimated and that the risk assessment requires estimates of PRB for the entire distribution of hourly O_3 concentrations, EPA

believes that the use of an estimated monthly diurnal hourly profile for PRB for each urban area was the most appropriate statistic to use to estimate risks in excess of PRB. This approach represents a significant improvement compared to the use of a single value for PRB in the prior 1987 review. In addition, even if it were possible to estimate the extreme values of PRB, it is not likely that they would significantly alter the risk estimates, since those extreme values would by definition occur on very few days and would have little impact on the overall risk estimates which are influenced by the entire distribution of O_3 concentrations.

Finally, EPA believes that some commenters have misread the CASAC Panel concern that the Final 2007 Staff Paper does not provide a sufficient base of evidence "to suggest that the current approach to determining PRB is the best method to make this estimation" (Henderson, 2007, p.2) as a criticism of the use of the GEOS-CHEM modeling approach and/or support for primary reliance on estimates based on remote monitoring sites. The CASAC Panel went on to state that one reason for its concern was that the contribution to PRB from beyond North America was uncontrollable by EPA and that "a better scientific understanding of intercontinental transport of air pollutants could serve as the basis for a more concerted effort to control its growth ..." (Henderson, 2007, p.3). Hence, CASAC did not express technical concerns about the model nor did they suggest that other methods would be more appropriate, their concern was with defining what emissions to include in defining PRB, and the role that PRB should play, as compared to the technical question of the best way to estimate PRB levels. In fact, in individual comments, one panel member specifically commenting on how PRB had been estimated using the GEOS-CHEM model concluded that the "current approach has been peer-reviewed, and is appropriate" (Henderson, 2006b, p.D-48).

(4) Some commenters raised concerns about aspects of the exposure modeling that they felt resulted in overestimates of modeled exposures, including: (i) O_3 measurements at downwind monitors

are usually higher than the overall area and may not reflect the overall outdoor exposures in the area; (ii) O_3 exposures near roadways will be below that measured at the monitor due to titration of O_3 from automobile emissions of NO; (iii) O_3 concentrations are lower at a person's breathing height compared to measurement height, (iv) exposure estimates do not account for O_3 avoidance behaviors; and (v) the APEX model overpredicts elevated ventilation rate occurrences, which results in an overestimation of the number of exposures of concern and risk estimates for lung function decrements.

The concern raised in the first point is unfounded since all O_3 monitors in each area are used to take into account the spatial variations of O_3 concentrations. The geographic variation of O_3 concentration is accounted for by using measurements from the closest O_3 monitor to represent concentrations in a neighborhood and the measurements at downwind monitors are applied only to the downwind areas.

Second, the reduction in O_3 concentrations near roadways due to titration of O_3 from automobile emissions of NO is accounted for and explicitly modeled in APEX and thus does not bias estimates of exposures. This phenomenon was modeled through the use of "proximity factors," which adjust the monitored concentrations to account for the titration of O_3 by NO emissions (the monitored concentrations are multiplied by the proximity factors). Three proximity factor distributions were developed, one for local roads, one for urban roads, and one for interstates, with mean factors of 0.75, 0.75, and 0.36 respectively (section 3.10.2, Exposure Analysis TSD). Furthermore, the uncertainty of these proximity factor distributions was included in the exposure uncertainty analysis.

Third, as discussed in the exposure uncertainty analysis, data were not available to quantify the potential biases of differences between O_3 concentrations at a person's breathing height compared to the heights of nearby monitors. EPA believes that these biases, to the extent that they exist, are relatively small during warm summer afternoons when O_3 concentrations tend to be higher.

Fourth, behavior changes in response to O_3 pollution or in response to AQI notification alerts ("avoidance behavior") are not explicitly taken into account in the exposure modeling. There is not much information about the extent to which people currently modify their activities in response to O_3 alerts. However, under the scenarios modeled for just meeting alternative standards, O_3 alerts would be infrequent relative to the number of alerts that currently occur in the nonattainment areas modeled. Consequently, EPA does not feel that this is an influential factor in the estimation of exposure for the scenarios simulating just meeting the then current or alternative standards.

Fifth, a comparison of ventilation rates predicted by APEX to actual measurements showed APEX overpredicting ventilation rates for ages 5 to 10, underpredicting ventilation rates for ages 11 to 29 and greater than 39, and in close agreement for ages 30 to 39. The overall agreement was judged favorable, and the errors of the predicted ventilation rates were taken into account into the overall uncertainty analysis in conjunction with the uncertainties of the metabolic equivalents (METs), which are the primary drivers of ventilation rates in this model.

(5) Comments from a number of industry organizations, businesses, and others contended that EPA's health risk assessment was biased and that the resulting risk assessment is "much higher than would have been obtained using objective methods" (NAM, 2007), and commenters raised one or more of the following points in support of this view: (i) EPA inappropriately based its risk assessment for respiratory symptoms, hospital admissions, and non-accidental and cardiorespiratory mortality on positive studies with high risk coefficients while ignoring negative studies and studies with lower coefficients; (ii) EPA focused on combined "national" effect estimates from multi-city studies when it should have relied on individual city effect estimates from these studies in its risk assessment; (iii) the risk assessment presented single-pollutant model results that overstate the likely impact of O_3 when co-pollutant model results were available which should have been used; (iv) the risk assessment used linear

concentration-response relationships for the health endpoints based on epidemiological studies when non-linear or threshold models should have been used; and (v) the lung function portion of the risk assessment should not rely on what they characterized as "outlier" information to define exposure-response relationships, with reference to the data from the Adams (2006) study, but rather should focus on group central tendency response levels. Each of these issues is discussed below and in more detail in the 2011 Response to Comments document.

First, several commenters asserted that the results of time-series studies should not be used at all in quantitative risk assessments, that risk estimates from single-city time-series studies should not be used since they are highly heterogeneous and influenced by publication bias, and that the panel study that served as the basis for the concentration-response relationships for respiratory symptoms in asthmatic children suffered from various weaknesses and was contradicted by a more recent study. EPA notes that the selection of specific studies and effect estimates was based on a careful evaluation of the evidence evaluated in the 2006 Criteria Document and that the criteria and rationale for selection of studies and effect estimates were presented and extensively reviewed and discussed by the CASAC Panel and in public comments presented to the CASAC Panel. EPA notes that the CASAC Panel judged the selection of the endpoints based on the epidemiological studies for inclusion in the quantitative risk assessment to be "appropriate." (Henderson, 2006c, p.12).

While EPA notes that two of the meta-analyses, Bell et al. (2005) and Ito et al. (2005), provided suggestive evidence of publication bias, O_3-mortality associations remained after accounting for that potential bias. The 2006 Criteria Document (p.7-97) concludes that the "positive O_3 effects estimates, along with the sensitivity analyses in these three meta-analyses, provide evidence of a robust association between ambient O_3 and mortality." Concerns about the heterogeneity of responses observed across

different urban areas, particularly for O_3-related mortality, are addressed in the section above on health effect considerations.

Second, as discussed in more detail in the 2007 Staff Paper (section 5.3.2.3), there are different advantages associated with use of single-city and multi-city effect estimates as the basis for estimating health risks in specific urban areas. Therefore, the risk assessment included risk estimates based on both single-city and multi-city models where such information was available.

Third, the risk assessment included risk estimates based on both single pollutant and multi-pollutant concentration-response relationships where such information was available for the health outcomes included in the assessment. Issues related to the consideration of single versus multi-pollutant models have been addressed in the section above on health effects evidence.

Fourth, EPA's approach of using linear concentration-response relationships for the health outcomes based on epidemiological studies and its decision on whether or not to include any non-linear models or assumed threshold were reviewed and discussed by the CASAC Panel during the development of the 2007 Staff Paper and risk assessment, and the Panel concurred with the approaches taken. The CASAC Panel has recently reiterated its support for the assumption that there is no threshold for the purpose of conducting risk assessments at this time (Samet, 2011). As discussed in the 2010 proposal, the Staff Paper (section 3.4.5), and above in the prior section on health effects evidence, EPA recognizes that the available epidemiological evidence neither supports or refutes the existence of thresholds at the population level for effects such as increased hospital admissions and premature mortality. Noting the limitations of epidemiological evidence to address such questions, EPA concluded that if a population threshold does exist, it would likely be well below the level of the then current O_3 standard. As discussed below in section II.C.3, the Administrator is very mindful of the uncertainties related to whether the observed associations between O_3 concentrations at levels well below 0.080 ppm

and the health outcomes reported in the epidemiological studies reflect actual causal relationships, and she has taken this into account in considering the risk assessment estimates in her decision.

Fifth, consistent with the 1997 review, the lung function component of the risk assessment has focused on the number and percentage of children that are estimated to experience a degree of lung function decrement that represents an adverse health effect. EPA does not agree that the focus of the quantitative risk assessment should be on the average lung function response in the population, since such an assessment would not address the public health policy question concerning to extent to which susceptible populations would likely experience health effects of concern. Looking at just the average for the population would ignore the evidence of health effects for susceptible populations, an important aspect of public health impact in this and past O_3 reviews. EPA believes that it is appropriate to include all of the individual data from the series of controlled human exposure studies that address lung function responses associated with 6.6 hour exposures to O_3 and that were reviewed and included in the final Criteria Document, including the Adams (2006) study. EPA notes that the CASAC Panel clearly did not judge the responses observed in this study to be an "outlier." Rather, CASAC stated in its comments on the 2007 Staff Paper's discussion of this study, "there were clearly a few individuals who experienced declines in lung function at these lower concentrations. These were healthy subjects so the percentage of asthmatic subjects, if they had been studied, would most likely be considerably greater" (Henderson, 2006c, p. 10). In its March 2011 consensus letter, CASAC specifically referred to Figure 8-2 of the 2006 Criteria Document and stated that it,

> …shows an approximately normal distribution in the ozone-induced decrements in FEV_1 with exposure to 0.060 ppm (60 ppb). The consistency of effects across ozone exposure levels within the Adams study, as well as the consistency with effects observed in an earlier independent study (McDonnell et al. 1991), supports the validity of the observed deficits in FEV_1 at 60 ppb from the Adams study. In other words, the evidence suggests that prolonged exposure to 60 ppb ozone causes a general shift in the distribution of FEV_1 towards lower values. Although the mean decrement is less than 3% and would not be considered clinically important, the shift to the

right in this distribution pushes a fraction of subjects (7%) into the region of clinical importance (>10% decrement). (Samet, 2011, p.7)

Having considered comments on the quantitative exposure and health risk assessments from both groups of commenters, as discussed below in section II.C.3, the Administrator finds no basis to change her position on these quantitative assessments that was taken at the time of the 2010 proposal. That is, as discussed above, while the Administrator recognizes that the assessments rest on a more extensive body of data and are more comprehensive in scope than the assessment conducted in the 1997 review, she is mindful that significant uncertainties and limitations continue to underlie the resulting quantitative exposure and risk estimates. Nevertheless, the Administrator concludes that the exposure and risk estimates are sufficiently reliable to inform her judgment about the significance of the exposures and risk of health effects in susceptible and vulnerable populations at O_3 levels associated with just meeting the then current 0.084 ppm standard, the 0.075 ppm standard set in March 2008 and alternative standards below these levels.

d. Consideration of the 2009 Provisional Assessment and "New" Studies

Comments on the 2009 Provisional Assessment are addressed in this section, subsection (i) below, in section I.E above, and more fully in the 2011 Response to Comments document. Comments on "new" studies are addressed in this section, in subsection (ii) below, and more fully in the 2011 Response to Comments document. In general, only industry groups commented on the Provisional Assessment; medical, public health, environmental and industry groups commented on "new" studies.

i Comments on the Provisional Assessment

Several commenters, mainly industry groups including UARG, NAM, AAM, API, and others, compared the 2009 Provisional Assessment to a Criteria Document or Integrated Science Assessment in

terms of comprehensiveness, external peer-review, and its role in the reconsideration of the 2008 decision on the O_3 primary standard.

These commenters stated that the 2009 Provisional Assessment is not a substitute for a Criteria Document or Integrated Science Assessment. One commenter expressed the view that the Provisional Assessment cannot legally serve as a Criteria Document and "does not satisfy the requirement for air quality criteria that accurately reflect the latest scientific knowledge" (API, 2010, Part I, p.6). Another commenter asserted that the "assessment lacks the depth of analysis that the Criteria Document (CD) or Integrated Science Assessment (ISA) would bring to a review process" (AAM, 2010, p.2), and that the "Provisional Assessment cannot fulfill the CAA requirements regarding accuracy because it does not fully and completely analyze the required wide variety of health effects, inputs, welfare effects and policy relevant background" (AAM, 2010, p.5).

Another limitation of the 2009 Provisional Assessment cited by commenters is the fact that it has not undergone external peer-review. Citing a former EPA Administrator, one commenter stated that EPA has recognized that it cannot rely on scientific studies that have not been included in air quality criteria reviewed by CASAC (UARG, 2010, p.10). Another commenter noted that the Provisional Assessment was prepared without an opportunity for comment by CASAC or the public, and that it was subject only to internal EPA peer-review. This commenter goes on to note that by law a revised Criteria Document or Integrated Science Assessment must be reviewed by CASAC, and that EPA has a long-standing practice of soliciting public comments on multiple drafts of a Criteria Document or Integrated Science Assessment (API, 2010, Part I, p.7).

Finally, these commenters expressed the view that, for the reasons discussed above, the 2009 Provisional Assessment cannot remedy the Agency's failure in the reconsideration proposal to comply with the CAA's requirement that the Administrator rely on "the latest scientific knowledge useful in

indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [the] pollutant in the ambient air, in varying quantities" (UARG, 2010, p.10).

All of these comments about the role of the 2009 Provisional Assessment in the reconsideration of the 2008 decision on the O_3 primary standard, relative to the 2006 Criteria Document, indicate a fundamental misunderstanding about how the Administrator is considering the Provisional Assessment in this reconsideration process. As discussed in section I.E.2 above, EPA's reconsideration complies with all CAA requirements. All of the comments about the Provisional Assessment, in terms of comparing it to a Criteria Document or Integrated Science Assessment with respect to comprehensiveness, external peer-review, and its role in the reconsideration of the 2008 decision on the O_3 primary standard, are addressed in section I.E.2 above.

With regard to the scientific and technical merit of the 2009 Provisional Assessment, several commenters state that the assessment is flawed. They express the view that the Provisional Assessment does not accurately reflect the latest science since it overlooks several significant "new" scientific studies, does not thoroughly assess the studies it does summarize, and omits consideration of "new" information concerning a key issue in the 2008 review, background O_3 concentrations. These commenters challenged EPA's conclusion that, taken in context, the "new" information and findings do not materially change any of the broad scientific conclusions regarding the health and ecological effects of O_3 exposure made in the 2006 Criteria Document and that the "new" evidence strengthens conclusions in the Criteria Document related to the potential for health effects at exposure concentrations of less than 0.080 ppm (EPA, 2009). One commenter stated that this assertion is not supported by even a quick review of newer information brought to EPA's attention during the 2008 rulemaking and addressed in the Provisional Assessment (API, 2010, Part I, p.8). This commenter goes

on to point to studies included in the Provisional Assessment that did not find associations between O_3 exposures and lung function decrement and exacerbation of asthma symptoms in children (API, 2010, Part I, p.9). Other commenters pointed to other studies in the Provisional Assessment that did not find associations between O_3 exposure and other health outcomes to challenge EPA's conclusions. These commenters also mentioned studies that were not included in the Provisional Assessment.

The commenters' statements reflect a fundamental misunderstanding of the intent of the 2009 Provisional Assessment and the basis for conclusions therein. The intent of the Provisional Assessment was to determine if studies published since the 2006 Criteria materially changed conclusions related to health and ecological effects of that document. Overall, EPA's Provisional Assessment led to the conclusion that, "taken in context, the new information and findings do not materially change any of the broad scientific conclusions regarding the health and ecological effects of O_3 exposure made in the 2006 O_3 AQCD." Clearly, a review of only the most recent literature in the Provisional Assessment could not, nor was it intended to, capture the larger body of evidence reviewed in the Criteria Document.

Consideration of limited "new" data in the 2009 Provisional Assessment versus the larger body of evidence reviewed in the 2006 Criteria Document lead to differing impressions of the science on the part of some commenters. For instance, with reference to recent epidemiological studies in the Provisional Assessment, NAM (NAM, 2010a?; p.15) stated that, "All three new studies that evaluated the relationship between ozone and airway inflammation report no effects due to ozone exposure." In the Criteria Document, however, EPA concluded that, "The extensive human clinical and animal toxicological evidence, together with the limited available epidemiological evidence, is clearly indicative of a causal role for O_3 in inflammatory responses in the airways." (EPA, 2006a, p.E-14) Three epidemiological studies evaluating inflammation in the Provisional Assessment do not affect conclusions in the Criteria Document based primarily on extensive human clinical and animal

toxicological evidence. Information about the various types of "new" studies and responses to comments received on these "new" studies are presented below and more detailed responses regarding specific studies are discussed in the 2011 Response to Comments document.

ii Comments on "new" studies

Many commenters identified "new" studies that were not included in the 2006 Criteria Document that they stated support arguments both for and against reconsidering the decision on the 0.075 ppm standard announced in March 2008. Some commenters also cited "new" studies that were not included in EPA's 2009 Provisional Assessment. These commenters stated that the "new" studies support arguments both for and against the reconsideration of the 2008 decision on the primary O_3 standard. Commenters who supported the reconsideration of the O_3 standard identified new studies that generally supported EPA's conclusions about the associations between O_3 exposure and a range of respiratory and cardiovascular health outcomes. These commenters also identified "new" studies that provide evidence for associations with health outcomes that EPA has not linked to O_3 exposure, such as cancer, and populations that EPA has not identified as being susceptible or vulnerable to O_3 exposure, including African-Americans and women. Commenters who did not support reconsideration of the 2008 decision on the O_3 standard often submitted the same "new" studies, but focused on different aspects of the findings. Commenters who did not support the reconsideration of the O_3 standard stated that these "new" studies provide inconsistent and sometimes conflicting findings that do little to resolve uncertainties regarding whether O_3 has a causal role in the reported associations with adverse health outcomes, including premature mortality and various morbidity outcomes.

The "new" studies submitted in the comments generally covered three topic areas: controlled human exposures; epidemiology; and PRB. Sometimes commenters that supported the reconsideration of the 2008 decision pointed to the same "new" studies to support their point of view as the commenters

who did not support the reconsideration. One example of this is a "new" controlled human exposure study that was included in the 2009 Provisional Assessment. Some commenters (ALA et al., 2010, pp.39 - 40) that supported the reconsideration cited a study funded by the API (Schelegle et al., 2009) that investigated the effect of 6.6 hour inhalation of O_3 concentrations from 0.060 to 0.087 ppm in 31 healthy young adults. They noted that this study reported statistically significant effects on respiratory symptoms and pulmonary function in healthy individuals at 0.070 ppm. The study also found decrements in lung function at 0.060 ppm, of about the same magnitude as reported in the Adams studies (Adams, 2002, 2006). This group of commenters focused on the discussion in the study of subjects that had larger lung function responses than average, noting that 16% of the subjects tested had lung function decrements greater than 10% at 0.060 ppm, confirming that some healthy individuals are more sensitive to O_3 than average. These commenters also cited an accompanying commentary (Brown, 2009) noting that there are at least three important findings from Schelegle et al. (2009) with public health implications. First, statistically significant changes in FEV_1 and symptoms occurred in healthy individuals at 0.070 ppm. Second, the magnitude of the mean FEV_1 decrement (3.5% corrected for filtered air) at 0.060 ppm was about the same as reported by Adams, indicating that these findings further support a smooth dose-response curve without evidence of a threshold for exposures between 0.040 and 0.120 ppm O_3. Third, consistent with numerous studies, there is considerable intersubject variability in response to O_3, with Schelegle and colleagues finding that 16% of individuals have greater than 10% FEV_1 decrements at 0.060 ppm, and this proportion increased to 19, 29, and 42% at 0.070, 0.080, and 0.087 ppm, respectively.

Other commenters who did not support reconsideration of the 2008 O_3 standard also cited the study by Schelegle et al. (2009) as evidence to support their position. One commenter (NAM, 2010a?) stated that the study by Schelegle et al. (2009) confirms the findings by Adams (2006, 2002) that no

statistically significant changes in pulmonary function occur in healthy subjects exposed for 5-6 hour to 0.060 ppm using a step function exposure versus filtered air. This commenter goes on to express the view that "this is a critical confirmatory finding since in the last review as well as the current reconsideration EPA is assuming that based on their internal reanalysis of a small amount of the data from Adams (2006) that pulmonary function changes occur at 0.060 ppm" (NAM, 2010a, Attachment 1, p.1) This commenter also focused on the magnitude of the group mean lung function changes in this study, noting that Schelegle et al. (2009) also reported a small (5%) but statistically significant change in FEV_1 in subjects exposed to 0.070 ppm versus filtered air, but that this small level of reversible effect is not considered to be adverse according to criteria defined by the ATS.

The EPA disagrees with NAM's characterization of and conclusions based on the Schelegle et al. (2009) study. EPA's analysis of the Adams (2006) data supported the position that observable health effects do not abruptly taper off or terminate below 0.08 ppm. Brown et al. (2008) confirm the statistical significance of effects in the Adams (2006) study at 0.060 ppm. The Schelegle et al. (2009) study does not undermine that finding, rather it shows a mean FEV_1 decrement (3.5% corrected for filtered air) at 0.060 ppm that is nearly equivalent to that in the Adams (2006) study (2.9% corrected for filtered air). That measurable health effects should be expected to occur below 0.08 ppm is further confirmed by statistically significant changes in FEV_1 and respiratory symptoms in healthy individuals at 0.070 ppm in the Schelegle et al. (2009) study. EPA also disagrees with NAM's focus on only mean FEV_1 responses. In an individual with relatively "normal" lung function, recognizing technical and biological variability in measurements, within-day changes in FEV_1 of $\geq$ 5% are clinically meaningful (ATS, 1991; Pellegrino et al., 2005). In the context of standard setting, CASAC has indicated that a focus on the middle to upper end of the range of moderate levels of functional responses (e.g., FEV_1 decrements $\geq$ 15% but < 20%) is appropriate for estimating potentially adverse lung function decrements

in active healthy people. Schelegle et al. (2009) found > 15% FEV_1 decrements in 3, 10, and 16% of individuals exposed for 6.6 hours to 0.060, 0.070, and 0.080 ppm, respectively. These estimated proportions of affected individuals were based on O_3 exposures alone and were not adjusted for responses of the individuals following filtered air exposure. Given that lung function typically improves in healthy adults during filtered air exposures, these uncorrected proportions likely underestimate the actual fraction of healthy individuals affected by these O_3 exposure levels. Considering individual responses, adverse effects are observed in the Schelegle et al. (2009) down to a level of at least 0.070 ppm. Group mean lung function responses, although small, were statistically significant at 0.070 ppm in this study.

With respect to "new" epidemiological studies, commenters who supported the reconsideration of the 2008 decision on the O_3 standard cited an number of "new" studies, all of which were not included in the 2006 Criteria Document, and some of which were not included in the 2009 Provisional Assessment as supporting that low O_3 exposures can: (1) increase the frequency of airway and allergic diseases; (2) represent a significant health risk based on evidence of a variety of health effects including premature mortality; (3) result in adverse effects in vulnerable populations, including children with asthma, elderly individuals, and people with chronic airway diseases, (ATS, 2010, pp. 2 - 3), especially asthma and COPD (ALA, 2010, p.54, p.57).

The EPA generally agrees with these commenters; however, their conclusions are largely drawn from studies in the broader literature, not from "new" studies alone. These commenters (e.g., ATS, ALA) cite both "new" studies and studies included in the 2006 Criteria Document.

Commenters who did not support the reconsideration of the 2008 decision on the O_3 standard cited a number of "new" epidemiological studies, all of which were not included in the 2006 Criteria Document, and some of which were not included in the 2009 Provisional Assessment as supporting the

following points: (1) results of "new" epidemiological studies were mixed for respiratory and cardiovascular morbidity and for health effects associated with long-term exposure; and (2) some "new" studies suggest that thresholds may exist for O_3-related mortality and morbidity. In addition, as noted above, these commenters also generally reiterated issues raised previously, such as sensitivity of epidemiological studies to model specification or exposure error.

The EPA does not agree that the "new" study results are "mixed" and would alter previous conclusions. In the 2009 Provisional Assessment, it was found that these results are consistent with the findings of studies included in the 2006 Criteria Document and thus do not materially change the conclusions regarding health effects of O_3. Some commenters (e.g., NAM, 2010a, Attachment 1) counted studies in the Provisional Assessment and report how many are "positive" and "negative." EPA observes that commenters are inappropriately using these terms to distinguish statistically significant results from those not reaching statistical significance, and the "negative" studies are not showing that O_3 is beneficial to health. These studies are often in fact positive, but the positive associations are not statistically significant. In an evaluation of the scientific evidence, EPA considers the pattern of results for a given endpoint and does not simply count studies that attain statistical significance. The study results summarized in the Provisional Assessment were very similar to those in the Criteria Document. EPA concluded that there was a causal relationship between short-term O_3 exposure and respiratory morbidity outcomes in the Criteria Document, and the Provisional Assessment also found generally positive, though not always statistically significant, associations between short-term O_3 exposure and respiratory morbidity outcomes. In the Criteria Document, there was a "generally limited" body of evidence that suggested associations with cardiovascular health effects, and similarly the studies included in the Provisional Assessment provided some indications of associations with cardiovascular health outcomes, but a number of studies reported no associations. The Criteria Document concluded

that there was insufficient evidence to conclude that long-term O_3 exposure was associated with health effects. The Provisional Assessment concludes that the recent study findings were "generally mixed" with some but not all studies reporting evidence of associations for long-term exposure to O_3, which is consistent with findings of the previous review. Thus, the "new" study results are not inconsistent with those reported previously, and in fact EPA concluded that "[t]his new evidence strengthens conclusions in the 2006 Criteria Document related to the potential for health effects as exposure concentrations of less than 80 ppb" (EPA, 2009, p.3).

In addition, some commenters cited other "new" studies to draw conclusions about model specification or sensitivity to confounding by other pollutants. EPA finds that the "new" study findings are, in fact, consistent with studies available in the 2006 Criteria Document. For example, some commenters cite "new" multi-city studies (Bell and Dominici, 2008; Smith et al, 2009; Franklin and Schwartz, 2008) to conclude that O_3 effects are confounded by PM (AAM, 2010). EPA observes that the variability of effect estimates for the O_3–mortality relationship between cities was greater than reductions seen in effect estimates with adjustment for PM or sulfates in these studies. As has been previously observed, small reductions in effect estimates can result when using multi-pollutant models with correlated pollutants; thus these findings are consistent with those in the Criteria Document.

Commenters (Exxon Mobil, 2010) also refer to a "new" study that indicates evidence of a "threshold" for O_3-related health effects, Stylianou and Nicolich (2009), a study that was published after completion of the 2009 Provisional Assessment. In a "preliminary and exploratory" analysis, the authors evaluated associations between nonaccidental, cardiovascular disease, and respiratory mortality and short-term exposure to O_3 and PM_{10} in nine US cities. They report that dose–response relationships are not necessarily linear, that some relationship shapes are suggestive of no-effect thresholds with some exhibiting apparent thresholds. No evidence of a threshold was found in the APHENA study, discussed

in the next paragraph, which also conducted threshold analyses for the O_3-mortality relationship in European and Canadian cities (the U.S. data were analyzed for PM_{10} only). These findings are consistent with the conclusion of the Criteria Document that "if a population threshold level exists in O_3 health effects, it is likely near the lower limit of ambient O_3 concentrations in the United States" (EPA, 2006, p.7-159).

A number of commenters claimed that a major multilocation study, APHENA (Air Pollution and Health: A European and North American Approach), indicates that O_3 exposure is not associated with mortality or morbidity. EPA does not agree with this characterization of the APHENA study. Focusing on respiratory morbidity, the results of this study are consistent with the results for studies of respiratory hospital admissions characterized in the 2006 Criteria Document and the Provisional Assessment. EPA notes that this study was not published until after completion of the Provisional Assessment, and thus not included in that assessment. The APHENA study combined data from existing multi-city study databases from Canada, Europe (APHEA2; Katsouyanni et al., 2001), and the U.S. (NMMAPS; Samet et al., 2000) in order to "develop more reliable estimates of the potential acute effects of air pollution on human health [and] provide a common basis for [the] comparison of risks across geographic areas" (Katsouyanni et al., 2009). In an attempt to address both of these issues the investigators conducted extensive sensitivity analyses to evaluate the robustness of the results to different model specifications (e.g., penalized splines vs. natural splines) and the extent of smoothing to control for seasonal and temporal trends. For the U.S. in all-year analyses, the investigators reported a 1.9% increase in respiratory hospital admissions ranging from 2.1% (95% CI: 0.08-4.1%) to 2.6% (95% CI: 0.63-4.6%). Associations remained robust in two-pollutant models with PM_{10}. In the Canadian cities, statistically significant associations between O_3 and respiratory hospital admissions were reported, and the associations remained robust in two-pollutant models with PM_{10}, but with larger confidence intervals in

the U.S. and Canadian datasets due to the every 6th day sampling schedule for PM_{10} which limited the number of days included in the analysis. Weaker but positive associations were also observed for Europe in all-year analyses, also with robust associations in two-pollutant models with PM_{10}. The authors conclude: "The new findings confirm that O_3 remains associated with risk for hospitalization" (Katsouyanni et al., 2009, p.76). When focusing on the models using either 8df/yr or 12 df/year consistent positive associations were observed across study areas with O_3 mortality effect estimates reaching statistical significance for some lags.

Several industry commenters cited "new" studies in comments on EPA's estimation of PRB., One business group (NAM, 2010a) cited a number of "new" studies as supporting the following concerns about EPA's approach to estimating PRB: (1) lightning NO_x is a significant source of tropospheric O_3, (2) there is an increase in springtime background O_3 mixing ratio due to Asian transport, which may be related to increasing O_3 levels observed in some rural and marine sites, (3) a recent study which used GEOS-CHEM to evaluate interannual variability of tropospheric O_3 showed poor performance for estimating O_3 levels, (4) stratospheric intrusion events frequently reach the middle troposphere where they mix in and contribute to background O_3 levels, (5) an evaluation of four global models, including GEOS-CHEM, demonstrated substantial uncertainty in the modeling of O_3 precursors. Additional technical issues cited by commenters related to the estimation of PRB are discussed in more detail in the 2011 Response to Comments document.

The EPA does not agree with many aspects of the characterization of the "new" studies cited by business and industry groups or that these "new" studies raise any significant concerns about the approach EPA has used to estimate PRB. With respect to the first concern about lightning NO_x being a significant source of O_3, the data and paper cited refer to free tropospheric O_3, not to surface O_3, and it is the surface O_3 that is relevant for human health risk assessment. EPA provisionally notes that a recent

study that specifically examined the impact of lightning production of NO_x on O_3 PRB concluded that lightning production can have significant local impacts on a few occasions, but that they "have a relatively small impact on typical maximum levels and determination of Policy Relevant Background levels" (Kaynak et al., 2008).

Second, with respect to the concern about increased springtime mixing ratios due to Asian transport, EPA notes that the results of the cited "new" study (Cooper et al., 2010) refer to the free troposphere above the planetary layer and that these increases translate into much smaller increases at the surface due to mixing and dilution, and chemical loss during downward transport to the surface (2006 Criteria Document, sections AX2.3 - mixing and dilution, and AX3.9 - chemical loss).

Third, regarding concerns raised that "new" studies have shown poor performance for GEOS-CHEM in estimating O_3 levels, EPA notes that the study cited (Komoutsaris et al., 2008) found issues with O_3 mainly occur in the free troposphere over Europe and were not related to estimation of O_3 at the surface nor did the authors consider estimation for the continental U.S.

Fourth, with respect to concerns raised that stratospheric intrusion events frequently reach the middle troposphere and impact PRB levels, EPA discussed this process in the 2006 Criteria Document and notes that the occurrence of stratospheric intrusions depends strongly on latitude and season. The study cited (Trickl et al., 2009) refers to higher latitudes in Central Europe than found in the continental U.S. The patterns and depths of penetration of stratospheric intrusions over North America were noted in the Criteria Document. EPA notes that stratospheric intrusion events that result in high observed O_3 levels may be excluded for purposes of evaluating compliance with the O_3 standard under EPA's Exceptional Events Rule (40 CFR 50.14).

Fifth, EPA notes that the study cited (Singh et al., 2007) as showing concerns about the performance of GEOS-CHEM in an evaluation of four global models was a study examining the free

troposphere above the planetary boundary layer. This study did not evaluate the models' performance with respect to surface O_3 levels, which are the levels that are relevant for characterizing PRB for human health risk assessment.

More detail about all the topic areas covered in the "new" studies, as well as responses to these comments, can be found in the Response to Comments document.

To the extent that these commenters included "new" scientific studies, studies that were published too late to be considered in the 2006 Criteria Document, or were not included in the 2009 Provisional Assessment, in support of their arguments for reconsidering the March 2008 standard decision or not revising the standards, EPA notes, as discussed in section I above, that as in past NAAQS reviews, it is basing the final decisions in this review on the studies and related information included in the O_3 air quality criteria that have undergone CASAC and public review and will consider newly published studies for purposes of decision making in the next O_3 NAAQS review. In provisionally evaluating commenters' arguments, as discussed above and in the 2011 Response to Comments document, EPA notes that its provisional consideration of "new" science found that such studies did not materially change the conclusions in the Criteria Document. After considering these comments, as discussed more fully in the 2010 Response to Comment document, EPA continues to conclude that these studies do not materially change the conclusions in the 2006 Criteria Document.

3. Additional CASAC Advice

As noted in Section I.E.4 above, in January, 2011 EPA asked the CASAC Ozone Reconsideration Panel that reviewed the evidence, risk and exposure assessments, and Staff Paper for the 2008 O_3 NAAQS review to provide further advice about the strengths and limitations of the scientific evidence and the results of the exposure and health risk assessments. In the process of evaluating the extensive body of scientific and technical information available in the 2008 review and

the many comments received on the proposed reconsideration, and determining how to exercise her judgment concerning the appropriate O_3 NAAQS to set, the EPA Administrator determined that additional advice from CASAC would be useful and important in evaluating the scientific and technical information from the 2008 review upon which the reconsideration of the primary (health-based) standard is based. To ensure that a final decision on the reconsideration of the 2008 O_3 primary standard is based on the most appropriate interpretation of the scientific evidence and exposure/risk information that was available in the 2008 review, the Administrator asked the CASAC Ozone Reconsideration Panel to provide further advice about the strengths and limitations of the scientific evidence and the results of the exposure and health risk assessments to aid in her interpretation of this information. The Panel was requested to consider only the information available in the record for the 2008 O_3 NAAQS review. The EPA's OAQPS prepared specific charge questions (Wegman, 2011). The Panel held teleconferences on February 18, March 3, and March 23, 2011, to address these charge questions and provided advice to her in a letter dated March 30, 2011 (Samet, 2011). [27]

With respect to its overarching recommendations about the range of levels of the primary O_3 standard that is supported by the scientific evidence, CASAC reaffirmed its past unanimous advice that the evidence "strongly supports the selection of a new primary ozone standard within the 60-70 ppb range" (Samet, 2011, p.ii).[28] Moreover, within that range, "CASAC finds that the evidence was sufficiently certain to be confident of public health benefits and additional protection of susceptible groups" (Samet, 2011, p.iii-iv, 3). CASAC further advised that the evidence from controlled human exposure and epidemiological studies, taken together, "strongly support the selection of a new primary

[27] Public comments submitted to the Panel as part of the Panel's consideration of the charge questions are included in the docket and responded to as part of the 2011 Response to Comments document or in the preamble to the final rule.

[28] As requested, CASAC's consensus letter and response to the charge questions are based on the literature considered in the 2008 O_3 NAAQS review (Samet, 2011, iii).

ozone 8-hour concentration limit that is well below the 1997 limit of 80 ppb over an 8-hour averaging time," (Samet, 2011, p.2)

In considering the available evidence, CASAC found that "large segments of the population fall into what EPA terms a 'sensitive population group,' i.e., those at increased risk because they are more intrinsically susceptible (children, the elderly, and individuals with chronic lung disease) and those who are more vulnerable due to increased exposure because they work outside or live in areas that are more polluted than the mean levels in their communities" (Samet, 2011, p.iii). In considering the evidence from clinical studies, CASAC noted that controlled human exposure studies typically employ healthy adult volunteers. For example, a study by Adams (2006), which CASAC characterized as being "well designed and conducted with appropriate methods" (Samet, 2011, p.6), found lung function decrements in the region of clinical importance, greater than a 10% reduction in $FEV_{1,}$ in a fraction of healthy adult subjects (7%) (Samet, 2011, p.7) . CASAC advised that "[f]rom a public health standpoint, these results suggest that a large number of individuals in the general population (that are otherwise healthy) are likely to experience FEV_1 deficits greater than 10% with prolonged exposure to 60 ppb ozone" (Samet, 2011, p.7). Moreover, a 10% decrement in FEV_1 could lead to moderate or severe respiratory symptoms, especially in individuals with decreased ventilatory reserve (i.e., decreased baseline FEV_1) such as individuals with pre-existing pulmonary (e.g., chronic obstructive pulmonary disease) or cardiac disease. Id. CASAC also noted that there was "scant human clinical data that were available for consideration at exposure concentrations below 80 ppb, and that the data available are largely limited to effects on lung function" (Samet, 2011, p.13).

In considering the evidence from epidemiologic studies, CASAC concluded that "[w]hile epidemiological studies are inherently more uncertain as exposures and risk estimates decrease (due to the greater potential for biases to dominate small effect estimates), specific evidence in the literature

does not suggest that our confidence on the specific attribution of the estimated effects of ozone on health outcomes differs over the proposed range of 60-70 ppb" (Samet, 2011, p.10). CASAC also concluded that "it is likely that reductions in population exposures to ozone will result in fewer adverse health effects. Our confidence in this statement does not change at the lower levels of the proposed range" (Samet, 2011, p.11).

In considering the exposure and risk assessments, CASAC observed that the assessments conducted for the last review of the O_3 NAAQS "clearly document that a substantial proportion of the U.S. population is exposed to levels of ozone at the various alternative standards considered. This means that even if a NAAQS of 60 ppb were to be adopted, some sensitive individuals could still be exposed to concentrations that could cause them to have a clinically relevant decrement in lung function" (Samet, 2011, p.7). However, in considering the public health significance of reductions in exposures above benchmark levels of concern for the range of standards from 70 to 60 ppb, as estimated in the exposure assessment, CASAC observed that while "the predicted number exposed increases at every level of the standard as the benchmark level of concern is reduced, the public health impact of this increase in number exposed becomes less certain" and "the public health significance of such exposures is difficult to gauge" for health endpoints other than, perhaps, lung function decrements (Samet, 2011, p.13). CASAC also judged that in terms of exposures above the lowest benchmark level of concern considered by EPA (60 ppb), "a further reduction in the standard from 70 ppb is estimated to have a small public health impact" although, because of the absence of a threshold at the benchmark level, this . . . analysis . . . is an underestimate of the true public health impact" (Samet, 2011, p.13).

In providing advice as to the range of standard levels that is supported by the scientific evidence and assessments, CASAC recognized that selecting a standard level within that range which would provide an adequate margin of safety requires a public health policy judgment by the Administrator. In

expressing its views with regard to such a judgment, CASAC observed that "since the relative strength of the evidence is weaker at lower ozone concentrations" the range of 60-70 ppb "allows the Administrator to place her judgment on the weight that any uncertainties and limitations in the science play" in selecting such a standard (Samet, 2011, pp. 9). Recognizing the limitations in the evidence, CASAC expressed the view that "without having specific studies among asthmatics and children at these levels of exposure, it is prudent, in spite of the uncertainty," to select a level "below the current standard (closer to the 60 ppb level) to 'protect public health with an adequate margin of safety, including the need to protect susceptible populations'." (Samet, 2011, pp.7-8). Further, in also considering the results of the exposure and risk assessments, CASAC expressed the view that "setting a new NAAQS in the range of 60 to 70 ppb is appropriate, but would provide little margin of safety at its upper end" (Samet, 2011, p.2). Nonetheless, CASAC advised that "[i]n summary, the strengths of the evidence from controlled human exposure and epidemiological studies enumerated in the Criteria Document…were substantial, and the evidence is more than adequate to support the recommended range for the NAAQS of 60 to 70 ppb" (Samet, 2011, p.2).

4. Conclusions on the Level of the Primary Standard

As a result of the reconsideration, the Administrator has determined that a different level of the primary O_3 standard than the 0.075 ppm level set in 2008 is requisite to protect public health with an adequate margin of safety. For the reasons discussed below, the Administrator has decided to set the level of the 8-hour primary O_3 at 0.070 ppm.[29]

a. Reconsideration of the adequacy of the standard level set in 2008

[29]As discussed above at the beginning of section II, the Administrator has focused her reconsideration of the primary O_3 standard set in the 2008 final rule on the level of the standard, having decided not to reopen the 2008 final rule with regard to the need to revise the 1997 primary O_3 standard to provide increased public health protection nor with regard to the indicator, averaging time, and form of the 2008 standard.

In the 2010 proposal, the Administrator concluded it was appropriate to propose to set the primary O_3 standard below 0.075 ppm. This conclusion was based on the evidence and exposure/risk-based considerations discussed above in section II.C.1 and the Administrator's determination that 0.075 ppm was a level at which the evidence provides a high degree of certainty about the adverse effects of O_3 exposure on healthy people. The Administrator's public health policy judgment on the proposed range for the level of the primary O_3 standard was framed by the evidence and exposure/risk-based considerations discussed above in this notice and informed by the following key observations and conclusions on the controlled human exposure and epidemiological studies and the results of the human exposure and health risk assessments.

(1) There is a strong body of evidence from controlled human exposure studies evaluating healthy people at O_3 exposure levels of 0.080 ppm and above that demonstrated lung function decrements, respiratory symptoms, pulmonary inflammation, and other medically significant airway responses. Newly available for the 2008 review, there is the limited but important evidence of lung function decrements and respiratory symptoms in healthy people down to O_3 exposure levels of 0.060 ppm. These studies also report that a percentage of subjects (7 to 20%) experienced moderate lung function decrements ($\geq$ 10%) at the 0.060 ppm exposure level. For people with lung disease, moderate levels of functional responses (e.g., FEV_1 decrements of $\geq$ 10% but < 20%) and/or moderate respiratory symptom responses would likely interfere with normal activity for many individuals, and would likely result in more frequent use of medication. CASAC indicated that a focus on the lower end of the range of moderate levels of functional responses (e.g., FEV_1 decrements $\geq$ 10%) is most appropriate for estimating potentially adverse lung function decrements in people with lung disease (Henderson, 2006c).

(2) A large number of epidemiological studies have reported statistically significant associations between ambient O_3 levels and a wide array of respiratory symptoms and other morbidity outcomes including school absences, emergency department visits, and hospital admissions. More specifically, positive and robust associations were found between ambient O_3 concentrations and respiratory hospital admissions and emergency department visits, when focusing particularly on the results of warm season analyses. The body of epidemiological evidence indicates associations for a wide range of serious health effects, including respiratory hospital admissions and emergency department visits and premature mortality, across distributions of ambient O_3 concentrations that extend well below the 2008 standard level of 0.075 ppm. While some epidemiological studies provide some indication of possible 8-hour average threshold levels from below about 0.025 to 0.035 ppm (within the range of background concentrations) up to approximately 0.050 ppm, other studies observe linear concentration-response functions suggesting that there may be no effects thresholds at the population level above background O_3 concentrations. However, there are questions of biological plausibility in attributing the observed effects to O_3 alone at the lower end of the concentration ranges extending down to background levels.

(3) There is substantial evidence, newly available for consideration in the 2008 review, from controlled human exposure and epidemiological studies indicating that children and adults with asthma and other preexisting lung diseases are at increased risk from O_3 exposure. Children and adults with asthma are the group that has been studied most extensively. Evidence from controlled human exposure studies indicates that asthmatics are likely to experience larger and more serious effects in response to O_3 exposure than healthy people. This evidence indicates that relative to the healthy, non-asthmatic subjects used in most

controlled human exposure studies, a greater proportion of children and adults with asthma may be affected, and those who are affected may have as large or larger lung function and symptomatic responses to O_3 exposures, such that controlled human exposure studies of lung function decrements and respiratory symptoms that evaluate only healthy, non-asthmatic subjects likely underestimate the effects of O_3 exposure on asthmatics and other people with preexisting lung diseases. However, there is uncertainty about the magnitude of the differences in their responses such that we are not able to quantify the magnitude of any such differences.

(4) The assessments of exposures of concern and risks for a range of health effects indicate that important improvements in public health are very likely associated with O_3 levels just meeting alternative standard levels evaluated in these assessments, especially for the alternative levels of 0.070 and 0.064[30] ppm, relative to levels at and above 0.075 ppm.

With respect to the exposures of concern in all and asthmatic school age children estimated to occur one or more times above two benchmark levels (0.070 ppm and 0.060 ppm), the Administrator's judgments were informed by the following key observations: a) there is a similar pattern for all children and asthmatic school age children in terms of exposures of concern over selected benchmark levels when estimates are expressed in terms of percentage of the population; b) the aggregate estimates of exposures of concern reflecting estimates for the 12 urban areas included in the assessment are considerably larger for the benchmark level of 0.060 ppm compared to the 0.070 ppm benchmark; c) there is notable

[30]EPA estimated exposures of concern above specific benchmark levels and health risks associated with air quality allowed by alternative standards at and above 0.064 ppm, which is generally representative of exposures and risks for a standard level of 0.065 ppm. At the time the analyses were conducted, due to the rounding convention, 0.064 ppm (specified to three significant figures after the decimal) would have been the effective level of a 0.06 ppm standard (specified to two significant figures after the decimal, consistent with the definition of the 1997 standard).

year-to-year variability in exposure and risk estimates with higher exposure and risk estimates occurring in simulations involving a year with generally poorer air quality in most areas (2002) compared to a year with generally better air quality (2004); and d) there is significant city-to-city variability in exposure and risk estimates, with some cities receiving considerably less protection associated with air quality just meeting the same standard.

Important reductions in risk, including risk of moderate lung function decrements in all and asthmatic school age children, respiratory symptoms in asthmatic children, respiratory hospital admissions, and non-accidental mortality were estimated to occur across the range of alternative standards. EPA also recognized that the risk estimates for the health outcomes included are limited and that the overall health effects evidence is indicative of a much broader array of O_3-related health effects that are part of a ‘‘pyramid of effects’’ that include various indicators of morbidity that could not be included in the risk assessment (e.g., school absences, increased medication use, doctor’s visits, and emergency department visits), some of which have a greater impact on susceptible populations.

These observations and conclusions led the Administrator to propose to set the primary O_3 standard at a level in the range of 0.060 to 0.070 ppm. In so doing she placed significant weight on the information newly available in the 2008 review that had been reviewed by CASAC, and took into consideration public comments that had been received during the 2008 review. She also placed significant weight on CASAC’s conclusion that important public health protections can be achieved by a standard set below 0.075 ppm, within the range of 0.060 to 0.070 ppm.

In reaching a final decision on the level of the primary O_3 standard, the Administrator again considered whether the standard level of 0.075 ppm set in the 2008 final rule is sufficiently below 0.080 ppm to be requisite to protect public health with an adequate margin of safety. In considering this

standard level, the Administrator looked to the rationale for selecting this level presented in the 2008 final rule, as summarized above in section II.B. In that rationale, EPA observed that a level of 0.075 ppm is above the range of 0.060 to 0.070 ppm recommended by CASAC, and that the CASAC Panel appeared to place greater weight on the evidence from the Adams studies and on the results of the exposure and risk assessments, whereas EPA placed greater weight on the limitations and uncertainties associated with that evidence and the quantitative exposure and risk assessments. Additionally in 2008, EPA's rationale did not discuss and thus placed no weight on exposures of concern relative to the 0.060 ppm benchmark level. Further, EPA concluded that ''[a] standard set at a lower level than 0.075 ppm would only result in significant further public health protection if, in fact, there is a continuum of health risks in areas with 8-hour average O_3 concentrations that are well below the concentrations observed in the key controlled human exposure studies and if the reported associations observed in epidemiological studies are, in fact, causally related to O_3 at those lower levels. Based on the available evidence, [EPA] is not prepared to make these assumptions'' (73 FR 16483).

In reconsidering the entire body of evidence available in the 2008 rulemaking, including the Agency's own assessment of the epidemiological evidence in the 2006 Criteria Document, the views of CASAC, including its most recent advice (Samet, 2011), and the public comments received on the 2010 reconsideration proposal, the Administrator finds no basis to change her conclusion that important and significant risks to public health are likely to occur at a standard level of 0.075 ppm. Thus, she judges that a standard level of 0.075 ppm is not sufficient to protect public health with an adequate margin of safety. In support of this conclusion, the Administrator finds that setting a standard that would protect public health, including the health of susceptible populations, with an adequate margin of safety should reasonably depend upon giving some weight to the results of the Adams studies and EPA's analysis of the Adams's data, and some weight to the results of epidemiological studies of respiratory morbidity

effects that may extend down to levels below 0.060 ppm. Moreover, the Administrator concludes that, in setting such a standard, consideration should be given to how effectively alternative standard levels would serve to limit exposures of concern relative to the 0.060 ppm benchmark level as well as the 0.070 ppm benchmark level, based on EPA's exposure and risk assessments. In light of estimates of exposures of concern and the available evidence, the Administrator judges that a standard set as high as 0.075 is not requisite to protect public health with an adequate margin of safety, and that consideration of a level within the proposed range of 0.060 to 0.070 ppm is warranted. In so doing, the Administrator again agrees with CASAC's conclusion that important public health protections could be achieved by a standard set below 0.075 ppm, within the range of 0.060 to 0.070 ppm (Samet, 2011).

In reaching this conclusion, the Administrator has considered the views of those public commenters, including primarily industry organizations and businesses, which did not support changing the level of the standard in the context of this reconsideration.[31] These commenters generally refer to the uncertainties and limitations in the evidence and exposure/risk information newly available in the 2008 review as a basis for concluding that the information is too uncertain to infer that the 2008 standard is not requisite to protect public health with an adequate margin of safety. In considering these comments, the Administrator recognizes these uncertainties and limitations but finds no basis to conclude that these uncertainties and limitations warrant completely discounting the newly available evidence from controlled human exposure and epidemiological studies, and the assessment of that evidence conducted by the Agency and reviewed by CASAC, nor completely discounting the results of the exposure and risk assessments conducted by the Agency and reviewed by CASAC. To do so would be to ignore important new research and assessments, as evaluated and weighed in the 2006 Criteria Document and 2007 Staff Paper that appropriately recognize and take into account the uncertainties and

[31]Many of these commenters have previously expressed the view that the 1997 standard should not have been revised as a result of the 2008 review.

limitations in the evidence and assessments, as well as the repeated unanimous advice of CASAC that the available information, assessed in light of relevant uncertainties and limitations, does not support consideration of a standard level above 0.070 ppm.

b. Selection of a standard level within the proposed range

The Administrator next considered what standard level within the proposed range of 0.060 to 0.070 ppm would be requisite to protect public health, including the health of susceptible populations, with an adequate margin of safety -- i.e., a level that is sufficient but not more than necessary to achieve that result. She recognizes that neither the health evidence nor the human exposure and health risk assessments provide any "bright line" for selecting a specific level within the proposed range. No controlled human exposure studies were conducted at intermediate levels between 0.070 and 0.060 ppm. Associations reported in epidemiological studies generally ranged from well above to well below this range, with no suggestion of a possible threshold within this range. While there is substantial evidence that asthmatics have greater responses than healthy, non-asthmatic people, there is uncertainty about the magnitude of the differences in their responses within this range. Moreover, within this range, exposure and health risk assessments estimated the exposures of concern and health risks only for standard levels of 0.070 and 0.064 ppm. Thus, there is a combination of scientific evidence and other information that the Administrator needs to consider as a whole in making the public health policy judgment to select a standard level from within the proposed range.

In deciding on the level of an 8-hour O_3 standard, the Administrator recognizes that the CAA requires her to reach a public health policy judgment as to what standard would be requisite to protect public health with an adequate margin of safety, based on scientific evidence and technical assessments that have inherent uncertainties and limitations. She is mindful that this judgment is to be based on an interpretation of the evidence and other information that neither overstates nor understates the strength

and limitations of the evidence and information. She recognizes that this judgment requires making reasoned decisions as to how to weigh appropriately the various types of evidence and assessments and the related uncertainties and limitations.

After weighing the strengths and the inherent uncertainties and limitations in the evidence and assessments, and taking into account the range of views and judgments expressed by the CASAC Panel, including CASAC's most recent advice, and in the public comments, as discussed above, the Administrator finds the evidence and other information on the public health impacts from exposure to O_3 warrant an 8-hour primary standard set at 0.070 ppm. Looking at the scientific evidence and information as a whole, she judges that a standard set at a level of 0.070 ppm appropriately weighs the evidence from controlled human exposure and epidemiological studies of adverse effects, the evidence that children and adults with lung disease have more serious responses to O_3 exposures than healthy people, the results of analyses of exposures of concern and risks to susceptible populations, as well as the uncertainties and limitations in this evidence and information.

The Administrator notes that the most certain evidence of adverse health effects from exposure to O_3 comes from the controlled human exposure studies. She recognizes that the large bulk of this evidence derives from studies of exposures at levels of 0.080 ppm and above, where there is consistent evidence of lung function decrements and respiratory symptoms in healthy young adults, as well as evidence of O_3-induced pulmonary inflammation, airway responsiveness, impaired host defense capabilities, and other medically significant airway responses. The Administrator notes that there is now limited evidence from controlled human exposure studies of O_3-related lung function decrements and respiratory symptoms at the 0.060 ppm exposure level. She notes that CASAC characterized the available evidence from controlled human exposure studies at exposure concentrations below 0.080 ppm as being "scant" and largely limited to effects on lung function (Samet, 2011, p. 13).

In particular, the Administrator notes two studies by Adams (2002, 2006), newly available in the 2008 rulemaking, that CASAC characterized as being well designed and conducted with appropriate methods (Samet, 2011, p.6). These studies, which examined lung function and respiratory symptom effects in healthy adults associated with prolonged O_3 exposures at levels below 0.080 ppm, did not report statistically significant effects at the 0.060 ppm exposure level. She also notes EPA's analysis of the data from the Adams (2006) study at a 0.060 ppm exposure level did find small, but statistically significant group mean differences in lung function decrements in healthy adults at the 0.060 ppm exposure level. These studies did report that a percentage of subjects (7 to 20%) experienced moderate lung function decrements ($\geq$ 10%) at the 0.060 ppm exposure level. She also notes that CASAC advised that from a public health standpoint, the results from the Adams (2006) study suggest that a large number of healthy individuals in the general population are likely to experience FEV_1 deficits greater than 10% with prolonged exposure to 0.060 ppm ozone (Samet, 2011, p.7). The Administrator notes that for people with lung disease, even moderate functional or symptomatic responses would likely interfere with normal activity for many individuals, and would likely result in more frequent use of medication. Further, she notes that CASAC indicated that a focus on the lower end of the range of moderate levels of functional responses (e.g., FEV_1 decrements $\geq$ 10%) is most appropriate for estimating potentially adverse lung function decrements in people with lung disease (Henderson, 2006c).

In weighing the information the Adams studies provide, the Administrator also recognizes that these studies at a 0.060 ppm exposure level are limited, with only two studies available from one investigator conducted at only one research facility, such that the health effects at this level have not been replicated by other investigators in other studies involving subjects from different locations in the record of this review. The Administrator concludes this is an important limitation that should be

reflected in the weight that is appropriately placed on these studies relative to the large number of studies that examined O_3-related respiratory effects at higher exposure levels, at and above 0.080 ppm.

Based on all the above considerations, the Administrator concludes that the Adams studies (2002, 2006) provide limited but important evidence informing the Administrator's decision on the level of the primary O_3. The Administrator concludes that these limited studies, considered in light of the larger body of controlled human exposure studies at higher exposure levels, provide support for a standard set no higher than 0.070 ppm, but do not provide sufficient evidence to warrant a lower standard level. She also concludes that while these studies provide support for taking into consideration the extent to which a standard would limit exposures of susceptible populations to concentrations at and above the 0.060 ppm benchmark level, the limited nature of these studies does not compel essentially eliminating such exposures. Thus, the Administrator concludes that these studies do not warrant setting a standard below 0.070 ppm down to 0.060 ppm.

With regard to epidemiological studies, the Administrator observes that statistically significant associations between ambient O_3 levels and a wide array of respiratory symptoms and other morbidity outcomes, including school absences, emergency department visits, and hospital admissions, have been reported in a large number of studies. These associations occur across distributions of ambient O_3 concentrations that generally extend from above to well below the proposed range, although the Administrator recognizes that there are questions of biological plausibility in attributing the observed effects to O_3 alone at the lower end of the concentration ranges extending down to background levels. The Administrator also recognizes the uncertainty inherent in translating information from such studies into the basis for selecting a specific level from within the proposed range. The Administrator notes that in its most recent advice, CASAC concluded that epidemiological studies are inherently more uncertain as ambient O_3 concentrations decrease and effect estimates become smaller, although CASAC's

confidence in attributing reported effects on health outcomes to O_3 did not change over the range of 0.060 to 0.070 ppm (Samet, 2011. p.10-11). In weighing this evidence and the related uncertainties, the Administrator concludes that while the epidemiological evidence provides support for a standard set no higher than 0.070 ppm, it does not warrant selecting a lower standard level within the proposed range.

The Administrator has also considered the evidence from controlled human exposure and epidemiological studies that children and adults with asthma and other lung diseases are likely to experience larger and more serious responses to O_3 exposures than healthy, non-asthmatic people. She observes that relative to the healthy, non-asthmatic subjects used in most controlled human exposure studies, a greater proportion of children and adults with asthma may be affected, and those who are affected may have as large or larger lung function and symptomatic responses to O_3 exposures. Further, she notes CASAC's advice that while some healthy individuals have been shown to have clinically relevant responses at 0.060 ppm, decrements in lung function may be greater for susceptible groups than healthy volunteers and are likely to have greater clinical significance (Samet, 2011, pp.ii-iii). Thus, the Administrator recognizes that controlled human exposure studies conducted using healthy subjects likely underestimate effects in this susceptible population. The Administrator also recognizes, however, that there is uncertainty about the magnitude of any such differences in responses. Thus, the Administrator concludes that while this evidence supports taking into consideration the extent to which a standard would limit exposures of susceptible populations to concentrations at and above the 0.070 and 0.060 ppm benchmark levels, it does not further inform the translation of the available evidence of O_3-related effects in healthy subjects into the basis for selecting any specific standard level from within the proposed range.

Looking beyond the evidence, the Administrator has also considered quantitative exposures and health risks associated with air quality simulated to just meet various alternative standard levels. In so

doing, she is mindful of the important uncertainties and limitations that are associated with the exposure and risk assessments.

In considering the exposure assessment results, the Administrator focused on the extent to which alternative standard levels within the proposed range of 0.060 to 0.070 ppm would likely limit exposures at and above the health benchmark levels of 0.070 and 0.060 ppm for all and asthmatic school age children in the 12 urban areas included in the assessment. In weighing this information, the Administrator considered the public health significance of estimates of exposures at and above the 0.070 ppm benchmark level relative to the 0.060 ppm benchmark. In particular, the Administrator notes that the 0.070 ppm benchmark level reflects the information that asthmatics likely have larger and more serious effects than healthy people at any given exposure level, such that studies done with healthy subjects may underestimate effects for susceptible populations. Thus, in considering the strong body of evidence from the large number of controlled human exposure studies showing O_3-related respiratory effects in healthy people at exposure levels of 0.080 ppm and above, the Administrator concludes it is appropriate to give substantial weight to estimates of exposures at and above the 0.070 ppm benchmark level. With regard to the 0.060 ppm benchmark level, the Administrator notes that this benchmark reflects additional consideration of the evidence from the Adams studies at the 0.060 ppm exposure level. In considering the important but limited nature of this evidence, the Administrator concludes it is appropriate to give some weight to estimates of exposures at and above the 0.060 ppm benchmark level, while recognizing that the public health significance of such exposures is appreciably more uncertain than for the 0.070 ppm benchmark level.

Considering the exposure information shown in Table 1 above in light of these considerations, the Administrator observes that a standard set at 0.070 ppm would likely very substantially limit children's exposures at and above the 0.070 ppm benchmark, considering both the year-to-year

variability and the city-to-city variability in the exposure estimates across the 12 cities included in the assessment. In particular, for the more recent year in the assessment, which had generally better air quality, such exposures were essentially eliminated, whereas in the earlier year with generally poorer air quality, exposures at and above the benchmark level were limited to approximately 2% of asthmatic children in the aggregate across the 12 cities, ranging from 0% up to 6% in the city with the least degree of protection. In weighing this information and in judging the public health implications of these exposure estimates, the Administrator recognizes that only a subset of this susceptible population with exposures at and above the benchmark level would likely be at risk of experiencing O_3-related health effects.

With regard to the 0.060 ppm benchmark level, a standard set at 0.070 ppm would likely also limit exposures at and above this benchmark level, but to a lesser degree. For example, as shown above in Table 1, for the more recent year, exposures at and above the 0.060 ppm benchmark level were limited to approximately 1 % of asthmatic children in the aggregate, whereas for the earlier year approximately 18% of asthmatic children were estimated to experience exposures at and above this benchmark level. In weighing this information and judging the public health implications of these exposure estimates, the Administrator recognizes that relative to the 0.070 ppm benchmark, an even smaller, but unquantifiable subset of this susceptible population with exposure at and above the 0.060 ppm benchmark would likely be at risk of experiencing O_3-related health effects, and that there is greater uncertainty as to the occurrence of such effects based on the limited evidence available from the Adams studies. The Administrator also notes that these estimates are substantially below the exposures that would likely be allowed by the 0.075 ppm standard (which would be somewhat higher than the estimates in Table 1 for a 0.074 ppm standard).

In also considering exposure estimates for the lowest alternative standard level considered in the exposure assessment, 0.064 ppm, the Administrator notes that the estimates of exposures at and above both health benchmark levels are even lower than for a 0.070 ppm standard. For example, for all years in the assessment, exposures of asthmatic children at and above the 0.070 ppm benchmark were essentially eliminated for a 0.064 ppm standard; even in the year with generally poorer air quality and in the city with the least degree of protection, exposures at and above the benchmark level were very substantially limited to approximately 1% of asthmatic children. Further, exposures of asthmatic children at and above the 0.060 ppm benchmark were also essentially eliminated in the more recent year for a 0.064 ppm standard, while in the year with generally poorer air quality such exposures were appreciably limited to approximately 6% of asthmatic children.

In considering these results, the Administrator notes that in its most recent advice, CASAC considered the public health significance of reductions in exposures above these benchmark levels of concern. In so doing, CASAC observed that while the predicted number of exposures of concern increases at every standard level as the benchmark level of concern is reduced, the public health impact of this increase becomes less certain, and that the public health significance of such exposures is difficult to gauge (Samet, 2011, p. 13). The Administrator also notes that CASAC judged that in terms of exposures above the 0.060 ppm benchmark level of concern, a further reduction in the standard from 0.070 ppm is estimated to have a small public health impact, although, in the absence of a threshold at the benchmark level of concern, this analysis is likely to be an underestimate of the true public health impact.

Taken together, in weighing this exposure information and judging the public health implications of the exposure estimates for the alternative standard levels, the Administrator finds that a standard of 0.070 ppm appropriately limits exposures of concern relative to the 0.070 and 0.060 ppm benchmark

levels for the susceptible population of asthmatic children, as well as for the broader population of all children. Particularly in light of the relatively more uncertain public health implications of exposure at and above the 0.060 ppm benchmark, the Administrator concludes the exposure assessment provides support for a standard no higher than 0.070 ppm, but does not warrant selecting a standard set below that level.

In considering the estimates provided by the risk assessment, the Administrator notes that significant reductions in health risks for lung function, respiratory symptoms, hospital admissions and mortality have been estimated to occur across the standard levels analyzed, including 0.084 ppm, the level of the 1997 standard, 0.080, 0.074, 0.070, and 0.064 ppm. In looking across these alternative standards, as discussed above in section II.A.2, the patterns in risk reductions are similar to the patterns observed in the exposure assessment for exposures at and above the health benchmark levels. In considering these results, the Administrator recognizes there is increasing uncertainty about the various concentration-response relationships used in the risk assessment at lower O_3 concentrations, such that as estimated risk reductions increase for lower alternative standard levels so too do the uncertainties in those estimates. In light of this and other uncertainties in the assessment, the Administrator concludes that the risk assessment reinforces the exposure assessment in supporting a standard level no higher than 0.070 ppm, but it does not warrant selecting a lower standard level.

Based on all the above evidence-based and exposure/risk-based considerations, the Administrator judges that a standard set at 0.070 ppm would be sufficient but not more than necessary to protect public health with an adequate margin of safety. In reaching this conclusion, the Administrator carefully considered the unanimous advice of CASAC that the evidence "strongly supports" selecting a standard level within the range of 0.060 to 0.070 ppm (Samet, 2011, p.ii). Moreover, she notes that

within that range, CASAC found the evidence was "sufficiently certain to be confident of public health benefits and additional protection of susceptible groups" (Samet, 2011, p.iii-iv, 3).

With regard to selecting a standard level from within that range, the Administrator observes that CASAC recognized that she must make a public health policy judgment to select a specific standard that in her judgment protects public health with an adequate margin of safety. The Administrator notes that CASAC found the relative strength of the evidence to be weaker at lower concentrations, and that their recommended range of 0.060 to 0.070 ppm allowed her to judge the appropriate weight to place on any uncertainties and limitations in the science in selecting a standard level within that range (Samet, 2011, p.9). The Administrator further notes that CASAC expressed the view that selecting a level below the current standard, closer to 0.060 ppm, would be "prudent," in spite of the uncertainties (Samet, 2011, p.7-8), and that selecting a standard level at the upper end of their recommended range would provide "little" margin of safety (Samet, 2011, p.2).

In reaching her public health policy judgment, after carefully considering the available evidence and assessments, the associated uncertainties and limitations, and the advice and views of CASAC, the Administrator judges that a standard set at 0.070 ppm appropriately balances the uncertainties in the assessments and evidence with the requirement to protect public health with an adequate margin of safety for susceptible populations, especially children and people with lung disease. In so doing, she also concludes that a standard set at a lower level would be more than is necessary to protect public health with an adequate margin of safety for these susceptible populations. This judgment by the Administrator appropriately considers the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety. Further, this judgment is consistent with and supported

by the advice and unanimous recommendation of CASAC to set a standard within a range that included but was no higher than 0.070 ppm.

The Administrator places a great deal of weight on CASAC's advice and recommendations as to the range of standard levels that are strongly supported by the science, and CASAC's views on ways to evaluate standard levels within that range**,** recognizing that she is required to make her own judgment on the appropriate standard to set. The Administrator's decision reflects her judgment as to the appropriate weight to place on the uncertainties in the evidence and assessments, and the appropriate balance to draw in providing protection that is sufficient but not more than necessary to provide an adequate margin of safety. In her judgment, a standard set at 0.070 ppm is requisite to protect public health with an adequate margin of safety. In this case, the Administrator has given full consideration to CASAC's advice and recommendations, and has weighed its public health policy judgments, in reaching her judgment as to the standard that is requisite to protect public health with an adequate margin of safety, from within the range of 0.060 to 0.070 ppm that was strongly supported by CASAC.

Next, the Administrator considered the views of those, including medical, public health and environmental organizations and some state and tribal air agencies that supported a standard set at 0.060 ppm, the lower end of the proposed range, so as to provide the maximum health benefits possible in the new primary O_3 standard. Some of these commenters asserted that the primary standard should be set at 0.060 ppm to protect against all known and anticipated adverse health effects so as to provide an adequate margin of safety as required by the CAA.

The Administrator disagrees with the premise of such comments, noting that the CAA does not require standards to be set to provide the maximum potential for public health benefit possible, regardless of the uncertainties and limitations in the available evidence. Rather, the standard is to be set to provide requisite protection – neither more than less than necessary. In reaching this judgment, as

noted above, the Administrator needs to give appropriate weight to the available information, and the related uncertainties and limitations, and to select a standard that will protect public health with an adequate margin of safety, with reference to protecting susceptible populations rather than all individuals within such populations.

Looking at the scientific evidence and information as a whole, setting a standard at 0.060 ppm would require the Administrator to conclude that the risks of adverse effects from exposures to 0.060 ppm are significant and important enough to warrant essentially eliminating all exposures to 0.060 ppm. As discussed above, the Administrator judges that would not be an appropriate conclusion, given the uncertainties and limitations in the body of evidence from controlled human exposure and epidemiological studies, the evidence from some epidemiological studies of a potential population threshold just below this level, the uncertainty about the magnitude of the differences in the responses of healthy people and people with asthma at this level, and the uncertainties and limitations in estimates of exposures and health risks for the alternative standards analyzed within the proposed range (i.e., 0.070 and 0.064 ppm) together with the recognition that these uncertainties would be greater if assessments results were to be extrapolated down to a standard level as low as 0.060 ppm. The Administrator observes that while CASAC supported a range of levels that extended down to 0.060 ppm, they also supported a level up to 0.070 ppm, indicating that they do not agree that the evidence from controlled human exposure and epidemiological studies, or the results of the exposure and risk assessments, can only be interpreted or judged as supporting a standard level of 0.060 ppm. Based on the above considerations and on the evidence and information available in this reconsideration, the Administrator concludes that a standard set at 0.060 ppm is more than what is necessary to protect public health with an adequate margin of safety.

Based on all the above considerations, the Administrator concludes that a primary O_3 standard set at 0.070 ppm O_3 is requisite to protect public health with an adequate margin of safety for susceptible populations, especially children and people with lung disease such as asthma. In so doing, she also concludes that a primary O_3 standard set at a lower level would be more than is necessary to protect public health with an adequate margin of safety for these susceptible populations.

D. Final Decision on the Primary O_3 Standard

For the reasons discussed above, and taking into account information and assessments presented in the 2006 Criteria Document and 2007 Staff Paper, the advice and recommendations of CASAC, and public comments received during the 2008 rulemaking and on the 2010 proposal, the Administrator has decided to set a new level for the 8-hour primary O_3 standard. Specifically, the Administrator is setting the level of the 8-hour primary O_3 standard at 0.070 ppm. The 8-hour primary standard will be met at an ambient air monitoring site when the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentration is less than or equal to 0.070 ppm O_3. Data handling conventions are specified in the new Appendix P that is adopted, as discussed in section V below.

At this time, EPA is also promulgating revisions to the AQI for O_3 to conform to the revision of the primary O_3 standard. These AQI revisions are discussed below in section III. Issues related to the monitoring requirements for the revised primary O_3 standard are discussed below in section VI.

III. Communication of Public Health Information

Information on the public health implications of ambient concentrations of criteria pollutants is currently made available primarily through EPA's Air Quality Index (AQI) program. The current Air Quality Index has been in use since its inception in 1999 (64 FR 42530). It provides accurate, timely, and easily understandable information about daily levels of pollution (40 CFR 58.50). The AQI

establishes a nationally uniform system of indexing pollution levels for O_3, carbon monoxide, nitrogen dioxide, particulate matter and sulfur dioxide. The AQI converts pollutant concentrations in a community's air to a number on a scale from 0 to 500. Reported AQI values enable the public to know whether air pollution levels in a particular location are characterized as good (0 - 50), moderate (51 - 100), unhealthy for sensitive groups (101 - 150), unhealthy (151 - 200), very unhealthy (201 - 300), or hazardous (300 - 500). The AQI index value of 100 typically corresponds to the level of the short-term NAAQS for each pollutant. An AQI value greater than 100 means that a pollutant is in one of the unhealthy categories (i.e., unhealthy for sensitive groups, unhealthy, very unhealthy, or hazardous) on a given day; whereas an AQI value at or below 100 means that a pollutant concentration is in one of the satisfactory categories (i.e., moderate or good). Decisions about the pollutant concentrations at which to set the various AQI breakpoints, that delineate the various AQI categories, draw directly from the underlying health information that supports the NAAQS review.

In the 2008 rulemaking, the AQI for O_3 was revised by setting an AQI value of 100 equal to 0.075 ppm, 8-hour average, the level of the revised primary O_3 standard. The other AQI breakpoints at the lower end of the range were also revised as follows: An AQI value of 50 is set at 0.059 ppm; an AQI value of 150 was set at 0.095 ppm; and an AQI value of 200 was set at 0.115 ppm. All these levels are averaged over 8 hours. These levels were developed by making proportional adjustments to the other AQI breakpoints (i.e., AQI values of 50, 150 and 200).

The Agency recognizes the importance of revising the AQI in a timely manner to be consistent with any changes to the NAAQS. In January 2010 EPA proposed to finalize conforming changes to the AQI in connection with the Agency's final decision on the level of the primary O_3 standard. The proposed conforming changes included setting the 100 level of the AQI at the same level as that set for the primary O_3 standard resulting from this rulemaking, and also making proportional adjustments to

other AQI breakpoints at the lower end of the range (i.e., AQI values of 50, 150 and 200). We did not propose to change breakpoints at the higher end of the range (from 300 to 500), which would apply to state contingency plans or the Significant Harm Level (40 CFR 51.16), because the information from the reconsideration of the 2008 final rule did not inform decisions about breakpoints at those higher levels.

The EPA received relatively few comments on the proposed revisions to the AQI. Almost all of the State commenters were supportive of revising the AQI for O_3 in conjunction with setting a different level of the primary O_3 standard, especially with regard to setting an AQI value of 100 equal to the level of the standard. Therefore, EPA is setting an AQI value of 100 equal to the level of the primary O_3 standard at 0.070 ppm, 8-hour average. EPA is also making a proportional adjustment to an AQI value of 50, setting it equal to 0.055 ppm O_3, 8-hour average. This change will also allow the moderate category to span an air quality range (0.014 ppm) sufficiently wide for air quality forecasting.

With respect to AQI values above 100 (i.e., AQI values of 150 and 200), the comments were mixed, with some State commenters expressing the view that these values should also be adjusted proportionally with the changes made to reflect the new standard, while other State commenters did not support such an adjustment. The State of Missouri Department of Natural Resources (DNR) recommended that "…EPA maintain the 200, 300 and 400 AQI breakpoints at the current ozone values, and reserve these levels for truly extreme episodes…" (MO DNR, 2010, p.8). The Louisiana Department of Environmental Quality (DEQ) stated that "A significant portion of the general public follows the Ozone Action Day suggestions…" and expressed concern that at lower levels "…the public will begin to become complacent with the alerts, thus leading to less interest in supporting this effort" (LA DEQ, 2010, p.2).

In response to these concerns, EPA turned to the controlled human exposure data for lung function decrements upon which, along with information about symptomatic responses, the AQI

breakpoints and advisories for O_3 are based. Since these AQI values for these higher breakpoints and advisories are designed to caution members of the general public, as well as members of sensitive groups, EPA concluded that it was appropriate to consider the proportion of the exposed population likely to have moderate lung function changes of ≥ 15% decrements in FEV_1. In the context of standard setting, CASAC indicated that a focus on the mid to upper end of the range of moderate levels of functional responses (e.g., FEV_1 decrements ≥ 15% but < 20%) is appropriate for estimating potentially adverse lung function decrements in active healthy people. The exposure-response functions are described in Sections 5.3.1.3 and 5.3.1.4 of the 2007 Staff Paper (EPA 2007, pp. 5-18 - 5-28). The estimated functions shown in Table 5-2b were created using pooled data from several controlled human exposure studies.[32] For the exposure-response curve for 15% decrements in FEV_1, the 2.5th percentile and 97.5th percentile responses estimates comprise the lower and upper bounds of the credible interval around the median estimate (50th percentile) of responses. Based on this information, at 0.095 ppm O_3, the current breakpoint between the Unhealthy for Sensitive Groups and Unhealthy categories (AQI value of 150), the median estimate indicates that approximately 25% (down to approximately 18% and up to approximately 30%) of people exposed while at moderate exertion would experience moderate lung function decrements (FEV_1 decrements ≥ 15%). EPA judges that 0.095 ppm O_3 remains an appropriate breakpoint for an AQI value of 150. When about 25% of the people exposed are likely to experience moderate or greater lung function decrements, that can be considered a population-level effect and advisories of Unhealthy air quality conditions are appropriate.

Based on the information in Table 5-2b, at 0.115 ppm O_3, the current breakpoint between the Unhealthy and Very Unhealthy categories (AQI value of 200), the median estimate indicates that

[32]The combined data set included data from six studies that have been used to estimate the exposure-response relationships for 8-hour exposures under moderate exertion, including: Folinsbee et al. (1988); Horstman et al. (1990); McDonnell et al. (1991); and Adams (2002, 2003, 2006).

approximately 40% (down to approximately 30% and up to approximately 50%) of people exposed while at moderate exertion would experience moderate lung function decrements (FEV_1 decrements ≥ 15%). EPA judges that 0.115 ppm O_3 remains an appropriate breakpoint for an AQI value of 200. When about 40% of people exposed are likely to experience moderate or greater lung function decrements, advisories of Very Unhealthy air quality conditions are appropriate. Therefore, EPA is not revising the AQI values of 150 or 200.

In response to the Louisiana DEQ's concerns that the general public will become complacent to Ozone Action Day suggestions, EPA notes that air quality action day programs are voluntary. We do not place requirements on them. State and local agencies can, and do, call action days at different AQI values or air quality concentrations. Changing AQI breakpoints does not affect or change any air quality agency's action day program. We encourage State and local air agencies to use these voluntary programs, and to call for public action at AQI values or air quality concentrations that support their programs' goals.

With respect to reporting requirements (40 CFR Part 58, §58.50), EPA proposed to revise 40 CFR Part 58, §58.50 (c) to require the reporting requirements to be based on the latest available census figures, rather than the most recent decennial U.S. census. This change would be consistent with our current practice of using the latest population figures to make monitoring requirements more responsive to changes in population. The Agency solicited comments on this proposed revision to the AQI reporting requirements. We received very few comments on the proposed revision, and they were generally supportive of the revision. There were no comments that caused us to reconsider the proposed revision. EPA continues to believe that it is important to base the monitoring requirements on the latest available census figures. Therefore, with respect to reporting requirements (40 CFR Part 58, §58.50),

EPA is promulgating the proposed change to 40 CFR Part 58, §58.50 (c) to require the reporting requirements to be based on the latest available census figures.

IV. Rationale for Final Decisions on the Secondary O_3 Standard

As an initial matter, the Administrator noted in the proposed rule that the 2008 final rule concluded that (1) the protection afforded by the 1997 secondary O_3 standard was "not sufficient and that the standard needs to be revised to provide additional protection from known and anticipated adverse effects on sensitive natural vegetation and sensitive ecosystems, and that such a revised standard could also be expected to provide additional protection to sensitive ornamental vegetation" and (2) "that there is not adequate information to establish a separate secondary standard based on other effects of O_3 on public welfare" (73 FR 16497). The Administrator did not reconsider these aspects of the 2008 decision, which are based on the reasons discussed in section IV.B of the 2008 final rule (73 FR 16489-16497). The Administrator also notes that the 2008 final rule concluded that it was appropriate to retain the O_3 indicator for the secondary O_3 standard. The Administrator did not reconsider this aspect of the 2008 decision, which was based on the reasons discussed in sections II.C.1 and IV.C of the 2008 final rule (73 FR 16489-16497). For these reasons, the Administrator did not reopen the 2008 decision with regard to the need to revise the 1997 secondary O_3 standard to provide additional protection from known and anticipated adverse effects on sensitive natural vegetation and sensitive ecosystems, nor with regard to the appropriate indicator for the secondary standard. Thus, the information that follows in this section specifically focuses on a reconsideration of the 8-hour secondary O_3 standard set in the 2008 final rule for the purpose of determining whether and, if so, how to revise the form, averaging time, and level of the standard to provide appropriate protection from known and anticipated adverse effects on sensitive natural vegetation and sensitive ecosystems.

This section presents the rationale for the Administrator's final decision that the secondary O_3 standard, which was set identical to the revised primary standard in the 2008 final rule, should instead be

a new cumulative, seasonal standard[33]. This new standard is defined in terms of a concentration-weighted index, commonly called the W126 index, which uses a sigmoidal weighting function to assign a weight to each hourly O_3 concentration within the 12-hour daytime period (8:00 am to 8:00 pm). This daily O_3 index is defined as follows:[34]

$$daily\ W126 = \sum_{i=8am}^{i=7\,pm} w_{c_i} C_i \text{ , where } C_i = \text{hourly } O_3 \text{ concentration in ppm for hour starting at time i, and}$$

$$w_c = \frac{1}{1 + 4403e^{-126C}} .$$

The daily index values are then summed over each month and the highest consecutive 3-month sum is determined for each calendar year. The standard is set at a level of 13 ppm-hours, based on the 3-year average of the maximum 3-month index value for each year.

As discussed more fully below, the rationale for this new secondary standard is based on a thorough review, in the 2006 Criteria Document, of the latest scientific information on vegetation, ecological and other public welfare effects associated with the presence of O_3 in the ambient air, building on information evaluated in the 1996 Criteria Document. This rationale also takes into account and is consistent with: (1) staff assessments of the most policy-relevant information in the 2006 Criteria Document and staff analyses of air quality, vegetation effects evidence, exposure, and risks, presented in the 2007 Staff Paper, upon which staff recommendations for revisions to the secondary O_3 standard are based; (2) CASAC advice and recommendations as reflected in discussions of drafts of the 2006 Criteria Document and 2007 Staff Paper at public meetings, in separate written comments, and in CASAC's letters to the Administrator, both before and after the 2008 rulemaking and on the 2010 proposal; (3)

[33] In describing the secondary standard as a "seasonal' standard, EPA is referring generally to the growing season of O_3-sensitive vegetation, not to the seasons of the year (i.e., spring, summer, fall, winter), as discussed most fully below in section IV.C.2.

[34] This definition is equivalent to that presented in the 2010 proposal and the 2007 Staff Paper; slight modifications to the summation term in the equation and the definition of the parameter C_i were made to provide more clarity in defining the hourly concentrations being summed.

public comments received during development of these documents, either in conjunction with CASAC meetings or separately, and on the 2007 and 2010 proposed rules; and (4) consideration of the degree of protection to vegetation potentially afforded by a new standard with a cumulative, seasonal form as compared to an 8-hour secondary standard set equal to the primary standard.

In developing this rationale, the Administrator has again focused on direct O_3 effects on vegetation, specifically drawing upon an integrative synthesis of the entire body of evidence in the 2006 Criteria Document (chapter 9), published through early 2006, on the broad array of vegetation effects associated with the presence of O_3 in the ambient air. In addition, because O_3 can also indirectly affect other ecosystem components such as soils, water, and wildlife and their associated ecosystem goods and services, through its effects on vegetation, a qualitative discussion of these other indirect impacts is also included, though these effects were not quantifiable at the time of the 2008 rulemaking. As briefly outlined below in section IV.A.1, the peer-reviewed literature includes studies conducted in the U.S., Canada, Europe, and many other countries around the world.[35] Section IV.A.2 outlines the evidence related to biologically relevant exposure indices. This rationale also draws upon the results of quantitative exposure and risk assessments, summarized below in section IV.A.3. Section IV.B below summarizes the rationale for the 2008 decision on the secondary standard. Section IV.C below describes the Administrator's reconsideration of the 2008 decision on the secondary standard, including reconsideration of the form (section IV.C.1), averaging times (section IV.C.2), and level (section IV.C.3). Each subsection within section IV.C includes a summary of the 2010 proposed decision, public comments on the proposed decision and EPA's responses to those comments, and the Administrator's

[35] In its assessment of the evidence judged to be most relevant to making decisions on the level of the O_3 secondary standard, however, EPA has placed greater weight on U.S. studies, due to the often species-, site- and climate-specific nature of O_3-related vegetation response.

final conclusions on each element of a new secondary standard. Section IV.D summarizes the final decisions on the secondary O_3 standard.

A. Evidence and Exposure/Risk-Based Considerations

1. Vegetation Effects Evidence

This section outlines the information presented in section IV.A of the 2010 proposal on known or potential effects on public welfare which may be expected from the presence of O_3 in ambient air. Exposures to O_3 have been associated quantitatively and qualitatively with a wide range of vegetation effects. The decision in the 1997 review to set a more protective secondary standard primarily reflected consideration of the quantitative information on vegetation effects available at that time, particularly growth impairment (e.g., biomass loss) in sensitive forest tree species during the seedling growth stage and yield loss in important commercial crops. This information, derived mainly using the open top chamber (OTC) exposure method, found cumulative, seasonal O_3 exposures were most strongly associated with observed vegetation response. The 2006 Criteria Document discussed a number of additional studies that support and strengthen key conclusions regarding O_3 effects on vegetation and ecosystems found in the previous Criteria Document (EPA, 1996a, 2006a), including further clarification of the underlying mechanistic and physiological processes at the sub-cellular, cellular, and whole system levels within the plant. More importantly, however, in the context of this review, new quantitative information is now available across a broader array of vegetation effects (e.g., growth impairment during seedlings, saplings and mature tree growth stages, visible foliar injury, and yield loss in annual crops) and across a more diverse set of exposure methods, including chamber, free air, gradient, model, and field-based observation. These non-chambered, field-based study results begin to address one of the key data gaps cited by the Administrator in the 1997 review.

Section IV.A of the proposal provides a detailed summary of key information contained in the 2006 Criteria Document (chapter 9) and in the 2007 Staff Paper (chapter 7) on known or potential effects on public welfare which may be expected from the presence of O_3 in ambient air (72 FR 37883-37890). The information in that section summarized:

(1) new information available in the 2008 rulemaking on potential mechanisms for vegetation effects associated with exposure to O_3, including information on plant uptake of O_3, cellular to systemic responses, compensation and detoxification responses, changes to plant metabolism, and plant responses to chronic O_3 exposures;

(2) the nature of effects on vegetation that have been associated with exposure to O_3, including effects related to carbohydrate production and allocation, growth effects on trees and yield reductions in crops, visible foliar injury, and reduced plant vigor, as well as consequent potential impacts on ecosystems, including potential alteration of ecosystem structure and function and effects on ecosystem services and carbon sequestration; and

(3) considerations in characterizing what constitutes an adverse welfare impact of O_3, including an approach that expands the consideration of adversity beyond the species level by making explicit the linkages between stress-related effects such as O_3 exposure at the species level and at higher levels within an ecosystem hierarchy.

2. Evidence Related to Biologically Relevant Exposure Indices

This section outlines the information presented in section IV.B of the 2010 proposal on biologically relevant exposure indices that relate known or potential effects on vegetation to exposure to O_3 in ambient air. The 2006 Criteria Document concluded that O_3 exposure indices that cumulate differentially weighted hourly concentrations are the best candidates for relating exposure to plant growth responses. This conclusion followed from the extensive evaluation of the relevant studies in the

1996 Criteria Document and the evaluation of studies that have been published since that time. The depth and strength of these conclusions are illustrated by the following observations that are drawn from the 1996 Criteria Document (EPA, 1996a, section 5.5):

(1) Specifically, with respect to the importance of taking into account exposure duration, "when O_3 effects are the primary cause of variation in plant response, plants from replicate studies of varying duration showed greater reductions in yield or growth when exposed for the longer duration" and "the mean exposure index of unspecified duration could not account for the year-to-year variation in response" (EPA, 1996a, pg. 5-96).

(2) "[B]ecause the mean exposure index treats all concentrations equally and does not specifically include an exposure duration component, the use of a mean exposure index for characterizing plant exposures appears inappropriate for relating exposure with vegetation effects" (EPA, 1996a, pg. 5-88).

(3) Regarding the relative importance of higher concentrations than lower in determining plant response, "the ultimate impact of long-term exposures to O_3 on crops and seedling biomass response depends on the integration of repeated peak concentrations during the growth of the plant" (EPA, 1996a, pg. 5-104).

(4) "[A]t this time, exposure indices that weight the hourly O_3 concentrations differentially appear to be the best candidates for relating exposure with predicted plant response" (EPA, 1996a, pgs. 5-136).

At the conclusion of the 1997 review, the biological basis for a cumulative, seasonal form was not in dispute. There was general agreement between the EPA staff, CASAC, and the Administrator, based on their review of the air quality criteria, that a cumulative, seasonal form was more biologically relevant than the previous 1-hour and new 8-hour average forms (61 FR 65716).

The 2007 Staff Paper prepared for the 2008 review evaluated the most appropriate choice of a cumulative, seasonal form for a secondary standard to protect the public welfare from known and anticipated adverse vegetation effects in light of the new information available in this review. Specifically, the Staff Paper considered: (1) the continued lack of evidence within the vegetation effects literature of a biological threshold for vegetation exposures of concern and (2) new estimates of PRB that are lower than in the last review. One form, commonly called the W126 index (Lefohn and Runeckles, 1987; Lefohn et al., 1988), was evaluated in the 1997 review and was compared with the form called SUM06, which incorporates a threshold level above which exposures are summed, that was proposed in the 1997 review. The concentration-weighted form commonly called W126 is defined as the sum of sigmoidally weighted hourly O_3 concentrations over a specified period, where the daily sigmoidal weighting function is defined as:

$$daily\ W126 = \sum_{i=8am}^{i=7pm} w_{c_i} C_i \text{ , where } C_i = \text{hourly } O_3 \text{ concentration in ppm for hour starting at time i, and}$$

$$w_c = \frac{1}{1 + 4403e^{-126C}} .$$

Regarding the first consideration, the 2007 Staff Paper noted that the W126 form, by its incorporation of a continuous sigmoidal weighting scheme, does not create an artificially imposed concentration threshold, yet also gives proportionally more weight to the higher and typically more biologically potent concentrations, as supported by the scientific evidence. Second, the index value is not significantly influenced by O_3 concentrations within the range of estimated PRB, as the weights assigned to concentrations in this range are very small. Thus, the Staff Paper concluded that it would provide a more appropriate target for air quality management programs designed to reduce emissions from anthropogenic sources contributing to O_3 formation. On the basis of these considerations, the 2007

Staff Paper and the CASAC Panel concluded that the W126 form is the most biologically relevant cumulative, seasonal form appropriate to consider in the context of the secondary standard review.

3. Vegetation Exposure and Risk Assessments

This section summarizes the information presented in section IV.C of the 2010 proposal on the vegetation exposure and risk assessments conducted for this review, which improved and built upon similar analyses performed in the 1997 review. The vegetation exposure assessment was performed using interpolation and included information from ambient monitoring networks and results from air quality modeling. The vegetation risk assessment included both tree and crop analyses. The tree risk analysis included three distinct lines of evidence: (1) observations of visible foliar injury in the field linked to recent monitored O_3 air quality for the years 2001 – 2004; (2) estimates of seedling growth loss under current and alternative O_3 exposure conditions; and (3) simulated mature tree growth reductions using the TREGRO model to simulate the effect of meeting alternative air quality standards on the predicted annual growth of a single western species (ponderosa pine) and two eastern species (red maple and tulip poplar). The crop analysis includes estimates of the risks to crop yields from current and alternative O_3 exposure conditions and the associated change in economic benefits expected to accrue in the agriculture sector upon meeting the levels of various alternative standards. Each element of the assessment is outlined below, together with key observations from this assessment.

a. Exposure Characterization

The exposure analyses examined O_3 air quality patterns in the U.S. relative to the location of O_3-sensitive species that have a known concentration-response in order to predict whether adverse effects are occurring at current levels of air quality, and whether they are likely to occur under alternative standard forms and levels. The most important information about exposure to vegetation comes from the O_3 monitoring data that are available from two national networks: (1) Air Quality System (AQS;

http://www.epa.gov/ttn/airs/airsaqs) and (2) Clean Air Status and Trends Network (CASTNET; http://www.epa.gov/castnet/). In order to characterize exposures to vegetation at the national scale, however, the Staff Paper concluded that it could not rely solely on limited site-specific monitoring data, and that it was necessary to use an interpolation method to characterize O_3 air quality over broad geographic areas. The analyses used the O_3 outputs from the EPA/NOAA Community Multi-scale Air Quality (CMAQ)[36] model system (http://www.epa.gov/asmdnerl/CMAQ, Byun and Ching, 1999; Arnold et al. 2003, Eder and Yu, 2005) to improve spatial interpolations based solely on existing monitoring networks.

Based on the significant difference in monitor network density between the eastern and western U.S., the 2007 Staff Paper concluded that it was appropriate to use separate interpolation techniques in these two regions: AQS and CASTNET monitoring data were solely used for the eastern interpolation, and in the western U.S., where rural monitoring is more sparse, O_3 values generated by the CMAQ model were used to develop scaling factors to augment the interpolation. In order to characterize uncertainty in the interpolation method, monitored O_3 concentrations were systematically compared to interpolated O_3 concentrations in areas where monitors were located. In general, the interpolation method used in the current review performed well in many areas in the U.S., although it under-predicted higher 12-hour W126 exposures in rural areas. Due to the important influence of higher exposures in determining risks to plants, this feature of the interpolated surface could result in an under-estimation of risks to vegetation in some areas. Taking these uncertainties into account, and given the absence of

[36] The CMAQ model is a multi-pollutant, multi-scale air quality model that contains state-of-the-science techniques for simulating all atmospheric and land processes that affect the transport, transformation, and deposition of atmospheric pollutants and/or their precursors on both regional and urban scales. It is designed as a science-based modeling tool for handling many major pollutants (including photochemical oxidants/O_3, particulate matter, and nutrient deposition) holistically. The CMAQ model can generate estimates of hourly O_3 concentrations for the contiguous U.S., making it possible to express model outputs in terms of a variety of exposure indices (e.g., W126, 8-hour average).

more complete rural monitoring data, this approach was used in developing national vegetation exposure and risk assessments that estimate relative changes in risk for the various alternative standards analyzed.

To evaluate changing vegetation exposures and risks under selected air quality scenarios, the 2007 Staff Paper utilized adjusted 2001 base year O_3 air quality distributions with a rollback method (Horst and Duff, 1995; Rizzo, 2005, 2006) to reflect meeting the then-current 0.08 ppm and alternative secondary standard options. The following key observations were drawn from comparing predicted changes in interpolated air quality under each alternative standard form and level scenario analyzed:

(1) The results of the exposure assessment indicate that then-current air quality levels could result in significant impacts to vegetation in some areas. For example, for the base year (2001), a large portion of California had 12-hr W126 O_3 levels above 31 ppm-hours, which has been associated with approximately up to 14% biomass loss in 50% of tree seedling cases studies. Broader multi-state regions in the East (NC, TN, KY, IN, OH, PA, NJ, NY, DE, MD, VA) and West (CA, NV, AZ, OK, TX) are predicted to have levels of air quality above the W126 level of 21 ppm-hours, which is approximately equal to the secondary standard proposed in 1996 and is associated with biomass loss levels no greater than approximately 9% in 50% of tree seedling cases studied, and biomass loss levels greater than approximately 9% in the other 50%. Much of the East and Arizona and California have 12-hour W126 O_3 levels above 13 ppm-hours which has been associated with biomass loss levels no greater than approximately 7% biomass loss in 75% of tree seedling cases studied and biomass loss levels greater than approximately 7% in the remaining 25% of cases studied.

(2) When 2001 air quality was rolled back to meet the then current 8-hour secondary standard, the overall 3-month 12-hour W126 O_3 levels were somewhat improved, but not substantially. Under this scenario, there were still many areas in California with 12-hour W126 O_3 levels above 31 ppm-

hours. A broad multi-state region in the East (NC, TN, KY, IN, OH, PA, MD) and West (CA, NV, AZ, OK, TX) were still predicted to have O_3 levels above the W126 level of 21 ppm-hours.

(3) Exposures generated for just meeting a 0.070 ppm, 4th-highest maximum 8-hour average alternative standard (the lower end of the proposed range for the primary O_3 standard) showed substantially improved O_3 air quality when compared to just meeting the then-current 0.08 ppm, 8-hour standard. Most areas were predicted to have O_3 levels below the W126 level of 21 ppm-hr, although some areas in the East (KY, TN, MI, AR, MO, IL) and West (CA, NV, AZ, UT, NM, CO, OK, TX) were still predicted to have O_3 levels above the W126 level of 13 ppm-hours.

(4) While these results suggested that meeting a proposed 0.070 ppm, 8-hour secondary standard would provide substantially improved protection in some areas, the Staff Paper recognized that other areas could continue to have elevated seasonal exposures, including forested park lands and other natural areas, and Class I areas which are federally mandated to preserve certain air quality related values. This is especially important in the high elevation forests in the western U.S. where there are few O_3 monitors and where air quality patterns can result in relatively low 8-hour averages while still experiencing relatively high cumulative exposures.

To further characterize O_3 air quality in terms of the 8-hour and alternative secondary standard forms, an analysis was performed in the 2007 Staff Paper to evaluate the extent to which county-level O_3 air quality measured in terms of various levels of the 8-hour average form overlapped with that measured in terms of various levels of the 12-hour W126 cumulative, seasonal form.[37] This analysis was limited by the lack of monitoring in rural areas where important vegetation and ecosystems are located, especially at higher elevation sites. This is because O_3 air quality distributions at high elevation

[37] The 2007 Staff Paper presented this analysis using 2002-2004 county-level O_3 air quality data (using 3-year average data as well as data from each individual year) from AQS sites and the subset of CASTNET sites having the highest O_3 levels for the counties in which they are located.

sites often do not reflect the typical urban and near-urban pattern of low morning and evening O_3 concentrations with a high mid-day peak, but instead maintain relatively flat patterns with many concentrations in the mid-range (e.g., 0.05-0.09 ppm) for extended periods. These conditions can lead to relatively low daily maximum 8-hour averages concurrently with high cumulative values so that there is potentially less overlap between an 8-hour average and a cumulative, seasonal form at these sites. The 2007 Staff Paper concluded that it is reasonable to anticipate that additional unmonitored rural high elevation areas important for vegetation may not be adequately protected even with a lower level of the 8-hour form.

It continues to remain uncertain as to the extent to which air quality improvements designed to reduce 8-hour O_3 average concentrations would reduce O_3 exposures measured by a seasonal, cumulative W126 index. The 2007 Staff Paper indicated this to be an important consideration because: (1) the biological database stresses the importance of cumulative, seasonal exposures in determining plant response; (2) plants have not been specifically tested for the importance of daily maximum 8-hour O_3 concentrations in relation to plant response; and (3) the effects of attainment of a 8-hour standard in upwind urban areas on rural air quality distributions cannot be characterized with confidence due to the lack of monitoring data in rural and remote areas. These factors remain important considerations in the Administrator's reconsideration of whether the current 8-hour form can appropriately provide requisite protection for vegetation.

b. Assessment of Risk to Vegetation

The 2007 Staff Paper presented results from quantitative and qualitative risk assessments of O_3 risks to vegetation. In the 1997 review, crop yield and seedling biomass loss OTC data provided the basis for staff analyses, conclusions, and recommendations (EPA, 1996b). Since then, several additional lines of evidence have progressed sufficiently to provide a basis for a more complete and coherent picture of the scope of O_3-related vegetation risks, especially those currently faced by seedling, sapling

and mature tree species growing in field settings and indirectly, forested ecosystems. Specifically, new research reflects an increased emphasis on field-based exposure methods (e.g., free air exposure and ambient gradient), improved field survey biomonitoring techniques, and mechanistic tree process models. Key observations and insights from the vegetation risk assessment, together with important caveats and limitations, were discussed in section IV.C of the 2010 proposal. Highlights from the analyses that addressed visible foliar injury, seedling and mature tree biomass loss, and effects on crops are summarized below:

(1) Visible foliar injury. Recent systematic injury surveys continue to document visible foliar injury symptoms diagnostic of phytotoxic O_3 exposures on sensitive bioindicator plants. These surveys produced more expansive evidence than that available at the time of the 1997 review that visible foliar injury is occurring in many areas of the U.S. under recent ambient conditions. The Staff Paper presented an assessment combining recent U.S. Forest Service Forest Inventory and Analysis (FIA) biomonitoring site data with the county level air quality data for those counties containing the FIA biomonitoring sites. This assessment showed that incidence of visible foliar injury ranged from 21 to 39% during the four-year period (2001-2004) across all counties with air quality levels at or below that of the then-current 0.08 ppm 8-hour standard. Of the counties that met an 8-hour level of 0.07 ppm in those years, 11 to 30% still had incidence of visible foliar injury. The magnitude of these percentages suggests that phytotoxic exposures sufficient to induce visible foliar injury would still occur in many areas after meeting the level of the then current secondary standard or an alternative 0.07 ppm 8-hour standard. Additionally, the data show that visible foliar injury occurrence is geographically widespread and is occurring on a variety of plant species in forested and other natural systems. Linking visible foliar injury to other plant effects is still problematic. However, its presence indicates that other O_3–related vegetation effects could also be present.

(2) Seedling and mature tree biomass loss. In the 1997 review, analyses of the effects of O_3 on trees were limited to 11 tree species for which C-R functions for the seedling growth stage had been developed from OTC studies. Important tree species such as quaking aspen, ponderosa pine, black cherry, and tulip poplar were found to be sensitive to cumulative seasonal O_3 exposures. Work done since the 1997 review at the AspenFACE site in Wisconsin on quaking aspen (Karnosky et al., 2005) and a gradient study performed in the New York City area (Gregg et al., 2003) have confirmed the detrimental effects of O_3 exposure on tree growth in field studies without chambers and beyond the seedling stage (King et al., 2005). To update the seedling biomass loss analysis, C-R functions for biomass loss for available seedling tree species taken from the Criteria Document and information on tree growing regions derived from the U.S. Department of Agriculture's Atlas of United States Trees were combined with projections of air quality based on 2001 interpolated exposures, to produce estimated biomass loss for each of the seedling tree species individually.[38] In summary, these analyses showed that biomass loss still occurred in many tree species when O_3 air quality was adjusted to meet the then-current 8-hour standard. For instance, black cherry, ponderosa pine, eastern white pine, and aspen had estimated median seedling biomass losses over portions of their growing range as high as 24, 11, 6, and 6%, respectively, when O_3 air quality was rolled back to just meet the then-current 8-hour standard. The 2007 Staff Paper noted that these results are for tree seedlings and that mature trees of the same species may have more or less of a response to O_3 exposure. Due to the potential for compounding effects over multiple years, a Consensus Workshop on O_3 effects reported that a biomass loss greater than 2% annually can be significant (Heck and Cowling, 1997). Decreased seedling root growth and survivability could affect overall stand health and composition in the long term.

[38] Maps of these biomass loss projections were presented in the 2007 Staff Paper (chapter 7).

Recent work has also enhanced our understanding of risks beyond the seedling stage. In order to better characterize the potential O_3 effects on mature tree growth, a tree growth model (TREGRO) was used to evaluate the effect of changing O_3 air quality scenarios from just meeting alternative O_3 standards on the growth of mature trees.[39] The model integrates interactions between O_3 exposure, precipitation and temperature as they affect vegetation, thus providing an internal consistency for comparing effects in trees under different exposure scenarios and climatic conditions. The TREGRO model was used to assess O_3-related impacts on the growth of Ponderosa pine in the San Bernardino Mountains of California (Crestline) and the growth of yellow poplar and red maple in the Appalachian mountains of Virginia and North Carolina, Shenandoah National Park (Big Meadows) and Linville Gorge Wilderness Area (Cranberry), respectively. Ponderosa pine is one of the most widely distributed pines in western North America, a major source of timber, important as wildlife habitat, and valued for aesthetics (Burns and Honkala, 1990). Red maple is one of the most abundant species in the eastern U.S. and is important for its brilliant fall foliage and highly desirable wildlife browse food (Burns and Honkala, 1990). Yellow poplar is an abundant species in the southern Appalachian forest. It is 10% of the cove hardwood stands in the southern Appalachians which are widely viewed as some of the country's most treasured forests because the protected, rich, moist set of conditions permit trees to grow the largest in the eastern U.S. The wood has high commercial value because of its versatility and as a substitute for increasingly scarce softwoods in furniture and framing construction. Yellow poplar is also valued as a honey tree, a source of wildlife food, and a shade tree for large areas (Burns and Honkala, 1990).

[39] TREGRO is a process-based, individual tree growth simulation model (Weinstein et al, 1991) and has been used to evaluate the effects of a variety of O_3 scenarios and linked with concurrent climate data to account for O_3 and climate/meteorology interactions on several species of trees in different regions of the U.S. (Tingey et al., 2001; Weinstein et al., 1991; Retzlaff et al., 2000; Laurence et al., 1993; Laurence et al., 2001; Weinstein et al., 2005).

The 2007 Staff Paper analyses found that just meeting the then-current 8-hour 0.08 ppm standard would likely continue to allow O_3-related reductions in annual net biomass gain in these species. This is based on model outputs that estimate that as O_3 levels are reduced below those of the 0.08 ppm standard, significant improvements in growth would occur. Though there is uncertainty associated with the above analyses, it is important to note that new evidence from experimental studies that go beyond the seedling growth stage continues to show decreased growth under elevated O_3 (King et al., 2005); some mature trees such as red oak have shown an even greater sensitivity of photosynthesis to O_3 than seedlings of the same species (Hanson et al., 1994); and the potential for cumulative "carry-over" effects as well as compounding must be considered since the accumulation of such "carry-over" effects over time may affect long-term survival and reproduction of individuals and ultimately the abundance of sensitive tree species in forest stands.

(3) Crops. Similar to the tree seedling analysis, an analysis that combined C-R information on crops, crop growing regions, and interpolated exposures during each crop growing season was conducted for commodity crops, fruits and vegetables. NCLAN crop functions were used for commodity crops, including 9 commodity crop species (i.e., cotton, field corn, grain sorghum, peanut, soybean, winter wheat, lettuce, kidney bean, potato) that accounted for 69% of 2004 principal crop acreage planted in the U.S. in 2004. The C-R functions for six fruit and vegetable species (tomatoes-processing, grapes, onions, rice, cantaloupes, Valencia oranges) were identified from the California fruit and vegetable analysis from the last review (Abt, 1995). The risk assessment estimated that just meeting the then-current 8-hour standard would still allow O_3–related yield loss to occur in some commodity crop species and fruit and vegetable species currently grown in the U.S. For example, based on median C-R function response, in counties with the highest O_3 levels, potatoes and cotton had estimated yield losses of 9-15% and 5-10%, respectively, when O_3 air quality just met the level of the then-current

standard. Estimated yield improved in these counties when the alternative W126 standard levels were met. The very important soybean crop had generally small yield losses throughout the country under just meeting the current standard (0-4%).

The 2007 Staff Paper also presented estimates of monetized benefits for crops associated with the current and alternative standards. The Agriculture Simulation Model (AGSIM) (Taylor, 1994; Taylor, 1993) was used to calculate annual average changes in total undiscounted economic surplus for commodity crops and fruits and vegetables when then current and alternative standard levels were met. Meeting the various alternative standards did show some significant benefits beyond the 0.08 ppm, 8-hour standard. However, the 2007 Staff Paper recognized that the modeled economic benefits from AGSIM had many associated uncertainties which limited the usefulness of these estimates.

B. 2008 Decision on the Secondary Standard

This section presents the rationale for the 2008 final decision on the secondary O_3 standard as presented in the 2008 final rule (73 FR 16499). The EPA's final decision on the secondary standard involved making a choice between the two fundamentally different options that had been proposed in 2007. In the 2007 proposal, EPA agreed with the conclusions drawn in the 2006 Criteria Document, the 2007 Staff Paper and by CASAC that the scientific evidence available in the 2008 review continued to demonstrate the cumulative nature of O_3-induced plant effects and the need to give greater weight to higher concentrations. Thus, EPA proposed that a cumulative exposure index that differentially weights O_3 concentrations could represent a reasonable policy choice for a seasonal secondary standard to protect against the effects of O_3 on vegetation. EPA further agreed with both the 2007 Staff Paper and CASAC that the most appropriate cumulative, concentration-weighted form to consider in the 2008 review was the sigmoidally weighted W126 form, due to the recognition that there is no evidence in the

literature for an exposure threshold that would be appropriate across all O_3-sensitive vegetation and that this form is unlikely to be significantly influenced by O_3 air quality within the range of PRB levels identified in the 2008 review. Thus, EPA proposed as one option to replace the 1997 8-hour average secondary standard form with the cumulative, seasonal W126 form**.** The EPA also proposed to revise the 1997 secondary standard by making it identical to the 8-hour primary standard proposed in 2007, which was proposed to be within the range of 0.070 to 0.075 ppm. In putting forward such a proposal, EPA focused on the decision made in the 1997 review, and the rationale for that decision that made the revised secondary standard identical to the revised primary standard.

The 2008 final rule reported that within the Administration at that time there had been a robust discussion of the strengths and weaknesses associated with each option that had been proposed in 2007. The process by which EPA reached its final conclusion is described in the 2008 final rule (73 FR 16497). The rationale for the decision presented in the 2008 final rule (73 FR 16499-16500) is described below.

In considering the appropriateness of establishing a new standard defined in terms of a cumulative, seasonal form, or revising the 1997 secondary standard by making it identical to the revised primary standard, EPA took into account the approach used by the Agency in the 1997 review, the conclusions of the 2007 Staff Paper, CASAC advice, and the views of public commenters. In giving consideration to the approach taken in the 1997 review, EPA first considered the 2007 Staff Paper analysis of the projected degree of overlap between counties with air quality expected to meet the revised 8-hour primary standard, set at a level of 0.075 ppm, and alternative levels of a W126 standard based on currently monitored air quality data. This analysis showed significant overlap between the revised 8-hour primary standard and selected levels of the W126 standard form being considered, with the degree of overlap between these alternative standards depending greatly on the W126 level selected

and the distribution of hourly O_3 concentrations within the annual and/or 3-year average period.[40] On this basis, as an initial matter, EPA concluded that a secondary standard set identical to the proposed primary standard would provide a significant degree of additional protection for vegetation as compared to that provided by the then-current 0.084 ppm secondary standard. In further considering the significant uncertainties that remain in the available body of evidence of O_3-related vegetation effects and in the exposure and risk analyses conducted for the 2008 rulemaking, and the difficulty in determining at what point various types of vegetation effects become adverse for sensitive vegetation and ecosystems, EPA focused its consideration on a level for an alternative W126 standard at the upper end of the proposed range (i.e., 21 ppm-hours). The 2007 Staff Paper analysis showed that at that W126 standard level, there would be essentially no counties with air quality that would be expected both to exceed such an alternative W126 standard and to meet the revised 8-hour primary standard – that is, based on this analysis of currently monitored counties, a W126 standard would be unlikely to provide additional protection in any monitored areas beyond that likely to be provided by the revised primary standard.

The EPA also recognized that the general lack of rural monitoring data made uncertain the degree to which the revised 8-hour standard or an alternative W126 standard would be protective in those areas, and that there would be the potential for not providing the appropriate degree of protection for vegetation in areas with air quality distributions that result in a high cumulative, seasonal exposure but do not result in high 8-hour average exposures. While this potential for under-protection using an 8-hour standard was clear, the number and size of areas at issue and the degree of risk was hard to determine. However, EPA concluded at that time that an 8-hour standard would also tend to avoid the potential for providing more protection than is necessary, a risk that EPA concluded would arise from

[40] Prior to publication of the 2008 final rule, EPA did further analysis of the degree of overlap to extend the 2007 Staff Paper analyses, and that analysis was available in the docket.

moving to a new form for the secondary standard despite significant uncertainty in determining the degree of risk for any exposure level and the appropriate level of protection, as well as uncertainty in predicting exposure and risk patterns.

The EPA also considered the views and recommendations of CASAC and agreed that a cumulative, seasonal standard was the most biologically relevant way to relate exposure to plant growth response. However, as reflected in some public comments, EPA also judged that there remained significant uncertainties in determining or quantifying the degree of risk attributable to varying levels of O_3 exposure, the degree of protection that any specific cumulative, seasonal standard would produce, and the associated potential for error in determining the standard that will provide a requisite degree of protection — i.e., sufficient but not more than what is necessary. Given these significant uncertainties, EPA concluded at that time that establishing a new secondary standard with a cumulative, seasonal form would result in uncertain benefits beyond those afforded by the revised primary standard and therefore may be more than necessary to provide the requisite degree of protection.

Based on its consideration of the views discussed above, EPA judged in the 2008 rulemaking that the appropriate balance to be drawn was to revise the secondary standard to be identical in every way to the revised primary standard. The EPA believed that such a standard would be sufficient to protect public welfare from known or anticipated adverse effects and did not believe that an alternative cumulative, seasonal standard was needed to provide this degree of protection. The EPA believed that this judgment appropriately considered the requirement for a standard that is neither more nor less stringent than necessary for this purpose.

For the reasons discussed above, and taking into account information and assessments presented in the 2006 Criteria Document and 2007 Staff Paper, the advice and recommendations of the CASAC Panel, and the public comments to date, EPA decided to revise the existing 8-hour secondary standard.

Specifically, in 2008 EPA revised the then-current 8-hour average 0.084 ppm secondary standard by making it identical to the revised 8-hour primary standard set at a level of 0.075 ppm.

Following the 2008 decision on the O_3 standards, serious questions were raised as to whether the standards met the requirements of the CAA. In April 2008, the members of the CASAC Ozone Review Panel sent a letter to EPA stating "[i]n our most-recent letters to you on this subject - dated October 2006 and March 2007 - … *the Committee recommended an alternative secondary standard of cumulative form that is substantially different from the primary Ozone NAAQS in averaging time, level and form — specifically, the W126 index* within the range of 7 to 15 ppm-hours, accumulated over at least the 12 "daylight" hours and the three maximum ozone months of the summer growing season" (Henderson, 2008). The letter continued: "[t]he CASAC now wishes to convey, by means of this letter, its additional, unsolicited advice with regard to the primary and secondary Ozone NAAQS. *In doing so, the participating members of the CASAC Ozone Review Panel are unanimous in strongly urging you or your successor as EPA Administrator to ensure that these recommendations be considered during the next review cycle for the Ozone NAAQS that will begin next year"* (id.). The letter further stated the following views:

> The CASAC was … greatly disappointed that you failed to change the form of the secondary standard to make it different from the primary standard. As stated in the preamble to the Final Rule, even in the previous 1996 ozone review, 'there was general agreement between the EPA staff, CASAC, and the Administrator, … that a cumulative, seasonal form was more biologically relevant than the previous 1-hour and new 8-hour average forms (61 FR 65716)' for the secondary standard. *Therefore, in both the previous review and in this review, the Agency staff and its advisors agreed that a change in the form of the secondary standard was scientifically well-justified.*

Unfortunately, this scientifically-sound approach of using a cumulative exposure index for welfare effects was not adopted, and the default position of using the primary standard for the secondary standard was once again instituted. Keeping the same form for the secondary Ozone NAAQS as for the primary standard is not supported by current scientific knowledge indicating that different indicator variables are needed to protect vegetation compared to public health. The CASAC was further disappointed that a secondary standard of the W126 form was not considered from within the Committee's previously-recommended range of 7 to 15 ppm-hours. *The CASAC sincerely hopes that, in the next round of Ozone NAAQS review, the Agency will be able to support and establish a reasonable and scientifically-defensible cumulative form for the secondary standard."* (Henderson, 2008)

C. Reconsideration of the Secondary Standard

This section presents the Administrator's final decision in the reconsideration of the form (section IV.C.1), averaging times (section IV.C.2), and level (section IV.C.3) of the secondary O_3 standard set in 2008. Each subsection below includes (a) a summary of the 2010 proposed decision, (b) public comments on the 2010 proposed decision and EPA's responses to those comments, and (c) the Administrator's final conclusions on each element of a new secondary O_3 standard.

Significant new comments on the proposed decisions were received in a number of areas, and are responded to in this section and more fully in the 2011 Response to Comments document. EPA notes that many commenters essentially reiterated the scientific and technical comments they had made in the 2008 rulemaking. These comments are addressed briefly in this section and more fully in the 2011 Response to Comments document.

In reaching her proposed decisions, the Administrator considered: the information and assessments presented in the 2006 Criteria Document and the 2007 Staff Paper and related technical support documents, the advice and recommendations of CASAC both during and following the 2008 rulemaking, and public comments received in conjunction with review of drafts of these documents and on the 2007 proposed rule. In reaching her final decisions, the Administrator has also considered public comments on the 2010 proposed decision.

1. Form

a. 2010 Proposed Decision on Form

In January 2010, the Administrator proposed to set a new cumulative, seasonal standard, expressed in terms of a concentration-weighted form commonly called W126, as defined above in section IV.A.2. In reaching her proposed decision, as discussed below and in section IV.D.5.a of the 2010 proposal (75 FR 3018-3020), the Administrator noted that the 2006 Criteria Document and 2007 Staff Paper concluded that the recent vegetation effects literature evaluated in the 2008 rulemaking strengthened and reaffirmed conclusions made in the 1997 review that the use of a cumulative exposure index that differentially weights ambient concentrations is best able to relate ambient exposures to vegetation response at this time (EPA, 2006a, b; section IV.B of the proposal notice (75 FR 3006); section IV.A.2 above). The 1997 review focused in particular on two of these cumulative forms, the SUM06 and W126, selecting the SUM06 form to propose on the basis of policy considerations. While the 1997 final rule set the secondary equal to the primary, the biological basis for a cumulative, seasonal form was not in dispute (75 FR 3007).

In the 2008 rulemaking, the 2007 Staff Paper again evaluated these two forms in light of two key pieces of then-recent information: estimates of PRB that were lower than in the 1997 review and a continued lack of evidence within the vegetation effects literature of a biological threshold for

vegetation exposures of concern. On the basis of those policy and science-related considerations, the 2007 Staff Paper concluded that the W126 form was more appropriate in the context of the 2008 rulemaking. Specifically, the W126 form, by its incorporation of a sigmoidal weighting scheme, does not create an artificially imposed concentration threshold and, by giving proportionally more weight to the higher and typically more biologically potent concentrations, is not significantly influenced by O_3 concentrations within the range of estimated PRB. The 2007 Staff Paper further concluded that "it is not appropriate to continue to use an 8-hour averaging time for the secondary standard" and that "the 8-hour average form should be replaced with a cumulative, seasonal, concentration weighted form" (EPA, 2007b; pg.8-25).

The CASAC, based on its assessment of the same vegetation effects science, agreed with the 2006 Criteria Document and 2007 Staff Paper and unanimously concluded that it is not appropriate to try to protect vegetation from the known or anticipated adverse effects of ambient O_3 by continuing to promulgate identical primary and secondary standards for O_3. Moreover, the members of the CASAC and a substantial majority of the CASAC O_3 Panel agreed with 2007 Staff Paper conclusions and encouraged EPA to establish an alternative cumulative secondary standard for O_3 and related photochemical oxidants that is distinctly different in averaging time, form and level from the current or potentially revised 8-hour primary standard. The CASAC also stated that "the recommended metric for the secondary ozone standard is the (sigmoidally-weighted) W126 index" (Henderson, 2007).

In reconsidering the 2008 final rule in the 2010 proposal, the Administrator agreed with the conclusions drawn in the 2006 Criteria Document, 2007 Staff Paper and by CASAC that the scientific evidence available in the 2008 rulemaking continues to demonstrate the cumulative nature of O_3-induced plant effects and the need to give greater weight to higher concentrations. Thus, the Administrator concluded that a cumulative exposure index that differentially weights O_3 concentrations

represents a reasonable policy choice for a secondary standard to protect against the effects of O_3 on vegetation during the growing season. The Administrator further agreed with both the 2007 Staff Paper and CASAC that the most appropriate cumulative, concentration-weighted form to consider is the sigmoidally weighted W126 form.

The Administrator noted that in the 2007 proposed rule, EPA proposed a second option of revising the then-current 8-hour average secondary standard by making it identical to the proposed 8-hour primary standard. The 2007 Staff Paper analyzed the degree of overlap expected between alternative 8-hour and cumulative seasonal secondary standards using recent air quality monitoring data. Based on the results, the 2007 Staff Paper concluded that the degree to which the current 8-hour standard form and level would overlap with areas of concern for vegetation expressed in terms of the 12-hour W126 standard is inconsistent from year to year and would depend greatly on the level of the 12-hour W126 and 8-hour standards selected and the distribution of hourly O_3 concentrations within the annual and/or 3-year average period. The 2007 Staff Paper also recognized that meeting the then-current or alternative levels of the 8-hour average standard could result in air quality improvements that would potentially benefit vegetation in some areas, but urged caution be used in evaluating the likely vegetation impacts associated with a given level of air quality expressed in terms of the 8-hour average form in the absence of parallel W126 information. This caution was due to the concern that the analysis in the 2007 Staff Paper may not be an accurate reflection of the true situation in non-monitored, rural counties due to the lack of more complete monitor coverage in many rural areas. Further, of the counties that did not show overlap between the two standard forms, most were located in rural/remote high elevation areas which have O_3 air quality patterns that are typically different from those associated with urban and near urban sites at lower elevations. Because the majority of such areas are currently not monitored, there are likely to be additional areas that have similar air quality distributions that would

lead to the same disconnect between forms. Thus, the 2007 Staff Paper concluded that it remains problematic to determine the appropriate level of protection for vegetation using an 8-hour average form.

The Administrator also noted in the 2010 proposal that CASAC recognized that an important difference between the effects of acute exposures to O_3 on human health and the effects of O_3 exposures on welfare is that vegetation effects are more dependent on the cumulative exposure to, and uptake of, O_3 over the course of the entire growing season (Henderson, 2006c). The CASAC O_3 Panel members were unanimous in concluding the protection of natural terrestrial ecosystems and managed agricultural crops requires a secondary O_3 standard that is substantially different from the primary O_3 standard in form, averaging time, and level (Henderson, 2007).

In reaching her proposed decision in this reconsideration of the 2008 final rule, the Administrator considered the comments received on the 2007 proposed rule regarding revising the secondary standard either to reflect a new, cumulative form or by remaining equal to a revised primary standard. The commenters generally fell into two groups.

One group of commenters, including environmental organizations, strongly supported the proposed option of moving to a cumulative, seasonal standard, generally based on the reasoning explained in the 2007 proposal. Commenters in this group also expressed serious concerns with the other proposed option of setting a secondary O_3 standard in terms of the same form and averaging time (i.e., daily maximum 8-hour average O_3 concentration) as the primary standard. These commenters expressed the view that such a standard would fail to protect public welfare because the maximum daily 8-hour average O_3 concentration failed to adequately characterize harmful O_3 exposures to vegetation. This view was generally based on the observation that there is no consistent relationship in areas across the U.S. between 8-hour peak O_3 concentrations and the longer-term cumulative exposures aggregated

over a growing season that are biologically relevant in characterizing O_3-related effects on sensitive vegetation. Thus, as EPA noted in the 2007 proposed rule, there is a lack of a rational connection between the level of an 8-hour standard and the requisite degree of protection required for a secondary O_3 NAAQS.

Another group of commenters, including industry organizations, agreed that a cumulative form of the standard may better match the underlying data, but expressed the view that remaining uncertainties associated with the vegetation effects evidence and/or EPA's exposure, risk and benefits assessments were so great that the available information did not provide an adequate basis to adopt a standard with a level based on a cumulative, seasonal form. These commenters asserted that because of the substantial uncertainties remaining at the time of the 2008 rulemaking, the benefits of changing to a W126 form were too uncertain to warrant revising the form of the standard at that time.

The Administrator noted that in both the 1997 and the 2008 decisions, EPA recognized that the risk to vegetation from O_3 exposures comes from cumulative exposures over a season or seasons. The CASAC has fully endorsed this view based on the available scientific evidence and assessments, and there is no significant disagreement on this issue by commenters. Thus, it is clear that the secondary O_3 NAAQS should provide an appropriate degree of protection against cumulative, seasonal exposures to O_3 that are known or anticipated to harm sensitive vegetation or ecosystems. In reconsidering the 2008 final rule, the Administrator recognized that the issue before the Agency is what form of the standard is most appropriate to perform that function.

Within this framework, the Administrator recognized in the 2010 proposal that it is clear that a cumulative, seasonal form has a distinct advantage in protecting against cumulative, seasonal exposures. Such a form is specifically designed to measure directly the kind of O_3 exposures that can cause harm to vegetation during the growing season. In contrast, an 8-hour standard does not measure cumulative,

seasonal exposures directly and can only indirectly afford some degree of protection against such exposures. To the extent that clear relationships exist between 8-hour daily peak O_3 concentrations and cumulative, seasonal exposures, the 8-hour form and averaging time would have the potential to be effective as an indirect surrogate. However, as discussed in the 2007 proposed rule and the 2008 final rule, the evidence shows that there are known types of O_3 air quality patterns that can lead to high levels of cumulative, seasonal O_3 exposures without the occurrence of high daily 8-hour peak O_3 concentrations. An 8-hour form and averaging time is an indirect way to measure biologically relevant exposure patterns, is poorly correlated with such exposure patterns, and therefore is less likely to identify and protect against the kind of cumulative, seasonal exposure patterns that have been determined to be harmful.

As noted in the 2010 proposal (75 FR 3019), past arguments or reasons for not moving to a cumulative, seasonal form, with appropriate exposure periods, have not been based on disagreement over the biological relevance of the cumulative, seasonal form or the recognized disadvantages of an 8-hour standard in measuring and identifying a specified cumulative, seasonal exposure pattern. The reasons for not moving to such a form have been based on concerns over whether EPA has an adequate basis to identify the nature and magnitude of cumulative, seasonal exposure patterns that the standard should be designed to protect against, given the various uncertainties in the evidence and the lack of rural O_3 monitoring data. This most directly translates into a concern over whether EPA has an adequate basis to determine an appropriate level for a cumulative, seasonal secondary standard.

In reaching her proposed decision, the Administrator also considered issues associated with selection of the W126 cumulative form, as reflected in the following assertions made by some commenters on the 2007 proposed rule: (1) the W126 form lacks a biological basis, since it is merely a mathematical expression of exposure that has been fit to specific responses in OTC studies, such that its

relevance for real world biological responses is unclear; (2) a flux-based model would be a better choice than a cumulative metric because it is an improvement over the many limitations and simplifications associated with the cumulative form; however, there is insufficient data to apply such a model at present; (3) the European experience with cumulative O_3 metrics has been disappointing, and now Europeans are working on their second level approach, which will be flux-based; and (4) a second index that reflects the accumulation of peaks at or above 0.10 ppm (called N100) should be added to a W126 index to achieve appropriate protection.

With regard to whether the W126 index lacks a biological basis, the Administrator found no basis for reaching such a conclusion. As noted above in section IV.A, and discussed more fully in sections IV.A-B in the 2010 proposal, the vegetation effects science is clear that exposures of concern to plants are not based on one discrete 8-hour period but on the repeated occurrence of elevated O_3 levels throughout the plant's growing season. The cumulative nature of the W126 is supported by the basic biological understanding that plants in the U.S. are generally most biologically active during the warm season and are exposed to ambient O_3 throughout this biologically active period. In addition, it has been shown in the scientific literature that during this biologically active period, all else being equal, plants respond proportionately more to higher O_3 concentrations, with no evidence of an exposure threshold for vegetation effects. The W126 sigmoidal weighting function reflects both of these understandings, by not including a threshold below which concentrations are not included, and by differentially weighting concentrations to give greater weight to higher concentrations and less weight to lower ones.

With regard to whether a flux-based model would be a better choice, the 2007 Staff Paper acknowledged that flux models may produce a more accurate calculation of dose to a specific plant species in a specific area. However, dose-response relationships have not been developed for these flux calculations for plants growing in the U.S. Further, flux calculations require large amounts of data for

the physiology of each plant species and the local conditions for the growing range of each plant species. These exercises may be useful for limited small-scale risk assessments but do not provide an appropriate basis for a national standard at this time.

With regard to dissatisfaction with the performance of a particular cumulative index in use in Europe,[41] and growing interest in development of flux-based models, the 2007 Staff Paper (Appendix 7A) noted that "because of a lack of flux-response data, a cumulative, cutoff concentration based (e.g., AOT40) exposure index will remain in use in Europe for the near future for most crops and for forests and semi-natural herbaceous vegetation (Ashmore et al., 2004a)." Further, like the SUM06 index, the AOT40 index incorporates a threshold below which concentrations are not considered. Though the AOT40 threshold is lower than the threshold value in SUM06, the 2007 Staff Paper concluded that the vegetation effects information does not provide evidence of an effects threshold that applies to all species. Thus, the Administrator concluded in the 2010 proposal that neither of these forms is as biologically relevant as the W126 form.

With regard to consideration of coupling a W126 form with a separate N100 index, there was very little research on the N100 index or a coupled approach to be evaluated in the 2008 rulemaking. The CASAC, after reviewing all the information in the 2006 Criteria Document and the 2007 Staff Paper, did not recommend an additional N100 index for consideration. Therefore, there is no basis at this time to judge the extent to which such a coupled W126-N100 form would be a better choice than the proposed W126 form. Further, the W126 form incorporates a weighting scheme that places greater weight on increasing concentrations and gives every concentration of 0.10 ppm and above an equal weight of 1, which is the highest weight in this sigmoidal weighting function.

[41] The AOT40 index used in Europe is a cumulative index that incorporates a threshold at 0.04 ppm (40 ppb). This index is calculated as the area over the threshold (AOT) by subtracting 40 ppb from the value of each hourly concentration above that threshold and then cumulating each hourly difference over a specified window.

In summary, having considered the scientific information and assessment results available in the 2008 rulemaking, as well as the recommendations of the staff and CASAC, and having taken into consideration issues raised in public comments received as part of the 2008 rulemaking, and recognizing the determinations made on level as discussed in section IV.D.5.c of the 2010 proposal (75 FR 3021-3026), the Administrator concluded that it is appropriate to set the secondary standard using a cumulative, seasonal form. The Administrator also concluded that the W126 form is best suited to reflect the biological impacts of O_3 exposure on vegetation, and that there is adequate certainty in the information available in the 2008 rulemaking to support such a change in form. Thus, the Administrator proposed to set the secondary standard using a cumulative, seasonal W126 form.

b. Comments on Form

Significant comments received on the 2010 proposal with regard to the proposed form for the secondary O_3 standard are responded to in this section and more fully in the 2011 Response to Comments document. These commenters generally fell into three groups, including those who supported replacing the 2008 8-hour secondary standard with a new cumulative, seasonal form, those who did not support any change to the 2008 secondary standard at this time, including the adoption of a cumulative form, and some from both groups who also expressed the view that a secondary standard set in terms of a W126 metric cumulated over the consecutive 3-month period within the annual O_3 monitoring period would not be relevant during certain periods of the year when plants were not biologically active.

The first group of commenters, including the National Park Service (NPS), NESCAUM, NACAA, Environmental Defense, Clean Air Task Force, individual States, Tribal Associations, and local environmental organizations, asserted that the weight of scientific evidence was unambiguous with regard to the need for a cumulative form and specifically supported the proposed W126 exposure index.

For example, the NPS stated that "the NPS supports both the conclusion that a seasonal, cumulative metric is needed to protect vegetation, and that the W126 is a more appropriate metric than the SUM06." Similarly, Environmental Defense stated "CASAC and Staff further amply justified the need for a separate cumulative seasonal welfare standard to protect against these effects, rather than relying solely on the primary standards to provide such protection." The Clean Air Task Force stated that "there is overwhelming scientific evidence supporting a revised secondary to be a cumulative, seasonal standard ….In 1997 there was no dispute that a cumulative seasonal form was the most biologically relevant and the 2008 CASAC was steadfast in its insistence that the 8-hour average form was not appropriate for the secondary …." New York State DEC explained that "scientific research recognizes that exposure-based indices considering seasonal time period, exposure duration, diurnal dynamics, peak hourly ozone concentrations, and cumulative effects are important when assessing vegetation effects of ozone exposure (Musselman et al., 2006). The W126 exposure index has long been recognized as a biologically meaningful and useful way to summarize hourly ozone data as a measure of ozone exposure to vegetation (Lefohn et al., 1989)". EPA agrees with these comments for the reasons discussed above in sections IV.A-B.

The EPA notes that this same group of commenters had previously expressed serious concerns with the option of setting the secondary standard equal to a revised primary standard that EPA had proposed in 2007. For example, NPS agreed with CASAC that "retaining the current form of the 8-hour standard for the secondary NAAQS is inappropriate and inadequate for characterizing ozone exposures to vegetation." NESCAUM stated, "we also strongly encourage EPA to avoid the flawed rationale employed in the previous 1997 ozone NAAQS review, i.e., that many of the benefits of a secondary NAAQS would be achieved if the primary NAAQS were attained. This rationale is flawed in at least two ways: first, ozone damage to vegetation persists in areas that attain the primary NAAQS; and

second, the relationship between short-term 8-hour peak concentrations and longer-term seasonal aggregations is not constant, but varies over space and time…EPA should set a secondary NAAQS on its own independent merits based on adverse welfare effects. Real or perceived relationships between primary and secondary nonattainment areas are irrelevant to setting the appropriate form and level of the secondary NAAQS." Environmental Defense made the argument that "[b]ecause there is no rational connection between the proposed primary standards and the level of protection needed to protect vegetation against adverse ozone-induced welfare effects, any EPA finding that the primary standards would be sufficient for secondary standards purposes would be arbitrary….The mere fact that the primary might provide ancillary welfare benefits does not satisfy the statute and does not provide a rational basis for concluding that the primary standards are also requisite to protect to [sic] any adverse welfare effects." For the reasons discussed in the 2010 proposal, EPA agreed with these comments in deciding to propose to set a new cumulative, seasonal standard based on a biologically relevant form.

The second group of commenters, including UARG, API, Exxon Mobil, EEI, AAM, Agricultural Retailers Association, American Farm Bureau Federation, and some individual States, Tribal Associations, and local organizations did not support adopting a cumulative form for the secondary standard at this time. Some of these commenters, while agreeing that directionally a cumulative form of the standard may better match the underlying data, expressed the view that further work is needed to determine whether a cumulative exposure index for the form of the secondary standard is requisite to protect public welfare.

Some of these commenters also reiterated their concerns regarding perceived limitations associated with selection of the W126 cumulative form. Commenters variously asserted that the W126 form lacks a biological basis; a flux-based model would be a better choice than a cumulative metric; the European experience with cumulative O_3 metrics has been disappointing; and the W126 form cannot

provide nationally uniform protection without the addition of a second index that reflects the accumulation of peaks at or above 0.10 ppm (called N100). The Administrator considered these comments in reaching her proposed decision, and EPA's responses to these comments are discussed above in section IV.C.1.a in the context of discussing the 2010 proposed decision on the form of the standard. Some of these commenters also asserted that without producing concentration-response functions for the 8-hour form of the standard, EPA has failed to show that the current 8-hour standard would provide less than requisite protection. These commenters asserted that substantial uncertainties remain in this review, and that the benefits of changing to a W126 form are too uncertain to warrant revising the form of the standard at this time.

The third group of commenters, which included some of those who both supported a change to the new form and some of those who were opposed to such a change, expressed concern that the expansion of the O_3 monitoring season expected to occur in most states to better measure for air quality levels relevant to the proposed range of primary standard levels (as discussed in the 2009 proposed Ozone Monitoring Rule, 74 FR 34525), could lead to situations in which high cumulative seasonal O_3 exposures expressed in terms of a W126 index occur outside of the growing season for vegetation in an area. For example, the State of Colorado noted that "…ozone has proven to be highest in the winter in certain areas of the western US. At these times, not only are most plants dormant, but they are typically covered with snow. In addition, deciduous trees have little or no potential for uptake in the winter as their leaves have dropped. The secondary standard would be much better served by setting it on the maximum three-month period during the true growing seasons of spring and summer." Similar comments were received from WESTAR and others.

In responding to these three groups of commenters in order, EPA agrees with the first group that the science is unambiguous regarding the biological relevance of the cumulative, seasonal form and in

particular the W126 index. EPA notes that the cumulative effect of O_3 on plants has been researched for over 40 years and this research has been documented in EPA's AQCDs (EPA 1996, 2006). EPA notes that the 2006 Criteria Document and 2007 Staff Paper concluded that the recent vegetation effects literature evaluated in the 2008 rulemaking strengthened and reaffirmed conclusions made in the 1997 review that the use of a cumulative exposure index that differentially weights ambient concentrations is best able to relate ambient exposures to vegetation response at this time (EPA, 2006a, b; section IV.B of the proposal notice (75 FR 3006); section IV.A.2 above). EPA further notes that the cumulative nature of the W126 index is supported by the basic biological understanding that plants in the U.S. are generally most biologically active during the warm season and are exposed to ambient O_3 throughout this biologically active period. Moreover, CASAC agreed with the 2007 Staff Paper conclusions and advised EPA to establish an alternative cumulative secondary standard for O_3 that is distinctly different in averaging time, form and level from the current or potentially revised 8-hour primary standard. The CASAC also stated that "the recommended metric for the secondary ozone standard is the (sigmoidally-weighted) W126 index" (Henderson, 2007). EPA concludes that ample support is available in the 2008 rulemaking to reach the determination that a cumulative, seasonal form is both appropriate and necessary for a secondary O_3 that is requisite to protect public welfare from O_3-related effects on vegetation.

Therefore, EPA disagrees with the second group of commenters that additional information is needed at this time to establish that a cumulative, seasonal form is the appropriate form for a standard that is requisite to protect the public welfare. In particular, EPA emphasizes that the 2006 Criteria Document has reviewed hundreds of studies that demonstrate that cumulative metrics, such as the W126 index, are the most biologically relevant concentration-based metrics for vegetation available at this time. EPA has found no evidence that, from the perspective of biological impact of O_3 exposure, the 8-

hour standard form is an appropriate metric to protect vegetation. Thus, EPA concludes that any estimates of public welfare benefits associated with a standard based on an 8-hour averaging time are more uncertain than are benefits estimated to be associated with a cumulative, seasonal standard based on the W126 exposure index. EPA disagrees that it is inappropriate at this time to select a form that is more directly relevant to vegetation response and that would, together with appropriate averaging times and level, be better suited to provide the appropriate degree of protection. EPA also notes that examples of crop concentration-response functions in the 8-hour form were provided in the 2007 Staff Paper (Figure 7E-1 of Appendix 7E). The EPA further notes that these commenters point to "new" studies that were published too late to be included in the 2006 Criteria Document, as a basis for their view that the 8-hour standard form is appropriate for a secondary standard and should be preferred over the cumulative W126 metric. With regard to comments citing "new" studies, EPA notes, as discussed above in section I.E, that as in past NAAQS reviews, it is basing the final decision in this reconsideration on the studies and related information included in the 2006 Criteria Document that have undergone CASAC and public review and will consider newly published studies for the purposes of decision making in the next O_3 NAAQS review. Nonetheless, EPA has provisionally evaluated these studies, as discussed below and more fully in the 2011 Response to Comments document and finds that such studies do not materially change the conclusions reached in the 2006 Criteria Document and that the ecological analyses provisionally assessed expand the already large body of evidence indicating that O_3 exposure causes injury to plants (EPA 2009).

Regarding "new" studies cited by the second group of commenters one study in particular, Percy et al., 2009 and a companion study Percy et al., 2007 played a central role in the comments provided by a number of industry and State commenters, including API, American Electric Power Service Corporation, Agricultural Retailers Association, Colorado Livestock Association, American Farm

Bureau Federation, and Florida Department of Environmental Protection, and are thus discussed below as well as in the 2011 Response to Comments document. These commenters cited the Percy et al. studies as providing the basis for their assertions that EPA is incorrect in concluding that the available scientific evidence provides strong support for the use of the W126 index and that the cumulative seasonal W126 index is biologically relevant and best suited for predicting vegetation response to O_3. For example, API states "…peer-reviewed research based by [sic] Percy, et al. that examined ten years of responses by trees to open-air O_3 exposures 'concluded that W126 greatly overestimated the negative response to ozone and… the growing season 4th highest daily maximum 8-hour average ozone concentration index had high statistical significance and a much greater association with biological endpoints'". These commenters then make the further claim that the W126 lacks a biological or mechanistic basis which makes it an inappropriate choice for the secondary NAAQS. Often commenters cite these studies as providing support for their views that changing to a W126 form is not necessary or appropriate. They assert instead that Percy et al. (2009) provides support for the use of the 8-hour average metric to provide appropriate welfare protection.

In provisionally evaluating the "new" Percy et al. studies, EPA first notes that Percy et al. (2009) was published as part of a book chapter after the drafting of the 2009 Provisional Assessment and was thus not included in that assessment. A companion study, Percy et al. 2007, was included in the 2009 Provisional Assessment but was not discussed extensively because it did not include W126 as part of the analysis presented in the study.

As an initial matter, EPA notes that both publications refer to the same analysis of a multi-year study of one species of tree at a single site. On the basis of its provisional evaluation of Percy et al. (2007, 2009), EPA has identified a number of basic flaws in this analysis that call into question the validity of the findings and conclusions of the two studies. Several of the more critical flaws are

discussed here, while additional limitations are discussed in the 2011 Response to Comments Document. First, the Percy studies purported to relate growth of aspen trees that occurred during the five year period (1999-2003) to O_3 exposure. Trees were planted in 1997 and exposed to either ambient or 1.5 times ambient O_3 concentrations as they grew for the next six years. Each plot and each year was treated as an independent exposure experiment in order to create an exposure-response relationship over multiple years. The major problem with this study is that the authors did not take into account the fact that the size of the trees changed over time independent of the ozone exposures. In other words, they neglected to take the age of the trees into consideration. Thus, they attribute the small size of the trees in the first year of the experiment to O_3 being especially elevated that year, not to the fact that the trees had just been planted two years prior. In subsequent years ambient and elevated exposures were lower, due to local meteorology, and the trees naturally grew larger with age. The authors incorrectly attributed the greater size of the trees to less O_3 exposure. This critical error invalidates further analyses in the Percy et al. publications, and their conclusions are therefore unsupported.

Second, even if a more appropriate measurement of tree growth had been used, such as annual incremental growth, the appropriate comparison between the predictive capabilities of the 8-hour and cumulative metrics was never made in either Percy et al. study. The preference for the 8-hour metric is stated on the basis of results from a multivariate model that only included the 8-hour metric and no other (Percy et al., 2009). Because this multivariate model was never used with any other metric, no comparisons regarding the performance of other metrics (including the W126) can appropriately be made.

Third, Percy et al. (2009) asserts that the W126 metric "overestimates" the effects of exposure to O_3. The data in this experiment were from several genotypes of aspen, one of which had previously been shown to be less sensitive to O_3 exposure. When using the W126 metric in a univariate model, the

authors found a small but significant effect of O_3 in that genotype. When claiming that W126 "overestimates" effects in that one genotype, the authors apparently mean that a metric that would find no effect, such as the 4th-highest 8-hour average O_3 concentration, would be preferable. EPA disagrees with this conclusion, noting that it is based on a fundamentally flawed analysis.

On the basis of these critical limitations, EPA provisionally concludes that neither of the Percy et al. (2007, 2009) studies support the commenter's assertions, and therefore, EPA disagrees that the Percy et al. publications support the view that the 8-hour index is a better predictor of vegetation response than the W126 index. Further EPA response to the assertion of a lack of a biological or mechanistic basis for the W126 is provided in response to other comments below.

In additional comments by this group, by far the most extensive critique of the W126 standard form is provided by Wakelyn Associates, LLC, in an attachment to the American Farm Bureau comments. Many of these comments are also based in part on the Percy et al. studies, and have therefore been responded to in the above discussion on Percy et al (2007, 2009). Other commenters also incorporate the Wakelyn comments either directly by reference or by reiterating many of the same points discussed therein, including UARG, API, American Farm Bureau and Agricultural Retailers Associates.

As a preliminary matter, EPA notes that at the outset of the detailed comments provided in Appendix 1 of Wakelyn Associates, LLC, the commenter mistakenly defines "Sigmoid" or S-shape as relating to the general diurnal patterns of hourly ozone concentrations occurring at low elevation sites. This is incorrect. Instead, the sigmoidal weighting scheme refers to the formula used to assign a weight to each hourly average O_3 concentration independent of time of day. It is possible that this misunderstanding influenced the commenters' perception of the lack of a biological basis for this form, as discussed below.

Comments from Wakelyn Associates, LLC asserted that the W126 index is flawed for the following reasons:

(1) The W126 does not have a biological or mechanistic basis. Statistical fit does not establish the existence of a mechanistic or biologically relevant association between the W126 indicator and ozone exposures that are harmful to vegetation (i.e., an association is not verification of causation). The relationship is a statistical one and is not based on a mechanistic or a biological meaning.

In response, EPA agrees that statistical fit alone does not establish a mechanistic relationship. However, as the 1996 and 2006 Criteria Documents describe, much is known about the mechanistic relationship between ozone and plant response. The W126 exposure index is more biologically based than the current 8-hour standard in that it is based on the observation in both controlled and uncontrolled experiments that effects on plants are cumulative, and higher hourly average concentrations should be weighted greater than the mid- and low-level values.

(2) The W126 does not adequately address plant uptake and therefore is not scientifically valid. It does not take into account the timing of greatest plant uptake, which usually occurs before noon, while the highest O_3 concentrations often occur late in the day when stomata are likely to be partially closed. Conditions that favor high O_3 concentrations do not favor high stomatal conductance. The 8:00 am to 8:00 pm period may not coincide with the period of maximum O_3 uptake by a plant which is in most cases highest by noon.

In response, EPA concludes that the 3-month 12-hr W126 exposure metric is a necessary simplification of the cumulative, peak-weighted effects that are understood from the large body of science reviewed in the 2006 Criteria Document. It has not been clearly demonstrated that stomatal deposition models are feasible or represent a better indicator for effects on vegetation. While EPA agrees that uptake plays an important role, simply taking into account uptake still does not eliminate the

non-linearity that is observed between plant response and ozone exposure. Other factors may also contribute to the effect of any particular dose received by the plant. Recent work by Massman et al. (2000) and Massman (2004) discuss detoxification and plant defenses, which vary among species, as possible explanations for the non-linearity that is sometimes observed between exposure and response.

(3) EPA has ignored phenological physiology – i.e., that different stages of crop growth respond differently to the same level of stress. The proposal assumes that the three months with the highest O_3 concentrations must represent active ozone uptake conditions.

In response, EPA agrees that phenology plays a role in plant response to ozone stress and that not every plant will experience the highest 3-month cumulative exposure during its most sensitive growth stage. However, as recognized in the 2006 Criteria Document, adding phenology to exposure metrics depends upon knowledge of species-specific and site-specific conditions, making specification of weighting functions difficult for general use for setting a national standard. The 2006 Criteria Document found that using cumulative, differentially weighted metrics, such as the W126 index, works well for describing O_3-related effects on vegetation. EPA has concluded, and CASAC has agreed, that the highest 3-month cumulative W126 index is a good predictor of O_3 stress to vegetation during the growing season.

(4) Much of what is stated in the proposal is based on univariate O_3 studies that have little to do with ambient conditions.

In response, EPA disagrees with this comment. All types of studies were reviewed including open-top chamber studies, free-air exposure (FACE) and gradient studies. These studies showed coherence of effects across studies.

In summary, EPA disagrees with these commenters' views regarding the biological relevance and scientific validity of the W126 index. Since the development of the W126 index (Lefohn and

Runeckles, 1987; Lefohn et al,1988), there have been several studies conducted to test and compare the performance of different O_3 indices. For example, Lee et al. (1989) tested over 600 different variations of ozone metrics and identified cumulative concentration weighted indices, like SUM06 and W126, as among the highest performing in predicting plant response based on NCLAN crop data. In addition, Finnan and Burke (1997) compared the performance of indices using exposure-response functions for spring wheat and reported that the best performing index employed a sigmoid function. The 2006 Criteria Document assessed a large number of studies involving a broad assortment of species, sites, and conditions. Many such studies conducted appropriate comparisons of different exposure metrics. The 2006 Criteria Document, which was reviewed by CASAC, concluded that a cumulative, concentration-weighted exposure metric, such as the W126 index, was the best approach for relating plant response to O_3 exposure.

Finally, in response to the third group of commenters, EPA agrees with the views expressed that the goal of the secondary standard, i.e., to protect sensitive vegetation from the adverse effects of O_3 exposure, would not be furthered by including in the W126 index calculation O_3 exposures that occur when plants are much less likely to be biologically active due to freezing temperatures. Plants adapted to living in colder climes undergo a process known as hardening as temperatures decrease for the winter. Once in this hardened state, plants are less likely to be active and have limited gas exchange or photosynthesis. After a sufficient period of warmer air temperatures has raised soil temperature above freezing, the plants de-harden and biological activity resumes. After this point, plants may remain biologically active even if air temperatures fluctuate above and below freezing. EPA has investigated the issue of whether high W126 index values occur in places and times for which hardening may have already occurred but de-hardening has not begun. EPA has found that among areas that have sub-freezing winter temperatures, occurrences during the winter of 1-month W126 values high enough to

possibly contribute to a violation of the 3-month secondary NAAQS appear to date to have been limited to a small number of cases in western areas. These cases have involved the combination of emissions from oil and gas activity, snow cover, and atmospheric inversion.

EPA has addressed this issue in the context of determining what data are to be used in comparison to the secondary standard, as discussed below in section V.B.1, which gives the Regional Administrator authority to approve a request or otherwise make a determination that all 12 hourly daytime O_3 concentrations for one or more days be excluded from the calculation of the W126 index value during cold winter conditions, on the basis that sensitive plant species in the geographic area for which air quality is represented by the monitoring site on those days were in a dormant or hardened condition making them less likely to be susceptible to O_3-related injury. Since these conditions are expected to occur in only a few areas, the application of this provision is not expected to be widespread.

c. Conclusions on Form

Having considered the scientific information discussed in the 2010 proposal and summarized above, as well as the recommendations of the 2007 Staff Paper and CASAC and the public comments on this issue, the Administrator concludes that O_3-related effects on vegetation are clearly linked to cumulative, seasonal exposures and are not appropriately characterized by the use of an 8-hour daily measure of O_3 exposure. Recognizing that the newly available information in the 2008 review has strengthened the basis for the conclusion that the W126 index is better suited to reflect the biological impacts of O_3 exposure on vegetation, and there is adequate certainty in this information to support such a change in the form of the standard, the Administrator concludes that a secondary standard that is distinctly different in form from the 8-hour primary standard is necessary and that it is appropriate to replace the 8-hour average secondary standard form retained in 2008 with the cumulative, seasonal W126 form.

2. Averaging Times[42]

a. 2010 Proposed Decision on Averaging Times

In the 2010 proposal, the Administrator reached conclusions regarding exposure periods (e.g., seasonal and diurnal windows), and the annual versus 3-year average index, that have the most biological relevance for plant response, in conjunction with the W126 form. As discussed below and in section IV.D.5.b of the 2010 proposal (75 FR 3020-21), the Administrator proposed to define the new cumulative, seasonal W126 standard in terms of an annual index, cumulated over 12 hours per day (8 am to 8 pm) during the consecutive 3-month period within the O_3 season with the maximum index value, averaged over 3 years.

In considering an appropriate seasonal window, the Administrator noted that the 2007 Staff Paper concluded that the consecutive 3-month period within the O_3 season with the highest W126 index value (e.g., maximum 3-month period) was a reasonable seasonal time period to consider. The Administrator further noted that the 2007 Staff Paper acknowledged that the selection of any single seasonal exposure period for a national standard would necessarily represent a compromise, given the significant variability in growth patterns and lengths of growing seasons among the wide range of sensitive vegetation species occurring within the U.S. However, the Administrator also considered the Staff Paper conclusion that the period of maximum potential plant uptake of O_3 would also likely coincide with the period of highest O_3 occurring within the intra-annual period defined as the O_3 season, since the high temperature and light conditions conducive to O_3 formation are also conducive for plant activity. The Administrator also observed that the CASAC panel was supportive of the Staff Paper views, while recognizing that three months likely represented the minimum timeframe appropriate to

[42] While the term "averaging time" is used, for the cumulative, seasonal standard the seasonal and diurnal time periods at issue are those over which exposures during a specified period of time are cumulated, not averaged.

consider. Therefore, the Administrator concluded in the 2010 proposal, on these bases, that the consecutive 3-month period within the O_3 season with the highest W126 index value (e.g., maximum 3-month period) was an appropriate seasonal window to propose for the protection of sensitive vegetation.

With regard to consideration of an appropriate diurnal window, the Administrator took into account the 2007 Staff Paper conclusion that for the vast majority of studied species, daytime exposures represent the majority of diurnal plant O_3 uptake and are responsible for inducing the plant response of most significance to the health and productivity of the plant (e.g., reduced carbohydrate production). For example, the 2007 Staff Paper states "In general, stomata are most open during daylight hours in order to allow sufficient CO_2 uptake for use in carbohydrate production through the light driven process of photosynthesis. At most locations, O_3 concentrations are also highest during the daytime, potentially coinciding with maximum stomatal uptake. Ozone uptake during daylight hours impairs the light-driven process of photosynthesis, which can then lead to impacts on carbohydrate production, plant growth, reproduction (yield) and root function. Thus, in the last review, staff selected the 12-hr daylight window (8 am to 8 pm) to capture the diurnal window with most relevance to the photosynthetic process." The Administrator was also aware, based on discussions in the 2007 Staff Paper, that there are some number of species that show non-negligible amounts of O_3 uptake at night due to incomplete stomatal closure. In reaching her proposed conclusion that the 2007 Staff Paper recommendation of a 12-hour daytime window (8:00 a.m. to 8:00 p.m.) was the most appropriate period over which to cumulate diurnal O_3 exposures, specifically those most relevant to plant growth and yield responses, the Administrator placed weight on the fact that the CASAC comments were also supportive of this diurnal window, recognizing again that it likely represents a minimum period over which plants can be vulnerable to O_3 uptake. Therefore, the Administrator proposed the 12-hour daytime window (8:00 a.m. to 8:00 p.m.) as an appropriate diurnal window to protect against O_3-induced plant effects.

Finally, in considering whether an annual or a 3-year average index is more appropriate, the Administrator noted that in addition to the available scientific evidence regarding plant effects that can be brought to bear, there are also other public welfare considerations that may be appropriate to consider. In taking this view, the Administrator noted that the 2007 Staff Paper recognized that though most cumulative seasonal exposure levels of concern for vegetation have been expressed in terms of the annual timeframe, it may be appropriate to consider a 3-year average for purposes of standard stability. The Administrator considered that while the 2007 Staff Paper notes that for certain welfare effects of concern (e.g., foliar injury, yield loss for annual crops, growth effects on other annual vegetation and potentially tree seedlings), an annual time frame may be a more appropriate period in which to assess what level would provide the requisite degree of protection, for other welfare effects (e.g., mature tree biomass loss), a 3-year average may also be appropriate. The Administrator further observed that in concluding that it was appropriate to consider both an annual and a 3-year average, the 2007 Staff Paper also concluded that should a 3-year average of the 3-month, 12-hour W126 form be selected, a potentially lower level should be considered to reduce the potential of adverse impacts to annual species from a single high O_3 year that could still occur while attaining a standard on average over 3-years. The Administrator also took note that the CASAC Panel, in addressing this issue of annual versus 3-year average concluded that multi-year averaging to promote a "stable" secondary standard is less appropriate for a cumulative, seasonal secondary standard than for a primary standard based on maximum 8-hour concentrations, and further concluded that if multi-year averaging is employed to increase the stability of the secondary standard, the level of the standard should be revised downward to assure that the desired degree of protection is not exceeded in individual years. The Administrator, in considering the merits of both the annual and 3-year average, and taking into account both the 2007 Staff Paper and CASAC views, concluded that it is important to place more weight on the public welfare

benefit in having a stable standard, and that appropriate protection for vegetation can be achieved using a 3-year average form. The Administrator thus proposed a 3-year average. However, given the uncertain nature of the evidence and potential concerns with using a 3-year average form, the Administrator solicited comment on the appropriateness of the specific seasonal and diurnal exposure periods proposed, as well as the use of a 3-year average, and, as discussed below in section IV.C.3, the impact that selection of these proposed seasonal and diurnal exposure periods would have, in conjunction with a 3-year average form, on the appropriateness of the proposed range of levels.

b. Comments on Averaging Times

The EPA received a number of comments on each of the three aspects of averaging time identified above: a 3-month season, 12-hour diurnal window, and annual versus 3-year average. Many commenters who focused on these aspects of averaging times reiterated comments made in 2007, as discussed briefly below. These commenters were generally in support of setting a new secondary standard with a cumulative 3-month W126 form. This group of commenters included the DOI/NPS, NESCAUM, Appalachian Mountain Club, and various State, Tribal and local environmental organizations. In addition, new comments on seasonal averaging time were submitted primarily by States or State organizations, such as NACAA and WESTAR, and are discussed more fully below.

(1) Seasonal window. First, regarding the appropriateness of using a 3-month period to represent the relevant portion of the growing season, the NPS supported the 3-month period. Specifically, the NPS stated that "we agree that the maximum consecutive 3-month period within the ozone season is a reasonable averaging time for vegetation in many areas of the country." Many commenters simply stated support for the recommendations of the Staff Paper and CASAC with regard to the W126 form which included a 3-month seasonal window. In contrast, other commenters recommended a longer seasonal averaging time. For example, The Appalachian Mountain Club

commented that EPA should not limit the season to the highest three contiguous months, as O_3 impacts are cumulative throughout the biologically active season. Further, they expressed the view that the standard should be a sum across the active growing season, accounting for regional and elevational differences, and that consideration should be given to the active growing seasons for O_3-sensitive species including deciduous, coniferous, and herb species.

In contrast, a number of state and local groups questioned the appropriateness of the 3-month growing season. For example, the City of Corpus Christi states that its concern with a 3-month seasonal window was related to the idea that one size fits all and the assumption that the O_3 monitoring season and the growing season overlap. In Corpus Christi, the record high O_3 events occur typically in the spring or late fall which means that O_3 events are occurring before some crops have started growing or well after they have been harvested.

As stated above, EPA agrees that many plants, including tree species, have growing seasons longer than three months and that the selection of any single seasonal exposure period for a national standard must necessarily represent a compromise, given the significant variability in growth patterns and lengths of growing seasons among the wide range of vegetation species occurring within the U.S. that may experience adverse effects associated with O_3 exposures. However, EPA does not agree that to be protective the W126 index must be cumulated over the entire growing season for each different plant species, or that the 3-month period must overlap exactly with the most sensitive part of the growing season for each species. In so doing, EPA considered the 2007 Staff Paper conclusion that the consecutive 3-month period within the O_3 season with the highest W126 index value (i.e., the maximum 3-month period) would, in most cases, likely coincide with the period of greatest plant susceptibility to O_3 exposure on an annual basis, i.e. the time when plants are both active and most likely to be exposed to high O_3 concentrations. By limiting the worst 3-month period within the growing season, EPA

believes concentrations outside this 3-month period would most likely also be reduced, thereby providing increased protection across the entire growing season. Therefore, EPA concludes that the annual maximum consecutive 3-month period is a reasonable seasonal time period, when combined with a cumulative, concentration weighted form, for protection of sensitive vegetation. Since the standard looks at the maximum 3-month period, it will focus protection on the likely period of greatest plant susceptibility, and will continue to provide protection outside of that maximum 3-month period as well. EPA further notes that the new secondary standard is not intended to provide additional protection to commercial crops, but rather is meant to provide protection primarily for sensitive tree species growing in specially designated areas, as discussed below in section IV.C.3.

(2) Diurnal window. With respect to the 12-hour diurnal window, the NPS has expressed the view that for most areas of the country, the daytime 12-hour window is an appropriate period over which to cumulate diurnal O_3 exposures. Other commenters, however, including NESCAUM, NY DEQ, NC DFR and AMC, expressed the view that the appropriate diurnal window for vegetation exposure is longer than 12 hours and several commenters recommended a 24-hour window. Some of these commenters provided additional air quality analyses and cited both published and unpublished sources of data that document the co-occurrence of sensitive species and elevated nighttime exposures. NESCAUM, for example "believes the literature on nighttime adverse ozone impacts is sufficiently strong to support a secondary ozone NAAQS that encompasses nighttime hours so that a 24-hour secondary standard may be more appropriate." Further, NESCAUM pointed out that "several studies (i.e., Mereu, et al., 2009 and Caird and Donovan, 2007) have appeared in the peer-reviewed literature since the EPA 2007 Staff Paper that further implicate nocturnal ozone exposure as an important stress factor for vegetation. ….Accounting for an extended exposure period is important to the NESCAUM states as elevated nighttime ozone concentrations occur in many [high elevation] locations throughout

the region." NESCAUM also noted that the number of daylight hours during EPA's presumed 3-month growing season is greater than 12 hours at the latitudes of the NESCAUM region.

Likewise, the NYDEC stated that "a 24-hour time period will consider diurnal variation, will more accurately characterize the total exposure to vegetation, and will effectively capture all potential peak concentrations. NY State monitoring sites at Whiteface Mountain demonstrate elevated W126 values during the nighttime period." NY DEC further stated that "…considerable ozone uptake and conductance at night have also been reported (Musselman and Minnick, 2000). Some plants may even be more susceptible to nighttime ozone exposure and injury because of a reduction in photosynthesis and defensive mechanisms….Paoletti (2005) observed an ozone-impaired function of stomata control mechanism in which the slowed stomata closure persisted for 10 days after cessation of exposure."

The Appalachian Mountain Club and its signatories (National Parks Conservation Association, Adirondack Mountain Club, Appalachian Trail Conservancy, NY-NJ Trail Conservancy, and the Sierra Club) reiterated and expanded upon their 2007 comments. These comments state that "EPA should adopt a 24-hour summative form of the secondary standard as a means of fully protecting vegetation from cumulative ozone and consideration of Class I areas that have peak ozone concentrations at night. … We respectfully disagree with the EPA 2007 Staff Paper's conclusions that there is little information on the co-occurrence of sensitive species and elevated nocturnal ozone exposures. ….While we understand that other factors, such as turbulence, are important for ozone flux into plants, there are studies that have demonstrated ozone uptake and injury from nighttime exposures (Winner, et al., 1989, Grulke et al., 2004, Massman, 2004)." AMC also provided an update of key examples of National Parks and other federal lands with both elevated nighttime O_3 exposure and the presence of sensitive species, some of which have been identified as showing nocturnal stomatal conductance. They also provide information that highlights that both high and mid-elevation locations can experience a significant

portion of their total O_3 exposure overnight. AMC also stated that "if EPA chooses not to promulgate a 24-hr based standard the Agency should consider that daytime is not restricted to 12 hours in much of the U.S. during the ozone monitoring season. It would be more scientifically relevant to use a summation window that reflects spatial and seasonal daytime regimes…..Therefore, as a second-best approach…we urge EPA to consider a longer 'daytime' window and weigh in its consideration of the standard level in the context that anything less than a 24-hr sum underestimates exposure. EPA should clarify whether the start and stop of the cumulative window is in local standard time or daylight savings time."

The EPA agrees that some species of O_3-sensitive plants with known nocturnal stomatal conductance co-occur with high or elevated nighttime O_3 levels. EPA is also aware of the "new" studies cited by these commenters in support of their view and notes that they will be considered in the next review. However, EPA does not agree that there is sufficient evidence at this time to establish a secondary ozone standard to provide the requisite degree of protection from nighttime exposures for the reasons discussed below. As an initial matter, it remains unclear how to appropriately weight nocturnal exposures and to determine at what level they become adverse because for the vast majority of studied species, daytime exposures represent the majority of diurnal plant O_3 uptake and are responsible for inducing the plant response of most significance to the health and productivity of the plant (e.g., reduced carbohydrate production). Further, EPA also notes that the CASAC comments were also supportive of this diurnal window, recognizing again that it likely represents a minimum period over which plants can be vulnerable to O_3 uptake. Therefore, EPA again concludes that 12-hour daytime window (8:00 a.m. to 8:00 p.m.) is an appropriate diurnal window to protect against the O_3-induced plant growth and yield responses important to the public welfare.

For significant nocturnal stomatal uptake and O_3 effects to occur, specific conditions must exist. A susceptible plant with nocturnal stomatal conductance and low defense must be growing in an area with relatively high night-time O_3 concentrations and appreciable nocturnal turbulence to facilitate O_3 deposition to the leaf surface. It is unclear how many areas there are in the U.S. where these conditions occur. Further, many areas across the U.S. have low O_3 concentrations at night. While EPA agrees that there is expanding evidence that the stomates of some species can remain open at night due to sluggish stomatal control resulting from O_3 exposure, and that this loss of stomatal control can lead to excess water loss both during the day and night, EPA believes this information is still insufficient to inform the selection of an appropriate level of protection for a national standard against adverse effects that are occurring solely as the result of nighttime exposures. With regard to the AMC comment regarding a second-best approach, i.e., one that would use a summation window that reflects spatial and seasonal daytime regimes, EPA believes that this would result in an overly complex standard that would be difficult to define at this time. With regard to the need for EPA to specify local standard or daylight savings time, EPA agrees and has specified local standard time in the final rule.

(3) Annual versus 3-year average. With respect to comments concerning the annual versus 3-year averaging period for the cumulative form, comments were fairly evenly divided. Some commenters expressed support for the annual averaging time. Many of these same commenters also made the argument that should a 3-year averaging time be selected, the level of the standard should be lower than if an annual standard were selected. For example, the NPS stated that "averaging W126 values over 3-years has the potential to underestimate the effect of a single high ozone year, whereas in that one year the plant may be sufficiently injured to experience long-lasting growth and reproductive effects in later years. Because of this, CASAC recommended that if multi-year averaging is used, the level of the standard should be revised downward to assure that the desired threshold is not exceeded in individual

years. The Department agrees, and if EPA uses a 3-year average for the standard, as we recommend above, the level of the standard should not exceed 7-9 ppm-hours to protect sensitive vegetation."

In addition, NESCAUM "disagrees with using a three-year (or other multi-year) average, and instead supports a W126 secondary ozone standard that is based on an annual cumulative index of exposure. Adverse vegetation damage occurs on an annual basis….Research indicates that there can be significant year- to- year variations in the extent of observed vegetation damage due to ozone, therefore the desire for a more 'stable' secondary NAAQS should not outweigh the need to set the NAAQS at an annual level protective of the welfare values at risk.…If multi-year averaging is employed to promote a more 'stable' NAAQS (as opposed to more stable ecological health), the level should be set lower than what would otherwise have been set for an annual NAAQS. A reduction of the needed annual level by at least one-third can help assure that the intended threshold is not exceeded in individual years."

In contrast, several other commenters, including NC DENR, NC DAQ, Ohio EPA, SC DHEC, and MI DNRE, stated that the cumulative, seasonal standard should be based on a 3-year average, rather than a 1-year average.

The EPA agrees that the adverse impact of some O_3-induced vegetation effects are realized within an annual timeframe and are based on the cumulative O_3 exposure that occurs in that same year. These effects can include growth and reproductive effects in annual species, crop yield loss, and foliar injury symptoms on both annuals and perennial species, including trees growing in protected national areas. EPA notes that, with regard to crop yield loss, as discussed in the 2010 proposal and below in section IV.C.3, the standard is not intended to provide additional protection against such effects for agricultural crops. With regard to growth and reproductive effects in other annual species and foliar injury symptoms, EPA recognizes that determining what degree of vegetation impact is adverse, and therefore for which appropriate protection is required in any given year, is more uncertain. Based on the

information in the 2007 Staff Paper, and taking into consideration the views of CASAC, and as discussed in the 2010 proposal, EPA concludes that in combination with an appropriate form and level, appropriate protection for vegetation can be achieved using a 3-year average of the cumulative, seasonal W126 form. In addition, many of the comments received on this issue also acknowledged this was the case, even when expressing a preference for an annual time period. Further, in proposing a 3-year average index, EPA concluded that it is also important to place significant weight on the public welfare benefit in having a standard with more year-to-year stability. A more stable standard contributes to the public welfare protection provided by that standard by limiting year-to-year disruptions in ongoing control programs that would occur if an area was frequently shifting in and out of attainment due to extreme year-to-year variations in meteorological conditions. Comments regarding the 3-year averaging time as it relates to the standard level are addressed below in section IV.C.3.b.

c. Conclusions on Averaging Times

Having considered the scientific information discussed in the 2010 proposal and summarized above, as well as the recommendations of the 2007 Staff Paper and CASAC and the public comments on this issue, the Administrator has reached the following conclusions with regard to averaging times that are appropriate when combined with the cumulative, seasonal W126 form.

With regard to the seasonal window, the Administrator recognizes that many plants, including tree species, have growing seasons longer than three months and that the selection of any single seasonal exposure period for a national standard must necessarily represent a compromise, given the significant variability in growth patterns and lengths of growing seasons among the wide range of vegetation species occurring within the U.S. that may experience adverse effects associated with O_3 exposures. However, based on the 2007 Staff Paper conclusion that the consecutive 3-month period within the O_3 season with the highest W126 index value (e.g., maximum 3 month period) would, in most cases, likely

coincide with the period of greatest plant susceptibility to O_3 exposure on an annual basis, the Administrator concludes that the annual maximum consecutive 3-month period is a reasonable seasonal time period, when combined with the W126 form, for protection of sensitive vegetation. Since the standard looks at the maximum 3-month period, it will focus protection on the period of greatest plant susceptibility, and will continue to provide protection outside of that maximum 3-month period as well.

With regard to the diurnal window, the Administrator recognizes that for the vast majority of studied species, daytime exposures represent the majority of diurnal plant O_3 uptake and are responsible for inducing the plant response of most significance to the health and productivity of the plant. The Administrator also recognizes that some species show non-negligible amounts of O_3 uptake at night, although she concludes that the available information regarding the potential for adverse impacts on vegetation due to nighttime exposures to O_3 is still preliminary and insufficient to inform selection of an appropriate level of protection against adverse effects that may occur as the result of nighttime exposures. Thus, the Administrator concludes that the 12-hour daytime window (8:00 a.m. to 8:00 p.m.) is an appropriate diurnal window to protect against O_3-induced plant effects.

With regard to choosing between an annual or a 3-year average index, the Administrator recognizes that the adverse impact of some O_3-induced vegetation effects are realized within an annual timeframe and are based on the cumulative O_3 exposure that occurs in that same year. However, the Administrator also recognizes that determining what degree of vegetation impact for these annual effects is adverse, and therefore for which appropriate protection is required in any given year, is more uncertain. Based on the available information and CASAC and public comments, she has concluded that appropriate protection for vegetation can be achieved using a 3-year average index, in combination with the cumulative, seasonal W126 index and selection of an appropriate level. In addition, the Administrator also judges that it is important to place significant weight on the public welfare benefit of

having a standard with more year-to-year stability. As noted above, a more stable standard contributes to the public welfare protection provided by that standard by limiting year-to-year disruptions in ongoing control programs that would occur if an area was frequently shifting in and out of attainment due to extreme year-to-year variations in meteorological conditions. Thus, the Administrator concludes that appropriate protection for vegetation can be achieved using a 3-year average standard, which also has the benefit of providing increased stability, such that a 3-year average is both desirable and appropriate.

3. Level

a. 2010 Proposed Decision on Level

In January 2010, the Administrator proposed to set a new cumulative, seasonal standard, in terms of the form and averaging times discussed above, at a level within the range of 7 to 15 ppm-hours. In reaching her proposed decision, as discussed below and in section IV.D.5.c of the 2010 proposal (75 FR 3021-3026), the Administrator considered the information and assessments that formed the basis for the range of levels proposed in 2007 in conjunction with the proposed option to set a cumulative, seasonal W126 standard, including information from the 2006 Criteria Document and the 2007 Staff Paper, the advice and recommendations of CASAC during the 2008 rulemaking, and public comments received on drafts of these documents and on the 2007 proposed rule.

The 2007 Staff Paper, in identifying a range of levels for a 3-month, 12-hour (daytime) W126 standard appropriate for the Administrator to consider in protecting the public welfare from known or anticipated adverse effects to vegetation from O_3 exposures, considered what information from the array of vegetation effects evidence and exposure and risk assessment results was most useful. With respect to the vegetation effects evidence, the 2007 Staff Paper found stronger support than what was available at the time of the 1997 review for an increased level of protection for trees and forested ecosystems.

Specifically, the expanded body of evidence included: (1) additional field-based data from free air, gradient and biomonitoring surveys demonstrating adverse levels of O_3-induced growth reductions on trees at the seedling, sapling and mature growth stages and incidence of visible foliar injury occurring at biomonitoring sites in the field at ambient levels of exposure; (2) qualitative support from free air (e.g., AspenFACE) and gradient studies on a limited number of tree species for the continued appropriateness of using OTC-derived C-R functions to predict tree seedling response in the field; (3) studies that continued to document below-ground effects on root growth and "carry-over" effects occurring in subsequent years from O_3 exposures; and (4) increased recognition and understanding of the structure and function of ecosystems and the complex linkages through which O_3, and other stressors, acting at the organism and species level can influence higher levels within the ecosystem hierarchy and disrupt essential ecological attributes critical to the maintenance of ecosystem goods and services important to the public welfare.

Based on the above sources of vegetation effects information and the results of the exposure and risk assessments summarized above (section IV.A.3), the 2007 Staff Paper concluded that just meeting the then-current 0.084 ppm, 8-hour average standard would continue to allow adverse levels of O_3-induced effects to occur in sensitive commercially and ecologically important tree species in many regions of the country. The 2007 Staff Paper further concluded that air quality levels would need to be substantially reduced to protect sensitive tree seedlings, such as black cherry, aspen, and cottonwood, from these growth and foliar injury effects.

In addition to the currently quantifiable risks to trees from ambient exposures, the 2007 Staff Paper also considered the more subtle impacts of O_3 acting in synergy with other natural and man-made stressors to adversely affect individual plants, populations and whole systems. By disrupting the photosynthetic process, decreasing carbon storage in the roots, increasing early senescence of leaves and

affecting water use efficiency in trees, O_3 exposures could potentially disrupt or change the nutrient and water flow of an entire system. Weakened trees can become more susceptible to other environmental stresses such as pest and pathogen outbreaks or harsh weather conditions. Though it is not possible to quantify all the ecological and societal benefits associated with varying levels of alternative secondary standards, the 2007 Staff Paper concluded that this information should be weighed in considering the extent to which a secondary standard should be set so as to provide potential protection against effects that are anticipated to occur.

The 2007 Staff Paper also recognized that in the 1997 review, EPA took into account the results of a 1996 Consensus Workshop. At this workshop, a group of independent scientists expressed their judgments on what standard form(s) and level(s) would provide vegetation with adequate protection from O_3-related adverse effects. Consensus was reached on protective ranges of levels in terms of a cumulative, seasonal 3-month, 12-hr SUM06 standard for a number of vegetation effects endpoints. These ranges are identified below, with the estimated approximate equivalent W126 standard levels shown in parentheses. For growth effects to tree seedlings in natural forest stands, a consensus was reached that a SUM06 range of 10 to 15 (W126 range of 7 to 13) ppm-hours would be protective. For growth effects to tree seedlings and saplings in plantations, the consensus SUM06 range was 12 to 16 (W126 range of 9 to 14) ppm-hours. For visible foliar injury to natural ecosystems, the consensus SUM06 range was 8 to 12 (W126 range of 5 to 9) ppm-hours.

The 2007 Staff Paper then considered to what extent recent research provided empirical support for the ranges of levels identified by the experts as protective of different types of O_3-induced effects. The 2007 Staff Paper concluded on the basis of the available evidence that it was appropriate to consider a range for a 3-month, 12-hour, W126 standard level that included the 1996 Consensus Workshop

recommendations regarding a range of levels protective against O_3-induced growth effects in tree seedlings in natural forest stands (i.e., 7-13 ppm-hours in terms of a W126 form).

In considering the newly available information on O_3-related effects on crops in the 2008 review, the 2007 Staff Paper observed the following regarding the strength of the underlying crop science: (1) nothing in the recent literature points to a change in the relationship between O_3 exposure and crop response across the range of species and/or cultivars of commodity crops currently grown in the U.S. that could be construed to make less appropriate the use of commodity crop C-R functions developed in the NCLAN program; (2) new field-based studies (e.g., SoyFACE) provide qualitative support in a few limited cases for the appropriateness of using OTC-derived C-R functions to predict crop response in the field; and (3) refinements in the exposure, risk and benefits assessments in this review reduce some of the uncertainties present in 1996. On the basis of these observations, the 2007 Staff Paper concluded that nothing in the newly assessed information calls into question the strength of the underlying science upon which EPA based its proposed decision in the last review to select a level of a cumulative, seasonal form associated with protecting 50% of crop cases from no more than 10% yield loss as providing the requisite degree of protection for commodity crops.

The 2007 Staff Paper then considered whether any additional information was available to inform judgments as to the adversity of various O_3-induced levels of crop yield loss to the public welfare. The 2007 Staff Paper observed that agricultural systems are heavily managed, and that in addition to stress from O_3, the annual productivity of agricultural systems is vulnerable to disruption from many other stressors (e.g., weather, insects, disease), whose impact in any given year can greatly outweigh the direct reduction in annual productivity resulting from elevated O_3 exposures. On the other hand, O_3 can also more subtly impact crop and forage nutritive quality and indirectly exacerbate the severity of the impact from other stressors. Since these latter effects could not be quantified at that time,

they could only be considered qualitatively in reaching judgments about an appropriate degree of protection for commodity crops from O_3-related effects.

Based on the above considerations, the 2007 Staff Paper concluded that the level of protection judged requisite in the 1997 review to protect the public welfare from adverse levels of O_3-induced reductions in crop yields and tree seedling biomass loss, as approximately provided by a W126 level of 21 ppm-hours, remained appropriate for consideration as an upper bound of a range of appropriate levels. The 2007 Staff Paper also recognized that a standard set at this level would not protect the most sensitive species or individuals within a species from all potential effects related to O_3 exposures and further, that this level derives from the extensive and quantitative historic and recent crop effects database, as well as current staff exposure and risk analyses (EPA, 2007, pg. 8-22).

In identifying a lower bound for the range of alternative standard levels appropriate for consideration, the 2007 Staff Paper concluded that several lines of evidence pointed to the need for greater protection for tree seedlings, mature trees, and associated forested ecosystems. Tree growth was characterized as an important endpoint to consider because it is related to other aspects of societal welfare such as sustainable production of timber and related goods, recreation, and carbon (CO_2) sequestration. Impacts on tree growth can also affect ecosystems through shifts in species composition and the loss of genetic diversity due to the loss of O_3-sensitive individuals or species. In selecting an appropriate level of protection for trees, the 2007 Staff Paper considered the results of the 1996 Consensus Workshop which identified the SUM06 range of 10 to 15 (W126 range of 7 to 13) ppm-hours for growth effects to tree seedlings in natural forest stands.

Because the 2007 Staff Paper concluded that O_3-related effects on forest tree species are important public welfare effects of concern, it therefore concluded, based on the above, that it was appropriate to include 7 ppm-hours as the lower bound of the recommended range, the lower end of the

approximate range recommended by CASAC (Henderson, 2006c) and identified by the 1996 Consensus Workshop participants as protective of forest trees. At this lower end of the range, the 2007 Staff Paper estimated, based on its analyses of risks of tree seedling biomass loss and mature tree growth reductions and on the basis of the scientific effects literature, that adverse effects of O_3 on forested ecosystems would be substantially reduced. Further, the 2007 Staff Paper concluded that the lower end of this range would likely provide increased protection from the more subtle impacts of O_3 acting in synergy with other natural and man-made stressors to adversely affect individual plants, populations and whole systems. The 2007 Staff Paper also noted that by disrupting the photosynthetic process, decreasing carbon storage in the roots, increasing early senescence of leaves and affecting water use efficiency in trees, O_3 exposure could potentially disrupt or change the nutrient and water flow of an entire system. Such weakened trees can become more susceptible to other environmental stresses such as pest and pathogen outbreaks or harsh weather conditions. While recognizing that it is not possible to quantify all the ecological and societal benefits associated with varying levels of alternative secondary standards, the 2007 Staff Paper concluded that this information should be weighed in considering the extent to which a secondary standard should be precautionary in nature in protecting against effects that have not yet been adequately studied and evaluated.

Thus, the 2007 Staff Paper concluded, based on all the above considerations, that an appropriate range of levels, for an annual standard using a 3-month, 12-hour W126 form, for the Administrator to consider was 7 to 21 ppm-hours, recognizing that the level selected is largely a policy judgment as to the requisite level of protection needed. In determining the requisite level of protection for crops and trees, the 2007 Staff Paper recognized that it was appropriate to weigh the importance of the predicted risks of these effects in the overall context of public welfare protection, along with a determination as to the appropriate weight to place on the associated uncertainties and limitations of this information.

In considering the evidence described in both the 2006 Criteria Document and 2006 draft Staff Paper, CASAC, in its October 24, 2006, letter to the Administrator, expressed its view regarding the appropriate form and range of levels for the Administrator to consider. The CASAC preferred a seasonal 3-month W126 standard in a range that is the approximate equivalent of the SUM06 at 10 to 20 ppm-hours. Following the 2007 proposal, EPA received additional CASAC and public comments regarding an appropriate range of levels of a W126 form for the Administrator to consider in finalizing a revised secondary NAAQS for O_3. The CASAC, in its final letter to the Administrator (Henderson, 2007), agreed with the 2007 Staff Paper recommendations that the lower bound of the range within which a seasonal W126 secondary O_3 standard should be considered is approximately 7 ppm-hours; however, it did not agree with staff's recommendation that the upper bound of the range should be as high as 21 ppm-hours. Rather, the CASAC Panel recommended that the upper bound of the range considered should be no higher than a W126 of 15 ppm-hours for an annual standard.

In considering what range of levels of a cumulative 3-month standard to propose, the Administrator noted that this choice requires judgment as to what standard will protect the public welfare from any known or anticipated adverse effects. This choice must be based on an interpretation of the evidence and other information, such as the exposure and risk assessments, that neither overstates nor understates the strength and limitations of the evidence and information nor the appropriate inferences to be drawn. In taking all of the above into consideration, the Administrator also noted that there is no bright line clearly directing the choice of level for any of the effects of concern, and the choice of what is appropriate is clearly a public welfare policy judgment entrusted to the Administrator.

In particular, the Administrator gave careful consideration to the following: (1) the nature and degree of effects of O_3 to the public welfare, including what constitutes an adverse effect; (2) the strengths and limitations of the evidence that is available regarding known or anticipated adverse effects

from cumulative, seasonal exposures, and its usefulness in informing selection of a proposed range; and (3) CASAC's views regarding the strength of the evidence and its adequacy to inform a range of levels. Each of these topics is discussed in turn below.

In determining the nature and degree of effects of O_3 on the public welfare, the Administrator recognized that the significance to the public welfare of O_3-induced effects on sensitive vegetation growing within the U.S. can vary, depending on the nature of the effect, the intended use of the sensitive plants or ecosystems, and the types of environments in which the sensitive vegetation and ecosystems are located. Any given O_3-related effect on vegetation and ecosystems (e.g., biomass loss, foliar injury), therefore, may be judged to have a different degree of impact on the public depending, for example, on whether that effect occurs in a Class I area, a city park, or commercial cropland. In her judgment, it is appropriate that this variation in the significance of O_3-related vegetation effects should be taken into consideration in judging the level of ambient O_3 that is requisite to protect the public welfare from any known or anticipated adverse effects. In this regard, the Administrator agreed with the definition of adversity, as described in section IV.A.3 of the 2010 proposal and in the 2008 final rule. As a result, the Administrator concluded that of those known and anticipated O_3-related vegetation and ecosystem effects identified and discussed in this reconsideration, the highest priority and significance should be given to those that occur on sensitive species that are known to or are likely to occur in federally protected areas such as Class I areas[43] or on lands set aside by States, Tribes and public interest groups to provide similar benefits to the public welfare, for residents on those lands, as well as visitors to those areas.

[43] For example, the level of protection granted by Congress under the Wilderness Act of 1964 for designated "wilderness areas" requires that these areas "shall be administered for the use and enjoyment of the American people in such manner as will leave them unimpaired for future use as wilderness, and so as to provide for the protection of these areas, the preservation of their wilderness character" (The Wilderness Act, 1964).

Likewise, the Administrator also noted that the same known or anticipated O_3-induced effects occurring in other areas may call for less protection. For example, the maintenance of adequate agricultural crop yields is extremely important to the public welfare and is currently achieved through the application of intensive management practices, including in some cases genetic engineering. These management practices, in conjunction with market forces and government programs, assure an appropriate balance is reached between costs of production and market availability. Thus, while research on agricultural crop species remains useful in illuminating mechanisms of action and physiological processes, information from this sector on O_3-induced effects is considered less useful in informing judgments on what level(s) would be sufficient but not more than necessary to protect the public welfare. With respect to commercial production of commodities, the Administrator noted that judgments about the extent to which O_3-related effects on commercially managed vegetation are adverse from a public welfare perspective are particularly difficult to reach, given that what is known about the relationship between O_3 exposures and agricultural crop yield response derives largely from data generated almost 20 years ago. The Administrator recognized that there is substantial uncertainty at this time as to whether these data remain relevant to the majority of species and cultivars of crops being grown in the field today. In addition, the extensive management of such vegetation may to some degree mitigate potential O_3-related effects. The management practices used on these lands are highly variable and are designed to achieve optimal yields, taking into consideration various environmental conditions. Thus, the Administrator concluded there is no need for such additional protection for agricultural crops through the NAAQS.

The Administrator also recognized that O_3-related effects on sensitive vegetation can occur in other areas that have not been afforded special Federal protections, ranging from effects on vegetation growing in residential or commercial settings, such as ornamentals used in urban/suburban landscaping,

to vegetation grown in land use categories that are heavily managed for commercial production of commodities such as timber. For vegetation used for residential or commercial ornamental purposes, such as urban/suburban landscaping, the Administrator concluded that there is not adequate information at this time to establish a secondary standard based specifically on impairment of urban/suburban landscaping and other uses of ornamental vegetation but noted that a secondary standard revised to provide protection for sensitive natural vegetation and ecosystems would likely also provide some degree of protection for such ornamental vegetation.

Based on the above, the Administrator found that the type of information most useful in informing the selection of an appropriate range of protective levels is appropriately focused on information regarding exposures and responses of sensitive trees and other native species known or anticipated to occur in protected areas such as Class I areas or on lands set aside by States, Tribes and public interest groups to provide similar benefits to the public welfare, for residents on those lands, as well as visitors to those areas.

With regard to the available evidence, the Administrator found the coherence and strength of the weight of evidence from the large body of available literature compelling. This evidence addresses a broad array of O_3-induced effects on a variety of tree species across a range of growth stages (i.e., seedlings, saplings and mature trees) using diverse field-based (e.g. free air, gradient and ambient) and OTC exposure methods. It demonstrates that significant numbers of forest tree species are potentially experiencing O_3-induced stress under levels of ambient air quality, both at and below the level of the 1997 standard.

In particular, the Administrator noted the evidence from recent field studies and a gradient study of eastern cottonwood saplings (Gregg et al., 2003). She observed that this study found that cottonwood saplings grown in urban New York City grew faster than saplings grown in downwind rural areas where

cumulative O_3 exposures were higher, and the difference in biomass production between the urban site with the lowest cumulative exposure and the rural site with the highest cumulative exposure is dramatic (Figure 7-17 in the 2007 Staff Paper). The Administrator further noted that cottonwood is one of the most sensitive tree species studied to date and it is also important both from an ecological and public welfare perspective.

The Administrator also noted the evidence related to the O_3-induced effect of visible foliar injury. The Administrator observed that the visible foliar injury database created from the ambient field-based monitoring network managed by the Unites States Forest Service (USFS) Forest Inventory and Analysis (FIA) Program has continued to expand since the conclusion of the 1997 review. In utilizing this dataset, EPA staff collaborated with FIA staff to compare the incidence of visible foliar injury at different levels of air quality by county throughout the U.S. in counties with FIA monitoring sites. In considering the results of this analysis, depicted in Table 7-4 of the 2007 Staff Paper, the Administrator noted that for the 2001-2004 period, the percent of counties with documented foliar injury at a level approximately equivalent to the W126 of 21 ppm-hours was 26 to 49%, while at the lower level approximately equivalent to a W126 of 13 ppm-hours, incidence values ranged from 12 to 35%. The Administrator concluded that it was likely that some sensitive species occurring in specially protected areas would also exhibit visible foliar injury symptoms to a similar degree at these exposure levels. She further noted that while direct links between O_3-induced visible foliar injury symptoms and other adverse effects (e.g., biomass loss) are not always found, visible foliar injury in itself is considered by the National Park Service (NPS) to affect adversely air quality related values (AQRV) in Class I areas.

The Administrator also placed significant weight on the judgments of CASAC. In so doing, the Administrator carefully considered its stated views and the basis for the range of levels the CASAC O_3 Panel recommended. In its 2007 letter to the Administrator, the CASAC O_3 Panel agreed with EPA

staff recommendations that the lower bound of the range within which a seasonal W126 O_3 standard should be considered is approximately 7 ppm-hours. However, "it *does not* agree with Staff's recommendations that the upper bound of the range should be as high as 21 ppm-hours. Rather, the Panel recommends that the upper bound of the range considered should be no higher than 15 ppm-hours, which the Panel estimates is approximately equivalent to a seasonal 12-hour SUM06 level of 20 ppm-hours" (Henderson, 2007). The Administrator noted that CASAC views concerning an appropriate range of levels for the Administrator to consider were presented after CASAC had considered the entire body of evidence presented in both the 2006 Criteria Document and 2007 Staff Paper and are generally consistent with the 1996 Consensus Workshop recommendations.

In considering the issues raised by commenters on the 2007 proposed rule, the Administrator noted that many public commenters supported the range of levels recommended by CASAC. The Administrator also considered the views expressed by the NPS as to what range of levels it identified as useful in helping it achieve its mandate to protect AQRVs in national parks and wilderness areas and to provide a level of protection for its resources in keeping with the Congressional mandate set forth in The Wilderness Act of 1964. In so doing, the Administrator noted that the NPS supported the range recommended by CASAC, while emphasizing that the lower end of the range was more appropriate. The NPS noted that though some visible foliar injury would still be expected to occur above the lower end of the CASAC recommended range (i.e., 7 ppm-hours), the potential for growth impacts at that level would be very low. The NPS further noted that most of these parks contain aspen, black cherry, or ponderosa pine, all sensitive species predicted to have significant growth effects at current W126 levels.

The Administrator also considered those comments that highlighted sources of uncertainty in the evidence and risk assessments to inform her judgments on how much weight to place on these associated uncertainties. As discussed below, uncertainties highlighted by these commenters included: (1)

potential confounders, such as soil moisture, on visible foliar injury and the lack of a clear relationship between visible foliar injury symptoms and other vegetation effects; (2) lack of documentation of the basis for the recommendations from the 1996 Consensus Workshop in selecting a range of levels, indicating that these recommendations should be used with great caution; (3) failure of CASAC and EPA to take into account the monitor height measurement gradient when making their recommendations concerning the level of the secondary standard; and (4) inability to quantitatively estimate ecosystem effects of O_3 or to extrapolate meaningfully from effects on individual plants to ecosystem effects due to inadequate data.

With regard to the issue of possible confounders of foliar injury information, the Administrator recognized that visible foliar injury, like other O_3-induced plant effects, is moderated by environmental factors other than O_3 exposure. However, the Administrator also noted that the O_3-related visible foliar injury effect persisted across a 4-year period (2001-2004), despite year-to-year variability in meteorology and other environmental factors (see Table 7-4 in the 2007 Staff Paper). She also noted that approximately 26 to 49% of counties had visible foliar injury incidence at the approximate W126 level of 21 ppm-hours, while at a W126 level of 13 ppm-hours, this range of percentages dropped to approximately 12 to 35%. In an area such as a national park, where visitors come in part for the aesthetic quality of the landscape, the Administrator recognized that visible foliar injury incidence is an important welfare effect which should be considered in determining an appropriately protective standard level.

With regard to the issues of what weight to place on the recommendations from the 1996 Consensus Workshop in selecting a range of levels, as the 1997 Workshop Report did not clearly document the basis for its recommendations, the Administrator recognized that the absence of such documentation does call for care in placing weight on such recommendations. However, the

Administrator noted that the Workshop participants were asked prior to attending the workshop to review both the 1996 O_3 Criteria Document and Staff Paper, representing the most up-to-date compilation of the state of the science available at that time, in order to ensure that their expert judgments made were also informed by the latest science. She also noted that another group of experts, the 2008 CASAC O_3 Panel, reached a similar consensus based upon an expanded and more recent body of scientific evidence. In addition, the 2007 Staff Paper evaluated the same recommendations in the context of subsequent empirical evidence, and reached similar views, with the exception of the upper end of the recommended range, which in the 2007 Staff Paper was based on effects on commercial crops that had been considered in the 1997 review. While it would always be more useful to have documentation of the reasoning and basis for an expert's advice, in this case, the Administrator judged that the 1996 Consensus Workshop recommendations should be given substantial weight.

With regard to other issues raised by some commenters related to uncertainties in the technical evidence and analyses, the Administrator noted that such issues had been addressed in the 2007 Staff Paper that reflected CASAC's advice on such issues. For example, while the Administrator recognized that uncertainty remains as to what level of annual tree seedling biomass loss when compounded over multiple years should be judged adverse to the public welfare, she concluded that the potential for such anticipated effects should be considered in judging to what degree a standard should be precautionary.

In considering all of the issues discussed above, the Administrator decided to propose a range of 7-15 ppm-hours. In selecting as an upper bound a level of 15 ppm-hours, the Administrator noted that this level was specifically supported by the CASAC O_3 Panel and is just above the range identified in the 1996 Consensus Workshop report as needed to provide adequate protection for trees growing in natural areas. In addition, the NPS, along with many public commenters, were in support of the CASAC range, including the upper bound of 15 ppm-hours, and indicated that lower values within this range

would be more protective for sensitive trees in protected areas from biomass loss and visible foliar injury symptoms.

While the upper end of this range is lower than the upper end of 21 ppm-hours recommended in the 2007 Staff Paper, this upper level of 21 ppm-hours was originally put forward in the 1997 review in terms of a SUM06 of 25 ppm-hours (W126 of 21 ppm-hours) and was justified on the basis that it was predicted to allow up to approximately 10% biomass loss annually in 50% of studied commercial crops and tree seedling species. Recognizing the significant uncertainties that are associated with evaluating effects on commercial crops from a public welfare perspective, the Administrator concluded that commercial crop data are no longer useful for setting the upper level of the range for proposal.

With regard to her selection of a proposed range, the Administrator considered that the direction from Congress to provide a high degree of protection in Class I areas creates a clearer target for gauging what types and magnitudes of effects would be known or anticipated to affect the intended use of these and other similarly protected areas, that would thus be considered adverse to the public welfare. Such similar areas include lands set aside by States, Tribes and public interest groups to provide similar benefits to the public welfare, for residents on those lands, as well as visitors to those areas. The Administrator also concluded that in order to preserve wilderness areas in an unimpaired state for future generations, she must consider a level that affords substantial protection from known adverse O_3-related effects of biomass loss and foliar injury on sensitive tree species, as well as a level that takes into account potential "anticipated" adverse O_3-related effects, including effects that result in continued impairment in the year following O_3 exposure (i.e., carry-over effects), below ground impacts, ecosystem level impacts, and reduced CO_2 sequestration.

While the Administrator acknowledged that growth effects and visible foliar injury can still occur in sensitive species at levels below the upper bound of the proposed range, the Administrator also

recognized that some significant uncertainties remain regarding the risk of these effects, as discussed above. For example, the Administrator concluded that remaining uncertainties make it difficult to judge the point at which visible foliar injury becomes adverse to the public welfare in various types of specially protected areas. Uncertainties associated with monitoring ambient exposures must be considered in evaluating the strength of predictions regarding the degree of tree seedling growth impairment estimated to occur at varying ambient exposures. These uncertainties add to the challenge of judging which exposure levels are expected to be associated with levels of tree seedling growth effects considered adverse to public welfare. The Administrator concluded that it is important to consider these uncertainties, and the weight to place on such uncertainties, in selecting a range of standard levels to propose. Establishing 15 ppm-hours as the upper end of the proposed range reflected her judgment regarding the appropriate weight to place on these uncertainties in determining the degree of protection that is warranted for known and anticipated adverse effects.

With regard to her selection of a lower bound for the proposed range, the Administrator believed that if weight is placed on taking a more precautionary approach, recognizing that the real world impacts on trees and ecosystems could, in some cases, be greater than predicted, then the lower end of the range of 7 ppm-hours could be warranted. There is clear evidence that higher cumulative exposures can occur in rural areas downwind of urban areas and potentially in Class I areas. Unmonitored high elevation sites would also likely have higher cumulative exposures than lower elevation sites that are currently monitored. All of these considerations lead the Administrator to propose 7 ppm-hours as the low end of the proposed range.

As discussed above in section IV.C.1.a, the main opposition to changing to a secondary standard with a cumulative, seasonal form has been the view that EPA does not have an adequate basis, given the various uncertainties in the evidence, to determine an appropriate level for a cumulative, seasonal

secondary standard. While EPA took this position in the 1997 review, the Administrator concluded in the 2010 proposal that the newly available evidence in the 2008 review strengthens the information available in the 1997 review and reduces remaining uncertainties. She further concluded that this stronger body of evidence appropriately supports a secondary standard that is distinctly different in form and averaging time from the 8-hour primary standard and that such a standard is necessary to provide sufficient protection from cumulative, seasonal exposures to O_3.

Such newly available information includes quantitative information for a broader array of vegetation effects (extending to sapling and mature tree growth stages) obtained using a more diverse set of field-based research study designs and improved analytical methods for assessing O_3-related exposures and risks, as summarized above in section IV.A and more fully in sections IV.A-C in the 2010 proposal. These newly available studies also provide important support to the quantitative estimates of impaired tree growth based on earlier studies available in the 1997 review and address one of the key data gaps cited in the 1997 review. Additional qualitative information is also available regarding improved understanding of linkages between stress-related effects of O_3 exposures at the species level and those at higher levels within ecosystems. Finally, this information includes the use of new analytical methods, including a new multi-pollutant, multi-scale air quality model used to characterize exposures of O_3-sensitive tree and crop species, to further address uncertainties in the assessments done in the 1997 review. In total, this newly available information increased the Administrator's confidence in important aspects of this rulemaking

The decision in 2008 to set the secondary O_3 standard identical to the 8-hour primary standard largely mirrored the decision in 1997 but failed to account for this significant increase in the body of knowledge available to support the 2008 rulemaking. This body of knowledge, while continuing to reflect significant uncertainties, provides an appropriate basis for determining a level of a cumulative,

seasonal standard that, in the judgment of the Administrator, provides sufficient but not more than necessary protection from cumulative, seasonal exposures to O_3. This is clearly so when compared to a standard that uses an indirect form that is not biologically relevant, an 8-hour average standard aimed at peak daily exposures. This judgment is fully consistent with the advice provided by CASAC.

After carefully taking the above considerations into account, and giving significant weight to the views of CASAC, the Administrator decided to propose a range of levels of 7-15 ppm-hours for a cumulative, seasonal secondary O_3 standard expressed as an index of the annual sum of weighted hourly concentrations (i.e., the W126 form), cumulated over 12 hours per day during the consecutive 3-month period within the O_3 season with the maximum index value, averaged over three years. In the Administrator's judgment, based on the information available in the 2008 rulemaking, a standard could be set within this range that would be requisite to protect public welfare from known or anticipated adverse effects to O_3-sensitive vegetation and ecosystems. In the Administrator's judgment, a standard set at a level below the lower end of the range is not now supported by the weight of evidence and would not give sufficient weight to the important uncertainties and limitations inherent in the available scientific evidence and in the quantitative assessments conducted for the 2008 rulemaking. A standard set at a level above the upper end of the range is also not now supported by the weight of evidence and would not give sufficient weight to the credible inferences that the Agency has drawn from the scientific evidence nor to the quantitative assessments conducted for the 2008 rulemaking. In the 2010 proposal, the Administrator judged that the appropriate balance to be drawn, based on the entire body of evidence and information available in the 2008 rulemaking, is a range between 7 and 15 ppm-hours. On balance, the Administrator concluded that a standard could be set within this range that would be sufficient but not more than necessary to protect public welfare from known or anticipated adverse effects due to O_3.

b. Comments on Level

Comments on the 2010 proposal regarding an appropriate level within the proposed range of 7-15 ppm-hours for a W126 cumulative, seasonal standard generally fell into three groups. One group, which includes OTC, Sierra Club, NACAA, and WI DNR, expressed general support for any level within the CASAC-recommended or EPA- proposed range.[44] EPA's response to this group of comments is reflected in its response to the other two groups identified below.

A second group of commenters, consisting mainly of environmental groups, including DOI/NPS, AMC, EarthJustice, EDF, Clean Air Task Force, State agencies, such as NESCAUM, NY DEC, PA DEP, NH DES, and some Tribal and local environmental groups, emphasized the lower end of the proposed range as necessary to provide adequate protection for sensitive species, with some citing the context of multi-year averaging as part of their justification. Some of these commenters suggested a level within the narrow range of 7-9 ppm-hours (i.e., NPS), while others asserted that the level must be set at 7 ppm-hours or even below (EarthJustice).

In support of their views, these commenters in general rely on the entire body of evidence available for consideration in the 2008 review, including evidence assessed previously in the 1997 review, pointing to the information and analyses in the 2007 Staff Paper and the conclusions and recommendations of CASAC in asserting that the available science clearly shows that O_3-induced vegetation and ecosystem effects are occurring at and below levels that meet the 2008 8-hour standard, the 2008 standard does not adequately protect vegetation from an array of O_3-related effects, and appropriate protection can only be provided by going to the lower end of the proposed range.

A few of these commenters also provided additional exposure, risk and benefits information from localized assessments conducted by themselves or others on their behalf in support of their view

[44] With respect to comments that expressed support for a specific standard level without a specific rationale, this final notice and the 2011 Response to Significant Comments are EPA's response to those comments.

that the 2008 standard is not adequate. For example, NESCAUM, NY DEC, DOI/NPS and the AMC provided recent air quality analyses and supplemental information, including a list of O_3-sensitive species in specific national parks, to support their assertions that vegetation effects are being observed in areas with air quality that would meet the 2008 standard.

A third group of commenters, consisting mainly of some states and industry groups, such as MS DEQ, NC DENR/NC DAQ, NE DEQ, Western Sugar Cooperative, and Savannah River Nuclear Solutions, LLC, expressed strong support for not going below the upper end of the CASAC range of 15 ppm-hours for a variety of reasons, including: 1) CASAC believes this to be protective of the environment (NE DEQ); (2) the amount of uncertainty associated with this being EPA's first attempt at setting this type of secondary standard (Savannah River Nuclear Solutions, LLC); and (3) given the uncertainties in the current scientific studies, the upper end of the range would sufficiently protect public welfare (NC DENR/NC DAQ).

In addition to the groups of commenters that commented on specific levels within the proposed range, another group of commenters did not support reconsidering or changing the 2008 secondary standard at all, and thus, did not provide specific comments on any specific levels with the proposed range. Nonetheless, to the extent that their comments are relevant to the issue of the level of the standard, their comments are addressed here. This group, which includes industry and agricultural groups such as EEI, API, UARG, Exxon Mobil, NAHB, NCBA, AFBF, some states, Tribal Associations and local agencies, provided comments on the vegetation effects evidence, exposure and risk assessments, and their associated uncertainties that are relevant in informing the Administrator's judgments regarding the appropriate weight to place on the evidence, assessments, and associated uncertainties in selecting a level that is neither more or less than requisite to protect the public welfare.

The discussion of the comments that follows is organized around topics relating to the different types of information available to inform the Administrator's decision on level. These include information regarding the vegetation effects evidence, including evidence related to visible foliar injury, impaired tree growth, and agricultural crops, as well as the interpretation of that evidence in conjunction with the 1996 Consensus Workshop; the exposure and risk assessments; and information related to the adversity of effects.

i. Comments on Vegetation Effects Evidence

(a) Foliar injury evidence

Several commenters pointed directly to foliar injury evidence as an important part of the justification for their recommendations regarding level. Specifically, the NPS stated that "[w]idespread foliar injury has been documented in areas meeting the current standard; field and chamber studies indicate that O_3-induced significant growth reductions are also occurring at levels below the current standard….The Department agrees that the current standards are not protective of sensitive natural vegetation. Ozone injury…has been documented in several areas currently designated attainment, including Mammoth Cave National Park and Cumberland Gap National Historic Park. In addition, EPA's modeling indicates that trees in many areas currently designated attainment are experiencing significant growth losses at current ozone levels." This information provides the basis for the NPS recommendation that it "strongly recommends a value from 7-9 ppm-hours for the secondary standard to provide the best level of protection to sensitive vegetation in national parks and other protected areas." EarthJustice stated "Evidence cited by EPA itself in the reconsideration proposal, by the Staff Paper, and by the Park Service's 2007 comments show adverse welfare effects on vegetation from ozone levels as low as 7-ppm-hours – and even lower. See, e.g., 2007 Park Service Comments at 4 (foliar injury W126 as low as 4 ppm-hours); ….Because the record documents known or anticipated adverse ozone welfare

effects on vegetation at levels of 7 ppm-hours and below, EPA must set the standard at or below that level." Similarly, NESCAUM described observed ozone damage to forests in the NESCAUM region occurring at current ozone levels as the basis for its recommendation that a level selected from the lower end of the CASAC-recommended range would provide better protection in the NESCAUM region, and the AMC, urges that the more protective 7 ppm-hours level be selected in order to enable Federal Land Managers to protect the air quality related values (AQRVs) in our National Parks and Forests and Wilderness areas as they are mandated to do by Congress.

In contrast, a number of industry and state commenters raised concerns regarding the strength of the visible foliar injury information and EPA's reliance on it for standard setting. For example, Edison Electric Institute stated, "foliar damage is a prominent rationale for the Administrator's decision on proposing the level of the secondary ozone NAAQS, yet the 2008 Response to Comments document indicates that 'foliar injury data available at this time is *insufficient to specifically inform quantitative judgments regarding the selection of an appropriate standard* and should only be considered qualitatively.' (Emphasis added). Given the lack of data and deficiencies with respect to available data, the Administrator's decision with respect to the proposed level of the secondary ozone NAAQS is arbitrary and capricious." SD DENR also stated that "the uncertainties with establishing a point at which visible foliar injury becomes adverse to the public welfare and the lack of rural monitoring data make it difficult for DENR to support the Administrator's recommendation." Another commenter, the Louisiana Chemical Association and Louisiana Mid-Continent Oil and Gas Association, further challenged EPA's use of foliar injury data, claiming that information from another EPA report, the 2008 Report on the Environment (ROE), shows that "ozone levels even higher than the 2008 adopted standard are not harming agriculture, timberlands, or even sensitive forests." The commenter further asserted that "EPA needs to explain this to have a biologically plausible argument that it is ozone, and not some other

confounding factor, that is responsible for the observed foliar damage in the Eastern United States." Another commenter, Exxon Mobil, stated, "…field studies often fail to control for potential confounders, such as reduced soil moisture. EPA needs to take the impact of confounders into consideration."

In responding to the first group of commenters who placed a lot of weight on foliar injury information in recommending an appropriate level of a standard, EPA agrees that, when taken together with the other effects evidence, the entire body of vegetation and ecosystem effects information available in the 2008 review, including the visible foliar injury information, supports the need to set a new cumulative, seasonal standard to provide increased protection from the array of O_3-related effects on sensitive vegetation and ecosystems that would be allowed by the 2008 standard. In particular, EPA notes that the 2007 Staff Paper foliar injury analysis was based on an expanded database from the ambient field-based bio-monitoring network managed by the Unites States Forest Service (USFS) Forest Inventory and Analysis (FIA) Program. The Staff Paper presented maps from 2001 and 2002 providing county-level data regarding the presence or absence of O_3-related visible foliar injury. These maps demonstrated the widespread occurrence of visible foliar injury across the US. An analysis of the incidence of visible foliar injury at different levels of air quality in monitored counties showed that the percent of counties with some degree of documented foliar injury was appreciably reduced at a level approximately equivalent to the W126 index value of 13 ppm-hours, when compared to that of the higher level analyzed (approximate W126 of 21 ppm-hours) above the proposed range. Further analyses presented in the 2007 Staff Paper showed that in 2004 a total of 47 counties that were below a 4th highest daily maximum 8-hour average standard of 0.074 ppm still had reported visible foliar injury, indicating that visible injury to vegetation can still occur in many areas at levels below that of the 2008 secondary standard.

In responding to the second group of commenters, EPA first disagrees with the assertions of some in this group, that visible foliar injury evidence is the predominant rationale for the Agency's decision on level of the secondary standard. As described above, EPA is considering the entire body of vegetation effects evidence, as well as the results from the exposure and risk assessments to inform selection of a level within the proposed range. Second, EPA further disagrees that the 2007 Staff Paper assessment of the visible foliar injury data is contradicted by that included in the 2008 ROE. Indeed, the ROE shows that in 2002 at least 6 out of the 10 regions showed some level of foliar injury in the high and severe categories (a degree of foliar injury judged by the USFS as most likely to be associated with tree and ecosystem level response). This degree of high and severe foliar injury is important from a public welfare perspective and indicates that O_3 at this level is potentially harming vegetation, especially sensitive forests. Both documents show similar overall levels of foliar injury occurring in 2002 based on the same USFS FIA database.

In responding to comments by some in the second group of commenters that EPA has not taken into account the fact that the magnitude of observed visible foliar injury impacts can be confounded by other factors, i.e., low soil moisture in certain areas may result in less ozone induced foliar injury, EPA disagrees and points to the discussion in the 2007 Staff Paper (7-60/61) in which such confounders are described. EPA further notes that despite this potential for confounding, however, EPA's visible foliar injury assessment showed that a significant percentage of counties had foliar injury in each year across a four year period, even given year to year variations in meteorological conditions. Thus, there is evidence that this vegetation effect persists even with changing conditions.

EPA further disagrees with the comment by the Louisiana Chemical Company that the observed effects attributed to O_3 could instead be confounded with visible injury symptoms that could be caused by other stresses. EPA notes that the USFS FIA protocols are very specific to identify diagnostic of

foliar injury due to O_3 and very careful steps are taken to insure that observed injury is not due to other factors, and specific plant species are chosen to monitor that exhibit these diagnostic O_3 injuries. Some of the observed regional variation in injury is due to different plant species occurring across the U.S. Other factors, such as acid rain, do not create the diagnostic O_3 injury documented in the USFS surveys and do not account for the observed regional differences in injury.

Finally, with respect to the comment by the Louisiana Chemical Association and Louisiana Mid-Continent Oil and Gas Association that the 2008 ROE shows that "ozone levels even higher than the 2008 adopted standard are not harming agriculture, timberlands, or even sensitive forests," EPA disagrees that foliar injury information can be used as a surrogate for other important vegetation effects. The 2007 Staff Paper (pg. 7-61) states "It is important to note that direct links between O_3 induced visible foliar injury symptoms and other adverse effects (e.g., biomass loss) are not always found….[thus] it is not always a reliable indicator of damage or other injury endpoints. The lack of visible injury does not indicate a lack of phytotoxic concentrations of O_3 or a lack of non-visible O_3 effects." Indeed, the ROE also recognizes this limitation when it cites a number of cautions in using foliar injury as the overall indicator of forest health (see page 2-25 of the ROE, under the heading "Indicator Limitations") including:

- "Ozone may have other adverse impacts on plants (e.g., reduced productivity) that do not show signs of visible foliar injury (U.S. EPA, 2006)."
- "Though FIA has extensive spatial coverage based on a robust sample design, not all forested areas in the U.S. are monitored for ozone injury."
- "Even though the biosite data have been collected over multiple years, most biosites were not monitored over the entire period, so these data cannot provide more than a baseline for future trends."

In acknowledging that other O_3-induced effects can occur without foliar injury being present, the ROE implicitly recognizes that it is not appropriate to conclude that ozone levels are not harming vegetation based on visible foliar injury evidence alone.

In conclusion, EPA recognizes that the evidence of O_3-related growth effects and visible foliar injury does not provide a bright line clearly directing the choice of level for any of the effects of concern, and the choice of what is appropriate is clearly a public welfare policy judgment entrusted to the Administrator. However, EPA does conclude that the foliar injury data available at this time provides important information in combination with the entire body of evidence available in this review, useful in informing judgments regarding an appropriate level for a secondary standard.

(b) Tree Growth Effects Evidence

Some commenters pointed to tree growth effects evidence in support of their assertion that additional protection is needed beyond that provided by the 2008 standard. For example, NESCAUM stated "[s]cientific research shows that long-term, cumulative exposure to ozone reduces forest productivity. Estimates of seasonal reductions in stem growth for many important eastern US tree species exceeded 30% in recent average ozone years (2001, 2003), with additional growth decrements of 50% in a high ozone year (2002)." This commenter cited several studies, some published after the 2006 CD as the basis for these statements.

In contrast, a number of commenters asserted that the evidence on trees is still too limited and uncertain to use as a basis for concluding adverse effects on trees would occur at air quality levels below that of the 2008 standard. For example, Exxon Mobil asserted that key studies (e.g., King et al., 2005; Gregg et al., 2003; Karnosky, et al., 1999; and Isebrand, et al., 2001) cited by EPA as showing O_3 effects on seedlings, saplings and mature trees, while providing additional support for O_3-related

impacts on vegetation in field settings without chambers, do not provide support for the conclusion that ambient levels in compliance with the 2008 standard would result in significant O_3 impact.

EPA agrees with the first set of commenters and notes that recent research published after the 1997 review on trees growing in the field in combination with recent exposure and risk assessment results that continue to use OTC-derived C-R functions available during the 1997 review, has further strengthened the body of evidence demonstrating that O_3-induced effects on trees growing in the field would still be allowed by the 2008 standard.

In considering evidence of O_3-related growth effects in such tree species, which is one of the most studied effects, EPA notes that many of these species were included in a series of OTC studies conducted by EPA Office of Research and Development's National Health and Environmental Effects Research Laboratory-Western Ecology Division (NHEERL-WED), available in the 1997 review, that analyzed relative biomass loss in seedlings at various O_3 exposure levels in terms of a 12-hour W126 index. In considering evidence of growth effects newly available in the 2008 review, EPA observes that the newly available evidence strengthens the information available in the 1997 review and reduces remaining uncertainties. Such newly available information includes quantitative information for a broader array of growth effects (extending to sapling and mature tree growth stages) obtained using a more diverse set of field-based research study designs. As discussed in the 2010 proposal (75 FR 3003), these new studies provide compelling and important support for the continued use of the concentration-response functions developed in open-top chamber studies to estimate risk to these tree seedlings under ambient field exposure conditions.

In contrast, EPA disagrees with the assertion made by the second group of commenters that key studies relied upon by EPA to show effects on trees in the field do not provide evidence of vegetation effects below the current standard. In particular, evidence such as the Gregg et al. (2003) tree seedling

biomass loss gradient study show effects on a sensitive tree species occurring in the field across a range of exposure levels including levels of air quality allowed by the 2008 secondary standard. EPA further notes that with regard to the other key field-based studies from the AspenFACE site identified above, the commenter is mistaken in its assertion that EPA is claiming that these studies, in and of themselves, demonstrate support for concluding that adverse O_3-induced impacts on vegetation would occur at air quality levels that meet or are below the 2008 standard. Rather, the 2007 Staff Paper concludes that the combined evidence from the AspenFACE and Gregg et al. (2003) field studies provides compelling and important support for the appropriateness of continued use of the C-R functions derived using OTC from the NHEERL-WED studies to estimate risk to these tree seedlings under ambient field exposure conditions. These field studies make a significant contribution to the coherence in the weight of evidence available in the 2008 review and provide additional evidence that O_3-induced effects observed in chambers also occur in the field. Thus, the current body of evidence increases EPA's confidence in applying the concentration-response functions for tree seedlings obtained from OTC studies which continue to predict O_3-induced biomass loss on very sensitive tree species (e.g., cottonwood, black cherry and aspen) would be expected to occur at air quality levels allowed under the current standard, that additional protection is needed to protect sensitive tree species from such growth effects.

EPA further notes that based on 2009 air quality data, many areas that had air quality that would meet the level of the current 8-hour average secondary standard of 0.075 ppm in 2009 had annual W126 exposures well above the upper end of the recommended CASAC range of 15 ppm-hours. Over 100 counties that attained the current secondary standard had annual W126 levels above 15 ppm–hours. Thirty-one of these areas had annual W126 levels above 20 ppm-hours. Clearly sensitive vegetation in these counties would not be protected from substantial annual effects of cumulative O_3 exposure on growth and foliar injury that would be expected to occur at these levels (Herrick, 2011).

(c) Agricultural Commodity Crop Data

A number of commenters discussed ozone impacts on agricultural crops. One group of commenters continued to suggest a need for additional protection from ozone for agricultural crops. In particular, PA DEP stated "The DEP also supports EPA's proposal to set a secondary specifically on protection of forests, crops, and other environmental resources, such as ecosystems….[a]griculture, silviculture, …are important economic and quality of life assets for the citizens of the Commonwealth and the country….The DEP noted that the proposal has based most of its determinations on trees, plants and crops…" [s]imilarly, NY DEC stated that "[t]he Department also agrees with EPA that the secondary standard should be based on a biologically relevant cumulative ozone exposure index that protects our forests, vegetation and crops….[a]dequate protection of New York's agriculture is also essential for our public welfare and economy."

In contrast, other commenters asserted that there was no need for additional protection for agricultural commodity crops. For example, with regard to the uncertainties associated with using the OTC exposure-response functions, NAHB states in its comments on the 2010 proposal that "the same concentration-response functions from the OTC studies of the 1980's are still the only viable data to use to estimate crop loss …. The 1996 CASAC Panel agreed that the estimates of crop loss at that time were highly uncertain." Likewise, The National Cattleman's Beef Association comments pointed to a number of uncertainties and limitations in the crop analysis, including (1) use of out-of-date C-R functions; (2) extrapolation from univariate OTC studies to the real world; and (3) limited rural monitoring that calls into question the predicted estimates of crop loss at various levels of air quality. Most notably, however, NCBA further claimed that no additional protection for crops is needed, stating "yields for all the major crops in fact have been increasing over the past decade- not suffering 50 percent of greater yield loss as the chamber studies predict. The EPA purports to base the need for the standard

on crop yield losses, however, the United States has had record-breaking yields almost every year since reporting yields began in the 1800s. Additionally, the USDA projects large yield increases into the future….and there is evidence that some researchers are on the path to discovering the genetic instructions to help other species of plants decrease intake of ozone".

EPA disagrees with both sets of commenters that the new standard is intended to provide protection against adverse effects on agricultural commodity crops. As EPA has explicitly stated in the 2010 proposed rule (75 FR 3024), that while "the maintenance of adequate agricultural crop yields is extremely important to the public welfare…" it "is currently achieved through the application of intensive management practices, including in some cases, genetic engineering….Thus,…information from this sector on O_3-induced effects is considered less useful in informing judgments on what level(s) would be sufficient but not more than necessary to protect the public welfare." In addition, EPA agrees that important uncertainties continue to be associated with the use of the C-R functions generated many years ago using OTC studies for crop yield loss.

(d) Interpretation of Effects Evidence – 1996 Consensus Workshop Findings

A number of comments were received regarding the appropriateness of EPA's consideration of the 1996 Consensus Workshop's recommendations regarding the selection of different ranges of levels to protect against a variety of O_3-induced effects. In this regard, some commenters supported consideration by EPA of the range of levels identified in the 1997 Consensus Workshop Report. For instance, the NPS stated "[i]n its 2007 Staff Paper, the EPA noted that appropriate W126 ranges have been identified for various vegetation effects endpoints, and that these ranges could be used to inform a standard. The Wl26 ranges include 13-17 ppm-hours for crops, 7-13 ppm-hours for growth effects to tree seedlings in natural forest stands, and 5-9 ppm-hours for visible foliar injury to natural ecosystems."

The contrasting view, expressed by several commenters, highlights a number of concerns regarding the scientific rigor and transparency associated with the Workshop proceedings and results. For example, AAM stated that "[i]f the workshop recommendations are to be used for standard setting, then the studies underlying their basis, as well as the method for reaching the recommended values, should be stated in more detail than in the cited workshop summary. The basis for establishing a standard should be transparent and reproducible." More specifically, Exxon Mobil stated "this workshop was by invitation only, and documentation is not available to the public. The reference cited is short and provides consensus recommendations, but without details as to their basis…. If available, a more detailed report of the consensus workshop should be released. If studies to support the recommendations cannot be provided, then the recommendations should be used with great caution."

EPA agrees with the first group of commenters that important weight should be placed on the expert recommendations that came from the 1996 Consensus Workshop. In this regard, EPA notes that in considering the recommendations from the 1996 Consensus Workshop, the 2007 Staff Paper considered to what extent research published after 1997 provided empirical support for the ranges of levels identified by the experts as protective of different types of O_3-induced effects. In view of the empirical evidence available in the 2008 review, EPA reached a similar view with regard to a range of levels appropriate to provide protection across the broad array of vegetation effects, with the exception of the upper end of the recommended range, which in the 2007 Staff Paper was based on effects on commercial crops that had been considered in the 1997 review.

Further, while EPA agrees with the second group of commenters that the 1997 Consensus Report does not clearly document the specific research upon which the consensus statements and recommendations published therein are based and that the absence of such documentation calls for care in placing weight on such recommendations, EPA does not agree that these recommendations were

without support or basis. In particular, EPA notes that the Workshop participants were asked to review both the 1996 O_3 Criteria Document and Staff Paper, representing the most up-to-date compilation of the state of the science available at that time, in order to ensure that their expert judgments made were also informed by the latest science. EPA further notes that another group of experts, the CASAC O_3 Panel, reached a similar consensus based upon a independent review of the expanded body of scientific evidence available in the 2008 review, and that the recommendations made by CASAC and EPA staff regarding an appropriate range of levels for the Administrator to consider and the information upon which they were based, were clearly documented and repeatedly vetted through a transparent and public review process.

Thus, EPA concludes that the fact that these publically examined and peer-reviewed conclusions are generally consistent with the 1996 Consensus Workshop recommendations suggests that the science in this regard is being consistently interpreted by a large number of scientists. EPA further concludes that these consensus views should be given weight in reaching decisions on the level of the standard.

ii. Comments on the Vegetation Exposure and Risk Assessments

Comments regarding the vegetation exposure and risk assessments, and the conclusions that can appropriately be drawn from them, primarily came from commenters who expressed the view that no change to the 2008 standard was appropriate.

This group of commenters, which included industry and agricultural groups such as Exxon Mobil, UARG, API, EEI, National Cattleman's Beef Association, American Farm Bureau Federation, and individual States and other organizations representing local energy or business interests, expressed the view that the limited number of studies published since the 1997 review and addressed in the 2006 Criteria Document do not materially reduce the uncertainties that were present and cited by the Administrator in both the 1997 and 2008 reviews as important factors in her/his decision to set the

secondary identical to the revised primary and therefore provide insufficient evidence to support the conclusion that additional protection for vegetation and ecosystems is needed.

This group of commenters expressed a number of concerns with these assessments which generally focused on: (1) the method used by EPA to estimate PRB, (2) EPA's rollback methodology; (3) limitations and uncertainties associated with the exposure and risk assessments. These comments are addressed below.

(1) With respect to PRB, commenters asserted that that EPA used unrealistically low levels of PRB that resulted in an overestimate of risks and benefits associated with just meeting alternative standards. In particular, NCBA stated "the same underestimates of natural background ozone levels and failure to adequately consider extremes of background that were discussed above with respect to the primary standard lead to overestimates of the improvements in vegetative growth that may result from reducing the secondary standard. In fact, the proposed secondary standard may be within the range of uncontrollable background and thus not produce the benefits claimed."

With respect to PRB, EPA notes that this issue has been raised repeatedly throughout the review in the context of both the primary and secondary standards. EPA strongly disagrees with the view that EPA's estimates of PRB are too low for the reasons discussed above in section II.C.2, which addresses this and other comments related to EPA's approach to estimating PRB and its role in exposure and risk assessments related to the primary standard. EPA further notes that some commenters explicitly expressed support for EPA's estimates of PRB.

(2) With respect to concerns raised regarding the method used by EPA to adjust modeled air quality to reflect attainment of various alternative standards, one commenter, NCBA, stated that the approach used by EPA, i.e., the quadratic rollback approach, for estimating the air quality that would

result from just attaining the proposed standard is problematic. In making this assertion, this commenter referenced its earlier comments on the primary standard in this regard.

EPA again concludes, as noted above in section II.B.2.b, based on information in the 2007 Staff Paper (section 4.5.6) and in more detail in a staff memorandum (Rizzo, 2006), that the quadratic air quality adjustment approach used in this assessment generally best represented the pattern of reductions across the O_3 air quality distribution observed over the last decade in areas implementing control programs designed to attain the O_3 NAAQS. While EPA recognizes that future changes in air quality distributions are area-specific, and will be affected by whatever specific control strategies are implemented in the future to attain a revised NAAQS, there is no empirical evidence to suggest that future reductions in ambient O_3 will be significantly different from past reductions with respect to impacting the overall shape of the O_3 distribution.

(3) With regard to EPA's exposure and risk assessments, commenters asserted that the uncertainties associated with these assessments from a variety of sources make it inappropriate for the Administrator to rely on it in selecting a level of a standard. For example, a number of commenters cited limitations in the O_3 monitoring network, especially in rural areas, as making the results of the exposure and risk assessments too uncertain to usefully inform the Administrator's judgments. In particular, NCBA stated that as a result of the limitations in the monitoring network, "there is insufficient data to validate or judge the model predictions. EPA has not accounted for these differences in rural and urban ozone exposure. The proposal relies too heavily on modeling effects in rural areas based on data from urban areas. … EPA confirms that monitoring ozone exposure in rural areas remains problematic."

In addition, other commenters (UARG, AAM, NAM, Dow, Southern Company, and Duke Energy) asserted that there is a lack of any new information that would materially reduce the

uncertainties present in the exposure, risk and benefits assessments conducted for the 1997 review and thus, the estimated exposures and risks associated with air quality just meeting the current standard have not appreciably changed since the 1997 review. For example, Dow stated "[t]here is little in the new data that reduces the uncertainty noted in the 1996/1997 review. Because of the lack of new data or substantive improvements in risk assessment, many of these same uncertainties exist today." UARG further stated that "the record provides no evidence to support concerns about effects of ozone on vegetation that were not considered in setting the 0.08 ppm 8-hour secondary NAAQS, and that new science had not been developed since that time to change what is known quantitatively about ozone effects on vegetation. Thus, it is not surprising that the record did not (and does not) demonstrate that any risk posed to vegetation by ozone is known to be greater than in 1997 or that a revised NAAQS was, or is now, appropriate."

EPA agrees that there continue to be important uncertainties associated with its exposure and risk assessments of tree seedling biomass and crop yield losses, including those associated with limitations in the extent of the rural monitoring network, especially in the western US. However, EPA notes that there has been an increase in the amount of rural monitors and advancements in the tools and methods used for such extrapolations since the 1997 review. In this review, EPA's CASTNET monitoring was used in the assessment which added approximately 80 more rural monitors to the 2007 risk assessment than the 1996 assessment. With respect to the generation of interpolated O_3 exposure surfaces, EPA employed a different approach than that used in the 1997 review and undertook a quantitative assessment of the uncertainties associated with the use of this method. As discussed in the Staff Paper, EPA concludes that this method represents a notable improvement over the 1996 assessment and that, in general, the sources and likely direction of uncertainties associated with the exposure and risk assessments have been better accounted for and characterized than in the 1997 review.

In conclusion, as noted above, EPA strongly disagrees with the commenters' assertion that the currently available evidence has not materially reduced key uncertainties present in the 1997 review that factored into the Administrator's decision. EPA further believes that this claim is fundamentally flawed for the following reasons. First, it is inappropriate to compare quantitative vegetation risks estimated in the last review with those estimated in the current review. The 1997 risk estimates, or any comparison of the 1997 risks estimates to the current estimates, are irrelevant for the purpose of judging the adequacy of the current standard, as the 1997 estimates reflect outdated analyses and air quality data that have been updated in this review to reflect the current science and as there have been significant improvements to the modeling approaches and model inputs. Second, it is important to take into account EPA's increased confidence in some of the model inputs, as discussed above, since in judging the weight to place on quantitative risk estimates it is important to examine not only the magnitude of the estimated risks but also the degree of confidence in those estimates.

iii. Adversity of Effects

Some commenters questioned the Administrator's approach to making judgments as to what constitutes "adverse" effects. Edison Electric Institute stated "[t]he preamble to this rulemaking indicates that an "adverse" welfare effect can be considered within a 'broader paradigm'….The Administrator, without apparent reference to this paradigm, otherwise concludes that, of the known effects of ozone on the public welfare, the 'highest priority and significance should be given to those that occur on sensitive species that are known or likely to occur in federally protected areas such as Class I areas…'. The preamble then prominently discusses a study on cottonwood trees and a U.S. Forest Service program to assess visible foliar injury. Altogether, the preamble discussion of adversity and how this adversity was determined by the Administrator …in proposing a NAAQS level…is almost wholly lacking in detail."

Similar comments are provided by the BCCA Appeals Group which stated "Although the Administrator proposes to focus the NAAQS with respect to trees and ecosystems…the preamble does not detail how the Administrator has decided that the overall effect on trees and ecosystems is "adverse", nor is a specific quantification of this adversity attempted. Instead, the preamble …largely cites anecdotal information, such as a study of cottonwood trees in New York, as supporting the Administrator's generalized assessment that adversity exists broadly as to trees and various undefined ecosystems."

First, EPA disagrees that the discussion of adversity is lacking in detail. EPA explicitly explains how it is defining adversity (75 FR at page 3006). In particular it notes "that the statute requires that a secondary standard be protective against ''adverse'' O_3 effects, not all identifiable O_3-induced effects." EPA then identifies what types of effects have traditionally been considered adverse i.e., in particular those effects that have been classified as "damage" have been defined to include those injury effects that reach sufficient magnitude as to also reduce or impair the intended use or value of the plant. However, the Administrator further noted that "a more recent construct for assessing risks to forests described in Hogsett *et al.* (1997) suggests that 'adverse effects could be classified into one or more of the following categories: (1) economic production, (2) ecological structure, (3) genetic resources, and (4) cultural values'" and that "…[a]nother recent publication, *A Framework for Assessing and Reporting on Ecological Condition: An SAB report* (Young and Sanzone, 2002), provides additional support for expanding the consideration of adversity beyond the species level by making explicit the linkages between stress-related effects (*e.g.*, O_3 exposure) at the species level and at higher levels within an ecosystem hierarchy." Taking this recent literature into account, the 2007 Staff Paper concluded that a determination of what constitutes an adverse welfare effect in the context of the secondary NAAQS review can appropriately occur within this broader paradigm. In the context of this rulemaking, the

Administrator again concludes that it is appropriate, given the improved understanding of the linkages between the individual species level impacts and those at the ecosystem level, that adverse impacts at the species level be viewed, not in isolation, but in the context of known or anticipated effects to ecosystems as a whole. Thus, this broader paradigm expands the context for evaluating the adversity of O_3–related effects beyond the species level to that of ecosystems.

In applying this broader construct, EPA states in the 2010 proposal that "In determining the nature and degree of effects of O_3 on the public welfare, the Administrator recognizes that the significance to the public welfare of O_3- induced effects on sensitive vegetation growing within the U.S. can vary, depending on the nature of the effect, the intended use of the sensitive plants or ecosystems, and the types of environments in which the sensitive vegetation and ecosystems are located. Any given O_3-related effect on vegetation and ecosystems (*e.g.,* biomass loss, foliar injury), therefore, may be judged to have a different degree of impact on the public depending, for example, on whether that effect occurs in a Class I area, a city park, or commercial cropland. In her judgment, it is appropriate that this variation in the significance of O_3-related vegetation effects should be taken into consideration in judging the level of ambient O_3 that is requisite to protect the public welfare from any known or anticipated adverse effects" (75 FR at 3023/24)." The 2010 proposal then describes the evidence the Administrator considered in selecting the upper and lower ends of the proposed range. As noted in the 2010 proposal, the Staff Paper concluded that several lines of evidence pointed to the need for greater protection for tree seedlings, mature trees and forested ecosystems. Staff believed that tree growth was an important endpoint to consider because it is related to other aspects of societal welfare such as sustainable production … Impacts on tree growth can also affect ecosystems through shifts in species composition and the loss of genetic diversity …." (75 FR at 3022). Building on the above, in the 2010 proposal EPA "finds that the types of information most useful in informing the selection of an

appropriate range of protective levels is appropriately focused on information regarding exposures and responses of sensitive trees and other native species known or anticipated to occur in protected areas such as Class I areas or on lands set aside by States, Tribes and public interest groups…." (75 FR at 3024).

Thus, EPA disagrees, based on the discussion of the Administrator's rationale in reaching conclusions on the appropriate range of levels to propose in the 2010 proposal (75 FR at 3023 to 3026), that it has not provided a detailed explanation of what the Administrator took into account in proposing a range for a secondary NAAQS that would provide appropriate protection from adverse effects on the public welfare.

EPA further notes that support for use of this broader construct in defining adversity is provided by several commenters which assert that in considering the need for additional protection, the Administrator should take into account effects on ecosystems. Many of these commenters cited "new" studies that were published after the 2006 CD. For example, EarthJustice stated "[t]he record for the 2008 standard shows that ozone has significant adverse impacts on vegetation and forested ecosystems, including impairment of growth in trees, tree biomass loss, foliar injury, and associated ecosystem disruption." Similarly, the AMC stated "[w]e reiterate from our past comments that EPA should closely consider studies (McLaughlin et al., 2007 a and b; Grulke et al., 2004) showing that cumulative ozone exposure reduces stomatal control, amplifies water loss, and reduces tree growth…. McLaughlin et al., (2007b) shows evidence that ecosystem wide impacts occur from cumulative ozone exposures detecting a reduction in late season stream flows from a forested watershed." NY DEC stated "[r]ecent studies indicate that ozone alters the carbon source-sink balance in plants and ozone can significantly increase water use by forest trees, thereby amplifying the effects of drought and impacting stress resistance (Andersen, 2003; Matyssek et al., 2006; McLaughlin et al., 2007)."

As noted above, EPA agrees that consideration of known and anticipated adverse effects of ozone on ecosystems is appropriate. EPA further notes that it is relying on the information available in the 2008 review and will consider relevant "new" studies in the next review.

c. Conclusions on Level

As a result of the reconsideration, for the reasons discussed below, the Administrator has decided to set the level of a new cumulative, seasonal secondary O_3 standard at a level of 13 ppm-hours, in conjunction with the specific 3-month W126 form, averaged over three years.

Having carefully considered the public comments on the appropriate level of the secondary O_3 standard, as discussed above, the Administrator concludes that the fundamental scientific conclusions on the effects of O_3 reached in the 2006 Criteria Document and 2007 Staff Paper, summarized above in section IV.A and discussed more fully in sections IV.A-C of the 2010 proposal, remain valid. In considering the level at which a cumulative, seasonal secondary O_3 standard, with the specific W126 form and averaging times discussed above, should be set, the Administrator continues to place weight on both the expanded body of scientific evidence available in the 2008 review on the vegetation effects associated with O_3 exposure and on the results of vegetation exposure and risk assessments as providing information in support of her decision. In considering the available scientific evidence and assessment results, and the uncertainties associated with that information, the views of CASAC, and public comments, she judges that, as at the time of the proposal, a focus on the proposed range of 7 to 15 ppm-hours is appropriate.

In reaching a decision as to what level within the proposed range is requisite to protect the public welfare, the Administrator first recognizes that while the secondary standard is to be set at a level requisite to protect the public welfare from any known and anticipated adverse effects, the secondary standard is also not intended to be a zero risk standard. Thus, the Administrator recognizes that it

important to appropriately weigh not only the large body of evidence of O_3-related vegetation effects and results of exposure and risk assessments, but also the significant uncertainties that remain in characterizing or quantifying the degree of risk attributable to varying levels of O_3 exposure and the degree of protection that any specific cumulative, seasonal standard would afford in determining the standard that will provide a requisite degree of protection – i.e., sufficient but not more than necessary.

In selecting a level for a cumulative, seasonal standard from within the proposed range, the Administrator has given careful consideration to the nature and degree of O_3-related effects on sensitive natural vegetation and ecosystems; the strengths and limitations in that evidence and its usefulness in informing selection of a standard level; CASAC's views regarding the strength of the evidence and its adequacy to inform selection of a standard level; and the views expressed in public comments on the 2010 proposal.

In considering the nature and degree of O_3-related effects on the public welfare, the Administrator continues to recognize that the significance of O_3-related effects on sensitive vegetation growing in the U.S. can vary, depending on the nature of the effect, the intended use of the sensitive plants or ecosystems, and the types of environments in which the sensitive vegetation and ecosystems are located. Any given O_3-related effect on vegetation and ecosystems (e.g., impairment of growth, visible foliar injury, increased susceptibility to disease and insects, reduced ecosystem services and carbon sequestration), therefore, may be judged to have a different degree of impact on public welfare depending, for example, on whether that effect occurs in a Class I area or a city park, or on commercial cropland.

In considering this variation in the significance of O_3-related vegetation effects, the Administrator continues to conclude that the highest priority should be given to those effects that occur on sensitive species that are known to or are likely to occur in federally protected areas such as Class I

areas[45] or on lands set aside by States, Tribes and public interest groups to provide similar benefits to the public welfare, including both for residents on those lands, as well as visitors to those areas. This priority focuses the public welfare benefits of the secondary O_3 standard on cultural values related to the use and enjoyment of such areas by current and future generations. It also serves to focus on benefits related to the protection of ecological services provided by natural forested ecosystems in such areas.

With regard to O_3-related effects on agricultural crops, the Administrator continues to conclude there is no need for additional protection against such effects for agricultural crops through the NAAQS. In reaching this conclusion, the Administrator again notes that the maintenance of adequate agricultural crop yields is extremely important to the public welfare and is currently achieved through the application of intensive management practices, including in some cases, genetic engineering. These management practices, in conjunction with market forces and government programs, assure an appropriate balance is reached between costs of production and market availability. Thus, while research on agricultural crop species remains useful in illuminating mechanisms of action and physiological processes, information from this sector on O_3-induced effects is considered less useful in informing judgments on what standard level would be sufficient but not more than necessary to protect public welfare.

With regard to O_3-related effects on sensitive vegetation such as ornamentals used in urban/suburban landscaping that occur in areas that have not been afforded special Federal protections, the Administrator continues to conclude that there is not adequate information to establish a secondary standard based specifically on impairment of such vegetation. Nonetheless, she notes that a secondary

[45] For example, the level of protection granted by Congress under the Wilderness Act of 1964 for designated "wilderness areas" requires that these areas "shall be administered for the use and enjoyment of the American people in such manner as will leave them unimpaired for future use as wilderness, and so as to provide for the protection of these areas, the preservation of their wilderness character" (The Wilderness Act, 1964).

standard which provides protection for sensitive natural vegetation and ecosystems would likely also provide some degree of protection for such ornamental vegetation.

Thus, the Administrator finds that the type of information most useful in informing the selection of an appropriate level is information that focuses on exposures and responses of sensitive trees and other native species known or anticipated to occur in protected areas such as Class I areas or on lands set aside by States, Tribes and public interest groups to provide similar benefits to the public welfare. In considering such information, she notes that a large number of O_3-sensitive tree species are prevalent in state and national parks and forested ecosystems across the U.S. These species include many ecologically and commercially important species such as cottonwood, black cherry, quaking aspen, red maple, yellow poplar, and white pine in eastern forests; white ash, black cherry, birch, and quaking aspen in midwestern forests; and ponderosa pine in western forests.

In considering evidence of O_3-related growth effects in such tree species, which is one of the most studied effects, the Administrator recognizes that many of these species were included in open-top chamber studies, available in the 1997 review, that analyzed relative biomass loss in seedlings at various O_3 exposure levels in terms of a 12-hour W126 index. In considering all tree species studied, as discussed in the 2007 Staff Paper, this analysis predicted, for example, that for a W126 annual standard at a level of 13 ppm-hours, 75% of the species would be protected from biomass losses of no more than 7% per year. This analysis also showed appreciable variability across species in their relative sensitivity to O_3 exposures.

In considering evidence of growth effects newly available in the 2008 review, the Administrator recognizes that the newly available evidence strengthens the information available in the 1997 review and reduces remaining uncertainties. Such newly available information includes quantitative information for a broader array of growth effects (extending to sapling and mature tree growth stages)

obtained using a more diverse set of field-based research study designs and improved analytical methods for assessing O_3-related exposures and risks. Taken together, this information increases the Administrator's confidence in setting a new cumulative, seasonal standard. As discussed in the 2010 proposal (75 FR 3003), these new studies provide compelling and important support for the continued use of the concentration-response functions developed in open-top chamber studies to estimate risk to these tree seedlings under ambient field exposure conditions.

The Administrator also notes the evidence related to the O_3-induced effect of visible foliar injury, which includes an expanded database from the ambient field-based bio-monitoring network managed by the Unites States Forest Service (USFS) Forest Inventory and Analysis (FIA) Program. An analysis of the incidence of visible foliar injury at different levels of air quality in monitored counties showed that the percent of counties with some degree of documented foliar injury was appreciably reduced at a level approximately equivalent to an annual W126 index value of 13 ppm-hours, ranging from an annual incidence of 12 to 35%, relative to higher levels analyzed above the proposed range. The Administrator concludes that it is likely that some sensitive species occurring in specially protected areas would also exhibit visible foliar injury symptoms to a similar degree at these exposure levels. She further notes that while direct links between O_3 induced visible foliar injury symptoms and other effects (e.g., biomass loss) are not always found, visible foliar injury in itself is considered by the National Park Service (NPS) to affect adversely air quality related values (AQRV) in Class I areas.

At the same time, the Administrator recognizes that the evidence of O_3-related growth effects and visible foliar injury does not provide a bright line clearly directing the choice of level for any of the effects of concern. Thus, the choice of what is appropriate is clearly a public welfare policy judgment entrusted to the Administrator.

In considering the results of EPA's quantitative exposure and risk assessments, as discussed in section IV.C of the 2010 proposal, the Administrator concludes that important benefits would likely result from setting an annual W126 standard within the proposed range of levels. In particular, for a standard level of 13 ppm-hours, which was the only level in the proposed range evaluated in the assessments, important benefits were estimated in terms of a reduction in O_3-related growth losses in sensitive tree seedlings (including black cherry, Ponderosa pine, and quaking aspen) and mature trees and less wide-spread visible foliar injury. In considering this information, the Administrator first notes that these assessments are based on an annual standard, such that for some years somewhat less protection and for other years somewhat more protection would be afforded by a standard set at this level but averaged over three years. The Administrator recognizes that growth effects and visible foliar injury can still occur in sensitive species at lower levels, while also recognizing that significant uncertainties remain regarding the quantitative estimation of risks of these effects, as well as uncertainties associated with monitoring ambient exposures, including the limited ambient monitoring data currently available in rural areas. The Administrator continues to conclude that such remaining uncertainties, while reduced from the 1997 review, together with the substantial variability in sensitivity and responses across O_3-sensitive plant species, make it difficult to judge the exposure levels at which visible foliar injury and growth effects become adverse to the public welfare in various types of specially protected areas. Further, these uncertainties and the substantial variability in sensitivities and responses also make it difficult to judge the level of a standard that would afford protection from such exposure levels.

In considering and placing significant weight on the views of CASAC, the Administrator notes that the CASAC Panel clearly did not support consideration of a standard level as high as 21 ppm-hours, but did however recommend consideration of a range of levels no higher than 15 ppm-hours and as low

as 7 ppm-hours for an annual standard. She notes that in making this recommendation, the CASAC Panel had considered the entire body of evidence presented in the 2006 Criteria Document and the 2007 Staff Paper, and that CASAC's recommendation is generally consistent with the 1996 Consensus Workshop recommendations (Heck and Cowling, 1997).

The Administrator further notes that the comments received on the proposal, discussed above, were widely divergent with regard to an appropriate standard level. Of those commenters who supported setting a new cumulative, seasonal standard, some generally supported a level from the mid- to lower end of the proposed range, others supported a level at the upper end of the proposed range, while others simply supported a level within the proposed range, with many placing great emphasis on the CASAC Panel's recommended range. Those who did not support reconsidering or changing the 2008 standard at all focused strongly on the many uncertainties and limitations in the currently available evidence and assessments, and in uncertainties related to reaching policy judgments as to the degree of O_3-related impacts on vegetation that is important from a public welfare perspective. In considering these comments, the Administrator concludes that they reinforce her views that it is both necessary and appropriate to set a new cumulative, seasonal standard within the proposed range of levels, and that it is important to balance the weight of the evidence and assessments that show important benefits to public welfare from a standard set at a level within the proposed range with the significant remaining uncertainties in selecting the level of such a standard.

After carefully taking all the above considerations into account, the Administrator has decided to set the level of a new cumulative, seasonal standard at 13 ppm-hours, in conjunction with the specific 3-month W126 form, averaged over three years. In reaching this decision, the Administrator places significant weight on the importance of setting a standard with a biologically relevant and stable form, as discussed above in sections IV.C.1 and IV.C.2, that would focus protection on sensitive natural

vegetation and ecosystems that are known to or are likely to occur in federally protected areas such as Class I areas or on lands set aside by States, Tribes and public interest groups to provide similar benefits to the public welfare. While finding the evidence compelling that such a standard is necessary to protect public welfare from known or anticipated adverse effects, she finds that there are important remaining uncertainties that also need to be given significant weight so that the standard is sufficient but not more than necessary for that purpose, especially in conjunction with moving to a new cumulative, seasonal form of a standard. She also places significant weight on the views of CASAC, and takes into consideration the broad range of views expressed in public comments.

Based on the above considerations, the Administrator first focused on a level of 15 ppm-hours, the upper end of both the proposed range and the range recommended by CASAC for an annual standard. The Administrator concludes that a level of 15 ppm-hours, from an annual perspective, is consistent with placing significant weight on the important uncertainties that remain, including those related to quantifying the exposure levels that are likely associated with adverse effects across the large number of O_3-sensitive tree species that are prevalent in state and national parks and forested ecosystems across the U.S., especially considering that sensitivity to O_3 is highly variable across species. As discussed above, these uncertainties are in part related to the very limited O_3 monitoring data that are currently available in such areas. These uncertainties are also related to the challenges associated with determining the extent to which O_3-related effects should reasonably be judged to be adverse to public welfare, including impaired growth, the aesthetic impacts of visible foliar injury, and more subtle effects such as increased susceptibility to disease and insects, as well as ecosystem level effects such as potential changes in biodiversity, impacts on water availability in watersheds, and reduced carbon sequestration. The Administrator judges that it is appropriate to give significant weight to these uncertainties. In so doing, the Administrator concludes that the evidence and assessments support

significantly limiting the number of years with levels above 15 ppm-hours, and also suggest the potential for benefits to public welfare from having years below this level.

From the perspective of a 3-year average standard, however, a level of 15 ppm-hours would allow a large number of years to be above 15 ppm-hours, when averaged with other years below this level. Thus, in setting a standard that would significantly limit the number of years above 15 ppm-hours, the Administrator further considered a somewhat lower standard level that would be appropriate in conjunction with a standard defined in terms of a 3-year average rather than an annual W126 index value. Consideration of a lower standard level in conjunction with a 3-year average is consistent with CASAC's recommendation that if multi-year averaging is used, the level of the standard should be lower than if the standard is defined in terms of an annual index value to assure that the desired annual level is not exceeded in individual years. Based on recent air quality data, the Administrator recognizes that a 3-year average standard set at 13 ppm-hours would likely provide protection in a large majority of currently monitored areas from exceeding a level of 15 ppm-hours in any one year.[46] Based on the currently available evidence, assessments, and related uncertainties, as discussed above, the Administrator has a high degree of confidence that such a standard set at a level of 13 ppm-hours would afford increased and appropriate protection compared to the 2008 standard based both on the level chosen and the use of a form that is a biologically relevant index of O_3 exposure.

The Administrator has also considered levels in the mid- to lower part of the proposed range, from below 13 down to 7 ppm-hours. In considering the evidence of effects within this lower range of levels, the Administrator recognizes that while there is evidence that O_3-related visible foliar injury can occur at such lower levels, it is particularly challenging to judge the extent to which such effects should be considered adverse to public welfare. She also recognizes that while there is a field-based study that

[46] This observation is based on an analysis of recent air quality data (2007 to 2009) that compares 3-year average and 1-year values of the W126 index (Mintz, 2010).

shows O_3-related impaired growth in the field in one very sensitive tree species at such low levels (Gregg et al., 2003), this evidence is available for only one species from only one study, such that it has not been replicated by other investigators in other studies. She also recognizes that relatively recent free-air exposure studies, designed to evaluate tree growth effects beyond the seedling stage, also provide qualitative support for the concentration-response relationships developed in earlier open-top chamber studies for tree seedlings, but do not provide new quantitative concentration-response relationships for larger trees growing in the field that would help inform consideration of a standard level within this lower range. In considering this evidence, the Administrator recognizes that important uncertainties remain in interpreting the quantitative O_3-related growth effects for tree seedlings assessed in open-top chamber studies for the purpose of characterizing long-term growth effects, and other more subtle but important effects on sensitive tree species, natural forests, and forested ecosystems in the broader context of protection of public welfare. The Administrator also notes that standard levels within this lower range were not assessed in EPA's quantitative exposure and risk assessments.

In addition, the Administrator observes that while the CASAC Panel supported consideration of levels within this lower part of the proposed range from an annual perspective, they also supported a level at the upper end of the proposed range. Thus, the Panel recognized that the evidence and exposure and risk assessments, and the associated uncertainties and limitations, were subject to differing interpretations and public welfare policy judgments as to what weight to place on the various types of information and related uncertainties and limitations in setting the standard.

In the Administrator's judgment, a 3-year average standard set at a level in the mid- to lower part of the proposed range would not give sufficient weight to the important uncertainties and limitations inherent in the currently available scientific evidence and in the quantitative assessments conducted for the 2008 review. Taking into account the uncertainties that remain in interpreting the evidence, the

likelihood of obtaining benefits to public welfare decreases with a standard set below a level of 13 ppm-hours, while the likelihood of requiring reductions in ambient concentrations that go beyond those that are needed to reduce adverse impacts to public welfare increases.

Based on the above considerations, the Administrator judges that the appropriate balance to be drawn, based on the entire body of evidence and information available in this reconsideration, is a 3-year average standard set at 13 ppm-hours. This judgment by the Administrator appropriately considers the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that secondary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently but not more than what is necessary to protect public welfare from known or anticipated adverse effects.

D. Final Decisions on the Secondary O_3 Standard

For the reasons discussed above, and taking into account information and assessments presented in the 2006 Criteria Document and 2007 Staff Paper, the advice and recommendations of the CASAC Panel, and the public comments, the Administrator has decided to replace the 2008 8-hour secondary O_3 standard by setting a new cumulative, seasonal standard. This new secondary O_3 standard is set at a level of 13 ppm-hours. This new secondary standard is defined in terms of a concentration-weighted index, which is used to sum weighted hourly O_3 concentrations over 12 hours per day (8:00 am to 8:00 pm) and over 3-month periods within each calendar year. The standard is based on the 3-year average of the maximum 3-month index values for each year. This standard would be met at an ambient air monitoring site when the 3-year average of the annual maximum values of the 3-month index value is less than or equal to 13 ppm-hours. Data handling conventions are specified in the new Appendix P that is adopted, as discussed in section V.B below. Issues related to the monitoring requirements for the new O_3 secondary standard are discussed below in section VII.

V. Interpretation of the NAAQS for O_3 and Revisions to the Exceptional Events Rule

The EPA is finalizing with some changes the proposed revisions to Appendix P to 40 CFR part 50, Interpretation of the Primary and Secondary National Ambient Air Quality Standards for Ozone. The purpose of a data interpretation appendix in general is to provide the practical details on how to make a comparison between a set of ambient air concentration data and the level of the NAAQS, so that determinations of compliance and violation are as objective as possible. Data interpretation guidelines also provide criteria for determining whether there are sufficient data to make a NAAQS level comparison at all.

The proposed revisions to Appendix P regarding the primary O_3 NAAQS included the following: the addition of provisions addressing data to be used in making comparisons to the NAAQS; revisions to the provisions regarding the data completeness requirements across three years; revisions to the provisions regarding the use of incomplete data sets, including the addition of a provision providing the Administrator discretion to use incomplete data as if they were complete; a change from truncation to rounding of multi-hour and multi-year average O_3 concentrations; and clarification of certain language in the current provisions applicable to the primary NAAQS to reduce potential confusion. The proposed revisions also included changes in organization for greater clarity and consistency with other data interpretation appendices to 40 CFR part 50. EPA also proposed all-new data interpretation procedures applicable to the proposed cumulative, seasonal secondary O_3 NAAQS.

The EPA is also finalizing revisions to the O_3-specific deadlines in 40 CFR 50.14, by which states must flag ambient air data that they believe have been affected by exceptional events and submit initial descriptions of those events, and revisions to the deadlines by which states must submit detailed

justifications to support the exclusion of such ambient air data from EPA determinations of attainment or nonattainment with the NAAQS. These new O_3-specific deadlines are appropriate given the anticipated schedule for the designations of areas under the revised O_3 NAAQS. An exceptional event is defined in 40 CFR 50.1 as an event that affects air quality, is not reasonably controllable or preventable, is an event caused by human activity that is unlikely to recur at a particular location or a natural event, and is determined by the Administrator in accordance with 40 CFR 50.14 to be an exceptional event. Air quality data that are determined to have been affected by an exceptional event under the procedural steps and substantive criteria specified in section 50.14 may be excluded from consideration when EPA makes a determination that an area is meeting or violating the associated NAAQS.

A. Primary NAAQS

1. Data to Be Used in Comparisons to the Primary NAAQS

a. Proposal

The EPA proposed Appendix P language addressing what ambient monitoring data for O_3 can and must be compared to the primary and secondary O_3 NAAQS. The pre-existing version of Appendix P did not explicitly address this issue. The proposed language was similar to provisions that had been recently proposed to be included in new data interpretation appendices for nitrogen dioxide and sulfur dioxide.[47] The proposed new language in Appendix P provided that for both the primary and secondary NAAQS, all quality assured data collected with EPA-approved monitoring methods and known to EPA shall be compared to the NAAQS, even if not submitted to EPA's Air Quality System (AQS). For the primary NAAQS in particular, the proposed new language also made it clear that when determining the fourth-highest daily maximum 8-hour O_3 concentration for a year, all days with monitoring data are to be considered, not just days within the required O_3 monitoring season.

[47]Appendix S applicable to sulfur dioxide and Appendix T applicable to nitrogen dioxide have since been finalized, with this proposed language.

The EPA also proposed Appendix P language addressing the question of what O_3 data should be used when two or more O_3 monitors have been operating and have reported data for the same period at the same monitoring site. The pre-existing version of Appendix P did not explicitly address this issue. The proposed procedure for multiple O_3 monitors was similar to the one that EPA had recently proposed and finalized for the new 1-hour NAAQS for nitrogen dioxide. In the proposed procedure, the state would designate a primary monitor each year and only data from that monitor would be considered in that year. Data from different monitors in different years would be mixed, but only when needed to create a sufficiently complete 3-year record for a design value to be calculated. [48]

b. Comments

Some commenters expressed concern about the possibility that data that have not been submitted to AQS and that may not be subject to a rigorous quality assurance process would be used in determining whether a site has met the primary NAAQS. Commenters pointed in particular to EPA's Clean Air Status and Trends Network (CASTNET, see http://www.epa.gov/castnet/) as having uncertain future data quality given that over time different contractors may be responsible for site operation.

One association of state air agencies supported the proposal to clarify that data from outside the required monitoring season are to be fully considered in determining attainment with the primary NAAQS.

Two states objected to their understanding that EPA was proposing to prohibit the mixing of data from two physical instruments within one year. These agencies explained that they have been using

[48]In the proposal, EPA did not make clear whether the term "monitor" meant a single physical instrument or a single "monitor" as used in AQS terminology, namely whatever set or sequence of physical equipment is the source of data reported under one Pollutant Occurrence Code (an assigned code number used in AQS to link individual hourly measurements into a unique time series for data storage and retrieval purposes). This ambiguity left commenters to infer the meaning, and most appear to have understood "monitor" to mean a single physical instrument. When needed for clarity in the remainder of this preamble, "physical instrument" and "Pollutant Occurrence Code" are used instead of the ambiguous "monitor."

a second physical instrument to provide data when hourly concentrations from the primary physical instrument were not successfully collected or were invalidated during the quality assurance review process. This substitution helps these states meet the completeness requirements in Appendix P. These commenters interpreted the proposed rule to prohibit this hour-by-hour substitution approach. Another commenter recommended that if two O_3 physical instruments at the same site are adequately maintained and one cannot be determined to be more accurate than the other, the higher 8-hour concentration should be used.

One commenter apparently understood EPA to be proposing that the Administrator have discretion to use data collected with non-reference/equivalent monitoring instruments, which was not the case, and objected to such discretion. This commenter also objected to the Administrator using non-state data that had not been certified by the appropriate state agency.

c. Conclusions

The final rule incorporates the proposed provision that all valid FRM/FEM O_3 data submitted to EPA's Air Quality System (AQS), or otherwise available to EPA, meeting the requirements of 40 CFR 50 Part 58 including Appendices A, C, and E shall be used in design value calculations. Appendix A addresses quality assurance requirements, Appendix C addresses monitoring methods, and Appendix E addresses monitor siting requirements such as the minimum distance between a monitor and a highway. EPA recognizes the commenters' concern about the quality of data that may be collected by organizations other than state monitoring agencies. If data that have not been submitted to AQS are available to EPA for possible use in making determinations as to whether a site meets the NAAQS, EPA intends to determine on a case-by-case basis whether the requirements in 40 CFR 58 have been met for that data. If EPA determines that the requirements are met, it would be unreasonable for EPA to ignore the data when making determinations as to whether the NAAQS has been met.

As proposed, the final rule clarifies that data from outside the required monitoring season are to be fully considered in determining attainment with the primary NAAQS. EPA has proposed revisions to the required monitoring seasons (74 FR 35425, July 16, 2009) and the final decisions on these changes are outlined in the O_3 monitoring rule that the Agency also issued today. As in the past, EPA anticipates that some states will operate some of their O_3 monitors in months outside their required monitoring seasons. While EPA believes it to be quite unlikely that an 8-hour average concentration exceeding the primary NAAQS will occur outside of the final revised required O_3 monitoring seasons and be high enough to affect the selection of the fourth-highest concentration for the year, when and if such an occurrence does happen the data from outside the required monitoring season should be considered.

Regarding situations where multiple physical instruments have operated simultaneously at one site, we note that there appear to be relatively few cases of this situation for O_3 monitoring. Out of almost 1,300 O_3 monitoring sites in operation for any time during 2007-2009, only eight sites reported data to the Air Quality System in the same year under two or more distinct Pollutant Occurrence Codes (POC), indicating the presence of multiple physical instruments.[49] Even so, we believe that is it important to have a well-defined data handling procedure for such situations. A procedure that is simple to implement also has advantages in implementation. It is also important that the procedure does not introduce any upward or downward bias in the determination of the design value for the monitoring site.[50]

[49]These eight sites are in Illinois, Kentucky, Missouri (three sites), New York, North Carolina, and South Carolina. For only four of these sites was there an extended period of simultaneous operation during 2007-2009. Comments from the Missouri Department of Natural Resources indicate that it mixes data from two physical instruments into a single POC, but also submits data in a second POC. Comments from the Iowa Department of Natural Resources indicate that Iowa also operates one or more monitors at some sites but uses only one POC when submitting data; Iowa's 2009 monitoring plan does not indicate which or how many ozone sites have multiple monitors. It is not clear whether the other states currently mix data from two physical instruments into one POC.

[50]Selecting the maximum or minimum observed concentration for an hour, the maximum or

The EPA's proposed approach to multiple monitor situations was for the state to designate in advance one of the monitors as primary and thus to be the only source of data to be considered in a given calendar year, and to allow the Administrator to make this designation retrospectively if the state has failed to make it prospectively. The comment favoring hour-by-hour substitution of data from a secondary physical instrument within a given calendar year when the designated primary physical instrument has not given a valid measurement has caused EPA to rethink the possible approaches to this issue, and to finalize Appendix P with some changes from the proposal.

There are several possible approaches to the multiple physical instrument issue that would not cause a bias in the results, including the following: (1) the proposed approach of designating in advance one of the physical instruments as the only instrument to be considered for a given calendar year; (2) averaging data from the two physical instruments in every hour; (3) designating one of the physical instruments as primary, with substitution by EPA (via AQS processing) of missing data from that instrument with data from a secondary physical instrument; and, (4) designating one of the physical instruments as primary, with substitution by the monitoring agency of data from that instrument with data from a secondary instrument, before submission to AQS. This is the approach the two commenters have been using.

We believe the second approach may be unduly complex. Also, this approach might not be transparent if the averaging were performed by the monitoring agency before submission to AQS. Averaging by AQS software after submission of data from both physical instruments would be more transparent, but in light of the rarity of collocated physical instruments it would be an unreasonable demand on limited EPA resources to develop, maintain, and run AQS software for hour-by-hour data averaging. As in the case of hour-by-hour averaging, in light of the rarity of collocated instruments it

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minimum annual 4th daily maximum, or the maximum or minimum 3-year design value would introduce such a bias.

would be an unreasonable demand on limited EPA resources to develop, maintain, and run AQS software for hour-by-hour data substitution as required from the third approach.

Hour-by-hour substitution of only missing primary data by the monitoring agency (approach 4) appears to EPA to be an attractive approach in that it is unbiased and does not put an unreasonable demand on EPA resources, provided it is transparent. The comments from the two monitoring agencies indicate that they currently perform this substitution before submitting data to AQS under a single POC, but there currently is no way in AQS for them to indicate which hourly concentration values have been affected. Therefore, EPA believes that the most practical, technically valid approach is to allow monitoring agencies the option of hour-by-hour substitution between secondary and primary monitors before submission of data to EPA under a single POC, but to require monitoring agencies to include a quality assurance flag with each substituted hourly concentration value indicating that substitution has taken place. This flag will make transparent to EPA and the public what values have been substituted by the monitoring agency, and allow EPA to request more information from the monitoring agency for the specific hour(s) if appropriate. The final rule is based on this approach. Under the final rule, EPA will never combine data from two POCs within one calendar year in an attempt to increase data completeness, but monitoring agencies are free to combine data from two physical monitors into one POC before data submission.[51]

The proposal also addressed whether annual data sets from different POCs should be used to calculate 3-year design values. Specifically, the proposal said that if the primary "monitor" had sufficiently complete data for all three years, only its data would be used even if another "monitor" had more complete data in one or more of the years. Under the adopted approach to combining data from two physical instruments into a single POC, AQS will not distinguish any POC as "primary."

[51]EPA will soon inform monitoring agencies of the details of this new procedure via the AQS user e-mail list.

Therefore, the proposed approach is not applicable. Instead, the final rule directs EPA to select for use in calculating design values the one annual POC data set for a given calendar year that has the highest degree of completeness within the monitoring season. The final rule approach provides a clear logic for arriving at a unique end result when there could otherwise appear to be multiple seemingly valid design values for one site, and the approach ensures that the 3-year design value for a site will be as robust as possible, i.e., that it will be based on as much valid data as possible.[52] Also, the final rule approach may sometimes allow for the calculation of a valid 3-year design value when neither 3-year POC data set by itself would meet the 3-year data completeness requirements. It will not place an unreasonable demand on EPA resources to change the AQS software to implement this provision.[53]

2. Data Completeness Requirements

a. Proposal

The EPA proposed a change to Appendix P to clarify that the standard data completeness requirement, namely that valid daily maximum 8-hour values exist for 75% of all days, refers to only days within the required O_3 monitoring season. The pre-existing wording of Appendix P was somewhat open to a reading that the requirement applies to all days in the actual monitoring record for a site, which could be longer than the required season if a state voluntarily has monitored on additional days, or shorter than the required season if a monitor had started or ceased operation sometime during the required season.

[52]EPA recognizes that it is possible for the more complete of two data sets to produce a lower annual 4th high daily maximum 8-hour concentration than the less complete data set, depending on when the monitors happened to have operated relative to ozone episodes. However, this is an example of variability and not of systematic bias, as would be produced if the choice of data set were based on which has the higher or lower annual statistic.

[53]Design values reports are a recently added capability in AQS. EPA will notify AQS users when design values consistent with the final version of Appendix P are available from AQS.

The pre-existing Appendix P required that in order for a design value equal to or less than the standard to be valid, at least 75% of the days in each of three consecutive required monitoring seasons must have a valid daily maximum 8-hour average concentration value, i.e., the pre-existing Appendix P required that 75% of the days in each of the three required monitoring seasons have at least eighteen 8-hour periods that each have at least six out of the eight possible reported hourly concentrations.[54] It also required that the average of the percentages from three consecutive required seasons be at least 90%. EPA proposed to eliminate this 90% requirement for the average of three seasons and to retain only the requirement that each individual season have a percentage of at least 75%. EPA noted that as a practical matter, the current 90% requirement over three consecutive seasons in effect required a minimum data capture rate somewhat above 75% in each season, because if data capture in any one season were as low as 75% the data capture required in the other two seasons in order to meet the 90% requirement averaged over three seasons would be difficult to achieve. EPA invited comment on whether the 75% completeness requirement in each individual season should be changed to 80% or 85%.

b. Comments

Most comments on data completeness came from state air agencies and most of the commenters supported the elimination of the 90% requirement for the 3-year average of data completeness and retention of the 75% requirement for individual years. One commenter specifically endorsed clarifying that the 75% requirement does not apply to days outside the required O_3 monitoring season.

Several environmental groups recommended that the 75% requirement be increased to 85%.

An industry commenter opposed dropping the 90% requirement. This commenter said that EPA had not adequately justified the change and called it outcome-oriented, but did not provide any rationale

[54]In implementing the pre-existing Appendix P, EPA as a matter of guidance also credited towards the 75% requirement any 8-hour period that had five or fewer measured concentration values, if substituting one-half the MDL for all the missing values resulted in an 8-hour average above the level of the NAAQS.

or evidence against the change. Another commenter who advocated retaining the 90% requirement apparently assumed that EPA had proposed that hours without reported data for which low concentrations are substituted (see section V.A.3 below) would not count against data completeness, so that achieving 90% completeness after substitution would not be burdensome.

c. Conclusions

The final rule eliminates the 90% requirement across three required monitoring seasons of data and retains the 75% requirement for individual required seasons. EPA's rationale for this change was explained in the proposal notice. While some commenters expressed support for increasing the 75% requirement for individual years, they did not provide any specific counter arguments or data to support the appropriateness of a higher completeness requirement, other than the general point that more complete data reduces the possibility that a period of high O_3 will go unmonitored.

The EPA notes that the 75% level is not the level of data completeness that EPA encourages and expects monitoring programs to attain. It is the level of completeness required for a design value below the level of the NAAQS to be considered valid, allowing the site to be found to meet the NAAQS rather than to be left in an indeterminate status. A considerably higher level of completeness is typical among monitoring agencies, and should be a goal for all agencies. However, the prospective goal for the completeness of monitoring data is a separate and distinct issue from making a NAAQS compliance determination, after the fact, using whatever data have been collected. EPA does not believe that the level of the completeness requirement for a valid design value influences monitoring agency diligence in obtaining and reporting data. While only 100% data completeness can provide absolute confidence that a monitoring site has not violated the NAAQS, EPA believes that the 75% requirement applied to individual years is a reasonable compromise for regulatory purposes between the risk of not detecting a violation of the NAAQS and not correctly recognizing that an area meets the NAAQS.

The following information regarding data completeness for 2009 will put the distinction between a 75% and an 80% or 85% completeness requirement into perspective. There were 1,151 O_3 monitoring sites that achieved at least 75% completeness in 2009. Eighty-five percent of these achieved completeness of 95% or more. Only 10 of these had data completeness less than 80%, and only 21 had completeness of at least 80% but less than 85%. Thus, the choice of the completeness requirement for a valid design value between these three possible values affects only one to three percent of all monitoring sites. Moreover, for more than one-half of these sites, another site in the same metropolitan area (or county) had 2009 data that were 85% or more complete, reducing the possibility that the area might be found to meet the NAAQS because high O_3 days were not successfully monitored. Thus, EPA believes that the choice of the level of the completeness requirement in the range of 75-85% is not a large factor in the level of protection provided by the NAAQS.

The EPA notes that contrary to the assumption of one commenter, the proposal would not have given credit for substituted hours towards either the 75% or the 90% requirement. The final rule does not give credit for substituted hours towards the 75% requirement.

3. Data Substitution in Cases of Incomplete Data

a. Proposal

The EPA proposed to revise portions of Appendix P that describe certain exceptions to the standard data completeness requirements, under which a monitoring site can in some cases be determined to be violating the primary NAAQS despite not meeting the standard data completeness requirements. EPA proposed to replace three separate statements of exceptions to the standard completeness requirements with a new data substitution step. Specifically, EPA proposed that in the event that only one, two, three, four, or five hourly concentrations are available for an 8-hour period, a partially substituted 8-hour average would be computed by substituting a low hourly average value for

all the hours without hourly averages, and then using 8 as the divisor. Substituted data would be selected as follows. For days within the required O_3 monitoring season, the substitution value would be the lowest hourly average O_3 concentration observed during the required O_3 monitoring season of that year. Because a robust set of hourly measurements might not always be available for the year, EPA also proposed that if the number of hourly concentration values available for the required O_3 monitoring season for the year is less than 50% of all hours during the required O_3 monitoring season, one-half the method detection limit (MDL) of the O_3 monitoring instrument would be used in the substitution instead of the lowest observed concentration. EPA invited comment on whether another percentage should be used for this purpose instead of 50%, whether the MDL-based substitution should be used at all, and on alternative approaches. Additionally, EPA proposed that for simplicity and to further reduce any risk of a false finding that a site does not meet the standard, for days outside the required O_3 monitoring season the substitution value would always be one-half the MDL of the O_3 instrument. EPA similarly invited comment on this aspect. Under the proposal, there would be no precondition that a partially substituted 8-hour average exceed the level of the standard for it to be used in the calculation of the design value. An 8-hour period with no available hourly averages would not undergo substitution and consequently would never have a valid 8-hour average, as was the case with the pre-existing version of Appendix P.

In addition, EPA proposed that a design value that is greater than the level of the primary standard would be valid provided that in each year there were at least four days with at least one valid 8-hour concentration.[55] One or more of these 8-hour average concentrations could be the partially substituted 8-hour average concentration resulting from the above described substitution procedure.

[55]The requirement that there be at least four days with at least one hourly measurement is actually redundant and was stated only for ease of understanding, since there would be no annual fourth-highest daily maximum 8-hour concentration unless there are at least four days with some monitoring data. The final rule omits this redundant text in the interest of simpler exposition.

Finally, as noted in section V.A.2, EPA proposed that a design value equal to or less than the level of the standard would be valid only if at least 75% of the days in the required O_3 monitoring season of each year have daily maximum 8-hour concentrations that are based on at least 18 periods with at least 6 reported hourly concentrations. Thus, a site could be found to meet the standard only if this percentage of the days in the required O_3 monitoring season have reasonably complete hourly data obtained through actual measurement. Substituted values of one-half the MDL could not count towards this requirement. This limits the probability of a false finding that the site meets the NAAQS due to measurements not having been taken during all the periods of high O_3 concentration.

b. Comments

The subject of data substitution drew a variety of responses from commenters. There was a broad recognition that some provision must be made to allow for a finding that the NAAQS has not been met when this conclusion is inescapable given the statistical form of the NAAQS, even though there are missing concentration values. The proposed data substitution approach is, in effect, a way to test whether this conclusion is inescapable. Some commenters endorsed the specific substitution approach proposed by EPA, while others suggested alternative substitution approaches. Some of these alternatives could be considered minor variations of the proposed approach, for example to draw the low concentration value for substitution only from available data for the same calendar month or quarter and/or from the same hour of the day, rather than from all hours in the entire required O_3 monitoring season. Other suggested alternatives were fundamentally different in that they were aimed at substituting a "best estimate" of the missing concentration value which would then always be used as if it were a measured concentration to calculate a valid design value.

Some commenters opposed the use of any data substitution for the period outside the required O_3 monitoring season, the period for which EPA had proposed the use of one-half the method detection limit as the substitution value.

One commenter pointed out that the lowest concentration observed during a year cannot be known until the year is complete (unless a value of zero ppm has been recorded). As a result, a monitoring agency (and EPA) would be able to make only provisional substitutions as the year progressed, possibly leading to different numerical outcomes each time the process was repeated, which could cause public confusion as well as additional cost.

The pre-existing Appendix P provided that in the event that only six or seven hourly averages are available, the valid 8-hour average shall be computed on the basis of the hours available, using six or seven as the divisor. We proposed to retain this approach. However, we proposed the retain the historical practice of substituting for all missing hours when there are five or fewer reported hourly measurements, and using eight as the divisor. Some commenters noted that when, for example, only four hourly measurements are available, it would be more consistent to substitute for only two of the remaining hours and use six as the divisor, rather than the proposed approach of substituting for all missing hours and using eight as the divisor.

c. Conclusions

The final rule incorporates the proposed substitution approach, with the one change that the substitution value will always be 0.0025 ppm. As in the pre-existing Appendix P, substitution applies only when an 8-hour period has fewer than six measured hourly O_3 concentrations. If there are six or seven hourly values, those values are averaged with six or seven as the divisor, and the result is used as the 8-hour average concentration.

There are several reasons for this change. First, upon further investigation prompted by comments on this issue, EPA determined that as actually programmed, AQS has to date always been substituting the fixed value of 0.0025 ppm for missing hourly data. While 0.0025 ppm is in fact one-half of the EPA-provided default value of the MDL for all of the instruments that have historically been used in state, local, and tribal monitoring of O3 concentration for regulatory purposes (also referred to as the "federal MDL"), AQS has not been checking for the possibility that a monitoring agency may have determined and submitted a different, locally applicable MDL value. Second, even if resources were devoted to reprogramming AQS to do such a check and to performing the check every time a concentration value is missing, there would in the vast majority of cases be zero effect on calculated 8-hour average concentrations because monitoring agencies have rarely (if at all) submitted a different MDL value. Third, EPA has found that for about 95% of monitoring sites in the example year of 2009, the lowest O_3 concentration reported during the year was actually less than 0.0025 ppm. This is because ambient O_3 concentrations can drop to extremely low values at night if there are local sources of nitric oxide (NO) near the monitoring site, which is often the case. Thus, the proposed approach would often be less protective of public health than retaining 0.0025 ppm as the substitution value. Fourth, EPA agrees with the commenter who noted that public confusion and extra costs could occur with an approach that used the lowest measured concentration from the current year, because that value might change several times during the year as lower and lower values are observed. This could require retraction and revision of previously disseminated information about O_3 concentrations. Moreover, even after a very low but non-zero value was observed, EPA and monitoring agencies would have to continually watch for the occurrence of an even lower value later in the year.

The EPA notes that because a design value below the NAAQS is valid only if based on a data set that is 75% complete within the monitoring season, with no credit for substituted data, substitution

cannot result in a finding that a site meets the NAAQS, when an indeterminate outcome would result but for substitution. It was the concern of some commenters to avoid such an outcome. When the 75% completeness requirement is not met, a design value determined using data substitution that is below the NAAQS will not be valid and no conclusion regarding meeting the NAAQS will be possible until more complete data are collected, or data showing a clear violation are collected (unless the discretion provision discussed in the next section is used by the EPA Regional Administrator).

The EPA notes that under the final rule, as also under the proposed rule, it is possible for an 8-hour average concentration that includes three or more substituted hourly concentrations to become the daily maximum 8-hour concentration. This value could then become one of the four highest daily maximum concentrations for the year, and thus affect the 3-year design value calculation, even if the 8-hour concentration is below the level of the NAAQS. In the pre-existing Appendix P, such an 8-hour concentration could be used in this way only if it were above the level of the NAAQS. This change from the pre-existing Appendix P approach remedies a problem that was fully explained in the preamble to the proposed rule.

As summarized above, some commenters recommended that EPA adopt a "best estimate" approach to substitution. In some situations, such an approach could result in higher calculated valid design values than the approach proposed by EPA and finalized today. Also, depending on the particulars of the substitution approach, a "best estimate" substitution approach could have the effect that all design values would be considered valid. Thus, this type of substitution might result in more sites correctly being found to exceed the NAAQS, and it could also allow additional truly clean sites to be found to meet the NAAQS, rather than some sites of each type being left in an indeterminate status due to incomplete data. The practice of substituting low values instead of "best estimate" values has been in place since the 8-hour NAAQS was first set in 1997, is clearly stated, and is familiar to air

control agencies. The proposal did not present a particular version of "best estimate" substitution for comment. EPA believes it best to retain the historical practice until more analysis of the implications of a change and broader comments can be solicited as part of the next review of the NAAQS.

The final rule does not incorporate the suggestion that when there are five or fewer reported hourly concentrations only enough missing hourly concentration values be substituted to reach six concentration values for averaging, rather than eight, with six used as the divisor. The practice of substituting until there are eight values for averaging has been in place since the 8-hour NAAQS was first set in 1997, is clearly stated, and is familiar to air control agencies. Most commenters did not address this provision, as the proposed Appendix P followed the pre-existing Appendix P on this aspect, and EPA did not highlight the issue for comment. EPA believes it best to retain this practice until more analysis of the implications of a change and broader comments can be solicited as part of the next review of the NAAQS.

4. Regional Administrator Discretion to Use Incomplete Data

a. Proposal

The EPA proposed that the Administrator should have general discretion to use incomplete data to calculate design values that would be treated as valid for comparison to the primary NAAQS despite the incompleteness, either at the request of a state or at her own initiative. At the time of proposal, similar provisions existed already for the $PM_{2.5}$ and lead NAAQS, and EPA had recently proposed such provisions to accompany the proposed 1-hour NO_2 and SO_2 primary NAAQS.[56] Under the proposal, the Administrator could consider monitoring site closures/moves, monitoring diligence, and nearby concentrations in determining whether to use such data.

b. Comments

[56]Since proposal of the revised primary O_3 NAAQS, EPA has finalized the data interpretation appendices for the new 1-hour NO_2 and SO_2 primary NAAQS with the provision as proposed.

Several commenters objected to the Administrator having discretion to use incomplete data sets to determine compliance with the primary NAAQS. Some of these commenters were especially concerned about using incomplete data sets to designate an area as nonattainment, because such an action triggers new and potentially extensive regulatory requirements. Another commenter opposed using incomplete data sets to determine that an already designated nonattainment area has achieved the NAAQS, especially if the discretion is open-ended. One commenter said that the proposed rule did not sufficiently specify what factors the Administrator would consider and how they would be applied.

c. Conclusions

The final version of Appendix P contains the proposed provision regarding Administrator discretion, except that "may consider" has been replaced with "shall consider" in the passage listing the factors to be considered, and the reference to the Administrator has been changed to refer to the Regional Administrator for reasons of administrative efficiency. "Shall consider" is more consistent with EPA's intention in proposing this discretion, and will ensure that the Regional Administrator considers the listed factors.

Given the statistical form of the primary NAAQS based on 8-hour averages and the annual 4th highest daily maximum, and the other final provisions for calculating the design value including the substitution procedure using 0.0025 ppm, the effect of substituting for missing data up to the 75% completeness level is always to reduce the design value compared to what it would have been had enough concentration values been available to reach or exceed the 75% completeness level. Therefore, it is impossible for a completeness level below 75% to cause an area that actually meets the primary NAAQS to appear to violate it. This is why the final version of Appendix P by its own terms treats as valid any 8-hour design value greater than the level of the NAAQS regardless of data completeness, making Regional Administrator discretion irrelevant.

Discretion or lack of discretion to use an incomplete data set as if it were complete could make a practical difference when the calculated design value is below the level of the NAAQS. When EPA follows the Appendix P procedures strictly, EPA will sometimes not be able to determine that a monitoring site meets the NAAQS, because the design value, although below the level of the NAAQS, is invalid due to one or more of the three consecutive required monitoring seasons not having data for 75% of the days in the season. This may not always be a scientifically supportable outcome. For example, there could be a case in which data from other O_3 monitors that usually have higher readings show low concentrations on the days for which the first monitor is missing data. In such a situation, Regional Administrator discretion to use incomplete data on a case-by-case basis could allow scientifically supportable outcomes of two types: (1) the initial designation under the primary NAAQS for an area that actually meets the NAAQS could be attainment, rather than unclassifiable; and (2) a previously designated nonattainment area for the primary NAAQS that has improved its air quality enough to actually meet the NAAQS could receive a clean data determination, and thus could be redesignated to maintenance, without having to wait until three additional years of sufficiently complete monitoring data were obtained. While the first alternate outcome would not have regulatory consequences because there are no differential regulatory requirements for unclassifiable and attainment areas, the second alternate outcome could affect costs to industry, government, and the public.

Because EPA cannot anticipate and devise special Appendix P treatments for all the possible situations in which strict application of the completeness requirement in Appendix P might not lead to a scientifically supportable result, EPA believes it is in the public interest for the final rule to include the proposed discretion provision, with the substitution of "shall" for "may" as described.[57] It has been EPA

[57]The pre-existing Appendix P and the final rule both have a discretionary provision for a situation in which a state can show that meteorological conditions were such that unmeasured ozone concentrations were low. EPA believes this does not encompass all the situations in which strict

practice to allow a public comment period, announced in the Federal Register, for any official determination that a monitoring site meets a NAAQS if that finding has regulatory consequences for a state or other party. EPA expects to continue this practice. This comment period will provide transparency to the discretion process.

5. Rounding

a. Proposal

With respect to rounding, EPA proposed that (1) 1-hour concentrations continue to be reported to only three decimal places, the same as specified in the pre-existing Appendix P, i.e., that the current practice of truncating the 1-hour data to the nearest 0.001 ppm be retained; (2) all decimal digits resulting from the calculation of 8-hour averages be retained; and (3) the 3-year average of annual fourth-highest daily maximum 8-hour concentrations be rounded to three decimal places before comparison to the NAAQS. The proposed text of Appendix P expressed the requirement for retaining all decimal digits using the phrase "all digits supported by the calculator or calculation software must be retained." EPA noted that the pre-existing O_3 NAAQS is the only NAAQS for which multi-hour, multi-day, or multi-year averages of concentrations are truncated rather than rounded, but that with the proposed change this aspect of O_3 data interpretation would be consistent with data interpretation procedures for the other criteria pollutants.

b. Comments

Many commenters supported the proposal regarding rounding. However, some commenters opposed the proposal. One commenter opposed to the change recommended that if the proposed change from truncation to rounding were adopted in the final rule, a less stringent level of the standard should be selected in order to compensate for the stringency effect. Another commenter did not object to the

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application of the 75% requirement may be inappropriate.

concept of rounding, but said that EPA's phrase "all digits supported by the calculator or calculation software" was too specific and could force expensive re-programming for no practical effect. This commenter recommended that EPA should instead specify that a certain number of decimal digits, for example six digits, be retained until the final rounding step. A third commenter recommended the use of true running 8-hour averages; by this, the commenter apparently meant that O_3 monitor data loggers should be programmed to integrate and average the continuous O_3 concentration signal over rolling 8-hour periods that started at intervals shorter than one hour, rather than reporting the average concentrations for individual (blocked) clock hours with averaging across hours performed afterwards. One commenter said rounding instead of truncating averages would create confusion in historical O_3 trends, particularly in areas that are meeting the standard using the current methodology but are not meeting the standard using the proposed methodology. EPA also received comments regarding the accuracy of O_3 monitors and the relationship of the alleged accuracy to the proposed provisions regarding rounding.

c. Conclusions

The final rule provides for rounding averages, but now specifies that the 8-hour average be rounded to six decimal digits. This is sufficient to ensure that intermediate calculations are extremely unlikely to affect the final outcome of the design value calculation.

Regarding the suggestion to use "true running 8-hour averages," EPA believes this would impose unnecessary costs on state agencies because it inevitably would require re-programming of data loggers.

Regarding the potential for confusion between previous and new reports of O_3 concentrations and attainment status, EPA believes there is no reason for concern. Because the level of the O_3 standard is being revised, pre-existing information about compliance with the previous level is necessarily obsolete and cannot logically be compared or contrasted to new information about compliance with the

revised standard. EPA's AQS data system will automatically re-calculate all historical 8-hour average concentrations using the new rounding method, and going forward will report only those values. States operating their own data systems may choose to do the same for their historical data.

The comments about the accuracy of O_3 monitors are identical in substance to those offered during public comment on the review of the NAAQS completed in 2006. These comments are addressed in the "Response to Comments" document in the docket for this rulemaking.

With respect to the comment regarding the stringency effect of rounding rather than truncating intermediate averages, the Administrator has considered this effect in choosing the level of the standard, as she has considered the statistical form and other aspects of the standard.

6. Other Aspects of Data Interpretation

The EPA proposed to add to Appendix P a cross reference to the Exceptional Events Rule (40 CFR 50.1, 50.14, and 51.930) with regard to the exclusion of monitoring data affected by exceptional events, positioned so as to be applicable to both the primary and secondary NAAQS. This cross reference is included in the final rule. In addition, while reviewing public comments EPA realized that the proposed language left ambiguity about exactly how to calculate and validate a 3-year design value for the primary NAAQS when one or more hourly concentrations have been approved for exclusions. Further consideration of this issue revealed it to be quite complex, with significant potential for regulatory uncertainty if the matter was not made clear in the final rule. The final text of Appendix P makes clear that (1) if a 1-hour concentration value has been approved for exclusion by EPA under the Exceptional Events Rule for the purposes of the 8-hour NAAQS, it cannot be used in the calculation of an 8-hour concentration, and (2) excluded hourly concentrations nevertheless will be credited when determining whether the 75% data completeness requirement for a valid design value below the NAAQS has been met. Thus, a day will be counted towards the 75% data completeness requirement if at least 18

of the 24 possible 8-hour periods each have at least six observed hourly concentrations reported to EPA even if some of those hours have been approved for exclusion. EPA further considered whether and how to assign an 8-hour average concentration to an 8-hour period in which there are only five or fewer reported concentrations remaining after some other hourly concentrations within that period have been approved for exclusion as having been affected by an exceptional event. As described in section V.A.3 of this preamble, 0.0025 ppm will be substituted when no hourly concentrations were ever reported. To avoid any perverse situation in which two sites would be treated unequally when one site did not succeed in measuring and reporting an hourly concentration at all and the other site measured a concentration which EPA later approved for exclusion, the final version of Appendix P provides for 0.0025 ppm to be substituted for both originally missing and excluded values whenever any combination of originally missing values and excluded values results in there being five or fewer retained measured values for the 8-hour period.[58]

The pre-existing Appendix P provided that each 8-hour period would be associated with the starting hour of the period. This provides a clear method of assigning the 8-hour average concentration for a period that includes hours from two days to just one of those two days. EPA received several comments advocating one or another different approach, for example assigning the 8-hour average to the day that contains the one hour of the eight hours that has the highest hourly concentration, or requiring that the daily maximum 8-hour concentrations on successive days be from periods that do not overlap. The commenters provided anecdotal cases in which the different approaches result in different outcomes

[58]This approach in the final rule is very similar to the approach used for many years by AQS when calculating 8-hour ozone averages for periods in which some hourly data had been approved for exclusion under the EPA policies that preceded the Exceptional Events Rule. In this long-standing AQS approach, one-half the MDL was substituted, but the resulting 8-hour average was considered valid for identification as the daily maximum only if it exceeded the level of the NAAQS. This AQS practice was not codified in the pre-existing Appendix P. Under the final Appendix P, the resulting 8-hour average is always eligible for identification of the daily maximum.

in terms of the daily maximum 8-hour concentrations for the two days that share an 8-hour period, which conceivably could affect the level of the annual 4th highest 8-hour average concentration and thus the 3-year design value. EPA did not propose to change the pre-existing approach, and accordingly EPA considers these comments to be outside the scope of this rulemaking. EPA may consider alternatives like those recommended by the commenters in the next review of the NAAQS. In that context, EPA would be able to more systematically assess the implications of alternative approaches and solicit informed public comment.

The EPA received a comment to the effect that when data completeness is below 75%, the annual 3rd highest daily maximum 8-hour concentration should be used in the design value instead of the annual 4th highest such concentration. This suggestion addresses the statistical form of the NAAQS, an issue addressed elsewhere in this preamble and in the response to comments document, rather than the data interpretation procedures of Appendix P.

Some comments recommended that O_3 concentrations be corrected to monitoring site temperature and pressure, so that the NAAQS would set a uniform limit on the mass of O_3 per actual cubic meter, rather than a uniform limit on the mixing ratio of O_3. Another commenter suggested that the NAAQS limit only the increase in O_3 concentration that occurs during daytime, rather than the actual O_3 concentration. These suggestions address the selection of the indicator for the NAAQS, which EPA did not propose to reconsider and which EPA considers outside the scope of this rulemaking. Nevertheless, the response to comments document addresses these comments more completely.

The EPA has revised Example 1 in section 3 of the final version of Appendix P to illustrate correctly an example of a monitoring site that meets the final revised level of the primary NAAQS. In addition, some passages of the final version of Appendix P relevant to the primary standard have been re-ordered or have minor wording changes for greater clarity.

B. Secondary NAAQS

The EPA is adopting with some changes the proposed data interpretation procedures for the new secondary O_3 NAAQS, which is defined in terms of a specific cumulative, seasonal form, commonly referred to as the W126 form, as described above in section IV. The "design value" for the secondary standard, the statistic for a monitoring site that would be compared to the level of the secondary standard to determine if the site meets the standard, is the average of the annual maximum values of the 3-month index value from three consecutive calendar years. The new section 4 to Appendix P provides clear directions and examples for the calculation of the daily index value, the monthly cumulative index value, the annual maximum index value for a year, which are intermediate values, and the final 3-year design value itself. It also provides criteria for determining when a design value for the secondary standard is valid for comparison to the secondary NAAQS.

1. Data to be Used in Comparisons to the Secondary NAAQS

a. Proposal

The EPA proposed Appendix P language addressing what ambient monitoring data for O_3 can and must be compared to the secondary O_3 NAAQS. The proposed new language in Appendix P provided that for the secondary NAAQS, all quality assured data collected with EPA-approved monitoring methods and known to EPA shall be compared to the NAAQS, even if not submitted to EPA's Air Quality System (AQS).[59] In this regard, the proposal for the secondary standard was the same as for the primary standard, discussed above in section V.A.1. However, in the instructions for actually making the comparison to the NAAQS, the proposed Appendix P section for the secondary NAAQS provided that only those 3-month periods entirely within the required O_3 monitoring season

[59]Given the proposed and final form of the secondary NAAQS, only concentration data for the 12 hours beginning 8:00 am through 7:00 pm local standard time are actually used in comparisons to the NAAQS.

were to be considered. Moreover, in a situation in which the required O_3 monitoring season was the entire year, EPA proposed that the W126 index values would not be calculated for November-January and December-February.

The EPA also proposed Appendix P language addressing the question of what O_3 data should be used when two or more O_3 monitors have been operating and have reported data for the same period at one monitoring site. The pre-existing version of Appendix P did not explicitly address this issue. The proposed procedure for multiple O_3 monitors was the same as EPA had recently proposed for the new 1-hour NAAQS for nitrogen dioxide. In the proposed procedure, in general, data from two monitors would never be mixed within a year but data from different monitors in different years could be used to calculate the 3-year design value. In this regard, the proposal for the secondary standard was the same as for the primary standard, discussed above in section V.A.1.

b. Comments

Many commenters addressed the proposal regarding what data should be used for purposes of comparing air quality to the secondary NAAQS. These commenters noted that with the expected expansion of the O_3 monitoring season in many states based on EPA's proposed Ozone Monitoring Rule (74 FR 34525, July 16, 2009), monitors will be operational in some states during times outside of the plant growing season. The commenters expressed concern that as proposed, Appendix P might result in an area being determined to not meet the secondary NAAQS only due to a high value of the W126 cumulative index during a period when plants are dormant and not subject to harm from O_3. Some pointed to recent winter episodes in certain western states, in which O_3 levels have been high due to the combination of snow cover reflecting sunlight back into the air, low inversion height, and precursor emissions from oil and gas exploration and production activity.

One commenter noted the phrase "the annual W126 index value is computed on a calendar year basis" and recommended that this be revised to refer to the required monitoring season instead of the calendar year, to be consistent with the actual calculation procedure proposed for the secondary NAAQS design value.

c. Conclusions

The final version of Appendix P contains three changes from the proposed version in response to the comments received.

First, EPA agrees with the views expressed that the goal of the secondary standard, i.e., to protect sensitive vegetation from the adverse effects of O_3 exposure, would not be furthered by including in the W126 calculation O_3 exposures that occur when plants are much less likely to be physiologically active due to freezing temperatures. As explained in section IV.C.1 of this preamble, plants adapted to living in colder climes undergo a process known as hardening as temperatures decrease for the winter. Once in this hardened state, plants are less likely to be active and have limited gas exchange or photosynthesis. After a sufficient period of warmer air temperatures has raised soil temperature, the plants de-harden and physiological activity resumes. After this point, plants may remain physiologically active even if air temperatures fluctuate above and below freezing. EPA has investigated the issue of whether high W126 index values occur in places and times for which hardening may have already occurred but de-hardening has not begun. EPA has found that among areas that have sub-freezing winter temperatures, occurrences during the winter of 1-month W126 values high enough to possibly contribute to a violation of the 3-month secondary NAAQS appear to date to have been limited to a small number of cases in western areas. These cases have involved the combination of emissions from oil and gas activity, snow cover, and atmospheric inversion, as described above in the summary of comments on this issue.

To address this issue, a provision has been added to the final Appendix P under which the Regional Administrator may approve a request or otherwise make a determination that all 12 hourly daytime O_3 concentrations from one or more days be excluded from the calculation of the 3-year design value (and replaced with 0.0 ppm) on the basis that sensitive plant species in the geographic area for which air quality is represented by the monitoring site on those days were in a dormant or hardened condition making them less likely to be susceptible to injury by the exposure to the measured daytime O_3 concentrations.[60] The rule lists the following factors that the Regional Administrator shall consider in approving such a request, to the extent such information is available: air temperatures and snow cover on that day and on the preceding days, their likely effect on soil temperatures on that day and in preceding days, and the plant species that may be present in the geographic area for which air quality is represented by the monitoring site. The rule also provides that exclusion will not be granted for concentration data collected by state or local agencies at monitoring sites after January 1, 2013 unless on-site temperature data have been submitted to AQS. EPA believes that with this lead time it is reasonable to expect that the few states that may need to take advantage of the Regional Administrator's discretionary authority will support their requests for exclusion with such site-specific temperature data. EPA anticipates that any official regulatory action affected by an exclusion under this provision, or by denial of such an exclusion, for example the designation of an area for the secondary NAAQS, would be preceded by an opportunity for public comment.

Second, after considering the comment suggesting that a particular phrase in the rule be changed to refer to the required ozone monitoring season rather than to the calendar year, EPA has decided to retain that passage as proposed and to modify other passages in the final rule to provide that all days

[60]The replacement of the actual daytime O_3 concentrations with 0.0 ppm in the calculation of the 3-month W126 index recognizes that no incremental injury occurs when the plants are dormant, while also distinguishing between such days and days on which no O_3 concentration was measured so that the adjustment of the W126 index for truly missing O_3 concentration data is not disrupted.

with O_3 concentration data will be considered when calculating the design value for the secondary NAAQS, including days outside the required monitoring season. In a separate action today, EPA is finalizing a required monitoring season for each state that for all parts of the state encompasses the 3-month period in which the W126 index is a maximum. However, when the available quality assured O_3 data show that the maximum 3-month period includes a month or months outside the required monitoring season and that the 3-month W126 index in that period exceeds the NAAQS, EPA believes it would be inappropriate to ignore such data. With this change, the approach to the use of data from outside the required monitoring season will be the same for the primary and secondary NAAQS. This minor change from the proposal for the secondary NAAQS is consistent with the goal of the proposal, ensuring that the maximum 3-month period would be considered. This minor modification is a more appropriate way to achieve that goal and avoids an unnecessary difference between the primary and secondary NAAQS EPA notes that the final rule provides the Regional Administrator with discretion to exclude data collected in times and places where plants are not sensitive to the effects of O_3, as discussed immediately above.

Third, changes have been made in the provision regarding how data from multiple physical instruments at a single site are used to develop a design value. The provisions applicable to the secondary standard are the same as for the primary standard, discussed above in section V.A.1.c, except that in considering which Pollutant Occurrence Code data set is more complete for a year and thus should be selected for use in calculating the 3-year design value, only daytime hours (as defined in Appendix P) will be considered.

2. Data Completeness Requirements and Adjustment of the Monthly W126 Index in Cases of Incomplete Data

a. Proposal

The EPA proposed that for each month in the required monitoring season, hourly O_3 concentrations normally would have to be available for at least 75% of all the daytime hours (defined for this purpose as the 12 hours beginning 8:00 a.m. through 7:00 p.m. local standard time) in the month, for a design value below the NAAQS to be valid.[61] One implication of this proposal was that if any month within the required O_3 monitoring season did not meet the 75% completeness requirement, it would not be possible to determine that the monitoring site meets the secondary NAAQS for a 3-year period that includes that month. Note, however, that as explained in the next section EPA did propose a data substitution procedure that could result in a determination in such a case that the site did not meet the secondary NAAQS, depending on the concentrations that were measured.

The EPA also proposed that if data are available for at least 75% but fewer than 100% of these daytime hours in a month, the cumulative index value calculated from the available daytime hours in the month would be adjusted higher to compensate for the missing hours, based on an assumption that in the aggregate the missing hours would have the same distribution of O_3 concentrations as the available hours. The proposed adjustment effectively eliminates the bias due to summation over different number of hourly concentrations, so that sites with higher data completeness are not penalized relative to sites with less complete data.

b. Comments

No distinct comments were received on the data completeness requirement for the secondary NAAQS.

c. Conclusions

[61]For convenience, the preamble and rule text refer to this period as the "daytime hours" even though this period generally does not actually align exactly with the time between sunrise and sunset.

The final data completeness requirements for a design value below the NAAQS to be valid and the final adjustment procedure to compensate for completeness between 75% and 100% are the same as were proposed.

3. Data Substitution Procedure

a. Proposal

The EPA proposed a data substitution procedure for the secondary NAAQS under which months that have O_3 concentration data for fewer than 75% of their nominal daytime hours might nevertheless be useable for calculating a valid design value. Such months would be used when the available O_3 concentrations are high enough that even substituting a low concentration value for missing hours would result in a 3-year design value greater than the level of the standard. EPA proposed that the substitution value would be the lowest 1-hour O_3 concentration observed at the monitoring site during daytime hours during the required O_3 monitoring season, in that calendar year. EPA invited comment on whether for simplicity the substituted 1-hour O_3 concentration value should instead be zero or one-half the method detection limit (MDL) of the O_3 instrument, noting that because of the sigmoidal weighting factor the exact magnitude of the low substitution value is highly unlikely to influence the final design value, which is rounded to a whole number.

b. Comments

The EPA received no comments specifically about data substitution for the secondary NAAQS. However, EPA has considered how the comments received regarding data substitution for the primary NAAQS would logically extend to the secondary NAAQS.

c. Conclusions

The final rule incorporates the proposed substitution approach, with the one change that the substitution value will always be 0.0025 ppm, the same value used for the primary standard in analogous

situations. The use of a fixed substitution value avoids public confusion and the extra costs that could occur with an approach that would use the lowest measured concentration from the current monitoring period, which could not be finally determined until the end of the monitoring period.

The EPA notes that the substitution procedure in the final rule can only have the effect of allowing a site to be properly found to not meet the NAAQS, relative to an approach which does not use substitution at all and therefore would result in one or more months with no valid monthly W126 index value and hence no valid annual 3-month W126 index value. A design value below the secondary NAAQS is valid only if it is based on a data set that is 75% complete for every month within three consecutive required monitoring seasons, with no credit for substituted data. Thus, substitution cannot result in a finding that a site meets the NAAQS. When the 75% completeness requirement is not met, a design value determined using data substitution that is below the NAAQS will not be valid and no conclusion regarding meeting the NAAQS will be possible until more complete data are collected, or data showing a clear violation are collected (unless the discretion provision discussed in the section V.B.4 immediately below is used by the Regional Administrator).

4. Regional Administrator Discretion to Use Incomplete Data

a. Proposal

In the proposed rule, EPA included discussion of the Administrator's discretion to use incomplete data sets within the primary standard section of Appendix P. However, this concept applies equally to the secondary standard. Therefore, EPA considered use of incomplete data sets for the secondary standard as well.

b. Comments

The EPA received no comments specifically about Administrator or Regional Administrator discretion to use incomplete data for the secondary NAAQS. However, EPA has considered how the

comments received regarding Administrator discretion for the primary NAAQS would logically extend to the secondary NAAQS.

c. Conclusions

Given the statistical form of the secondary NAAQS based on the cumulative W126 index and the other final provisions for calculating the design value including the substitution procedure using 0.0025 ppm, the effect of substituting for missing data up to the 75% completeness level is always to reduce the design value compared to what it would have been had enough daytime concentration values been available to reach or exceed the 75% completeness level. Therefore, it is impossible for a completeness level below 75% to cause an area that actually meets the secondary NAAQS to appear to violate it. This is why the final version of Appendix P by its own terms treats as valid any W126 design value greater than the level of the NAAQS regardless of data completeness, making Administrator or Regional Administrator discretion irrelevant.

Discretion or lack of discretion to use an incomplete data set as if it were complete could make a practical difference when the calculated design value is below the level of the NAAQS. When EPA follows the Appendix P procedures strictly, EPA will sometimes not be able to determine that a monitoring site meets the NAAQS, because the design value, although below the level of the NAAQS, is invalid due to one or more months in the three consecutive required monitoring seasons not having data for 75% of the daytime hours in the month. This may not always be a scientifically supportable outcome. For example, in most areas the spring start and fall end months of the required monitoring season typically have lower monthly W126 index values than do the summer months.[62] In the future, it may happen in such an area that the summer months of the required monitoring season meet the 75% completeness requirement and show annual maximum 3-month W126 index values (and a 3-year design

[62]Some of these edge months may be included in the required monitoring season only for reasons of the primary NAAQS, and have no history of high W126 index values.

value) below the level of the secondary NAAQS, but a spring or fall end month of the required monitoring season of one of the 3 years fails to meet the 75% completeness requirement. In such a situation, Administrator or Regional Administrator discretion to use incomplete data on a case-by-case basis could allow scientifically supportable outcomes of two types: (1) the initial designation under the secondary NAAQS for an area that actually meets the NAAQS could be attainment, rather than unclassifiable; and (2) a previously designated nonattainment area for the secondary NAAQS that has improved its air quality enough to actually meet the NAAQS could receive a clean data determination, and thus could be redesignated to maintenance, without having to wait until three additional years of sufficiently complete monitoring data were obtained. While the first alternate outcome would not have regulatory consequences because there are no differential regulatory requirements for unclassifiable and attainment areas, the second alternate outcome could affect costs to industry, government, and the public.

The EPA has considered the comments received on the proposal for Administrator discretion to use incomplete data with respect to the primary NAAQS, as discussed in section V.A.4 above, including the logical extension of those comments to the case of the secondary NAAQS. EPA believes it is in the public interest to allow the Regional Administrator discretion to, in effect, overlook the requirement for having hourly O_3 concentrations for at least 75% of daytime hours in a month that historically has not been part of the period that has produced the highest 3-month W126 index value of the monitoring season. The final rule therefore includes a discretion provision applicable to the secondary standard that matches the wording of the final discretion provision for the primary standard, except for the addition of a requirement for the Regional Administrator to consider the historical pattern of monthly W126 index values at the site. It has been EPA practice to allow a public comment period, announced in the Federal Register, for any official determination that a monitoring site meets a NAAQS if that finding has

regulatory consequences for a state or other party. EPA expects to continue this practice. This comment period will provide transparency to the discretion process.

5. Rounding

a. Proposal

The EPA proposed that all decimal digits be retained in intermediate steps of the calculation of the cumulative W126 index. The proposed text of Appendix P states that "all digits supported by the calculator or calculation software must be retained." The 3-year average of the annual W126 index values would be rounded to have no decimal digits when expressed in ppm-hours before comparison against the level of the secondary NAAQS.

b. Comments

No comments about rounding for the secondary NAAQS in particular were received. EPA did receive comments regarding the accuracy of O_3 monitors and the relationship of the alleged accuracy to the proposed provisions regarding rounding.

c. Conclusions

While no comments about rounding for the secondary NAAQS in particular were received, EPA has considered the logical implications of the comments on the same subject in the context of the primary NAAQS, as discussed in section V.A.5, to the case of the secondary NAAQS. EPA has concluded that retention of six decimal digits after rounding in all the intermediate steps of the calculation of the W126 index is sufficient. The final rule therefore incorporates the same rounding procedures for the secondary NAAQS as for the primary.

The comments about the accuracy of O_3 monitors are identical in substance to those offered during public comment on the review of the NAAQS completed in 2006. These comments are addressed in the "Response to Comments" document in the public docket for this rulemaking.

6. Other Aspects of Data Interpretation

The EPA proposed to add to Appendix P a cross reference to the Exceptional Events Rule (40 CFR 50.14) with regard to the exclusion of monitoring data affected by exceptional events, positioned so as to be applicable to both the primary and secondary NAAQS. This cross reference is included in the final rule. However, since proposal EPA has realized that the proposed Appendix P text did not make clear how the exclusion of data under the Exceptional Events Rule would affect the calculation of a design value for the secondary NAAQS, or how exclusion affects the validity of the design value. The final text of Appendix P provides that if any 1-hour concentration value during daytime hours has been approved for exclusion by EPA under the Exceptional Events Rule, (1) the excluded hourly concentration value is not to be used in the calculation of the daily W126 index, but instead a concentration of 0.0025 ppm will be substituted, (2) the excluded hourly concentration will be treated as a non-missing hour for purposes of the adjustment of the monthly W126 index to reflect 100% completeness, and (3) the excluded hour is treated as a non-missing hour for purposes of the determination of whether the monthly requirement for 75% completeness for daytime hours has been met (and thus whether a design value below the level of the NAAQS is valid). Together, these provisions mean that the final W126 design value will be the same as if 0.0025 ppm had been reported as the actual concentration for the hour. This provides a simple and transparent approach for dealing with exceptional event situations that is consistent with the approach used for the primary NAAQS.

In addition, some passages of the final version of Appendix P relevant to the secondary standard have been re-ordered or have minor wording changes for greater clarity.

C. Exceptional Events

The EPA is finalizing O_3-specific deadlines in 40 CFR 50.14 by which states must flag ambient air data that they believe have been affected by exceptional events and submit initial descriptions of

those events. EPA is also finalizing the deadlines by which states must submit detailed justifications to support the exclusion of those data from EPA's monitoring-based determinations of attainment or nonattainment with the primary and secondary O_3 NAAQS.

Because the final O_3 NAAQS signature and promulgation dates changed from the proposed dates and because the designation schedules for the primary and secondary O_3 standards are now aligned, as discussed in greater detail in section VI, the exceptional events-related schedule has also changed from the proposed dates corresponding to the changes in the designations schedules. The final exceptional events-related schedule also lengthens the state's exceptional events response time from the proposed schedule in an effort to respond to commenters who noted that the proposed schedule for flagging exceptional events was unrealistic.

The Exceptional Events Rule at 40 CFR 50.14 contains generic deadlines for a state to submit to EPA specified information about exceptional events and associated air pollutant concentration data. A state must initially notify EPA that data have been affected by an event by July 1 of the calendar year following the year in which the event occurred. This is done by flagging the data in AQS and providing an initial event description. The state must also, after notice and opportunity for public comment, submit a demonstration to justify any claim within three years after the quarter in which the data were collected. However, if a regulatory decision based on the data (for example, a designation action) is anticipated, the schedule to flag data in AQS and submit complete documentation to EPA for review is shortened, and all information must be submitted to EPA no later than one year before the decision is to be made.

These generic deadlines in the Exceptional Events Rule are suitable after initial designations have been made under a NAAQS or when an area is to be redesignated, either from attainment to nonattainment or from nonattainment to attainment, and the redesignation status may depend on the

excluded data. However, these same generic deadlines may need to be adjusted to accommodate the initial area designation process and schedule under a newly revised NAAQS. Until the level and form of the NAAQS have been promulgated, a state does not know whether the criteria for excluding data (which are tied to the level and form of the NAAQS) were met on a given day. In some cases, the generic deadlines, especially the deadlines for flagging some relevant data, may have already passed by the time the revised NAAQS is promulgated. In addition, it may not be feasible for information on some exceptional events that may affect final designations decisions to be collected and submitted to EPA at least one year in advance of the final designation decision. This scheduling constraint could have the unintended consequence of EPA designating an area nonattainment because of uncontrollable natural or other qualified exceptional events.

The Exceptional Events Rule at section 50.14(c)(2)(vi) indicates "when EPA sets a NAAQS for a new pollutant or revises the NAAQS for an existing pollutant, it may revise or set a new schedule for flagging exceptional event data, providing initial data descriptions and providing detailed data documentation in AQS for the initial designations of areas for those NAAQS."

For the specific case of O_3, the signature date for the reconsidered O_3 NAAQS is July 29, 2011. State/Tribal area designations recommendations will be due by July 27, 2012, and EPA intends to make initial area designations under the reconsidered NAAQS by July 29, 2013. The designation decisions will be informed by air quality data from the years 2008-2010 or 2009-2011 if there are sufficient data for these years. Because final O_3 designations are scheduled to be made by July 29, 2013, all events to be considered during the designations process would need to be flagged and fully documented by states one year prior to designations, or by July 27, 2012 under the generic deadline in the Exceptional Events Rule. The EPA is adopting revisions to 40 CFR 50.14 to change submission dates for information supporting claimed exceptional events affecting O_3 data for initial area designations under this

reconsidered O_3 NAAQS. For air quality data collected in 2008, 2009, or 2010, we propose extending to March 30, 2012, the otherwise applicable generic deadlines of July 1, 2009; July 1, 2010; and July 1, 2011, respectively, for flagging data and providing an initial description of an event. We are similarly proposing to extend to July 27, 2012 the deadline for submitting documentation to justify O_3-related exceptional events occurring in 2008 through 2010. EPA believes these extensions will provide adequate time for states to review the impact of exceptional events from 2008 through 2010 on the revised standard, notify EPA by flagging the relevant data and providing an initial description in AQS, and submitting documentation to support claims for exceptional events.

If a state intends EPA to consider in the O_3 designations decisions whether 2011 O_3 data have been affected by exceptional events, these data must be flagged and detailed event documentation submitted by July 27, 2012.

Therefore, using the authority provided in CAA section 319(b)(2) and in the Exceptional Events Rule at 40 CFR 50.14(c)(2)(vi), EPA is finalizing the schedule for data flagging and submission of demonstrations for exceptional events data considered for initial area designations under the reconsidered O_3 primary and secondary NAAQS as presented in Table 2.

Table 2. Revised Schedule for Exceptional Event Flagging and Documentation Submission for Data to be Used in Initial Area Designations for the 2011 O_3 NAAQS

NAAQS Pollutant/ Standard/(Level)/ Promulgation Date	Air Quality Data Collected for Calendar Year	Event Flagging & Initial Description Deadline	Detailed Documentation Submission Deadline
Primary Ozone 8-Hr Standard (0.070 ppm) Promulgated [insert date of signature]	2008 - 2010	March 30, 2012	July 27, 2012
	2011	July 27, 2012	July 27, 2012

Secondary Ozone (13 ppm-hours) Promulgated [insert date of signature]	2008 - 2010	March 30, 2012	July 27, 2012
	2011	July 27, 2012	July 27, 2012

Note: The table of revised deadlines only applies to data EPA will use to establish the final initial area designations for new NAAQS. The general schedule applies for all other purposes, most notably, for data used by EPA for redesignations to attainment.

VI. Designations Schedule for Primary and Secondary O_3 Standards

A. Overview of Clean Air Act Designations Requirements

After EPA establishes or revises a NAAQS, the CAA directs EPA and the states to take steps to ensure that the new or revised NAAQS are met. The first step is to identify areas of the country as meeting or not meeting the new or revised NAAQS. This step is known as the initial area designations.

The CAA provides that, "By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised national ambient air quality standard for any pollutant under section 109, the Governor of each state shall * * * submit to the Administrator a list of all areas (or portions thereof) in the state" that designates those areas as nonattainment, attainment, or unclassifiable. The CAA specifies that, "The Administrator may not require the Governor to submit the required list sooner than 120 days after promulgating a new or revised national ambient air quality standard." The CAA defines an area as nonattainment if it is violating the NAAQS or if it is contributing to a violation in a nearby area. (See CAA section 107(d)(1).)

The CAA further provides, "Upon promulgation or revision of a national ambient air quality standard, the Administrator shall promulgate the designations of all areas (or portions thereof) * * * as expeditiously as practicable, but in no case later than 2 years from the date of promulgation of the new or revised national ambient air quality standard. Such period may be extended for up to one year in the event the Administrator has insufficient information to promulgate the designations." EPA is required

to notify states of any intended modifications to their recommendations that EPA may deem necessary no later than 120 days prior to promulgating designations. States then have an opportunity to demonstrate why any such proposed modification is inappropriate. Whether or not a state provides a recommendation, EPA must promulgate the designation that the Agency deems appropriate. (See CAA section 107(d)(1)(B).)

B. Proposed Designations Schedules

On September 16, 2009, when the Administrator first announced her decision to reconsider the 2008 O_3 NAAQS, she also indicated that the Agency intended to work with states to accelerate implementation of O_3 standards adopted pursuant to the reconsideration, including the initial area designations process. Acceleration of designations for the primary standard would help limit any delays in health protections associated with the reconsideration of the standards.

With that goal in mind, EPA expressed its intent to promulgate final designations for any new primary O3 NAAQS resulting from the reconsideration on an accelerated schedule to allow the designations to be effective 1 year after the new standard was promulgated. This would require EPA to sign a final decision on designations in approximately 10 and a half months after a final primary NAAQS is signed. In order to meet that schedule, EPA proposed that states would be required to submit their designations recommendations for any new primary standard 129 days after the Administrator signs a final rule promulgating that standard. EPA acknowledged that the proposed deadline for states to submit recommendations would be an ambitious schedule. Therefore, EPA said it intended to provide technical information and guidance for states as early as possible to facilitate the development of their recommendations. EPA noted that many of the areas that would be violating a new primary O_3 standard within the proposed range were also violating the 2008 primary O_3 standard. State Governors previously submitted designation recommendations for those areas pursuant to the 2008 standard and

EPA anticipated those recommendations might not need much further evaluation by the states for purposes of submitting recommendations for a new primary O_3 standard.

For a new secondary standard resulting from the reconsideration that differs from a new primary standard, EPA proposed two alternative deadlines for states to submit their designation recommendations. Under the first alternative, states would be required to make recommendations for the secondary standard on the same accelerated schedule discussed above for the primary standard and EPA would finalize designations on the same one year schedule as for the primary standard. Under the second alternative, EPA would complete designations on a 2-year schedule and states would be required to submit recommendations within 1 year of signature of a new secondary O_3 NAAQS, the maximum time period allowed under the CAA.

EPA stated that weighing in favor of designating areas for the secondary standard on the same 1-year schedule proposed for the primary standard is that planning for both standards would occur on the same schedule. Our examination of air quality data that were current at the time of proposal indicated that for the range of proposed levels for the primary and secondary standards, it was likely that the vast majority of areas violating the secondary standard would overlap with areas violating the primary standard. In this case, implementing requirements for the primary and secondary standards on different schedules could present resource challenges to state and local agencies by requiring duplication of effort and hindering consideration of all factors when deciding which control strategies to adopt for each standard. For example, if designations for the secondary standard did not occur until a year after designations for the primary standard, then attainment SIPs for the secondary standard would likely not be due until a year after attainment demonstration SIPs for the primary standard. Similarly, the initial transportation conformity determination for the secondary standard would be required approximately one year later than the initial determination for the primary standard.

However, weighing in favor of taking the full 2-year period allowed for designating areas for a secondary standard was that EPA had not previously set a seasonal secondary standard for O_3 and neither EPA nor states have experience in implementing this type of standard. Thus, states and EPA would likely need more time to consider the relevant designation factors in the context of this new standard in making designation recommendations and in issuing final designations. EPA questioned whether the proposed alternative accelerated schedule for a seasonal secondary standard would provide adequate time for resolving unanticipated issues that might arise.

In proposing the designations schedules for the primary and secondary NAAQS, EPA also requested comments on whether the designations schedules should be aligned if EPA promulgates a separate, seasonal secondary standard.

C. Public Comments

EPA received numerous comments on the proposed designations schedules from states, state organizations, local air pollution control agencies, regional organizations, industry, environmental organizations, health-related organizations, and the U.S. Department of the Interior. The regional organizations included groups that represent state air agencies, major metropolitan areas, regional councils, counties, regionwide associations of local governments (councils of government), regional planning and development agencies, and metropolitan planning organizations. The commenters identified a variety of concerns regarding what designations schedules would be desirable and feasible.

1. Comments on Designations Schedule for Primary O_3 NAAQS

Comments: The majority of the commenters did not support the proposed accelerated designation schedule for the primary standard. Instead, these commenters expressed support for the full 2-year schedule allowed under the CAA, which would give states up to 1 year to submit their designation recommendations. This group of commenters includes all individual state commenters

except one, all local air pollution control agency commenters, and all industry commenters. A few of these commenters said they appreciated the public health reasons for EPA proposing an accelerated schedule, even though they challenged the feasibility of such a schedule. Comments from regional organizations were mixed. An organization representing western state air agencies, an organization representing regional planning organizations and their local elected officials, and an organization representing counties also supported a 2-year schedule. A national organization representing air pollution control agencies and major metropolitan areas said there would be significant challenges for states in meeting the accelerated designations schedule, especially for new nonattainment areas and rural nonattainment areas. However, an organization representing states in the northeast and mid-Atlantic regions and another organization representing northeast states supported the accelerated schedule. Commenters representing environmental and health-related groups also supported the accelerated schedule.

The commenters who opposed the accelerated schedule gave a variety of reasons why they believed the schedule was too short. Some commenters pointed out that, based on the proposed range for the primary O_3 standard, there would be many more nonattainment areas than ever before. Several added that many areas will be nonattainment for the first time and that some states have limited experience in nonattainment planning. The commenters asserted that four months to submit recommendations does not give sufficient time for states to conduct the detailed technical analyses to support area boundary recommendations. Commenters also said the schedule does not provide sufficient time for meaningful public outreach, for educating and discussing boundary recommendations with elected officials, and for state administrative processes. Some commenters pointed out that some states will need additional time to coordinate with other states, tribes, EPA Regions, and/or other jurisdictions. Many commenters noted that states are facing economic hard times and some have limited

staff, which would make it difficult to meet the accelerated schedule. One state commenter added that even with extraordinary assistance from EPA, if the state had multiple nonattainment areas, it would not have the necessary resources to complete designations recommendations in 129 days. Some commenters said EPA should consider the cumulative workload and resource impacts from implementing other new NAAQS. A number of commenters said additional time is needed to investigate and document exceptional events affecting attainment status. Several commenters argued that the proposed accelerated deadline for states to submit their area recommendations violates the CAA section 107(d)(1)(A) requirement that such date be "reasonably" required. These commenters thought it unreasonable for EPA to conclude what time period would be necessary prior to the time Governors have had the opportunity to review the final NAAQS decision. Some commenters also expressed concern that the accelerated designation schedule would not provide EPA with sufficient time to evaluate the recommendations.

Commenters who supported the accelerated schedule thought it would help minimize delays in public health protections due to reconsideration of the 2008 standard and that it would help maintain momentum in air quality planning. One commenter thought the schedule was a reasonable compromise between the need not to lose momentum and the resource constraints facing federal, state, and local air agencies in developing SIPs. One commenter thought much of the data will have already been collected for purposes of designations for the 2008 standard and could be updated on an expedited schedule for any new standard adopted as a result of the reconsideration.

Response: When EPA proposed the accelerated schedule for the primary standard, it recognized that the schedule would be challenging. EPA believes the commenters who opposed the accelerated schedule raised valid and compelling reasons why 129 days would not be sufficient time for states to make recommendations for a new standard. Decisions on designations and area boundaries set the

foundation for future state air quality planning efforts. Therefore, EPA agrees states should be provided time to conduct the necessary analyses to support their area recommendations. EPA understands that many states will need to coordinate with other jurisdictions as they determine what they believe are appropriate nonattainment area boundaries. EPA also agrees that it is important for states to have sufficient time to work with elected officials and to provide for public outreach. Further, EPA recognizes that state resources may not be adequate to meet an accelerated 4-month schedule to submit recommendations. Based on current air quality data, for the level of the primary standard being established by this rule, there would be a significant number of new O_3 nonattainment areas. While many states have experience in O_3 nonattainment issues, others do not. EPA believes it is important that the Agency set a schedule that accommodates the different levels of expertise among the states. For all of these reasons, EPA agrees that 129 days is not sufficient time for states to develop and submit their recommendations.

EPA also has substantial concerns that signing a final designations rule in approximately 10 and one half months would not provide EPA adequate time to carefully evaluate the significant number of recommendations and determine whether modifications are appropriate.

Therefore, EPA intends to promulgate designations for the primary standard on a 2-year schedule and is requiring states to submit their recommendations to EPA no later than 1 year after signature of the final 2011 O_3 NAAQS rule.

2. Comments on Designations Schedule for Secondary O_3 NAAQS

Comments: For a seasonal secondary standard, EPA proposed two alternative designations schedules: the same accelerated schedule as for the primary standard or a 2-year schedule. As with the schedule for the primary standard, all individual state commenters except one, all local air pollution control agency commenters, and industry commenters supported the 2-year schedule for the secondary

standard. One regional state organization supported the accelerated schedule, while the other regional organizations who commented supported the 2-year schedule. Commenters representing environmental and health-related groups supported the accelerated schedule. The U.S. Department of Interior supported the accelerated schedule for the secondary standard.

The commenters who supported the 2-year designations schedule generally raised the same feasibility issues that were raised regarding the designations schedule for the primary standard. In addition, commenters noted that states have no experience in determining appropriate area boundaries for a seasonal O_3 standard. They reiterated concerns that EPA had expressed at proposal that unanticipated issues may arise that may require additional time to address. Some commenters said it would require analysis of new, non-urban areas that were not evaluated in past nonattainment recommendations. Several commenters pointed out that EPA needs to develop designations guidance for the seasonal standard, especially for rural nonattainment areas.

Commenters who supported the accelerated schedule for the secondary standard generally did so because they believed the designations schedules for the primary and secondary standards should be aligned for air quality planning and efficiency reasons and they either supported the accelerated schedule for the primary standard or they assumed that EPA would finalize the accelerated schedule for the primary standard. A few commenters added that an accelerated schedule would provide protection for our forests and the National Park Service resources sooner.

Response: For the same reasons provided above for the primary standard, EPA believes that 129 days does not provide sufficient time for states to carry out the necessary activities in developing their recommendations for the secondary standard. Because it is likely that the vast majority, if not all, of the areas violating the seasonal secondary standard will overlap with areas violating the primary standard, EPA believes it would be beneficial to designate areas for the primary and secondary standards

on the same schedule. As we noted in the proposal, and as many state and local commenters noted, state resources are limited. It would be a much more efficient use of these limited resources for both designation and implementation planning for the two standards to occur on the same schedule. Therefore, EPA intends to designate areas for the secondary O_3 NAAQS on a 2-year schedule and is requiring states to submit their designation recommendations to EPA no later than 1 year after signature of the final 2011 O_3 NAAQS rule.

3. Comments on Whether to Align Designations Schedules for Primary and Secondary NAAQS

Nearly all of the commenters who weighed in on whether EPA should set the same designation schedule for the primary and secondary O_3 NAAQS supported aligning the designations schedules, in large part for the same reasons EPA raised in the proposal. State commenters, in particular, expressed concerns that different designations schedules would result in additional planning burdens associated with designations and SIP development, which would not be the best use of limited state and local area resources. The majority of these commenters added that the schedule for both standards should be the full 2 years allowed under that CAA rather than the proposed accelerated schedule. One regional state organization agreed that aligning the designations schedules would be helpful, however it supported the accelerated schedule for the primary standard and believed a new seasonal secondary standard would create its own set of issues that would require extra time to address. Some commenters expressed concerns that if the designations process for the primary standard was on the proposed accelerated schedule, designating areas for the secondary standard on the same schedule would not provide adequate time to address public welfare issues and the unique issues related to the secondary standard.

As discussed in the previous section, after considering the public comments, EPA is aligning the designations schedules for the 2011 primary and secondary NAAQS and is requiring states to submit

their designation recommendations to EPA no later than 1 year after signature of the final 2011 O_3 NAAQS rule.

D. Final Decision on Designations Schedules

In this final rule, EPA is setting a new more protective 8-hour primary NAAQS and a new more protective cumulative, seasonal secondary NAAQS. This will result in the largest designations effort that EPA and states have ever faced for O_3 NAAQS. After taking into account the public comments and for the reasons discussed above, EPA intends to designate areas for the primary and secondary O_3 NAAQS on a 2-year schedule from signature of this final O_3 NAAQS rule. EPA is requiring states to submit their designation recommendations to EPA for both the 2011 primary and secondary O_3 NAAQS no later than July 27, 2012, which is 1 year from signature of the 2011 O_3 NAAQS rule. If EPA intends to make any modifications to a state's recommendations, EPA intends to notify the state no later than March 29, 2013. States will then have an opportunity to comment on EPA's intended designations before EPA makes the final designation decisions. EPA intends to sign a final rule promulgating the initial area designations for the 2011 primary and secondary O_3 NAAQS by July 29, 2013.

In the proposal, EPA stated its intention to provide technical information and guidance to states as early as possible to assist states in the development of their recommendations. EPA understands that developing recommendations on appropriate nonattainment area boundaries is a significant effort for states, especially for states with little or no experience in ozone air quality planning. Therefore, EPA plans to offer assistance to states throughout the process on technical and policy-related issues. EPA intends to provide additional designations guidance for the new 2011 O_3 NAAQS in the very near future. Within the next few of weeks, EPA will be launching a new O_3 designations webpage for the 2011 NAAQS that will provide information and data sources relevant to making designations decisions. A link for that webpage will be included on the general O_3 designations website at

www.epa.gov/ozonedesignations. EPA encourages states to consult with their EPA Regional Office as states develop their area recommendations.

While CAA section 107, which governs the process for initial area designations, specifically addresses states, EPA intends to follow the same process for tribes to the extent practicable, pursuant to section 301(d) of the CAA regarding tribal authority and the Tribal Authority Rule (63 FR 7254; February 12, 1998). EPA is working with the tribes and tribal organizations on designations issues and intends to develop guidance and training to help tribes participate in the designations process.

E. Termination of Designations Process for 2008 O_3 NAAQS

As discussed above, EPA has reconsidered the 2008 O_3 NAAQS and determined that different standards are necessary to provide requisite protection of public health and welfare, respectively. Because the O_3 NAAQS reconsideration rulemaking action is a reconsideration of the 2008 O_3 NAAQS, rather than a new periodic NAAQS review under CAA section 109(d)(1), a decision to promulgate different standards results in a full replacement of the 2008 O_3 NAAQS. That is, our decision under the reconsideration to promulgate standards different than the 2008 standards and based on the record that was before us at the time we promulgated the 2008 NAAQS, is an express recognition that the 2008 NAAQS were not supported by that record and thus were invalidly promulgated. As a result, implementation requirements associated with the 2008 NAAQS, including area designations, no longer exist. Therefore, all obligations and activities to designate areas for the now invalid 2008 O_3 NAAQS and all state obligations to implement that NAAQS are terminated by this final rule promulgating the 2011 primary and secondary ozone NAAQS.

VII. Ambient Monitoring Related to Primary and Secondary O_3 Standards

Presently, States (including the District of Columbia, Puerto Rico, and the Virgin Islands, and including local agencies when so delegated by the State) are required to operate minimum numbers of EPA-approved O_3 monitors based on the population of each of their Metropolitan Statistical Areas (MSA) and the most recently measured O_3 levels in each area. Each State (or in some cases portions of a State) also has a required O_3 monitoring season based on historical experience on when O_3 levels are high enough to be of regulatory or public health concern. These requirements are contained in 40 CFR part 58 Appendix D, Network Design Criteria for Ambient Air Quality Monitoring. See section 4.1, especially Tables D–2 and D–3. These requirements were last revised on October 17, 2006 as part of a comprehensive review of ambient monitoring requirements for all criteria pollutants (71 FR 61236).

A. Background

In the 2007 proposed rule for the O_3 NAAQS (72 FR 37818), EPA did not propose specific changes to monitoring requirements to support the proposed NAAQS revisions, but instead solicited comment on several key matters that were expected to be important issues affecting the potential redesign of monitoring networks if revisions to the NAAQS were finalized. These matters included O_3 monitoring requirements in urban areas, the potential need for monitoring to support multiple objectives important to characterization in non-urban areas including the support of the secondary O_3 NAAQS, and the length of the required O_3 monitoring seasons. Comments on these monitoring issues were received during the ensuing public comment period, and these comments were summarized in the 2008 final rule for the O_3 NAAQS (73 FR 16501). As noted in that action, EPA stated its intention to propose, in a separate rulemaking, the specific changes to O_3 monitoring requirements that were deemed necessary to support the 2008 O_3 NAAQS which set the level of the primary 8-hour O_3 standard to 0.075 ppm and set the secondary standard identical in all respects to the primary standard. EPA published these proposed changes to O_3 monitoring requirements in a proposal dated July 16, 2009, Ambient Ozone Monitoring

Regulations: Revisions to Network Design Requirements (74 FR 34525). As noted below, EPA is finalizing some of these changes in an O_3 monitoring rule that is being published today in a separate action.

In the following sections, the specific provisions of the 2009 O_3 monitoring proposal are briefly reviewed, and then discussed in the context of the final decisions on the primary and secondary O_3 NAAQS in section II.D and IV.E, respectively, above in this notice. During the comment period on the 2010 proposed reconsideration of the O_3 NAAQS, EPA received some comments that pertained to ambient O_3 monitoring. EPA provided a summary of the monitoring proposal for the convenience of the readers but did not re-open or seek comment on the monitoring proposal. EPA believes that comments on the O_3 monitoring proposal are outside the scope of this particular rulemaking. However, in this particular instance, because of the interplay between the monitoring proposal and the NAAQS proposal, EPA has considered and addressed relevant comments in the final O_3 monitoring rule being published today.

B. Urban Monitoring Requirements

As noted earlier, current O_3 monitoring requirements for urban areas are based on two factors: MSA population and the most recent 3-year design value concentrations within each MSA. There are higher minimum monitoring requirements for areas that have most recent design values greater than or equal to 85 percent of the NAAQS (i.e., design value concentrations that are greater than or equal to 85 percent of the level of the NAAQS), and lower requirements for areas that have design values less than 85 percent of the NAAQS. These minimum monitoring requirements for O_3 were revised during the 2006 monitoring rulemaking to ensure that additional monitors would be required in areas with higher design values and to also ensure that these requirements would remain applicable through future NAAQS reviews and potential revisions of the standards. Accordingly, the 85 percent threshold will be

applied to the final primary standard level of 0.070 ppm O_3, 8-hour average and the secondary standard level of 13 ppm-hours O_3.[63] With the level of the primary standard set at 0.070 ppm, the level of the 85 percent threshold that requires greater minimum monitoring requirements is 0.060 ppm. With the level of the secondary standard set at 13 ppm-hours, the level of the 85 percent threshold that requires greater minimum monitoring requirements is 11 ppm-hours.

EPA did propose one change to urban monitoring requirements in the 2009 O_3 monitoring proposal. Specifically, EPA proposed to modify the minimum O_3 monitoring requirements to require one monitor to be placed in MSAs of populations ranging from 50,000 to less than 350,000 in situations where there is no current monitor and no history of O_3 monitoring within the previous 5 years indicating a design value of less than 85 percent of the NAAQS.[64] As noted in the O_3 monitoring final rule, EPA is not finalizing this proposed change in network design requirements. The Agency is considering alternative schedules for considering these changes in future actions, such as re-proposing the network design revisions as part of the ongoing 5-year review cycle of the O_3 NAAQS that commenced in 2009, or as part of a future stand-alone rulemaking devoted to ambient monitoring.

C. Non-Urban Monitoring Requirements

In the 2007 proposed rule for the O_3 NAAQS, EPA solicited comment on the status of monitoring requirements for non-urban areas, specifically whether non-urban areas with sensitive vegetation that are only currently sparsely monitored for O_3 could experience undetected violations of the secondary NAAQS as a result of transport from urban areas with high precursor emissions and/or O_3 concentrations or from formation of additional O_3 from precursors emitted from sources outside urban areas.

[63] The requirements specified in Table D-2 of Appendix D to part 58, as noted in the third footnote of Table D-2, are applicable to the levels of the O_3 NAAQS as defined in 40 CFR part 50. Accordingly, the 85 percent threshold for requiring higher minimum monitoring requirements within MSAs applies to the level of the cumulative, seasonal secondary standard as well as to the level of the 8-hour primary standard.
[64] These MSAs are not currently required to monitor for O_3.

Comments that were received in response to the 2007 O_3 NAAQS proposal noted the voluntary nature of most non-urban O_3 monitoring and the resulting relative lack of non-urban O_3 monitors in some areas. These commenters stated that EPA should consider adding monitoring requirements to support the secondary NAAQS by requiring O_3 monitors in locations that contain O_3-sensitive plants or ecosystems. These commenters also noted that the placement of current O_3 monitors may not be appropriate for evaluating issues such as vegetation exposure since many of these monitors were likely located to meet other objectives.

Based on these comments as well as analyses of O_3 concentrations from discretionary non-urban monitors located across the U.S, EPA included new proposed non-urban O_3 monitoring requirements in the 2009 O_3 monitoring proposal. These proposed requirements were intended to satisfy several important objectives including: (1) better characterization of O_3 concentrations to which O_3-sensitive vegetation and ecosystems are exposed in rural/remote areas to ensure that potential secondary NAAQS violations are measured; (2) assessment of O_3 concentrations in smaller communities located outside of the larger urban MSAs covered by urban monitoring requirements; and (3) the assessment of the location and severity of maximum O_3 concentrations that occur in non-urban areas and may be attributable to upwind urban sources.

As noted in the O_3 monitoring final rule, EPA is not finalizing this proposed change in network design requirements. The Agency is considering alternative schedules for considering these changes in future actions, such as re-proposing the network design revisions as part of the ongoing 5-year review cycle of the O_3 NAAQS that commenced in 2009, or as part of a future stand-alone rulemaking devoted to ambient monitoring.

D. Revisions to the Length of the Required O_3 Monitoring Seasons

Ozone monitoring is only required during the seasons of the year that are conducive to O_3 formation. In some locations, conditions conducive to O_3 formation are limited to a few summer months of the year while in other locations these conditions occur year-round. As a result, the length of currently required O_3 monitoring seasons can vary from a length of 4 months in colder climates to a length of 12 months in warmer climates.

The 2009 O_3 monitoring proposal also addressed the issue of whether the required O_3 monitoring season should be made longer in some areas. The proposal also addressed the status of any currently effective Regional Administrator-granted waiver approvals to O_3 monitoring seasons, and the impact of proposed changes to monitoring requirements on such waiver approvals.

The EPA performed several analyses in support of proposed changes to the required O_3 monitoring seasons. The first analysis determined the number of observed exceedances of the 0.075 ppm level of the 2008 8-hour NAAQS in the months falling outside the currently required local O_3 monitoring season using monitors in areas that collected O_3 data year-round in 2004–2006. The second analysis examined observed occurrences of daily maximum 8-hour O_3 averages of at least 0.060 ppm. This threshold was chosen because it represented 80 percent of the 2008 0.075 ppm NAAQS level and provides an indicator of ambient conditions that may be conducive to the formation of O_3 concentrations that approach or exceed the NAAQS. While proposals for revising each State's required monitoring season were based on observed data in and surrounding each State, statistically predicted exceedances were also used to validate conclusions for each State.

The aforementioned analyses provided several results. The analysis of observed exceedances of the 0.075 ppm level of the 2008 O_3 NAAQS indicated occurrences in eight States during months outside of the current required monitoring season. The eight States were Maine, Massachusetts, New Hampshire, New Jersey, New York, South Carolina, Vermont, and Wyoming. With the exception of

Wyoming, these exceedances occurred in a very limited manner and timeframe, just before the beginning of these States' required O_3 monitoring season (beginning in these States on April 1). The frequency of observed occurrences of maximum 8-hour average O_3 levels of at least 0.060 ppm was quite high across the country in months outside of the current required monitoring season. A total of 32 States experienced such occurrences; 22 States had such levels only before the required monitoring season; 9 States had such levels both before and after the required monitoring season; and 1 State had such levels only after the required monitoring season. In a number of cases, the frequency of such ambient concentrations was high, with some States experiencing between 31 to 46 out-of-season days during 2004 to 2006 at a high percentage of all operating year-round O_3 monitors.

Based on these analyses, EPA proposed a lengthening of the O_3 monitoring season requirements in many areas. The 2009 proposed changes were based not only on the goal of monitoring out-of-season O_3 NAAQS violations but also on the goal of ensuring monitoring when ambient O_3 levels approach the NAAQS so that people who are unusually sensitive to O_3 could be alerted to potential NAAQS exceedances.

The EPA believes that the factors used to support the 2009 proposed changes to O_3 monitoring seasons are appropriate to support the primary and secondary O_3 NAAQS promulgated in this final rule. With regard to the primary standard, we note that the revised 8-hour level of 0.070 ppm is higher than the 0.060 ppm level that was utilized in one of the analyses discussed above. Therefore, since EPA finalized the level of the primary standard at a level above 80 percent of the 2008 NAAQS, the O_3 monitoring seasons that have been proposed as part of the 2009 O_3 monitoring proposal would provide sufficient monitoring coverage to ensure the goal of measuring potential violations of the revised primary standard. EPA is finalizing changes to the required O_3 monitoring seasons in a final rulemaking being published today as part of a separate action.

VIII. Statutory and Executive Order Reviews

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

Under section 3(f)(1) of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is an "economically significant regulatory action" because it is likely to have an annual effect on the economy of $100 million or more. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011) and any changes made in response to OMB recommendations have been documented in the docket for this action.

In addition, EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis is contained in the *Final Ozone NAAQS Regulatory Impact Analysis, March 2008* (henceforth, "RIA"). A copy of the analysis is available in the RIA docket (EPA-HQ-OAR-2007-0225) and the analysis is briefly summarized here. The RIA estimates the costs and monetized human health and welfare benefits of attaining the 2008 standard and three alternative O_3 standards nationwide. Specifically, the RIA examines the 2008 O_3 standard of 075 ppm, and the alternative standards of 0.070 ppm, 0.065 ppm, and 0.060 ppm. The RIA contains illustrative analyses that consider a limited number of emissions control scenarios that States and Regional Planning Organizations might implement to achieve these alternative O_3 NAAQS. In addition, EPA prepared a supplemental analysis of the potential costs and benefits associated with the 2010 reconsideration. This analysis is contained in the *Regulatory Impact Analysis (RIA) for the Reconsideration of the 2008 Ozone National Ambient Air Quality Standard (NAAQS)*. A copy of the supplemental analysis is available in the RIA docket (EPA-HQ-OAR-2007-0225). This supplement to the RIA contains an updated illustrative analysis of the

potential costs and human health and welfare benefits of nationally attaining a new primary O_3 standard of 0.070 ppm. However, the CAA and judicial decisions make clear that the economic and technical feasibility of attaining ambient standards are not to be considered in setting or revising NAAQS, although such factors may be considered in the development of State plans to implement the standards. Accordingly, although a RIA has been prepared, the results of the RIA have not been considered in issuing this final rule.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. Burden is defined at CFR 1320.3(b). There are no information collection requirements directly associated with the establishment of a NAAQS under section 109 of the CAA.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) a small business that is a small industrial entity as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any requirements on small entities. Rather, this rule establishes national standards for allowable concentrations of O_3 in ambient air as required by section 109 of the CAA. *American Trucking Assn v. EPA,* 175 F. 3d 1027, 1044-45 (D.C.cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities).

D. Unfunded Mandates Reform Act

This final rule contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act (UMRA) 2 U.S.C. 1531-1538 for State, local, or Tribal governments or the private sector. The rule imposes no enforceable duty on any State, local or Tribal governments or the private sector. Furthermore, as indicated previously, in setting a NAAQS EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards, although such factors may be considered to a degree in the development of State plans to implement the standards. *See also American Trucking Ass'ns v. EPA*, 175 F. 3d at 1043 (noting that because EPA is precluded from considering costs of implementation in establishing NAAQS, preparation of a Regulatory Impact Analysis pursuant to the Unfunded Mandates Reform Act would not furnish any information which the court could consider in reviewing the NAAQS). Therefore, this rule is not subject to the requirements of sections 202 and 205 of the UMRA. This action is also not subject to the requirements of Section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132: Federalism

This final rule does not have federalism implications. Within the meaning of the Executive Order, it will not have substantial direct effects on the States, on the relationship between the national

government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The rule does not alter the relationship between the Federal government and the States regarding the establishment and implementation of air quality improvement programs as codified in the CAA. Under section 109 of the CAA, EPA is mandated to establish NAAQS; however, CAA section 116 preserves the rights of States to establish more stringent requirements if deemed necessary by a State. Furthermore, this rule does not impact CAA section 107 which establishes that the States have primary responsibility for implementation of the NAAQS. Finally, as noted in section E (above) on UMRA, this rule does not impose significant costs on State, local, or Tribal governments or the private sector. Thus, Executive Order 13132 does not apply to this rule. EPA specifically solicited additional comment on the proposed rule from State and local officials. Comments from State and local officials on the proposed rule are summarized in the Response to Comments document.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This final rule does not have Tribal implications, as specified in Executive Order 13175 65 FR 67249, November 9, 2000). Within the meaning of the Executive Order, it does not have a substantial direct effect on one or more Indian Tribes, since Tribes are not obligated to adopt or implement any NAAQS. Thus, Executive Order 13175 does not apply to this rule.

Although Executive Order 13175 does not apply to this rule, EPA contacted Tribal officials during the development of this rule. EPA staff participated in the regularly scheduled Tribal Air call sponsored by the National Tribal Air Association during the spring of 2007 as the proposal was under development. EPA specifically solicited additional comment on the proposed rule from Tribal officials. Comments from Tribal officials on the proposed rule are summarized in the Response to Comments document.

G. Executive Order 13045: Protection of Children from Environmental Health & Safety Risks

This final rule is subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is an economically significant regulatory action as defined by Executive Order 12866, and EPA believes that the environmental health risk addressed by this action may have a disproportionate effect on children. Accordingly, we have evaluated the environmental health or safety effects of exposure to O_3 pollution among children. Setting the O_3 standard at 0.070 ppm will have a significant beneficial effect on all children, especially asthmatic children. These effects and the size of the population affected are summarized in section 8.7 of the 2006 Criteria Document and section 3.6 of the 2007 Staff Paper, and the results of our evaluation of the effects of O_3 pollution on children are discussed in sections II.A-C of this preamble.

H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution or Use

This action is not a "significant energy action" as defined in Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)) because in the Agency's judgment it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this rule is to establish revised NAAQS for O_3. The rule does not prescribe specific pollution control strategies by which these ambient standards will be met. Such strategies will be developed by States on a case-by-case basis, and EPA cannot predict whether the control options selected by States will include regulations on energy suppliers, distributors, or users. Thus, EPA concludes that this rule is not likely to have any adverse energy effects and does not constitute a significant energy action as defined in Executive Order 13211.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law No. 104-113, §12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards

in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

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

The EPA considers issues and concerns related to Environmental Justice consistent with Executive Order 12898, *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, Feb. 16, 1994), existing environmental and civil rights laws and their implementing regulations, and the Agency's environmental justice policies. To the greatest extent practicable and permitted by law, EPA makes environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority, low-income, and indigenous populations in the United States.

The EPA has determined that this final rule will not have new disproportionately high and adverse human health or environmental effects on minority, low-income, or indigenous populations nor will it adversely affect the current level of protection provided to human health or the environment of these populations. That is because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. This final rule will

establish uniform national standards for O_3 air pollution.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. A major rule cannot take effect until 60 days after it is published in the Federal Register. This action is a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective **[insert date 60 days after publication in the Federal Register]**.

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List of Subjects in 40 CFR Parts 50 and 58

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

Environmental protection, Air pollution control, Air quality surveillance and data reporting, Ambient air quality monitoring network design and siting, Intergovernmental
relations, pollutant standards index, Quality assurance program.

_____
Dated:

_____
Lisa P. Jackson, Administrator

For the reasons stated in the preamble, Title 40, Chapter I of the code of Federal regulations is amended as follows:

PART 50--NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

1. The authority citation for part 50 continues to read as follows:

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

2. Table 1 in Section 50.14(c)(2)(vi) is revised to read as follows:

§ 50.14 Treatment of air quality monitoring data influenced by exceptional events.

* * * * *

(c) ***

(2) ***

(vi) ***

Table 1. Special Schedules for Exceptional Event Flagging and Documentation Submission for Data to be Used in Initial Designations for New or Revised NAAQS

NAAQS Pollutant/ Standard/(Level)/ Promulgation Date	Air Quality Data Collected for Calendar Year	Event Flagging & Initial Description Deadline	Detailed Documentation Submission Deadline
$PM_{2.5}$/24-Hr Standard (35 μg/m^3) Promulgated October 17, 2006.	2004-2006	October 1, 2007	April 15, 2008
NO_2/1-Hr Standard (100 ppb) Promulgated February 9, 2010.	2008	July 1, 2010	January 22, 2011
	2009	July 1, 2010[a]	January 22, 2011
	2010	April 1, 2011	July 1, 2011
SO_2/1-Hr Standard (75 ppb) Promulgated June 22, 2010.	2008	October 1, 2010	June 1, 2011
	2009	October 1, 2010	June 1, 2011
	2010	June 1, 2011	June 1, 2011
	2011	60 days after the end of the calendar quarter	60 days after the end of the calendar quarter in

		in which the event occurred or March 31, 2012, whichever date occurs first.	which the event occurred or March 31, 2012, whichever date occurs first.
Primary Ozone/8-Hr Standard (0.070 ppm) Promulgated [insert date of signature]	2008 – 2010	March 30, 2012	July 27, 2012
	2011	July 27, 2012	July 27, 2012
Secondary Ozone (13 ppm-hours) Promulgated [insert date of signature]	2008 – 2010	March 30, 2012	July 27, 2012
	2011	July 27, 2012	July 27, 2012

[a] This date is the same as the general schedule in 40 CFR 50.14.

Note: The table of revised deadlines only applies to data EPA will use to establish the final initial area designations for new NAAQS. The general schedule applies for all other purposes, most notably, for data used by EPA for redesignations to attainment.

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3. Section 50.15 is revised to read as follows:

§ 50.15 National primary and secondary ambient air quality standards for ozone.

(a) The level of the national 8-hour primary ambient air quality standard for ozone (O_3) is 0.070 parts per million (ppm), daily maximum 8-hour average, measured by a reference method based on appendix D to this part and designated in accordance with part 53 of this chapter or an equivalent method designated in accordance with part 53 of this chapter.

(b) The 8-hour primary O_3 ambient air quality standard is met at an ambient air quality monitoring site when the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentration is less than or equal to 0.070 ppm, as determined in accordance with appendix P to this part.

(c) The level of the national secondary ambient air quality standard for O_3 is 13 ppm-hours for a 3-month cumulative weighted index (W126) that is calculated using O_3 concentrations measured by a

reference method based on appendix D to this part and designated in accordance with part 53 of this chapter. The cumulative weighted index (W126) is the rolling 3-month sum of weighted hourly concentrations, cumulated over the 12-hour daytime period from 8:00 a.m. to 8:00 p.m. local standard time.

(d) The secondary O_3 standard is met at an ambient air quality monitoring site when the average of the annual maximum 3-month cumulative index values (W126) from three consecutive calendar years, as determined in accordance with appendix P to this part, is less than or equal to 13 ppm-hours.

4. Appendix P to part 50 is revised to read as follows:

Appendix P to Part 50 -- Interpretation of the Primary and Secondary National Ambient Air Quality Standards for Ozone

1. *General*

(a) This appendix explains the data handling conventions and computations necessary for determining whether the 8-hour primary and the secondary national ambient air quality standards (NAAQS) for ozone (O_3) specified in §50.15 are met at an ambient O_3 air quality monitoring site. Ozone is measured in the ambient air by a federal reference method (FRM) based on Appendix D of this part, as applicable, and designated in accordance with part 53 of this chapter, or by a federal equivalent method (FEM) designated in accordance with part 53 of this chapter. Data reporting, data handling, and computation procedures to be used in making comparisons between reported O_3 concentrations and the levels of the O_3 standards are specified in the following sections.

(b) Whether to exclude, retain, or make adjustments to the data affected by exceptional events, including stratospheric O_3 intrusion and other natural events, is determined by the requirements under §50.1, §50.14 and §51.930.

(c) The terms used in this appendix are defined as follows:

8-hour average is the rolling average of eight hourly O_3 concentrations as explained in section 3 of this appendix.

Annual fourth-highest daily maximum refers to the fourth-highest value measured at a monitoring site during a particular year.

Annual Cumulative W126 Index is the maximum sum of the monthly W126 index over any three consecutive calendar months in the year, as explained in section 4 of this appendix.

Daily maximum 8-hour average concentration refers to the maximum calculated 8-hour average for a particular day as explained in section 3 of this appendix.

Daily W126 Index (D.I.) is the sum of the sigmoidally weighted hourly O_3 concentrations during the 12-hour daytime period, 8:00 a.m. to 8:00 p.m. local standard time (LST), as explained in section 4 of this appendix.

Design values are the metrics (i.e., statistics) that are compared to the primary and secondary NAAQS levels to determine compliance, calculated as shown in sections 3 and 4 of this appendix.

Monthly W126 Index (M.I.) is the sum of the daily W126 index over one calendar month during the calendar year, adjusted for incomplete data if appropriate, as explained in section 4 of this appendix.

Required O_3 monitoring season refers to the span of time within a calendar year when individual States are required to measure ambient O_3 concentrations as listed in part 58 Appendix D to this chapter.

Year refers to calendar year.

2. *Requirements for Data Used for Comparisons with the Ozone NAAQS*

(a) *Data to be Used*

All valid FRM/FEM O_3 data submitted to EPA's Air Quality System (AQS), or otherwise available to EPA, meeting the requirements of part 58 of this chapter including appendices A, C, and E shall be used in design value calculations.

(b) *Use of Data from Multiple Monitors at One Site*

(i) Data from two or more monitors from the same year at the same site that have been reported to EPA under distinct Pollutant Occurrence Codes (POCs) shall not be combined when calculating the design value for the primary or secondary O_3 NAAQS.

(ii) Data from two or more monitors from different years at the same site that have been reported to EPA under distinct Pollutant Occurrence Codes (POCs) may be combined as follows when calculating the design value for the primary or secondary O_3 NAAQS.

(A) For the primary O_3 NAAQS, EPA will combine annual 4^{th} highest daily maximum 8-hour concentration values from different monitors in different years, if reported under distinct POCs, for the purpose of developing a valid primary standard design value using the procedures described in section 3. The annual 4^{th} highest daily maximum 8-hour concentration values to be combined shall be selected as described here. For each year, select for use in the 3-year design value the annual 4^{th} highest daily maximum 8-hour concentration value that came from the data set from the distinct POC that has the highest number of days in the required O_3 monitoring season for which there are at least 18 8-hour periods in the day having at least six measured hourly average concentrations. In calculating this number of days, include hourly concentrations that have been approved under 40 CFR 50.14 as having been affected by exceptional events.

(B) For the secondary O_3 NAAQS, EPA will combine annual W126 index values from different monitors in different years, if reported under distinct POCs, for the purpose of developing a valid secondary standard design value using the procedures described in section 4. The annual W126 index

values to be combined shall be selected as described here. For each year, select for use in the 3-year design value the annual W126 index value that came from the data set from the distinct POC that has the highest number of daytime hours with valid measurements during the required O_3 monitoring season. In calculating this number of daytime hours, include hourly concentrations that have been approved under 40 CFR 50.14 as having been affected by exceptional events.

(iii) This paragraph does not prohibit a monitoring agency from making a local designation of one of two or more physical monitors as the primary monitor for generating the O_3 concentration data reported under a particular POC at a particular monitoring site. Hourly O_3 concentration data from a second (or third, etc.) physical monitor at the same site (normally reporting under a different POC) may be substituted whenever a valid concentration value is not obtained from the primary monitor. If a monitoring agency substitutes data in this manner, each substituted value must be accompanied by an AQS quality assurance flag indicating that substitution with a value from a second physical monitor has taken place.

(c) Hourly average concentrations shall be reported in parts per million (ppm) to the third decimal place, with additional digits to the right of the third decimal place truncated. Each hour shall be identified using local standard time (LST).

3. *Comparison to the Primary Ozone NAAQS*

(a) *Computing 8-hour Averages*

(i) Running 8-hour averages shall be computed from the hourly O_3 concentration data for each hour of the year and shall be stored in the first, or start, hour of the 8-hour period. In the event that only 6 or 7 hourly O_3 concentrations are available, the valid 8-hour average shall be computed on the basis of the hours available, using 6 or 7 as the divisor. In the event that only 1, 2, 3, 4, or 5 hourly O_3 concentrations are available, the 8-hour average shall be computed on the basis of substituting 0.0025 ppm for all the

hours without hourly concentrations, using 8 as the divisor. The computed 8-hour average O_3 concentrations shall be rounded to 6 decimal digits. Values greater than or equal to 0.XXXXXX5 ppm shall be rounded up.

(ii) Measured hourly average O_3 concentrations that have been approved under 40 CFR 50.14 as having been affected by exceptional events for the purposes of the 8-hour NAAQS shall not be used in the calculation of any 8-hour average concentration. Such hours shall be counted toward the data completeness requirement in section 3(d)(ii), but shall be interpreted as missing or unavailable hourly concentrations for the purpose of calculating an 8-hour average concentration and shall be substituted in accordance with section (3)(a)(i) if the exclusion results in there being only five or fewer retained hourly concentrations for the 8-hour period.

(b) *Daily Maximum 8-hour Average Concentrations*

There are 24 8-hour periods that start in each calendar day. The daily maximum 8-hour concentration for a given calendar day is the highest of the 8-hour average concentrations computed for 8-hour periods that start in that day. This process is repeated, yielding a daily maximum 8-hour average O_3 concentration for each day with ambient O_3 monitoring data, including days outside the required O_3 monitoring season if data are available. The daily maximum 8-hour concentrations from two consecutive days may have some hourly concentrations in common. Generally, overlapping daily maximum 8-hour averages are not likely, except in those non-urban monitoring locations with less pronounced diurnal variation in hourly concentrations or with a pronounced diurnal pattern that peaks at night due to transport lag time. In these cases, the maximum 8-hour average concentration from each day is used, even if the two averages have some hours in common.

(c) *Primary Standard Design Value*

The primary standard design value is the annual fourth-highest daily maximum 8-hour O_3 concentration considering all days with monitoring data including any days outside the required O_3 monitoring season, expressed in parts per million, averaged over three years. The 3-year average shall be computed using the three most recent, consecutive years of monitoring data that can yield a valid design value. For a design value to be valid for comparison to the standard, the monitoring data on which it is based must meet the data completeness requirements described in section 3(d). The computed 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentrations shall be rounded to three decimal places. Values greater than or equal to 0.XXX5 ppm shall be rounded up.

(d) *Data Completeness Requirements for a Valid Primary Standard Design Value*

(i) A primary standard design value greater than the primary O_3 NAAQS is always valid.

(ii) A primary standard design value less than or equal to the primary O_3 NAAQS is valid if for at least 75% of the days in the required O_3 monitoring season in each of the three years there are at least 18 8-hour periods in the day for which there are at least six measured hourly average concentrations, including hourly concentrations that have been approved under 40 CFR 50.14 as having been affected by an exceptional event and excluding missing (unreported) hourly concentrations for which substituted values were used under section 3(a)(i).

(iii) When computing whether the minimum data completeness requirement in section 3(d)(ii) has been met for the purpose of showing that a design value equal to or less than the standard is valid, meteorological or ambient data may be sufficient to demonstrate that O_3 levels on days with missing data would not have affected the design value. The Regional Administrator may consider demonstrations that on one or more days in the required O_3 monitoring season which do not have sufficiently complete data, local meteorological conditions could not have caused a daily maximum 8-hour concentration high enough to have been one of the four highest daily maximum 8-hour

concentrations for the year. At the request of the state, days so demonstrated may be counted toward the 75% requirement for the purpose of validating the design value, subject to the approval of the Regional Administrator.

(iv) Data that do not meet the completeness criteria stated in 3(d)(ii) may nevertheless be used to calculate a design value that will be deemed valid with the approval of, or at the initiative of, the Regional Administrator, who shall consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, and nearby concentrations in determining whether to use such data.

(e) *Comparison with the Primary Ozone NAAQS*

(i) The primary O_3 ambient air quality standard is met at an ambient air quality monitoring site when the design value is less than or equal to 0.070 ppm.

(ii) Comparison with the primary O_3 standard is demonstrated in examples 1 and 2 below:

Example 1: Ambient monitoring site attaining the primary O_3 NAAQS

Year	Percent Valid Days (Within the Required Monitoring Season)	1st Highest Daily Max 8-hour Conc. (ppm)	2nd Highest Daily Max 8-hour Conc. (ppm)	3rd Highest Daily Max 8-hour Conc. (ppm)	4th Highest Daily Max 8-hour Conc. (ppm)	5th Highest Daily Max 8-hour Conc. (ppm)
2006	80%	0.092500	0.090375	0.085125	0.058375	0.058125
2007	96%	0.084750	0.083500	0.075375	0.051875	0.050625
2008	98%	0.080875	0.079750	0.077625	0.055500	0.040375
Average					0.055250	
Rounded					0.055	

As shown in Example 1, this monitoring site meets the primary O_3 standard because the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentrations (i.e., 0.055250 ppm, rounded to 0.055 ppm) is less than or equal to 0.070 ppm. The data completeness requirement is also met because no single year has less than 75% data completeness. The individual 8-hour averages are rounded to six decimal digits and the 3-year average is rounded to three decimal digits.

Example 2: Ambient monitoring site failing to meet the primary O_3 NAAQS

Year	Percent Valid Days (Within the Required Monitoring Season)	1st Highest Daily Max 8-hour Conc. (ppm)	2nd Highest Daily Max 8-hour Conc. (ppm)	3rd Highest Daily Max 8-hour Conc. (ppm)	4th Highest Daily Max 8-hour Conc. (ppm)	5th Highest Daily Max 8-hour Conc. (ppm)
2006	96%	0.105125	0.103500	0.101125	0.078625	0.072375
2007	74%	0.104250	0.103625	0.093000	0.080250	0.069500
2008	98%	0.103125	0.101875	0.101750	0.075375	0.074625
Average					0.078083	
Rounded					0.078	

As shown in Example 2, the data capture in 2007 is less than 75%. The primary O_3 standard is not met for this monitoring site because the 3-year average of the fourth-highest daily maximum 8-hour average O_3 concentrations (i.e., 0.078083 ppm, rounded to 0.078 ppm) is greater than 0.070 ppm and is therefore valid despite this incompleteness. The individual 8-hour averages are rounded to 6 decimal digits and the 3-year average is rounded to three decimal digits.

4. *Comparison to the Secondary Ozone NAAQS*

(a) *Computing the Daily W126 Index Value*

The level of the national secondary ambient air quality standard for O_3 is 13 ppm-hours for a 3-month cumulative weighted index (W126) that is calculated using hourly O_3 concentrations. The cumulative weighted index (W126) is the rolling 3-month sum of weighted hourly concentrations, cumulated over the 12-hour daytime period from 8:00 a.m. to 8:00 p.m. local standard time. Hourly ambient O_3 measurements are compared with the secondary standard using a design value called the W126 statistic. The first step in determining whether the secondary standard is met at a monitoring site is to compute the Daily W126 Index (D.I.) value. The D.I. is calculated for all days with monitoring data including

any days outside the required O_3 monitoring season. The weighted hourly concentrations are obtained by applying the sigmoidal weighting function in Equation 1 to each measured hourly concentration.[65]

Equation 1

$$D.I. = \sum_{i=8a.m.}^{i=7p.m.} w_{c_i} C_i$$

where C_i = hourly O_3 concentration in ppm for hour starting at time i, and

$$w_c = \frac{1}{1 + 4403e^{-126C}}$$

The computed values of the sigmoidally weighted hourly concentrations shall be rounded to six decimal digits. Values greater than or equal to 0.XXXXXX5 shall be rounded up. The D.I. is formed by summing the twelve weighted hourly concentrations, retaining all six decimal digits. Example 3 below illustrates the computation of a D.I. value:

Example 3: D.I. value calculation for an ambient O_3 monitoring site

Start of hour	Concentration (ppm)	Weighted Concentration (ppm)
8:00 a.m.	0.045	0.002781
9:00 a.m.	0.060	0.018218
10:00 a.m.	0.075	0.055701
11:00 a.m.	0.080	0.067537
12:00 p.m.	0.079	0.065327
1:00 p.m.	0.082	0.071715
2:00 p.m.	0.085	0.077394
3:00 p.m.	0.088	0.082448
4:00 p.m.	0.083	0.073683

[65] An algebraically identical form for w_c is as follows. This expression makes clear that the weighting factor is about 0.5 for an O_3 concentration of 0.067 ppm. This form of w_c is for explanatory purposes only and is not to be used in calculating the W126 index.

$$w_c = \frac{1}{1 + e^{-((C - 0.066588\,ppm)/0.0079365\,ppm)}}$$

5:00 p.m.	0.081	0.069667
6:00 p.m.	0.065	0.029260
7:00 p.m.	0.056	0.011676
Sum=Daily W126 Index (D.I.)		0.625406 ppm-hours

In Example 3, the individual weighted concentrations have been rounded to six decimal digits, and all six digits are retained in their sum. There are no data completeness requirements or adjustments for incomplete data associated with the D.I. If fewer than 12 hourly concentrations are available, only the available hours are weighted and summed. However, there is a required adjustment for incomplete data associated with the Monthly W126 Index, which is described in section 4(b).

(b) *Computing the Monthly W126 Index*

(i) As described in section 4(a), the D.I. value is computed at each monitoring site for all days with monitoring data including any days outside the required O_3 monitoring season. The preliminary Monthly W126 Index (M.I.) is the sum of the D.I. values over one calendar month, with all six decimal digits retained.

(ii) If measured hourly O_3 concentrations are available for fewer than 75% of the daytime hours in any given month, then 0.0025 ppm shall be substituted for the fewest number of missing hourly concentrations required to make the month at least 75% complete, and the preliminary monthly W126 index shall be recalculated. The choice of which missing hours to substitute will not affect the outcome of the calculation of the new value of the preliminary M.I. value because of the forms of the D.I and the preliminary M.I.

(iii) The final M.I. value shall be calculated by adjusting the preliminary M.I. value (which may already have been recalculated once to incorporate substituted values according to section 4(b)(ii)) for any remaining incomplete data by multiplying the preliminary M.I. value by the ratio of the number of possible reporting hours in the month to the number of hours with reported or substituted ambient hourly concentrations using Equation 2:

Equation 2

$$\text{Final M.I.} = \text{Preliminary M.I.} * (n*12)/v$$

where n = the number of days in the calendar month, and

v = the number of daytime reporting hours (those starting at 8:00 a.m. – 7:00 p.m. LST) in the month with reported valid hourly O_3 concentrations or missing concentrations that have been substituted with one-half the method detection limit of the O_3 instrument.

The resulting value of the final M.I. shall be rounded to six decimal digits. Values greater than or equal to 0.XXXXXX5 shall be rounded up.

(c) *Exceptional Situations When Computing the Daily and Monthly W126 Indices*

(i) The Regional Administrator may approve a request or otherwise make a determination that all 12 hourly daytime O_3 concentrations from one or more days be excluded from the calculation of the D.I. and final M.I. on the basis that sensitive plant species in the geographical area for which air quality is represented by the monitoring site on those days were in a dormant or hardened condition making them less likely to be susceptible to injury by the exposure to the measured daytime O_3 concentrations. The Regional Administrator shall consider the following factors in approving such a request, to the extent such information is available: air temperatures and snow cover on that day and on the preceding days, their likely effect on soil temperatures on that day and in preceding days, and the plant species that may be present in the geographical area for which air quality is represented by the monitoring site. The Regional Administrator will not grant exclusion for concentration data collected by state or local agencies at monitoring sites after January 1, 2013 unless on-site temperature data have been submitted to AQS. If the Regional Administrator has made a determination that all 12 hourly daytime concentrations from one or more days will be excluded, the reported concentrations for those hours shall be replaced

with 0.0 ppm when performing the steps specified in section 4(a). After this substitution, those hours shall be counted towards the 75% completeness requirement in section 4(e). Those hours shall also be included in the value of "v" in Equation 2 of section 4(b)(iii).

(ii) Measured hourly average O_3 concentrations that have been approved under 40 CFR 50.14 as having been affected by exceptional events, but have not been approved for exclusion under section 4(c)(i), shall be replaced with 0.0025 ppm when performing the steps specified in section 4(a). After this substitution, those hours shall be counted toward the 75% completeness requirement in section 4(e). Those hours shall also be included in the value of "v" in Equation 2 of section 4(b)(iii).

(d) *Computing the Secondary Standard Design Value*

The secondary standard design value is the 3-year average of the annual maximum consecutive 3-month sum of the final M.I. values, expressed in units of ppm-hours. Specifically, the annual W126 index value is computed on a calendar year basis using the highest sum of three consecutive final M.I. values, with all six decimal digits retained. No 3-month sum shall include months from different calendar years. The 3-year average shall be computed using the three most recent, consecutive calendar years of monitoring data that can yield a valid design value. For a design value to be valid for comparison to the standard, the monitoring data on which it is based must meet the data completeness requirements described in section 4(e). The computed 3-year average of the annual maximum consecutive 3-month sum of final M.I. values expressed in units of ppm-hours shall be rounded to a whole number. Values greater than or equal to XX.5 shall be rounded up.

(e) *Data Completeness Requirement for a Valid Secondary Standard Design Value*

(i) A secondary standard design value greater than the secondary O_3 NAAQS is always valid.

(ii) A design value less than or equal to the standard is valid if for each of the months in the required O_3 monitoring season in each of the three years, there were reported hourly concentrations for at least 75%

of the daytime hours, including any reported concentrations that have been approved under 40 CFR 50.14 as having been affected by an exceptional event and excluding missing (unreported) hourly concentrations for which substituted values were used under section 4(b)(ii).

(iii) Data that do not meet the completeness criteria stated in 4(e)(ii) may nevertheless be used to calculate a design value that will be deemed valid with the approval of, or at the initiative of, the Regional Administrator, who shall consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, the historical pattern of M.I. values across months of the required O_3 monitoring season, and nearby concentrations in determining whether to use such data.

(f) Comparisons with the Secondary Ozone NAAQS

(i) The secondary ambient O_3 air quality standard is met at an ambient air quality monitoring site when the design value is less than or equal to 13 ppm-hours and the data meet the completeness requirement in section 4(e).

(ii) Comparison with the secondary O_3 standard is demonstrated in example 4 below:

Example 4: Ambient Monitoring Site Failing to Meet the Secondary O_3 NAAQS[66]

	April	May	June	July	August	September	October	Overall
2006								
Adjusted monthly W126 index	4.442	9.124	12.983	16.153	13.555	4.364	1.302	
3-Month sum	na	na	26.549	38.260	42.691	34.072	19.221	
2006 Maximum					42.691			42.691
2007								
Adjusted monthly W126 index	3.114	7.214	8.214	8.111	7.455	7.331	5.115	
3-Month sum	na	na	18.542	23.539	23.780	22.897	19.901	
2007 Maximum					23.780			23.780
2008								
Adjusted monthly W126 index	4.574	5.978	6.786	8.214	5.579	4.331	2.115	
3-Month sum	na	na	17.338	20.978	20.579	18.124	12.025	
2008 Maximum				20.978				20.978

[66] This example assumes that data was only collected at the site from April through October.

3-Year average W126 index								29.149666
Rounded								29

As shown in example 4, the secondary O_3 standard is not met for this monitoring site because the rounded 3-year average of the annual W126 index values for this site is greater than 13 ppm-hours.

PART 58 – AMBIENT AIR QUALITY SURVEILLANCE

5. The authority citation for part 58 continues to read as follows:

Authority: 42 U.S.C. 7410 7403, 7410, 7601(a), 7611, and 7619.

6. Section 58.50 is amended by revising paragraph (c) to read as follows:

§ 58.50 Index reporting.

*** * * * ***

(c) The population of a metropolitan statistical area for purposes of index reporting is the latest available U.S. census population.

7. Appendix G of Part 58 is amended by revising table 2 to read as follows:

Appendix G to Part 58—Uniform Air Quality Index (AQI) and Daily Reporting

* * * * *

TABLE 2.—BREAKPOINTS FOR THE AQI

These breakpoints							Equal these AQI's	
O_3 (ppm) 8-hour	O_3 (ppm) 1-hour[1]	$PM_{2.5}$ ($\mu g/m^3$)	PM_{10} ($\mu g/m^3$)	CO (ppm)	SO_2 (ppm) 1-hour	NO_2 (ppm) 1-hour	AQI	Category
0.000-0.055	.....	0.0-15.4	0-54	0.0-4.4	0-0.035	0-0.053	0-50	Good.
0.056-0.070	.....	15.5-40.4	55-154	4.5-9.4	0.036-0.075	0.054-0.100	51-100	Moderate.
0.071-0.095	0.125-0.164	40.5-65.4	155-254	9.5-12.4	0.076-0.185	0.101-0.360	101-150	Unhealthy for Sensitive Groups.
0.096-0.115	0.165-0.204	[3]65.5-150.4	255-354	12.5-15.4	[4]0.186-0.304	0.361-0.64	151-200	Unhealthy.
0.116-0.374	0.205-0.404	[3]150.5-250.4	355-424	15.5-30.4	[4]0.305-0.604	0.65-1.24	201-300	Very Unhealthy.
([2]).....	0.405-0.504	[3]250.5-350.4	425-504	30.5-40.4	[4]0.605-0.804	1.25-1.64	301-400	
([2]).....	0.505-0.604	[3]350.5-500.4	505-604	40.5-50.4	[4]0.805-1.004	1.65-2.04	401-500	Hazardous.

[1] Areas are generally required to report the AQI based on 8-hour ozone values. However, there are a small number of areas where an AQI based on 1-hour ozone values would be more precautionary. In these cases, in addition to calculating the 8-hour ozone index value, the 1-hour ozone index value may be calculated, and the maximum of the two values reported.

[2] 8-hour O_3 values do not define higher AQI values (≥ 301). AQI values of 301 or greater are calculated with 1-hour O_3 concentrations.

[3] If a different SHL for $PM_{2.5}$ is promulgated, these numbers will change accordingly.

[4] 1-hr SO2 values do not define higher AQI values (≥ 200). AQI values of 200 or greater are calculated with 24-hour SO_2 concentrations.