ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50 and 40 CFR Part 58

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

RIN 2060-AN24

National Ambient Air Quality Standards for Ozone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Based on its review of the air quality criteria for ozone (O_3) and related photochemical oxidants and national ambient air quality standards (NAAQS) for O_3, EPA is making revisions to the primary and secondary NAAQS for O_3 to provide requisite protection of public health and welfare, respectively. With regard to the primary standard for O_3, EPA is revising the level of the 8-hour standard to 0.075 parts per million (ppm), expressed to three decimal places. With regard to the secondary standard for O_3, EPA is revising the current 8-hour standard by making it identical to the revised primary standard. EPA is also making 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.

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

ADDRESSES: 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.

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I. Background

A. Summary of Revisions to the O_3 NAAQS

Based on its review of the air quality criteria for O_3 and related photochemical oxidants and national ambient air quality standards (NAAQS) for O_3, EPA is making revisions to the primary and secondary NAAQS for O_3 to provide protection of public health and welfare, respectively, that is appropriate 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 revising the level of the 8-hour standard to a level of 0.075 parts per million (ppm), 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 is specifying the level of the primary standard to the nearest thousandth ppm.

With regard to the secondary standard for O_3, EPA is revising the standard by.making it identical to the revised primary standard.

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. 7408) directs the Administrator to identify and list "air pollutants" emissions of which "in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare," whose "presence . . . in the ambient air results from numerous or diverse mobile or stationary sources," and for which the Administrator plans to issue air quality criteria, and to issue air quality criteria for those that are listed. Air quality criteria are to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in ambient air, in varying quantities . . . ." Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants listed under section 108. 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."[1] 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 criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air." [2]

The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *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). 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 provide 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

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

[2] 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, manmade materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being."

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.

The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *Lead Industries Association v. EPA*, 647 F.2d at 1161-62. 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.

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. *Whitman v. America Trucking Associations*, 531 U.S. 457, 473. Further the Supreme Court ruled that "[t]he text of § 109(b), interpreted in its statutory and historical context and with appreciation for its importance to the CAA as a whole, unambiguously bars cost considerations from the NAAQS-setting process. . ." *Id.* at 472.[3]

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 . . .

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[3] In considering whether the CAA allowed for economic considerations to play a role in the promulgation of the NAAQS, the Surpreme Court rejected arguments that because many more factors than air pollution might affect public health, EPA should consider compliance costs that produce health losses in setting the NAAQS. 531 U.S. at 466. Thus, EPA may not take into account possible public health impacts from the economic cost of implementation. *Id.*

and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate in accordance with section 108 and [109(b)]." 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 under section 108 and [section 109(b)]." This independent review function is performed by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board.

C. Review of Air Quality Criteria and Standards for O_3

Ground-level O_3 is formed from biogenic and anthropogenic precursor emissions. Naturally occurring O_3 in the troposphere can result from biogenic organic precursors reacting with naturally occurring nitrogen oxides (NO_x) and by stratospheric O_3 intrusion into the troposphere. Anthropogenic precursors of O_3, specifically NO_x and volatile organic compounds (VOC), originate from a wide variety of stationary and mobile sources. Ambient O_3 concentrations produced by these emissions are directly affected by temperature, solar radiation, wind speed and other meteorological factors.

The last review of the O_3 NAAQS was completed on July 18, 1997, based on the 1996 O_3 Air Quality Criteria Document (EPA, 1996a) and 1996 O_3 Staff Paper (EPA, 1996b). EPA revised the primary and secondary O_3 standards on the basis of the then latest scientific evidence linking exposures to ambient O_3 to adverse health and welfare effects at levels allowed by the 1-hour average standards (62 FR 38856). The O_3 standards were revised by replacing the existing primary 1-hour average standard with an 8-hour average O_3 standard set at a level of 0.08 ppm, which is equivalent to 0.084 ppm

using the standard rounding conventions. The form of the primary standard was changed to the annual fourth-highest daily maximum 8-hour average concentration, averaged over 3 years. The secondary O_3 standard was changed by making it identical in all respects to the revised primary standard.

EPA initiated this current review in September 2000 with a call for information (65 FR 57810) for the development of a revised Air Quality Criteria Document for O_3 and Other Photochemical Oxidants (henceforth the "Criteria Document"). A project work plan (EPA, 2002) for the preparation of the Criteria Document was released in November 2002 for CASAC O_3 Panel[4] (henceforth, "CASAC Panel") 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 Panel and public review on January 31, 2005; a CASAC Panel 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 Panel and public review on August 31, 2005, and was discussed along with a first draft Staff Paper (EPA, 2005c) at a CASAC Panel meeting held on December 6-8, 2005. In a February 16, 2006 letter to the Administrator, the CASAC Panel offered final comments on all chapters of the Criteria Document (Henderson, 2006a), and the final Criteria Document (EPA, 2006a) was released on March 21, 2006. In a June 8, 2006 letter (Henderson, 2006b) to the Administrator, the CASAC Panel offered additional advice to

[4] The CASAC O_3 Review Panel includes the seven members of the chartered CASAC, supplemented by fifteen subject-matter experts appointed by the Administrator to provide additional scientific expertise relevant to this review of the O_3 NAAQS.

the Agency concerning chapter 8 of the final 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 the CASAC Panel on August 24 and 25, 2006. In an October 24, 2006 letter to the Administrator, CASAC Panel provided advice and recommendations to the Agency concerning the second draft Staff Paper (Henderson, 2006c). A final Staff Paper (EPA, 2007a) was released on January 31, 2007. Around the time of the release of the final Staff Paper in January 2007, EPA discovered a small error in the exposure model that when corrected resulted in slight increases in the human exposure estimates. Since the exposure estimates are an input to the lung function portion of the health risk assessment, this correction also resulted in slight increases in the lung function risk estimates as well. The exposure and risk estimates discussed in this final rule reflect the corrected estimates, and thus are slightly different than the exposure and risk estimates cited in the January 31, 2007 Staff Paper.[5] In a March 26, 2007 letter (Henderson, 2007), the CASAC Panel 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 this review has been 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 current review within the period provided by statute.[6] The modified consent decree that currently governs this review provides that EPA sign for publication notices

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[5] EPA made available corrected versions of the final Staff Paper (EPA, 2007b, henceforth, "Staff Paper") and the human exposure and health risk assessment technical support documents on July 31, 2007 on the EPA web site www.epa.gov/ttn/naaqs.

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

of proposed and final rulemaking concerning its review of the O_3 NAAQS no later than June 20, 2007 and March 12, 2008, respectively. The proposed decision (henceforth "proposal") was signed on June 20, 2007 and published in the Federal Register on July 11, 2007.

A large number of comments were received from various commenters on the proposed revisions to the O_3 NAAQS. Significant issues raised in the public comments are discussed throughout the preamble of this final action. A comprehensive summary of all significant comments, along with EPA's responses (henceforth "Response to Comments"), can be found in the docket for this rulemaking.

Various commenters have referred to and discussed a number of new scientific studies on the health effects of O_3 that had been published recently and therefore were not included in the Criteria Document (EPA, 2006a, henceforth "Criteria Document).[7] EPA has provisionally considered any significant "new" studies, including those submitted during the public comment period. The purpose of this effort was to ensure that the Administrator was fully aware of the "new" science before making a final decision on whether to revise the current O_3 NAAQS. EPA provisionally considered these studies to place their results in the context of the findings of the Criteria Document.

As in prior NAAQS reviews, EPA is basing its decision in this review on studies and related information included in the Criteria Document and Staff Paper, which have

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[7] For ease of reference, these studies will be referred to as "new" studies or "new" science, using quotation marks around the word *new*. Referring to studies that were published too recently to have been included in the 2004 Criteria Document as "new" studies is intended to clearly differentiate such studies from those that have been published since the last review and are included in the 2004 Criteria Document (these studies are sometimes referred to as new (without quotation marks) or more recent studies, to indicate that they were not included in the 1996 Criteria Document and thus are newly available in this review.

undergone CASAC and public review. The studies assessed in the Criteria Document, and the integration of the scientific evidence presented in that document, have undergone extensive critical review by EPA, CASAC, and the public during the development of the Criteria Document. The rigor of that review makes these studies, and their integrative assessment, the most reliable source of scientific information on which to base decisions on the NAAQS, decisions that all parties recognize as of great import. NAAQS decisions can have profound impacts on public health and welfare, and NAAQS decisions should be based on studies that have been rigorously assessed in an integrative manner not only by EPA but also by the statutorily mandated independent advisory committee, as well as the public review that accompanies this process. As described above, EPA's provisional consideration of these studies did not and could not provide that kind of in-depth critical review.

This decision is consistent with EPA's practice in prior NAAQS reviews. Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria, and has consistently followed this approach. See 71 FR 61144, 61148 (October 17, 2006) (final decision on review of PM NAAQS) for a detailed discussion of this issue and EPA's past practice.

As discussed in EPA's 1993 decision not to revise the NAAQS for O_3 "new" studies may sometimes be of such significance that it is appropriate to delay a decision on revision of a NAAQS and to supplement the pertinent air quality criteria so the studies can be taken into account (58 FR at 13013-13014, March 9, 1993). In the present case, EPA's provisional consideration of "new" studies concludes that, taken in context, the

"new" information and findings do not materially change any of the broad scientific conclusions regarding the health effects of O_3 exposure made in the Criteria Document. For this reason, reopening the air quality criteria review would not be warranted even if there were time to do so under the court order governing the schedule for this rulemaking. Accordingly, EPA is basing the final decisions in this review on the studies and related information included in the O_3 air quality criteria that have undergone CASAC and public review. EPA will consider the newly published studies for purposes of decision making in the next periodic review of the O_3 NAAQS, which will provide the opportunity to fully assess them through a more rigorous review process involving EPA, CASAC, and the public. Further discussion of these "new" studies can be found in the Response to Comments document.

This action presents the Administrator's final decisions on the review of the current primary and secondary O_3 standards. Throughout this preamble a number of conclusions, findings, and determinations made by the Administrator are noted. They identify the reasoning that supports this final decision and are intended to be final and conclusive.

D. Summary of Proposed Revisions to the O_3 *NAAQS*

For reasons discussed in the proposal, the Administrator proposed to revise the current primary and secondary O_3 standards. With regard to the primary O_3 standard, the Administrator proposed to revise the level of the 8-hour O_3 standard to a level within the range of 0.070 ppm to 0.075 ppm, based on a 3-year average of the fourth-highest maximum 8-hour average concentration. Related revisions for O_3 data handling conventions and for the reference method for monitoring O_3 were also proposed. These

revisions were 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 also proposed to specify the level of the primary standard to the nearest thousandth ppm. EPA solicited comment on alternative levels down to 0.060 ppm and up to and including retaining the current 8-hour standard of 0.08 ppm (effectively 0.084 ppm using current data rounding conventions).

With regard to the secondary standard for O_3, EPA proposed to revise the current 8-hour standard with one of two options to provide increased protection against O_3-related adverse impacts on vegetation and forested ecosystems. One option was to replace the current standard with a cumulative, seasonal standard expressed as an index of the annual sum of weighted hourly concentrations, cumulated over 12 hours per day (8:00 am to 8:00 pm) during the consecutive 3-month period within the O_3 season with the maximum index value, set at a level within the range of 7 to 21 ppm-hours. The other option was to make the secondary standard identical to the proposed primary 8-hour standard. EPA solicited comment on specifying a cumulative, seasonal standard in terms of a 3-year average of the annual sums of weighted hourly concentrations; on the range of alternative 8-hour standard levels for which comment was being solicited for the primary standard, including retaining the current secondary standard, which is identical to the current primary standard; and on an alternative approach to setting a cumulative, seasonal secondary standards.

E. Organization and Approach to Final O_3 NAAQS Decisions

This action presents the Administrator's final decisions regarding the need to revise the current primary and secondary O_3 standards. Revisions to the primary standard for O_3 are addressed below in section II, and a discussion on communication of public health information regarding revisions to the primary O_3 standard is presented in section III. The secondary O_3 standard is addressed below in section IV. Related data completeness and data handling and rounding conventions are addressed in section V, and federal reference methods for monitoring O_3 are addressed below in section VI. Future implementation steps and related control requirements are discussed in section VII. A discussion of statutory and executive order reviews is provided in section VIII.

Today's final decisions are based on a thorough review in the Criteria Document of scientific information on known and potential human health and welfare effects associated with exposure to O_3 at levels typically found in the ambient air. These final decisions also take into account: (1) staff assessments in the Staff Paper of the most policy-relevant information in the Criteria Document as well as quantitative exposure and risk assessments based on that information; (2) CASAC Panel advice and recommendations, as reflected in its letters to the Administrator, its discussions of drafts of the Criteria Document and Staff Paper at public meetings, and separate written comments prepared by individual members of the CASAC Panel; (3) public comments received during the development of these documents, either in connection with CASAC Panel meetings or separately; and (4) extensive public comments received on the proposed rulemaking.

II. Rationale for Final Decisions on the Primary O_3 Standard

A. Introduction

1. Overview

This section presents the Administrator's final decisions regarding the need to revise the current primary O_3 NAAQS, and the appropriate revision to the level of the 8-hour standard. As discussed more fully below, the rationale for the final decision on appropriate revisions to the primary O_3 NAAQS includes consideration of: (1) evidence of health effects related to short-term exposures to O_3; (2) insights gained from quantitative exposure and health risk assessments; (3) public and CASAC Panel comments received during the development and review of the Criteria Document, Staff Paper, exposure and risk assessments and on the proposal notice.

In developing this rationale, EPA has drawn upon an integrative synthesis of the entire body of evidence[8] relevant to examining associations between exposure to ambient O_3 and a broad range of health endpoints (EPA, 2006a, Chapter 8), focusing on those health endpoints for which the Criteria Document concluded that the associations are causal or likely to be causal. This body of evidence includes hundreds of studies conducted in many countries around the world. In its assessment of the evidence judged to be most relevant to decisions on elements of the primary O_3 standards, EPA has placed greater weight on U.S. and Canadian studies, since studies conducted in other countries may well reflect different demographic and air pollution characteristics.

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[8] The word "evidence" is used in this notice to refer to studies that provide information relevant to an area of inquiry, which can include studies that report positive or negative results or that provide interpretative information.

As discussed below, a significant amount of new research has been conducted since the last review, with important new information coming from epidemiological, toxicological, controlled human exposure, and dosimetric studies. Moreover, the newly available research studies evaluated in the Criteria Document have undergone intensive scrutiny through multiple layers of peer review, with extended opportunities for review and comment by CASAC Panel and the public. As with virtually any policy-relevant scientific research, there is uncertainty in the characterization of health effects attributable to exposure to ambient O_3, most generally with regard to whether observed health effects and associations are causal or likely causal in nature and, if so, the certainty of a causal associations at various exposure levels. While important uncertainties remain, the review of the health effects information has been extensive and deliberate. In the judgment of the Administrator, this intensive evaluation of the scientific evidence provides an adequate basis for regulatory decision making at this time. This review also provides important input to EPA's research plan for improving our future understanding of the relationships between exposures to ambient O_3 and health effects.

The health effects information and quantitative exposure and health risk assessment were summarized in sections II.A and II.B of the proposal (72 FR at 37824-37862) and are only briefly outlined below in sections II.A.2 and II.A.3. Subsequent sections of this preamble provide a more complete discussion of the Administrator's rationale, in light of key issues raised in public comments, for concluding that the current standard is not requisite to protect public health with an adequate margin of safety, and it is appropriate to revise the current primary O_3 standards to provide additional public health protection (section II.B), as well as a more complete discussion of the

Administrator's rationale for retaining or revising the specific elements of the primary O_3 standards (section II.C), namely the indicator (section II.C.1); averaging time (section II.C.2); form (section II.C.3); and level (section II.C.4). A summary of the final decisions on revisions to the primary O_3 standards is presented in section II.D.

2. Overview of Health Effects

This section outlines the information presented in Section II.A of the proposal on known or potential effects on public health which may be expected from the presence of O_3 in ambient air. The decision in the last review focused primarily on evidence from short-term (e.g., 1 to 3 hours) and prolonged (6 to 8 hours) controlled-exposure studies reporting lung function decrements, respiratory symptoms, and respiratory inflammation in humans, as well as epidemiology studies reporting excess hospital admissions and emergency department visits for respiratory causes. The Criteria Document prepared for this review emphasizes a large number of epidemiological studies published since the last review with these and additional health endpoints, including the effects of acute (short-term and prolonged) and chronic exposures to O_3 on lung function decrements and enhanced respiratory symptoms in asthmatic individuals, school absences, and premature mortality. It also emphasizes important new information from toxicology, dosimetry, and controlled human exposure studies. Highlights of the evidence include:

(1) Two new controlled human-exposure studies are now available that examine 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.

(2) Numerous recent controlled human-exposure studies have examined indicators of O_3-induced inflammatory response in both the upper respiratory tract (URT)

and lower respiratory tract (LRT), while other studies have examined changes in host defense capability following O_3 exposure of healthy young adults and increased airway responsiveness to allergens in subjects with allergic asthma and allergic rhinitis exposed to O_3.

(3) New evidence from controlled human exposure studies showing that asthmatics have greater respiratory-related physiological responses than healthy subjects and new evidence from epidemiological studies showing associations between O_3 exposure and lung function and respiratory symptom responses; these findings differ from the presumption in the last review that people with asthma had generally the same magnitude of respiratory responses to O_3 as those experienced by healthy individuals.

(4) Animal toxicology studies provide new information regarding potential mechanisms of action, increased susceptibility to respiratory infection, and biological plausibility of acute effects as well as chronic, irreversible respiratory damage observed in animals.

(5) Numerous epidemiological studies published during the past decade offer added evidence of associations between acute ambient O_3 exposures and lung function decrements and respiratory symptoms in physically active healthy subjects and asthmatic subjects, as well as new evidence regarding additional health endpoints, including relationships between ambient O_3 concentrations and school absenteeism and between ambient O_3 and cardiac-related physiological endpoints.

(6) Several additional studies have been published over the last decade examining the temporal associations between acute O_3 exposures and both emergency department visits for respiratory diseases and respiratory-related hospital admissions.

(7) A large number of newly available epidemiological studies have examined the effects of acute exposure to PM and O_3 on premature mortality, notably including large multi-city studies that provide much more robust information than was available in the last review, as well as recent meta-analyses that have evaluated potential sources of heterogeneity in O_3-mortality associations.

Section II.A of the proposal provides a detailed summary of key information contained in the Criteria Document (chapters 4-8) and in the Staff Paper (chapter 3), on the known and potential effects of O_3 exposure and information on the effects of O_3 exposure in combination with other pollutants that are routinely present in the ambient air (72 FR 37824—37851). The information there summarizes:

(1) new information available on potential mechanisms for morbidity and mortality effects associated with exposure to O_3, including potential mechanisms or pathways related to direct effects on the respiratory system, systemic effects that are secondary to effects in the respiratory system (e.g., cardiovascular effects);

(2) the nature of effects that have been associated directly with exposure to O_3 or indirectly with the presence of O_3 in ambient air, including premature mortality, aggravation of respiratory and cardiovascular disease (as indicated by increased hospital admissions and emergency department visits), changes in lung function and increased respiratory symptoms, as well as new evidence for more subtle indicators of cardiovascular health;

(3) an integrative interpretation of the health effects evidence, focusing on the biological plausibility and coherence of the evidence and key issues raised in interpreting

epidemiological studies, along with supporting evidence from experimental (e.g., dosimetric and toxicological) studies as well as the limitations of the evidence; and

(4) considerations in characterizing the public health impact of O_3, including the identification of sensitive and vulnerable subpopulations that are potentially at risk to such effects, including active people, people with pre-existing lung and heart diseases, children and older adults, and people with increased responsiveness to O_3.

3. Overview of Human Exposure and Health Risk Assessments

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.

As discussed in more detail in section II.B of the proposal, 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 last 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).

In modeling exposures and health risks associated with just meeting the current and alternative O_3 standards, EPA simulated air quality just meeting these standards based on O_3 air quality patterns in several recent years and on how the shape of the O_3 air quality distributions has changed over time based on historical trends in monitored O_3 air quality data. As discussed in the proposal notice and in the Staff Paper (section 4.5.8), recent O_3 air quality distributions were statistically adjusted to simulate just meeting the current and selected alternative standards. Specifically, the exposure and risk assessment included estimates for a recent year of air quality and for air quality adjusted to simulate just meeting the current and alternative standards based on O_3 season data from a recent three-year period (2002-2004). The O_3 season in each area included the period of the year for which routine hourly O_3 monitoring data are available. Typically this period spans from March or April through September or October, although in some areas it includes the entire year. Three years were modeled to reflect the substantial year-to-year variability that occurs in O_3 levels and related meteorological conditions, and because the standard is specified in terms of a three-year period. The year-to-year variability observed in O_3 levels is due to a combination of different weather patterns and the variation in emissions of O_3 precursors. Nationally, 2002 was a relatively high year with respect to the 4th highest daily maximum 8-hour O_3 levels observed in urban areas across the U.S. (see Staff Paper, Figure 2-16), with the mean of the distribution of annual 4th highest daily maximum 8-hour O_3 levels for urban monitors nationwide being in the upper third among the years 1990 through 2004. In contrast, on a national basis, 2004 was the lowest year on record with respect to the mean of the distribution of annual 4th highest daily maximum 8-hour O_3 levels for this same 15 year period. The 4th highest

daily maximum 8-hour levels observed in most, but not all of the 12 urban areas included in the exposure and risk assessment, were relatively low in 2004 compared to other recent years. The 4th highest daily maximum 8-hour O_3 levels observed in 2003 in the 12 urban areas and nationally generally were between those observed in 2002 and 2004. As a result of the variability in air quality, the exposure and risk estimates associated with just meeting the current or any alternative standard also will vary depending on the year chosen for the analysis. Thus, exposure and risk estimates based on 2002 air quality generally show relatively higher numbers of children affected and the estimates based on 2004 air quality generally show relatively fewer numbers of children affected.

These simulations do not reflect any consideration of specific control programs or strategies designed to achieve the reductions in emissions required to meet the specified standards. Further, these simulations do not represent predictions of when, whether, or how areas might meet the specified standards.[9] Instead these simulations represent a projection of the kind of air quality levels that would be likely to occur in areas just attaining various alternative standards, when historical patterns of air quality, reflecting averages over many areas, are applied in the urban areas examined.

a. Exposure Analyses

As discussed in section II.B.1 of the proposal, EPA conducted human exposure analyses using a simulation model to estimate O_3 exposures for the general population, school age children (ages 5-18), and school age children with asthma living in 12 U.S. metropolitan areas representing different regions of the country where the current 8-hour

[9] For informational purposes only, modeling that projects how areas might attain alternative standards in a future year as a result of Federal, State, local, and Tribal efforts is presented in the final Regulatory Impact Analysis being prepared in connection with this decision.

O_3 standard is not met. The emphasis on children reflected the finding of the last review that children are an important at-risk group. Exposure estimates were developed using a probabilistic exposure model that is designed to explicitly model the numerous sources of variability that affect people's exposures. This exposure assessment is more fully described and presented in the Staff Paper and in a technical support document, *Ozone Population Exposure Analysis for Selected Urban Areas* (EPA, 2007c; henceforth "Exposure Analysis TSD"). As noted in the proposal, the scope and methodology for this exposure assessment were developed over the last few years with considerable input from the CASAC Panel and the public.

As discussed in the proposal notice and in greater detail in the Staff Paper (chapter 4) and Exposure Analysis TSD, EPA recognized that there are many sources of variability and uncertainty inherent in the input to this assessment and that there was uncertainty in the resulting O_3 exposure estimates. In EPA's judgment, the most important uncertainties affecting the exposure estimates are related to the modeling of human activity patterns over an O_3 season, the modeling of variations in ambient concentrations near roadways, and the modeling of air exchange rates that affect the amount of O_3 that penetrates indoors. Another important uncertainty that affects the estimation of how many exposures are associated with moderate or greater exertion is the characterization of energy expenditure for children engaged in various activities. As discussed in more detail in the Staff Paper (section 4.3.4.7), the uncertainty in energy expenditure values carries over to the uncertainty of the modeled breathing rates, which are important since they are used to classify exposures occurring at moderate or greater exertion. These are the relevant exposures since O_3-related effects observed in clinical

studies only are observed when individuals are engaged in some form of exercise. The uncertainties in the exposure model inputs and the estimated exposures have been assessed using quantitative uncertainty and sensitivity analyses. Details are discussed in the Staff Paper (section 4.6) and in a technical memorandum describing the exposure modeling uncertainty analysis (Langstaff, 2007).

The exposure assessment, which provided estimates of the number of people exposed to different levels of ambient O_3 while at elevated exertion[10], served two purposes. First, the entire range of modeled personal exposures to ambient O_3 was an essential input to the portion of the health risk assessment based on exposure-response functions from controlled human exposure studies, discussed in the next section. Second, estimates of personal exposures to ambient O_3 concentrations at and above specified benchmark levels while at elevated exertion provided some perspective on the public health impacts of health effects that we cannot currently evaluate in quantitative risk assessments but that may occur at current air quality levels, and the extent to which such impacts might be reduced by meeting the current and alternative standards. In the proposal, we referred to exposures at and above these benchmark levels while at elevated exertion as "exposures of concern."

Based on the observation from the exposure analyses conducted in the prior review that children represented the population subgroup with the greatest exposure to ambient O_3, EPA chose to model 8-hour exposures at elevated exertion for all school age children, and separately for asthmatic school age children, as well as for the general

[10] As discussed in section II.A of the proposal, O_3 health responses observed in controlled human exposure studies are associated with exposures while subjects are engaged in moderate or greater exertion on average over the exposure period (hereafter referred to as "elevated exertion") and, therefore, these are the exposures of interest.

population in the current exposure assessment. While outdoor workers and other adults who engage in moderate or greater exertion for prolonged periods while outdoors during the day in areas experiencing elevated O_3 concentrations also are at risk for O_3-related health effects, EPA did not focus on developing quantitative exposure estimates for these population subgroups due to the lack of information about the number of individuals who regularly work or exercise outdoors. Thus, as presented in the proposal and in the Staff Paper the exposure estimates are most useful for making relative comparisons of estimated exposures in school age children across alternative air quality scenarios. This assessment does not provide information on exposures for adult subgroups within the general population associated with the air quality scenarios.

EPA noted in the proposal key observations that were important to consider in comparing exposure estimates associated with just meeting the current NAAQS and alternative standards considered. These included:

(1) As shown in Table 6-1 of the Staff Paper, the patterns of exposures in terms of percentages of the population exceeding given exposure levels were very similar for the general population and for asthmatic and all school age (5-18) children, although children were about twice as likely as the general population to be exposed at any given level.

(2) As shown in Table 1 in the proposal (72 FR 37855), the number and percentage of asthmatic and all school age children aggregated across the 12 urban areas estimated to experience 1 or more exposures of concern declined from simulations of just meeting the current standard to simulations of alternative 8-hour standards by varying

amounts, depending on the benchmark level, the population subgroup considered, and the air quality year chosen.[11]

(3) Substantial year-to-year variability in exposure estimates was observed over the three-year modeling period.

(4) There was substantial variability observed across the 12 urban areas in the percent of the population subgroups estimated to experience exposures at and above specified benchmark levels while at elevated exertion.

(5) Of particular note, there is high inter-individual variability in responsiveness such that only a subset of individuals who were exposed at and above a given benchmark level while at elevated exertion would actually be expected to experience any such potential adverse health effects.

(6) In considering these observations, it was important to take into account the variability, uncertainties, and limitations associated with this assessment, including the degree of uncertainty associated with a number of model inputs and uncertainty in the model itself.

b. Quantitative Health Risk Assessment

As discussed in section II.B.2 of the proposal, the approach used to develop quantitative risk estimates associated with exposures to O_3 builds upon the risk assessment conducted during the last review.[12] The expanded and updated assessment

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[11]While the proposal notice stated in the text that "approximately 2 to 4 percent of all and asthmatic children" were estimated to experience exposures of concern at and above the 0.070 ppm benchmark level for standards in the range of 0.070 to 0.075 ppm (72 FR 37879), the correct range is about 1 to 5 perecent consistent with the estimates provided in Table 1 of the proposal (72 FR 37855).

[12] The methodology, scope, and results from the risk assessment conducted in the last review are described in Chapter 6 of the 1996 Staff Paper (EPA, 1996) and in several technical reports (Whitfield et al., 1996; Whitfield, 1997) and publication (Whitfield et al., 1998).

conducted in this review includes estimates of (1) risks of lung function decrements in all and asthmatic school age children, respiratory symptoms in asthmatic children, respiratory-related hospital admissions, and non-accidental and cardiorespiratory-related mortality associated with recent short-term ambient O_3 levels; (2) risk reductions and remaining risks associated with just meeting the current 8-hour O_3 NAAQS; and (3) risk reductions and remaining risks associated with just meeting various alternative 8-hour O_3 NAAQS in a number of example urban areas. The health risk assessment was discussed in the Staff Paper (chapter 5) and presented more fully in a technical support document, *Ozone Health Risk Assessment for Selected Urban Areas* (Abt Associates, 2007a). As noted in the proposal, the scope and methodology for this risk assessment was developed over several years with considerable input from the CASAC Panel and the public.

EPA recognized that there were many sources of uncertainty and variability inherent in the inputs to these assessments and that there was a high degree of uncertainty in the resulting O_3 risk estimates. Such uncertainties generally relate to a lack of clear understanding of a number of important factors, including, for example, the shape of exposure-response and concentration-response functions, particularly when, as here, effect thresholds can neither be discerned nor determined not to exist; issues related to selection of appropriate statistical models for the analysis of the epidemiologic data; the role of potentially confounding and modifying factors in the concentration-response relationships; and issues related to simulating how O_3 air quality distributions will likely change in any given area upon attaining a particular standard, since strategies to reduce emissions are not yet fully defined. While some of these uncertainties were addressed quantitatively in the form of estimated confidence ranges around central risk estimates,

other uncertainties and the variability in key inputs were not reflected in these confidence ranges, but rather were partially characterized through separate sensitivity analyses or discussed qualitatively.

Key observations and insights from the O_3 risk assessment, together with important caveats and limitations, were discussed in section II.B of the proposal. In general, estimated risk reductions associated with going from current O_3 levels to just meeting the current and alternative 8-hour standards show patterns of increasing estimated risk reductions associated with just meeting the lower alternative 8-hour standards considered. Furthermore, the estimated percentage reductions in risk were strongly influenced by the baseline air quality year used in the analysis (see Staff Paper, Figures 6-1 through 6-6)

Key observations important in comparing estimated health risks associated with attainment of the current NAAQS and alternative standards included:

(1) As discussed in the Staff paper (section 5.4.5), EPA has greater confidence in relative comparisons in risk estimates between alternative standards than in the absolute magnitude of risk estimates associated with any particular standard.

(2) Significant year-to-year variability in O_3 concentrations combined with the use of a 3-year design value to determine the amount of air quality adjustment to be applied to each year analyzed, results in significant year-to-year variability in the annual health risk estimates upon just meeting the current and potential alternative standards.

(3) There is noticeable city-to-city variability in estimated O_3-related incidence of morbidity and mortality across the 12 urban areas analyzed for both recent years of air quality and for air quality adjusted to simulate just meeting the current and selected

potential alternative standards. This variability is likely due to differences in air quality distributions, differences in estimated exposure related to many factors including varying activity patterns and air exchange rates, differences in baseline incidence rates, and differences in susceptible populations and age distributions across the 12 urban areas.

(4) With respect to the uncertainties about estimated policy-relevant background (PRB) concentrations,[13] as discussed in the Staff Paper (section 5.4.3), alternative assumptions about background levels had a variable impact depending on the health effect considered and the location and standard analyzed in terms of the absolute magnitude and relative changes in the risk estimates. There was relatively little impact on either absolute magnitude or relative changes in lung function risk estimates due to alternative assumptions about background levels.[14] With respect to O_3-related non-accidental mortality, while notable differences (i.e., greater than 50 percent) were observed in some areas, particularly for more stringent standards, the overall pattern of

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[13] PRB O_3 concentrations used in the O_3 risk assessment were defined in chapter 2 of the Staff Paper (EPA, 2007, pp. 2-48, 2-54) as the O_3 concentrations that would be observed in the U.S. in the absence of anthropogenic emissions of precursors (e.g., VOC, NO_x, and CO) in the U.S., Canada, and Mexico. Based on runs of the GEOS-CHEM model (a global tropospheric O_3 model) applied for the 2001 warm season (i.e., April to September), monthly background daily diurnal profiles for each of the 12 urban areas for each month of the O_3 season were simulated using meteorology for the year 2001. Based on these model runs, the Criteria Document states that current estimates of PRB O_3 concentrations are generally in the range of 0.015 to 0.035 ppm in the afternoon, and they are generally lower under conditions conducive to high O_3 episodes. They are highest during spring due to contributions from hemispheric pollution and stratospheric intrusions. The Criteria Document states that the GEOS-CHEM model applied for the 2001 warm season reports PRB O_3 concentrations for afternoon surface air over the United States that are likely 10 ppbv too high in the southeast in summer, and accurate within 5 ppbv in other regions and seasons.

[14] Sensitivity analyses examining the impact of alternative assumptions about PRB were only conducted for lung function decrements and non-accidental mortality.

estimated reductions, expressed in terms of percentage reduction relative to the current standard, was significantly less impacted.

(5) Concerning the part of the risk assessment based on effects reported in epidemiological studies, important uncertainties include uncertainties (1) surrounding estimates of the O_3 coefficients for concentration-response relationships used in the assessment, (2) involving 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) related to 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 relationships for the same locations with lower air quality distributions and/or different behavior and/or housing conditions, and (4) concerning 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.

As discussed in the proposal, 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 percent credible

intervals. EPA recognizes that these credible intervals do not reflect all of the uncertainties noted above.

B. Need for Revision of the Current Primary O_3 Standard

1. Introduction

The initial issue to be addressed in this review of the primary O_3 standard is whether, in view of the advances in scientific knowledge reflected in the Criteria Document and Staff Paper, the current standard should be revised. As discussed in section II.C of the proposal, in evaluating whether it was appropriate to propose to retain or revise the current standard, the Administrator built upon the last review and reflected the broader body of evidence and information now available. In the proposal, EPA presented information, judgments, and conclusions from the last review, which revised the level, averaging time, and form of the standard, from the Staff Paper's evaluation of the adequacy of the current primary standard, including both evidence- and exposure/risk-based considerations, as well as from the CASAC Panel's advice and recommendations. The Staff Paper evaluation, CASAC Panel's views, and the Administrator's proposed conclusions on the adequacy of the current primary standard are presented below.

a. Staff Paper Evaluation

The Staff Paper considered the evidence presented in the Criteria Document as a basis for evaluating the adequacy of the current O_3 standard, recognizing that important uncertainties remain. The extensive body of human clinical, toxicological, and epidemiological evidence, highlighted above in section II.A.2 and discussed in section II.A of the proposal, serves as the basis for judgments about O_3-related health effects,

including judgments about causal relationships with a range of respiratory morbidity effects, including lung function decrements, increased respiratory symptoms, airway inflammation, increased airway responsiveness, and respiratory-related hospitalizations and emergency department visits in the warm season, and about the evidence being highly suggestive that O_3 directly or indirectly contributes to non-accidental and cardiorespiratory-related mortality.

These judgments take into account important uncertainties that remain in interpreting this evidence. For example, with regard to the utility of time-series epidemiological studies to inform judgments about a NAAQS for an individual pollutant, such as O_3, within a mix of highly correlated pollutants, such as the mix of oxidants produced in photochemical reactions in the atmosphere, the Staff Paper noted that there are limitations especially at ambient O_3 concentrations below levels at which O_3-related effects have been observed in controlled human exposure studies. The Staff Paper also recognized that the available epidemiological evidence neither supports nor refutes the existence of thresholds at the population level for effects such as increased hospital admissions and premature mortality. 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 variability in susceptibility to O_3-related effects in populations.

While noting these limitations in the interpretation of the findings from the epidemiological studies, the Staff Paper concluded that if a population threshold level does exist, it would likely be well below the level of the current O_3 standard and possibly within the range of background levels. This conclusion is supported by several

epidemiological studies that have explored the question of potential thresholds either by using a statistical curve-fitting approach to evaluate whether linear or non-linear models fit the data better using, or by analyzing sub-sets of the data where days over or under a specific cutpoint (e.g., 0.080 ppm or even lower O_3 levels) were excluded and then evaluating the association for statistical significance. In addition to consideration of the epidemiological studies, findings from controlled human exposure studies indicate that prolonged exposures produced statistically significant group mean FEV_1 decrements and symptoms in healthy adult subjects at levels down to at least 0.060 ppm, with a small percentage of subjects experiencing notable effects (e.g., >10 percent FEV_1 decrement, pain on deep inspiration). Controlled human exposure studies evaluated in the last review also found significant responses in indicators of lung inflammation and cell injury at 0.080 ppm in healthy adult subjects. The effects in these controlled human exposure studies were observed in healthy young adult subjects, and it is likely that more serious responses, and responses at lower levels, would occur in people with asthma and other respiratory diseases. These physiological effects can lead to aggravation of asthma and increased susceptibility to respiratory infection. The observations provide support for the conclusion in the Staff Paper that the associations observed in the epidemiological studies, particularly for respiratory-related effects such as increased medication use, increased school and work absences, increased visits to doctors' offices and emergency departments, and increased hospital admissions, extend down to O_3 levels well below the current standard (i.e., 0.084 ppm) (p. 6-7).

The newly available information reinforces the judgments in the Staff Paper from the last review about the likelihood of causal relationships between O_3 exposures and

respiratory effects and broadens the evidence of O_3-related associations to include additional respiratory-related endpoints, newly identified cardiovascular-related health endpoints, and mortality. Newly available evidence also led the Staff Paper to conclude that people with asthma are likely to experience more serious effects than people who do not have asthma. The Staff Paper also concluded that substantial progress has been made since the last review in advancing the understanding of potential mechanisms by which ambient O_3, alone and in combination with other pollutants, is causally linked to a range of respiratory-related health endpoints, and may be causally linked to a range of cardiovascular-related health endpoints. Thus, the Staff Paper found strong support in the evidence available since the last review, for consideration of an O_3 standard that is at least as protective as the current standard and finds no support for consideration of an O_3 standard that is less protective than the current standard. This conclusion is consistent with the advice and recommendations of the CASAC Panel and with the views expressed by all interested parties who provided comments on drafts of the Staff Paper. While the CASAC Panel and some commenters on drafts of the Staff Paper supported revising the current standard to provide increased public health protection and other such commenters supported retaining the current standard, no one who provided comments on drafts of the Staff Paper supported a standard that would be less protective than the current standard.

i. Evidence-Based Considerations

In looking more specifically at the controlled human exposure and epidemiological evidence, the Staff Paper first noted that controlled human exposure studies provide the clearest and most compelling evidence for an array of human health effects that are directly attributable to acute exposures to O_3 *per se*. Evidence from such

human studies, together with animal toxicological studies, help to provide biological plausibility for health effects observed in epidemiological studies. In considering the available evidence, the Staff Paper focused on studies that examined health effects that have been demonstrated to be caused by exposure to O_3, or for which the Criteria Document judges associations with O_3 to be causal or likely causal, or for which the evidence is highly suggestive that O_3 contributes to the reported effects.

In considering the epidemiological evidence as a basis for reaching conclusions about the adequacy of the current standard, the Staff Paper focused on studies reporting effects in the warm season, for which the effect estimates are more consistently positive and statistically significant than those from all-year studies. The Staff Paper considered the extent to which such studies provide evidence of associations that extend down to ambient O_3 concentrations below the level of the current standard, which would thereby call into question the adequacy of the current standard. In so doing, the Staff Paper noted that if a population threshold level does exist for an effect observed in such studies, it would likely be at a level well below the level of the current standard. The Staff Paper also attempted to characterize whether the area in which a study was conducted likely would or would not have met the current standard during the time of the study, although it recognizes that the confidence that would appropriately be placed on the associations observed in any given study, or on the extent to which the association would likely extend down to relatively low O_3 concentrations, is not dependent on this distinction. Further, the Staff Paper considered studies that examined subsets of data that include only days with ambient O_3 concentrations below the level of the current O_3 standard, or below even lower O_3 concentrations, and continue to report statistically significant associations.

The Staff Paper judged that such studies are directly relevant to considering the adequacy of the current standard, particularly in light of reported responses to O_3 at levels below the current standard found in controlled human exposure studies.

The Staff Paper evaluation of such studies is discussed below and in section II.C.2.a of the proposal, focusing in turn on studies of (1) lung function, respiratory symptoms and other respiratory-related physiological effects, (2) respiratory hospital admissions and emergency department visits, and (3) mortality.

(1) Lung function, respiratory symptoms and other respiratory-related physiological effects. Health effects for which the Criteria Document continued to find clear evidence of causal associations with short-term O_3 exposures include lung function decrements, respiratory symptoms, pulmonary inflammation, and increased airway responsiveness. In the last review, these O_3-induced effects were demonstrated with statistical significance down to the lowest level tested in controlled human exposure studies at that time (i.e., 0.080 ppm). Two new studies are notable in that they are the only controlled human exposure studies that examined respiratory effects, including lung function decrements and respiratory symptoms, in healthy adults at lower exposure levels than had previously been examined. EPA's reanalysis of the data from the most recent study shows small group mean decrements in lung function responses to be statistically significant at the 0.060 ppm exposure level, while the author's analysis did not yield statistically significant lung function responses but did yield some statistically significant respiratory symptom responses toward the end of the exposure period. These studies report a small percentage of subjects experiencing lung function decrements ($\geq$ 10 percent) at the 0.060 ppm exposure level. These studies provide very limited evidence of

O_3-related lung function decrements and respiratory symptoms at this lower exposure level.

The Staff Paper noted that evidence from controlled human exposures studies indicates that people with moderate-to-severe asthma have somewhat larger decreases in lung function in response to O_3 relative to healthy individuals. In addition, lung function responses in people with asthma appear to be affected by baseline lung function (i.e., magnitude of responses increases with increasing disease severity). This newer information expands our understanding of the physiological basis for increased sensitivity in people with asthma and other airway diseases, recognizing that people with asthma present a different response profile for cellular, molecular, and biochemical responses than people who do not have asthma. New evidence indicates that some people with asthma have increased occurrence and duration of nonspecific airway responsiveness, which is an increased bronchoconstrictive response to airway irritants. Controlled human exposure studies also indicate that some people with allergic asthma and rhinitis have increased airway responsiveness to allergens following O_3 exposure. Exposures to O_3 exacerbated lung function decrements in people with pre-existing allergic airway disease, with and without asthma. Ozone-induced exacerbation of airway responsiveness persists longer and attenuates more slowly than O_3-induced lung function decrements and respiratory symptom responses and can have important clinical implications for asthmatics.

The Staff Paper also concluded that newly available human exposure studies suggest that some people with asthma also have increased inflammatory responses, relative to non-asthmatic subjects, and that this inflammation may take longer to resolve.

The new data on airway responsiveness, inflammation, and various molecular markers of inflammation and bronchoconstriction indicate that people with asthma and allergic rhinitis (with or without asthma) comprise susceptible groups for O_3-induced adverse effects. This body of evidence qualitatively informs the Staff Paper's evaluation of the adequacy of the current O_3 standard in that it indicates that controlled human exposure and epidemiological panel 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.

The Staff Paper noted that in addition to the experimental evidence of lung function decrements, respiratory symptoms, and other respiratory effects in healthy and asthmatic populations discussed above, epidemiological studies have reported associations of lung function decrements and respiratory symptoms in several locations. Two large U.S. panel studies which together followed over 1000 asthmatic children on a daily basis (Mortimer et al., 2002, the National Cooperative Inner-City Asthma Study, or NCICAS; and Gent et al., 2003), as well as several smaller U.S. and international studies, have reported robust associations between ambient O_3 concentrations and measures of lung function, daily respiratory symptoms (e.g., chest tightness, wheeze, shortness of breath), and increased asthma medication use in children with moderate to severe asthma. Mortimer et al. (2002) found that of the pollutants measured (including O_3, NO_2, SO_2 and PM_{10}), O_3 was the only one that had a statistically significant effect on lung function. Mortimer et al. (2002) also found associations between NO_2, SO_2 and PM_{10} and respiratory symptoms that were stronger than those between O_3 and respiratory symptoms. Gent et al. (2003) found that in co-pollutant models, O_3 but not $PM_{2.5}$

significantly predicted increased risk of respiratory symptoms and rescue medication use among children using asthma maintenance medication. Overall, the multi-city NCICAS (Mortimer et al., 2002), Gent et al. (2003), and several other single-city studies indicate a robust positive association between ambient O_3 concentrations and increased respiratory symptoms and increased medication use in asthmatic children.

In considering the large number of single-city epidemiological studies reporting lung function or respiratory symptoms effects in healthy or asthmatic populations, the Staff Paper noted that most such studies that reported positive and often statistically significant associations in the warm season were conducted in areas that likely would not have met the current standard. In considering the large multi-city NCICAS (Mortimer et al., 2002), the Staff Paper noted that the 98th percentile 8-hour daily maximum O_3 concentrations at the monitor reporting the highest O_3 concentrations in each of the study areas ranged from 0.084 ppm to > 0.10 ppm. However, the authors indicate that less than 5 percent of the days in the eight urban areas had 8-hour daily O_3 concentrations exceeding 0.080 ppm. Moreover, the authors observed that when days with 8-hour average O_3 levels greater than 0.080 ppm were excluded, similar effect estimates were seen compared to estimates that included all of the days. There are also a few other studies in which the relevant air quality statistics provide some indication that lung function and respiratory symptom effects may be occurring in areas that likely would have met the current standard (EPA, 2007b, p.6-12).

(2) Respiratory hospital admissions and emergency department visits. At the time of the last review, many time-series studies indicated positive associations between ambient O_3 and increased respiratory hospital admissions and emergency room visits,

providing strong evidence for a relationship between O_3 exposure and increased exacerbations of preexisting lung disease extending below the level of the then current 1-hour O_3 standard (EPA 2007b, section 3.3.1.1.6). Analyses of data from studies conducted in the northeastern U.S. indicated that O_3 air pollution was consistently and strongly associated with summertime respiratory hospital admissions.

Since the last review, new epidemiological studies have evaluated the association between short-term exposures to O_3 and unscheduled hospital admissions for respiratory causes. Large multi-city studies, as well as many studies from individual cities, have reported positive and often statistically significant O_3 associations with total respiratory hospitalizations as well as asthma- and chronic obstructive pulmonary disease (COPD)-related hospitalizations, especially in studies analyzing the O_3 effect during the summer or warm season. Analyses using multipollutant regression models generally indicate that copollutants do not confound the association between O_3 and respiratory hospitalizations and that the O_3 effect estimates were robust to PM adjustment in all-year and warm-season only data. The Criteria Document concluded that the evidence supports a causal relationship between acute O_3 exposures and increased respiratory-related hospitalizations during the warm season.

In looking specifically at U.S. and Canadian respiratory hospitalization studies that reported positive and often statistically significant associations (and that either did not use GAM or were reanalyzed to address GAM-related problems), the Staff Paper noted that many such studies were conducted in areas that likely would not have met the current O_3 standard, with many providing only all-year effect estimates, and with some reporting a statistically significant association in the warm season. Of the studies that

provide some indication that O_3-related respiratory hospitalizations may be occurring in areas that likely would have met the current standard, the Staff Paper noted that some are all-year studies, whereas others reported statistically significant warm-season associations.

Emergency department visits for respiratory causes have been the focus of a number of new studies that have examined visits related to asthma, COPD, bronchitis, pneumonia, and other upper and lower respiratory infections, such as influenza, with asthma visits typically dominating the daily incidence counts. Among studies with adequate controls for seasonal patterns, many reported at least one significant positive association involving O_3. However, inconsistencies were observed which were at least partially attributable to differences in model specifications and analysis approach among various studies. In general, O_3 effect estimates from summer-only analyses tended to be positive and larger compared to results from cool season or all-year analyses. Almost all of the studies that reported statistically significant effect estimates were conducted in areas that likely would not have met the current standard. The Criteria Document concluded that analyses stratified by season generally supported a positive association between O_3 concentrations and emergency department visits for asthma in the warm season. These studies provide evidence of effects in areas that likely would not have met the current standard and evidence of associations that likely extend down to relatively low ambient O_3 concentrations.

(3) Mortality. The 1996 Criteria Document concluded that an association between daily mortality and O_3 concentrations for areas with high O_3 levels (e.g., Los Angeles) was suggested. However, due to inconsistencies in the results from the very

limited number of studies available at that time, there was insufficient evidence to determine whether the observed association was likely causal, and thus the possibility that O_3 exposure may be associated with mortality was not relied upon in the 1997 decision on the O_3 primary standard.

Since the last review, the body of evidence with regard to O_3-related health effects has been expanded by animal, controlled human exposure, and epidemiological studies and now identifies biologically plausible mechanisms by which O_3 may affect the cardiovascular system. In addition, there is stronger information linking O_3 to serious morbidity outcomes, such as hospitalization, that are associated with increased mortality. Thus, there is now a coherent body of evidence that describes a range of health outcomes from lung function decrements to hospitalization and premature mortality.

Newly available large multi-city studies and related analyses (Bell et al., 2004; Huang et al., 2005; and Schwartz, 2005) designed specifically to examine the effect of O_3 and other pollutants on mortality have provided much more robust and credible information. Together these studies have reported significant associations between O_3 and mortality that were robust to adjustment for PM and different adjustment methods for temperature and suggest that the effect of O_3 on mortality may be immediate but may also persists for several days. Further analysis of one of these multi-city studies (Bell et al., 2006) examined the shape of the concentration-response function for the O_3-mortality relationship in 98 U.S. urban communities for the period 1987 to 2000 specifically to evaluate whether a threshold level exists. Results from various analytic methods all indicated that any threshold, if it exists, would likely occur at very low concentrations, far below the level of the current O_3 NAAQS and nearing background levels.

New data are also available from several single-city studies conducted worldwide, as well as from several meta-analyses that have combined information from multiple studies. Three recent meta-analyses evaluated potential sources of heterogeneity in O_3-mortality associations. All three analyses reported common findings, including effect estimates that were statistically significant and larger in warm season analyses. Reanalysis of results using default GAM criteria did not change the effect estimates, and there was no strong evidence of confounding by PM.

Overall, the Criteria Document (p.8-78) found that the results from U.S. multi-city time-series studies, along with the meta-analyses, provide relatively strong evidence for associations between short-term O_3 exposure and all-cause mortality even after adjustment for the influence of season and PM. The results of these analyses of studies considered in this review indicate that copollutants generally do not appear to substantially confound the association between O_3 and mortality. In addition, several single-city studies observed positive associations of ambient O_3 concentrations with total nonaccidental and cardiorespiratory mortality.

Finally, from those studies that included assessment of associations with specific causes of death, it appears that effect estimates for associations with cardiovascular mortality are larger than those for total mortality; effect estimates for respiratory mortality are less consistent in size, possibly due to reduced statistical power in this subcategory of mortality. For cardiovascular mortality, the Criteria Document (p.7-106) suggested that effect estimates are consistently positive and more likely to be larger and statistically significant in warm season analyses. The Criteria Document (p.8-78) concluded that these findings are highly suggestive that short-term O_3 exposure directly

or indirectly contributes to nonaccidental and cardiorespiratory-related mortality, but additional research is needed to more fully establish underlying mechanisms by which such effects occur.[15]

ii. Exposure- and Risk-Based Considerations

In evaluating the adequacy of the current standard, the Staff Paper also considered estimated quantitative exposures and health risks, and important uncertainties and limitations in those estimates, which are highlighted above in section II.A.3 and discussed in section II.B of the proposal. These estimates are derived from an EPA assessment of exposures and health risks associated with recent air quality levels and with air quality simulated to just meet the current standard to help inform judgments about whether or not the current standard provides adequate protection of public health.

The Staff Paper (and the CASAC Panel) 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 Staff Paper did not have sufficient information to evaluate all relevant at-risk groups (e.g., outdoor workers, children under age 5) or all O_3-related health outcomes (e.g., increased medication use, school absences, and emergency department visits that are part of a broader pyramid of effects), and the scope of the Staff

[15] In commenting on the Criteria Document, the CASAC Ozone Panel raised questions about the implications of these time-series results in a policy context, emphasizing that "…while the time-series study design is a powerful tool to detect very small effects that could not be detected using other designs, it is also a blunt tool" (Henderson, 2006b). They note that ". . .not only is the interpretation of these associations complicated by the fact that the day-to-day variation in concentrations of these pollutants is, to a varying degree, determined by meteorology, the pollutants are often part of a large and highly correlated mix of pollutants, only a very few of which are measured" (Henderson, 2006b). Even with these uncertainties, the CASAC Ozone Panel, in its review of the Staff Paper, found "…premature total non-accidental and cardiorespiratory mortality for inclusion in the quantitative risk assessment to be appropriate." (Henderson, 2006b)

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, due to the limited geographic scope of the exposure and risk assessments, EPA recognizes that national-scale public health impacts of ambient O_3 exposures would be much larger than the quantitative exposure and risk estimates associated with recent air quality or air quality that just meets the current or alternative standards in the 12 urban areas analyzed. On the other hand, inter-individual variability in responsiveness means that only a subset of individuals in each group estimated to experience exposures at and above a given benchmark level while at elevated exertion would actually be expected to experience such adverse health effects.

The Staff Paper estimated exposures and risks for the three most recent years (2002 - 2004) for which data were available at the time of the analyses. As discussed above in section II.A.3.a, within this 3-year period, 2002 was a year with relatively higher O_3 levels in most, but not all, areas and simulation of just meeting the current standard based on 2002 air quality data provides a generally higher-end estimate of exposures and risks, while 2004 was a year with relatively lower O_3 levels in most, but not all, areas and simulation of just meeting the current standard using 2004 air quality data provides a generally lower-end estimate of exposures and risks.

The Staff Paper consideration of such exposure and risk analyses is discussed below and in section II.C.2.b of the proposal, focusing on both the exposure analyses and the human health risk assessment.

(1) Exposure analyses. EPA's exposure analysis estimated personal exposures to ambient O_3 levels at and above specific benchmark levels while at elevated exertion to

provide some perspective on the potential public health impacts of respiratory symptoms and respiratory-related physiological effects that cannot currently be evaluated in quantitative risk assessments but that may occur at current air quality levels, and the extent to which such impacts might be reduced by meeting the current and alternative standards. As noted above in section II.A.3, the Staff Paper referred to exposures at and above these benchmark levels as "exposures of concern." The Staff Paper noted that potential public health impacts likely occur across a range of O_3 exposure levels, such that there is no one exposure level that addresses all relevant public health impacts. Therefore, with the concurrence of the CASAC Panel, the Staff Paper estimated exposures of concern not only at 0.080 ppm O_3, a level at which there are demonstrated effects, but also at 0.070 and 0.060 ppm O_3. The Staff Paper recognized that there will be varying degrees of concern about exposures at each of these levels, based in part on the population subgroups experiencing them. Given that there is clear evidence of inflammation, increased airway responsiveness, and changes in host defenses in healthy people exposed to 0.080 ppm O_3 and reason to infer that such effects will continue at lower exposure levels, but with increasing uncertainty about the extent to which such effects occur at lower O_3 concentrations, the Staff Paper focused on exposures at or above benchmark levels of 0.070 and 0.060 ppm O_3 while at elevated exertion for purposes of evaluating the adequacy of the current standard.

Exposure estimates were presented in the Staff Paper and in section II.B (Table 1) of the proposal for the number and percent of all school age children and asthmatic school age 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. The percent of population exposed at any given level is very similar for all and asthmatic school age children. Substantial year-to-year variability in exposure estimates is observed, ranging to over an order of magnitude at the current standard level, in estimates of the number of children and the number of occurrences of exposures at both of these benchmark levels while at elevated exertion. The Staff Paper stated that it is appropriate to consider not just the average estimates across all years, but also to consider public health impacts in years with relatively higher O_3 levels. The Staff Paper also noted 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 where these estimates are higher than the average upon meeting the current standard.

About 50 percent of asthmatic or all school age children, representing nearly 1.3 million asthmatic children and about 8.5 million school age children in the 12 urban areas examined, are estimated to experience exposures at or above the 0.070 ppm benchmark level while at elevated exertion (i.e., these individuals are estimated to experience 8-hour O_3 exposures at or above 0.070 ppm while engaged in moderate or greater exertion 1 or more times during the O_3 season) associated with 2002 O_3 air quality levels. In contrast, about 17 percent of asthmatic and all school age children are estimated to experience exposures at or above the 0.070 ppm benchmark level while at elevated exertion associated with 2004 O_3 air quality levels. Just meeting the current standard results in an aggregate estimate of about 20 percent of asthmatic or 18 percent or all school age children likely to experience exposures at or above the 0.070 ppm benchmark level while at elevated exertion using the 2002 simulation. The exposure estimates for this

benchmark level range up to about 40 percent of asthmatic or all school age children in the single city with the highest estimate among the cities analyzed. Just meeting the current standard based on the 2004 simulation, results in an aggregate estimate of about 1 percent of asthmatic or all school age children experiencing exposures exceeding the 0.070 ppm benchmark level while at elevated exertion.

At the benchmark level of 0.060 ppm, about 70 percent of all or asthmatic school age children are estimated to experience exposures at or above this benchmark level while at elevated exertion for the aggregate of the 12 urban areas associated with 2002 O_3 levels. Just meeting the current standard would result in an aggregate estimate of about 45 percent of asthmatic or all school age children likely to experience exposures at or above the 0.060 ppm benchmark level while at elevated exertion using the 2002 simulation. The exposure estimates for this benchmark level range up to nearly 70 percent of all or asthmatic school age children in the single city with the highest estimate among the cities analyzed associated with just meeting the current standard using the 2002 simulation. The Staff Paper indicated an aggregate estimate of about 10 percent of asthmatic or all school age children would experience exposures at or above the 0.060 ppm benchmark level while at elevated exertion associated with just meeting the current standard using the 2004 simulation.

(2) Risk assessment. The health risk assessment estimated risks for several important health endpoints, including: (1) lung function decrements (i.e., ≥ 15 percent and ≥ 20 percent reductions in FEV_1) in all school age children for 12 urban areas; (2) lung function decrements (i.e., ≥ 10 percent and ≥ 20 percent reductions in FEV_1) in asthmatic school age children for 5 urban areas (a subset of the 12 urban areas); (3)

respiratory symptoms (i.e., chest tightness, shortness of breath, wheeze) in moderate to severe asthmatic children for the Boston area; (4) respiratory-related hospital admissions for 3 urban areas; and (5) nonaccidental and cardiorespiratory mortality for 12 urban areas for three recent years (2002 to 2004) and for just meeting the current standard using a 2002 simulation and a 2004 simulation.

With regard to estimates of moderate lung function decrements, meeting the current standard substantially reduces the estimated number of school age children experiencing one or more occurrences of FEV_1 decrements $\geq$ 15 percent for the 12 urban areas, going from about 1.3 million children (7 percent of children) under 2002 air quality to about 610,000 (3 percent of children) based on the 2002 simulation, and from about 620,000 children (3 percent of children) to about 230,000 (1 percent of children) using the 2004 simulation. In asthmatic children, the estimated number of children experiencing one or more occurrences of FEV_1 decrements $\geq$ 10 percent for the 5 urban areas goes from about 250,000 children (16 percent of asthmatic children) under 2002 air quality to about 130,000 (8 percent of asthmatic children) using the 2002 simulation, and from about 160,000 (10 percent of asthmatic children) to about 70,000 (4 percent of asthmatic children) using the 2004 simulation. Thus, even when the current standard is met, about 4 to 8 percent of asthmatic school age children are estimated to experience one or more occurrences of moderate lung function decrements, resulting in about 1 million occurrences (using the 2002 simulation) and nearly 700,000 occurrence (using the 2004 simulation) in just 5 urban areas. Moreover, the estimated number of occurrences of moderate or greater lung function decrements per child is on average approximately 6 to 7 in all children and 8 to 10 in asthmatic children in an O_3 season, even when the current

standard is met, depending on the year used to simulate meeting the current standard. In the 1997 review of the O_3 standard a general consensus view of the adversity of such moderate responses emerged as the frequency of occurrences increases, with the judgment that repeated occurrences of moderate responses, even in otherwise healthy individuals, may be considered adverse since they may well set the stage for more serious illness.

With regard to estimates of large lung function decrements, the Staff Paper noted that FEV_1 decrements > 20 percent would likely interfere with normal activities in many healthy individuals, therefore single occurrences would be considered to be adverse. In people with asthma, large lung function responses would likely interfere with normal activities for most individuals and would also increase the likelihood that these individuals would use additional medication or seek medical treatment. Single occurrences would be considered to be adverse to asthmatic individuals under the ATS definition. They also would be cause for medical concern in some individuals. While the current standard reduces the occurrences of large lung function decrements in all children and asthmatic children from about 60 to 70%, in a year with relatively higher O_3 levels (2002), there are estimated to be about 500,000 occurrences in all school children across the entire 12 urban areas, and about 40,000 occurrences in asthmatic children across just 5 urban areas. As noted above, it is clear that even when the current standard is met over a three-year period, O_3 levels in each year can vary considerably, as evidenced by relatively large differences between risk estimates based on 2002 to 2004 air quality. The Staff Paper expressed the view that it was appropriate to consider this yearly variation in O_3 levels allowed by the current standard in judging the extent to which impacts on

members of at-risk groups in a year with relatively higher O_3 levels remains of concern from a public health perspective.

With regard to other O_3-related health effects, the estimated risks of respiratory symptom days in moderate to severe asthmatic children, respiratory-related hospital admissions, and non-accidental and cardiorespiratory mortality, respectively, are not reduced to as great an extent by meeting the current standard as are lung function decrements. For example, just meeting the current standard reduces the estimated average incidence of chest tightness in moderate to severe asthmatic children living in the Boston urban area by 11 to 15%, based on 2002 and 2004 simulations, respectively, resulting in an estimated incidence of about 23,000 to 31,000 per 100,000 children attributable to O_3 exposure (Table 6-4). Just meeting the current standard is estimated to reduce the incidence of respiratory-related hospital admissions in the New York City urban area by about 16 to 18%, based on 2002 and 2004 simulations, respectively, resulting in an estimated incidence per 100,000 population of 4.6 to 6.4, respectively. Across the 12 urban areas, the estimates of non-accidental mortality incidence per 100,000 relevant population range from 0.4 to 2.6 (for 2002) and 0.5 to 1.5 (for 2004). Meeting the current standard results in a reduction of the estimated incidence per 100,000 population to a range of 0.3 to 2.4 based on the 2002 simulation and a range of 0.3 to 1.2 based on the 2004 simulation. Estimates for cardiorespiratory mortality show similar patterns.

In considering the estimates of the proportion of population affected and the number of occurrences of the health effects that are included in the risk assessment, the Staff Paper noted that these limited estimates are indicative of a much broader array of

potential O_3-related health endpoints that we consider 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, emergency department visits) and which primarily affect members of at-risk groups. While the Staff Paper had sufficient information to estimate and consider the number of symptom days in children with moderate to severe asthma, it recognized that there are many other effects that may be associated with symptom days, such as increased medication use, school and work absences, or visits to doctors' offices, for which there was not sufficient information to estimate risks but which are important to consider in assessing the adequacy of the current standard. The same is true for more serious, but less frequent effects. The Staff Paper estimated hospital admissions, but there was not sufficient information to estimate emergency department visits in a quantitative risk assessment. Consideration of such unquantified risks in the Staff Paper reinforced the Staff Paper conclusion that consideration should be given to revising the standard so as to provide increased public health protection, especially for at-risk groups such as people with asthma or other lung diseases, as well as children and older adults, particularly those active outdoors, and outdoor workers.

iii. Summary of Staff Paper Considerations

The Staff Paper concluded that the overall body of evidence clearly calls into question the adequacy of the current standard in protecting at-risk groups against an array of adverse health effects that range from decreased lung function and respiratory symptoms to serious indicators of respiratory morbidity including emergency department visits and hospital admissions for respiratory causes, nonaccidental mortality, and

possibly cardiovascular effects. These at-risk groups notably include asthmatic children and other people with lung disease, as well as all children and older adults, especially those active outdoors, and outdoor workers.[16] The available information provides strong support for consideration of an O_3 standard that would provide increased health protection for these at-risk groups. The Staff Paper also concluded that risks projected to remain upon meeting the current standard are indicative of risks to at-risk groups that can be judged to be important from a public health perspective. This information reinforced the Staff Paper conclusion that consideration should be given to revising the level of the standard so as to provide increased public health protection.

b. CASAC Views

The CASAC Panel unanimously concluded in a letter to the Administrator that there is "no scientific justification for retaining" the current primary O_3 standard, and the current standard "needs to be substantially reduced to protect human health, particularly in sensitive subpopulations" (Henderson, 2006c, pp. 1-2). In its rationale for this conclusion, the CASAC Panel concluded that "new evidence supports and build-upon key, health-related conclusions drawn in the 1997 O_3 NAAQS review" (id., p. 3). The Panel noted that several new single-city studies and large multi-city studies have provided more evidence for adverse health effects at concentrations lower than the current standard, and that these epidemiological studies are backed-up by evidence from controlled human exposure studies. The Panel specifically noted evidence from the recent Adams (2006) study that reported statistically significant decrements in the lung function of healthy, moderately exercising adults at a 0.080 ppm exposure level, and

[16] In defining at-risk groups this way we are including both groups with greater inherent sensitivity and those more likely to be exposed.

importantly, also reported adverse lung function effects in some healthy individuals at 0.060 ppm. The CASAC Panel concluded that these results indicate that the current standard "is not sufficiently health-protective with an adequate margin of safety," noting that while similar studies in sensitive groups such as asthmatics have yet to be conducted, "people with asthma, and particularly children, have been found to be more sensitive and to experience larger decrements in lung function in response to O_3 exposures than would healthy volunteers (Mortimer et al., 2002)" (Henderson, 2006c, p. 4).

The CASAC Panel also highlighted a number of O_3-related adverse health effects that are associated with exposure to ambient O_3, below the level of the current standard based on a broad range of epidemiological studies (Henderson, 2006c). These adverse health effects include increases in school absenteeism, respiratory hospital emergency department visits among asthmatics and patients with other respiratory diseases, hospitalizations for respiratory illnesses, symptoms associated with adverse health effects (including chest tightness and medication usage), and premature mortality (nonaccidental, cardiorespiratory deaths) reported at exposure levels well below the current standard. "The CASAC considers each of these findings to be an important indicator of adverse health effects" (Henderson, 2006c).

The CASAC Panel expressed the view that more emphasis should be placed on the subjects in controlled human exposure studies with FEV_1 decrements greater than 10 percent, which can be clinically significant, rather than on the relatively small average decrements. The Panel also emphasized significant O_3-related inflammatory responses and markers of injury to the epithelial lining of the lung that are independent of spirometric responses. Further, the Panel expressed the view that the Staff Paper did not

place enough emphasis on serious morbidity (e.g., hospital admissions) and mortality observed in epidemiological studies. On the basis of the large amount of recent data evaluating adverse health effects at levels at and below the current O_3 standard, it was the unanimous opinion of the CASAC Panel that the current primary O_3 standard is not adequate to protect human health, that the relevant scientific data do not support consideration of retaining the current standard, and that the current standard needs to be substantially reduced to be protective of human health, particularly in sensitive subpopulations (Henderson, 2006c, pp. 4-5).

Further, the CASAC letter noted that "there is no longer significant scientific uncertainty regarding the CASAC's conclusion that the current 8-hour primary NAAQS must be lowered" (Henderson, 2006c, p. 5). The Panel noted that a "large body of data clearly demonstrates adverse human health effects at the current level" of the standard, such that "[R]etaining this standard would continue to put large numbers of individuals at risk for respiratory effects and/or significant impact on quality of life including asthma exacerbations, emergency room visits, hospital admissions and mortality" (Henderson, 2006c).

c. Administrator's Proposed Conclusions

At the time of proposal, in considering whether the current primary standard should be revised, the Administrator carefully considered the conclusions contained in the Criteria Document, the rationale and recommendations contained in the Staff Paper, the advice and recommendations from CASAC, and public comments to date on this issue. In so doing, the Administrator noted the following: (1) that evidence of a range of respiratory-related morbidity effects seen in the last review has been considerably

strengthened, both through toxicological and controlled human exposure studies as well as through many new panel and epidemiological studies; (2) that new evidence from controlled human exposure and epidemiological studies identifies people with asthma (including children with asthma) as an important susceptible population for which estimates of respiratory effects in the general population likely underestimate the magnitude or importance of these effects; (3) that new evidence about mechanisms of toxicity further contributes to the biological plausibility of O_3-induced respiratory effects and is beginning to suggest mechanisms that may link O_3 exposure to cardiovascular effects; (4) that there is now relatively strong evidence for associations between O_3 and total nonaccidental and cardiopulmonary mortality, even after adjustment for the influence of season and PM; and (5) the limits of the available evidence. Relative to the information that was available to inform the Agency's 1997 decision to set the current standard, the newly available evidence increased the Administrator's confidence that respiratory morbidity effects such as lung function decrements and respiratory symptoms are causally related to O_3 exposures, that indicators of respiratory morbidity such as emergency department visits and hospital admissions are causally related to O_3 exposures, and that the evidence is highly suggestive that O_3 exposures during the O_3 season contribute to premature mortality.

The Administrator judged that there is important new evidence demonstrating that exposures to O_3 at levels below the level of the current standard are associated with a broad array of adverse health effects, especially in at-risk populations that include people with asthma or other lung diseases who are likely to experience more serious effects from exposure to O_3, children and older adults with increased susceptibility, as well as those

who are likely to be vulnerable as a result of spending a lot of time outdoors engaged in physical activity, especially active children and outdoor workers. Examples of this important new evidence include demonstration of O_3-induced lung function effects and respiratory symptoms in some healthy individuals down to the previously observed exposure level of 0.080 ppm, as well as very limited new evidence at exposure levels well below the level of the current standard. In addition, there is now epidemiological evidence of statistically significant O_3-related associations with lung function and respiratory symptom effects, respiratory-related emergency department visits and hospital admissions, and increased mortality, in areas that likely would have met the current standard. There are also many epidemiological studies done in areas that likely would not have met the current standard but which nonetheless report statistically significant associations that generally extend down to ambient O_3 concentrations that are below the level of the current standard. Further, there are a few studies that have examined subsets of data that include only days with ambient O_3 concentrations below the level of the current standard, or below even much lower O_3 concentrations, and continue to report statistically significant associations with respiratory morbidity outcomes and mortality. The Administrator recognized that the evidence from controlled human exposure studies, together with animal toxicological studies, provides considerable support for the biological plausibility of the respiratory morbidity associations observed in the epidemiological studies and for concluding that the associations extend below the level of the current standard. However, the Administrator recognized that in the body of epidemiological evidence, many studies reported positive and statistically significant associations, while others reported positive results that were not statistically significant,

and a few did not report any positive O_3-related associations. In addition, the Administrator judged that evidence of a causal relationship between adverse health outcomes and O_3 exposures became increasingly uncertain at lower levels of exposure.

Based on the strength of the currently available evidence of adverse health effects, and on the extent to which the evidence indicates that such effects likely result from exposures to ambient O_3 concentrations below the level of the current standard, the Administrator judged that the current standard does not protect public health with an adequate margin of safety and that the standard should be revised to provide such protection, especially for at-risk groups, against a broad array of adverse health effects.

In reaching this judgment, the Administrator had also considered the results of both the exposure and risk assessments conducted for this review, to provide some perspective on the extent to which at-risk groups would likely experience "exposures of concern"[17] and on the potential magnitude of the risk of experiencing various adverse health effects when recent air quality data (from 2002 to 2004) are used to simulate meeting the current standard and alternative standards in a number of urban areas in the U.S.[18] In considering the results of the health risk assessment, as discussed in the proposal notice (section II.C.2), the Administrator noted that there were important

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[17] As discussed in section II.A.3 above, "exposures of concern" are estimates of personal exposures while at moderate or greater exertion to 8-hour average ambient O_3 levels at and above specific benchmark levels which represent exposure levels at which O_3-related health effects are known or can with varying degrees of certainty be inferred to occur in some individuals. Estimates of exposures of concern provide some perspective on the public health impacts of health effects that may occur in some individuals at recent air quality levels but cannot be evaluated in quantitative risk assessments, and the extent to which such impacts might be reduced by meeting the current and alternative standards.

[18] As noted above in section II.A.3, recent O_3 air quality distributions have been statistically adjusted to simulate just meeting the current and selected alternative standards. These simulations do not represent predictions of when, whether, or how areas might meet the specified standards.

uncertainties and assumptions inherent in the risk assessment and that this assessment was most appropriately used to simulate trends and patterns that could be expected, as well as providing informed, but still imprecise, estimates of the potential magnitude of risks.

In considering the exposure assessment results at the time of proposal, the Administrator considered analyses that define "exposures of concern" by three benchmark exposure levels: 0.080, 0.070, and 0.060 ppm. Estimates of exposures in at-risk groups at and above these benchmark levels while at elevated exertion, using O_3 air quality data in 2002 and 2004, provide some indication of the potential magnitude of the incidence of health outcomes that cannot currently be evaluated in a quantitative risk assessment, such as increased airway responsiveness, increased pulmonary inflammation, increased cellular permeability, and decreased pulmonary defense mechanisms. These respiratory-related physiological effects have been demonstrated to occur in healthy people at O_3 exposures as low as 0.080 ppm, the lowest level tested for these effects. These physiological effects provide plausible mechanisms underlying observed associations with aggravation of asthma, increased medication use, increased school and work absences, increased susceptibility to respiratory infection, increased visits to doctors' offices and emergency departments, and increased admissions to hospitals. In addition, these physiological effects, if repeated over time, have the potential to lead to chronic effects such as chronic bronchitis or long-term damage to the lungs that can lead to reduced quality of life.

In considering these various benchmark levels for exposures of concern at the time of proposal, the Administrator focused primarily on estimated exposures at and

above the 0.070 ppm benchmark level while at elevated exertion as an important surrogate measure for potentially more serious health effects in at-risk groups such as people with asthma. This judgment was based on the strong evidence of effects in healthy people at the 0.080 ppm exposure level and the new evidence that people with asthma are likely to experience larger and more serious effects than healthy people at the same level of exposure. In the Administrator's view at the time of proposal, this evidence did not support a focus on exposures at and above the benchmark level of 0.080 ppm O_3, as it would not adequately account for the increased risk of harm from exposure for members of at-risk groups, especially people with asthma. The Administrator also judged that the evidence of demonstrated effects is too limited to support a primary focus on exposures down to the lowest benchmark level considered of 0.060 ppm. The Administrator particularly noted that although the analysis of "exposures of concern" was conducted to estimate exposures at and above three discrete benchmark levels (0.080, 0.070, and 0.060 ppm) while at elevated exertion, the concept is appropriately viewed as a continuum. In so doing, the Administrator sought to balance concern 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 exposure levels.

The Administrator observed that based on the aggregate exposure estimates for the 2002 simulation (summarized in section II.B.1, Table 1, of the proposal) for the 12 U.S. urban areas included in the exposure analysis, upon just meeting the current standard up to about 20 percent of asthmatic or all school age children are likely to experience one or more exposures at and above the 0.070 ppm benchmark level while at elevated exertion; the 2004 simulation yielded an estimate of about 1 percent of such children.

The Administrator noted from this comparison that there is substantial year-to-year variability, ranging up to an order of magnitude or more in estimates of the number of people and the number of occurrences of exposures at and above this benchmark level while at elevated exertion. Moreover, within any given year, the exposure assessment indicates that there is substantial city-to-city variability in the estimates of the children exposed or the number of occurrences of exposure at and above this benchmark level while at elevated exertion. For example, city-specific estimates of the percent of asthmatic or all school age children likely to experience exposures at and above the benchmark level of 0.070 ppm while at elevated exertion ranges from about 1 percent up to about 40 percent across the 12 urban areas upon just meeting the current standard based on the 2002 simulation; the 2004 simulation yielded estimates that range from about 0 up to about 7 percent. The Administrator judged that it was important to recognize the substantial year-to-year and city-to-city variability in considering these estimates.

With regard to the results of the risk assessment, the Administrator focused on the risks estimated to remain upon just meeting the current standard. Based on the aggregate risk estimates (summarized in section II.B.2, Table 2, of the proposal), the Administrator observed that upon just meeting the current standard based on the 2002 simulation, approximately 8 percent of asthmatic school age children across 5 urban areas (ranging up to about 11 percent in the city with the highest estimate among the cities analyzed) would still be estimated to experience moderate or greater lung function decrements one or more times within an O_3 season. These estimated percentages would be approximately 3 percent of all school age children across 12 urban areas (ranging up to over 5 percent in

the city with the highest estimate among the cities analyzed). The Administrator recognized that, as with the estimates of exposures of concern, there is substantial year-to-year and city-to-city variability in these risk estimates.

In addition to the percentage of asthmatic or all children estimated to experience one or more occurrences of an effect, the Administrator recognized that some individuals are estimated to have multiple occurrences. For example, across all the cities in the assessment, approximately 6 to 7 occurrences of moderate or greater lung function decrements per child are estimated to occur in all children and approximately 8 to 10 occurrences are estimated to occur in asthmatic children in an O_3 season, even upon just meeting the current standard. In the last review, a general consensus view of the adversity of such responses emerged as the frequency of occurrences increases, with the judgment that repeated occurrences of moderate responses, even in otherwise healthy individuals, may be considered adverse since they may well set the stage for more serious illness. The Administrator continued to support this view.

Large lung function decrements (i.e., ≥ 20 percent FEV_1 decrement) would likely interfere with normal activities in many healthy individuals, therefore single occurrences would be considered to be adverse. In people with asthma, large lung function responses (i.e., ≥ 20 percent FEV_1 decrement), would likely interfere with normal activities for most individuals and would also increase the likelihood that these individuals would use additional medication or seek medical treatment. Not only would single occurrences be considered to be adverse to asthmatic individuals under the ATS definition, but they also would be cause for medical concern for some individuals. Upon just meeting the current standard based on the 2002 simulation, close to 1 percent of asthmatic and all school age

children are estimated to experience one or more occurrences of large lung function decrements in the aggregate across 5 and 12 urban areas, respectively, with close to 2 percent of both asthmatic and all school age children estimated to experience such effects in the city that receives relatively less protection from this standard. These estimates translate into approximately 500,000 occurrences of large lung function decrements in all children across 12 urban areas, and about 40,000 occurrences in asthmatic children across 5 urban areas upon just meeting the current standard based on the 2002 simulation; the 2004 simulation yielded estimates that translate into approximately 160,000 and 10,000 such occurrences in all children and asthmatic children, respectively.

Upon just meeting the current standard based on the 2002 simulation, the estimate of the O_3-related risk of respiratory symptom days in moderate to severe asthmatic children in the Boston area is about 8,000 symptom days; the 2004 simulation yielded an estimate of about 6,000 such symptoms days. These estimates translate into as many as one symptom day in six, and one symptom day in eight, respectively, that are attributable to O_3 exposure during the O_3 season of the total number of symptom days associated with all causes of respiratory symptoms in asthmatic children during those years.

The estimated O_3-related risk of respiratory-related hospital admissions upon just meeting the current standard based on the 2002 simulation is greater than 500 hospital admissions in the New York City area alone, or about 1.5 percent of the total incidence of respiratory-related admissions associated with all causes; the 2004 simulation yielded an estimate of approximately 400 such hospital admissions. For nonaccidental mortality, just meeting the current standard based on the 2002 simulation results in an estimated incidence of from 0.3 to 2.4 per 100,000 population; the 2004 simulation resulted in an

estimated incidence of from 0.3 to 1.2 per 100,000 population. Estimates for cardiorespiratory mortality show similar patterns (Abt Associates, 2007a, Table 4-26).

The Administrator recognized that in considering the estimates of the proportion of population affected and the number of occurrences of those specific health effects that are included in the risk assessment, these limited estimates based on 2002 and 2004 simulations are indicative of a much broader array of O_3-related health endpoints that are part of a "pyramid of effects" (discussed in section II.A.4.d of the proposal) that include various indicators of morbidity that could not be included in the risk assessment (e.g., school absences, increased medication use, emergency department visits) and which primarily affect members of at-risk groups. Moreover, the Administrator noted that the CASAC Panel supported a qualitative consideration of the much broader array of O_3-related health endpoints, and specifically referred to respiratory emergency department visits in asthmatics and people with other lung diseases, increased medication use, and increased respiratory symptoms reported at exposure levels well below the current standard.

The Administrator expressed the view in the proposal that the exposure and risk estimates discussed in the Staff Paper and summarized above are important from a public health perspective and indicative of potential exposures and risks to at-risk groups. In reaching this proposed judgment, the Administrator considered the following factors: (1) the estimates of numbers of persons exposed at and above the 0.070 ppm benchmark level; (2) the risk estimates of the proportion of the population and number of occurrences of various health effects in areas upon just meeting the current standard; (3) the year-to-year and city-to-city variability in both the exposure and risk estimates; (4)

the uncertainties in these estimates; and (5) recognition 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 at-risk populations, leading to an incomplete estimation of public health impacts associated with O_3 exposures across the country. The Administrator also noted that it was the unanimous conclusion of the CASAC Panel that there is no scientific justification for retaining the current primary O_3 standard, that the current standard is not sufficiently health-protective with an adequate margin of safety, and that the standard needs to be substantially reduced to protect human health, particularly in at-risk subpopulations.

Based on all of these considerations, the Administrator proposed that the current O_3 standard is not requisite to protect public health with an adequate margin of safety because it does not provide sufficient protection and that revision would result in increased public health protection, especially for members of at-risk groups.

2. Comments on the Need for Revision

The above section outlines the health effects evidence and assessments used by the Administrator to inform his proposed judgments about the adequacy of the current O_3 primary standard. General comments received on the proposal that either supported or opposed the proposed decision to revise the current O_3 primary standard are addressed in this section. Comments on the health effects evidence, which includes evidence from controlled human exposure and epidemiological studies, are considered in section II.B.2.a below. Comments on human exposure and health risk assessments are considered in section II.B.2.b, and comments on other policy-related issues are considered in section

II.B.2.c, below. Comments on specific issues, health effects evidence, or the human exposure and health risk assessments that relate to consideration of the appropriate averaging time, form, or level of the O_3 standard are addressed below in sections II.C.3 and II.C.4. General comments based on implementation-related factors that are not a permissible basis for considering the need to revise the current standard are noted in the Response to Comments document.

a. Consideration of Health Effects Evidence

With regard to the need to revise the current primary O_3 standard, sharply divergent comments were received from two general sets of commenters. Many public comments received on the proposal asserted that the current O_3 standard is insufficient to protect public health, especially the health of sensitive groups, with an adequate margin of safety and revisions to the standard are appropriate. Among those calling for revisions to the current primary standard were medical groups, including for example, the American Medical Association (AMA), the American Thoracic Society (ATS), the American Academy of Pediatrics (AAP), and the American College of Chest Physicians (ACCP), as well as medical doctors and academic researchers. For example, the ATS stated:

> We believe that the Administrator has correctly stated that, beyond any degree of scientific uncertainty, convincing and compelling evidence has demonstrated that exposure to ozone at levels below the current standard is responsible for measurable and significant adverse health effects, both in terms of morbidity and mortality. ..... The known respiratory, cardiac and perinatal effects of ozone pollution are each in their own right major public health issues. In combination they provide immediate, actionable information and require a meaningful public health policy response from the EPA. [ATS et al. pp. 1, 11]

Similar conclusions were also reached in comments by many national, State, and local public health organizations, including, for example, the American Lung Association

(ALA) in a joint set of comments with several environmental groups, the American Heart Association (AHA), the American Nurses Association (ANA), the American Public Health Association (APHA), and the National Association of County and City Health Officials (NACCHO), as well as in letters to the Administrator from EPA's advisory panel on children's environmental health (Children's Health Protection Advisory Committee; Marty et al., 2007a, 2007b). Environmental groups also commented in support of revising the standard, including the Sierra Club, Environmental Defense, the Natural Resources Defense Council (NRDC), Earthjustice, and the US Public Interest Research Group (US PIRG). All of these medical, environmental and public health commenters stated that the current O_3 standard needs to be revised and that an even more protective standard than proposed by EPA is needed to protect the health of sensitive population groups. Many individual commenters also expressed such views.

The majority of State and local air pollution control authorities who commented on the O_3 standard supported revision of the current O_3 standard, as did the National Tribal Air Association (NTAA). Environmental agencies that supported revising the standard include agencies from: Arkansas; California; Delaware; Iowa; Illinois; Michigan; North Carolina; New Mexico; New York; Oklahoma; Oregon; Pennsylvania; Utah; Wisconsin; and Washington, DC. State organizations, including the National Association of Clean Air Agencies (NACAA), Northeast States for Coordinated Air Use Management (NESCAUM), and the Ozone Transport Commission (OTC) urged that EPA revise the O_3 standard. All of these commenters supported revisions to the current standard, with most supporting a standard consistent with CASAC's recommendations.

In general, the commenters noted above primarily based their views on the body of evidence assessed in the Criteria Document, finding it to be stronger and more compelling than in the last review. Some specifically agreed with the weight of evidence approach taken by the Criteria Document. These commenters generally placed much weight on CASAC's interpretation of the body of available evidence and the results of EPA's exposure and risk assessments, both of which formed the basis for CASAC's recommendation to revise the O_3 standard to provide increased public health protection.

> In recent years, a broad scientific consensus has emerged that EPA's current air quality standards for ozone are not sufficient to protect public health, and that the levels and form must be greatly tightened. This consensus is evidenced by the by the strong unanimous comments of the CASAC, which was backed by the endorsement of over 100 leading independent air quality scientists, EPA's Children's Health Protection Advisory Committee, and many others. In the face of this strong consensus, it is untenable to cite "uncertainty" as a rationale for failing to propose tighter standards. [ALA et al., p. 15]

Medical and public health commenters also expressed the view that EPA must not use uncertainty in the scientific evidence as justification for retaining the current O_3 standard.

EPA generally agrees with these commenters' conclusion regarding the need to revise the current primary O_3 standard. The scientific evidence related health effects to O_3 exposure noted by these commenters was generally the same as that assessed in the Criteria Document and the proposal. EPA agrees that this information provides a basis for concluding that the current O_3 standard is not adequately protective of public health. For reasons discussed below in sections II.C.3 and II.C.4, however, EPA disagrees with aspects of these commenters' views on the level of protection that is appropriate and supported by the available scientific information.

Another group of commenters representing industry associations and businesses opposed revising the current primary O_3 standard. These views were extensively

presented in comments from the Utility Air Regulatory Group (UARG), representing a group of electric generating companies and organizations and several national trade associations, and in comments from other industry and business associations including, for example: Exxon Mobil Corporation; the Alliance of Automobile Manufacturers (AAM); the National Association of Manufacturers (NAM), the American Petroleum Institute (API). The API sponsored a workshop at the University of Rochester in June 2007 to review the scientific information and health risk assessment considered by EPA during the review of the O_3 NAAQS. Although the report (hereafter, "Rochester Report") from this workshop does not offer judgments on the specific elements of the current or proposed standard, it has been cited in a number of public comments that opposed revision of the current 8-hour standard. The Annapolis Center for Science-Based Public Policy issued a report (hereafter, "Annapolis Center") on the science and health effects of O_3, which explicitly opposed revising the current O_3 primary standard. Several State environmental agencies also opposed revising the current O_3 primary standard, including agencies from: Georgia; Indiana; Kentucky; Louisiana; Nevada; and Texas.

As discussed more fully below in sections dealing with specific comments, these and other commenters in this group generally mentioned many of the same studies from the body of evidence in the Criteria Document that were cited by the commenters who supported revising the standards, but highlighted different aspects of these studies in reaching substantially different conclusions about their strength and the extent to which progress has been made in reducing uncertainties in the evidence since the last review. They then considered whether the evidence that has become available since the last

review has established a more certain risk or a risk of effects that is significantly different in character from those that provided a basis for the current standards, or whether the evidence demonstrates that the risk to public health upon attainment of the current standards would be greater than was understood when EPA established the current O_3 standard in 1997. These commenters generally expressed the view that the current standard provides the requisite degree of public health protection.

In supporting their view that the present primary O_3 standard continues to provide the requisite public health protection and should not be revised, UARG and others generally stated: that the effects of concern have not changed significantly since 1997; that the uncertainties in the underlying health science are as great or greater than in 1997; that the estimated number of exposures of concern and health risks upon attainment of the current O_3 standard has not changed or decreased since 1997; and that "new" studies not included in the Criteria Document continue to demonstrate uncertainties about possible health risks associated with exposure to O_3 at levels below the current standard. As noted above, EPA disagrees with this general assessment, and agrees with the general position that the available information provides a basis for concluding that the current O_3 standard is not adequately protective of public health. The rationale for this position is discussed more fully in the responses to specific comments that are presented below.

More specific comments on the evidence and EPA's responses are discussed below. Section II.B.2.a.i contains comments on evidence from controlled human exposure studies; section II.B.2.a.ii contains comments on evidence from epidemiological studies, including interpretation of the evidence and specific methodological issues. Comments on evidence pertaining to at-risk subgroups for O_3-related effects can be found

in section II.B.2.a.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 Criteria Document and the Staff Paper. Most of these issues were highlighted and thoroughly discussed during the review of these documents by the CASAC. More detailed responses related to the interpretation of the health effects evidence and its role in the decision on the O_3 NAAQS are contained in the Response to Comments document.

i. Evidence from Controlled Human Exposure Studies

As noted in the overview of health effects evidence, section II.A.2 above, two new controlled human-exposure studies (Adams 2002, 2006) are now available that examine 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 medical (e.g., ATS, AMA, ACCP) and national environmental and public health organizations (e.g., ALA in a joint set of comments with Environmental Defense, Sierra Club),agreed with EPA's reanalysis of the Adams' data while disagreeing with EPA's characterization of the evidence from the Adams studies as "very limited" (72 FR 37870). These commenters expressed the view that the Adams studies provide evidence of effects at lower concentrations than had previously been reported. They noted that Adams, while finding small group mean changes at 0.060 ppm, reported total subjective symptom scores 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 made the point that the responses of 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 percent response rate is far from trivial. Seven percent of the U.S. population is 21.2 million people (ALA et al., p. 51). Noting that the subjects in the Adams' studies were all healthy adults, these groups expressed concern that "in some vulnerable populations the magnitude of the response would be greater and the exposure level at which responses are observed to occur would be lower" (ATS, p. 4).

These commenters generally supported EPA's reanalysis of the Adams' data, stating that EPA has undertaken a careful reanalysis 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 reanalysis employs the standard approach used by other researchers, and supported by CASAC" (ALA et al., p. 49), and "we believe that the Adams study shows significant health effects at 0.06 ppm exposure levels" (ATS, p. 5). The American Thoracic Society, AMA and other medical organizations conclude:

> The Adams study confirms our understanding that in healthy populations, an important fraction of the population will experience larger-than-average decrements in FEV_1 when exposed to low levels of ozone. It is reasonable to assume that these effects would be even greater when extrapolated to other populations known to have sensitivities to ozone (children, asthmatics, COPD patients). We feel the correct conclusion to draw from the Adams study is that there is a significant fraction of the population that will express significant responses to low levels of ozone. [ATS, p.5]

EPA generally agrees with most of 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 and 0.040 ppm exposure levels. As characterized in the proposal notice, EPA's reanalysis of the data from the most recent Adams study 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 report a small percentage of subjects experiencing lung function decrements (≥ 10 percent) at the 0.060 ppm exposure level. EPA disagrees with these commenters that the percent of subjects that experienced FEV_1 decrements greater than 10% in this study of 30 subjects can appropriately be generalized to the U.S. population. The Administrator concludes that these studies provide very limited evidence of O_3-related lung function decrements and respiratory symptoms at this lower exposure level.

The second group of commenters, who opposed revision of the standard, raised many concerns about the role of the Adams studies and EPA's reanalysis of the Adams data in the decision. With regard to the results reported by Adams, these commenters expressed the view that the group mean FEV_1 decrement measured at 0.060 ppm was small, less than 3%, which is within the 3 to 5% range of normal measurement variability for an individual (UARG, p. 12). Moreover even the reported group mean FEV_1 decrements in Adams subjects when exposed to an O_3 concentration of 0.080 ppm were described as quite minimal, likely non-detectable by the subjects and within the range that the EPA would consider to be normal or mild (UARG, p.13); 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 "reliance on the individual responses of such a miniscule number of subjects (2 of 30) is woefully inadequate as any basis for a nationwide O_3 standard" (UARG, p.14). Some of these commenters put the results of the Adams studies (2002, 2006) in the context of the 1997 decision on the O_3 standard to reach the conclusion that there is no basis for revising that standard. They stated that the data from Adams (2002, 2006) on O_3 levels below 0.080 ppm was 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 last review (Exxon Mobil, pp. 5-6).

These commenters raised one or more of the following concerns about EPA's reanalysis of the Adams data: (1) EPA's re-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, 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; (3) EPA's reanalysis did not employ an appropriate statistical test; the ANOVA statistical test employed by Adams was preferred over the statistical test used in EPA's reanalysis (paired t-test); and (4) the reanalysis of the Adams data is evidence that EPA interpreted and presented scientific information in a systematically biased manner, reflecting purposeful bias because the reanalysis supported staff policy recommendations and Adams' own analysis did not, and the 10% decrement

in FEV_1 was a post-hoc threshold chosen for compatibility with EPA staff policy recommendations (NAM, p.19).

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, EPA and the CASAC Panel observed that the study showed some individuals experienced lung function decrements ≥ 10 percent, which is the most important finding from this study in terms of public health implications. 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 group mean to the response of subsets of the group to evaluate the potential impact for sensitive or susceptible parts of the population. The Administrator also agrees with both EPA staff and CASAC's views 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.

Second, EPA notes that its reanalysis 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 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 reanalysis was focused on the different 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, with respect to the concerns raised by Dr. Adams and other commenters that EPA had used an inappropriate statistical approach to address the question regarding statistical significance of the average lung function response at 0.060 ppm, members of the CASAC Panel noted on the March 5, 2007 teleconference the very conservative nature of the approach used by Adams to evaluate the research questions posed by the author. These same CASAC Panel members also supported the use of the statistical approach (i.e., paired *t* test) used in the analysis prepared by the public commenter, which was the same approach later used in EPA's reanalysis, as the preferred method for analyzing the pre- minus post-exposure lung function responses reported in this study. EPA agrees with the characterization of the Adams (2006) study in the Rochester Report, which stated, "Although these findings have not been confirmed or replicated, the responses to 0.06 ppm ozone in this [Adams] study are consistent with the presence of an exposure-response curve with responses that do not end abruptly below 0.08 ppm." This same report also concluded,

> The statistical test used in Adams (2006) did not identify the response of the 0.06 ppm exposure as statistically different from that of the filtered air exposure. However, alternative statistical tests suggest that the observed small group mean

> response in FEV_1 induced by exposure to 0.06 ppm compared to filtered air is not the result of chance alone. [Rochester Report, p.56].

Fourth, EPA rejects the contention that the conduct and presentation of its reanalysis of the Adams (2006) study to address issues raised by public commenters represents purposeful bias and was developed only to support a pre-determined policy position. As discussed above, EPA's reanalysis addressed a different question than the author's analysis contained in the publication. Other controlled human exposure studies had routinely examined the same question EPA's reanalysis addressed, whether or not there was a statistically significant group mean response for the entire exposure period compared to filtered air.

ii Evidence from Epidemiological Studies

This section contains major comments on EPA's assessment of epidemiological studies in the proposal and the Agency's general responses to those comments. Many of the issues discussed below are addressed in more detail in the Response to Comments document. Comments on EPA's interpretation and assessment of the body of epidemiological evidence are 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 Criteria Document and 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 O_3 Criteria Document and O_3 Staff Paper and approved of the scientific content and accuracy of both documents. The CASAC chairman sent to the Administrator one letter (Henderson, 2006a) for the O_3 Criteria Document and another letter for the O_3 Staff Paper (Henderson, 2006c) indicating that these documents provided an appropriate basis for use in regulatory decision making regarding the O_3 NAAQS.

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 (72 FR 37838, section II.a.3.a-c) 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. Comments of 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 Criteria Document and point to a figure from the Staff Paper and proposal (72 FR 37842, Figure 1) of short-term O_3 exposures and respiratory health outcome 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 these "real world" studies support the findings of chamber studies to show adverse respiratory health effects at levels below the current 8-hour O_3 standard. These commenters generally expressed agreement with the weight of evidence approach taken by the Criteria Document and the conclusions

reached, which were reviewed by CASAC, that the effects of O_3 on respiratory symptoms, lung function changes, emergency department visits for respiratory and cardiovascular effects, and hospital admissions can be considered causal.

EPA generally agrees with this interpretation of the epidemiological evidence. The 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 with EPA, 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 and cardiovascular system effects are well-supported by the Hill criteria[19] of judging causality: strength of association, consistency between studies, coherence among studies, and biological plausibility (ALA et al., pp. 51-52). They also noted that recent studies provide

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[19] 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).

compelling evidence that exposure to O_3 results in adverse cardiovascular health effects (ATS, p. 6-7).

EPA disagrees with the assertion of these commenters that the causal associations extend down to the lowest ambient O_3 concentrations reported in these studies. The biological plausibility of the epidemiological 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 at much 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 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 new epidemiological studies have been published since the current 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 (UARG, p. 15). With regard to daily mortality, the proposal emphasizes the multi-city studies, suggesting that they have the 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 (API, p. 15). 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 of 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 (UARG, p. 16).

EPA has accurately characterized the inconsistencies and uncertainties in the epidemiological evidence and strongly denies 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 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. In general, in the proposal, the Administrator recognized that in the body of epidemiological evidence, many studies reported positive and statistically significant associations, while others reported positive results that were not statistically significant, and a few did not report any positive O_3-related associations. In addition, the Administrator judged that evidence of a causal relationship between adverse health outcomes and O_3 exposures became increasingly uncertain at lower levels of exposure.

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 larger statistical power. 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, pp. 10-11).

In the 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 (72 FR 37879). Throughout the O_3 review, a standard set of criteria have been used to evaluate evidence of a causal link. The critical assessment of epidemiological evidence presented in the 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 (Criteria Document, pp. 7-3 - 7-4). Moreover, consistent with the 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 from controlled human exposure studies and the toxicological studies that demonstrate biological plausibility and mechanisms for effects. More detailed discussion of the criteria used to evaluate evidence with regard to judgments about causality can be found in the Response to Comments document.

Several commenters made the point that the results of the new epidemiological studies included in this 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 indicates 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 for cardiovascular causes. Most studies of cardiovascular causes have not found statistically significant associations with O_3 exposures (UARG, pp. 16-17).

EPA strongly disagrees that it has failed to appropriately characterize the association between O_3 exposure and potential cardiovascular morbidity and mortality effects. As noted above, the 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/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 HRV, 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 provide some plausibility for the observed associations between O_3 and cardiovascular outcomes. EPA believes that its characterization of the evidence for O3-related cardiovascular system effects is appropriate. It is clear that coherence is stronger in the much larger body of evidence of O_3-related respiratory morbidity and mortality effects.

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: the adequacy of exposure data; confounding by copollutants; model selection; evidence of mortality; and, new studies not included in the Criteria Document. Some of the major comments on methodological issues raised by these commenters are discussed below. The Response to Comments document contains more detailed responses to many of these comments, as well as responses to other comments not considered 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 the Administrator'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. These commenters

also note that, in its June 2006 letter, the CASAC Panel raised the issue of exposure error, concluding that it called into question whether observed associations could be attributed to O_3 alone (API, p. 17). One of these commenters cited studies (e.g., Sarnat et al., 2001; Sarnat et al., 2005) that show a lack of correlation between personal exposures and ambient concentrations (NAM, p. 22). Another cited studies (Sarnat et al., 2001, 2005, and 2006; and Koutrakis et al., 2005) that have found that the ability of ambient gas monitors to represent personal exposure to such gases is similarly quite limited, including: (1) 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; (2) O_3 measurements from ambient monitors are a better surrogate for personal exposure to $PM_{2.5}$ than to O_3; and (3) 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 (Exxon Mobil, pp. 15-16). These commenters contended that without such a correlation 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. 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, p. 20).

With regard to the views on exposure measurement error expressed by CASAC, while the commenter is correct that the CASAC Panel raised the question of exposure error and whether observed associations could be attributed to O_3 alone, the commenter failed to note that CASAC's comment was focused on the association between O_3 and

mortality, at very low O_3 concentrations and in the group of people most susceptible to premature mortality. The CASAC Panel in its June 2006 letter stated:

> The population that would be expected to be potentially susceptible to dying from exposure to ozone is likely to have ozone exposures that are at the lower end of the ozone population distribution, in which case the population would be exposed to very low ozone concentrations, and especially so in winter. Therefore it seems unlikely that the observed associations between short-term ozone concentrations and daily mortality are due solely to ozone itself. [Henderson 2006b, pp. 3-4]

This section of the quote, which was not addressed in the comment submitted by API, together with the conclusions in the final CASAC letter (Henderson, 2007), leads EPA to conclude that contrary to the commenters' assertion, the CASAC Panel was not calling into question the association between O_3 exposure and the full range of morbidity effects found in panel or time-series studies that rely on ambient monitoring data as a surrogate for personal exposure data. It is important to note that EPA agrees that the evidence is only highly suggestive that O_3 directly or indirectly contributes to mortality, as compared to the stronger evidence of causality for respiratory morbidity effects.

EPA agrees that exposure measurement error may result from the use of stationary ambient monitors as an indicator of personal exposure 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 Criteria Document. However, the possibility of measurement error does not preclude the use of ambient monitoring data as a surrogate for personal exposure data in time-series or panel studies. It simply means that in some situations where the likelihood of measurement error is greatest, effects estimates must be evaluated carefully and that caution must be used in interpreting the results from these studies. Throughout this review, EPA has 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 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 exposure and ambient monitoring data is necessarily poor, especially in 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). However, the Criteria Document notes that there is some concern in considering certain mortality and hospitalization time-series studies regarding the extent to which ambient O_3 concentrations are representative of personal O_3 exposures in another particularly susceptible group of individuals, the debilitated elderly, as the correlation between the two measurements has not been examined in this population. A better understanding of the relationship between ambient concentrations and personal exposures, as well as of the factors that affect the relationship, will improve the interpretation of observed associations between ambient concentration and population health response.

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 one study conducted 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 Criteria Document, conducted in Steubenville (Sarnat et al., 2006), also observed significant associations between ambient O_3 concentrations and personal O_3. 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. EPA is not relying on studies that are not in the Criteria Document, such as Sarnat et al. (2006), to refute the commenters. However, EPA notes that Sarnat et al. (2006) does not support the conclusion drawn by the commenters that this study shows very limited associations between ambient O_3 concentrations and personal exposures.

Existing epidemiologic models may not fully take into consideration all the biologically relevant exposure history or reflect the complexities of all the underlying biological processes. 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 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 to 7-10). Nonetheless, as noted in section II.C.3 of the proposal, 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 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 (72 FR 37839).

(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 and lung function became non-significant.

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. A more general discussion and response to this issue concerning confounding by copollutants is presented in the Response to Comments document.

(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, concerns were expressed regarding the following issues: (i) commenters

noted that recent meta-analyses have confirmed 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 Staff Paper's conclusion on the robustness of the models used in the O_3 time-series studies (Exxon Mobil, p. 41); (ii) 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; and (iii) commenters expressed the view that to appropriately address concerns about model selection in the O_3 time-series studies, EPA should rely on an alternative statistical approach, Bayesian model averaging, that incorporates a range of models addressing confounding variables, pollutants, and lags rather than a single model.

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 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 Criteria Document (see section 7.1.3.6) and evaluated in some of the meta-analyses reviewed in the Criteria Document and 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 Administrator 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.3. As discussed later in this notice, the Administrator is not relying on any specific quantitative effect estimates from the time-series studies or any risk

estimates based on the time-series studies in reaching his judgment about the need to revise the current 8-hour O_3 standard.

Third, in response to commenters who suggested that EPA adopt an alternative statistical approach, i.e., Bayesian model averaging, to address concerns about potential arbitrary selection of models, the Criteria Document evaluated the strengths and weaknesses of such methods in the context of air pollution epidemiology. The Criteria Document noted several limitations, especially where there are many interaction terms and meteorological variables and where variables are highly correlated, as is the case for air pollution studies, which makes it very difficult to interpret the results using this alternative approach. EPA believes further research is needed to address concerns about model selection and to develop appropriate methods addressing these concerns.

(4) Evidence of mortality. Many commenters, including those that argued for revising the current O_3 standard as well as those that argued against revisions, 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, multiple-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 (ATS, p. 4). These commenters noted that people may die from O_3 exposure even when the concentrations are well below the current standard. 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. The authors 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., p. 74). Another approach also indicated that the mortality effect is unlikely to be confounded by temperature. 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, 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., p. 76). These commenters argue that meta-analyses also provide compelling evidence that the O_3-mortality findings are consistent. They point to three independent 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 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. 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 risk coefficient (EPA, 2006a, p. 7-175). The Criteria Document 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 (72 FR 37836). Thus while EPA generally agrees with the direction of the comment, EPA believes the evidence supports a view as noted above. In addition, it must be noted that the Administrator did not focus on mortality as a basis for proposing that the current O_3 standard was not adequate. In the proposal, the Administrator focused on the very strong evidence of respiratory morbidity effects in healthy people at the 0.080 ppm exposure level 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 (72 FR 37870). With regard to the ambient concentrations at which O_3-related mortality effects may be occurring, EPA recognized in the proposal that evidence of a causal relationship between adverse health effects and O_3 exposures becomes increasingly uncertain at lower levels of exposure (72 FR 37880). This is discussed more fully in section (b) below.

Several industry organizations argued against placing any reliance on the time-series epidemiological studies, especially those studies related to mortality effects. The Annapolis Center (p. 46) makes the point that although there may be somewhat more positive associations than negative associations, there is so much noise or variability in the data that identifying which positive associations may be real health effects and which are not is beyond the capability of current methods. They cite the view that the CASAC

Panel expressed in a June 2006 letter (Henderson, 2006b), noting that "Because results of time-series studies implicate all of the criteria pollutants, findings of mortality time-series studies do not seem to allow us to confidently attribute observed effects specifically to individual pollutants."

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, including some large cities that have very slight or negligible effects (e.g., Los Angeles) (Bell et al., 2004), thus causing several commenters to question the relevance of a "national" effect of O_3 on mortality and argue that a single national O_3 concentration-mortality coefficient should be used and interpreted with caution (Rochester Report p. 4); (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 necessary 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 (Annapolis Center, p. 42); 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 (Annapolis Center, p. 42).

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 show

elevated risk of total, non-accidental mortality, cardiorespiratory, and respiratory mortality (> 20 studies), including one study in an area that would have met current standard (Vedal et al., 2003). 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 asserts 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 effect thresholds exist but can not 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 can not be interpreted with confidence as providing evidence that the observed health effects can be attributed to O_3 alone.

In the letter cited, the CASAC Panel did raise the issue of the utility of time-series studies in the standard setting process with regard to time-series mortality studies. Nevertheless, in a subsequent letter to the Administrator, CASAC noted these mortality studies as evidence to support a recommendation to revise the current primary O_3 standard. "Several new single-city studies and large multi-city studies designed specifically to examine the effects of ozone and other pollutants on both morbidity and mortality have provided more evidence for adverse health effects at concentrations lower than the current standard (Henderson, 2006c, p. 3)."

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 was used for Los Angeles, the

median O_3 concentration for Los Angeles is fairly low compared to the other communities, ranked 23rd 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.

(b) In section 7.4.6, O_3 mortality risk estimates adjusting for PM exposure, the 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, 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. (2000) calculated O_3 risk estimates based on mean (45 ppb) less background (not stated) levels of 1-hour max 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. 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 $_{2.5}$) 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 copollutants, including PM, generally do not appear to substantially confound the association between O_3 and mortality.

(c) With regard to the biological plausibility of O_3-related mortality occurring at levels well within natural background, EPA concluded in the 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 can not 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.

(5) "New" studies not included in the Criteria Document. Many commenters identified "new" studies that were not included in the Criteria Document that they stated support arguments both for and against the revision of the current O_3 standard. Commenters who supported revising the current 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-American and women. Commenters who did not support revision of the current O_3 standard often submitted the same "new" studies, but focused on different aspects of the findings. Commenters who did not support revision of the current 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. More detail about the topic areas covered in the "new" studies 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 Criteria Document, in support of their arguments for revising 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 in the 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.

iii. Evidence Pertaining to At-Risk Subgroups 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 sensitive subpopulations. Since new information 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, many of the comments focused on this information and the conclusions drawn from it. There were also comments on other sensitive groups identified by EPA, as well as comments suggesting that additional groups 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 Response to Comments document.

As with the comments on controlled human exposure and epidemiological studies, upon which judgments about sensitive subpopulations 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 subpopulations that are at increased risk from O_3 exposure, but commented that there are additional groups that need to be considered. A comment from ATS, AMA and other medical associations noted:

> Within this population exists a number of individuals uniquely at much higher risk for adverse health effects from ozone exposures, including children, people with respiratory illness, the elderly, outdoor workers and healthy children and adults who exercise outdoors. [ATS, p. 2]

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. Further, the Rochester Report, funded by API, evaluated some of the same the studies that EPA did and found similar results with regard to the increased inflammatory responses and increased airway responsiveness of people with asthma when exposed to O_3. The Rochester Report reached the same conclusion that EPA did, that this increased responsiveness provides biological plausibility for the respiratory morbidity effects found in epidemiological studies.

> Several new studies have demonstrated that exposure of individuals with atopic asthma to sufficient levels of ozone produces an increase in specific airway responsiveness to inhaled allergens……These findings, in combination with previously observed effects of ozone on nonspecific airway responsiveness and airway inflammation, supports the idea that ambient ozone exposure could result in exacerbation of asthma several days following exposure, and provides biological plausibility for the epidemiologic studies in which ambient ozone concentration has been associated with increased asthma symptoms, medication use, emergency room visits, and hospitalizations for asthma. [Rochester Report, pp. 57-58]

Commenters also often mentioned the increased susceptibility of people with COPD, and in this case cited new studies not considered in the Criteria Document.

They identify one potentially susceptible subpopulation that EPA did not focus on in the proposal is infants. 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. Exposure to O_3 during pregnancy, especially during the second and third trimesters, was associated with reduced birth weight in full-term infants. Although this effect was noted at relatively low O_3 exposure levels, the ATS notes that, "…the reduced birth weight in infants in the highest ozone exposures communities equaled the reduced birth weight observed in pregnant women who smoke" (ATS, p. 7).

In general, 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 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 therefore 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 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 made the following major comments: (1) lung function decrements and respiratory symptoms observed in controlled human exposure studies of asthmatics are not clinically important; (2) EPA postulates that asthmatics would likely experience more serious responses and responses at lower levels than the subjects of controlled human exposure experiments, but that hypothesis is not supported by scientific evidence; and, (3) EPA recognized asthmatics as a sensitive subpopulation in 1997, and new information does not suggest greater susceptibility than was previously believed.

With regard to the first point, these commenters expressed the view that asthmatics are not likely to experience medically significant lung function changes or respiratory symptoms at ambient O_3 concentrations at or even above the level of the current standard. Many of these commenters cited the opinion of one physician who was asked on behalf of a group of trade associations and companies to provide his views on the health significance for asthmatics of the types of responses that have been reported in

controlled human exposure studies of O_3. This commenter (McFadden) reviewed earlier controlled human exposure studies of asthmatics (from the last review) as well as the recent controlled human exposure studies of healthy individuals (Adams 2002, 2003a,b, and 2006) at 0.12, 0.08, 0.06, and 0.04 ppm and expressed the view that "…these studies on asthmatics indicate that ozone exposures at ~ 0.12 ppm do not produce medically significant functional changes and are right around the inflection point where one begins to see an increase in symptoms; however, that increase is small" (McFadden, p. 3). This commenter went on to express the view that responses to O_3 exposure at levels < 0 .08 ppm would be even less and that the available data are not sufficiently robust to indicate that such exposures would present a significant health concern even to sensitive people like asthmatics.

EPA notes that this commenter based his comment on the group mean functional and respiratory symptom changes in the studies he reviewed. EPA agrees that group mean changes at these levels are relatively small and has described them as such in both the previous review and this one (72 FR 37828). The importance of group mean changes is to evaluate the statistical significance of the association between the exposures and the observed effects, to try to determine if the observed effects are likely due to O_3 exposure rather than chance. In the previous review as well as in this one, EPA has also focused on the fact that some individuals experience more severe effects that may be clinically significant. With regard to the significance of individual responses, this commenter (McFadden, p. 2) states "...transient decreases in FEV_1 of 10-20% are not by themselves significant or meaningful to asthmatics…. It has been my experience from examining and studying thousands of patients for both clinical and research purposes that asthmatics

typically will not begin to sense bronchoconstriction until their FEV_1 falls about 50% from normal." EPA strongly disagrees with this assessment. As stated in the Criteria Document (Table 8-3, p. 8-68) for people with lung disease, even moderate functional responses (e.g., FEV_1 decrements ≥ 10% but < 20%) would likely interfere with normal activities for many individuals, and would likely result in more frequent medication use. EPA notes that in the context of standard setting, CASAC indicated (Henderson, 2006c) that a focus on the lower end of the range of moderate functional responses (e.g., FEV_1 decrements ≥ 10%) is most appropriate for estimating potentially adverse lung function decrements in people with lung disease.

With regard to the second point, whether asthmatics would likely experience more serious responses and responses at lower levels than the subjects of controlled human exposure experiments and EPA's discussion of the relationship of increased airway responsiveness and inflammation experienced by asthmatics to exacerbation of asthma, this commenter stated that "there simply are no data to support the sequence described" and that "the assumption that these responses would lead to clinical manifestations in terms of exacerbations of asthma or other adverse health effects remains unproven theory" (McFadden, p. 3).

In these sections of the proposal (72 FR 37826 and 37846-37847), 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.

There are two ways to interpret these comments. One way to interpret them is that because these controlled human exposure studies have not produced exacerbations of asthma in study subjects resulting in the need for medical attention, there are no data to support the clinical significance of the results. EPA rejects this interpretation because it would be unethical to knowingly conduct a controlled human exposure study that would lead to exacerbation of asthma. Controlled human exposure studies are specifically designed to avoid these types of responses. The other interpretation is that the commenter does not agree that the differences in lung function, inflammation and increased airway responsiveness found in these controlled human exposure studies support the inference that asthmatics are likely to have more serious responses than healthy subjects, and that these responses could have important clinical implications. EPA rejects this interpretation as well. 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 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, p. 4). Moreover, the Rochester Report, cited above, reaches essentially the same conclusions as EPA did, that the evidence from controlled human exposure studies provides biological plausibility for the epidemiological studies in which ambient O_3 concentrations have been associated with increased asthma symptoms, medication use, emergency room visits, and hospitalizations for asthma. Therefore, EPA continues to assert that there is strong evidence that asthmatics likely 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 third point, 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 (UARG, pp. 22-23). To support this view, these commenters noted the points made above and expressed the view that epidemiological studies of asthmatics that provide new evidence of respiratory symptoms and medication use in asthmatic children are subject to the limitations of epidemiological studies discussed above (e.g., confounding by co-pollutants, heterogeneity of results). In addition, these commenters identified a new, large multi-city panel study, not included in the Criteria Document, by Schildcrout et al.

(2006), which the commenters characterize as reporting no association between O_3 concentrations and exacerbation of asthma.

At the time of the last 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. The new results from controlled exposure and epidemiologic 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. EPA notes that comments on the limitations of epidemiological studies and evidence from "new" studies (not in the Criteria Document) have been addressed above. As with other "new" studies, this study by Schildcrout et al. (2006) is specifically discussed in the Response to Comments document.

b. Consideration of Human Exposure and Health Risk Assessments

Section II.A.3 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 attainment of the current and alternative standards. EPA notes here that most of the issues and concerns raised by commenters concerning the methods used in the exposure and risk assessments are essentially

restatements of concerns raised during the review of the Criteria Document and the development and review of these quantitative assessments as part of the preparation and review of the 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 proposal notice, EPA believes and CASAC Panel concurred, that the model selected to estimate exposure represent the state of the art and that the risk assessment was "well done, balanced and reasonably communicated" and that the selection of health endpoints for inclusion in the quantitative risk assessment was appropriate (Henderson, 2006c). EPA does not believe that the exposure or risk assessments are fundamentally biased in one direction or the other as claimed in some of the comments.

Comments received after 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 the need to revise the current 8-hour O_3 standard 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), NESCAUM, and some State and local health and air pollution agencies 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, adults who exercise outdoors; and (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 also underestimated. The joint set of comments from ALA and several environmental groups contended that the "exposures of concern" metric presented in the Staff Paper and proposal is "an inappropriate basis for decision making" and urged EPA to set the standard based on the concentrations shown by health studies to cause adverse effects, not on how much O_3 Americans inhale. This same set of commenters stated that if exposures of concern were to be considered then the benchmark level of 0.060 ppm should be the focus, and not higher benchmark levels. These same 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, these same 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 discussed in turn below.

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 draft Health Assessment Plan, 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 proposal notice made note of this important point and stated that "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 recent air quality or air quality that just meets the current or alternative standards" (72 FR 37866).

However, as stated in the proposal notice, 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. 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 at-risk 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 his conclusion that observations from the exposure and health risk assessments provide additional support for his judgment that the current 8-hour standard does not protect public health with an adequate margin of safety and must be revised. For reasons discussed below in section II.C.4, 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.

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 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.

As noted in the 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. EPA recognized that there was no sharp breakpoint within the continuum ranging from at and above 0.080 ppm down to 0.060 ppm. In considering the concept of exposures of concern, the proposal noted that it was 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 levels.

As noted above, environmental and public health group comments expressed the view that if exposures of concern were considered, then the Administrator should focus only on the 0.060 ppm benchmark based on the contention that adverse health effects had been demonstrated down to this level. In contrast, other commenters, primarily industry and business groups focused on comparisons of the exposures of concern at the 0.080 ppm benchmark level based on their view that there was no convincing evidence demonstrating adverse health effects at levels below this benchmark. In view of the comments received related to the definition and use of the term "exposure of concern" at the time of proposal, the Administrator recognizes that that there is a risk for confusion, as it could be read to imply a determination that a certain benchmark level of exposure

has been shown to be causally associated with adverse health effects. As a consequence, the Administrator believes that it is more appropriate to consider such exposure estimates in the context of a continuum rather than focusing on any one discrete benchmark level, as was done at the time of proposal, since the Administrator does not believe that the underlying scientific evidence is certain enough to support a focus on any single bright-line benchmark level. Thus, the Administrator believes it is appropriate to consider a range of benchmark levels from 0.080 down to 0.060 ppm, recognizing that exposures of concern must be considered in the context of a continuum of the potential for health effects of concern, and their severity, with increasing uncertainty associated with the likelihood of such effects at lower O_3 exposure levels.

EPA recognizes that the 0.080 ppm benchmark level represents a level at which several health outcomes including lung inflammation, increased airway responsiveness, and decreased resistance to infection have been shown to occur in healthy adults. The Administrator places relatively great weight on the public health significance of exposures at and above this benchmark level given these physiological effects measured in healthy adults at O_3 exposures of 0.080 ppm and the evidence from controlled human exposure studies showing that people with asthma have more serious responses than people without asthma. However, the Administrator does not agree with those commenters who would only consider this single benchmark level. While the Administrator places less weight on exposures at and above the 0.070 pm benchmark level, given the increased uncertainty about the fraction of the population and severity of the health responses that might occur associated with exposures at and above this level, he believes that it is appropriate to consider exposures at and above this benchmark as

well in judging the adequacy of the current standard to protect public health. Considering exposures at and above the 0.070 ppm benchmark level provides some consideration for the fact that the effects observed at 0.080 ppm were in healthy adult subjects but sensitive population groups such as asthmatics are likely to respond at lower O_3 levels than healthy individuals. The Administrator considered but placed very little weight on exposures at and above the 0.060 ppm benchmark given the very limited scientific evidence supporting a conclusion that O_3 is causally related to various health outcomes at this exposure level.

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 current standard taking total risks into account would not impact the Administrator's decision, since he judges that the current 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 impacted at all by consideration of current PRB estimates.

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 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 to revising the 8-hour standard, and most extensively presented in comments from UARG, API, Exxon-Mobil, AAM, and NAM, raised one or more of the following concerns: (1) that exposures of concern and health risk estimates have not changed significantly since the prior review in 1997; (2) that 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) that EPA should have defined PRB differently and that EPA underestimated PRB levels which results in health risk reductions associated with more stringent standards being overestimated; (4) that exposures are overestimated based on specific methodological choices made by EPA including, for example, O_3 measurements at fixed-site monitors can be higher than other locations where individuals are exposed, the exposure estimates do not account for O_3 avoidance behaviors, and the exposure model overestimates elevated breathing rates; and (5) that health risks are overestimated based on specific methodological choices made by EPA including, for example, selection of inappropriate effect estimates from health effect studies and EPA's approach to addressing the shape of exposure-response relationships and whether or not to incorporate thresholds into its models for the various health effects analyzed. These comments are discussed in turn below. 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 can be found in the Response to Comments document.

(1) In asserting that the estimated exposures and risks associated with air quality just meeting the current standard have not appreciably changed since the prior review, comments from Exxon-Mobil, the Annapolis Center and others have compared results of EPA's lung function risk assessment done in the last review with those from the Agency's risk assessment done as part of this review and have concluded that lung function risks upon attainment of the 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 current 8-hour standard is requisite to protect public health.

EPA believes that this claim is fundamentally flawed for three 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; (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 last review, and (iii) it fails to recognize that the Administrator has used these estimates in a supportive role, in light of significant uncertainties in the exposure and risk estimates, to inform the conclusions drawn primarily from integrative assessment of the controlled human exposure and epidemiological evidence on whether ambient O_3 levels allowed under the current standard present a serious public health problem warranting revision of the O_3 standard.

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 current 8-hour standard, as the 1997 estimates reflect outdated analyses that have been updated in this 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 Staff Paper, there have been significant improvements to the exposure model and the model inputs 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 and 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 prior 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 prior 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 are different between those considered in the 1997 and current review, making comparison of the resulting estimates inappropriate. Another important difference making comparison between the 1997 health risk assessment and the current assessment inappropriate is that a number of additional health effects were included in the current 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 current 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 last and current 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 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 human and animal studies documenting effects, new laboratory studies identifying and investigating biological mechanisms of O_3 toxicity, and new studies addressing the utility of using ambient monitors to assess population exposures to ambient O_3. 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 above 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 the current level of the standard than in the last review.

Third, quantitative risk estimates were not the only basis for EPA's decision in setting a level for the O_3 standard in 1997, and they do not set any quantified "benchmark" for the Agency's decision to revise the O_3 standard at this time. While EPA believes that confidence in the causal relationships between short-term exposures to O_3 and various health effects reported in epidemiological studies has increased markedly since 1997, the Administrator also recognizes that the risk estimates for these effects must be considered in the light of uncertainties about whether or not these O_3-related effects occur at very low O_3 concentrations. The Administrator continues to believe that the exposure and risk estimates associated with just meeting the current standard discussed in the Staff Paper and summarized in the proposal notice are important from a public health perspective and are indicative of potential exposures and risks to at-risk groups. In considering the exposure and risk estimates, the Administrator has considered the year-to-year and city-to-city variability in both the exposure and risk estimates, the uncertainties in these estimates, and recognition 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, at-risk populations, leading to an incomplete estimation of public health impacts associated with O_3 exposures across the country.

(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 standard, 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 the current and alternative standards; (ii) uncertainties and limitations associated with the definition and estimation of PRB concentrations; (iii) 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 current standard; and (iv) 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. In summary, 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 current 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 Response to Comments document.

With respect to the air quality adjustment approach used in the current review to simulate air quality just meeting the current and alternative O_3 standards, as discussed in the 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 proposal notice, 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 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 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 last review. 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 exposures and health risks associated with meeting the current 8-hour standard are important from a public health perspective and that the 8-hour standard needs to be revised to provide additional protection in order to protect public health with an adequate margin of safety.

(3) Comments from several industry organizations, businesses, and others related to PRB included: (i) that EPA should have defined PRB differently so as to include anthropogenic emissions from Canada and Mexico; (ii) that EPA underestimated PRB levels by relying on estimates from the GEOS-CHEM model using 2001 meteorology and EPA should instead rely on O_3 levels observed at remote monitoring locations or sites that represent PRB conditions; and (iii) that the use of underestimated PRB levels in the risk assessment results in overestimated health risks associated with air quality just meeting the current standard. Finally, some commenters cited concerns expressed by the CASAC Panel that "the current approach to determining PRB is the best method to make

this estimation" (Henderson, 2007, p. 2). Each of these concerns is addressed below and in more detail in the 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 O3 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 Criteria Document. Both EPA's experts and CASAC 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 reflecting 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 that declines from spring to summer and is generally < 0.025 ppm under conditions conducive to high O_3 episodes. The Criteria Document acknowledges that PRB can be higher, especially at elevated sites in the spring due to stratospheric exchange. However, unusually high springtime O_3 episodes tied to stratospheric intrusion are rare and generally occur at elevated locations and these 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.

Third, 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 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 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 Criteria Document and 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 current standard 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).

Finally, EPA believes that some commenters have misread the CASAC Panel concern "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. However, 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's concern appeared to be more 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 reviewing the Staff Paper, the atmospheric modeling expert on the CASAC Panel in his comments 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 over predicts 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") is 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 current or proposed standards.

Fifth, a comparison of ventilation rates predicted by APEX to 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 partially incorporated into the overall uncertainty analysis with the uncertainties of the metabolic equivalents (METs), which are the primary drivers of ventilation rates.

(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), 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 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 which 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 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" and that the risk assessment chapter of the Staff Paper and its accompanying risk assessment were "well done, balanced and reasonably communicated" (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 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 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 estimates based on both types of effect estimates 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 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 Staff Paper and risk assessment, and the Panel concurred with the approach used. As discussed in the proposal notice, 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 current O_3 standard. 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 has taken this into account in considering the risk assessment estimates in his decision.

Fifth, consistent with the prior 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 a portion of the population would likely experience health effects of concern. Looking at just the average for the population would ignore the evidence of health effects for sensitive subpopulations, an important aspect of public health impact in this and other 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 which were reviewed and included in the final Criteria Document, and this includes 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 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).

Having considered comments on the quantitative exposure and health risk assessments from both groups of commenters, the Administrator finds no basis to change his position on these quantitative assessments that was taken at the time of proposal. That is, as discussed above, while the Administrator recognizes that the assessments rest on a more extensive body of data and is more comprehensive in scope than the assessment conducted in the last review, he is mindful that significant uncertainties 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 his 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 current 8-hour standard. 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.

3. Conclusions Regarding the Need for Revision

Having carefully considered the public comments, as discussed above, the Administrator believes the fundamental scientific conclusions on the effects of O_3 reached in the Criteria Document and Staff Paper, briefly summarized above in section II.A.2 and discussed more fully in section II.A of the proposal, remain valid. In considering whether the primary O_3 standard should be revised, the Administrator places primary consideration on the body of scientific evidence available in this review on the health effects associated with O_3 exposure, as summarized above in section II.B.1. The Administrator notes that there is much new evidence that has become available since the last review, including an especially large number of new epidemiological studies. The Administrator believes that this body of scientific evidence is very robust, recognizing that it includes large numbers of various types of studies, including toxicological studies, controlled human exposure studies, field panel studies, and community epidemiological studies, that provide consistent and coherent evidence of an array of O_3-related respiratory morbidity effects and possibly cardiovascular-related morbidity as well as total nonaccidental and cardiorespiratory mortality. The Administrator observes that (1)

the evidence of a range of respiratory-related morbidity effects seen in the last review has been considerably strengthened, both through toxicological and controlled human exposure studies as well as through many new panel and epidemiological studies; (2) newly available evidence from controlled human exposure and epidemiological studies identifies people with asthma as an important susceptible population for which estimates of respiratory effects in the general population likely underestimate the magnitude or importance of these effects; (3) newly available evidence about mechanisms of toxicity more completely explains the biological plausibility of O_3-induced respiratory effects and is beginning to suggest mechanisms that may link O_3 exposure to cardiovascular effects; and (4) there is now relatively strong evidence for associations between O_3 and total nonaccidental and cardiopulmonary mortality, even after adjustment for the influence of season and PM. The Administrator believes that this very robust body of evidence, taken together, enhances our understanding of O_3-related effects relative to what was known at the time of the last review. Further, he believes that the available evidence provides increased confidence that respiratory morbidity effects such as lung function decrements and respiratory symptoms are causally related to O_3 exposures, that indicators of respiratory morbidity such as emergency department visits and hospital admissions are causally related to O_3 exposures, and that the evidence is highly suggestive that O_3 exposures during the warm O_3 season contribute to premature mortality.

Further, the Administrator judges that there is important new evidence demonstrating that exposures to O_3 at levels below the level of the current standard are associated with a broad array of adverse health effects. This is especially true in at-risk populations that include people with asthma or other lung diseases, who are likely to

experience more serious effects from exposure to O_3, children, and older adults with increased susceptibility, as well as those who are likely to be vulnerable as a result of spending a lot of time outdoors engaged in physical activity, especially active children and outdoor workers. The Administrator notes that this important new evidence demonstrates O_3-induced lung function effects and respiratory symptoms in some healthy individuals down to the previously observed exposure level of 0.080 ppm, as well as very limited new evidence at exposure levels well below the level of the current standard. In addition, the Administrator notes that (1) there is now epidemiological evidence of statistically significant O_3-related associations with lung function and respiratory symptom effects, respiratory-related emergency department visits and hospital admissions, and increased mortality, in areas that likely would have met the current standard; (2) there are also many epidemiological studies done in areas that likely would not have met the current standard but which nonetheless report statistically significant associations that generally extend down to ambient O_3 concentrations that are below the level of the current standard; (3) there are a few studies that have examined subsets of data that include only days with ambient O_3 concentrations below the level of the current standard, or below even much lower O_3 concentrations, and continue to report statistically significant associations with respiratory morbidity outcomes and mortality; and (4) the evidence from controlled human exposure studies, together with animal toxicological studies, provides considerable support for the biological plausibility of the respiratory morbidity associations observed in the epidemiological studies and for concluding that the associations extend below the level of the current standard.

Based on the available evidence, the Administrator agrees with the CASAC Panel and the majority of public commenters that the current standard is not requisite to protect public health with an adequate margin of safety because it is does not provide sufficient protection and that revision of the current O_3 standard is needed to provide increased public health protection. The Administrator notes that extensive critical review of this body of evidence and related uncertainties during the criteria and standard review process, including review by the CASAC Panel and the public of the basis for EPA's proposed decision to revise the primary O_3 standard, has identified a number of issues about which different reviewers disagree and for which additional research is warranted. Nonetheless, on balance, the Administrator believes that the remaining uncertainties in the available evidence do not diminish confidence in the causal relationships between O_3 exposures and indicators of serious respiratory morbidity effects, or the highly suggestive evidence of associations between O_3 exposures and premature mortality, nor do they diminish confidence in the conclusion that the associations extend below the level of the current standard.

Beyond a primary consideration of the available evidence, the Administrator has also taken into consideration the Agency's exposure and risk assessments to help inform his evaluation of the adequacy of the current standard. As at the time of proposal, the Administrator believes the results of those assessments inform his judgment on the adequacy of the current standard to protect against health effects of concern. In considering the exposure analysis results at this time, the Administrator recognizes that that there is a risk for confusion in the term "exposure of concern" that was used at the time of proposal, as it could be read to imply a determination that a certain benchmark

level of exposure has been shown to be causally associated with adverse health effects. As a consequence, the Administrator believes that it is more appropriate to consider such exposure estimates in the context of a continuum rather than focusing on any one discrete benchmark level, as was done at the time of proposal, since the Administrator does not believe that the underlying scientific evidence is certain enough to support a focus on any bright-line benchmark level. In so doing, the Administrator recognizes that associations between O_3 exposures and health effects of concern become increasingly uncertain at lower O_3 exposure levels. Thus, the Administrator has taken into consideration the pattern of such exposure estimates across the range of discrete benchmark levels considered in EPA's exposure assessment to provide some indication of the potential magnitude of the incidence of health outcomes that could not be evaluated in the Agency's quantitative risk assessment but which have been demonstrated to occur in healthy people at O_3 exposures as low as 0.080 ppm, the lowest level at which such health outcomes have been tested.[20]

More specifically, the Administrator has considered the pattern of reductions in such exposures across the benchmark levels of 0.080, 0.070, and 0.060 ppm, which span the level at which there is strong evidence of effects in healthy people down to a level at which the Administrator judges the evidence of effects to be very limited. The

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[20] As noted above, such health outcomes include increased airway responsiveness, increased pulmonary inflammation, increased cellular permeability, and decreased pulmonary defense mechanisms. These physiological effects provide plausible mechanisms underlying observed associations with aggravation of asthma, increased medication use, increased school and work absences, increased susceptibility to respiratory infection, increased visits to doctors' offices and emergency departments, and increased admissions to hospitals. In addition, these physiological effects, if repeated over time, have the potential to lead to chronic effects such as chronic bronchitis or long-term damage to the lungs that can lead to reduced quality of life.

Administrator observes that based on the aggregated exposure estimates for the 2002 simulation for the 12 urban areas included in the exposure analysis, upon just meeting the current standard, the percentages of asthmatic or all school age children likely to experience one of more exposures at and above these benchmark levels of 0.080, 0.070, and 0.060 ppm (while at moderate or greater exertion) are approximately 4%, 20%, and 45%, respectively. As noted at the time of proposal, the Administrator recognizes that there is substantial year-to-year and city-to-city variability in these estimates and that it is important to recognize this variability in considering these estimates. For example, for the 0.080, 0.070, and 0.060 ppm benchmark levels, these percentages are estimated to range from approximately 1 to 10%, 1 to 40%, and 7 to 65%, respectively, across each of the 12 urban areas based on the 2002 simulation, and from approximately 0 to 1%, 0 to 7%, and 1 to 25%, respectively, based on the 2004 simulation.

With regard to the results of the risk assessment, the Administrator again considered the risks estimated to remain upon just meeting the current standard. The Administrator takes note of the estimated magnitudes of such risks, which are presented above in section II.B.1.c for a range of health effects including moderate and large lung function decrements (including percentages of children and number of occurrences), respiratory symptom days, respiratory-related hospital admissions, and nonaccidental and cardiorespiratory mortality, as well as year-to-year and city-to-city variability, and the uncertainties in these estimates. Further, the Administrator recognizes that these estimated risks for the specific health effects that could be analyzed in the Agency's risk assessment are indicative of a much broader array of O_3-related health endpoints 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, emergency department visits) and which primarily affect members of at-risk groups.

In considering these quantitative exposure and risk estimates, as well as the broader array of O_3-related health endpoints that could not be quantified, the Administrator believes that they are important from a public health perspective and indicative of potential exposures and risks to at-risk groups. The Administrator thus finds that the exposure and risk estimates provide additional support to the evidence-based conclusion, reached above, that the current standard needs to be revised. Based on these considerations, and consistent with CASAC Panel's unanimous conclusion that there is no scientific justification for retaining the current standard, the Administrator concludes that the current primary O_3 standard is 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. It is important to note that this conclusion, and the reasoning on which it is based, do not address the question of what specific revisions are appropriate. That requires looking specifically at the current indicator, averaging time, form, and level of the O_3 standard, and evaluating the evidence relevant to determining whether and to what extent any of these elements should be revised, as is discussed in the following section.

C. Conclusions on the Elements of the Primary O_3 Standard

1. Indicator

In the last review of the air quality criteria for O_3 and other photochemical oxidants and the O_3 standard, as in other prior reviews, EPA focused on a standard for O_3

as the most appropriate surrogate for ambient photochemical oxidants. In this review, while the complex atmospheric chemistry in which O_3 plays a key role has been highlighted, no alternatives to O_3 have been advanced as being a more appropriate surrogate for ambient photochemical oxidants.

The Staff Paper (section 2.2.2) noted that it is generally recognized that control of ambient O_3 levels provides the best means of controlling photochemical oxidants. Among the photochemical oxidants, the acute exposure chamber, panel, and field epidemiological human health database provides specific evidence for O_3 at levels commonly reported in the ambient air, in part because few other photochemical oxidants are routinely measured. However, recent investigations on copollutant interactions have used simulated urban photochemical oxidant mixes. These investigations suggest the need for similar studies to help in understanding the biological basis for effects observed in epidemiological studies that are associated with air pollutant mixtures, where O_3 is used as the surrogate for the mix of photochemical oxidants. Meeting the O_3 standard can be expected to provide some degree of protection against potential health effects that may be independently associated with other photochemical oxidants but which are not discernable from currently available studies indexed by O_3 alone. Since the precursor emissions that lead to the formation of O_3 generally also lead to the formation of other photochemical oxidants, measures leading to reductions in population exposures to O_3 can generally be expected to lead to reductions in population exposures to other photochemical oxidants.

The Staff Paper noted that while the new body of time-series epidemiological evidence cannot resolve questions about the relative contribution of other photochemical

oxidant species to the range of morbidity and mortality effects associated with O_3 in these types of studies, control of ambient O_3 levels is generally understood to provide the best means of controlling photochemical oxidants in general, and thus of protecting against effects that may be associated with individual species and/or the broader mix of photochemical oxidants, independent of effects specifically related to O_3. No public comments specifically suggested changing the indicator for the O_3 NAAQS.

In its letter to the Administrator, the CASAC Panel noted that O_3 is "the key indicator of the extent of oxidative chemistry and serves to integrate multiple pollutants." The CASAC also stated that "although O_3 itself has direct effects on human health and ecosystems, it can also be considered as indicator of the mixture of photochemical oxidants and of the oxidizing potency of the atmosphere" (Henderson, 2006c, p. 9).

Based on the available information, and consistent with the views of EPA staff and the CASAC, the Administrator concludes that it is appropriate to continue to use O_3 as the indicator for a standard that is intended to address effects associated with exposure to O_3, alone or in combination with related photochemical oxidants. In so doing, the Administrator recognizes that measures leading to reductions in population exposures to O_3 will also reduce exposures to other photochemical oxidants.

2. Averaging Time

a. Short-term and Prolonged (1 to 8 Hours)

The current 8-hour averaging time for the primary O_3 NAAQS was set in 1997. At that time, the decision to revise the averaging time of the primary standard from 1 hour to 8 hours was supported by the following key observations and conclusions:

(1) The 1-hour averaging time of the previous NAAQS was originally selected primarily on the basis of health effects associated with short-term (i.e., 1- to 3-hour) exposures.

(2) Substantial health effects information was available for the 1997 review that demonstrated associations between a wide range of health effects (e.g., moderate to large lung function decrements, moderate to severe respiratory symptoms and pulmonary inflammation) and prolonged (*i.e.*, 6- to 8-hour) exposures below the level of the then current 1-hour NAAQS.

(3) Results of the quantitative risk analyses showed that reductions in risks from both short-term and prolonged exposures could be achieved through a primary standard with an averaging period of either 1 hour or 8 hours. Thus establishing both a 1-hour and an 8-hour standard would not be necessary to reduce risks associated with the full range of observed health effects.

(4) The 8-hour averaging time was more directly associated with health effects of concern at lower O_3 concentrations than the 1-hour averaging time. It was thus the consensus of the CASAC "that an 8-hour standard was more appropriate for a human health-based standard than a 1-hour standard." (Wolff, 1995)

(5) An 8-hour averaging resulted in a significantly more uniformly protective national standard than the then current 1-hour standard.

(6) An 8-hour averaging time effectively limits both 1- and 8-hour exposures of concern.

In looking at the new information that is discussed in section 7.6.2 of the current Criteria Document, the Staff Paper noted that epidemiological studies have used various

averaging periods for O_3 concentrations, most commonly 1-hour, 8-hour and 24-hour averages. As described more specifically in sections 3.3 and 3.4 of the Staff Paper, in general the results presented from U.S. and Canadian studies showed no consistent difference for various averaging times in different studies. Because the 8-hour averaging time continues to be more directly associated with health effects of concern from controlled human exposure studies at lower concentrations than do shorter averaging periods, the Staff Paper did not evaluate alternative averaging times in this review and did not conduct exposure or risk assessments for standards with averaging times other than 8 hours.

The Staff Paper discussed an analysis of a recent three-year period of air quality data (2002 to 2004) which was conducted to determine whether the comparative 1- and 8-hour air quality patterns that were observed in the last review continue to be observed based on more recent air quality data. This updated air quality analysis (McCluney, 2007) was very consistent with the analysis done in the last review in that it indicated that only two urban areas of the U.S. have such "peaky" air quality patterns such that the ratio of 1-hour to 8-hour design values is greater than 1.5. This suggested that based on recent air quality data, it was again reasonable to conclude that an 8-hour average standard at or below the current level would generally be expected to provide protection equal to or greater than the previous 1-hour standard of 0.12 ppm in almost all urban areas. Thus, the Staff Paper again concluded that setting a standard with an 8-hour averaging time can effectively limit both 1- and 8-hour exposures of concern and is appropriate to provide adequate and more uniform protection of public health from both short-term and prolonged exposures to O_3 in the ambient air. In its letter to the Administrator, the

CASAC Panel unanimously supported the continued use of an 8-hour averaging time for the primary O_3 standard (Henderson 2007, p. 2).

With respect to comments received on the proposal, most public commenters did not address the issue of whether EPA should consider additional or alternative averaging time standards. A few commenters, most notably the CA EPA and joint comments by ALA and several environmental groups, expressed the view that consideration should be given to setting or reinstating a 1-hour standard, in addition to maintaining the use of an 8-hour averaging time, to protect people in those parts of the country with relatively more "peaky" exposure profiles (e.g., Los Angeles). These commenters pointed out that when controlled exposure studies using triangular exposure patterns (with relatively higher 1-hour peaks) have been compared to constant exposure patterns with the same aggregate O_3 dose (in terms of concentration multiplied by time), "peaky" exposure patterns are seen to lead to higher risks. The CA EPA made particular note of this point, expressing the view that a 1-hour standard would more closely represent actual exposures, in that many people spend only 1 to 2 hours a day outdoors, and that it would be better matched to O_3 concentration profiles along the coasts where O_3 levels are typically high for shorter averaging periods than 8 hours.

For the reasons discussed in the Staff Paper and summarized above and considering the unanimous views of the CASAC Panel supporting the continued use of an 8-hour averaging time for the primary O_3 standard, the Administrator finds that, in combination with the decisions on form and level described below, the 8-hour standard provides adequate protection from both short-term (1 to 3 hours) and prolonged (6 to 8

hours) exposures to O_3 in the ambient air and that it is appropriate to continue use of the 8-hour averaging time for the O_3 NAAQS.

b. Long-term

During the last review, there was a large animal toxicological database for consideration that provided clear evidence of associations between long-term (*e.g.*, from several months to years) exposures and lung tissue damage, with additional evidence of reduced lung elasticity and accelerated loss of lung function. However, there was no corresponding evidence for humans, and the state of the science had not progressed sufficiently to allow quantitative extrapolation of the animal study findings to humans. For these reasons, consideration of a separate long-term primary O_3 standard was not judged to be appropriate at that time, recognizing that the 8-hour standard would act to limit long-term exposures as well as short-term and prolonged exposures.

Taking into consideration the currently available evidence on long-term O_3 exposures, discussed above in section II.A.2.a.ii, the Staff Paper concluded that a health-based standard with a longer-term averaging time than 8 hours is not warranted at this time. The Staff Paper noted that while potentially more serious health effects have been identified as being associated with longer-term exposure studies of laboratory animals and in epidemiology studies, there remains substantial uncertainty regarding how these data could be used quantitatively to develop a basis for setting a long-term health standard. Because long-term air quality patterns would be improved in areas coming into attainment with an 8-hour standard, the potential risk of health effects associated with long-term exposures would be reduced in any area meeting an 8-hour standard. Thus, the

Staff Paper did not recommend consideration of a long-term, health-based standard at this time.

In its final letter to the Administrator, the CASAC Panel offered no views on the long-term exposure evidence, nor did it suggest that consideration of a primary O_3 standard with a long-term averaging time was appropriate, and instead the CASAC Panel agreed with the choice of an 8-hour averaging time for the primary O_3 NAAQS suggested by Agency staff (Henderson, 2007). Similarly, no public commenters expressed support for considering such a long-term standard. Taking into account the evidence, the CASAC Panel's views, and the public comments, the Administrator finds that there is not a sufficient basis for setting a long-term primary O_3 NAAQS at this time.

c. Administrator's Conclusions on Averaging Time

In considering the information discussed above, the CASAC Panel's views and public comments, the Administrator concludes that a standard with an 8-hour averaging time can effectively limit both 1- and 8-hour exposures of concern and that an 8-hour averaging time is appropriate to provide adequate and more uniform protection of public health from both short-term (1- to 3-hour) and prolonged (6- to 8-hour) exposures to O_3 in the ambient air. This conclusion is based on the observations summarized above, particularly: (1) the fact that the 8-hour averaging time is more directly associated with health effects of concern at lower O_3 concentrations than are averaging times of shorter duration and (2) results from quantitative risk analyses showing that attaining an 8-hour standard reduces the risk of experiencing health effects associated with both 8-hour and shorter duration exposures. Furthermore, the Administrator observes that the CASAC Panel agreed with the choice of averaging time (Henderson, 2007). Therefore, the

Administrator finds it appropriate to retain the 8-hour averaging time and to not set a separate 1-hour standard. The Administrator also concludes that a standard with a long-term averaging time is not warranted at this time.

3. Form

In 1997, the primary O_3 NAAQS was changed from a "1-expected-exceedance" form per year over three years[21] to a concentration-based statistic, specifically the 3-year average of the annual fourth-highest daily maximum 8-hour concentrations. The principal advantage of the concentration-based form is that it is more directly related to the ambient O_3 concentrations that are associated with health effects of concern. With a concentration-based form, days on which higher O_3 concentrations occur would weigh proportionally more than days with lower concentrations, since the actual concentrations are used in determining whether the standard is attained. That is, given that there is a continuum of effects associated with exposures to varying levels of O_3, the extent to which public health is affected by exposure to ambient O_3 is related to the actual magnitude of the O_3 concentration, not just whether the concentration is above a specified level.

During the 1997 review, consideration was given to a range of alternative forms, including the second-, third-, fourth- and fifth-highest daily maximum 8-hour concentrations in an O_3 season, recognizing that the public health risks associated with exposure to a pollutant without a clear, discernable threshold can be appropriately addressed through a standard that allows for multiple exceedances to provide increased

[21] The 1-expected-exceedance form essentially requires that the fourth-highest air quality value in 3 years, based on adjustments for missing data, be less than or equal to the level of the standard for the standard to be met at an air quality monitoring site.

stability, but that also significantly limits the number of days on which the level may be exceeded and the magnitude of such exceedances. Consideration was given to setting a standard with a form that would provide a margin of safety against possible, but uncertain, chronic effects and would also provide greater stability to ongoing control programs. The fourth-highest daily maximum was selected because it was decided that the differences in the degree of protection against potential chronic effects afforded by the alternatives within the range were not well enough understood to use any such differences as a basis for choosing the most restrictive forms. On the other hand, the relatively large percentage of sites that would experience O_3 peaks well above 0.08 ppm and the number of days on which the level of the standard may be exceeded even when attaining a fifth-highest 0.08 ppm concentration-based standard, argued against choosing that form.

As an initial matter, the Staff Paper considered whether it is appropriate to continue to specify the level of the O_3 standard to the nearest hundredth (two decimal places) ppm, or whether the precision with which ambient O_3 concentrations are measured supports specifying the standard level to the thousandth (three decimal places) ppm (i.e., to the part per billion (ppb)). The Staff Paper discussed an analysis conducted by EPA staff to determine the impact of ambient O_3 measurement error on calculated 8-hour average O_3 design value concentrations, which are compared to the level of the standard to determine whether the standard is attained (Cox and Camalier, 2006). The results of this analysis suggested that instrument measurement error, or possible instrument bias, contribute very little to the uncertainty in design values. More specifically, measurement imprecision was determined to contribute less than 1 ppb to

design value uncertainty, and a simulation study indicated that randomly occurring instrument bias could contribute approximately 1 ppb. EPA staff interpreted this analysis as being supportive of specifying the level of the standard to the thousandth ppm. If the current standard were to be specified to this degree of precision, the current standard would effectively be at a level of 0.084 ppm, reflecting the data rounding conventions that are part of the definition of the current 0.08 ppm 8-hour standard. This information was provided to the CASAC Panel and made available to the public.

In evaluating alternative forms for the primary standard in conjunction with specific standard levels, the Staff Paper considered the adequacy of the public health protection provided by the combination of the level and form to be the foremost consideration. In addition, the Staff Paper recognized that it is important to have a form of the standard that is stable and insulated from the impacts of extreme meteorological events that are conducive to O_3 formation. Such instability can have the effect of reducing public health protection, because frequent shifting in and out of attainment due of meteorological conditions can disrupt an area's ongoing implementation plans and associated control programs. Providing more stability is one of the reasons that EPA moved to a concentration-based form in 1997.

The Staff Paper considered two concentration-based forms of the standard: the nth-highest maximum concentration and a percentile-based form. A percentile-based statistic is useful for comparing datasets of varying length because it samples approximately the same place in the distribution of air quality values, whether the dataset is several months or several years long. However, a percentile-based form would allow more days with higher air quality values in locations with longer O_3 seasons relative to

places with shorter O_3 seasons. An nth-highest maximum concentration form would more effectively ensure that people who live in areas with different length O_3 seasons receive the same degree of public health protection. For this reason, the exposure and risk analyses were based on a form specified in terms of an nth-highest concentration, with n ranging from 3 to 5.

The results of some of these analyses are shown in the Staff Paper (Figures 6-1 through 6-4) and specifically discussed in chapter 6. These figures illustrate the estimated percent change in risk estimates for the incidence of moderate or greater decrements in lung function (≥ 15 percent FEV_1) in all school age children and moderate or greater lung function decrements (≥ 10 percent FEV_1) in asthmatic school age children, associated with going from meeting the current standard to meeting alternative standards with alternative forms based on the 2002 and 2004 simulations. Figures 6-5 and 6-6 illustrate the estimated percent change in the estimated incidence of non-accidental mortality, associated with going from meeting the current standard to meeting alternative standards, based on the 2002 and 2004 simulations. These results are generally representative of the patterns found in all of the analyses. The estimated reductions in risk associated with different forms of the standard, ranging from third- to fourth-highest daily maximum concentrations at 0.084 ppm, and from third- to fifth-highest daily maximum concentrations at 0.074 ppm, are generally less than the estimated reductions associated with the different levels that were analyzed. As seen in these figures, there is much city-to-city variability, particularly in the percent changes associated with going from a fourth-highest to third-highest form at the current level of 0.084 ppm, and with estimated reductions associated with the fifth-highest form at a

0.074 ppm level. In most cities, there are generally only small differences in the estimated reductions in risks associated with the third- to fifth-highest forms at a level of 0.074 ppm simulated using 2002 and 2004 O_3 monitoring data.

The Staff Paper noted that there is not a clear health-based rationale for selecting a particular nth-highest daily maximum form of the standard from among the ones analyzed. It also noted that the changes in the form considered in the analyses result in only small differences in the estimated reductions in risks in most cities, although in some cities larger differences are estimated. The Staff Paper concluded that a range of concentration-based forms from the third- to the fifth-highest daily maximum 8-hour average concentration is appropriate for consideration in setting the standard. Given that there is a continuum of effects associated with exposures to varying levels of O_3, the extent to which public health is affected by exposure to ambient O_3 is related to the actual magnitude of the O_3 concentration, not just whether the concentration is above a specified level. The principal advantage of a concentration-based form is that it is more directly related to the ambient O_3 concentrations that are associated with health effects. Robust, concentration-based forms, in the range of the third- to fifth-highest daily maximum 8-hour average concentration, including the current 4th-highest daily maximum form, minimize the inherent lack of year-to-year stability of exceedance-based forms and provide insulation from the impacts of extreme meteorological events. Such instability can have the effect of reducing public health protection by disrupting ongoing implementation plans and associated control programs.

With regard to the precision of the standard, in its letter to the Administrator, the CASAC concluded that current monitoring technology "allows accurate measurement of

O_3 concentrations with a precision of parts per *billion"* (Henderson, 2006c). The CASAC recommended that the specification of the level of the O_3 standard should reflect this degree of precision (Henderson, 2006c). While the CASAC Panel unanimously supported specifying the level of the standard to this degree of precision, public comments were mixed. Environmental organizations (e.g., ALA et al.) and some State/regional agencies (e.g., NESCAUM, PA Department of Environmental Protection) supported the proposed increased precision and but did not support truncating to the third decimal. However, several industry associations (e.g., API, EMA, AAAM) suggested that there is not sufficient evidence to modify the 1997 decision to round to two decimal places. These comments are addressed in the Response to Comments document.

The Administrator concludes that the level of the standard should be specified to the thousandth ppm (three decimal places), based on the staff's analysis and conclusions discussed in the Staff Paper that current monitoring technology allows accurate measurement of O_3 to support specifying the 8-hour standard to this degree of precision, and on the CASAC Panel's reasoning and recommendation with respect to this aspect of the standard.

With regard to the form of the standard, in its letter to the Administrator prior to proposal, the CASAC recommended that "*a range of concentration-based forms from the third- to the fifth-highest daily maximum 8-hour average concentration"* be considered (Henderson, 2006c, p. 5). Several commenters supported maintaining the current form of the standard because it strikes an appropriate balance between stability and protection, as well as because EPA used this form in their analyses (e.g., EMA, NESCAUM, and Pennsylvania Department of Environmental Protection). Some public commenters that

expressed the view that the current primary O_3 standard is not adequate also submitted comments that supported a more health-protective form of the standard than the current form (e.g., a second- or third-highest daily maximum form)(e.g., ALA et al.). Most commenters who expressed the view that the current standard should not be revised did not provide any views on alternative forms that would be appropriate for consideration should the Administrator consider revisions to the standard. A few industry association and business commenters supported changing to a 5th highest form (e.g., Dow Chemical, AAM). One commenter (Oklahoma Department of Transportation) suggested the use of a 6th or 7th highest daily maximum form.

The Administrator recognizes that there is not a clear health-based threshold for selecting a particular nth-highest daily maximum form of the standard from among the ones analyzed in the Staff Paper and that the current form of the standard provides a stable target for implementing programs to improve air quality. The Administrator also agrees that the adequacy of the public health protection provided by the combination of the level and form is a foremost consideration. Based on this, the Administrator finds that the form of the current standard, 4th-highest daily maximum 8-hour average concentration, should be retained, recognizing that the public health protection that would be provided by this standard is based on combining this form with the increased health protection provided by the lower level of the standard discussed in the section below.

4. Level

a. Proposed Range

For the reasons discussed below, and taking into account information and assessments presented in the Criteria Document and Staff Paper, the advice and

recommendations of the CASAC, and the public comments received prior to proposal, the Administrator proposed to revise the existing 8-hour primary O_3 standard. Specifically, the Administrator proposed to revise the level of the primary O_3 standard to within a range from 0.070 to 0.075 ppm.

The Administrator's consideration of alternative levels of the primary O_3 standard builds on his proposal, discussed above, that the overall body of evidence indicates that the current 8-hour O_3 standard is not requisite to protect public health with an adequate margin of safety because it does not provide sufficient protection, and that revision would result in increased public health protection, especially for members of at-risk groups, notably including asthmatic children and other people with lung disease, as well as all children and older adults, especially those active outdoors, and outdoor workers, against an array of adverse health effects. These effects range from health outcomes that could be quantified in the risk assessment, including decreased lung function, respiratory symptoms, serious indicators of respiratory morbidity such as hospital admissions for respiratory causes, and nonaccidental mortality, to health outcomes that could not be directly estimated, including pulmonary inflammation, increased medication use, emergency department visits, and possibly cardiovascular-related morbidity effects. In reaching a proposed decision about the level of the O_3 primary standard, the Administrator considered: the evidence-based considerations from the Criteria Document and the Staff Paper; the results of the exposure and risk assessments discussed above and in the Staff Paper, giving weight to the exposure and risk assessments as judged appropriate; CASAC advice and recommendations, as reflected in discussions of drafts of the Criteria Document and Staff Paper at public meetings, in separate written

comments, and in CASAC's letters to the Administrator; EPA staff recommendations; and public comments received during the development of these documents, either in connection with CASAC meetings or separately. In considering what 8-hour standard is requisite to protect public health with an adequate margin of safety, the Administrator noted at the time of proposal that he was mindful that this choice requires judgment based on an interpretation of the evidence and other information that neither overstates nor understates the strength and limitations of the evidence and information nor the appropriate inferences to be drawn.

The Administrator noted that the most certain evidence of adverse health effects from exposure to O_3 comes from the clinical studies and that the large bulk of this evidence derives from studies of exposures at levels of 0.080 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. Moreover, there is no evidence that the 0.080 ppm level is a threshold for these effects. Although the Administrator took note of the very limited new evidence of lung function decrements and respiratory symptoms in some healthy individuals at the 0.060 ppm exposure level, he judged this evidence too limited to support a primary focus at this level. The Administrator also noted that clinical studies, supported by epidemiological studies, provide important new evidence that people with asthma were likely to experience larger and more serious effects than healthy people from exposure to O_3. There were also epidemiological studies that provide evidence of statistically significant associations between short-term O_3 exposures and more serious health effects, such as emergency department visits, hospital admissions, and premature mortality, in

areas that likely would have met the current standard. The Administrator also took note of the many epidemiological studies done in areas that likely would not have met the current standard but which nonetheless report statistically significant associations that generally extend down to ambient O_3 concentrations that were below the level of the current standard. Further, there were a few studies that have examined subsets of data that include only days with ambient O_3 concentrations below the level of the current standard, or below even much lower O_3 concentrations, and continued to report statistically significant associations with respiratory morbidity outcomes and mortality. In considering this evidence, the Administrator noted that the extent to which these studies provide evidence of causal relationships with exposures to O_3 alone, down to the lowest levels observed, remains uncertain. EPA sought comment on the degree to which associations observed in epidemiological studies reflect causal relationships between important health endpoints and exposure to O_3 alone at ambient O_3 levels below the current standard.

Therefore, the Administrator judged at the time of proposal, and continues to judge as discussed in section II.B.3, that revising the current standard to protect public health with an adequate margin of safety is warranted and would reduce risk to public health, based on: (1) the strong body of clinical evidence in healthy people at exposure levels of 0.080 and above of lung function decrements, respiratory symptoms, pulmonary inflammation, and other medically significant airway responses, as well as some indication of lung function decrements and respiratory symptoms at lower levels; (2) the substantial body of clinical and epidemiological evidence indicating that people with asthma are likely to experience larger and more serious effects than healthy people; and

(3) the body of epidemiological evidence indicating associations are observed for a wide range of serious health effects, including respiratory emergency department visits, hospital admissions, and premature mortality, at and below 0.080 ppm. The Administrator also judged at the time of proposal and continues to conclude that the estimates of exposures of concern and risks remaining upon just meeting the current standard or a standard at the 0.080 ppm level provide additional support for this view. For the same reasons stated in the proposal notice and discussed above in section II.B on the adequacy of the current standard, the Administrator judges that the standard should be set below 0.080 ppm, a level at which the evidence provides a high degree of certainty about the adverse effects of O_3 exposure even in healthy people

The Administrator next considered what standard level below 0.080 ppm would be requisite to protect public health with an adequate margin of safety that is sufficient, but not more than necessary, to achieve that result, recognizing that such a standard would result in increased public health protection. The assessment of a standard level calls for consideration of both the degree of additional protection that alternative levels of the standard might be expected to provide as well as the certainty that any specific level will in fact provide such protection. In the circumstances present in this review, 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 holistically in making this public health policy judgment and selecting a standard level from a range of reasonable values.

The Administrator noted that at exposure levels below 0.080 ppm there is only a very limited amount of evidence from clinical studies, indicating effects in some healthy

individuals at levels as low as 0.060 ppm. The great majority of the evidence concerning effects below 0.080 ppm is from epidemiological studies. The epidemiological studies do not identify any bright-line threshold level for effects. At the same time, the epidemiological studies are not in and of themselves direct evidence of a causal link between exposure to O_3 and the occurrence of the effects. The Administrator considers these studies in the context of all the other available evidence in evaluating the degree of certainty that O_3-related adverse health effects would occur at various ambient levels below 0.080 ppm, including the strong human clinical studies and the toxicological studies that demonstrate the biological plausibility and mechanisms for the effects of O_3 on airway inflammation and increased airway responsiveness at exposure levels of 0.080 ppm and above.

Based on consideration of the entire body of evidence and information available at this time, as well as the recommendations of the CASAC, the Administrator proposed that a standard within the range of 0.070 to 0.075 ppm would be requisite to protect public health with an adequate margin of safety. As noted at the time of proposal, a standard level within this range is estimated to 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 clinical studies, and in emergency department visits, hospital admissions, and mortality effects indicated in the epidemiological studies. All of these effects are indicative of a much broader array of O_3-related health endpoints, as represented by the pyramid of effects, such as school absences and increased medication use that are plausibly linked to these observed effects.

The Administrator also considered the degree of improvements in public health that potentially could be achieved by a standard of 0.070 to 0.075 ppm, giving weight to the exposure and risk assessments as he judged appropriate. As discussed in the proposal notice (section II.D.4) in considering the results of the exposure assessment, the Administrator primarily focused on exposures at and above the 0.070 ppm benchmark level as an important surrogate measure for potentially more serious health effects for at-risk groups, including people with asthma. In so doing, the Administrator noted that although the analysis of "exposures of concern" was conducted to estimate exposures at and above three discrete benchmark levels, the concept is appropriately viewed as a continuum. As discussed above, the Administrator strives to balance concern 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 exposure levels. In focusing on this benchmark, the Administrator noted that upon just meeting a standard within the range of 0.070 to 0.075 ppm based on the 2002 simulation, the number of school age children likely to experience exposures at and above this benchmark level in aggregate (for the 12 cities in the assessment) was estimated to be approximately 2 to 4 percent of all and asthmatic children and generally less than 10 percent of children even in cities that receive the least degree of protection from such a standard in a recent year with relatively high O_3 levels. A standard within the 0.070 to 0.075 ppm range would thus substantially reduce exposures of concern by about 90 to 80 percent, respectively, from those estimated to occur upon just meeting the current standard. While placing less weight on the results of the risk assessment, in light of the important uncertainties inherent in the assessment, the Administrator noted that the results indicated that a

standard set within this range would likely reduce risks to at-risk groups from the O_3-related health effects considered in the risk assessment, and by inference across the much broader array of O_3-related health effects that could only be considered qualitatively, relative to the level of protection afforded by the current standard. This lent support to the proposed range.

The Administrator judged that a standard set within the range of 0.070 to 0.075 ppm would provide a degree of reduction in risk that is important from a public health perspective and that a standard within this range would be requisite to protect public health, including the health of at-risk groups, with an adequate margin of safety. EPA's evaluation of the body of scientific evidence and quantitative estimates of exposures and risks indicated that substantial reductions in public health risks would occur throughout this range. As noted in the proposal notice, because there is no bright line clearly directing the choice of level within this reasonable range, the choice of what is appropriate, considering the strengths and limitations of the evidence, and the appropriate inference to be drawn from the evidence and the exposure and risk assessments is a public health policy judgment. To further inform this judgment, EPA sought public comment on the extent to which the epidemiological and clinical evidence provide guidance as to the level of a standard that would be requisite to protect public health with an adequate margin of safety, especially for at-risk groups.

In considering the available information, the Administrator also judged that a standard level below 0.070 ppm would not be appropriate. In reaching this judgment, the Administrator noted that there was only quite limited evidence from clinical studies at exposure levels below 0.080 ppm O_3. Moreover, the Administrator recognized that in the

body of epidemiological evidence, many studies reported positive and statistically significant associations, while others reported positive results that were not statistically significant, and a few did not report any positive O_3-related associations. In addition, the Administrator judged that evidence of a causal relationship between adverse health outcomes and O_3 exposures became increasingly uncertain at lower levels of exposure.

The Administrator also considered the results of the exposure assessments in reaching his judgment that a standard level below 0.070 ppm would not be appropriate. The Administrator noted that in considering the results from the exposure assessment, a standard set at the 0.070 ppm level, with the same form as the current standard, was estimated to provide substantial reductions in exposures of concern (i.e., approximately 90 to 92 percent reductions in the numbers of school age children and 94 percent reduction in the total number of occurrences) for both all and asthmatic school age children relative to just meeting the current standard based on a simulation of a recent year with relatively high O_3 levels (2002). Thus, a 0.070 ppm standard would be expected to provide protection from the exposures of concern that the Administrator had primarily focused on for over 98 percent of all and asthmatic school age children even in a year with relatively high O_3 levels, increasing to over 99.9 percent of children in a year with relatively low O_3 levels (2004).

In considering the results of the health risk assessment, as discussed in the proposal notice (section II.C.2), the Administrator noted that there were important uncertainties and assumptions inherent in the risk assessment and that this assessment was most appropriately used to simulate trends and patterns that could be expected, as well as providing informed, but still imprecise, estimates of the potential magnitude of

risks. The Administrator particularly noted that as lower standard levels were modeled, including a standard set at a level below 0.070 ppm, the risk assessment continued to assume a causal link between O_3 exposures and the occurrence of the health effects examined, such that the assessment continued to indicate reductions in O_3-related risks upon meeting a lower standard level. As discussed above, however, the Administrator recognized that evidence of a causal relationship between adverse health effects and O_3 exposures becomes increasingly uncertain at lower levels of exposure. Given all of the information available to him at the time of the proposal, the Administrator judged that the increasing uncertainty of the existence and magnitude of additional public health protection that standards below 0.070 ppm might provide suggested that such lower standard levels would likely be below what is necessary to protect public health with an adequate margin of safety.

In addition, the Administrator judged that a standard level higher than 0.075 ppm would also not be appropriate. This judgment took into consideration the information discussed in the proposal notice (sections II.A and B) and was based on the strong body of clinical evidence in healthy people at exposure levels of 0.080 ppm and above, the substantial body of clinical and epidemiological evidence indicating that people with asthma are likely to experience larger and more serious effects than healthy people, the body of epidemiological evidence indicating that associations are observed for a wide range of more serious health effects at levels below 0.080 ppm, and the estimates of exposure and risk remaining upon just meeting a standard set at 0.080 ppm. The much greater certainty of the existence and magnitude of additional public health protection that such levels would forego provides the basis for judging that levels above 0.075 ppm

would be higher than what is requisite to protect public health, including the health of at-risk groups, with an adequate margin of safety.

For the reasons discussed in more detail in the proposal notice and summarized above, the Administrator proposed to revise the level of the primary O_3 standard to within the range of 0.070 to 0.075 ppm.

At the time of proposal, the Administrator recognized that sharply divergent views on the appropriate level of this standard had been presented to EPA as part of the NAAQS review process, and he solicited comment on a wide range of standard levels and alternative approaches to characterizing and addressing scientific uncertainties. One such alternative view focused very strongly on the uncertainties inherent in the controlled human exposure and epidemiological studies and quantitative exposure and health risk assessments as the basis for concluding that no change to the current 8-hour O_3 standard of 0.084 ppm was warranted. In sharp contrast, others viewed the controlled human exposure and epidemiological studies as strong and robust, and generally placed more weight on the results of the quantitative exposure and risk assessments and the unanimous CASAC recommendations as a basis for concluding that an 8-hour standard at or below 0.070 ppm was warranted. As discussed below, the same sharply divergent views were generally repeated in comments on the proposal by the two distinct groups of commenters identified in II.B.2 above.

b. Comments on Level

i. Health Evidence Considerations

With regard to the evaluation and consideration of the health effects evidence and how such information should be considered in the decision on the standard level, EPA

notes that the commenters fell into the same two groups discussed above in section II.B.2. The two groups often cited the same studies and evidence, but they reached sharply divergent conclusions as to what standard level is supported by the health effects evidence. The general views of both groups on the interpretation and use of the health effects evidence are presented above in section II.B.2.a, with most comments from one group arguing that this evidence supports a decision to revise the 8-hour standard to 0.060 ppm or below, and the other group arguing that it supports a decision not to revise the current 8-hour standard.

With regard to the evidence from controlled human exposure studies, commenters that included public health and environmental groups who supported revising the current standard expressed the view that the large body of evidence available at the time of the last review, demonstrating an array of adverse health effects (i.e., reduced lung function, respiratory symptoms, increased airway responsiveness, inflammation, and increased susceptibility to respiratory infection), at concentrations of 0.080 ppm O_3, indicated that the standard should have been set at a lower level. These commenters noted that standards must be set below the level shown to cause effects in healthy subjects in order to protect sensitive populations with an adequate margin of safety. As discussed in section II.B.2.a above, these commenters focused on the results of the Adams studies (2002, 2006) as evidence that exposure to 0.060 ppm O_3 will result in a significant proportion (i.e., 7%) of the adult population who do not have asthma or other lung diseases experiencing notable lung function decrements (FEV_1 decrement ≥ 10%), and furthermore that larger decrements in FEV_1 would be expected in more susceptible populations. This evidence caused these commenters to reject EPA's proposed range:

> Clearly, EPA's proposed standard of 0.070 to 0.075 ppm cannot be considered protective of public health in light of experimental evidence demonstrating adverse respiratory effects in healthy individuals exposed to 0.060 ppm, and the legal requirements to protect sensitive populations with an adequate margin of safety. [ALA et al., p. 51]

The second group of commenters, who opposed revision of the standard, expressed the view that the group mean changes reported in the Adams studies (2002, 2006) were small, that such decrements should not be considered to be adverse, and that the individuals who experienced larger responses were too few to serve as a basis for a revised O_3 standard. This group included virtually all commenters representing industry associations and businesses. These general comments are addressed above in section II.B.2.a and in more detail in the Response to Comments document.

In considering comments received on controlled human exposure studies, and how these studies support a focus on particular standard levels, the Administrator observes that in general the comments support his original view that these studies provide the most certain evidence of adverse health effects, and that the large bulk of evidence derives from studies of exposures at levels of 0.080 ppm and above. The Administrator notes that since the last review important new evidence includes demonstration of O_3-induced lung function effects and respiratory symptoms in some healthy adults down to the previously observed exposure level of 0.080 ppm, as well as very limited new evidence of the same effects at exposure levels well below the level of the current standard (Adams, 2002, 2006). EPA disagrees with these commenters that the percent of subjects that experienced FEV_1 decrements greater than 10% in this study of 30 subjects can appropriately be generalized to the U.S. population. Based on careful consideration of the comments, the Administrator again concludes that while the Adams studies

provide evidence that some healthy individuals will experience lung function decrements and respiratory symptoms at the 0.060 ppm exposure level, this evidence is too limited to support a primary focus at this level. Moreover, the Administrator notes that while the CASAC Panel supported a level of 0.060 ppm, they also supported a level above 0.060, indicating that they disagree with the commenters' view that the results of Adams studies mean that the level of the standard has to be set at 0.060 ppm.

With regard to the information from epidemiological studies, commenters representing public health, environmental, and medical organizations generally asserted that the large body of new epidemiological studies provides evidence of causal associations between O_3 exposures and a wide array of respiratory and cardiovascular morbidity effects, including emergency department visits and hospital admissions. They expressed the view that a significant body of strong, consistent evidence links short-term exposures to premature mortality and noted that this evidence is supported by new research that provides biological plausibility for such effects. These commenters noted that various approaches, including air quality assessments which show that statistically significant associations occurred in areas that likely would have met the current standard, or statistical approaches that examined subsets of the data which indicate that statistically significant associations remain down to very low ambient O_3 levels, show effects well below the level of the current standard. Moreover they identified particular studies, including some "new" studies not considered in the Criteria Document, that indicated there are additional sub-populations that are likely to be sensitive to O_3, including infants, women, and African-Americans, that should be considered in deciding the requisite level

of protection. They asserted that this information supports a standard set at a level no higher than 0.060 ppm O_3.

With regard to the information from epidemiological studies, the second group of commenters focused strongly on EPA's interpretation of the epidemiological evidence and the uncertainties they saw in this evidence as a basis for concluding that no change to the current level of the 8-hour O_3 standard is warranted. In commenting on the proposed range of levels, these commenters generally relied on the same arguments presented above in section II.B.2.a as to why they believed it would be inappropriate for EPA to make any revisions to the primary O_3 standard. That is, they asserted that the health effects of concern associated with short-term or prolonged exposures to O_3 have not changed significantly since 1997; that the inconsistencies and uncertainties inherent in these studies as a whole should preclude any reliance on them as justification for a more stringent standard; and that "new" science not included in the Criteria Document continues to increase uncertainty about possible health risks associated with exposure to O_3. Specific methodological issues cited as additional support for their conclusions included: adequacy of exposure data; potential confounding by copollutants; model selection; inconsistent evidence relating O_3 exposure to mortality, and "new" studies that provide additional evidence of inconsistencies. These general comments are addressed above in section II.B.2.a, and in greater detail in the Response to Comments document.

In considering these comments on the epidemiological evidence with regard to the interpretation of the epidemiological evidence and methodological issues, the Administrator notes that in general, most of the issues and concerns raised by those who do not support any revisions to the primary O_3 standard with regard to the interpretation

of the epidemiological evidence and methodological issues, are essentially restatements if issues raised during the review of the Criteria Document and Staff Paper. The same is true of the views of commenters who supported a level of the standard no higher than 0.060 ppm O_3. 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 the scientific content of both the Criteria Document and Staff Paper and advised the Administrator that these documents provided an appropriate basis for use in regulatory decision making. Therefore, these comments do not provide a basis for the Administrator to reach fundamentally different conclusions than he reached at the time of proposal.

Moreover, the Administrator notes that epidemiological evidence is most appropriately evaluated in the context of all available evidence, including evidence from controlled human exposure and toxicological studies. In general, the Administrator agrees with the weight of evidence approach used in the Criteria Document and believes that this body of scientific evidence across all types of studies is very robust, recognizing that it includes a large number of various types of studies that provide consistent and coherent evidence of an array of O_3-related respiratory morbidity effects and possibly cardiovascular-related morbidity as well as total nonaccidental and cardiorespiratory mortality. More specifically, the Administrator judges that the body of epidemiological evidence indicating associations with a wide range of serious health effects, including respiratory emergency department visits and hospital admissions and premature mortality, at and below 0.080 ppm supports revising the current standard to protect public

health. While the great majority of evidence concerning effects below 0.080 ppm was from epidemiological studies, the epidemiological studies do not identify any bright-line threshold level for effects. At the same time, the epidemiological studies are not themselves direct evidence of a causal link between exposure to O_3 and the occurrence of the effects. Therefore, Administrator has considered these studies in the context of all the other available evidence in evaluating the degree of certainty that O_3-related adverse health effects would occur at various ambient levels below 0.080 ppm. In that context, there is only quite limited evidence from controlled human exposure studies at exposure levels below 0.080 ppm O_3. The Administrator recognizes that in the body of epidemiological evidence, many studies reported positive and statistically significant associations, while others reported positive results that were not statistically significant, and a few did not report any positive O_3-related associations. In addition, the Administrator judged that evidence of a causal relationship between adverse health outcomes and O_3 exposures became increasingly uncertain at lower levels of exposure. Based on this the Administrator continues to believe that the body of epidemiological evidence does not support setting a standard as low as 0.060 as suggested by some commenters.

The Administrator also notes the many epidemiological studies done in areas that likely would not have met the current standard but which nonetheless report statistically significant associations that generally extend down to ambient O_3 concentrations that were below the level of the current standard. Further, there were a few studies that have examined subsets of data that include only days with ambient O_3 concentrations below the level of the current standard, or below even much lower O_3 concentrations, and

continued to report statistically significant associations with respiratory morbidity outcomes and mortality. In the context of the strong clinical evidence of adverse effect in healthy adults at 0.080, the Administrator finds that the body of epidemiological evidence does not support retaining a standard of 0.080, as suggested by commenters.

Both groups of commenters also considered evidence from controlled human exposure and epidemiological studies of increased susceptibility in people with lung disease, especially people with asthma, but they reached sharply divergent conclusions about what standard level is supported by this evidence. As discussed above in section II.B.2.a, medical organizations and public health and environmental groups agreed with EPA that, based on evidence from controlled human exposure and epidemiological 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. Furthermore, these commenters noted that epidemiological studies have identified other potentially sensitive subpopulations, including for example, infants, women and African-Americans, and that effects in these groups should be part of the consideration in providing an adequate margin of safety. These commenters concluded that the appropriate level for the primary O_3 standard is 0.060 ppm, to provide protection for members of sensitive groups, especially people with asthma, who are likely to have more serious responses and to respond at lower levels that healthy people. They also contended that a standard set at this level also would provide protection against anticipated, but as yet unproven effects in the additional groups cited. The Administrator agrees with these commenters that important new evidence shows that asthmatics have more serious responses, and are more

likely to respond at lower O_3 levels, than healthy individuals. Moreover, he agrees that this evidence supports a standard set at a level below 0.080 ppm O_3, based on the strong evidence from human clinical studies in healthy adults at this level. However, for the reasons described above, he does not agree that the controlled human exposure and epidemiological evidence provide support for a standard set at 0.060 ppm, for the reasons discussed above.

In contrast, industry association and business commenters 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 made the following major comments: (1) the lung function decrements and respiratory symptoms observed in clinical studies of asthmatics are not clinically important; (2) EPA postulates that asthmatics would likely experience more serious responses and responses at lower levels than the subjects of controlled human exposure experiments, but that hypothesis is not supported by scientific evidence; and, (3) EPA recognized asthmatics as a sensitive subpopulation in 1997, and new information does not suggest greater susceptibility than was previously believed. EPA has generally responded to these comments and those summarized in the paragraph above in section II.B.2.a above, and in greater detail in the Response to Comments document.

After careful consideration of these comments, the Administrator continues to judge that there is important new evidence demonstrating that exposures to O_3 at levels below the level of the current standard are associated with a broad array of adverse health effects, especially in at-risk populations that include people with asthma or other lung diseases who are likely to experience more serious effects from exposure to O_3, as well as

children and older adults with increased susceptibility, and those who are likely to be vulnerable as a result of spending a lot of time outdoors engaged in physical activity, especially active children and outdoor workers. The Administrator notes that this important new evidence demonstrates O_3-induced lung function effects and respiratory symptoms in some healthy individuals down to the previously observed exposure level of 0.080 ppm, as well as very limited new evidence at exposure levels well below the level of the current standard. In addition, there are many epidemiological studies done in areas that likely would not have met the current standard but which nonetheless report statistically significant associations that generally extend down to ambient O_3 concentrations that were below the level of the current standard. Further, there were a few studies that have examined subsets of data that include only days with ambient O_3 concentrations below the level of the current standard, or below even much lower O_3 concentrations, and continued to report statistically significant associations with respiratory morbidity outcomes and mortality. The Administrator recognizes that in the body of epidemiological evidence, many studies reported positive and statistically significant associations, while others reported positive results that were not statistically significant, and a few did not report any positive O_3-related associations. In addition, the Administrator judged that evidence of a causal relationship between adverse health outcomes and O_3 exposures became increasingly uncertain at lower levels of exposure. This body of evidence provides a strong basis for the Administrator's judgment that the standard needs to be revised to provide more protection, and that a revised standard must be set at a level appreciably below 0.080 ppm, the level at which there is considerable evidence of effects in healthy people. At the same time, for the reasons discussed above

the Administrator judges that this body of evidence does not support setting a standard as low as 0.060, as suggested by other commenters.

ii. Exposure and Risk Considerations

With regard to considering how the quantitative exposure and health risk assessments should factor into a decision on the standard level, EPA notes that both groups of commenters generally consider these assessments in their comments on the standard level, but they reach sharply divergent conclusions as to what standard level is supported by these assessments. The general views of both groups on the implications of the exposure and risk assessment are presented above in section II.B.2.b, with one group arguing that it supports a decision to revise the 8-hour standard to 0.060 ppm or below, and the other group arguing that it supports a decision not to revise the current 8-hour standard.

A joint set of comments from ALA and several environmental groups expressed the view that EPA cannot use exposures of concern to justify a standard in the range of 0.070 to 0.075 ppm. These commenters contended that standards in the proposed range would continue to expose too many asthmatic children, as well as other at risk groups such as outdoor workers and preschool children, to "demonstrably unhealthy levels of ozone pollution" in only 12 cities which does not represent a national estimate (ALA et al., p. 106). These same commenters asserted that if EPA were to consider exposures of concern, then the benchmark level must be defined as 0.060 ppm based on the considerable evidence of adverse health effects occurring at this level. As discussed in section II.B.2.b above, they also cited various reasons why the exposure estimates were underestimated, including: only 12 cities were included in the assessment, various at risk

groups including outdoor workers and preschool children were not included in the assessment, and EPA's exposure assessment underestimated exposures since it considers average children, not active children who spend more time outdoors and repeated exposures also were underestimated.

In contrast, industry association and business group commenters expressed the view that the concept of exposures of concern should not be considered as a basis for revising the level of the standard because it provided no indication of the probability that individuals would actually experience an adverse health effect. These same commenters also provided various reasons why the exposure estimates were overestimated based on specific methodological choices made by EPA including, for example, O_3 measurements at fixed-site monitors can be higher than other locations where individuals are exposed, the exposure estimates do not account for O_3 avoidance behaviors, and the exposure model overestimates elevated breathing rates. Finally, these commenters also contended that the estimates of exposures of concern associated with just meeting the current standard, using the 0.080 ppm benchmark levels, have not appreciably changed since the prior review and, thus provide no support for revising the current standard.

EPA has responded to the criticisms from both groups of commenters related to concerns that the exposure estimates are either underestimated or overestimated in section II.B.2.b above and in more detail in the Response to Comments document. EPA also has addressed the issues raised by both groups of commenters concerning the appropriateness of considering exposures at and above various benchmark levels as an element in the decision on the adequacy of the current standard in section II.B.2.b.

As discussed in section II.B.2b, the Administrator believes that it is appropriate to consider such exposure estimates in the context of a continuum rather than focusing on any one discrete benchmark level, as was done at the time of proposal, since the Administrator does not believe that the underlying evidence is certain enough to support a focus on any single bright-line benchmark level. Thus, the Administrator believes it is appropriate to consider a range of benchmark levels from 0.080 down to 0.060 ppm, recognizing that exposures at and above these benchmark levels must be considered in the context of a continuum of the potential for health effects of concern, and their severity, with increasing uncertainty associated with the likelihood of such effects at lower O_3 exposure levels.

The Administrator recognizes that the 0.080 ppm benchmark level represents a level at which several health outcomes, including lung inflammation, increased airway responsiveness, and decreased resistance to infection have been shown to occur in healthy adults. The Administrator places great weight on the public health significance of exposures at and above this benchmark level given the greater certainty that these adverse health responses are likely to be observed in a significant fraction of the at-risk population. With respect to his decision on the level of the 8-hour standard, the Administrator notes that upon just meeting a standard within the range of 0.070 to 0.075 ppm based on the 2002 simulation, the number of school age asthmatic children likely to experience exposures at and above the 0.080 ppm benchmark level in aggregate (for the 12 cities in the assessment) is estimated to range from 0.1 to 0.4 percent of asthmatic school age children. Based on the 2004 simulation, the estimates are even lower, with no asthmatic children estimated to experience exposures at and above the 0.080 ppm

benchmark level. Similar patterns are observed for all school age children. Recognizing the uncertainties inherent in the exposure assessment, the Administrator concludes that the exposure assessment suggests that exposures at and above the 0.080 ppm level, where several health effects have been shown to occur in healthy individuals, are eliminated or nearly eliminated depending on the modeling year upon just meeting a standard within the range of 0.070 to 0.075 ppm.

The Administrator does not agree with those commenters who would only consider the single benchmark level of 0.080 ppm. While the Administrator places less weight on exposures at and above the 0.070 pm benchmark level, given the increased uncertainty about the fraction of the population and severity of the health responses that might occur associated with exposures above this level, he believes that it is appropriate to consider exposures at this benchmark as well in judging the adequacy of the current standard to protect public health. Consideration of the 0.070 ppm benchmark level recognizes that the effects observed at 0.080 ppm were in healthy adult subjects and sensitive population groups, such as asthmatics, are expected to respond at lower O_3 levels than healthy individuals. The Administrator notes that upon just meeting a standard within the range of 0.070 to 0.075 ppm based on the 2002 simulation, the number of asthmatic school age children likely to experience exposures at and above the 0.070 ppm benchmark level in aggregate (for the 12 cities in the assessment) is estimated to range from about 2 to 5 percent of asthmatic school age children. Based on the 2004 simulation, the estimates are substantially lower, with 0 to 0.6 percent of asthmatic children estimated to experience exposures at and above the 0.070 ppm benchmark level upon just meeting a standard within the range of 0.070 to 0.075 ppm.

Finally, the Administrator has considered but places very little weight on the benchmark level of 0.060 ppm given the very limited scientific evidence supporting a conclusion that O_3 is causally related to various health outcomes at this exposure level. Nevertheless, the Administrator observes that there is a similar pattern of reductions in exposures of concern for all and asthmatic school age children at this benchmark level as well when comparing the 0.070 ppm and 0.075 ppm 8-hour standards.

Given the degree of uncertainty associated with the exposure assessment discussed in the Staff Paper and uncertainty assessment (Langstaff, 2007), the Administrator judges that for each specific benchmark level examined there is not an appreciable difference, from a public health perspective, in the estimates of exposures associated with air quality just meeting an 8-hour standard at 0.075 ppm versus an 8-hour standard set at 0.070 ppm. For example, given the uncertainty in the exposure estimates, the difference between an estimate of 2 percent and 5 percent of asthmatic children for the exposure benchmark of 0.070 is not an appreciable difference from a public health perspective. While directionally there are likely to be fewer exposures at and above this benchmark for a standard of 0.070 than a standard of 0.075 ppm, given the uncertainty in the exposure assessment it is not at all clear that the actual difference is large enough to present a public health concern.

With regard to considering how the quantitative risk assessment should factor into a decision on the standard level, as noted above both groups of commenters generally considered the risk assessment in their comments on the standard level, but they reached sharply divergent conclusions as to what standard level is supported by the risk assessment. More specifically, the environmental, public health, and most medical

organizations, and some State and regional air pollution agencies (e.g., California, NESCAUM) contended that EPA's proposed range of 0.070 to 0.075 ppm would result in significant residual public health risks. As articulated most fully in the joint set of comments from ALA and several environmental organizations, these commenters expressed the view that EPA's risk assessment clearly demonstrates that a more stringent 8-hour O_3 standard of 0.065 ppm, the most stringent standard analyzed by EPA, would significantly decrease O_3-related lung function decrements, respiratory symptoms, hospital admissions, and mortality and that "EPA must adopt a more stringent ozone standard of 0.060 ppm or below – a level that incorporates a more adequate margin of safety" (ALA et al., p. 108). These same commenters also cited various reasons for asserting that the risk assessment likely underestimates health risks to a substantial degree, including the limited nature of the assessment with respect to number of cities, populations covered, and health endpoints analyzed. EPA has responded to the comments concerning the scope of the risk assessment and assertion that health risks are likely underestimated both in section II.B.2.b above and in more detail in the Response to Comments document. The Administrator's reasoning and conclusions regarding the weight he places on the health risk assessment in reaching a judgment about the appropriate level for the primary standard are discussed below in section II.C.4.c.

In contrast, industry association and business group commenters who supported not revising the level of the current 8-hour standard generally asserted the following points: (1) that risk estimates have not changed significantly since the prior review in 1997; (2) that uncertainties and limitations underlying the risk assessment make it too speculative to be used in supporting a decision to revise the standard; (3) that EPA should

have defined PRB differently and that EPA underestimated PRB levels, which results in health risk reductions associated with more stringent standards being overestimated; and (4) that 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 or not to incorporate thresholds into its models for the various health effects analyzed. EPA has responded to these comments both in section II.B.2.b above and in more detail in the Response to Comments document.

In summary, the Administrator concludes that the exposure assessment suggests that exposures at and above the 0.080 ppm benchmark level, where several health effects have been shown to occur in healthy individuals, are essentially eliminated for standards in the range of 0.070 to 0.075 ppm. He also concludes that at the 0.070 ppm benchmark level, the exposures are substantially reduced and eliminated for the vast majority of people in at-risk groups, and that the very low estimates of such exposures are not appreciably different, from a public health perspective, between those exposures associated with just meeting a standard set at 0.070 ppm or 0.075 ppm. Further, the Administrator places relatively little weight on the exposures using the 0.060 ppm benchmark level given the very limited scientific evidence supporting a conclusion that O_3 is causally related to health outcomes at this exposure level. Considering the uncertainties associated with the exposure assessment, the Administrator concludes that the exposure estimates associated with each of the benchmark levels are not appreciably different, between a 0.070 or 0.075 ppm standard, and therefore, the exposure assessment does not provide a basis for choosing a level within the proposed range.

While the Administrator places less weight on the results of the risk assessment, he notes that the results indicate that a standard set within the proposed range would likely reduce risks to at-risk groups from the O_3-related health effects considered in the assessment, and by inference across the much broader array of O_3-related health effects that can only be considered qualitatively, relative to the level of protection afforded by the current standard. Moreover, he notes that the results of the assessment suggest a gradual reduction in risks with no clear breakpoint as increasingly lower standard levels are considered. In light of this continuum and the important uncertainties inherent in the assessment discussed above and in the proposal, the Administrator concludes that the risk assessment does not provide a basis for choosing a level within the proposed range.

c. Conclusions on Level

Having carefully considered the public comments on the appropriate level of the O_3 standard, as discussed above, the Administrator believes the fundamental scientific conclusions on the effects of O_3 reached in the Criteria Document and Staff Paper, briefly summarized above in section II.A.2 and discussed more fully in section II.A of the proposal, remain valid. In considering the level at which the primary O_3 standard should be set, the Administrator continues to place primary consideration on the body of scientific evidence available in this review on the health effects associated with O_3 exposure, as summarized above in section II.C.4.a, while viewing the results of exposure and risk assessment, discussed above in section II.C.4.b, as providing information in support of his decision. In considering the available scientific evidence he judges that, as at the proposal, a focus on the proposed range of 0.070 to 0.075 ppm is appropriate in light of the large body of controlled human exposure and epidemiological and other

scientific evidence. As discussed above, this body of evidence does not support retaining the current standard, as suggested by some commenters. Nor does 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 current 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). This body of evidence also does not support setting a level of 0.060 ppm or below, as suggested by other commenters. The Administrator has also evaluated the information from the exposure assessment and the risk assessment, and judges that this evidence does 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 O_3 standard, the Administrator notes that the level of 0.075 ppm is above the range recommended by the CASAC (i.e., 0.070 to 0.060 ppm). Placing great weight on the views of CASAC, the Administrator has carefully considered its stated views and the scientific basis and policy views for the range it recommended. In so doing, the Administrator notes that he fully agrees that the scientific evidence supports the conclusion that the current standard is not adequate and must be revised.

With respect to CASAC's recommended range of standard levels, the Administrator observes that the basis for its recommendation appears to be a mixture of scientific and policy considerations. The Administrator notes that he is in general agreement with CASAC's views concerning the interpretation of the scientific evidence. The Administrator also notes that there is no bright line clearly directing the choice of level, and the choice of what is appropriate is clearly a public health policy judgment

entrusted to the 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 recommendations for the range of the O_3 standard, the Administrator observes that he reaches 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 he 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, the Administrator observes that the CASAC Panel appears to place greater weight on this evidence, as indicated by its recommendation of a range down to 0.060 ppm. The Administrator also observes that while the CASAC Panel supported a level of 0.060 ppm, they also supported a level above 0.060, indicating that they do not believe that the results of Adams studies mean that the level of the standard has to be set at 0.060 ppm. The Administrator also observes 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 results of 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, the Administrator more heavily weighs the implications of the uncertainties associated with the Agency's quantitative human exposure and health risk assessments, as discussed above in section II.A.3. Given these uncertainties, the Administrator does not agree that these assessment

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

After carefully taking the above comments and considerations into account, and fully considering the scientific and policy views of the CASAC, the Administrator has decided to revise the level of the primary 8-hour O_3 standard to 0.075 ppm. In the Administrator's judgment, based on the currently available evidence, 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 is judged to be causally associated with short-term and prolonged exposures to O_3, and premature mortality. A standard set at this level provides a significant increase in protection compared to the current 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, 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 at-risk groups. 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, the Administrator is not prepared to make these assumptions. Taking into account the uncertainties that remain in interpreting the evidence from available controlled human exposure and epidemiological studies at very low levels, the

Adminisitrator notes that the likelihood of obtaining benefits to public health with a standard set below 0.075 ppm O_3 decreases, while the likelihood of requiring reductions in ambient concentrations that go beyond those that are needed to protect public health increases. The Administrator judges that the appropriate balance to be drawn, based on the entire body of evidence and information available in this review, is a standard set at 0.075. The Administrator believes that a standard set at 0.075 ppm would be sufficient to protect public health with an adequate margin of safety, and does not believe that a lower standard is needed to provide this degree of protection. 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.

D. Final Decision on the Primary O_3 Standard

For the reasons discussed above, and taking into account information and assessments presented in the Criteria Document and Staff Paper, the advice and recommendations of the CASAC Panel, and the public comments to date, the Administrator has decided to revise the existing 8-hour primary O_3 standard. Specifically, the Administrator is revising (1) the level of the primary O_3 standard to 0.075 ppm and (2) the degree of precision to which the level of the standard is specified to the thousandth ppm. The revised 8-hour primary standard, with a level of 0.075 ppm, would 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

0.075 ppm. 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 Air Quality Index for O_3 to be consistent with the revisions to the primary O_3 standard. These revisions are discussed below in section III. Issues related to the monitoring requirements for the revised O_3 primary 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 (40 CFR 58.50). 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. The AQI establishes a nationally uniform system of indexing pollution levels for O_3, CO, NO_2, PM and SO_2. 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 (301 - 500). The AQI index value of 100 typically corresponds to the level of the short-term NAAQS for each pollutant. For the 1997 O_3 NAAQS, an 8-hour average concentration of 0.084 ppm corresponds to an AQI value of 100. 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; an AQI value

at or below 100 means that a pollutant concentration is in one of the satisfactory categories (i.e., good or moderate). 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.

The Agency recognized the importance of revising the AQI in a timely manner to be consistent with any revisions to the NAAQS. Therefore, EPA proposed to finalize conforming changes to the AQI, in connection with the Agency's final decision on the O_3 NAAQS if revisions to the primary standard were promulgated. These conforming changes would include setting the 100 level of the AQI at the same level as the revised primary O_3 NAAQS, and also making proportional adjustments to AQI breakpoints at the lower end of the range (i.e., AQI values of 50, 150 and 200). EPA did not propose to change breakpoints at the higher end of the range (from 301 to 500), which would apply to State contingency plans or the Significant Harm Level (40 CFR 51.16), because the information from this review does not inform decisions about breakpoints at those higher levels.

EPA received relatively few comments on the proposed changes to the AQI. Three major issues came up in the comments, including: (1) whether the AQI should be revised at all, even if the primary standard is revised; (2) whether the AQI should be revised in conjunction with this rulemaking, or in a separate rulemaking; and, (3) whether an AQI value of 100 should be set equal to or lower than the level of the short-term primary O_3 standard, and the other breakpoints adjusted accordingly. UARG asserted that EPA should not revise the AQI at all, even if EPA does revise the primary O_3 standard. In support of this view, UARG noted that there is no requirement for EPA to

set an AQI value of 100 equal to the level of the short-term standard, and cited the 1999 decision to set the an AQI value of 100 for $PM_{2.5}$ equal to 40 $\mu g/m^3$, when the level of the short-term standard was then 65 $\mu g/m^3$. UARG also expressed the view that lowering the ambient concentrations associated with different AQI values would confuse and mislead the public about actual trends in air quality, which UARG asserted are improving. ALA and other environmental groups in a joint set of comments did not support revising the AQI in conjunction with this rulemaking. ALA et al. expressed the view that since EPA did not propose specific breakpoints in its proposed revisions to the AQI, EPA should conduct a separate rulemaking, specifying the proposed breakpoints to allow the public an opportunity to comment on them. Several State agencies, including agencies from Pennsylvania, Wisconsin and Oklahoma, and State organizations, including NACAA and NESCAUM, supported revising the AQI at the same time that the standard is revised. NACAA expressed the view that: "The effectiveness of the AQI as a public health tool will be undermined if EPA undertakes regulatory changes to the ozone NAAQS without simultaneously revising the AQI." (NACAA, p. 5) The Wisconsin Department of Natural Resources (WI DNR) further noted that:

> "…when the 24-hour $PM_{2.5}$ standard was revised, EPA missed an opportunity to adopt conforming changes to the AQI. The Administrator signed the Federal Register notice promulgating a revised fine-particle standard in September 2006, but EPA still has not changed the AQI to reflect the revised standard. We recommend that the AQI be amended to be consistent with the revised ozone and $PM_{2.5}$ standards." [WI DNR, p. 3]

Finally, ALA et al. and NESCAUM expressed the view that an AQI value of 100 should be set at an ambient concentration below the range for the proposed primary standard. These commenters cited the health evidence showing adverse health effects below the

proposed range of the standard, the recommended range of CASAC, and also cited the 1999 decision to set an AQI value of 100 for $PM_{2.5}$ equal to 40μg/m^3 when the level of the short-term standard was 65 μg/m^3, as support for this view. Most other State commenters supported setting an AQI value of 100 equal to the level of the primary O_3 standard.

Recognizing the importance of the AQI as a communication tool that allows the public to take exposure reduction measures when air quality may pose health risks, EPA agrees with State agencies and organizations that favored revising the AQI at the same time as the primary standard. EPA agrees with State agency commenters that its historical approach of setting an AQI value of 100 equal to the level of the revised primary standard is appropriate, both from a public health and a communication perspective.

Both UARG and ALA et al. cite the 1999 AQI rulemaking, which set an AQI value of 100 for $PM_{2.5}$ equal to 40 μg/m^3 a lower level than the level of the short-term $PM_{2.5}$ standard, as support for their view that an AQI value of 100 does not need to be set at the level of the revised O_3 standard. However, the sub-index for $PM_{2.5}$ was developed using an approach that was conceptually consistent with past practice for selecting the air quality concentrations associated with the AQI breakpoints. The Agency's historical approach to selecting index breakpoints had been to simply set the AQI value of 100 at the level of the short-term standard (e.g., 24 hours) for a pollutant. This method of structuring the index is appropriate in the case where a short-term standard is set to protect against the health effects associated with short-term exposures and/or an annual standard is set to protect against health effects associated with long-term exposures. In

such cases, the short-term standard in effect defines a level of health protection provided against short-term risks and thus can be a useful benchmark against which to compare daily air quality concentrations.

In the case of the 1997 $PM_{2.5}$ standards, EPA took a different approach to protecting against the health risks associated with short-term exposures. The intended level of protection against short-term risk was not defined by the 24-hour standard (set at a level of 65 $\mu g/m^3$) but by the combination of the 24-hour and the annual standards working in concert. In fact, the annual standard (set at a level of 15 $\mu g/m^3$) was intended to serve as the principal vehicle for protecting against both long-term and short-term $PM_{2.5}$ exposures by lowering the entire day-by-day distribution of $PM_{2.5}$ concentrations in an area throughout the year. See generally 62 FR at 38668-70 (July 18, 1997). Because the 24-hour standard served to provide additional protection against very high short-term concentrations, localized "hotspots," or risks arising from seasonal emissions that would not be well-controlled by a national annual standard, EPA consequently concluded that it would be appropriate to caution members of sensitive groups exposed to concentrations below the level of the 24-hour standard. EPA also concluded that it would be inappropriate to compare daily air quality concentrations directly with the level of the annual standard by setting an AQI value of 100 at that level. EPA wanted to set the AQI value of 100 to reflect the general level of health protection against short-term risks offered by the annual and 24-hour standards combined, consistent with the underlying logic of the historical approach to establishing AQI 100 levels. Therefore EPA set the AQI value of 100 at the midpoint of the range between the annual and the 24-hour $PM_{2.5}$ standards (i.e., 40 $\mu g/m^3$) in order to reflect the combined role of the 24-hour and the

annual $PM_{2.5}$ standards in protecting against short-term risks. Therefore, this approach for defining an AQI value of 100 is conceptually consistent with the proposed decision to set an AQI value of 100 equal to the level of the primary O_3 standard.

Therefore, EPA is revising the AQI for O_3 by setting an AQI value of 100 equal to 0.075 ppm, 8-hour average, the level of the revised primary O_3 standard. EPA is also revising the following breakpoints: an AQI value of 50 is set at 0.059 ppm, an AQI value of 150 is set at 0.095 ppm; and an AQI value of 200 is set at 0.115 ppm. All these levels are averaged over 8 hours. As indicated in the proposal, these levels were developed by making proportional adjustments to the other AQI breakpoints (i.e., AQI values of 50, 150 and 200). The proportional adjustments were modified slightly to allow for each category to span at least a 0.015 ppm range to allow for more accurate forecasting. So, for example, simply making a proportional adjustment to the level of an AQI value of 150 (0.104 ppm) would result in a level of about 0.092 ppm. Since most of these ranges are rounded to the nearest 5 thousandths of a ppm, that rounding would have resulted in a 0.014 ppm range (i.e., 0.076 to 0.090 ppm). So, the number was rounded upward to the nearest 5 thousandths of a ppm, to allow for at least a 0.015 ppm range for forecasting. The same principle applies to the calculation of an AQI value for 200 (0.115 ppm). EPA believes that the finalized breakpoints provide a balance between proportional adjustments to reflect the revised O_3 standard and providing category ranges that are large enough to be forecasted accurately, so that the new AQI for O_3 can be implemented more easily in the public forum for which the AQI ultimately exists.

IV. Rationale for Final Decision on Secondary O_3 Standard

A. Introduction

1. Overview

This section presents the rationale for the Administrator's final decisions regarding the need to revise the current secondary O_3 NAAQS, and the appropriate revisions to the standard. As discussed more fully below, the rationale for the final decisions on appropriate revisions to the secondary O_3 NAAQS is based on a thorough review of the latest scientific information on vegetation effects associated with exposure to ambient levels of O_3, as assessed in the Criteria Document. This rationale also takes into account: (1) staff assessments of the most policy-relevant information in the Criteria Document regarding the evidence of adverse effects of O_3 to vegetation and ecosystems, information on biologically-relevant exposure metrics, and staff analyses of air quality, vegetation exposure and risks, presented in the Staff Paper and described in greater detail in the associated Technical Report on Ozone Exposure, Risk, and Impact Assessments for Vegetation (Abt, 2007), upon which staff recommendations for revisions to the secondary O_3 standard were based; (2) CASAC Panel advice and recommendations as reflected in discussion of drafts of the Criteria Document and Staff Paper at public meetings, in separate written comments, and in CASAC's letters to the Administrator (Henderson, 2006a, b, c; 2007); (3) public comments received during development of these documents either in conjunction with CASAC meetings or separately and on the proposal notice; (4) consideration of the degree of protection to vegetation potentially afforded by the revised 8-hour primary standard; and (5) the limits of the available evidence.

In developing this rationale, EPA has again focused on direct O_3 effects on vegetation, specifically drawing upon an integrative synthesis of the entire body of evidence, published through early 2006, on the broad array of vegetation effects associated with exposure to ambient levels of O_3 (EPA, 2006a, chapter 9). 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 are not quantifiable at this time. As was concluded in the 1997 review, and based on the body of scientific literature assessed in the current Criteria Document, the Administrator believes that it is reasonable to conclude that a secondary standard protecting the public welfare from known or anticipated adverse effects to trees, native vegetation and crops would also afford increased protection from adverse effects to other environmental components relevant to the public welfare, including ecosystem services and function. The peer-reviewed literature includes studies conducted in the U.S., Canada, Europe, and many other countries around the world. 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.

As with virtually any policy-relevant vegetation effects research, there is uncertainty in the characterization of vegetation effects attributable to exposure to ambient O_3. As discussed below, however, research conducted since the last review provides important information coming from field-based exposure studies, including free air, gradient and biomonitoring surveys, in addition to the more traditional controlled

open top chamber (OTC) studies. Moreover, the newly available studies evaluated in the Criteria Document have undergone intensive scrutiny through multiple layers of peer review and many opportunities for public review and comment. While important uncertainties remain, the review of the vegetation effects information has been extensive and deliberate. In the judgment of the Administrator, the intensive evaluation of the scientific evidence that has occurred in this review has provided an adequate basis for regulatory decision-making at this time. This review also provides important input to EPA's research plan for improving our future understanding of the effects of ambient O_3 at lower levels.

Information related to vegetation and ecosystem effects, biologically relevant exposure indices, and quantitative vegetation exposure and risk assessments were summarized in sections IV.A through IV.C of the proposal (72 FR at 37883-37895), respectively, and are only briefly outlined below in sections IV.A.2 through IV.A.4. Subsequent sections of this preamble provide a more complete discussion of the Administrator's rationale, in light of key issues raised in public comments, for concluding that the current standard is not requisite to protect public welfare from known or anticipated adverse effects, and it is appropriate to revise the current secondary O_3 standard to provide additional public welfare protection (section IV.B) by making the secondary standard identical to the revised primary standard (section IV.C). A summary of the final decisions on revisions to the secondary O_3 standard is presented in section IV.D.

2. Overview of Vegetation Effects Evidence

This section outlines the information presented in section IV.A of the 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 last 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 OTC exposure method, found cumulative, seasonal O_3 exposures were most strongly associated with observed vegetation response. The Criteria Document prepared for this review 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 subcellular, 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 last review.

Section IV.A of the proposal provides a detailed summary of key information contained in the Criteria Document (EPA, 2006, chapter 9) and in the Staff Paper (EPA, 2007, 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 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.

3. Overview of Biologically Relevant Exposure Indices

This section outlines the information presented in section IV.B of the proposal on biologically relevant exposure indices that relate known or potential effects on vegetation to exposure to O_3 in ambient air. The 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 (EPA, 2006a). This conclusion followed from the extensive evaluation of the relevant studies in the 1996 Criteria Document (EPA, 1996a) and the recent evaluation of studies that have been published since that time (EPA, 2006a). 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 last 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 Staff Paper prepared for this 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. The form commonly called W126 was evaluated in the last review and was compared with the form called SUM06, which incorporates a threshold level above which exposures are summed, that was proposed in the last 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 in the Staff Paper (EPA, 2007a, p. 7-16.) as:

$$W126 = \sum_{i=8AM}^{i<8PM} w_{C_i} C_i, where\ C_i = hourly\ O_3\ at\ hour\ i, and\ w_{C_i} = \frac{1}{1+4403e^{-126C_i}}$$

Regarding the first consideration, the 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 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.

4. Overview of Vegetation Exposure and Risk Assessments

This section outlines the information presented in section IV.C of the proposal on the vegetation exposure and risk assessments conducted for this review, which improved and built upon similar analyses performed in the last 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)[22] model system (http://www.epa.gov/asmdnerl/CMAQ, Byun and Ching, 1999;

[22] The CMAQ model is a multi-pollutant, multiscale 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

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 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 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 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 current and alternative secondary standard options. The following key observations were

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express model outputs in terms of a variety of exposure indices (e.g., W126, 8-hour average).

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 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-hour, which has been associated with approximately up to 14 percent biomass loss in 50 percent 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-hour, which is approximately equal to the secondary standard proposed in 1996 and is associated with approximately up to 10 percent biomass loss in 50 percent of tree seedling cases studied. Much of the east and Arizona and California have 12-hour W126 O_3 levels above 13 ppm-hour which has been associated with approximately up to 10 percent biomass loss in 75 percent of tree seedling cases studied.

(2) When 2001 air quality is rolled back to meet the 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-hour. 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-hour.

(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 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-hour.

(4) While these results suggest 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. The proposal notes that 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 (72 FR 37892).

To further characterize O_3 air quality in terms of current and alternative secondary standard forms, an analysis was performed in the Staff Paper to evaluate the extent to which county-level O_3 air quality measured in terms of various levels of the current 8-hour average form overlapped with that measured in terms of various levels of the 12-hour W126 cumulative, seasonal form.[23] 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 sites often do not reflect the typical urban and near-urban pattern of low

[23] The Staff Paper presented this analysis using recent (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.

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 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.

The Staff Paper indicated that it further remains 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 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 are important considerations in determining whether the current 8-hour form can appropriately provide requisite protection for vegetation.

b. Assessment of Risk to Vegetation

The Staff Paper presented results from quantitative and qualitative risk assessments of O_3 risks to vegetation. In the last 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 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 last review that visible foliar injury is occurring in many areas of the U.S. under current 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 percent of the counties during the four-year period (2001-2004) across all counties with air quality levels at or below that of the 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 percent of the counties 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 current secondary standard or alternative 0.07 ppm 8-hour standard. While 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 might also be present.

(2) Seedling and mature tree biomass loss. In the last 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 last 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.[24] In summary, these analyses showed that biomass loss still occurred in many tree species when O_3 air quality was adjusted to meet the current 8-hour standard. For instance, black cherry, ponderosa pine, eastern

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

white pine, and aspen had estimated median seedling biomass losses over portions of their growing range as high as 24, 11, 6, and 6 percent, respectively, when O_3 air quality was rolled back to just meet the current 8-hour standard. The 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 percent 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.

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.[25] 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

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[25] 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).

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 percent of the cove hardwood stands in 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).

The Staff Paper analyses found that just meeting the current 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 current 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 developed in the 1980's 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 percent 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 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 percent and 5-10 percent, respectively, when O_3 air quality just met the level of the 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 percent).

The 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 current and alternative standard levels were met. Meeting the various alternative standards did show some significant benefits beyond the current 8-hour standard. However, the Staff Paper recognized that the modeled economic benefits from AGSIM had many associated uncertainties which limited the usefulness of these estimates.

B. Need for Revision of the Current Secondary O_3 Standard

1. Introduction

The initial issue to be addressed in this review of the O_3 standard is whether, in view of the advances in scientific knowledge reflected in the Criteria Document and Staff Paper, the current standard should be revised. As discussed in section IV.D of the proposal, in evaluating whether it was appropriate to propose to retain or revise the current standard, the Administrator built upon the last review and reflected the broader body of evidence and information now available. In the proposal, EPA presented information, judgments, and conclusions from the last review, which revised the secondary O_3 standard by setting it identical to the revised primary O_3 standard, and from the current review's evaluation of the adequacy of the current secondary standard, including both evidence- and exposure/risk-based considerations in the Staff Paper, as well as from the CASAC Panel's advice and recommendations. The Staff Paper evaluation, the CASAC Panel's views, and the Administrator's proposed conclusions on the adequacy of the current secondary standard are presented below.

a. Staff Paper Evaluation

The Staff Paper considered the evidence presented in the Criteria Document as a basis for evaluating the adequacy of the current O_3 standard, recognizing that important

uncertainties remain. The Staff Paper concluded that the new evidence available in this review as described in the Criteria Document continues to support and strengthen key policy-relevant conclusions drawn in the previous review. Based on this new evidence, the current Criteria Document once more concluded that: (1) a plant's response to O_3 depends upon the cumulative nature of ambient exposure as well as the temporal dynamics of those concentrations; (2) current ambient concentrations in many areas of the country are sufficient to impair growth of numerous common and economically valuable plant and tree species; (3) the entrance of O_3 into the leaf through the stomata is the critical step in O_3 effects; (4) effects can occur with only a few hourly concentrations above 0.08 ppm; (5) other environmental biotic and abiotic factors are also influential to the overall impact of O_3 on plants and trees; and (6) a high degree of uncertainty remains in our ability to assess the impact of O_3 on ecosystem services.

In light of the new evidence, as described in the Criteria Document, the Staff Paper evaluated the adequacy of the current standard based on assessments of both the most policy-relevant vegetation effects evidence and exposure and risk-based information, highlighted above in section IV.A and discussed in sections IV.A-C of the proposal. In evaluating the strength of this information, the Staff Paper took into account the uncertainties and limitations in the scientific evidence and analyses as well as the views of CASAC. The Staff Paper concluded that progress has been made since the last review and generally found support in the available effects-and exposure/risk-based information for consideration of an O_3 standard that is more protective than the current standard. The Staff Paper further concluded that there is no support for consideration of

an O_3 standard that is less protective than the current standard. This general conclusion is consistent with the advice and recommendations of CASAC.

i. Evidence-Based Considerations

In the last review, crop yield and tree seedling biomass loss data obtained in OTC studies provided the basis for the Administrator's judgment that the then current 1-hour, 0.12 ppm secondary standard was inadequate (EPA, 1996b). Since then, several additional lines of evidence have progressed sufficiently to provide a more complete and coherent picture of the scope of O_3-related vegetation risks, especially those currently faced by sensitive seedling, sapling and mature growth stage tree species growing in field settings, and their associated forested ecosystems. Specifically, new research reflects an increased emphasis on field-based exposure methods (e.g., free air, ambient gradient, and biomonitoring surveys). In reaching conclusions regarding the adequacy of the current standard, the Staff Paper considered the combined information from all these areas together, along with associated uncertainties, in an integrated, weight-of-evidence approach.

Regarding the O_3-induced effect of visible foliar injury, observations for the years 2001 to 2004 at USDA FIA biomonitoring sites showed widespread O_3-induced leaf injury occurring in the field, including in forested ecosystems, under current ambient O_3 conditions. For a few studied species, it has been shown that the presence of visible foliar injury is further linked to the presence of other vegetation effects (e.g., reduced plant growth and impaired below ground root development) (EPA, 2006), though for most species, this linkage has not been specifically studied or where studied, has not been found. Nevertheless, when visible foliar injury is present, the possibility that other O_3-

induced vegetation effects could also be present for some species should be considered. Likewise, the absence of visible foliar injury should not be construed to demonstrate the absence of other O_3-induced vegetation effects. The Staff Paper concluded that it is not possible at this time to quantitatively assess the degree of visible foliar injury that should be judged adverse in all settings and across all species, and that other environmental factors can mitigate or exacerbate the degree of O_3-induced visible foliar injury expressed at any given concentration of O_3. However, the Staff Paper also concluded that the presence of visible foliar injury alone can be adverse to the public welfare, especially when it occurs in protected areas such as national parks and wilderness areas. Thus, on the basis of the available information on the widespread distribution of O_3-sensitive species within the U.S. including in areas, such as national parks, which are afforded a higher degree of protection, the Staff Paper concluded that the current standard continues to allow levels of visible foliar injury in some locations that could reasonably be considered to be adverse from a public welfare perspective. Additional monitoring of both O_3 air quality and foliar injury levels are needed in these areas of national significance to more fully characterize the spatial extent of this public welfare impact.

With respect to O_3-induced biomass loss in trees, the Staff Paper concluded that the new body of field-based research on trees strengthens the conclusions drawn on tree seedling biomass loss from earlier OTC work by documenting similar seedling responses in the field. For example, recent empirical studies conducted on quaking aspen at the AspenFACE site in Wisconsin have confirmed the detrimental effects of O_3 exposure on tree growth in a field setting without chambers (Isebrands et al., 2000, 2001). In addition, results from an ambient gradient study (Gregg et al., 2003), which evaluated biomass loss

in cottonwood along an urban-to-rural gradient at several locations, found that conditions in the field were sufficient to produce substantial biomass loss in cottonwood, with larger impacts observed in downwind rural areas due to the presence of higher O_3 concentrations. These gradients from low urban to higher rural O_3 concentrations occur when O_3 precursors generated in urban areas are transported to downwind sites and are transformed into O_3. In addition, O_3 concentrations typically fall to near 0 ppm at night in urban areas due to scavenging of O_3 by NOx and other compounds. In contrast, rural areas, due to a lack of nighttime scavenging, tend to maintain elevated O_3 concentrations for longer periods**.** On the basis of such key studies, the Staff Paper concluded that the expanded body of field-based evidence, in combination with the substantial corroborating evidence from OTC data, provides stronger evidence than that available in the last review that ambient levels of O_3 are sufficient to produce visible foliar injury symptoms and biomass loss in sensitive vegetative species growing in natural environments. Further, the Staff Paper judged that the consistency in response in studied species/genotypes to O_3 under a variety of exposure conditions and methodologies demonstrates that these sensitive genotypes and populations of plants are susceptible to adverse impacts from O_3 exposures at levels known to occur in the ambient air. Due to the potential for compounded risks from repeated insults over multiple years in perennial species, the Staff Paper concluded that these sensitive subpopulations are not afforded adequate protection under the current secondary O_3 standard. Despite the fact that only a relatively small portion of U.S. plant species have been studied with respect to O_3 sensitivity, those species/genotypes shown to have O_3 sensitivity span a broad range of vegetation types and public use categories, including direct-use categories like food production for human

and domestic animal consumption; fiber, materials, and medicinal production; urban/private landscaping. Many of these species also contribute to the structure and functioning of natural ecosystems (e.g., the EEAs) and thus, to the goods and services those ecosystems provide (Young and Sanzone, 2002), including non-use categories such as relevance to public welfare based on their aesthetic, existence or wildlife habitat value.

The Staff Paper therefore concluded that the current secondary *s*tandard is inadequate to protect the public welfare against the occurrence of adverse levels of visible foliar injury and tree seedling biomass loss occurring in tree species (e.g., ponderosa pine, aspen, black cherry, cottonwood) that are sensitive and clearly important to the public welfare.

ii. Exposure- and Risk-Based Considerations

In evaluating the adequacy of the current standard, the Staff Paper also presented the results of exposure and risk assessments, which are highlighted above in section IV.A.3 and discussed in section IV.C of the proposal. Due to multiple sources of uncertainty, both known and unknown, that continue to be associated with these analyses, the Staff Paper put less weight on this information in drawing conclusions on the adequacy of the current standard. However, the Staff Paper also recognized that some progress has been made since the last review in better characterizing some of these associated uncertainties and, therefore concluded that the results of the exposure and risk assessments continue to provide information useful to informing judgments as to the relative changes in risks predicted to occur under exposure scenarios associated with the different standard alternatives considered. Importantly, with respect to two key uncertainties, the uncertainty associated with continued reliance on C-R functions

developed from OTC exposure systems to predict plant response in the field and the potential for changes in tree seedling and crop sensitivities in the intervening period since the C-R functions were developed, the Staff Paper concluded that recent research has provided information useful in judging how much weight to put on these concerns. Specifically, new field-based studies, conducted on a limited number of tree seedling and crop species to date, demonstrate plant growth and visible foliar injury responses in the field that are similar in nature and magnitude to those observed previously under OTC exposure conditions, lending qualitative support to the conclusion that OTC conditions do not fundamentally alter the nature of the O_3-plant response. Second, nothing in the recent literature suggests that the O_3 sensitivity of crop or tree species studied in the last review and for which C-R functions were developed has changed significantly in the intervening period. Indeed, in the few recent studies where this is examined, O_3 sensitivities were found to be as great as or greater than those observed in the last review.

The Staff Paper consideration of such exposure and risk analyses is discussed below and in section IV.D.2.b of the proposal, focusing on seedling and mature tree biomass loss, qualitative ecosystem risks, and crop yield loss.

(1) Seedling and mature tree biomass loss. Biomass loss in sensitive tree seedlings is predicted to occur under O_3 exposures that meet the level of the current secondary standard. For instance, black cherry, ponderosa pine, eastern white pine, and aspen had estimated median seedling biomass losses as high as 24, 11, 6, and 6 percent, respectively, over some portions of their growing ranges when air quality was rolled back to meet the current 8-hr standard with the 10 percent downward adjustment for the potential O_3 gradient between monitor height and short plant canopies applied. The 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. Decreased root growth associated with biomass loss has the potential to indirectly affect the vigor and survivability of tree seedlings. If such effects occur on a sufficient number of seedlings within a stand, overall stand health and composition can be affected in the long term. Thus, the Staff Paper concluded that these levels of estimated tree seedling growth reduction should be considered significant and potentially adverse, given that they are well above the 2 percent level of concern identified by the 1997 consensus workshop (Heck and Cowling, 1997).

Though there is significant uncertainty associated with this analysis, the Staff Paper recommended that this information should be given careful consideration in light of several other pieces of evidence. Specifically, limited evidence from experimental studies that go beyond the seedling growth stage continues to show decreased growth under elevated O_3 levels (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). The potential for effects to "carry over" to the following year or cumulate over multiple years, including the potential for compounding, must be considered (see 72 FR 37885; Andersen et al., 1997; Hogsett et al., 1989; Sasek et al., 1991; Temple et al., 1993; EPA, 1996). The accumulation of such "carry-over" effects over time may affect long-term survival and reproduction of individual trees and ultimately the abundance of sensitive tree species in forest stands.

(2) Qualitative Ecosystem Risks. In addition to the quantifiable risk categories discussed above, the Staff Paper presented qualitative discussions on a number of other

public welfare effects categories. In so doing, the Staff Paper concluded that the quantified risks to vegetation estimated to be occurring under current air quality or upon meeting the current secondary standard likely represent only a portion of actual risks that may be occurring for a number of reasons.

First, as mentioned above, out of the over 43,000 plant species catalogued as growing within the U.S. (USDA PLANTS database, USDA, NRCS, 2006), only a small percentage have been studied with respect to O_3 sensitivity. Most of the studied species were selected because of their commercial importance or observed O_3-induced visible foliar injury in the field. Given that O_3 impacts to vegetation also include less obvious but often more significant impacts, such as reduced annual growth rates and below ground root loss, the paucity of information on other species means the number of O_3-sensitive species that exists within the U.S. is likely greater than what is now known. Since no state in the lower 48 states has less than seven known O_3 sensitive plant species, with the majority of states having between 11and 30 (see Appendix 7J-2 in Staff Paper), protecting O_3 sensitive vegetation is clearly important to the public welfare at the national scale.

Second, the Staff Paper also took into consideration the possibility that more subtle and hidden risks to ecosystems are potentially occurring in areas where vegetation is being significantly impacted. Given the importance of these qualitative and anticipated risks to important public welfare effects categories such as ecosystem impacts leading to potential losses or shifts in ecosystem goods and services (e.g., carbon sequestration, hydrology, and fire disturbance regimes), the Staff Paper concluded that any secondary standard set to protect against the known and quantifiable adverse effects to vegetation

should also consider the anticipated, but currently unquantifiable, potential effects on natural ecosystems.

(3) Crop Yield Loss. Exposure and risk assessments in the Staff Paper estimated that meeting the current 8-hour standard would still allow O_3-related yield loss to occur in several fruit and vegetable and commodity crop species currently grown in the U.S. These estimates of crop yield loss are substantially lower than those estimated in the last review as a result of several factors, including adjusted exposure levels to reflect the presence of a variable O_3 gradient between monitor height and crop canopies, and use of a different econometric agricultural benefits model updated to reflect more recent agricultural policies (EPA, 2006b). Though these sources of uncertainty associated with the crop risk and benefits assessments were better documented in this review, the Staff Paper concluded that the presence of these uncertainties make the risk estimates suitable only as a basis for understanding potential trends in relative yield loss and economic benefits. The Staff Paper further recognized that actual conditions in the field and management practices vary from farm to farm, that agricultural systems are heavily managed, and that adverse impacts from a variety of other factors (e.g., weather, insects, disease) can be orders of magnitude greater than that of yield impacts predicted for a given O_3 exposure. Thus, the relevance of such estimated impacts on crop yields to the public welfare are considered highly uncertain and less useful as a basis for assessing the adequacy of the current standard. The Staff Paper noted, however, that in some experimental cases, exposure to O_3 has made plants more sensitive or vulnerable to some of these other important stressors, including disease, insect pests, and harsh weather (EPA, 2006a). The Staff Paper therefore concluded that this remains an important area of

uncertainty and that additional research to better characterize the nature and significance of these interactions between O_3 and other plant stressors would be useful.

iii. Summary of Staff Paper Considerations

In summary, the Staff Paper concluded that the current secondary O_3 standard is inadequate. This conclusion was based on the extensive vegetation effects evidence, in particular the recent empirical field-based evidence on biomass loss in seedlings, saplings and mature trees, and foliar injury incidence that has become available in this review, which demonstrates the occurrence of adverse vegetation effects at ambient levels of recent O_3 air quality, as well as evidence and exposure- and risk-based analyses indicating that adverse effects would be predicted to occur under air quality scenarios that meet the current standard.

b. CASAC Views

In a letter to the Administrator (Henderson, 2006c), the CASAC O_3 Panel, with full endorsement of the chartered CASAC, unanimously concluded that "despite limited recent research, it has become clear since the last review that adverse effects on a wide range of vegetation including visible foliar injury are to be expected and have been observed in areas that are below the level of the current 8-hour primary and secondary ozone standards." Therefore, "based on the Ozone Panel's review of Chapters 7 and 8 [of the Staff Paper], the CASAC unanimously agrees that it is not appropriate to try to protect vegetation from the substantial, known or anticipated, direct and/or indirect, adverse effects of ambient O_3 by continuing to promulgate identical primary and secondary standards for O_3. Moreover, the members of the Committee and a substantial majority of the Ozone Panel agree with EPA staff conclusions and encourage the

Administrator 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 currently existing or potentially revised 8-hour primary standard" (Henderson, 2006c).[26]

c. Administrator's Proposed Conclusions

At the time of proposal, in considering whether the current secondary standard should be revised, the Administrator carefully considered the conclusions contained in the Criteria Document, the rationale and recommendations contained in the Staff Paper, the advice and recommendations from CASAC, and public comments to date on this issue. In so doing, the Administrator recognized that the secondary standard is to protect against "adverse" O_3 effects, as discussed in section IV.A.3 of the proposal. In considering what constitutes a vegetation effect that is also adverse to the public welfare, the Administrator took into account the Staff Paper conclusions regarding the nature and strength of the vegetation effects evidence, the exposure and risk assessment results, the degree to which the associated uncertainties should be considered in interpreting the results, and the views of CASAC and members of the public. On these bases, the Administrator proposed that the current secondary standard is inadequate to protect the public welfare from known and anticipated adverse O_3-related effects on vegetation and ecosystems. Ozone levels that would be expected to remain after meeting the current

[26]One CASAC Panel member reached different conclusions from those of the broader Panel regarding certain aspects of the vegetation effects information and the appropriate degree of emphasis that should be placed on the associated uncertainties. These concerns related to how the results of O_3/vegetation exposure experiments carried out in OTC can be extrapolated to the ambient environment and how C-R functions developed in the 1980's can be used today given that he did not expect that current crop species/cultivars in use in 2002 would have the same O_3 sensitivity as those studied in NCLAN (Henderson, 2007, pg. C-18).

secondary standard were judged to be sufficient to cause visible foliar injury, seedling and mature tree biomass loss, and crop yield reductions to degrees that could be considered adverse depending on the intended use of the plant and its significance to the public welfare, and the current secondary standard does not provide adequate protection from such effects. Other O_3-induced effects described in the literature, including an impaired ability of many sensitive species and genotypes within species to adapt to or withstand other environmental stresses, such as freezing temperatures, pest infestations and/or disease, and to compete for available resources, would also be anticipated to occur. In the long run, the result of these impairments (e.g., loss in vigor) could lead to premature plant death in O_3 sensitive species. Though effects on other ecosystem components have only been examined in isolated cases, effects such as those described above could have significant implications for plant community and associated species biodiversity and the structure and function of whole ecosystems. These considerations also support the proposed conclusion that the current secondary standard is not adequate and that revision is needed to provide additional public welfare protection.

2. Comments on the Need for Revision

The above section outlines the vegetation and ecosystem effects evidence and assessments used by the Administrator to inform his proposed judgments about the adequacy of the current O_3 secondary standard. General comments received on the proposal that either supported or opposed the proposed decision to revise the current O_3 secondary standard are addressed in this section. Comments related to the vegetation and ecosystem effects evidence and information related to exposure indices are considered in section IV.B.2.a below, and comments on vegetation exposure and risk assessments are

considered in section IV.B.2.b. Comments on specific issues, vegetation and ecosystem effects evidence, information on exposure indices, or the vegetation exposure and risk assessments that relate to consideration of the appropriate form, averaging time, or level of the O_3 standard are addressed below in section IV.C. General comments based on implementation-related factors that are not a permissible basis for considering the need to revise the current standard are noted in the Response to Comments document.

a. Evidence of Effects and Exposure Indices

Sections IV.A.2 and IV.A.3 above provide a summary overview of the information on vegetation and ecosystem effects and exposure indices used by the Administrator to inform his proposed judgments about the adequacy of the current O_3 secondary standard. As discussed more fully below, comments received on the proposal regarding the nature and strength of the vegetation and ecosystem effects information, information on exposure indices, and the conclusions that could appropriately be drawn from such information fell generally into two groups.

One group of commenters that included national and local environmental organizations (e.g., Environmental Defense, Appalachian Mountain Club, Rocky Mountain Clean Air Action), NESCAUM, NACAA, individual States, Tribal Associations, and the National Park Service (NPS) argued that the available science clearly showed that O_3-induced vegetation and ecosystem effects are occurring at and below levels that meet the current 8-hour standard, and therefore provides a strong basis and support for the conclusion that the current secondary standard is inadequate. In support of their view, these commenters relied on the entire body of evidence available for consideration in this review, including evidence assessed previously in the last

review. These commenters pointed to the information and analyses in the Staff Paper and the conclusions and recommendations of CASAC as providing a clear basis for concluding that the current standard does not adequately protect vegetation from an array of O_3-related effects. For example, the NPS noted 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" (NPS, p. 3).

In addition to the body of information already considered by EPA in this review, these same commenters also presented new information for the Administrator's consideration, including a number of "new" studies published after completion of the Criteria Document, as well as additional information on air quality and vegetation exposures and effects pertaining to local conditions within their State, Tribal or federal lands, as additional support for their views that the current standard is inadequate. For example, NESCAUM, NY, PA, and NPS all provided air quality information describing typical O_3 concentrations in areas that rarely, if ever, exceeded the level of the current 8-hour standard in areas that still showed O_3-related vegetation effects, particularly visible foliar injury.

Building on EPA's qualitative discussions of the potential linkage between O_3 vegetation effects and effects on ecosystems, a number of these commenters expressed concern that the possible impact of O_3-related reductions in plant productivity could result in a reduced capacity of vegetation to serve as a carbon sink to mitigate the impacts of rising CO_2 in a changing climate, citing to a "new" study on that topic (Sitch et al., 2007). Many of these same commenters also cited to "new" field-based studies in the

Great Smoky Mountain National Park that find a relationship between O_3 exposure, tree stem growth loss, tree water use and stream flow as evidence that current ambient O_3 levels can impact ecosystems and that ecosystems should be afforded protection from such potential effects. For example, some of these commenters note that "new" studies in the Great Smoky Mountain National Park (McLaughlin, et al., 2007a,b) have found that (1) ambient O_3 caused substantial growth reductions in mature trees in a mixed deciduous forest, which was due in part to increased O_3-induced water loss and led to seasonal losses in stem growth of 30 - 50 percent for most species in a high-ozone year; (2) increasing ambient O_3 levels also resulted in depletion of soil moisture in the rooting zone and reduced late-season streamflow in the watershed; and (3) O_3 may amplify the adverse effects of increasing temperature on forest growth and forest hydrology and may exacerbate the effects of drought on forest growth and stream health. Other "new" research noted by these commenters as supporting EPA's findings that current O_3 exposures cause significant biomass losses in sensitive seedlings of various tree species include a study that predicted up to 31 percent growth loss in aspen in certain areas of its North American range in 2001-2003 (Percy, et al., 2007). These commenters encouraged the Administrator to consider these "new" studies in making his final decision.

This group of commenters strongly supported revising the current standard, not only because in their view the available evidence conclusively demonstrates that the current standard is inadequate to protect sensitive vegetation, but also because the Staff Paper provides abundant evidence that it is appropriate to establish an alternative cumulative, seasonal secondary standard that is distinctly different in form from the current or revised primary standard. For example, NESCAUM states that "[i]n light of

the EPA Staff and CASAC recommendations, and the extensive body of historical and recent monitoring and research data upon which these recommendations were based, the option of equating the ozone secondary NAAQS with the 8-hour primary is inappropriate and clearly not supported by the weight of scientific evidence."

EPA agrees with these commenters that when evaluated as a whole, the entire body of vegetation and ecosystem effects information available in this review supports the need to revise the current standard to provide increased protection from an array of O_3-related effects on sensitive vegetation and ecosystems. EPA also agrees that the available evidence indicates that a cumulative, seasonal form better reflects the scientific information on biologically relevant exposures for vegetation. For reasons discussed below in sections IV.C, however, EPA disagrees with aspects of these commenters' views as to whether a standard defined in terms of a cumulative, seasonal form is requisite to protect public welfare.based on the available scientific information.

To the extent that these and other commenters whose comments are discussed below included "new" scientific studies, studies that were published too late to be considered in the Criteria Document, in support of their arguments for revising 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 in the 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.

The other main group of commenters, which included Exxon-Mobil, UARG, API, other industry groups, The Annapolis Center for Science Based Public Policy, individual States and other organizations representing local energy, agriculture or business interests, expressed the contrasting view that the limited number of studies published since the last review and addressed in the Criteria Document provided insufficient evidence to support a conclusion different than what was reached in the last review. In particular, they asserted that the types of vegetation effects evaluated in the last review have not changed, and that the Criteria Document, Staff Paper, and CASAC have acknowledged that the information that has become available since the last review does not fundamentally change the conclusions reached in the last review. As a result, they argued that the currently available evidence fails to show that revision to the standard is requisite to provide additional protection from these effects. In particular, Exxon-Mobil stated that "EPA is incorrect in concluding vegetation impacts [occur] at or below the level of the current standard" . . . and that the "newer field-based evidence EPA cites for ozone impacts on seedlings, saplings and mature trees indicates ozone impacts but at exposures that are likely in exceedence of the current secondary standard." This commenter concluded that while these studies provide additional support for O_3-related impacts on vegetation, including observing effects in field settings without chambers, they do not provide support for the conclusion that ambient levels in compliance with the current standard would result in significant O_3 impact. In addition, these commenters also generally asserted that the evidence that has become available since the last review does

not materially reduce the uncertainties that were present and cited by the Administrator in the last review as important factors in her decision to set the secondary identical to the revised primary. Those aspects of these comments that include uncertainties associated with the exposure, risk and benefits assessments are addressed below in section IV.2.b and in the Response to Comments document.

EPA disagrees with the commenters' assertion that the currently available evidence has not materially reduced key uncertainties present in the last review that factored into the Administrator's decision. For example, there is an expansion of field-based evidence across a broad array of vegetation effects categories, as discussed in the Criteria Document, Staff Paper, and highlighted above in section IV.A.2. Though in some such studies (e.g., the FACE studies) the O_3 exposures are indeed at or above ambient levels, the observed vegetation response is similar to that observed in OTC studies at similar levels of exposure. Though these studies are still limited in scope, it is nevertheless EPA's view that such field-based evidence reduces the uncertainties associated with the C-R functions generated in OTC studies that were noted by the Administrator in the last review. Thus, the current body of evidence increases EPA's confidence in the results from the OTC studies which demonstrate O_3-related effects below the level of the current standard. EPA has also considered this evidence in conjunction with USDA FIA foliar injury survey data and the Gregg et al. (2003) tree seedling biomass loss gradient study showing effects on a sensitive tree species occurring in the field across a range of exposure levels including levels of air quality at to well below the level of the current secondary standard. Taken together, EPA concludes that these studies form a coherent body of evidence that significantly strengthens EPA's

confidence that such effects are currently occurring in the field and would continue to be anticipated at and below the level of the current secondary standard. A more detailed discussion of these issues can be found in the Response to Comments document.

b. Vegetation Exposure and Risk Assessments

Section IV.A.4 above provides a summary overview of the vegetation exposure and risk assessment information used by the Administrator to help inform judgments about vegetation exposure and risk estimates associated with attainment of the current and alternative standards. As an initial matter, EPA notes that at the time of proposal, the Administrator primarily based his conclusion on whether revision of the secondary standard was needed primarily on evidence-based considerations, while using the more uncertain exposure and risk assessments in a supportive role. As discussed more fully below, comments received on the proposal regarding these assessments and the conclusions that could appropriately be drawn from them fell generally into two groups. One group of commenters generally included those noted above who supported revising the current secondary standard, while the other group of commenters were those noted above who expressed the view that no revision was appropriate.

The first group of commenters primarily focused on evidence-based considerations in their support of a revised standard, while some also referenced EPA's findings from the exposure and risk assessments in supporting their view that the standard needed to be revised to provide increased protection for sensitive vegetation. A few of these commenters also provided additional exposure, risk and benefits information from localized assessments conducted by themselves or others in their behalf in support of their view that the standard needed to be revised. In so doing, these commenters have

generally shown support for using such assessments to help inform a final decision on the need to revise.

The other group of commenters expressed a number of concerns with these assessments and generally asserted that these assessments do not support revision of the current standard. These commenters' concerns generally focused on (1) the method used by EPA to estimate PRB, (2) the lack of new information since the last review that would, in their judgment, materially reduce the uncertainties present in the assessments conducted for the last review, and (3) EPA's interpretation and use of the results in making a judgment about the adequacy of the current standard. These comments are addressed below.

(1) Regarding concerns related to the method used by EPA to estimate PRB, EPA notes that this issue has been raised repeatedly throughout the review in the context of both the primary and secondary standards. Most generally, these commenters asserted that EPA used unrealistically low levels of PRB that resulted in an overestimate of risks and benefits associated with just meeting alternative standards. EPA disagrees with this view, for the reasons discussed above in section II.B.2.b, 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.

(2) Another concern posed by these commenters was the lack of any new information that, in their judgment, would materially reduce the uncertainties present in the exposure, risk and benefits assessments conducted for the last review. For example, the Annapolis Center asserted that "[s]ome of the most important caveats and uncertainties concerning the exposure and risk assessments for crop yield that were listed

in the [1996] proposal included 1) extrapolating from exposure-response functions generated in open-top chambers to ambient conditions; 2) the lack of a performance evaluation of the national air quality extrapolation; 3) the methodology to adjust modeled air quality to reflect attainment of various alternative standard options; and 4) inherent uncertainties in models to estimate economic values associated with attainment of alternative standard. . . . Because of the lack of new data or substantive improvements in the risk assessment, these same issues remain today, contributing a similar degree of uncertainty, as was the case in the prior review." EPA recognizes that important uncertainties remain in estimates of vegetation exposure and O_3-related risk to vegetation, especially with regard to O_3-related effects on crop yields. However, EPA disagrees with comments that assert that uncertainties have not been reduced since the last review, as discussed below.

With regard to the uncertainties associated with using the OTC C-R functions, the Annapolis Center further stated that "ten years have now elapsed, and 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." While 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, EPA does not agree that the new information available in this review does nothing to reduce such uncertainties identified in the last review. As described above and in the Staff Paper and proposal, results from the new SoyFACE and AspenFACE studies provide qualitative support that the levels of vegetation response that have been observed in the field are of similar

magnitude as those predicted at similar exposure levels using the OTC generated C-R functions. Therefore, EPA believes that the uncertainties cited in the last review regarding the appropriateness of using OTC generated C-R functions to predict vegetation response in the field have been reduced. Providing some further support in this regard is the limited information available in this review on some sensitive crop species (e.g., soybean) suggesting that O_3 sensitivity has not changed significantly in the intervening years. Taking all the above into account, EPA's level of confidence in the applicability of the OTC generated C-R functions to represent ambient conditions in the field has increased.

With regard to the lack of a performance evaluation of the national air quality extrapolation, EPA notes that there have been advancements in the tools and methods used for such extrapolations since the last review. With respect to the generation of interpolated O_3 exposure surfaces, EPA employed a different approach than that used in the last review and undertook a quantitative assessment of the uncertainties associated with the use of this method. This uncertainty assessment was accomplished by sequentially dropping out of the interpolation each monitoring site, and then recalculating the exposure surface using the remaining monitoring sites. As discussed in the Staff Paper, this method of evaluation may result in a slight overestimation of error and bias for the exposure surface, since dropping out monitors loses information that the interpolation uses in that local area. As another point of comparison, EPA also examined the subset of rural CASTNET sites to illustrate how the interpolation technique predicted air quality in that rural monitoring network. For this subset, the evaluation indicated that in general, the interpolation technique slightly overestimated W126 exposures at

relatively low levels and underestimated W126 exposure at relatively high levels. This aspect of the estimation method potentially resulted in an underestimation of the more important risks associated with higher cumulative exposures in some areas. Based on this evaluation, EPA reiterates the conclusion in the Staff Paper that "the calculation of error and bias metrics for the interpolation represents a notable improvement over the 1996 assessment which did not have such an evaluation." EPA further concludes 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 last review.

With regard to criticisms of the methodology used to adjust modeled air quality to reflect attainment of various alternative standard options, EPA notes that this issue has been raised in the context of both the primary and secondary standards. As noted above in section II.B.2.b, based on information in the 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 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.

With regard to comments that asserted that inherent uncertainties in models to estimate economic values of crop loss have not been reduced since the last review, EPA

acknowledges that while an updated state of the art model, the AGSIM benefits model, was used in this review, substantial uncertainties remain in these estimates of economic crop loss. Further, EPA notes that these estimates were not relied on as a basis for reaching a decision on the need to revise the current standard.

(3) Some commenters also asserted that the estimated exposures and risks associated with air quality just meeting the current standard have not appreciably changed since the last review. 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 current secondary standard is requisite to protect public welfare. EPA believes that this claim is fundamentally flawed for three 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 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. Third, quantitative vegetation risk estimates were not the main basis for EPA's decision in setting a level for the secondary standard in 1997, and they do not set any quantified "benchmark" for the Agency's decision to revise the current standard at this time. The proposal notice made clear that decisions about the need to revise the

current standard are mainly based on an integrated evaluation of evidence available across a broad array of vegetation effects, while the more uncertain exposure, risk and benefits estimates were used in a supportive role. Both the Staff Paper and proposal clearly distinguished the roles that these different types of information played in informing the Administrator's proposed decision. The proposal states that "due to multiple sources of uncertainty, both known and unknown, that continue to be associated with these analyses, the Staff Paper put less weight on this information in drawing conclusions on the adequacy of the current standard. However, the Staff Paper also recognizes that some progress has been made since the last review in better characterizing some of these associated uncertainties and, therefore, concluded that the results of the exposure and risk assessments continue to provide information useful to informing judgments as to the relative changes in risks predicted to occur under exposure scenarios associated with the different standard alternatives considered." In determining the requisite level of protection, the Staff Paper recognized that it is 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. Thus, while the Administrator is fully mindful of the uncertainties associated with the estimates of exposure, risk and benefits, as discussed above, he judges that these estimates are still useful in providing additional support for his judgment that the current 8-hour secondary standard does not adequately protect sensitive vegetation.

3. Conclusions Regarding the Need for Revision

Having carefully considered the public comments, discussed above, the Administrator believes the fundamental scientific conclusions on the effects of O_3 on vegetation and sensitive ecosystems reached in the Criteria Document and Staff Paper, as discussed above in section IV.A, remain valid. In considering whether the secondary O_3 standard should be revised, the Administrator finds that evidence that has become available in this review demonstrates the occurrence of adverse vegetation effects at ambient levels of recent O_3 air quality, and that evidence and exposure- and risk-based analyses indicate that adverse effects would be predicted to occur under air quality scenarios that meet the current standard, taking into consideration both the level and form of the current standard. Ozone exposures that would be expected to remain after meeting the current secondary standard are sufficient to cause visible foliar injury and seedling and mature tree biomass loss in O_3-sensitive vegetation. The Administrator believes that the degree to which such effects should be considered to be adverse depends on the intended use of the vegetation and its significance to the public welfare. Other O_3-induced effects described in the literature, including an impaired ability of many sensitive species and genotypes within species to adapt to or withstand other environmental stresses, such as freezing temperatures, pest infestations and/or disease, and to compete for available resources, would also be anticipated to occur. In the long run, the result of these impairments (e.g., loss in vigor) could lead to premature plant death in O_3 sensitive species. Though effects on other ecosystem components have only been examined in isolated cases, effects such as those described above could have significant implications

for plant community and associated species biodiversity and the structure and function of whole ecosystems.

The Administrator recognizes that the secondary standard is not meant to protect against all known observed or anticipated O_3-related effects, but only those that can reasonably be judged to be adverse to the public welfare. In considering what constitutes a vegetation effect that is adverse from a public welfare perspective, the Administrator believes it is appropriate to continue to rely on the definition of "adverse," discussed in section IV.A.3 of the proposal, that imbeds the concept of "intended use" of the ecological receptors and resources that are affected, and applies that concept beyond the species level to the ecosystem level.[27] In so doing, the Administrator has taken note of a number of actions taken by Congress to establish public lands that are set aside for specific uses that are intended to provide benefits to the public welfare, including lands that are to be protected so as to conserve the scenic value and the natural vegetation and wildlife within such areas, and to leave them unimpaired for the enjoyment of future generations. Such public lands that are protected areas of national interest include national parks and forests, wildlife refuges, and wilderness areas. Because O_3-sensitive species are generally found in such areas, and because levels of O_3 allowed by the current secondary standard are sufficient to cause known or anticipated impairment that the Administrator judges to be adverse to sensitive vegetation and ecosystems in such areas, the Administrator concludes that it is appropriate to revise the secondary standard, in part, to provide increased protection against O_3-caused impairment to such protected vegetation and ecosystems.

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[27] The Administrator also recognizes that other aspects of public welfare, as welfare is defined in the CAA, may rely on concepts other than "intended use."

The Administrator further recognizes that States, Tribes and public interest groups also set aside areas that are intended to provide similar benefits to the public welfare, for residents on State and Tribal lands, as well as for visitors to those areas. Given the clear public interest in and value of maintaining these areas in a condition that does not impair their intended use, and the fact that many of these areas contain O_3-sensitive vegetation, the Administrator further concludes that it is appropriate to revise the secondary standard in part to provide increased protection against O_3-caused impairment to vegetation and ecosystems in such specially designated areas.

The Administrator also recognizes that O_3-related effects on sensitive vegetation occur in areas that have not been afforded such special protections, ranging from vegetation used for residential or commercial ornamental purposes, such as urban/suburban landscaping, to land use categories that are heavily managed for commercial production of commodities such as agricultural crops, timber, and ornamental vegetation. For vegetation used for residential or commercial ornamental purposes, such as urban/suburban landscaping, there are indications that impairment to the intended use of such vegetation can occur from O_3 exposures allowed by the current standard. While the Administrator believes 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, he notes that a secondary standard revised to provide protection for sensitive natural vegetation and ecosystems may also provide some degree of protection for such ornamental vegetation.

With respect to commercial production of commodities, however, the Administrator notes 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 recognizes 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, while the Administrator believes that a secondary standard revised to provide protection for sensitive natural vegetation and ecosystems may also provide some degree of additional protection for heavily managed commercial vegetation, the need for such additional protection is uncertain.

Based on these considerations, and taking into consideration the advice and recommendations of CASAC, the Administrator concludes that the protection afforded by the current secondary O_3 standard is 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. The Administrator also concludes that there is not adequate information to establish a separate secondary standard based on other effects of O_3 on public welfare. It is important to note that these conclusions, and the reasoning on which they are based, do not address the question of what specific revisions to the current secondary standard are

appropriate. Addressing that question requires looking specifically at the two proposed options: establishing a new standard defined in terms of a cumulative, seasonal form, or revising the current secondary standard by making it identical to the revised primary standard. These alternative secondary standards are discussed in the following section.

As highlighted below, the discussion of public comments above indicates that deciding the appropriate secondary standard involves making a difficult choice between two possible alternatives, each with their strengths and weaknesses. EPA's decision, and the reasons for it, are described in detail above. In reaching this decision, there has been a robust discussion within the Administration of these same strengths and weaknesses. As part of that process EPA received a Memorandum on March 6, 2008 from Susan Dudley, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget, indicating various concerns over adopting a cumulative, seasonal secondary standard. Deputy Administrator Marcus Peacock responded with a Memorandum dated March 7, 2008 stating EPA's views supporting adoption of a cumulative, seasonal secondary standard. On March 11, 2008, the President "concluded that, consistent with Administration policy, added protection should be afforded to public welfare by strengthening the secondary ozone standard and setting it to be identical to the new primary standard, the approach adopted when ozone standards were last promulgated. This policy thus recognizes the Administrator's judgment that the secondary standard needs to be adjusted to provide increased protection to public welfare and avoids setting a standard lower or higher than is necessary." EPA's decision therefore also reflects the view of the Administration as to the most appropriate secondary standard. While the Administrator fully considered the President's views, the

Administrator's decision, and the reasons for it, are based on and supported by the record in this rulemaking.

C. Conclusions on the Secondary O_3 Standard

As an initial matter, EPA has considered the indicator for a secondary O_3 standard. As discussed above in section II.C.1 on the primary standard, in the last review, EPA focused on a standard for O_3 as the most appropriate surrogate for ambient photochemical oxidants. In this review, while the complex atmospheric chemistry in which O_3 plays a key role has been highlighted, no alternatives to O_3 have been advanced as being a more appropriate surrogate for ambient photochemical oxidants and their effects on vegetation. Thus, as is the case for the primary standard, the Administrator concludes that it is appropriate to continue to use O_3 as the indicator for a standard that is intended to address effects associated with exposure to O_3, alone and in combination with related photochemical oxidants. In so doing, the Administrator recognizes that measures leading to reductions in vegetation exposures to O_3 will also reduce exposures to other photochemical oxidants.

1. Staff Paper Evaluation

The current Criteria Document and Staff Paper concluded that the recent vegetation effects literature evaluated in this review strengthens and reaffirms conclusions made in the last 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). The last review focused in particular on two of these cumulative forms, the SUM06 and W126 (EPA, 1996). Given that the data available at that time were unable to distinguish between these forms, the Administrator,

based on the policy consideration of not including O_3 concentrations considered to be within the PRB, estimated to be between 0.03 and 0.05 ppm, concluded that the SUM06 form would be the more appropriate choice for a cumulative, exposure index for a secondary standard, though a cumulative form was not adopted at that time.

In this review, the Staff Paper evaluated the continued appropriateness of the SUM06 form in light of two key pieces of information: new estimates of PRB that are lower than in the last review, and 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 Staff Paper concluded that the W126 form was more appropriate in the context of this review. Specifically, the W126, by its incorporation of a sigmoidal weighting function, does not create an artificially imposed concentration threshold, gives proportionally more weight to the higher and typically more biologically potent concentrations, and is not significantly influenced by O_3 concentrations within the range of estimated PRB.

The Staff Paper also considered that in the 1997 final rule, the decision was made, on the basis of both science and policy considerations, to make the secondary standard identical to the primary standard (62 FR 38876). On the basis of that history, the current 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 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.

Thus, though the Staff Paper recognized again that meeting the current or alternative levels of the 8-hour average standard could result in air quality improvements that would potentially benefit vegetation in some areas, it 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 is due to the concern that the analysis in the 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, it is believed there are likely to be additional areas that have similar air quality distributions that would lead to the same disconnect between forms. Thus, the Staff Paper concluded that it remains problematic to determine the appropriate level of protection for vegetation using an 8-hour average form.

2. CASAC Views

The CASAC, based on its assessment of the same vegetation effects science, agreed with the Criteria Document and Staff Paper and unanimously concluded that protection of vegetation from the known or anticipated adverse effects of ambient O_3 "requires a secondary standard that is substantially different from the primary standard in

averaging time, level, and form," i.e. not identical to the primary standard for O_3 (Henderson, 2007). Moreover, the members of CASAC and a substantial majority of the CASAC Panel agreed with Staff Paper conclusions and encouraged the Administrator 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 (Henderson, 2006c). The CASAC Panel also stated that "the recommended metric for the secondary ozone standard is the (sigmoidally weighted) W126 index" (Henderson, 2007).

3. Administrator's Proposed Conclusions

In EPA's proposal, the Administrator agreed with the conclusions drawn in the Criteria Document, Staff Paper and by CASAC that the scientific evidence available in the current review 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 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 The Administrator further agreed with both the Staff Paper and CASAC that the most appropriate cumulative, concentration-weighted form to consider in this review is the sigmoidally weighted W126 form, due to his 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 this review. Thus, the Administrator proposed as one option to replace the

current 8-hour average secondary standard form with the cumulative, seasonal W126 form**.**

The Administrator also proposed to revise the current secondary standard by making it identical to the proposed 8-hour primary standard, which was proposed to be within the range of 0.070 to 0.075 ppm. For this option, EPA also solicited comment on a wider range of 8-hour standard levels, including levels down to 0.060 ppm and up to the current standard (i.e., effectively 0.084 ppm with the current rounding convention). In putting forward such a proposal, the Administrator focused on the decision made in the last review, and the rationale for that decision that made the revised secondary standard identical to the revised primary standard,.

4. Comments on the Secondary Standard Options

Comments received following proposal regarding revising the secondary standard either to reflect a new, cumulative form or by remaining equal to a revised primary standard generally fell into two groups. These comments were similar to those raised prior to the proposal during earlier phases of the NAAQS review, as summarized in the proposal notice and highlighted below.

One group of commenters, including the National Park Service, Environmental Defense, NESCAUM, NACAA, 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, 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)". Similarly, Environmental Defense stated "[f]or reasons amply explained by CASAC and the Staff, neither the existing secondary standard for ozone nor the proposed primary standards are requisite to protect against adverse welfare effects on vegetation and forested ecosystems. 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 National Park Service (NPS) comment provided additional support to this view and more specifically 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." EPA agrees with these comments for the reasons discussed above in sections IV.A.3 and IV.B.2.a).

In addition to expressing strong support for the W126 cumulative seasonal form, commenters in this group also expressed serious concerns with EPA's other proposed option of setting the secondary standard equal to a revised primary standard. 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…as EPA notes at 72 FR 37904…. 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."

The other set of commenters, including UARG, API, Exxon-Mobil, The Annapolis Center, ASL and Associates, and AAM, did not support adopting an alternative, cumulative form for the secondary standard. Some of these commenters, while agreeing that "directionally a cumulative form of the standard may better match the underlying data," believe 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. These commenters also restated concerns that have been described above in section IV.B.2 regarding the remaining uncertainties associated with the vegetation effects evidence and/or the exposure, risk and benefits assessments. They point to the

uncertainties cited by the Administrator in the 1997 review as part of her rationale for deciding it was not appropriate to move forward with a seasonal secondary, and state that these same uncertainties have not been materially reduced in the current review. These commenters also asserted that EPA's analysis of the impact of the nation's O_3 control program for the 8-hour standard on W126 exposures is not scientifically sound due to the use of low estimates of PRB and an arbitrary rollback method that is uninformed by atmospheric chemistry from photochemical models. They argue that EPA must first realistically evaluate the total O_3 reductions that would occur by using a state-of-the-art photochemical model and perform an analysis of the exposure-response data to determine if effects are observed for exposures which do not exceed the 8-hour standard. These commenters also stated that without producing C-R 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.

This group of commenters also addressed limitations associated with selection of the W126 cumulative form. Commenters asserted that: (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) the W126 form cannot provide nationally uniform protection, as the same value of an exposure index may relate to different vegetation responses; some commenters support adding a second index that reflects the accumulation of peaks at or above 0.10 ppm (called N100).

5. Administrator's Final Conclusions

In considering the appropriateness of establishing a new standard defined in terms of a cumulative, seasonal form, or revising the current secondary standard by making it identical to the revised primary standard, the Administrator took into account the approach used by the Agency in the last review, the conclusions of the Staff Paper, CASAC advice, and the views of public commenters. In giving careful consideration to the approach taken in the last review, the Administrator first considered the 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.[28] On this basis, as an initial matter, the Administrator recognizes 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 current

[28] EPA has done further analysis of the degree of overlap, and that analysis is in the docket.

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 this review, and the difficulty in determining at what point various types of vegetation effects become adverse for sensitive vegetation and ecosystems, the Administrator focused his consideration on a level for an alternative W126 standard at the upper end of the proposed range (i.e., 21 ppm-hours). The Staff Paper analysis shows 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 areas beyond that likely to be provided by the revised primary standard.

The Administrator also recognizes that the general lack of rural monitoring data makes uncertain the degree to which the revised 8-hour standard or an alternative W126 standard would be protective, 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 is clear, the number and size of areas at issue and the degree of risk is hard to determine. However, such a standard would also tend to avoid the potential for providing more protection than is necessary, a risk that would arise from 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 Administrator also considered the views and recommendations of CASAC, and agrees that a cumulative, seasonal standard is the most biologically relevant way to relate exposure to plant growth response. However, as reflected in the public comments, the Administrator also recognizes that there remain 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, the Administrator concludes that establishing a new secondary standard with a cumulative, seasonal form at this time 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 his consideration of the full range of views as described above, the Administrator judges that the appropriate balance to be drawn is to revise the secondary standard to be identical in every way to the revised primary standard. The Administrator believes that such a standard would be sufficient to protect public welfare from known or anticipated adverse effects, and does not believe that an alternative cumulative, seasonal standard is needed to provide this degree of protection. This judgment by the Administrator appropriately considers the requirement for a standard that is neither more nor less stringent than necessary for this purpose.

D. Final Decision on the Secondary O_3 Standard

For the reasons discussed above, and taking into account information and assessments presented in the Criteria Document and Staff Paper, the advice and

recommendations of the CASAC Panel, and the public comments to date, the Administrator has decided to revise the existing 8-hour secondary standard. Specifically, the Administrator is revising the current standard by making it identical to the revised primary standard. Data handling conventions for the secondary standard are the same as for the primary standard, and are specified in the new Appendix P that is adopted, as discussed in section V below. Issues related to the monitoring requirements for the revised O_3 secondary standard are discussed below in section VI.

V. Creation of Appendix P -- Interpretation of the NAAQS for O_3

This section presents EPA's final decisions regarding the addition of Appendix P to 40 CFR part 50 on interpreting the primary and secondary NAAQS for O_3. EPA did not propose to address revocation of the existing 8-hour standard in this rulemaking. Therefore, EPA is retaining Appendix I to 40 CFR part 50 in its current form. A new Appendix P explains the computations necessary for determining when the new 8-hour primary and secondary standards are met. More specifically, Appendix P addresses data completeness requirements, data reporting and handling conventions, and rounding conventions, and provides example calculations.

In the proposal, two alternative secondary standards were proposed: a 3-month secondary standard expressed as a cumulative peak-weighted index form; or a standard set to be identical to the primary standard. For reasons stated above, the Administrator has decided to set the secondary standard to be identical in all respects to the primary standard. Therefore, the portions of the proposed Appendix P providing data handling procedures for a non-identical secondary standard are not included in the final rule.

Key elements of Appendix P are outlined below.

A. General

As proposed, EPA is adding several new definitions to section 1.0 and using these definitions throughout Appendix P.

B. Data Completeness

EPA proposed data completeness requirements for the new Appendix P for the revised 8-hour primary standard that would be the same as those in Appendix I applicable to the pre-existing standard. To satisfy the data completeness requirement, Appendix P as proposed would require 90% data completeness, on average, for the 3-year period at a monitoring site, with no single year within the period having less than 75% data completeness. This data completeness requirement applies only during the required O_3 monitoring season and must be satisfied in order to determine that the standard has been met at a monitoring site. A site could be found to violate the standard with less than complete data. EPA concluded in adopting these same data completeness requirements in Appendix I in 1997 that these proposed requirements are reasonable based on its earlier analysis of available air quality data that showed that 90% of all monitoring sites that are operated on a continuous basis routinely meet this objective. EPA received no comments on these requirements, and the final Appendix P includes them as proposed.

Appendix I and the proposed Appendix P allow missing days to be counted for the purpose of meeting the data completeness requirements if meteorological conditions on these missing days were not conducive to concentrations above the level of the standard. Such determinations under Appendix I and the proposed Appendix P would be made on a case-by-case basis using available evidence. In the proposal, EPA specifically requested comment on whether meteorological data could provide an objective basis for

determining, for a day for which there is missing data, that the meteorological conditions were not conducive to high O_3 concentrations, and therefore, that the day could be assumed to have an O_3 concentration less than the level of the NAAQS. Further, the proposal requested comments on whether days assumed less than the level of the standard should be counted as non-missing when computing whether the data completeness requirements have been met at the site. The proposal pointed out that this could allow a determination of attainment which would otherwise be precluded by the 75% and/or 90% completeness tests. Most commenters supported the use of meteorological data to establish that missing days could be assumed to have low O_3 levels. However, no commenter suggested any particular objective criteria or formula for making such determinations. Based on these comments, EPA will continue to use the current case-by-case approach as proposed in Appendix P, as is the current approach in Appendix I, to count missing days when computing whether the data completeness requirement has been met for the primary standard.

As noted above, because the Administrator has decided to set the secondary standard identical in all respects to the primary standard, the final Appendix P provides that its data completeness requirements apply to both standards.

C. Data Reporting and Handling and Rounding Conventions

For reasons discussed above, the Administrator has set the level of the revised 8-hour primary and secondary standards at 0.075 ppm. As explained in the proposal, the level of the 8-hour standard is expressed to the third decimal place. Almost all State agencies now report hourly O_3 concentrations to three decimal places, in ppm, or in a format easily convertible to ppm, since the typical incremental sensitivity of currently

used O_3 monitors is 0.001 ppm. Consistent with the current approach for computing 8-hour averages, in calculating 8-hour average O_3 concentrations from hourly data, any calculated digits beyond the third decimal place would be truncated, preserving the number of digits in the reported data. In calculating 3-year averages of the fourth highest maximum 8-hour average concentrations, digits to the right of the third decimal place would also be truncated, preserving the number of digits in the reported data. Analyses discussed in the Staff Paper demonstrated that taking into account the precision and bias in 1-hour O_3 measurements, the 8-hour design value has an uncertainty of approximately 0.001 ppm. Truncating both the individual 8-hour averages used to determine the annual fourth maximum as well as the 3-year average of the fourth maxima to the third decimal place is consistent with the approach used in Appendix I for the previous 8-hour O_3 standard. In the proposal, EPA sought comment on the appropriateness of rounding rather than truncating to the third decimal place as well as the scientific validity of truncating the 3-year average and the policy reasons behind either truncating or rounding the 3-year average to the third decimal place. Many of the comments EPA received on the rounding/truncation issue in effect were comments that supported expressing the level of the NAAQS to either the second or third decimal place. These comments are addressed in the Response to Comment document. EPA continues to believe the conclusions from the Staff paper regarding monitor precision and error propagation when calculating 8-hour O_3 averages are appropriate. EPA has decided to continue to truncate, as done in Appendix I, and this approach is included in the final Appendix P.

As discussed above in section II.C.3, EPA is setting an 8-hour standard extending to three decimal places. Given that both the standard and the calculated value of the 3-

year average of the fourth highest maximum 8-hour O_3 concentration are expressed to three decimal places, the two values can be compared directly.

As noted above, because the Administrator has decided to set the secondary standard identical in all respects to the primary standard, the same data reporting and handling and rounding conventions will apply to both.

VI. Ambient Monitoring Related to Revised O_3 Standards

As noted in the O_3 NAAQS proposal (see 72 FR 37906), EPA did not propose any specific changes to existing requirements for monitoring of O_3 in the ambient air. However, comment was invited on a number of specific issues which were expected to be of significance in the event that one or more of the O_3 NAAQS was revised. Comments were received from Federal agencies, State monitoring agencies, State organizations, environmental organizations, and industrial trade associations. As noted elsewhere in this rulemaking, EPA is finalizing changes to both the primary and secondary O_3 NAAQS. In light of these revisions, EPA intends to issue a monitoring rule to address the issues identified in the proposal, as well as other issues raised in the comments. EPA intends to issue a proposed monitoring rule in June 2008 and a final rule by March 2009. In recognition of the comments received on the proposed O_3 standards and to provide EPA's initial thinking on O_3 specific monitoring rule amendments, we offer the following observations. The following paragraphs also point out one way in which some State/local monitoring agencies might need to make changes to their O_3 monitoring network as a result of the revision to the primary and secondary O_3 NAAQS, based on the existing minimum monitoring requirements including a factor based on the comparison of design

value to the O_3 NAAQS (see 71 FR 61318). The following text explains why an amendment to the monitoring regulations is not required to trigger these increased O_3 monitoring requirements.

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. These requirements are contained in 40 CFR part 58 Appendix D, Network Design Criteria for Ambient Air Quality Monitoring, Table D-2. These requirements were last revised on October 17, 2006 as part of a comprehensive review of ambient monitoring requirements for all criteria pollutants. (See 71 FR 61236).

The minimum number of monitors required in an MSA ranges from zero (for an area with population under 350,000 and no recent history of an O_3 design value greater than 85 percent of the NAAQS) to four (for an area with population greater than 10 million and an O_3 design value greater than 85 percent of the NAAQS). Because these requirements apply at the MSA level, large urban areas consisting of multiple MSAs can require more than four monitors. In total, about 400 monitors are required in MSAs, but about 1100 are actually operating in MSAs because most States operate more than the minimum required number of monitors.

As noted above, the requirements listed in Table D-2 of 40 CFR part 58 Appendix D are based on the percentage of the O_3 NAAQS, with a design value break point at 85 percent of the NAAQS. For an MSA of a given population size, there are a greater number of required monitors when the design value is greater than or equal to 85 percent

of the O_3 NAAQS compared with MSAs that have a design value of less than 85 percent of the O_3 NAAQS. At the pre-existing level of 0.084 ppm for the 8-hour primary and secondary standards, an 8-hour O_3 design value of 0.068 ppm would trigger such increased minimum monitoring requirements for an MSA.[29] With the decision to revise the 8-hour primary and secondary standards to a level of 0.075 ppm, the 8-hour O_3 design value that will trigger increased minimum monitoring requirements for an MSA has decreased from 0.068 ppm to 0.064 ppm. Therefore, MSAs with 8-hour design values between 0.064 ppm and 0.067 ppm are now required to increase the number of monitors operating to meet minimum requirements based on existing monitoring requirements.[30] In practice, however, virtually all of these areas already are operating at least as many monitors as required based on the revised primary standard, so the number of new monitors that are needed (or needed to be moved from a location of excess monitors) is negligible to meet the existing minimum requirements.

About 100 MSAs with populations less than 350,000 presently are without any O_3 monitors, and hence they do not have an O_3 design value for use with Table D-2. These unmonitored MSAs are not required to add monitors. Commenters from State monitoring agencies and State organizations expressed concern that these current requirements ignore the needs that states and localities will have for additional monitors to measure O_3 levels in currently under-monitored areas and, in particular, in unmonitored areas with populations under 350,000. They stated that unless this

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[29] Calculated as 85 percent of 0.08 ppm, per the stated level of the pre-existing 8-hour primary and secondary standards.

[30] Approximately 16 MSAs that are subject to minimum monitoring requirements have 8-hour design values between 0.064 ppm and 0.067 ppm based on an analysis of 2004-2006 ambient O_3 data.

deficiency is corrected, the health benefits of EPA's O_3 NAAQS revision would likely be limited to those living in Metropolitan Statistical Areas (MSAs) having populations of more than 350,000. Other commenters noted the difficulty in defining the boundaries of new attainment/non-attainment areas without additional monitoring in the MSA's below 350,000.

EPA recognizes that the issues raised by the commenters are important. EPA intends to address these issues as part of its proposed monitoring rule.

In relation to the proposed secondary standard options, EPA invited comment on whether, where, and how monitoring in rural areas specifically focused on the secondary NAAQS should be required. As noted in the O_3 NAAQS proposal and described earlier in this section, existing O_3 monitoring requirements and current State monitoring practices are primarily oriented towards protecting against health effects in people and therefore the primary NAAQS. This accounts for the current focus of the monitoring requirements on urban areas, where large populations reside, in which significant emissions of O_3 -forming precursors are found, and where O_3 concentrations of concern are likely to occur.

There are no EPA requirements for O_3 monitoring in less populated areas outside of MSA boundaries or in rural areas. However, at present there are about 250 O_3 monitors in counties that are not part of MSAs. These monitors are operated by State, local, and tribal monitoring agencies for a variety of objectives including the assessment of O_3 transport and the support of research programs including studies of atmospheric chemistry and ecosystem impacts. Additionally, EPA operates a network of about 56 O_3 monitors as part of its Clean Air Status and Trends Network (CASTNET). The National

Park Service (NPS) operates about 27 monitors at other CASTNET sites. On an overall basis, the spatial density of non-urban O_3 monitors is relatively high in the eastern one-third of the U.S. and in California, with significant gaps in coverage elsewhere across the country.

Some commenters expressed concern about the quality assurance practices at CASTNET sites with regard to certain aspects of O_3 monitoring. They recommended that EPA upgrade such practices to meet the 40 CFR part 58 Appendix A quality assurance requirements already followed by the States so that the resulting data could be used in assessing compliance with the revised secondary standard. EPA notes that such upgrades have been completed at some of the CASTNET sites, and that such upgrades will be completed at all CASTNET sites by 2009. EPA notes that the resulting O_3 ambient data from the upgraded sites will meet Appendix A requirements as is presently the case for O_3 data from State operated monitors and NPS monitors. These data will be deemed acceptable for NAAQS-comparison objectives and available in the AQS database beginning in 2008.

Most commenters noted the relative lack of rural O_3 monitors, stating that EPA should consider adding monitoring requirements that support a revised secondary O_3 standard 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 vegetation exposure since many of these monitors were likely located to meet other objectives.

In light of the Administrator's decision to revise the 8-hour secondary standard, EPA believes that it is appropriate to consider whether the existing urban-based

monitoring requirements described elsewhere in this section are adequate and appropriate to characterize the exposure in more rural areas where O_3-sensitive plant species and more sensitive ecosystems exist and where resulting vegetation damage would adversely affect land usage. Such areas would likely include public lands that are protected areas of national interest (e.g., national parks, wilderness areas).

In consideration of the spatial gaps that currently exist in the rural ozone monitoring network, and to the extent that the existence of such gaps has contributed to the overall uncertainty that exists in the level of protection that would be provided by the revised secondary standard, EPA believes that there is merit in considering whether additional monitoring requirements in certain rural areas would help support ongoing ecosystem research studies as well as future reviews of the O_3 NAAQS by providing a more robust data set with which to assess the relationship of vegetation damage to O_3 concentrations.

Accordingly, as part of its separate monitoring rulemaking, EPA intends to consider specific requirements for a minimum number of rural monitors per State, with detailed rule language to ensure that States locate such monitors in appropriate areas. For example, these areas could include Federal, State, or Tribal lands characterized by areas of sensitive vegetation species subject to visible foliar injury, seedling and mature tree biomass loss, and other adverse impacts to a degree that could be considered adverse depending on the intended use of the plant and its significance to the public welfare. EPA is also considering recommending that States and Tribes employ other quantitative tools, such as photochemical modeling and/or the spatial interpolation of ambient data from existing O_3 monitors, to determine the adequacy of existing locations of rural

monitors and to inform the locations of new or relocated monitors that might be required to meet revised rural minimum monitoring requirements.

Finally, EPA solicited comment on the issue of O_3 monitoring seasons. Unlike the year-round monitoring required for other criteria pollutants, the required O_3 monitoring seasons[31] vary in length due to the inter-relationship of O_3-forming photochemical activity with ambient temperature, strength of solar insolation, and length of day. For example, in States with colder climates such as Montana and South Dakota, the O_3 season has a length of 4 months. In States with warmer climates such as California, Nevada, and Arizona, the O_3 season has a length of 12 months.

With the decision to revise the 8-hour primary standard to a level of 0.075 ppm, and to set the secondary standard identical in all respects to the primary standard, the issue arises of whether in some areas the required O_3 monitoring season should be made longer. EPA notes that under the existing regulations, the Regional Administrator may approve State-requested deviations from the established O_3 monitoring season but EPA may not increase the length of the season for an area at EPA's own initiative other than by notice and comment rulemaking.

EPA has done a preliminary analysis of 2004-2006 ambient data to address the issue of whether extensions of currently required O_3 monitoring seasons are appropriate in light of the revised level for the primary and secondary O_3 standards and the revised breakpoints for the AQI. The results of the analysis demonstrated that out-of-season exceedances of the revised level occurred in eight states during the study period. Additionally, the frequency of days with O_3 concentrations that reached the revised

[31] See 40 CFR Part 58 Appendix D, section 2.5 for a table of required O_3 seasons.

Moderate AQI category (based on a breakpoint of 0.060 ppm) was much greater compared with the frequency of days with concentrations that reached the pre-existing Moderate AQI category (based on a breakpoint of 0.065 ppm). This increased frequency of days with Moderate AQI levels was noted to occur during periods before and after the currently required O_3 seasons.

Based on these preliminary analyses, EPA intends to consider changes to the length of the required O_3 season for the coming monitoring rulemaking. Such changes could be based solely on the frequency of exceedances of the revised primary and secondary standards, or could also consider the frequency of concentrations in the Moderate category of the AQI.

VII. Implementation and Related Control Requirements

A. Future Implementation Steps

In today's rule, EPA is replacing the existing (1997) standards with revised primary and secondary O_3 standards. However, the 1997 standards -- and the implementation rules for those standards -- will remain in place for implementation purposes as EPA undertakes rulemaking to address the transition from the 1997 O_3 standards to the 2008 O_3 standards. States are required to continue to develop and implement their State Implementation Plans (SIPs) for the 1997 standards as they begin the process of recommending designations for the 2008 standards.

1. Designations

After EPA establishes or revises a NAAQS, the CAA requires EPA and States to begin taking steps to ensure that the new or revised standards are met. The first step is to

identify areas of the country that do not attain the new or revised standards, or that contribute to violations of the new or revised standards. Section 107(d)(1) provides "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. Section 107(d)(1)(B)(i) 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. Such period may be extended for up to one year in the event the Administrator has insufficient information to promulgate the designations."

The term "promulgation" has been interpreted by the courts to be signature and dissemination of a rule.[32] As noted above, the CAA requires EPA to establish a deadline for the States' submission of the designation recommendations, but under the CAA, it can be no later than March 12, 2009, one year after the promulgation of this rule. Therefore, Governors of States should submit their designation recommendations to EPA no later than March 12, 2009. EPA's promulgation of designations must occur no later than March 12, 2010, although that date may be extended by up to one year under the CAA (no later than March 12, 2011) if EPA has insufficient information to promulgate the designations.

[32] American Petroleum Institute v. Costle, 609 F.2d 20 (D.C. Cir. 1979).

EPA intends to provide additional guidance to the States concerning the technical considerations for establishing boundaries for designated areas. For the revised primary and secondary standards, we anticipate relying on past O_3 designation guidance issued by EPA prior to the designations for the 1997 O_3 standards.[33] We anticipate working closely with State air agencies and Tribes on establishing new guidance on designations, if needed.

2. State Implementation Plans

CAA section 110 provides the general requirements for SIPs. Within 3 years after the promulgation of new or revised NAAQS (or such shorter period as the Administrator may prescribe) each State must adopt and submit "infrastructure" SIPs to EPA to address the requirements of section 110(a)(1). Thus, States should submit these SIPs no later than March 12, 2011. These "infrastructure SIPs" provide assurances of State resources and authorities, and establish the basic State programs, to implement, maintain, and enforce new or revised standards.

In addition to the infrastructure SIPs, which apply to all States, CAA title I, part D outlines the State requirements for achieving clean air in designated nonattainment areas. These requirements include timelines for when designated nonattainment areas must attain the standards, deadlines for developing SIPs that demonstrate how the State will ensure attainment of the standards, and specific emissions control requirements. EPA plans to address how these requirements, such as attainment demonstrations and attainment dates, reasonable further progress, new source review, conformity, and other

[33] Memorandum of March 28, 2000 from John Seitz, "Boundary Guidance on Air Quality Designations for the 8-Hour Ozone National Ambient Air Quality Standards (NAAQS or Standard)."

implementation requirements, apply to the revised O_3 NAAQS in a proposed rulemaking in Fall 2008. Also in that rulemaking EPA will establish deadlines for submission of nonattainment area SIPs but anticipates that the deadlines will be no later than 3 years after final designation. Depending on the classification of an area, the SIP must provide for attainment within 3 years (for areas classified marginal) to 20 years (for areas classified extreme) after final designations.

3. Trans-boundary emissions

Cross border O_3 contributions from within North America (Canada and Mexico) entering the U.S. are generally thought to be small. Section 179B of the Clean Air Act allows designated nonattainment areas to petition EPA to consider whether such a locality might have met a clean air standard "but for" cross border contributions. To date, few areas have petitioned EPA under this authority. The impact of foreign emissions on domestic air quality in the United States is a challenging and complex problem to assess. EPA is engaged in a number of activities to improve our understanding of international transport. As work progresses on these activities, EPA will be able to better address the uncertainties associated with trans-boundary flows of air pollution and their impacts.

4. Monitoring Requirements

As discussed more fully in section VI, EPA intends, in light of the revisions the O_3 standards, to issue a monitoring rule to address a variety of monitoring-related issues identified in the preamble to the proposed rule or in comments received by the Agency on the proposal. EPA intends to issue a proposed monitoring rule in June 2008 and a final rule by March 2009.

B. Related Control Requirements

The man-made oxides of nitrogen (NO_x) and volatile organic carbon (VOC) emissions that contribute to O_3 formation in the United States come from a variety of source categories, including mobile sources, industrial processes, area-wide sources (which include consumer and commercial products), and the electric power industry.[34] Emissions from natural sources, such as trees and wildfires can also constitute a significant portion of total VOC emissions in certain regions of the country, especially during the O_3 season. Natural sources such as wildfires, lightning, and soils also emit NO_x. Emissions of VOCs and NO_x from these sources are considered natural background emissions.[35]

EPA has developed new emissions standards for many types of stationary sources and for nearly every class of mobile sources in the last decade to reduce O_3 by decreasing emissions of NO_x and VOC. These programs complement State and local efforts to improve air quality and to meet the national O_3 standards. Under the Federal Motor Vehicle Control Program (FMVCP, see title II of the CAA, 42 U.S.C. 7521-7574), EPA has established new emissions standards for nearly every type of automobile, truck, bus,

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[34] National Emission Inventory posted at the following web site: http://www.epa.gov/ttn/chief/trends/index.html

[35] In some cases natural emissions may cause or significantly contribute to violations of the ozone standard. EPA has issued rules that address how these "exceptional events" can be discounted in regulatory determinations. The Exceptional Events Rule (72 FR 13560 (March 22, 2007) implements CAA section 319(b)(3)(B) and section 107(d)(3) authority to exclude air quality monitoring data from regulatory determinations related to exceedances or violations of the National Ambient Air Quality Standards (NAAQS). If an event is determined by EPA to be a qualifying exceptional event, the affected area may avoid being designated as nonattainment, being redesignated as nonattainment, or being reclassifed to a higher classification. The requirements for demonstrating that elevated ozone levels are the result of a qualifying exceptional event are provided in the Exceptional Events Rule.

motorcycle, earth mover, and aircraft engine, and for the fuels used to power these engines. Also, EPA established new standards for the smaller engines used in small watercraft, lawn and garden equipment. Recently, EPA proposed new standards for locomotive and marine diesel engines. Vehicles and engines are replaced over time with newer, cleaner models. In time, these programs will yield substantial emissions reductions. Emissions reductions associated with fuel programs generally begin as soon as a new fuel is available.

The reduction of VOC emissions from industrial processes and consumer and commercial product categories has been achieved either directly or indirectly through implementation of control technology standards, including reasonably available control technology, best available control technology, and maximum achievable control technology standards; or is anticipated due to proposed or upcoming proposals based on generally available control technology or best available controls under provisions related to consumer and commercial products. These standards have resulted in VOC emissions reductions of almost a million tons per year accumulated starting in 1997 from a variety of sources including combustion sources, coating categories, and chemical manufacturing. In 2006 and 2007, EPA issued national rules and control techniques guidelines for control of VOC emissions from 10 categories of consumer and commercial products. EPA is currently working to finalize new Federal rules, or amendments to existing rules, intended to establish new nationwide VOC content limits for several categories of consumer and commercial products, including aerosol coatings, architectural and industrial maintenance coatings, and household and institutional

commercial products. EPA anticipates that final rules addressing emissions from these sources will take effect in 2009.

Fuel combustion is one of the largest anthropogenic sources of emissions of NO_x in the United States. Power industry emission sources include large electric generating units and some large industrial boilers and turbines. The EPA's landmark Clean Air Interstate Rule (CAIR), issued on March 10, 2005, permanently caps power industry emissions of NO_x in the eastern United States. The first phase of the cap begins in 2009, and a lower second phase cap begins in 2015. By 2015, EPA projects that the CAIR and other programs in the Eastern U.S. will reduce power industry annual NO_x emissions in that region by about 60 percent from 2003 levels.

With respect to agricultural sources, the U.S. Department of Agriculture (USDA) has recommended conservation systems and activities that can reduce agricultural emissions of NO_x and VOC. Current practices that may reduce emissions of NO_x and VOC include engine replacement programs, management of pesticide applications, and manure management techniques. The EPA recognizes that USDA has been working with the agricultural community to plan conservation systems and activities to manage emissions of O_3 precursors.

These conservation systems and activities can be voluntarily adopted in areas where mitigation of O_3 precursors have been identified as an air quality concern through the use of incentives provided to the agricultural producer. In cases where the States need these measures to attain the O_3 standards, agricultural producers could choose to adopt these measures. The EPA will continue to work with USDA on planning the implementation of these conservation systems and activities in order to identify and/or

improve mitigation efficiencies, prioritize their adoption, and ensure that appropriate criteria are used for identifying the most effective application of conservation systems and activities.

The EPA will work together with USDA and with States to identify appropriate measures to meet the primary and secondary standards, including site-specific conservation systems and activities. Based on prior experience identifying conservation measures and practices to meet the PM NAAQS requirements, the EPA will use a similar process to identify measures that could meet the O_3 requirements. The EPA anticipates that certain USDA-approved conservation systems and activities that reduce agricultural emissions of NO_x and VOC may be able to satisfy the requirements for applicable sources to implement reasonably available control measures for purposes of attaining the primary and secondary O_3 NAAQS.

VIII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and 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 EO 12866 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 three alternative O_3 NAAQS nationwide. Specifically, the RIA examines the alternatives of 0.079 ppm, 0.075 ppm, 0.070 ppm, and 0.065 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. 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. There are no information collection requirements directly associated with the establishment of a NAAQS under section 109 of the CAA.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable

instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

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 Ass'ns 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

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and to adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan

must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

This final rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or Tribal governments or the private sector. The rule imposes no new expenditure or enforceable duty on any State, local or Tribal governments or the private sector, and EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. 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). Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that 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."

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

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an

accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." This final rule does not have Tribal implications, as specified in Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes, 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 environmental professionals 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

Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is subject to Executive Order 13045 because it is an economically significant regulatory action as defined by Executive Order 12866, and we believe 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. These effects and the size of the population affected are summarized in section 8.7 of the Criteria Document and section 3.6 of the 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

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)), requires EPA to prepare and submit a Statement of Energy Effects to the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, for certain actions identified as "significant energy actions." Section 4(b) of Executive Order 13211 defines "significant energy actions" as "any action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) that is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action." The U.S. Office of Management of Budget has designated this rulemaking as a significant energy action. Accordingly, EPA has prepared

a Statement of Energy Effects for this action which appears in Chapter 9 of the RIA conducted for this rulemaking. A copy of the RIA is available in the RIA docket (EPA-HQ-OAR-2007-0225) and the energy analysis is briefly summarized here. The analysis estimates potential impacts of an illustrative control strategy for the 0.070 ppm primary standard alternative on the production of coal, crude oil, natural gas, and electricity; on energy prices; on control technologies adopted by the electricity generating sector; and on the mix of electricity generation. EPA believes that the energy impacts estimated for this illustrative control strategy for the 0.070 ppm primary standard alternative are higher than those that would be estimated for an illustrative control strategy for the primary standard level of 0.075 ppm which was selected by the Administrator. However, due to modeling limitations, EPA did not generate separate estimates of the energy impacts associated specifically with an illustrative control strategy designed for a primary standard of 0.075 ppm. It is important to note that the CAA make clear that the economic impacts associated with attaining ambient standards are not to be considered in setting or revising the NAAQS. Accordingly, although the Statement of Energy Effects has been prepared, the results of EPA's energy analysis have not been considered in issuing this final rule.

I. National Technology Transfer and Advancement Act

As noted in the proposed rule, 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

Executive Order 12898 (59 FR 7629; Feb. 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations 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]**.

List of Subjects in 40 CFR part 50

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

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Dated:

_____
Stephen L. Johnson, Administrator

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For the reasons stated in the preamble, Title 40, Chapter I of the code of Federal regulations is to be 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. Section 50.15 is added 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 and secondary ambient air quality standards for ozone (O_3) is 0.075 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 and secondary O_3 ambient air quality standards are 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 0.075 ppm, as determined in accordance with Appendix P to this part.

3. Appendix P is added 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 national 8-hour primary and secondary ambient air quality standards 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 reference method based on Appendix D of this part, as applicable, and designated in accordance with part 53 of this chapter, or by an equivalent method 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. 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.

(b) 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 2 of this appendix.

Annual fourth-highest daily maximum refers to the fourth highest value measured at a monitoring site during a particular year.

Daily maximum 8-hour average concentration refers to the maximum calculated 8-hour average for a particular day as explained in section 2 of this appendix.

Design values are the metrics (i.e., statistics) that are compared to the NAAQS levels to determine compliance, calculated as shown in section 3 of this appendix.

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. Primary and Secondary Ambient Air Quality Standards for Ozone

2.1 Data Reporting and Handling Conventions

Computing 8-hour averages. 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. 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. An 8-hour average shall be considered valid if at least 75% of the hourly averages for the 8-hour period are available. In the event that only 6 or 7 hourly averages are available, the 8-hour average shall be computed on the basis of the hours available using 6 or 7 as the divisor. 8-hour periods with three or more missing hours shall be considered valid also, if, after substituting one-half the minimum detectable limit for the missing hourly concentrations, the 8-hour average concentration is greater than the level of the standard. The computed 8-hour average O_3 concentrations shall be reported to three decimal places (the digits to the right of the third decimal place are truncated, consistent with the data handling procedures for the reported data).

Daily maximum 8-hour average concentrations. (a) There are 24 possible running 8-hour average O_3 concentrations for each calendar day during the O_3 monitoring season. The daily maximum 8-hour concentration for a given calendar day is the highest of the 24 possible 8-hour average concentrations computed for that day. This process is repeated, yielding a daily maximum 8-hour average O_3 concentration for each calendar day with ambient O_3 monitoring data. Because the 8-hour averages are recorded in the start hour, 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.

(b) An O_3 monitoring day shall be counted as a valid day if valid 8-hour averages are available for at least 75% of possible hours in the day (i.e., at least 18 of the 24 averages). In the event that less than 75% of the 8-hour averages are available, a day shall also be counted as a valid day if the daily maximum 8-hour average concentration for that day is greater than the level of the standard.

2.2 Primary and Secondary Standard-related Summary Statistic

The standard-related summary statistic is the annual fourth-highest daily maximum 8-hour O_3 concentration, expressed in parts per million, averaged over three years. The 3-year average shall be computed using the three most recent, consecutive calendar years of monitoring data meeting the data completeness requirements described in this appendix. The computed 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentrations shall be reported to three decimal places (the digits to the right of the third decimal place are truncated, consistent with the data handling procedures for the reported data).

2.3 Comparisons with the Primary and Secondary Ozone Standards

(a) The primary and secondary O_3 ambient air quality standards are 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 0.075 ppm.

(b) This comparison shall be based on three consecutive, complete calendar years of air quality monitoring data. This requirement is met for the 3-year period at a monitoring site

if daily maximum 8-hour average concentrations are available for at least 90% of the days within the O_3 monitoring season, on average, for the 3-year period, with a minimum data completeness requirement in any one year of at least 75% of the days within the O_3 monitoring season. When computing whether the minimum data completeness requirements have been met, meteorological or ambient data may be sufficient to demonstrate that meteorological conditions on missing days were not conducive to concentrations above the level of the standard. Missing days assumed less then the level of the standard are counted for the purpose of meeting the data completeness requirement, subject to the approval of the appropriate Regional Administrator.

(c) Years with concentrations greater than the level of the standard shall be included even if they have less than complete data. Thus, in computing the 3-year average fourth maximum concentration, calendar years with less than 75% data completeness shall be included in the computation if the 3-year average fourth-highest 8-hour concentration is greater than the level of the standard.

(d) Comparisons with the primary and secondary O_3 standards are demonstrated by examples 1 and 2 in paragraphs (d) (1) and (d) (2) respectively as follows:

Example 1. Ambient monitoring site attaining the primary and secondary O_3 standards.

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)
2004	100%	0.092	0.090	0.085	0.079	0.078
2005	96%	0.084	0.083	0.075	0.072	0.070
2006	98%	0.080	0.079	0.077	0.076	0.060
Average	98%				0.075	

(1) As shown in Example 1, this monitoring site meets the primary and secondary O_3 standards because the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentrations (i.e., 0.075666… ppm, truncated to 0.075 ppm) is less than or equal to 0.075 ppm. The data completeness requirement is also met because the average percent of days within the required monitoring season with valid ambient monitoring data is greater than 90%, and no single year has less than 75% data completeness. In Example 1, the individual 8-hour averages used to determine the annual fourth maximum have also been truncated to the third decimal place.

Example 2. Ambient monitoring site failing to meet the primary and secondary O_3 standards.

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)
2004	96%	0.105	0.103	0.103	0.103	0.102
2005	74%	0.104	0.103	0.092	0.091	0.088
2006	98%	0.103	0.101	0.101	0.095	0.094
Average	89%				0.096	

As shown in Example 2, the primary and secondary O_3 standards are 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., 0.096333… ppm, truncated to 0.096 ppm) is greater than 0.075 ppm, even though the data capture is less than 75% and the average data capture for the 3 years is less than 90% within the required monitoring season. In Example 2, the individual 8-hour averages used to determine the annual fourth maximum have also been truncated to the third decimal place.

3. Design Values for Primary and Secondary Ambient Air Quality Standards for Ozone

The air quality design value at a monitoring site is defined as that concentration that when reduced to the level of the standard ensures that the site meets the standard. For a concentration-based standard, the air quality design value is simply the standard-related

test statistic. Thus, for the primary and secondary standards, the 3-year average annual fourth-highest daily maximum 8-hour average O_3 concentration is also the air quality design value for the site.

For the reasons set forth in the preamble, 40 CFR part 58 is proposed to be amended as follows:

PART 58—AMBIENT AIR QUALITY SURVEILLANCE

1. The authority citation of part 58 continues to read as follows:

Authority: 42 U.S.C. 7410, 7601(a), and 7619.

2. Appendix G to Part 58 is amended as follows:

a. By revising section 9.

b. By revising section 10.

c. By revising section 12.

d. By revising section 13.

Appendix G to Part 58 - Uniform Air Quality Index (AQI) and Daily Reporting

* * * * *

9. How Does the AQI Relate to Air Pollution Levels?

For each pollutant, the AQI transforms ambient concentrations to a scale from 0 to 500. The AQI is keyed as appropriate to the national ambient air quality standards (NAAQS) for each pollutant. In most cases, the index value of 100 is associated with the numerical level of the short-term standard (i.e., averaging time of 24-hours or less) for each pollutant. A different approach is taken for NO_2, for which no short-term standard has been established. The index value of 50 is associated with the numerical level of the

annual standard for a pollutant, if there is one, at one-half the level of the short-term standard for the pollutant, or at the level at which it is appropriate to begin to provide guidance on cautionary language. Higher categories of the index are based on increasingly serious health effects and increasing proportions of the population that are likely to be affected. The index is related to other air pollution concentrations through linear interpolation based on these levels. The AQI is equal to the highest of the numbers corresponding to each pollutant. For the purposes of reporting the AQI, the sub-indexes for PM_{10} and $PM_{2.5}$ are to be considered separately. The pollutant responsible for the highest index value (the reported AQI) is called the "critical" pollutant.

10. What Monitors Should I Use to Get the Pollutant Concentrations For Calculating the AQI?

You must use concentration data from population-oriented State/Local Air Monitoring Station (SLAMS) or parts of the SLAMS required by 40 CFR 58.10 for each pollutant except PM. For PM, calculate and report the AQI on days for which you have measured air quality data (e.g., from continuous $PM_{2.5}$ monitors required in Appendix D to this part). You may use PM measurements from monitors that are not reference or equivalent methods (for example, continuous PM_{10} or $PM_{2.5}$ monitors). Detailed guidance for relating non-approved measurements to approved methods by statistical linear regression is referenced in section 13 below.

* * * * *

12. How Do I Calculate the AQI?

i. The AQI is the highest value calculated for each pollutant as follows:

a. Identify the highest concentration among all of the monitors within each reporting area and truncate the pollutant concentration to one more than the significant digits used to express the level of the NAAQS for that pollutant. This is equivalent to the rounding conventions used in the NAAQS.

b. Using Table 2, find the two breakpoints that contain the concentration.

c. Using Equation 1, calculate the index.

d. Round the index to the nearest integer.

TABLE 2.—BREAKPOINTS FOR THE AQI

These breakpoints							Equal these AQI's	
O_3 (ppm) 8-hour	O_3 (ppm) 1-hour[1]	$PM_{2.5}$ (μg/m^3)	PM_{10} (μg/m^3)	CO (ppm)	SO_2 (ppm)	NO_2 (ppm)	AQI	Category
0.000-0.059	.....	0.0-15.4	0-54	0.0-4.4	0.000-0.034	([3])	0-50	Good.
0.060-0.075	.....	15.5-40.4	55-154	4.5-9.4	0.035-0.144	([3])	51-100	Moderate.
0.076-0.095	0.125-0.164	40.5-65.4	155-254	9.5-12.4	0.145-0.224	([3])	101-150	Unhealthy for Sensitive Groups.
0.096-0.115	0.165-0.204	[4]65.5-150.4	255-354	12.5-15.4	0.225-0.304	([3])	151-200	Unhealthy.
0.116-0.374	0.205-0.404	[4]150.5-250.4	355-424	15.5-30.4	0.305-0.604	0.65-1.24	201-300	Very Unhealthy.
([2]).....	0.405-0.504	[4]250.5-350.4	425-504	30.5-40.4	0.605-0.804	1.25-1.64	301-400	
([2]).....	0.505-0.604	[4]350.5-500.4	505-604	40.5-50.4	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] NO_2 has no short-term NAAQS, and can generate an AQI only above the value of 200

[4] If a different SHL for $PM_{2.5}$ is promulgated, these numbers will change accordingly.

ii. If the concentration is equal to a breakpoint, then the index is equal to the corresponding index value in Table 2. However, Equation 1 can still be used. The results will be equal. If the concentration is between two breakpoints, then calculate the index of that pollutant with Equation 1. You must also note that in some areas, the AQI based on 1-hour O_3 will be more precautionary than using 8-hour values (see footnote 1 to Table 2). In these cases, you may use 1-hour values as well as 8-hour values to calculate index values and then use the maximum index value as the AQI for O_3.

$$I_p = \frac{I_{Hi} - I_{Lo}}{BP_{Hi} - BP_{Lo}} \left(C_p - BP_{Lo}\right) + I_{Lo} \qquad \text{(Equation 1)}$$

Where:

I_p = the index value for pollutant$_p$

C_p = the truncated concentration of pollutant$_p$

BP_{Hi} = the breakpoint that is greater than or equal to C_p

BP_{Lo} = the breakpoint that is less than or equal to C_p

I_{Hi} = the AQI value corresponding to BP_{Hi}

I_{lo} = the AQI value corresponding to BP_{Lo}.

iii. If the concentration is larger than the highest breakpoint in Table 2 then you may use the last two breakpoints in Table 2 when you apply Equation 1.

Example

iv. Using Table 2 and Equation 1, calculate the index value for each of the pollutants measured and select the one that produces the highest index value for the AQI. For

example, if you observe a PM_{10} value of 210 μg/m^3, a 1-hour O_3 value of 0.156 ppm, and an 8-hour O_3 value of 0.130 ppm, then do this:

a. Find the breakpoints for PM_{10} at 210 μg/m^3 as 155 μg/m^3 and 254 μg/m^3, corresponding to index values 101 and 150;

b. Find the breakpoints for 1-hour O_3 at 0.156 ppm as 0.125 ppm and 0.164 ppm, corresponding to index values 101 and 150;

c. Find the breakpoints for 8-hour O_3 at 0.130 ppm as 0.116 ppm and 0.374 ppm, corresponding to index values 201 and 300;

d. Apply Equation 1 for 210 μg/m^3, PM_{10}:

$$\frac{150-101}{254-155}\left(210-155\right) + 101 = 128$$

e. Apply Equation 1 for 0.156 ppm, 1-hour O_3:

$$\frac{150-101}{0.164-0.125}\left(0.156-0.125\right) + 101 = 140$$

f. Apply Equation 1 for 0.130 ppm, 8-hour O_3:

$$\frac{300-201}{0.374-0.116}\left(0.130-0.116\right) + 201 = 206$$

g. Find the maximum, 206. This is the AQI. The minimal AQI report would read:

v. Today, the AQI for my city is 206 which is Very Unhealthy, due to ozone. Children and people with asthma are the groups most at risk.

13. What Additional Information Should I Know?

The EPA has developed a computer program to calculate the AQI for you. The program prompts for inputs, and it displays all the pertinent information for the AQI (the index value, color, category, sensitive group, health effects, and cautionary language). The EPA has also prepared a brochure on the AQI that explains the index in detail (The Air Quality Index), Reporting Guidance (Guideline for Public Reporting of Daily Air Quality) that provides associated health effects and cautionary statements, and Forecasting Guidance (Guideline for Developing an Ozone Forecasting Program) that explains the steps necessary to start an air pollution forecasting program. You can download the program and the guidance documents at www.airnow.gov. Reference for relating non-approved PM measurements to approved methods (Eberly, S., T. Fitz-Simons, T. Hanley, L. Weinstock., T. Tamanini, G. Denniston, B. Lambeth, E. Michel, S. Bortnick. Data Quality Objectives (DQOs) For Relating Federal Reference Method (FRM) and Continuous $PM_{2.5}$ Measurements to Report an Air Quality Index (AQI). U.S. Environmental Protection Agency, research Triangle Park, NC. EPA-454/B-02-002, November 2002) can be found on the Ambient Monitoring Technology Information Center (AMTIC) Web site, http://www.epa.gov/ttnamti1/