EPA United States Environmental Protection Agency

# Integrated Review Plan for the Ozone National Ambient Air Quality Standards Review

## External Review Draft

**U. S. Environmental Protection Agency**

National Center for Environmental Assessment
Office of Research and Development
and
Office of Air Quality Planning and Standards
Office of Air and Radiation

Research Triangle Park, North Carolina 27711

# DISCLAIMER

This draft integrated review plan for the national ambient air quality standards (NAAQS) for ozone ($O_3$) serves as a public information document and a management tool for the United States Environmental Protection Agency's National Center for Environmental Assessment and the Office of Air Quality Planning and Standards. The approach described in this draft plan may be modified in the final plan to reflect input received during an upcoming consultation with the Clean Air Scientific Advisory Committee (CASAC) and public comments. Further modifications to the plan may result from information developed during this review of the $O_3$ NAAQS and to address advice and comments received from CASAC and the public throughout this review. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

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# 1 INTRODUCTION

The U.S. Environmental Protection Agency (EPA) last completed a rulemaking on the primary (health-based) and secondary (welfare-based) national ambient air quality standards (NAAQS) for ozone ($O_3$) in March 2008 (73 FR 16436), resulting in revisions to both standards. In May 2008, states, environmental groups and industry groups filed petitions with the D.C. Circuit Court of Appeals for review of the 2008 ozone standards. In March 2009, the court granted EPA's request to stay the litigation so the new administration could review the standards and determine whether they should be reconsidered. On September 16, 2009, the Administrator announced her decision to reconsider the 2008 primary and secondary ozone standards to ensure they are scientifically sound and protective of public health and the environment as required by the Clean Air Act (CAA). Prior to the decision to reconsider the 2008 $O_3$ standards, EPA had initiated a new periodic review of the existing air quality criteria and standards for $O_3$ in September 2008.

This draft Integrative Review Plan (IRP) contains the plans for the new periodic review of the air quality criteria for $O_3$-related effects on public health and public welfare and the current $O_3$ standards or any revised standards that may result from the reconsideration of the 2008 $O_3$ standards. This draft IRP is being released for the purpose of consulting with the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board[1] and obtaining public comment on the Agency's plans. The final IRP will be informed by comments received from the CASAC and the public.

This draft IRP is organized into eight chapters. Chapter 1 presents the legislative requirements for the review of the NAAQS, an overview of the NAAQS review process, a history of past reviews of the $O_3$ NAAQS, and the Agency's plans to reconsider the 2008 $O_3$ NAAQS. Chapters 2 through 8 outline the Agency's plans for the new periodic review of the existing air quality criteria and the $O_3$ standards that result from the reconsideration of the 2008 standards. Chapter 2 presents the status and schedule for the new review. Chapter 3 presents a set of policy-relevant questions that will serve to focus the new review on the critical scientific

[1] For purposes of this review, the 7-member CASAC has been supplemented by additional scientific experts collectively referred to as the CASAC $O_3$ NAAQS Review Panel.

and policy issues. Chapters 4 through 6 discuss the planned scope and organization of the key assessment documents, the planned approaches for preparing the documents, and plans for scientific and public review of the documents for the new review. Chapter 7 summarizes the policy assessment and rulemaking process for the new $O_3$ NAAQS review. Finally, chapter 8 discusses the current ambient air monitoring network and monitoring issues related to the $O_3$ NAAQS.

## 1.1 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" that meet three criteria, and to issue air quality criteria for those that are listed. 42 U.S.C. § 7408(a),(b). Air quality criteria are intended 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 . . . ." 42 U.S.C. § 7408(b).

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants for which air quality criteria have been issued. 42 U.S.C. § 7409 (a). Section 109(b) (1) defines a primary standard as one "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health."[2] 42 U.S.C. § 7409(b)(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 required to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air."[3] 42 U.S.C. § 7409(b)(2).

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

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

The requirement that primary standards include an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. See *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 include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

In selecting a margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. See *Lead Industries Association v. EPA*, supra, 647 F.2d at 1161-62.

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. In so doing, EPA may not consider the costs of implementing the standards. See generally *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001).

Section 109(d)(1) requires that "not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards . . . and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate . . . ." 42 U.S.C. § 7409(d)(1). 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 . . . ."

42 U.S.C. § 7409(d)(2). Since the early 1980's, this independent review function has been performed by CASAC.

## 1.2 OVERVIEW OF THE NAAQS REVIEW PROCESS

Since completion of the last $O_3$ NAAQS review, the Agency has made a number of changes to the process for reviewing the NAAQS.[4] In making these changes, the Agency considered the advice of CASAC and the public. As described below, this revised process contains four major components: planning, science assessment, risk/exposure assessment, and policy assessment/rulemaking.

The planning phase of the review process begins with a "kick-off" workshop to get input from CASAC, internal and external experts, and the public regarding policy-relevant science issues that have emerged since the last air quality criteria review. The workshop discussions help inform the preparation of an IRP jointly by staff from EPA's National Center fro Environmental Assessment, Research Triangle Park, NC (NCEA-RTP) and EPA's Office of Air Quality Planning and Standards (OAQPS). A draft IRP is presented for consultation with CASAC and for public comment. A final IRP reflects CASAC and public comments together with early guidance from Agency management. The IRP includes an outline of the process and schedule that the entire review will follow, the science-policy questions that will frame the review, and more complete descriptions of the purpose, contents, and approach for developing each of the key documents in the review.

The science assessment phase involves the preparation of an Integrated Science Assessment (ISA) by NCEA-RTP. The ISA provides a concise evaluation and integration of the policy-relevant science, including key science judgments that are important to inform the design and scope of the risk and exposure assessments. The ISA and its supporting annexes provide a comprehensive assessment of the current scientific literature pertaining to known and anticipated effects on public health and welfare associated with the presence of the pollutant in the ambient air, emphasizing information that has become available since the last air quality criteria review. The process generally includes production of a first and second draft ISA, both of which undergo CASAC and public review prior to completion of the final ISA. Chapter 4 presents a description

[4] See http://www.epa.gov/ttn/naaqs/ for more information.

of the planned scope, organization, and assessment approach for the ISA to be prepared for this review.

In the risk/exposure assessment phase, OAQPS staff draws upon information and conclusions presented in the ISA to develop quantitative estimates of the risks/exposures for health and/or welfare effects associated with current ambient levels of the pollutant, with levels that just meet the current standards, and with levels that just meet potential alternative standards. The Risk and Exposure Assessments (REAs) provide concise presentations of methods, key results, observations, and related uncertainties. These assessments begin with the preparation of a planning document that discusses the scope and methods planned for use in conducting the quantitative assessments. Such Scope and Methods Plans are generally prepared in conjunction with the first draft ISA and presented for consultation with CASAC and for public comment. Comments received on the Scope and Methods Plans are considered in conducting the assessments to be presented in the REAs. One or more drafts of each REA undergoes CASAC and public review, with the initial draft REAs generally being reviewed in conjunction with review of the second draft ISA, prior to completion of final REAs. Chapters 5 and 6 discuss possible approaches being considered by OAQPS for conducting human health and welfare-related assessments, respectively, for this review.

The review process ends with a policy assessment/rulemaking phase. Under recent revisions to the NAAQS review process, the EPA Administrator has reinstated the use of a Policy Assessment (PA), which is, like the previous OAQPS Staff Paper, a document that provides a transparent staff analysis of the scientific basis for alternative policy options for consideration by the Administrator prior to the issuance of proposed and final rules (Jackson, 2009). The PA integrates and interprets the information from the ISA and REAs to frame policy options for consideration by the Administrator. One or more drafts of a PA is released for CASAC review and public comment prior to completion of the final PA. The PA is intended to facilitate CASAC's advice and recommendations to the Administrator on any new standards or revisions to existing standards as may be appropriate, as provided for in the CAA. Following issuance of the final PA, the Agency publishes a proposed rule, followed by a public comment period during which public hearings are held. Taking into account comments received on the proposed rule, the Agency issues a final rule to complete the rulemaking process. Chapter 7 discusses the development of the PA and the rulemaking steps for this review.

## 1.3 HISTORY OF $O_3$ NAAQS REVIEWS

Tropospheric (ground-level) $O_3$ is the indicator for the mix of photochemical oxidants 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 $O_{3,}$ especially $NO_x$ and volatile organic compounds (VOCs), 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.

NAAQS are comprised of four basic elements: indicator, averaging time, level, and form. The indicator defines the pollutant to be measured in the ambient air for the purpose of determining compliance with the standard. The averaging time defines the time period over which air quality measurements are to be obtained and averaged or cumulated, considering evidence of effects associated with various time periods of exposure. The level of a standard defines the air quality concentration used (i.e., an ambient concentration of the indicator pollutant) in determining whether the standard is achieved. The form of the standard specifies the air quality measurements that are to be used for compliance purposes (e.g., the annual fourth-highest daily maximum 8-hr concentration, averaged over three years),, and whether the statistic is to be averaged across multiple years. These four elements taken together determine the degree of public health and welfare protection afforded by the NAAQS.

Table 1-1 summarizes the $O_3$ NAAQS that have been promulgated to date. In each review, the secondary standard has been set to be identical to the primary standard. These reviews are briefly described below.

**Table 1-1. Summary of Primary and Secondary National Ambient Air Quality Standards Promulgated for Ozone During the Period 1971-2008**

| Final Rule | Indicator | Ave. Time | Level (ppm) | Form |
|---|---|---|---|---|
| 1971 (36 FR 8186) | Total photochemical oxidants | 1-hr | 0.08 | Not to be exceeded more than one hr per year |
| 1979 (44 FR 8202) | $O_3$ | 1-hr | 0.12 | Attainment is defined when the expected number of days per calendar year, with maximum hourly average concentration greater than 0.12 ppm, is equal to or less than 1 |
| 1993 (58 FR 13008) | EPA decided that revisions to the standards were not warranted at the time. | | | |
| 1997 (62 FR 38856) | $O_3$ | 8-hr | 0.08 | Annual fourth-highest daily maximum 8-hr concentration, averaged over 3 years |
| 2008 (73 FR 16483) | $O_3$ | 8-hr | 0.075 | Form of the standards remained unchanged relative to the 1997 standard |

EPA first established primary and secondary NAAQS for photochemical oxidants in 1971 (36 FR 8186, April 30, 1971). Both primary and secondary standards were set at a level of 0.08 parts per million (ppm), 1-hr average, total photochemical oxidants, not to be exceeded more than one hr per year. The standards were based on scientific information contained in the 1970 CD (U.S. DHEW, 1970).

In 1977, EPA announced the first periodic review of the 1970 CD (U.S DHEW, 1970) in accordance with section 109(d)(1) of the Act. In 1978, EPA published a 1978 CD (U.S. EPA, 1978). Based on the 1978 CD, EPA published proposed revisions to the original NAAQS in 1978 (43 FR 16962) and final revisions in 1979 (44 FR 8202). The level of the primary and secondary standards was revised from 0.08 to 0.12 ppm; the indicator was revised from photochemical oxidants to $O_3$; and the form of the standards was revised from a deterministic to a statistical form, which defined attainment of the standards as occurring when the expected number of days per calendar year with maximum hourly average concentration greater than 0.12 ppm is equal to or less than one.

In 1982 (47 FR 11561), EPA announced plans to revise the 1978 CD (U.S. EPA, 1978). In 1983, EPA announced (48 FR 38009) that the second periodic review of the primary and secondary standards for $O_3$ had been initiated. EPA subsequently published the1986 CD (U.S. EPA, 1986) and 1989 Staff Paper (U.S. EPA, 1989). Following publication of the 1986 CD (U.S. EPA, 1986), a number of scientific abstracts and articles were published that appeared to be of sufficient importance concerning potential health and welfare effects of $O_3$ to warrant preparation of a Supplement to the 1986 CD (U.S. EPA, 1992). Under the terms of a court order, on August 10, 1992 (57 FR 35542) EPA published a proposed decision stating that revisions to the existing primary and secondary standards were not appropriate at the time. The notice explained (57 FR 35546 ) that the proposed decision would complete EPA's review of information on health and welfare effects of $O_3$ assembled over a 7 year period and contained in the 1986 CD (U.S. EPA,1986) and its Supplement to the 1986 CD (U.S. EPA, 1992). The proposal also announced EPA's intention to proceed as rapidly as possible with the next review of the air quality criteria and standards for $O_3$ in light of emerging evidence of health effects related to 6- to 8-hr $O_3$ exposures. On March 9, 1993, EPA concluded the review by deciding that revisions to the standards were not warranted at that time (58 FR 13008).

In August 1992 (57 FR 35542), EPA announced plans to initiate the third periodic review of the air quality criteria and $O_3$ NAAQS. On the basis of the scientific evidence contained in the 1996 CD (U.S. EPA 1996a) and the 1996 Staff Paper (U.S. EPA, 1996b), and related technical support documents, linking exposures to ambient $O_3$ to adverse health and welfare effects at levels allowed by the then existing standards, EPA proposed to revise the primary and secondary $O_3$ standards on December 13, 1996 (61 FR 65716). The EPA proposed to replace the then existing 1-hr primary and secondary standards with 8-hr average $O_3$ standards set at a level of 0.08 ppm (equivalent to 0.084 ppm using standard rounding conventions). The EPA also proposed, in the alternative, to establish a new distinct secondary standard using a biologically based cumulative seasonal form. The EPA completed the review on July 18, 1997 (62 FR 38856) by setting the primary standard at a level of 0.08 ppm, based on the annual fourth-highest daily maximum 8-hr average concentration, averaged over three years, and setting the secondary standard identical to the revised primary standard.

On May 14, 1999, in response to challenges to EPA's 1997 decision by industry and others, the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit Court) remanded the $O_3$ NAAQS to EPA, finding that section 109 of the Act, as interpreted by EPA, effected an unconstitutional delegation of legislative authority. In addition, the D.C. Circuit Court directed that, in responding to the remand, EPA should consider the potential beneficial health effects of $O_3$ pollution in shielding the public from the effects of solar ultraviolet (UV) radiation, as well as adverse health effects. On January 27, 2000, EPA petitioned the U.S. Supreme Court for certiorari on the constitutional issue (and two other issues) but did not request review of the D.C. Circuit Court ruling regarding the potential beneficial health effects of $O_3$. On February 27, 2001, the U.S. Supreme Court unanimously reversed the judgment of the D.C. Circuit Court on the constitutional issue, holding that section 109 of the CAA does not delegate legislative power to the EPA in contravention of the Constitution, and remanded the case to the D.C. Circuit Court to consider challenges to the $O_3$ NAAQS that had not been addressed by that Court's earlier decisions. On March 26, 2002, the D.C. Circuit Court issued its final decision, finding the 1997 $O_3$ NAAQS to be "neither arbitrary nor capricious," and denied the remaining petitions for review. In response to the D.C. Circuit Court remand to consider the potential beneficial health effects of $O_3$ pollution in shielding the public from effects of solar (UV) radiation, on November 14, 2001, EPA proposed to leave the 1997 8-hr NAAQS unchanged (66 FR 52768). After considering public comment on the proposed decision, EPA published its final response to this remand on January 6, 2003, reaffirming the 8-hr $O_3$ NAAQS set in 1997 (68 FR 614). Finally, on April 30, 2004, EPA announced the decision to make the 1-hr $O_3$ NAAQS no longer applicable to areas one year after the effective date of the designation of those areas for the 8-hr NAAQS (69 FR 23966). For most areas, the date that the 1-hr NAAQS no longer applied was June 15, 2005.

EPA initiated the next periodic review if the air quality criteria and $O_3$ standards in September 2000 with a call for information (65 FR 57810). The schedule for completion of that rulemaking later became governed by a consent decree resolving a lawsuit filed in March 2003 by a group of plaintiffs representing national environmental and public health organizations. Based on the CD (US EPA, 2006) published in March 2006 and the Staff Paper (U.S EPA, 2007) and related technical support documents published in July 2007, the proposed decision was published in the Federal Register on July 11, 2007 (72 FR 37818). The EPA proposed to revise the level of the primary standard to a level within the range of 0.075 to 0.070 ppm. Two options were proposed for the secondary standard: (1) replacing the current standard with a cumulative, seasonal standard, expressed as an index of the annual sum of weighted hourly concentrations cumulated over 12 daylight hours 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-hrs, and (2) setting the secondary standard identical to the revised primary standard. The EPA completed the rulemaking with publication of a final decision on March 27, 2008 (73 FR 16436), revising the level of the 8-hr primary $O_3$ standard from 0.08 ppm to 0.075 ppm and revising the secondary standard to be identical to the primary standard.

As discussed in the next section, on September 16, 2009 the EPA Administrator announced her decision to reconsider the March 2008 decisions on revisions to the primary and secondary $O_3$ NAAQS.

## 1.4 RECONSIDERATION OF THE 2008 OZONE NAAQS

In May 2008, state, public health, environmental, and industry petitioners filed suit against EPA regarding that final decision, and on December 23, 2008, the Court set a briefing schedule in the consolidated cases. On March 10, 2009, EPA requested that the Court vacate the briefing schedule and hold the consolidated cases in abeyance. This request for extension was made to allow time for appropriate EPA officials appointed by the new Administration to review the $O_3$ NAAQS to determine whether the standards established in the March 2008 $O_3$ NAAQS decision should be maintained, modified or otherwise reconsidered. In granting EPA's request, the Court directed EPA to notify the Court by September 16, 2009 of the action it will be taking with respect to the 2008 $O_3$ NAAQS rule and the Agency's schedule for undertaking such action.

The EPA notified the Court on September 16, 2009 of its decision to reconsider the primary and secondary $O_3$ NAAQS set in March 2008 to ensure they are scientifically sound and protective of public health and the environment.[5] The EPA will base this reconsideration on the scientific record from the 2008 rulemaking, including public comments and CASAC advice and

[5] The EPA also separately announced that it will move quickly to implement any new standards that might result from the reconsideration. To reduce the workload for states during the interim period of reconsideration, the Agency will propose to stay the 2008 standards for the purpose of attainment and nonattainment area designations. EPA will work with states, local governments and tribes to ensure that air quality is protected during that time.

recommendations. During the 2008 review, CASAC unanimously recommended a more health protective primary standard than was eventually set in 2008. The CASAC also recommended a new cumulative, seasonal secondary standard, distinct from the primary standard, while the 2008 rule made the secondary standard identical to the primary standard. Following the 2008 decision, CASAC offered unsolicited advice that reiterated its previous recommendations and urged the Agency to reconsider its advice in future action on the $O_3$ standards. The EPA's notice to the Court specifically stated that the Agency had concerns regarding whether the revisions to the primary and secondary NAAQS adopted in the 2008 $O_3$ NAAQS rule satisfy the requirements of the Clean Air Act.

The EPA plans to base the reconsideration of the 2008 $O_3$ NAAQS decision on the scientific and technical information that was assessed during the 2008 rulemaking, including information in the 2006 Air Quality Criteria Document (AQCD, U.S. EPA, 2006), the 2007 Policy Assessment of Scientific and Technical Information, referred to as the OAQPS Staff Paper (U.S. EPA, 2007a), and related technical support documents including the 2007 REAs (U.S. EPA, 2007b; Abt Associates, 2007a,b). Scientific and technical information developed since the 2006 AQCD will be considered in the new review, not in the reconsideration rulemaking, allowing the new information to receive careful and comprehensive review by CASAC and the public before it is used as a basis in a rulemaking that determines whether to revise the NAAQS. As in prior NAAQS rulemaking, EPA is also conducting a provisional assessment of such "new" scientific information (published since review of the 2006 AQCD) to consider whether that scientific literature would materially change the conclusions reached in the 2006 AQCD in conjunction with determining the appropriateness of proceeding with the reconsideration rulemaking. The provisional assessment is subject to internal EPA peer review, and the final provisional assessment will be made available to CASAC and the public at the time of proposal. Consistent with EPA's approach in other NAAQS reviews, the Agency will not base its decisions in the reconsideration on the new science but will instead review and consider the new science in the new review covered by this integrated review plan.

Consistent with EPA's notice to the Court, this reconsideration of the 2008 $O_3$ NAAQS rule will be conducted through notice and comment rulemaking, with a notice of proposed rulemaking to be signed by December 21, 2009.[6] Following the issuance of a proposed rule, the Agency will provide for a 60-day public comment period, hold public hearings, and solicit CASAC review of the proposed rule. Taking into consideration CASAC and public comments on the proposed rule, the final rule will be signed by August 31, 2010.

[6] This reconsideration will include review of the Air Quality Index (AQI) for $O_3$, such that changes to the AQI will be proposed if the reconsideration results in a proposed change to the 2008 primary $O_3$ standard.

# 2 STATUS AND SCHEDULE FOR NEW REVIEW

. On September 29, 2008, the EPA's NCEA-RTP announced the initiation of a new periodic review of the air quality criteria for $O_3$ and issued a call for information in the Federal Register (73 FR 56581). A wide range of external experts as well as EPA staff, representing a variety of areas of expertise (e.g., epidemiology, human and animal toxicology, statistics, risk/exposure analysis, atmospheric science, ecology, biology, plant science, benefits analysis) participated in a "kick-off" workshop, held by EPA on October 28-29, 2008 in RTP, NC. The proceedings of that workshop have been considered and the issues discussed at the workshop have been incorporated into this draft IRP.

The development of this draft IRP was extended while the Agency reviewed the 2008 $O_3$ NAAQS rule for the purpose of determining whether it would reconsider the 2008 standards, as discussed above in section 1.4. We are releasing this draft IRP for the purpose of conducting a public teleconference consultation with CASAC, planned for November 2009, on the Agency's plans for the continuation of this new review. The final IRP will reflect consideration of comments received from CASAC and the public in presenting plans for the new review of the air quality criteria and standards for $O_3$-related effects on public health and public welfare. This will involve updating the assessments presented in the 2006 AQCD (U.S. EPA, 2006) and the 2007 Staff Paper (U.S. EPA, 2007a) and REAs (U.S. EPA, 2007b; Abt Associates, 2007a,b). Recognizing that the reconsideration of the 2008 standards will be completed early in this new review, before any draft assessment documents are released, this new review will involve reviewing any $O_3$ standards that may be set in the August 2010 final rule that results from the reconsideration of the 2008 $O_3$ standards. While the Agency is reconsidering the 2008 $O_3$ standards, NCEA-RTP will continue the development of the first draft ISA, planned for release to CASAC and the public in November 2010.

The schedule for the entire new review of the air quality criteria and standards is shown below in Table 2-1. The scope of this review and of the key documents to be prepared during this review, are discussed throughout the rest of this document.

**Table 2-1. Proposed Schedule for the New Periodic $O_3$ NAAQS Review**

| **Stage of Review** | **Major Milestone** | **Target Dates** |
|---|---|---|
| Integrated Review Plan (IRP) | Literature Search | Ongoing |
| | Federal Register Call for Information | September 29, 2008 |
| | Workshop on Science/Policy Issues | October 29-30, 2008 |
| | Draft IRP | September 2009 |
| | CASAC Consultation on Draft IRP | November 2009 |
| | Final IRP | December 2009 |
| Integrated Science Assessment (ISA) | First Draft ISA | November 2010 |
| | CASAC/Public Review of First Draft ISA | February 2011 |
| | Second Draft ISA | June 2011 |
| | CASAC/Public Review of Second Draft ISA | September 2011 |
| | Final ISA | December 2011 |
| Risk/Exposure Assessments (REAs) | Prepare Draft Scope and Methods Plans | January 2011 |
| | CASAC Consultation on Draft Scope and Methods Plans | February 2011 |
| | First Draft REAs | July 2011 |
| | CASAC/Public Review of First Draft REAs | September 2011 |
| | Second Draft REAs | March 2012 |
| | CASAC/Public Review of Second Draft REAs | May 2012 |
| | Final REAs | September 2012 |
| Policy Assessment (PA)/ Rulemaking | First Draft PA for CASAC/Public Review | August 2011 |
| | CASAC/Public Review of First Draft PA | September 2011 |
| | Second Draft PA for CASAC/Public Review | April 2012 |
| | CASAC/Public Review of Second Draft PA | May 2012 |
| | Final PA | October 2012 |
| | Proposed Rulemaking | May 2013 |
| | Final Rulemaking | February 2014 |

# 3 KEY POLICY-RELEVANT ISSUES

The key policy-relevant issues to be addressed in this new review are presented below as a series of policy-relevant questions that will frame our approach to determining whether the primary and secondary NAAQS for $O_3$ that result from the Agency's reconsideration of the 2008 $O_3$ standards should be retained or revised. The ISA, REAs, and PA to be developed in this new review will provide the basis for addressing these questions and will inform the Agency's decisions as to whether to retain or revise those primary and secondary standards for $O_3$.

## 3.1 ISSUES RELATED TO THE PRIMARY OZONE NAAQS

The first step in reviewing the adequacy of the primary $O_3$ standard is to consider whether the available body of scientific evidence, assessed in the ISA and used as a basis for the analyses presented in the public health-related REA, supports or calls into question the scientific conclusions reached in the last rulemaking regarding health effects related to exposure to $O_3$ in ambient air. This evaluation of the available scientific evidence will focus on key policy-relevant issues by addressing a series of questions including the following:

- To what extent has new scientific information become available that alters or substantiates our understanding of the health effects associated with various time periods of exposure to ambient $O_3$, including short-term (1 to 3 hrs), prolonged (6 to 8 hrs), and chronic (months to years) exposures?
- To what extent has new scientific information become available that alters or substantiates our understanding of the health effects of $O_3$ on at-risk populations, including those with increased susceptible and/or vulnerability? [7]
- To what extent has new scientific information become available that alters or substantiates conclusions from previous reviews regarding the plausibility of adverse health effects caused by $O_3$ exposure?

[7] *Susceptibility* refers to innate (e.g., genetic or developmental) or acquired (e.g., age, disease, or smoking) factors that make individuals more likely to experience effects with exposure to $O_3$. *Vulnerability* refers to $O_3$-related effects due to factors including socioeconomic status (e.g., reduced access to health care) or particularly elevated exposure levels.

- At what levels of $O_3$ exposure are health effects observed? Is there evidence of effects at exposure levels lower than those previously observed, and what are the important uncertainties associated with that evidence? What is the nature of the exposure-response relationships of $O_3$ for the various health effects evaluated?
- To what extent has new scientific information become available that alters or substantiates our understanding of non-$O_3$-exposure factors that might influence the associations between $O_3$ levels and health effects being considered (e.g., weather-related factors; behavioral factors such as heating/air conditioning use; driving patterns; and time-activity patterns)?
- To what extent do risk and/or exposure analyses suggest that exposures of concern for $O_3$-related health effects are likely to occur with current ambient levels of $O_3$ or with levels that just meet the $O_3$ standard? Are these risks/exposures of sufficient magnitude such that the health effects might reasonably be judged to be important from a public health perspective? What are the important uncertainties associated with these risk/exposure estimates?
- To what extent have important uncertainties identified in the last rulemaking been addressed and/or have new uncertainties emerged?

Drawing upon the evidence and analyses presented in the ISA and REA, EPA will evaluate whether revisions to the primary $O_3$ standard might be appropriate, and, if so, how this standard might be revised. Specifically, EPA will evaluate how the scientific information and assessments inform decisions regarding the basic elements of the NAAQS: indicator, averaging time, level, and form. These elements will be considered collectively in evaluating the health protection afforded by the current or any alternative standards considered. Specific policy-relevant questions that will be addressed include:

- To what extent is there any new information that would support consideration of a different indicator for photochemical oxidants?
- To what extent do the health effects evidence evaluated in the ISA, air quality analyses, and the REA provide support for considering different averaging times?

- To what extent do air quality analyses and other information provide support for consideration of alternative forms?
- What range of alternative standard levels should be considered based on the scientific evidence evaluated in the ISA, air quality analyses, and the REA?
- In considering alternative standards, to what extent do alternative levels, averaging times and forms reduce estimated exposures and risks of concern attributable to $O_3$ and other photochemical oxidants, and what are the uncertainties associated with the estimated exposure and risk reductions?
- What are the important uncertainties and limitations in the evidence and assessments and how might those uncertainties and limitations be taken into consideration in identifying alternative standards for consideration?

## 3.2 ISSUES RELATED TO THE SECONDARY OZONE NAAQS

The first step in reviewing the adequacy of the secondary $O_3$ standard is to consider whether the available body of scientific evidence, assessed in the ISA and used as a basis for the analyses presented in the public welfare-related REA, supports or calls into question the scientific conclusions reached in the last rulemaking regarding welfare effects related to exposure to $O_3$ in ambient air. This evaluation of the available scientific evidence will focus on key policy-relevant issues by addressing a series of questions including the following::

- To what extent has new scientific information become available that alters or substantiates our understanding of the effects on vegetation and other welfare effects following exposures to levels of $O_3$ found in the ambient air?
- To what extent has new scientific information become available to inform our understanding of the nature of the exposures that are associated with such effects in terms of biologically relevant cumulative, seasonal exposure indices?
- To what extent has new scientific information become available that alters or substantiates our understanding of the effects of $O_3$ on sensitive plant species, ecological receptors, or ecosystem processes?

- To what extent has new scientific information become available that alters or substantiates our understanding of exposure factors other than $O_3$ that might influence the associations between $O_3$ levels and welfare effects being considered (e.g., site specific features such as elevation, soil moisture level, presence of co-occurring competitors, pests, pathogens, other pollutant stressors, weather-related factors)?
- To what extent has new scientific information become available that alters or substantiates conclusions regarding the occurrence of adverse welfare effects at levels of $O_3$ as low as or lower than those observed previously? What is the nature of the exposure-response relationships of $O_3$ for the various welfare effects evaluated?
- Given recognition in the last rulemaking that the significance of $O_3$-induced effects to the public welfare depends in part on the intended use of the plants or ecosystems on which those effects occurred, to what extent has new scientific evidence become available to suggest additional locations where the vulnerability of sensitive species or ecosystems would have special significance to the public welfare and should be given increased focus in this review?
- To what extent do risk and/or exposure analyses suggest that exposures of concern for $O_3$-related welfare effects are likely to occur with current ambient levels of $O_3$ or with levels that just meet the $O_3$ standard? Are these risks/exposures of sufficient magnitude such that the welfare effects might reasonably be judged to be important from a public welfare perspective? What are the important uncertainties associated with these risk/exposure estimates?
- To what extent have important uncertainties identified in the last rulemaking been addressed and/or have new uncertainties emerged?

Drawing upon the information and assessments presented in the ISA and REA, EPA will evaluate whether revisions to the secondary $O_3$ standard might be appropriate, and, if so, how this standard might be revised. Specifically, EPA will evaluate how the scientific information and assessments inform decisions regarding the basic elements of the NAAQS: indicator, averaging time, level, and form. These elements will be considered collectively in evaluating the welfare protection afforded by the current or any alternative standards considered. Specific policy-relevant questions that will be addressed include:

- To what extent is there any new information that would support consideration of a different indicator for photochemical oxidants?
- To what extent do the welfare effects evidence evaluated in the ISA, air quality analyses, and the REA provide support for considering different averaging times and forms that reflect biologically relevant exposure indices?
- What range of alternative standard levels should be considered based on the scientific information evaluated in the ISA, air quality analyses, and the REA?
- In considering alternative standards, to what extent do alternative levels, averaging times, and forms reduce estimated exposures and risks of concern attributable to $O_3$ and other photochemical oxidants, and what are the uncertainties associated with the estimated exposure and risk reductions?
- What are the important uncertainties and limitations in the evidence and assessments and how might those uncertainties and limitations be taken into consideration in identifying alternative standards for consideration?

# 4 SCIENCE ASSESSMENT

## 4.1 SCOPE AND ORGANIZATION

As noted in chapter 1, the Integrated Science Assessment (ISA) is a concise review, synthesis, and evaluation of the most policy-relevant science that communicates critical science judgments relevant to the NAAQS review. The current ISA serves to update and revise the scientific information available at the time of the last review of the air quality criteria. As such, the ISA forms the scientific foundation for the new review of the primary (health-based) and secondary (welfare-based) NAAQS. A general outline of the types of information that are considered is provided in the illustration below. The judgments and conclusions drawn in the ISA are intended to support risk, exposure and policy analyses as well as decisions to retain or revise the NAAQS.

**HEALTH EFFECTS**

- Effects on the health of the general population, or identifiable groups within the population, who are exposed to pollutants in ambient air
- Effects on mortality
- Effects on morbidity
- Effects on other health outcomes

**WELFARE EFFECTS**

- Effects on the environment, including:
  - animals
  - climate
  - crops
  - materials
  - soils
  - vegetation
  - visibility
  - water
  - weather
  - wildlife
- Effects on economic values
- Effects on personal comfort
- Deterioration of property

Source: Adapted from U.S. EPA (2001)

The science assessment will consist of an ISA and supporting annexes which are discussed in more detail in subsequent sections. In brief, the ISA critically evaluates and integrates the scientific information on the health and welfare effects associated with exposure to $O_3$ and related photochemical oxidants in ambient air. The annexes are intended to provide additional technical details of pertinent studies that may or may not otherwise be noted within the ISA. These documents will not provide a detailed literature review; but, rather, will discuss the current state of knowledge on the most relevant scientific literature on issues pertinent to the review of the NAAQS for $O_3$. Discussions in the ISA will primarily focus on scientific evaluations that can inform the key policy questions described in chapter 3 of this document. Although emphasis is placed on discussion of health and welfare effects information, other scientific data are presented and evaluated in order to provide a better understanding of the nature, sources, measurement, and concentration distribution of $O_3$ and related photochemical oxidants in ambient air, as well as the measurement of population exposure to these pollutants.

The ISA will build on the conclusions of the 2006 CD (U.S. EPA, 2006) and focus on peer reviewed literature published since the previous review of the air quality criteria for $O_3$. The 2006 CD (U.S. EPA, 2006) primarily evaluated literature published through December 2004. Major legal and historical aspects of prior review documents as well as key milestones and procedures for document preparation will be briefly summarized at the beginning of the ISA. In subsequent chapters the results of recent scientific studies will be integrated with previous findings. Important older studies will be more specifically discussed if they are open to reinterpretation in light of newer data and/or to reinforce key concepts and conclusions. Emphasis will be placed on studies conducted at or near $O_3$ concentrations found in ambient air. Other studies are included if they contain unique data, such as a previously unreported effect or mechanism for an observed effect, or examine multiple concentrations to elucidate exposure-response relationships.

## 4.2 ASSESSMENT APPROACH

**Introduction**

The EPA's National Center for Environmental Assessment in Research Triangle Park (NCEA-RTP) is responsible for preparing the ISA and its annexes for $O_3$. Expert authors include EPA staff with extensive knowledge in their respective fields and extramural scientists solicited by EPA for their expertise in specific fields. A diagram showing the standard protocol for development of an ISA is shown in Figure 4.1. A description of the recently revised NAAQS process is addressed in section 1.2.

## Literature Search

The NCEA-RTP will use a systematic approach to identify relevant studies for consideration. The EPA has already published a Federal Register notice (73 FR 56581, September 29, 2008) to announce the initiation of this review and request information from the public. In addition to the call for information, publications will be identified through an ongoing literature search process that includes extensive computer database mining on specific topics. Additional publications will be identified by EPA scientists in a variety of disciplines by combing through relevant, peer reviewed scientific literature obtained through these ongoing literature searches, reviewing previous EPA reports, and a review of reference lists from key publications; studies are also identified in the course of CASAC and public review.

Relevant epidemiologic, human clinical, and animal toxicological studies, including those related to exposure response relationships, mode(s) of action (MOA), susceptible or vulnerable subpopulations, and ecological or welfare effects studies published since the last air quality criteria review will be considered. Additionally, air quality and emissions data, studies on atmospheric chemistry, transport, and fate of these emissions, as well as issues related to $O_3$ exposure are considered. Further information will be acquired from consultation with content and area experts and the public. The studies identified will include research published or accepted for publication by a date determined to be as inclusive as possible given the relevant target dates in the $O_3$ NAAQS review schedule. Some additional studies, published after that date, may also be included if they provide new information that impacts one or more key scientific issues. The combination of these approaches should produce the comprehensive collection of pertinent studies needed to form the basis of the ISA.

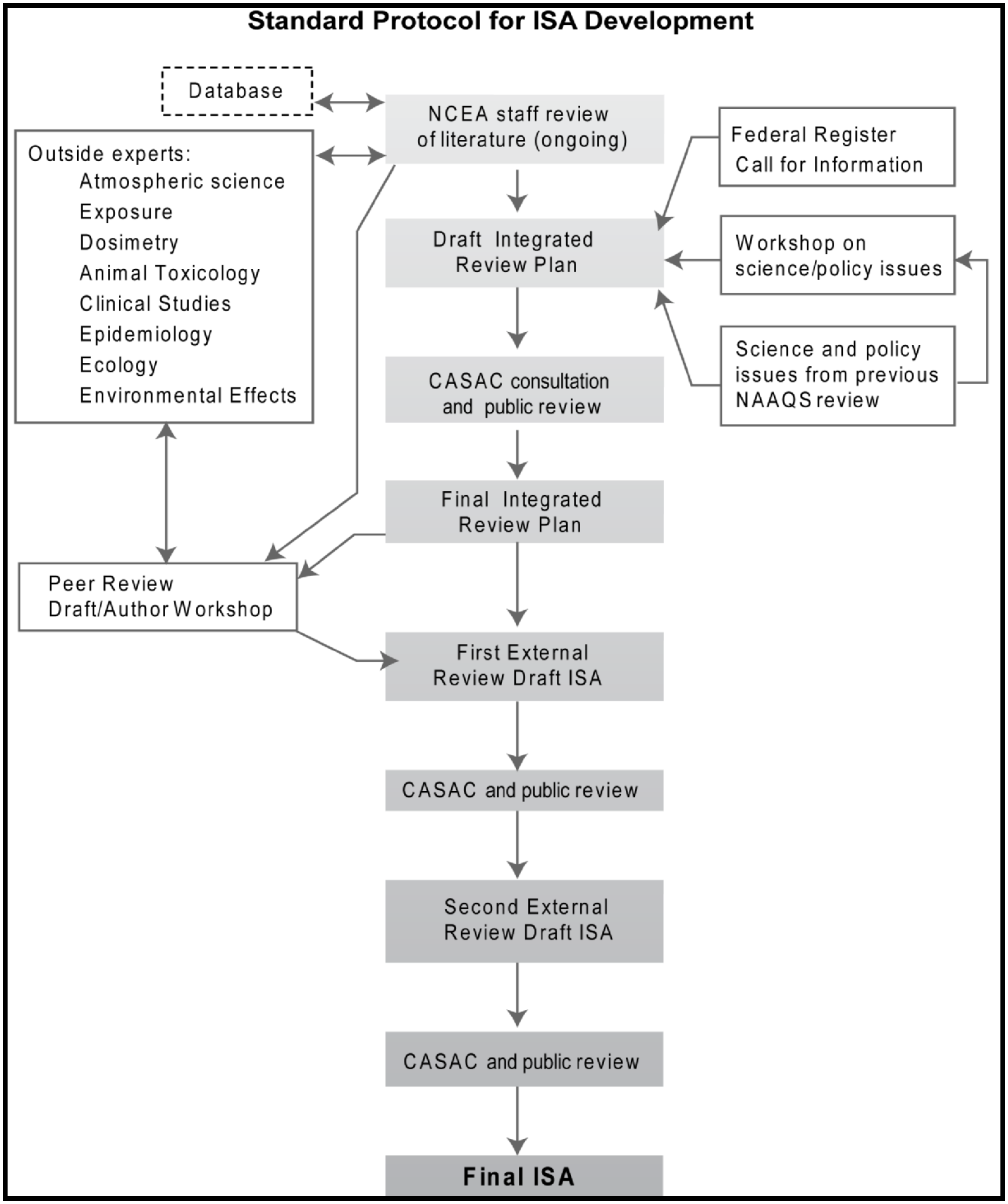


**Figure 4.1 Standard steps in the development of Integrated Science Assessments (ISAs)**

**Criteria for Study Selection**

In selecting epidemiologic studies for the present assessment, EPA will consider studies containing information on (1) short- or long-term exposures at or near ambient levels of $O_3$; (2) health endpoints that repeat or extend findings from earlier assessments as well as those not previously extensively researched; (3) populations that are susceptible and/or vulnerable to $O_3$ exposures; (4) issues related to potential confounding, and modification of effects; and/or (5) important methodological issues (e.g., lag of effects, model specifications, thresholds, mortality displacement) related to $O_3$ exposure effects. Among the epidemiologic studies, emphasis will be focused on those relevant to standard setting in the United States. Specifically, studies conducted in the U.S. or Canada will be generally accorded more emphasis than those from other geographic regions, as the potential impacts of different health care systems and the underlying health status of populations need to be accounted for in the assessment. However, informative studies conducted in other countries will be included, as appropriate. In addition, emphasis will be placed on discussion of (1) new, multi-city studies that employ standardized methodological analyses for evaluating $O_3$ effects, provide overall estimates for effects based on combined analyses of information pooled across cities, and examine results for consistency across cities; (2) new studies that provide quantitative effect estimates for populations of interest; and (3) studies that evaluate $O_3$ as a component of a complex mixture of air pollutants and thus give consideration to the levels of other co-pollutants.

The selection of research evaluating controlled exposures of laboratory animals will focus primarily on those studies conducted at or near ambient $O_3$ concentrations and those studies that approximate expected human dose conditions in terms of concentration and duration, which will depend on the toxicokinetics and biological sensitivity of the particular laboratory animals examined. Studies will be sought that reveal site-specific effects of $O_3$ exposure within the respiratory tract. Consideration will be given mainly to animal studies conducted at less than 1 ppm $O_3$. The necessity of such upper concentrations limits may be illustrated by rats, a key species used in $O_3$ toxicological studies, but a species having both behavioral and physiological mechanisms that can lower core temperature in response to acute exposures, thus limiting extrapolation of data to human responses. However, in recognition of the fact that toxicological studies using near ambient concentrations of $O_3$ or other pollutants do not necessarily reflect effects in the most sensitive populations, studies at higher exposure levels may be included when they provide information relevant to previously unreported effects, evidence of potential mechanisms for an observed effect, information on exposure-response relationships, or otherwise improve our understanding of interspecies differences or susceptible populations. Additionally, in vitro studies may provide information on related to mechanisms of $O_3$ uptake and effect or the influence of photochemical oxidation processes that would otherwise be unavailable through in vivo studies. The appropriateness of $O_3$ concentrations will be evaluated as necessary.

For research evaluating controlled human exposures to $O_3$, emphasis will be placed on studies that: (1) investigate effects in healthy populations and/or potentially susceptible populations such as those with preexisting respiratory diseases; (2) include appropriate control (or sham) exposures such as filtered air so that subjects serve as their own control as well as the use of age-matched healthy controls in studies of susceptible individuals; (3) address issues such as dose-response or time-course of responses; (4) investigate exposure to $O_3$ separately and in combination with other pollutants such as PM and $NO_2$; and (5) have sufficient sample size and statistical power to assess findings adequately. Due to the limited amount of recently published controlled human exposure studies, much of the available scientific information is expected to come from literature that has been included in prior reviews. This older literature will be reevaluated and discussed in light of more recent epidemiologic findings and mechanistic toxicological data, as well as new controlled human exposure studies.

For evaluation of welfare effects research, emphasis shall be placed on recent studies that: (1) evaluate effects at realistic ambient levels and (2) investigate effects on cultivated and non-cultivated vegetation and ecosystems that occur in the U.S. Studies conducted in other geographical areas will be included in the assessment when they contribute to the general knowledge of the effects of $O_3$ irrespective of species or locality. As in the evaluation of health-related scientific studies, the evaluation of welfare-related studies will assess advances in our understanding of mechanisms of direct $O_3$ effects on vegetation and the resulting consequences on growth and yield, principally. Effects on larger scale ecosystem structure, function and services will also be considered. These and other welfare effects will be addressed in the ISA for both short- and long-term $O_3$ exposures. Evaluations of research methodologies will be integrated into the discussion to allow for comparisons between methodologies and to allow characterization of the uncertainties associated with estimating exposure of vegetation using different types of experimental systems.

These criteria provide generalized benchmarks for evaluating various studies and for focusing on the highest quality studies in assessing the body of health and welfare effects evidence. Detailed critical analysis of all $O_3$ health and welfare effects studies, especially in relation to the above considerations, is beyond the scope of this document. Of most relevance for evaluation of studies is whether they provide useful qualitative or quantitative information on exposure-effect or exposure-response relationships for effects associated with current ambient air concentrations of $O_3$ likely to be encountered in the United States. Since the last scientific review was completed relatively recently, i.e., within the past four years, it is expected that a considerable portion of the current ISA could reasonably be devoted to reiterating the basis for scientific conclusions reached in last rulemaking.

**Quality Assurance**

Important quality assurance measures will be incorporated from the start of the current $O_3$ review. EPA uses scientific information found in peer-reviewed journal articles, books, and government reports. The approaches utilized to search the literature and criteria for study selection were detailed in the two preceding subsections. Additionally, NCEA has Data Quality Objectives which identify inputs to the science assessment and provide quality assurance (QA) instruction for researchers citing secondary information.

**Content and Organization of the ISA**

The organization of the ISA for $O_3$ will be consistent with that used in the second external review draft ISA for particulate matter (U.S. EPA, 2009a). The ISA will contain information relevant to considering whether it is appropriate to retain or revise the current standards. Taking into consideration the broad policy-relevant questions outlined in chapter 3, the policy-relevant questions that will guide development of the ISA are related to two overarching issues. The first issue is the extent to which new scientific evidence has become available that alters or substantiates the scientific evidence presented and evaluated in the last $O_3$ NAAQS review. The second issue is whether uncertainties from the last air quality criteria review have been addressed and/or whether new uncertainties have emerged. Specific questions related to the review of the scientific literature for $O_3$ that stem from these issues will guide the content of the ISA. These questions were derived from the last $O_3$ NAAQS rulemaking, as well as from discussions of new scientific evidence that occurred at the EPA kickoff workshop (October 29-30, 2008) for this review of $O_3$ and related photochemical oxidants. These questions are listed below by topic area.

**Source to Exposure**

Air Quality and Atmospheric Science: The ISA will present and evaluate data related to: ambient concentration distributions of $O_3$, and its potential associations with other photochemical oxidants and with other relevant atmospheric pollutants. New information concerning the mechanisms of formation $O_3$ and other photochemical oxidants and the physical properties governing their transport and lifetimes in the atmosphere will be considered. The ISA will assess the appropriateness and utility of using $O_3$ as the chemical indicator of the broad range of atmospheric oxidants for which this NAAQS is defined by evaluating relevant data concerning the origin, transformation and transport, and fate of atmospheric oxidants in addition to $O_3$. The assessment will also include information about the distribution of monitors in the regulatory $O_3$ network relevant for the interpretation of health and ecosystem effects and new studies dealing with the precision and accuracy of the Federal Reference and Federal Equivalent Methods (FRM and FEM, respectively) for $O_3$. New information on the distribution of ambient $O_3$ concentrations from in situ instruments, satellites, and other remote sensing tools will also be considered. Since a key issue for the Risk and Exposure Assessments (REAs) will be the distribution of the policy-relevant background (PRB)[8] concentration of $O_3$ in the U.S., the ISA will include an assessment of methods for producing these concentrations and will provide estimates of $O_3$ PRB concentrations for possible use in the REAs. Because the secondary standard includes treatment of $O_3$ effects on climate, the ISA will include evaluation of data relevant to the issue of tropospheric $O_3$ as a constituent greenhouse gas and its effects as an absorber of UV-B radiation in the troposphere.

[8] "Policy-relevant background" has been defined historically as the $O_3$ concentrations that would be observed in the U.S. in the absence of anthropogenic emissions of $O_3$ precursors (e.g., VOC and NOx) in the U.S., Canada, and Mexico. Under this definition, PRB concentrations include contributions from natural sources everywhere in the world and from anthropogenic sources outside continental North America (U.S. EPA, 2006).

Exposure: The ISA will compile and evaluate information new since the last assessment that helps characterize the variability and uncertainty in the relationships between ambient $O_3$ concentrations and exposures to $O_3$ of humans and ecosystems relevant to the primary and secondary standards. Regarding the primary standard for human health, this means assessing data concerning the range of measured $O_3$ concentrations in various human microenvironments including indoors, outdoors near roadways, in vehicles, etc. and its relationship with concentrations measured by ambient monitors. EPA will also assess data concerning errors in measurement or estimation of human exposures as well as the possibly differential exposures of some subpopulations.

**Human Health Effects**

The ISA will evaluate the literature related to respiratory, cardiovascular, and other health effects associated with short and/or long term exposures to $O_3$. Building upon the last air quality criteria review, EPA plans to continue to review the available scientific evidence related to these health endpoints and to integrate the previous findings with the results of new studies on these health endpoints and, to the extent data are available, on additional endpoints of concern (e.g., developmental, inflammatory, carcinogenic/mutagenic, and cellular outcomes). Health effects that occur following short- (including sub-daily) and/or long-term exposures to $O_3$ will be evaluated in epidemiologic, human clinical, and toxicological studies. The ISA will also integrate previous information on sensitive subpopulations (e.g., asthmatics, children, outdoor workers) with new evidence for these and possibly other sensitive subpopulations (e.g., fetuses, neonates, genetically susceptible populations).

For a given type of health outcome, the ISA will evaluate the strength, robustness and consistency of the findings from the different disciplines. The health findings will be further integrated, using the toxicological and human clinical studies to assess biological plausibility and mechanistic evidence for the epidemiologic findings. Efforts will be directed at identifying the lower levels at which effects are observed and at determining concentration-response relationships. Concentration-response relationships among these studies will be evaluated for coherence. The ISA will evaluate the scientific evidence on the occurrence of health effects from short-term or long-term exposure to $O_3$ at ambient levels. The ISA will also assess the evidence for uncertainties related to these associations and information on the public health implications related to ambient $O_3$ exposure. The evaluation will also focus on which exposure durations and developmental time periods of exposure are most strongly associated with effects, for both short-term and long-term exposures. Grouped by topic area, some of the scientific questions that EPA will seek to address in the ISA follow.

Health Effects from Exposure: The ISA will evaluate health effects evidence for a multitude of outcomes from epidemiologic, toxicological, and human clinical studies.

- How do results of recent studies expand our understanding of the relationship between short-term exposure to $O_3$ and respiratory effects, such as lung function changes, airways hyperresponsiveness, lung inflammation, and host defense against infectious disease? What new evidence is available on the potential clinical relevance of these effects? Do recent studies expand the current understanding of adaptation to repeated short-term $O_3$ exposures?
- Do long-term exposures to $O_3$ result in chronic effects manifested as permanent lung tissue damage, altered lung development, or accelerated decline in lung function with age? To what extent does long-term $O_3$ exposure promote development of asthma or chronic lung or cardiovascular disease?
- Does new evidence from studies of hospital admissions or emergency department visits support previous findings regarding respiratory or cardiovascular effects of $O_3$? Is there evidence of coherence and plausibility for such effects?
- What new evidence is available on associations between $O_3$ and mortality (total, respiratory or cardiovascular)?
- To what extent is key evidence becoming available that could inform the understanding of subpopulations that are particularly susceptible to $O_3$ exposures? What is known about genetic traits that underlie susceptibility? Are new animal models becoming available to better characterize sensitive subpopulations?
- What $O_3$-induced health effects are sufficiently characterized to be quantitatively compared across species?

- To what extent does exposure to $O_3$ contribute to health effects in other organ systems?
- What new evidence has become available to help discern health effects of multipollutant exposures (containing $O_3$) versus $O_3$ alone (e.g., additive, synergistic, or antagonistic effects)?

Uncertainties: The ISA will evaluate uncertainty in the scientific data, particularly in relation to observed epidemiologic findings and their consistency with toxicological and controlled human exposure studies in terms of observed effects and biological pathways.

- How do meteorological factors and co-exposure to other criteria pollutants (e.g., PM, $NO_2$, $SO_2$, and CO) influence the uncertainty of the evidence base for both short- and long-term $O_3$ exposures?
- To what extent are the observed health effects attributable to $O_3$ versus other oxidants that are associated with $O_3$?
- What are the uncertainties due to other factors in epidemiologic studies (e.g., demographic and lifestyle attributes, socioeconomic status, genetic susceptibility factors, occupational exposure, and medical care)?
- What is the nature and shape of the concentration-response models (e.g., linear, non-linear, threshold models) based on $O_3$ studies?
- What uncertainties surround the evidence for long-term effects such as life shortening and development/progression of disease?
- How do the findings of the available studies improve our understanding of exposure error? What evidence is newly available on the uncertainties related to statistical model specification and how can it be used to assess the influence of these uncertainties on the outcome of epidemiologic studies?

Biological Mechanism(s) or Modes of Action: The ISA will evaluate the data examining mechanisms for the health outcomes associated with exposure to $O_3$.

- Is there new information related to the pathways and underlying biological mechanism(s) or modes of action for $O_3$?
- What are the inherent interspecies differences in sensitivity to $O_3$ and in $O_3$ dosimetry in different regions of the respiratory tract? Are there site-specific responses to $O_3$ in the respiratory tract that would better explain local and systemic effects of $O_3$ exposure?
- What are the interspecies differences in basic mechanisms of lung injury and repair and cardiovascular responses? What are the implications of interspecies differences for extrapolation of results to humans?
- What are the mechanisms and time-courses of $O_3$-induced cellular and tissue injury, repair, and remodeling?

Susceptible and Vulnerable Populations: The ISA will examine health outcome data to identify specific groups that are more susceptible and/or vulnerable to the adverse effects of $O_3$ exposure than normal healthy adults (e.g., patients with COPD, children, and asthmatics). The host and environmental factors that are responsible for differential susceptibility to $O_3$ will be investigated.

- What do controlled human exposure, animal toxicological, and epidemiologic studies indicate regarding the relationship between acute exposures to $O_3$ and health effects of concern in healthy individuals and those with preexisting diseases (e.g., asthma, COPD, cardiovascular diseases)? What other medical conditions (e.g., diabetes, metabolic syndrome) are identified as increasing susceptibility to $O_3$ effects? What are the pathways and mechanisms through which $O_3$ may be acting for these groups? What is the nature and time-course of the development of effects in healthy persons and in persons with pre-existing disease (e.g., asthma, heart disease)?
- Are children and older adults are more sensitive than the general population to effects from $O_3$ exposure? With regard to the interpretation of epidemiologic results and exposure-response characteristics of populations, to what extent are these findings driven by effects in sensitive subpopulations?

- What evidence is available regarding susceptibility to $O_3$-induced responses in subgroups due to age, race, gender, or genetic makeup? To what extent is susceptibility to the effects of short-term $O_3$ exposure is associated with long-term $O_3$ susceptibility?
- What factors (e.g., demographic and socioeconomic) affect vulnerability to short- and long-term $O_3$ exposures? Are there new data regarding population groups with potentially greater vulnerability to effects of $O_3$?

Public Health Implications: The ISA will present concepts to define potential health outcomes and their implications on public health. This will include estimates of the numbers of people in specific at-risk populations groups (e.g., asthmatics, diabetics, older adults, and children).

Causality: EPA will assess the results of recent relevant publications, building upon evidence available during the previous NAAQS review, to draw conclusions on the causal relationships between health effects and $O_3$ exposures. The EPA has developed a framework that provides a consistent and transparent basis to evaluate the causal nature of air pollution-induced health or environmental effects (for a detailed discussion see chapter 1 of U.S. EPA, 2009a). Considerations that are expected to play a larger role in determination of causality are consistency of results across studies, coherence of effects observed in different study types or disciplines, biological plausibility, and exposure-response relationships. The ISA will place emphasis on health studies conducted at or near typical ambient levels, except those providing evidence of biological plausibility and mechanisms, as these may only be observable in animal or human exposure study populations at higher levels than they might be observed in susceptible human populations.

**Vegetation, Ecosystems and other Welfare Effects**

The ISA will evaluate the literature related to $O_3$ exposures on the growth of vegetation, visible foliar injury, ecosystem services and other welfare effects. This will include evaluation of $O_3$ exposures on productivity of ecosystems and crops systems and potential effects on services such as $CO_2$ sequestration. Other effects that will be evaluated include $O_3$ effects on materials. Grouped by topic area, some scientific questions that EPA will seek to address in the ISA follow.

Vegetation: Scientific studies have previously reported concentration response functions for the relationship between $O_3$ exposure and plant response for a range of endpoints. The ISA will consider key uncertainties identified in the last air quality criteria review and the extent to which new scientific evidence may be available to substantially inform our ability to characterize and/or reduce these uncertainties.

- Past reviews have highlighted evidence from $O_3$ exposure experiments performed in open-top chambers (OTCs). More recent studies have also utilized other techniques such as Free-air exposures (FACE) and gradient studies. In what ways does the more recent literature inform our understanding of $O_3$ exposure on vegetation? For example, topics may include: comparing OTC results to other studies and differences between small and large trees.
- Though there is a large, historic body of research on $O_3$ effects on vegetation, there has been no common metric used across studies to describe the relationship between $O_3$ exposures and plant response. How can $O_3$ studies which use various $O_3$ metrics, plant species and methodologies be appropriately quantitatively synthesized and assessed?

Ecosystem Services: Some recent research has examined further how $O_3$ effects are potentially linked to ecosystem services. Such linked ecosystem services identified in recent studies include water supply and quality, N-cycling, bee pollination, and $CO_2$ sequestration.

- What is the nature of the information linking $O_3$ pollution and ecosystem services? What are the existing studies that make direct or indirect linkages between $O_3$ exposure and ecosystem services? How can studies at smaller scales be used to address ecosystem services issues?
- Can information available in the older literature be re-examined in light of these broader linkages?
- What new information is available on potential effects of $O_3$ on $CO_2$ sequestration in ecosystems?
- How does $O_3$ influence the biodiversity of ecological systems?

- Has $O_3$ altered nutritional content of forage for domestic animals or wildlife populations?

<u>Materials Damage:</u> Ozone and other photochemical oxidants react with many economically important man-made materials, decreasing their useful life and aesthetic appearance. Materials damaged by $O_3$ include elastomers; textiles and fibers; dyes, pigments, and inks; and paints and other surface coatings. The new scientific literature will be evaluated in this area to determine the extent to which new scientific evidence may inform the standard.

**Annex Materials**

The ISA will be supplemented by a series of annexes. The annexes are intended to provide additional technical details of pertinent studies that may or may not otherwise be noted within the ISA. These materials will not provide a detailed literature review; but, rather, summarize the most relevant scientific literature on issues pertinent to the review of the NAAQS for $O_3$. The annexes will provide supplementary information on (1) the chemistry, physics, sources, emissions, and measurement of $O_3$; (2) environmental concentrations and human exposure to $O_3$; (3) dosimetry; (4) toxicological studies of $O_3$ health effects in laboratory animals and *in vitro* systems; (5) human clinical studies examining health effects following controlled exposure to $O_3$; (6) epidemiologic studies of health effects from short- and long-term exposure to $O_3$; (7) environmental studies on material damage and ecosystem stress; and (8) climate change related to $O_3$. More detailed information on various methods and results for the health and environmental studies will be summarized in tabular form in the annexes. These tables will generally be organized to include information about (1) concentrations of $O_3$ and related averaging times; (2) description of study methods used; (3) results and comments; and (4) quantitative outcomes for $O_3$ measures. Additionally, the annexes may contain background material on legislative requirements, the NAAQS review process, and the history of earlier $O_3$ reviews.

## 4.3 SCIENTIFIC AND PUBLIC REVIEW

Drafts of the ISA will be reviewed by the CASAC $O_3$ Review Panel and made available for public comment. The annexes to the ISA will also be made available to CASAC in order to assist with their review; however, the panel will not be specifically charged with reviewing the annexes.  The CASAC $O_3$ Review Panel will review the first draft ISA and discuss their comments in a public meeting announced in the Federal Register.  Based on CASAC's past practice, EPA anticipates that key CASAC advice and recommendations for revision of the first draft ISA will be summarized by the CASAC Chair in a letter to the EPA Administrator.  In revising the first draft ISA, EPA will take into account any such recommendations.  EPA will also consider comments received from CASAC or from the public at the meeting itself and any written public comments.  EPA will prepare a second draft ISA for CASAC review and public comment. The CASAC $O_3$ Review Panel will review the second draft ISA and discuss their comments in a public meeting announced in the Federal Register.  Again, based on CASAC's past practice, EPA anticipates that key CASAC advice and recommendations for revision of the second draft ISA will be summarized by the CASAC Chair in a letter to the EPA Administrator. In finalizing the ISA, EPA will take into account any such recommendations. EPA will also consider comments received from CASAC or from the public at the meeting itself and any written public comments.  After appropriate revision, the final document will be made publicly available on an EPA website and in hard copy.  A notice announcing the availability of the final ISA will be published in the Federal Register.  In addition, the final ISA will be placed in the rulemaking docket.

# 5 HUMAN HEALTH RISK AND EXPOSURE ASSESSMENTS

## 5.1 OVERVIEW

Characterizing health risks for the new periodic review of the primary NAAQS for $O_3$ will include conducting air quality analyses to support quantitative exposure and risk assessments in specific locations as well as putting the results into a broader public health perspective. These assessments will be designed to estimate human exposures and to characterize the potential health risks that are associated with current ambient levels, with ambient levels simulated to just meet the current standard, and with ambient levels simulated to just meet alternative standards that may be considered. The EPA is planning to focus the quantitative exposure/risk assessments on $O_3$, but recognizes that $O_3$ serves as an indicator of the broader photochemical oxidant mix. Therefore, health effects reported to be associated with exposure to $O_3$ may not be due to $O_3$ only, but to the broader mix of photochemical oxidants.

An important issue associated with conducting exposure and human health risk assessments is the treatment of variability and the characterization of uncertainty. *Variability* refers to the inherent heterogeneity in a population or variable of interest (e.g., residential air exchange rates) and cannot be reduced through further research, only better characterized with additional measurement. *Uncertainty* refers to the lack of knowledge regarding both the actual values of model input variables (i.e., *parameter* uncertainty) and the physical systems or relationships (i.e., *model* uncertainty – e.g., the shapes of concentration-response relationships). As part of such analyses, variability and uncertainty will be explicitly addressed, where feasible, in the planned air quality, exposure, and health risk assessments.

The major components of the risk characterization (e.g., air quality analyses, quantitative exposure assessment, quantitative health risk assessment, broad health risk characterization) are outlined below and will be described in more detail in a draft Scope and Methods Plan. Preparation of this draft plan will coincide with the development of the first draft ISA to facilitate the integration of policy-relevant science into both documents. In particular, the availability of air quality, exposure-response, concentration-response, and baseline incidence data will impact the type of risk and exposure assessments that will be developed.

## 5.2 EXPOSURE AND HEALTH RISK ASSESSMENTS FROM RULEMAKING COMPLETED IN MARCH 2008

The exposure and health risk assessment conducted in the rulemaking completed in March 2008 developed exposure and health risk estimates for 12 urban areas across the U.S. which were chosen based on the location of $O_3$ epidemiologic studies and to represent a range of geographic areas, population demographics, and $O_3$ climatology. This analysis was in part based upon the exposure and health risk assessments done as part of the review completed in 1997. The exposure and risk assessment incorporated air quality data (i.e., 2002 through 2004) and estimated annual or $O_3$ season-specific exposure and risk estimates for these recent years of air quality and for air quality scenarios simulating just meeting the existing 8-hr $O_3$ standard and several alternative 8-hr $O_3$ standards. Exposure estimates were used as an input to the risk assessment for lung function responses (i.e., a health endpoint for which exposure-response functions were available from controlled human exposure studies). Exposures were estimated for the general population and identified subpopulations, including school age children with asthma as well as all school age children. The modeled exposures were also used to estimate the number of persons having exposures above potential health effect benchmark levels. Staff identified the benchmark levels using the occurrence of observed health effect endpoints (e.g., lung inflammation, increased airway responsiveness, and decreased resistance to infection) that were associated with 6-8 hour exposures to $O_3$ while engaged in moderate exertion that were observed in several controlled human exposure studies.

The exposure analysis took into account several important factors including the magnitude and duration of exposures, frequency of repeated high exposures, and breathing rate of individuals at the time of exposure. Estimates were developed for several indicators of exposure to various levels of $O_3$ air quality, including counts of people exposed one or more times to a given $O_3$ concentration while at a specified breathing rate, and counts of person-occurrences which accumulate occurrences of specific exposure conditions over all people in the population groups of interest over an $O_3$ season.

As discussed in the Staff Paper and in section II.A of the $O_3$ Final Rule (73 FR 16440 to 16442, March 27, 2008), of the uncertainties identified and evaluated, the most important uncertainties affecting the exposure estimates were related to modeling human activity patterns over an $O_3$ season, modeling of variations in ambient concentrations near roadways, and modeling of air exchange rates that affect the amount of $O_3$ that penetrates indoors. Another important uncertainty, discussed in more detail in the Staff Paper (section 4.3.4.7), was the uncertainty in energy expenditure values which directly affect the modeled breathing rates. These were important since they were used to classify exposures occurring when children were engaged in moderate or greater exertion and health effects observed in the controlled human exposure studies generally occurred under these exertion levels for 6 to 8-hr exposures to $O_3$ concentrations at or near 0.08 ppm.

The human health risk assessment presented in the 2008 rulemaking was designed to estimate population risks in a number of urban areas across the U.S., consistent with the scope of the exposure analysis described above. The risk assessment included risk estimates based on both controlled human exposure studies and epidemiologic and field studies. Ozone-related risk estimates for lung function decrements were generated based on probabilistic exposure-response relationships developed based on data from controlled human exposure studies, together with probabilistic exposure estimates from the exposure analysis. For several other health endpoints, $O_3$-related risk estimates were generated based on concentration-response relationships reported in epidemiologic or field studies, together with ambient air quality concentrations, baseline health incidence rates, and population data for the various locations included in the assessment. Health endpoints included in the assessment based on epidemiologic or field studies included: hospital admissions for respiratory illness in 4 urban areas, premature mortality in 12 urban areas, and respiratory symptoms in asthmatic children in 1 urban area.

In the previous health risk assessment, EPA recognized that there were many sources of uncertainty and variability in the inputs to the assessment and that there was a high degree of uncertainty in the resulting risk estimates. The statistical uncertainty surrounding the estimated $O_3$ coefficients in concentration-response functions as well as the shape of the exposure-response relationship chosen were addressed quantitatively. Additional uncertainties were addressed through sensitivity analyses and/or qualitatively. The previous risk assessment incorporated some of the variability in key inputs to the assessment by using location-specific inputs (e.g., location-specific concentration-response function, baseline incidence rates and population data, and air quality data for epidemiologic –based endpoints, location specific air quality data and exposure estimates for the lung function risk assessment). In the previous health risk assessment, twelve urban areas were included to provide some sense of the variability in the risk estimates across the U.S. Sensitivity analysis was carried out for two sources of uncertainties. The first analysis investigated the impact of alternative estimates for policy-relevant background (PRB) levels in 3 of the 12 urban areas. The second sensitivity analysis looked at the impact of different assumptions around the shape of the exposure-response function.

Key observations and insight from the $O_3$ risk assessment, in addition to important caveats and limitations, were addressed in section II.B of the Final Rule notice (73 FR 16440 to 16443, March 27, 2008). In general, estimated risk reductions associated with going from current $O_3$ levels to just meeting the current and alternative 8-hr standards showed patterns of increasing estimated risk reductions associated with just meeting the lower alternative 8-hr standards considered. Furthermore, the estimated percentage reductions in risk were strongly influenced by the baseline air quality year used in the analysis, which was due to significant year-to-year variability in $O_3$ concentrations. There was also noticeable city-to-city variability in estimated $O_3$-related incidence of morbidity and mortality across the 12 urban areas. Uncertainties associated with estimated PRB concentrations were also addressed and revealed differential impacts on the risk estimates depending on the health effect considered as well as the location. The EPA also acknowledged that there were considerable uncertainties surrounding estimates of $O_3$ coefficients and the shape for concentration-response relationships and whether or not a population threshold or non-linear relationship exists within the range of concentrations examined in the epidemiologic studies.

## 5.3 AIR QUALITY CONSIDERATIONS

Air quality analyses are required to conduct both exposure and health risk assessments for NAAQS reviews. Air quality inputs to the exposure and/or health risk assessment include: (1) provision of ambient air quality data from the fixed-site ambient monitoring network for the period 2006-2008 for the urban areas included in the exposure and risk assessments, (2) estimates of PRB concentrations for the specific urban areas included in the risk assessment, and (3) ambient air quality scenario data sets that are obtained from simulation procedures that adjust recent air quality data to reflect changes in the distribution of air quality estimated to occur at some unspecified time in the future when an area just meets a given set of NAAQS. Broader national scale air quality analyses also will be conducted to place the results of the quantitative risk and exposure assessments into a broader public health context.

While incremental risk reductions do not require estimates of PRB, estimates of the risks in excess of PRB remaining upon meeting the current or potential alternative standards, do require EPA to estimate PRB. Both types of risk estimates are considered relevant to inform the EPA Administrator's decision on the adequacy of a given standard.

Historically, PRB has been defined as the "the distribution of $O_3$ concentrations that would be observed in the U.S. in the absence of anthropogenic (man-made) emissions of precursor emissions (e.g., VOC, $NO_x$, and CO) in the U.S., Canada, and Mexico" (US EPA, 2007, p.2-48). This has been referred to as PRB, since this definition of background facilitates separating pollution levels that can be controlled by U.S. regulations (or through international agreements with neighboring countries) from levels that are not generally controllable in this manner. Thus, PRB includes: (1) $O_3$ generated in the U.S. that arises from natural (biogenic) sources of emissions in the U.S., Canada, and Mexico and (2) $O_3$ in the U.S. from the transport of $O_3$ or the transport of precursor emissions from both natural and man-made sources, from outside of the U.S. and its neighboring countries. As discussed in chapter 4, the ISA will include an assessment of methods for estimating PRB concentrations and will produce $O_3$ PRB concentrations for use in the risk assessment. In this new review, EPA plans to place greater emphasis on understanding the contribution of the different components that contribute to PRB (e.g., what portion of PRB is due to natural emissions alone and what is the contribution of transport from outside the North American continent, as well as the contribution of Canadian and Mexican anthropogenic emissions to $O_3$ levels observed in the U.S. This additional information will help inform policy considerations for this review of the $O_3$ NAAQS as well as more broadly inform efforts related to international efforts to reduce trans-boundary $O_3$ air pollution.

As part of the exposure and risk assessments, it will be necessary to adjust recent $O_3$ air quality data to simulate just meeting the current standard and any alternative $O_3$ standards that might be considered. In the last rulemaking, EPA used a quadratic air quality rollback approach (U.S. EPA, 2007a, section 4.5.8). EPA will consider this approach and alternative air quality simulation procedures for use in this current review. Staff will evaluate candidate procedures to adjust air quality by analyzing historical changes in measured $O_3$ levels and by analyzing changes in $O_3$ levels predicted by air quality models. In this new review, EPA also will examine techniques that may be used to assess the variability and uncertainty of the simulated change in concentrations likely to result from just meeting the current or alternative standards.

## 5.4 POPULATION EXPOSURE ASSESSMENT APPROACH

Population exposure to $O_3$ will be evaluated using EPA's Air Pollutants Exposure model (APEX), a model that simulates microenvironmental personal exposures using temporally and spatially variable ambient concentrations and personal time-location-activity patterns. One objective is to provide exposure estimates as an input to the portion of the health risk assessment that uses exposure-response relationships from controlled human exposure studies. The exposure analysis will also provide estimates of population exposure exceeding potential health effect benchmarks, values identified based on $O_3$ exposure concentrations and associated health effects observed in controlled human exposure studies.

The approach to the current exposure assessment will build upon the methods developed and insights gained from the exposure assessment conducted for the 2008 rulemaking. Staff anticipates performing the exposure assessment, at a minimum, for the same 12 urban areas (i.e., Atlanta, Boston, Chicago, Cleveland, Detroit, Houston, Los Angeles, New York, Philadelphia, Sacramento, St. Louis, and Washington D.C). Several key considerations in planning for the exposure assessment are discussed below.

The most current version of the APEX model (also referred to as the Total Risk Integrated Methodology/Exposure (TRIM.Expo) model) will be used to estimate population exposures for the various air quality scenarios of interest. APEX simulates the movement of individuals through time and space and their exposure to $O_3$ in indoor, outdoor, and in-vehicle microenvironments. APEX is a probabilistic model that will be used to simulate a large number of randomly sampled individuals within each urban area (e.g., 200,000) to represent area-wide population exposures.

As in the previous exposure assessment, human activity data needed for the analysis will be drawn from the Consolidated Human Activity Database (CHAD) developed and maintained by ORD's National Exposure Research Laboratory (NERL). A number of additional activity diaries have been added to the database (i.e., the CHAD-Master file)[9] and will be used in this exposure assessment. This expanded database will likely improve the representation of the simulated exposure population of interest because there are increases in the numbers of data diaries available, in particular for children, and much of the added data are from studies conducted within the past decade. One key issue in this analysis regarding time-location activity patterns is the further evaluation and possible modification of the approach used for creating $O_3$-season or year-long activity sequences for individuals from primarily cross-sectional activity data diaries. The CHAD-Master file contains additional longitudinal diaries from numerous individuals ranging from 2 days in duration to 369 days that may be informative in the method evaluation and development.

As done in the last $O_3$ NAAQS rulemaking and other ongoing NAAQS reviews (e.g., US EPA, 2007a,b; US EPA, 2008; US EPA, 2009b) and where possible, staff will identify, incorporate, and describe any observed variability in input data sets and estimated parameters within the analyses performed. In addition, consistent with other NAAQS reviews, the exposure assessment will include an uncertainty characterization of the model inputs and model formulation.

Following the same general approach described in US EPA (2009b) and adapted from WHO (2008), staff will first perform a succinct qualitative characterization of the components contributing to uncertainty in estimated exposures in large part informed by the results of the prior uncertainty characterization conducted for the $O_3$ exposure assessment (Langstaff, 2007). This qualitative characterization will be performed early in the process of developing the exposure assessment to inform and prioritize potential exposure model development activities and to identify additional uncertainties that were not previously evaluated.

Briefly, staff will qualitatively characterize the potential magnitude[10] (*low*, *medium*, and *high*) and direction of influence (*over, under, both,* and *unknown*) for each major source of uncertainty; that is, qualitatively rate how the source of uncertainty, in the presence of alternative information, may affect the estimated exposures. In addition and consistent with the WHO (2008) guidance, staff will discuss the uncertainty in the knowledge-base (e.g., the accuracy of

[9] Approximately 18,000 diaries have been added to the previous 17,000 diaries used in the 2007 $O_3$ exposure assessment. The data are currently available through EPA at mccurdy.tom@epa.gov.
[10] This is synonymous with the "level of uncertainty" discussed in WHO (2008), section 5.1.2.2.

the data used, acknowledgement of data gaps) and decisions made (e.g., selection of particular model forms), though qualitative ratings will be assigned only to uncertainty regarding the knowledge-base.

A qualitative uncertainty characterization will be part of a tiered approach characterizing uncertainty. Qualitative rankings, along with available data and information, will be used to identify potential uncertainties to be propagated as part of a broader quantitative uncertainty characterization. Note that in performing exposure assessments, we often have information regarding the variability of model inputs, and sometimes the variability and uncertainty combined, but for most inputs it is difficult to estimate the uncertainty separately from the variability. There may be adequate information on APEX $O_3$ exposure modeling inputs and algorithms for staff to define reasonable bounds or ranges for the uncertainties of many of the model inputs. Thus, as part of a higher tier quantitative uncertainty characterization, staff may assess the combined impacts of the uncertainties of the model inputs across these ranges, and use these results to inform a discussion of model uncertainties.

Following the approach previously used (Langstaff, (2007), we may employ a 2-dimensional Monte Carlo/Latin hypercube sampling approach to generate a combined variability and uncertainty analysis for APEX. The 2-dimensional Monte Carlo method allows for the separate characterization of the variability and uncertainty in the model results (Morgan and Henrion, 1990). In addition, the sensitivity of the modeling procedure to selected model parameters, data, and algorithms may be assessed to identify the factors having the greatest impact on current exposure estimations. This may include uncertainties identified in the previous review such as the longitudinal activity algorithm, the activity pattern data base, the decay rate, and microenvironmental proximity factors, among other inputs potentially identified in the qualitative uncertainty characterization.

## 5.5 HUMAN HEALTH RISK ASSESSMENTS

The goals of the $O_3$ health risk assessment are: (1) to provide estimates of the potential magnitude of selected morbidity and mortality health effects in the population associated with recent ambient $O_3$ levels and with just meeting the current $O_3$ standard and any alternative standards that might be considered in specific urban areas, (2) to develop a better understanding of the influence of various inputs and assumptions on the risk estimates; and (3) to gain insights into the distribution of risks and patterns of risk reduction and uncertainties in those risk estimates. The approach to the current health risk assessment will build upon the methods developed and insights gained from the risk assessment conducted for the 2008 rulemaking. Staff anticipates performing the assessment, at a minimum, for the same 12 urban areas (i.e., Atlanta, Boston, Chicago, Cleveland, Detroit, Houston, Los Angeles, New York, Philadelphia, Sacramento, St. Louis, and Washington D.C). Several key considerations in planning for the health risk assessment are discussed below.

Staff is planning to focus the quantitative risk assessments on the most important health effect categories and endpoints from the standpoint of public health significance and for which the weight of the evidence supports the judgment that the effect category and specific health effects endpoints are judged sufficiently causal with respect to $O_3$ either alone and/or in combination with other pollutants to be included in the quantitative risk assessment. An important additional consideration in deciding which health effect endpoints to include in the risk assessment is the availability of sufficient information to conduct a quantitative assessment (e.g., characterization of exposure- or concentration-response relationship, information on baseline incidence).

The risk and exposure assessments will draw upon the information presented in the ISA and its annexes. This includes information on atmospheric chemistry, air quality, human exposure, and health effects of concern. In particular, the availability of air quality, concentration- and exposure-response relationships, and baseline incidence rate data will impact the type of risk assessments that will be performed.

As described in section 5.3 above, air quality inputs required to conduct the health risk assessment include: (1) recent $O_3$ air quality data from suitable monitors for each selected location, (2) estimates of PRB concentrations for each location, and (3) simulated air quality that reflects changes in the distribution of $O_3$ air quality estimated to occur when an area just meets a given $O_3$ standard.

### 5.5.1 Approach to Health Risk Assessment Based On Epidemiologic Studies

As noted above, the health risk assessment conducted in this review will build on the approach developed and applied in the 2008 rulemaking. Staff plans to rely on a weight-of-evidence approach, as provided in the ISA, based on evaluation of new and prior epidemiologic studies including identification of relevant concentration-response functions that characterize the relationships between $O_3$ exposures and health outcomes, particularly those conducted at or near current ambient concentrations. Quantitative relationships provided in the specific studies or derived from the data presented in the epidemiologic studies describe the change in concentration (generally based on ambient fixed-site monitors) associated with a change in health response. These concentration-response relationships will be combined with air quality data, baseline incidence data, and population data to develop population health risk estimates.

Epidemiologic studies typically provide estimated concentration-response relationships based on data collected in real-world settings. Ambient $O_3$ concentrations are typically measured as the area-wide average of monitor-specific measurements, although personal exposures are occasionally measured. Health responses for $O_3$ included in the prior risk assessment were: respiratory symptoms in asthmatic children, asthma and other respiratory-related hospital admissions, and premature mortality. Staff will consider the type of health response function(s) available and the availability of ambient $O_3$ concentration data to characterize public health risks. We consider that these analyses are most appropriately applied in areas where the specific epidemiologic studies were performed. It should be noted that a risk characterization based on epidemiologic studies also requires baseline incidence rates and population data for the specific locations evaluated in the risk assessment.

The inclusion of any particular health endpoint depends in part on the extent to which the $O_3$ ISA infers the likelihood of a causal relationship between $O_3$ exposure and a given health effect category and the weight of the evidence for concluding that $O_3$ exposures are related to the specific health effect endpoint. A number of issues related to the selection and application of appropriate concentration-response functions for use in the assessment will be addressed in the Scope and Methods Plan. For example, consideration will be given to the appropriate use of functions based on single- and multi-city studies, single- and multi-pollutant concentration-response models, and alternative lags.

### 5.5.2 Approach to Health Risk Assessment Based on Controlled Human Exposure Studies

As noted above, the health risk assessment conducted in this new review will build on the approach developed and applied in the 2008 rulemaking. In that previous assessment, risk estimates for lung function responses associated with 8-hr exposures while engaged in moderate exertion were developed. These estimates were based in part on exposure-response relationships estimated from the combined data sets from multiple $O_3$ controlled human exposure studies. Data from the studies by Folinsbee et al. (1988), Horstman et al. (1990), and McDonnell et al. (1991) in addition to more recent data from Adam (2002, 2003, 2006) were used to estimate exposure-response relationships for ≥10, 15, and 20% decrements in $FEV_1$. In this new review, staff intends to investigate the possibility of using a model (McDonnell et al., 2007) that estimates $FEV_1$ responses associated with $O_3$ short-term exposures. This model is based on the controlled human exposure data included in the prior lung function risk assessment as well as additional data sets for different averaging times and breathing rates. We will also consider whether there is sufficient evidence to consider adding other health endpoints observed in controlled human exposure studies to the quantitative risk assessment based on the information contained in the draft ISA.

### 5.5.3 Uncertainty and Variability

A persistent issue raised in CASAC and public comments on the quantitative risk assessment conducted for the 2008 rulemaking was the desire to provide a more comprehensive characterization of the most significant uncertainties impacting the health risk estimates. For the health risk assessment to be conducted for the new review, we will include both a qualitative characterization of uncertainty and variability, and where feasible, a quantitative characterization of uncertainty and/or sensitivity analyses for those aspects of the assessment judged most influential.

Following the same general approach described above in section 5.4, and adapted from WHO (2008), staff will first perform a succinct qualitative characterization of the components contributing to uncertainty in estimated health risks. This qualitative characterization will be performed early in the process of developing the risk assessment to inform and prioritize potential health risk model development activities and to identify additional uncertainties that were not previously evaluated.

### 5.5.4 Broader Risk Characterization

For this new review, staff is considering extending the risk assessment to a broader range of urban areas, beyond the 12 urban areas included in the previous assessment, in light of newly available data to provide greater coverage of additional regions of the country where significant $O_3$ exposures are likely to occur. We also will consider the feasibility of developing concentration-response relationships that can be applied on a regional basis. It is very likely that the geographic (and population) coverage will vary for different health endpoint categories due to data limitations (e.g., the availability of emergency department and hospital admission baseline incidence data is more limited than mortality baseline incidence data). However, we recognize that there have been noticeable improvements in the availability of baseline incidence data for emergency department and hospital admissions since the last rulemaking.

Beyond the quantitative risk and exposure assessments conducted for this review, staff will consider ways to put the results of those assessments into a broader context. Specifically, we will explore analyses that would complement quantitative risk and exposure assessments conducted for a limited number of locations and selected health endpoints to better characterize the nature, magnitude, extent, variability, and uncertainty of the public health impacts associated with $O_3$ exposures on a broader scale. We will consider how additional analyses can be used to inform our understanding of:

- Additional health endpoints not considered in the quantitative risk assessment;
- Additional locations not evaluated in the quantitative risk/exposure assessment to inform a broader understanding of public health impacts including non-urban environments;
- Regional differences in $O_3$ risks taking into consideration the following factors:
    - variations in individual and/or population susceptibility;
    - population demographics;
    - variations in exposures; and
    - impacts of potential effect modifiers (e.g., weather, co-pollutants).

## 5.6 SCIENTIFIC AND PUBLIC REVIEW

A draft of the Scope and Methods Plan for the risk/exposure assessment will be submitted to CASAC for consultation and will be provided to the public for comment subsequent to the release of the 1st draft ISA. The CASAC $O_3$ Review Panel will discuss its comments on the draft Scope and Methods Plan in a public meeting that will be announced in the Federal Register. In conducting the risk/exposure assessment, staff will take into account comments received from CASAC and from the public at the meeting itself and in any written comments. Staff plans to prepare two drafts of the risk/exposure assessment for CASAC review and public comment. The CASAC $O_3$ Review Panel will review each draft risk/exposure assessment and discuss their comments in two public meetings to be announced in the Federal Register. Based on CASAC's past practice, staff anticipates that key CASAC advice and recommendations for revision of the draft risk/exposure assessment will be presented in letters to the EPA Administrator. Staff will also consider comments received from CASAC and from the public at the meetings themselves and any written public comments. In finalizing the risk/exposure assessment, we will take into account any such comments and recommendations. After appropriate revision, the final risk/exposure assessment document will be made publicly available on an EPA website and in hard copies. A notice announcing the availability of the final document will be published in the Federal Register. In addition, the final risk/exposure assessment document will be placed in the rulemaking docket.

# 6 VEGETATION AND OTHER WELFARE-RELATED ASSESSMENTS

## 6.1 OVERVIEW

The assessments conducted in this new review of the secondary $O_3$ NAAQS will focus on new information that has become available since the 2008 rulemaking. Key-policy relevant findings from the ISA integrated with information from previous reviews will inform policy judgments in regard to the adequacy of the current indicators, averaging times, levels and forms of the $O_3$ standard. New information and methods available in this review are expected to improve characterization of $O_3$ exposures and associated impacts, especially in non-urban areas, forests, and Class I protected lands. Recent information regarding direct $O_3$ effects on plants, including emerging evidence that $O_3$ alters the chemical signature and longevity of scents released by plants to attract pollinators, and the indirect impacts that can occur in associated ecological processes that can lead to ecosystem level effects and shifts in or loss of ecosystem services (e.g., carbon sequestration, water balance, pollination and/or biodiversity) will be considered and evaluated using qualitative and/or quantitative exposure, risk and benefits assessments, where feasible. As in the last rulemaking, information regarding the interaction between $O_3$, local meteorological conditions, and climate will be reviewed, although we do not anticipate sufficient information being available for quantitative analyses of this complex relationship in this review. Ozone-related damage to certain manmade materials (e.g., elastomers, textile fibers, dyes, paints and pigments) will not be re-assessed, as the scientific literature contains very little new information to adequately quantify these effects. A more detailed description of assessment methods and approaches being considered for the exposure, risk and benefits assessments will be provided in a subsequent Scope and Methods Plan. Preparation of this plan will coincide with the development of the first draft ISA to facilitate the integration of policy-relevant science.

## 6.2 EXPOSURE, RISK, AND BENEFITS ASSESSMENTS FROM RULEMAKING COMPLETED IN MARCH 2008

The exposure, risk and benefits assessments conducted as part of the 2008 rulemaking focused on $O_3$-related impacts to sensitive vegetation and their associated ecosystems. The vegetation exposure assessment was performed using an interpolation approach that 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 monitored $O_3$ air quality for the years 2001 – 2004; (2) estimates of seedling growth loss under then 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 mature trees from three different species. The crop risk analysis included estimates of crop yields under current and alternative $O_3$ exposure conditions. The associated change in economic benefits expected to accrue to the agriculture sector upon meeting the levels of various alternative standards were analyzed using an agricultural benefits model. Key elements and observations from these exposure and risk assessments are outlined in the following sections.

### 6.2.1 Exposure Assessment

In many rural and remote areas where sensitive species of vegetation can occur, monitoring coverage remained limited. Thus, the Staff Paper concluded that it was necessary to use an interpolation method in order to better characterize $O_3$ air quality over broad geographic areas and at the national scale. Based on the significant difference in monitor network density between the eastern and western U.S., the Staff Paper further concluded that it was appropriate to use separate interpolation techniques in these two regions: The Air Quality System (AQS; http://www.epa.gov/ttn/airs/airsaqs) and Clean Air Status and Trends Network (CASTNET; http://www.epa.gov/castnet/) monitoring data were solely used for the eastern interpolation, and in the western U.S., where rural monitoring is more sparse, $O_3$ outputs from the EPA/NOAA Community Multi-scale Air Quality (CMAQ)[11] model system (http://www.epa.gov/asmdnerl/CMAQ, Byun and Ching, 1999) were used to develop scaling

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

factors to augment the monitor interpolation. In order to characterize uncertainty associated with the exposure estimates generated using 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 performed well in many areas in the U.S., although it under-predicted higher 12-hr W126 exposures in rural areas. This approach was used to develop a national vegetation $O_3$ exposure surface.

To evaluate changing vegetation exposures under selected air quality scenarios, a number of analyses were conducted. One analysis adjusted 2001 base year $O_3$ air quality distributions using a rollback method (Horst and Duff, 1995; Rizzo, 2005, 2006) to reflect meeting the current and alternative secondary standard options. For "just meet" and alternative 8-hr average standard scenarios, the associated maps of estimated 12-hr, W126 exposures were generated. Based on these comparisons, the following observations were drawn: (1) current $O_3$ air quality levels could result in significant $O_3$ exposures to vegetation in some areas; (2) overall 3-month 12-hr W126 $O_3$ levels were somewhat but not substantially improved under the "just meet" current scenario; (3) exposures generated for just meeting a 0.070 ppm, 4th-highest maximum 8-hr 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-hr standard.

A second analysis described in the Staff Paper was performed to evaluate the extent to which county-level $O_3$ air quality measured in terms of various levels of the current 8-hr average form overlapped with that measured in terms of various levels of the 12-hr W126 cumulative, seasonal form.[12] While these results also suggested that meeting a proposed 0.070 ppm, 8-hr secondary standard would provide substantially improved vegetation protection in some areas, the Staff Paper recognized that this analysis had several important limitations. In particular, the lack of monitoring in rural areas where sensitive vegetation and ecosystems are located, especially at higher elevation sites could have resulted in an inaccurate characterization of the degree of potential overlap at sites which have air quality patterns that can result in relatively low 8-hr averages while still experiencing relatively high cumulative

[12] 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.

exposures (72 FR 37892). Thus, the Staff Paper concluded that it is reasonable to anticipate that additional unmonitored rural high elevation areas with sensitive vegetation may not be adequately protected even with a lower level of the 8-hr form. The Staff Paper further indicated that it remained uncertain as to the extent to which air quality improvements designed to reduce 8-hr $O_3$ 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-hr $O_3$ concentrations in relation to plant response; and (3) the effects of attainment of a 8-hr 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.

### 6.2.2 Risk Assessment

The risk assessments in the last rulemaking reflected the availability of several additional lines of evidence that provided a basis for a more complete and coherent picture of the scope of $O_3$-related vegetation risks, especially those faced by seedling, sapling and mature tree species growing in field settings, and indirectly, forested ecosystems. Specifically, new research available at the time reflected 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. Highlights from the analyses that addressed visible foliar injury, seedling and mature tree biomass loss, and effects on crops are summarized below.

With regard to visible foliar injury, the Staff Paper presented an assessment that combined 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 then current 0.08 ppm 8-hr standard. Of the counties that met an 8-hr level of 0.07 ppm in those years, 11 to 30 percent of the counties still had incidence of visible foliar injury.

With respect to tree seedling biomass loss, concentration-response (C-R) functions developed from OTC data for biomass loss for available seedling tree species 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 individual seedling tree species. These analyses predicted that biomass loss could still occur in many tree species when $O_3$ air quality was adjusted to meet the current 8-hr standard. Though this type of analysis was not new to this review, the context for understanding these results had changed due to recent field work 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) which 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).

With respect to risk of mature tree growth reductions, 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.[13] The model was run for a single western species (ponderosa pine) and two eastern species (red maple and tulip poplar). 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. Though there was uncertainty associated with the above analyses, it was important to note that new evidence from experimental studies that go beyond the seedling growth stage continued 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 should be considered.

With respect to risks of yield loss in agricultural crops and fruit and vegetable species, little new information was available beyond that of the previous review. However, limited information from a free air field based soybean study (SoyFACE) and information on then current cultivar sensitivities, led to the conclusion that C-R functions developed in OTCs under the National Crop Loss Assessment Network (NCLAN) program could still be usefully applied.

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

The crop risk assessment, like the tree seedling assessment, combined C-R information on commodity crops, fruits and vegetables, crop growing regions, and interpolated exposures during each crop growing season. The risk assessment estimated that just meeting the 0.08 ppm, 8-hr standard would still allow $O_3$–related yield loss to occur in some sensitive commodity crops and fruit and vegetable species growing at that time in the U.S.

### 6.2.3 Benefits Assessment

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

## 6.3 AIR QUALITY CONSIDERATIONS

As in the last rulemaking, air quality analyses will be necessary to inform and support welfare-related exposure, risk, and benefits assessments in this new review. The required air quality analyses for this review will build upon those of the ISA and will include consideration of: (1) summaries of recent ambient air quality data, (2) estimation approaches to extrapolate air quality values for rural areas without monitors as well as Class I Federally designated natural areas important to welfare effects assessment, (3) estimates of policy-relevant background (PRB) concentrations, (4) air quality simulation procedures that modify recent air quality data to reflect changes in the distribution of air quality estimated to occur at some unspecified time in the future when an area just meets a given set of NAAQS. In this review, air quality analyses will be conducted to support quantitative exposure and risk assessments for specific locations, as well as at regional and national scales.

In addition to updating air quality summaries since the last rulemaking, these air quality analyses will include summaries of the most currently available ambient measurements for the current 8-hr average standard form, the cumulative concentration-weighted W126 form, and comparisons of these two types of forms. These air quality analyses will use monitor data from the AQS data base (which includes National Park Service monitors) and the CASTNET network. In addition, staff will explore the suitability of using other sources of $O_3$ concentration information that might be available, such as from portable monitors or satellites.

In the last rulemaking, the vegetation exposure analysis used a spatial interpolation technique, to create an interpolated air quality surface to fill in the gaps in ambient monitoring data, especially those left by a sparse rural monitoring network in the western United States. In this current review, additional approaches that potentially could be used to fill in the gaps in the rural monitoring network, as well as opportunities for enhancing the fusion of monitoring and modeled $O_3$ data will be explored.

While incremental risk reductions do not require estimates of PRB, estimates of the risks in excess of PRB remaining upon meeting the current or potential alternative standards, do require EPA to estimate PRB. Both types of risk estimates are considered relevant to inform the EPA Administrator's decision on the adequacy of a given standard. The current approach to estimating $O_3$ PRB for use in conducting the welfare risk assessment is the same as that outlined in section 5.3 above.

As part of the air quality analyses supporting the exposure, risk and benefits assessments, it will be necessary to adjust recent $O_3$ air quality data to simulate just meeting the current standard and any alternative $O_3$ standards. In the last rulemaking, EPA used a quadratic air quality rollback approach (U.S. EPA, 2007a, section 4.5.8). Staff will consider alternative air quality simulation procedures for use in this current review as previously characterized in section 5.3.

## 6.4 EXPOSURE ASSESSMENT APPROACH

Since the last rulemaking, little has changed in terms of the extent of monitoring coverage in non-urban areas. We will consider both past and alternative approaches for generating estimates of national $O_3$ exposures in an effort to continue enhancing our ability to characterize exposures in these non-monitored areas. It is expected that vegetation exposure assessments will again include assessments of recent air quality, air quality associated with just meet scenarios both for the current and alternative standards.

In addition, given the stated importance in the Final $O_3$ Rule (73 FR 16436) on providing protection for sensitive vegetation in areas afforded special protections such as in federally designated Class I natural areas, we will also consider alternative sources of $O_3$ exposure information for those types of sites. For example, portable $O_3$ monitors are being deployed in some national parks and a current exploratory study is underway to measure $O_3$ concentration variations with gradients in elevation. Though these monitors are not FRM or reported in AQS, information from these monitors could potentially decrease uncertainties associated with assessing $O_3$ distribution patterns in complex terrain and high elevations. New exposure data that informs the $O_3$ review will be considered where appropriate.

As described in 6.5 below, staff will conduct an analysis of associated exposure assessment uncertainties.

## 6.5 RISK ASSESSMENT APPROACH

Since the last rulemaking, new scientific information on the direct and indirect effects of $O_3$ on vegetation and ecosystems, respectively, has become available. With respect to mature trees and forests, the information regarding $O_3$ impacts to forest ecosystems has continued to expand, including limited new evidence that implicates $O_3$ as an indirect contributor to decreases in stream flow through direct impacts on whole tree level water use efficiencies. Long-term FACE (Free Air $CO_2$ enrichment) studies are continuing to provide additional evidence regarding chronic $O_3$ exposures in closed forest canopy scenarios including interspecies interactions such as decreased growth of branches and root mass in sensitive species. Also, lichen and moss communities on trees monitored in FACE sites have been shown to undergo species shifts when exposed to $O_3$. In addition, it is expected that as in the previous review, recent available data from annual field surveys conducted by the USFS to assess foliar damage to selected tree species will again be combined with recent county level air quality data to determine the incidence of visible $O_3$ damage occurring across the U.S. at air quality levels that meet or are below the current standard. To the extent possible, new information regarding $O_3$ effects on forest trees will be both qualitatively and quantitatively assessed and an effort made to place both the estimates of risk from more recent long-term studies and historic shorter-term studies in the appropriate context.

Additional information relevant to both tree and crop risk assessments expected to be available includes that regarding the interactions between elevated $O_3$ and $CO_2$ with respect to plant growth and how these interactions might be expected to be modified under different climatic conditions, and potential reactions of $O_3$ with chemicals released by plants to attract pollinators that could decrease the distance the floral "scent trail" travels and potentially changing the distance pollinators have to travel to find flowers. Staff also plans to consider any available information regarding potential risks to threatened or endangered species.

## 6.6 BENEFIT ASSESSMENT APPROACH

Qualitative and/or quantitative benefits assessments of ecosystem services impacted by $O_3$ will be conducted to inform the current review. In particular, the benefits assessments in this review will focus more broadly than the crop yield analyses conducted in the last rulemaking, to include impacts on ecosystem services such as impacts on biodiversity, biological community composition, health of forest ecosystems, aesthetic values of trees and plants and the nutritive quality of forage and other crops. The impact of $O_3$ on limiting potential $CO_2$ sequestration is another important ecosystem services. New preliminary evidence of $O_3$ effects on the ability of pollinators to find their target is also of special interest with respect to the possible implication for benefits assessment of ecosystem service. Impairment of the ability of pollinators to locate flowers could have broad implications for agriculture, horticulture and forestry.

A new benefits model, the Forest and Agricultural Sector Optimization Model (FASOM), is being considered in this review. This model jointly assesses the economic impacts of $O_3$ damage to forests and agricultural crops. FASOM is a dynamic, non-linear programming model designed for use by the EPA to evaluate welfare and market effects of carbon sequestration in trees, understory, forest floor, wood products and landfills that would occur under different agricultural and forestry scenarios. It may be possible to model damage by $O_3$ to the agriculture and forestry sectors and quantify how $O_3$-exposed vegetation impacts the ecosystem service of carbon sequestration.

A conclusion in the last rulemaking was that the science continued to support a change in the form of the secondary standard for $O_3$ to better reflect the effects of cumulative $O_3$ exposures on plants and crops. The current form of the secondary standard may not protect sensitive species that are chronically exposed to elevated $O_3$ concentrations. The risk assessment conducted in this review will once more evaluate the relative risks associated with both the current and potentially alternative cumulative seasonal forms, in light of new information on exposures, risks, non-plant effects, and ecosystem services. In addition, we plan to consider the impact of using different length diurnal windows (e.g., 12, 16 or 24 hrs), different seasonal periods (e.g., 3, 5, or 7 months), and annual vs. three-year averages.

## 6.7 UNCERTAINTY AND VARIABILITY

For the exposure, risk and benefits assessments planned for this review, staff is considering, at a minimum, a similar approach to that used in the previous review to characterize uncertainty and variability associated with these estimates. In addition, we are considering the feasibility of conducting additional analyses to better characterize the uncertainties and variability associated with these assessments.

Many of the sources of uncertainty and variability that were present in the last assessments are expected to remain in this review. In particular, uncertainties associated with the use of various models such as the CMAQ and FASOM models would be characterized and where possible, sensitivity analyses performed to test the impact of various assumptions imbedded in the models. The uncertainty associated with the monitor probe height is expected to remain due to lack of definitive information becoming available. Where information exists, staff plans to conduct an assessment of the impact of using different adjustment factors. As in the last rulemaking, every effort will be made to provide information on the uncertainties and variability associated with the exposure surface approach selected and risk assessments conducted. Uncertainties associated with empirical evidence due to exposure or research methods will be described.

## 6.8 SCIENTIFIC AND PUBLIC REVIEW

A draft of the Scope and Methods Plan for the vegetation and other welfare-related assessments will be submitted to CASAC for consultation and will be provided to the public for comment. The CASAC $O_3$ Review Panel will discuss their comments on the draft Scope and Methods Plan in a public meeting that will be announced in the Federal Register. In conducting the welfare-related assessments, staff will take into account comments received from CASAC and from the public at the meeting itself and in any written comments. Staff plans to prepare two drafts of the vegetation and other welfare-related assessments for CASAC review and public comment. The CASAC $O_3$ Review Panel will review each draft welfare-related assessment and discuss their comments in two public meetings to be announced in the Federal Register. Based on CASAC's past practice, we anticipate that key CASAC advice and recommendations for revision of the draft risk/exposure assessment will be presented in letters to the EPA

Administrator. Staff will also consider comments received from CASAC or from the public at the meetings themselves and any written public comments. In finalizing the vegetation and welfare-related assessments, we will take into account any such comments and recommendations. After appropriate revision, the final welfare-related assessment document will be made publicly available on an EPA website and in hard copy. A notice announcing the availability of the final document will be published in the Federal Register. In addition, the final welfare-related assessment document will be placed in the rulemaking docket.

# 7 POLICY ASSESSMENT/RULEMAKING

Based on the information in the ISA, the human health REA, and the vegetation REA, the Agency will develop a Policy Assessment (PA) that reflects EPA staff's initial views regarding the need to retain or revise the NAAQS for $O_3$. In doing so, the PA will consider the policy-relevant questions outlined in chapter 3, including the fundamental questions associated with the adequacy of the current standards and consideration of alternative standards in terms of the specific elements of the standards: indicator, averaging time, level, and form.

The PA will identify conceptual evidence-based and risk/exposure-based approaches for reaching public health and welfare policy judgments. It will discuss the implications of the science and risk/exposure assessments for the adequacy of the current standards, and for alternative standards under consideration. The PA will also describe a range of policy options for standard setting including a description of the underlying interpretations of the scientific evidence and risk/exposure information that might support such alternative standards and that could be considered by the Administrator in making decisions for the $O_3$ standards.

Use of the PA will provide an opportunity for CASAC and the public to evaluate the policy options under consideration and to offer comments and recommendations to inform the development of a proposed rule. Taking into account CASAC advice and recommendations and public comment on the PA, the Agency will publish a proposed rule. This proposal will be followed by a public comment period. Taking into account comments received on the proposed rule, the Agency will then issue a final rule to complete the rulemaking process.

Monitoring rule changes associated with review of the $O_3$ standards, as outlined below in chapter 8, will be developed, if necessary, in conjunction with this NAAQS rulemaking.

# 8 AMBIENT AIR MONITORING

## 8.1 OVERVIEW

The $O_3$ monitoring network provides data to meet a wide variety of objectives. They include ensuring the public has access to clean air by comparing data to the NAAQS, providing the public with reports and forecasts of their exposure to $O_3$ through the Air Quality Index, providing input to health and welfare studies utilized as part of the NAAQS review process, evaluating the performance of regional air quality models used in developing emission strategies, tracking trends in air pollution abatement control measures impact on improving air quality, and supporting research studies on atmospheric chemistry and transport or $O_3$.

To meet these multiple objectives, national $O_3$ sites are deployed in variety of locations to determine the following information: highest concentrations in an area, typical concentrations in areas of high population density, the impacts of significant sources or source categories on $O_3$ precursors and formation processes, general background concentration levels, the extent of regional pollutant transport among populated areas, assessment impacts on visibility, vegetation damage, or other welfare-based effects.

Federal rules that regulate ambient air monitoring programs are found in 40 CFR Parts 50, 53 and 58. During the last rulemaking completed in 2008, EPA followed a complementary process in which changes to monitoring regulations that were required to support the revised NAAQS were proposed in a separate rulemaking.[14] During this review, EPA intends to include any proposed monitoring rule changes as part of the NAAQS rule, potentially reducing the time necessary to institute monitoring changes that might be required by a decision to revise the NAAQS.

## 8.2 CURRENT $O_3$ NETWORK STATUS

Presently, states and local air quality management agencies operate minimum numbers of EPA-approved $O_3$ monitors based on the population of each of their Metropolitan Statistical Area (MSA) and the most recently measured $O_3$ levels for each area. Currently, there are 369 MSAs in the U.S. subject to minimum $O_3$ monitoring requirements. In these areas, a total of

[14] The proposed rule, Ambient Ozone Monitoring Regulations: Revisions to Network Design Requirements, was published on July 16, 2009 (74 FR 34525). A final rule is expected to be completed during the spring of 2010.

392 monitors are required to meet the minimum requirements. In actuality, 992 monitors were in operation during 2005 to 2007 representing these MSAs. This monitor count indicates the typical practice of operating more than the minimum required number of monitors to support the basic monitoring objectives described above. In addition, state and local agencies operated 55 monitors during 2005 to 2007 in MSAs that were not required to have monitors.

Many of these $O_3$ monitors that were operated in excess of minimum requirements were sited to characterize the $O_3$ concentrations in metropolitan areas and in downwind areas that were potentially impacted by transport from MSAs. As noted in the current monitoring regulations described in Part 58, $O_3$ minimum requirements do not account for the full breadth of additional factors that would be considered in designing a complete $O_3$ monitoring program for an area. Some of these additional factors include geographic size, population density, complexity of terrain and meteorology, presence of nearby $O_3$ monitoring sites operated by adjacent State programs, air pollution transport from neighboring areas, and measured air quality in comparison to all forms of the $O_3$ NAAQS (i.e., 8-hr and 1-hr forms). States and EPA Regional Administrators work together to design and/or maintain the most appropriate $O_3$ network to service the variety of data needs in an area. The results of these negotiations are documented in annual monitoring network plans that are made available for public inspection and then approved by the EPA Regional Administrator, and the $O_3$ monitoring requirements in approved plans become the basis for state $O_3$ monitoring requirements for the 1-year period following plan approval.

Although there are currently no EPA requirements for $O_3$ monitoring other than in or adjacent to MSAs , there are at present about 200 state-operated $O_3$ monitors in counties that are not part of MSAs, and these monitors can be categorized in several ways. States commonly locate $O_3$ monitors both upwind and downwind of major urban areas to evaluate the spatial gradient or extent of transported $O_3$ pollution and the lag time typically associated with photochemical production. In some cases, these $O_3$ monitors are located in non-urban or rural areas within MSAs or physically outside the MSA boundary if the expected location of maximum downwind $O_3$ concentration is outside the MSA.

As part of the Clean Air Status and Trends Network (CASTNET), the EPA operates 57 $O_3$ monitors, and the National Park Service (NPS) operates 23 monitors across the eastern and western U.S. The NPS also operates additional $O_3$ monitors independent of CASTNET stations. CASTNET $O_3$ monitors operate year-round and are primarily located in rural areas; siting criteria require distances of at least 40 kilometers from cities of greater than 50,000 population as well as other separation requirements from air pollution sources.

Taking into account both state and EPA/NPS-operated non-urban $O_3$ monitors, an analysis of the distribution of these monitors indicates a relatively uniform spatial density in the eastern one-third of the U.S. and in California, with significant gaps in coverage elsewhere across the country. Virtually all states east of the Mississippi River have at least two to four non-urban $O_3$ monitors, while many large mid-western and western states have one or no non-urban monitors.

Section 182(c)(1) of the Clean Air Act required EPA to promulgate rules requiring enhanced monitoring of $O_3$, NO, and VOC in $O_3$ nonattainment areas classified as serious, severe, or extreme. On February 12, 1993, EPA promulgated requirements for State and local monitoring agencies to establish Photochemical Assessment Monitoring Stations (PAMS) as part of their SIP monitoring networks in $O_3$ nonattainment areas classified as serious, severe, or extreme. Design criteria for the PAMS network are based on locations relative to $O_3$ precursor source areas and predominant wind directions associated with high $O_3$ events. Specific monitoring objectives are associated with each location. The overall design supports the characterization of precursor emission sources within an area, transport of $O_3$ and its precursors, and the photochemical processes related to $O_3$ nonattainment. EPA reduced PAMS requirements as part of the October 17, 2006 rulemaking. Current requirements include site-specific measurements for speciated VOC, carbonyls, NOx, NOy, CO, $O_3$, surface meteorology, and upper air meteorology.

Unlike the ambient monitoring requirements for other criteria pollutants that mandate year-round monitoring, $O_3$ monitoring is currently only required during the seasons of the year that are conducive to $O_3$ formation. These seasons vary in length from place to place as the conditions that determine the likely $O_3$ formation (i.e., seasonally-dependent factors such as ambient temperature, strength of solar insolation, and length of day) differ by location. In some locations, conditions conducive to $O_3$ formation are limited to a few summer months of the year. For example, in states with colder climates such as Montana and South Dakota, the currently required $O_3$ monitoring season has a length of 4 months. However, in other states with warmer climates such as California, Nevada, and Arizona, the currently required $O_3$ monitoring season for most sites continues all 12 months of the year.

## 8.3 MONITORING ISSUES RELATED TO THE $O_3$ NAAQS

This new review of the $O_3$ NAAQS will explore a number of policy-relevant issues associated with measuring and characterizing $O_3$ levels in ambient air. The EPA will draw upon the information presented in the ISA to inform the evaluation of appropriate ambient monitoring methods and network design for $O_3$, including consideration of the available information on probe and siting criteria that could best support the current or alternative standards.

**Monitoring Methods**

The nation's $O_3$ monitoring data currently being reported to AQS are obtained exclusively with ultraviolet (UV) absorption spectrometry based methods. These methods are approved Federal Equivalent Methods (FEMs) per 40 CFR Part 53; a number of commercial manufacturers supply such FEM instruments for use in the national network. The use of the Federal Reference Method (FRM) in ambient monitoring (a chemiluminescence-based method) has become basically non-existent with the adoption of FEMs. States utilize calibration and quality assurance procedures that relate their own calibrators to a network of Standard Reference Photometers (SRPs) that are maintained and operated by EPA.

Previous reviews of the $O_3$ NAAQS have considered the implications of interferences in the response of UV and chemiluminescence-based instruments due the effects of water vapor, VOC's, aromatic compounds and their oxidation products, and other organic and inorganic compounds.

Policy-relevant issues that will be considered in this review to inform the selection of monitoring methods are reflected in the following questions:

- To what extent is new information available to judge the adequacy of the current methodologies that are approved by EPA for use in judging compliance with the $O_3$ NAAQS and meeting other objectives?

- Has new information become available that supports the need for alternative methodologies to supplement the currently approved FRM and FEM's?
- What other technologies (e.g., portable monitors, passive or personal sampling) might be appropriate to consider where methods do not have to be EPA-approved, such as in the support of ecosystem or epidemiologic studies?

**Network Design**

Monitoring sites must represent ambient air (i.e., that portion of the atmosphere, external to buildings, to which the general public has access). The minimum number of required monitors for $O_3$ is stated in 40 CFR Part 58, Appendix D, Network Design Criteria for Ambient Air Quality Monitoring. The EPA negotiates with States to determine the total number of monitors needed to represent an area's air quality. It should be noted that although monitors are often sited with the intention to represent an area of a certain geographic scale, in general, a monitor need not be representative of the ambient air quality across an area of any specific size to be eligible for comparison to most NAAQS.

Network design issues that will be considered in this review are reflected in the following questions:

- Are further revisions to urban $O_3$ monitoring requirements necessary to improve characterization of $O_3$ concentrations in metropolitan areas? If so, what specific changes are needed?
- Are there situations where fewer monitors could be utilized in urban areas without increasing the uncertainty surrounding data analysis? If so, what criteria should be considered when monitors are evaluated for potential termination or relocation?
- Are further revisions to non-urban $O_3$ monitoring requirements necessary to improve characterization of $O_3$ concentrations outside of metropolitan areas? If so, what specific objectives should considered in any proposed changes to these requirements?
- What new information is available to inform network design options and technologies that are utilized in the PAMS network? What specific changes, if any, should be considered in PAMS requirements?

- $O_3$ monitoring sites are typically located to meet very specific probe and monitor siting criteria described in 40 CFR Part 58, Appendix E (e.g., acceptable probe height). Are there situations where a different set of monitor placement criteria would be appropriate to consider depending on the specific objective being characterized? For example, would a different set of probe height criteria be appropriate for monitors deployed in ecosystems with $O_3$-sensitive vegetation versus monitors deployed in cities for NAAQS compliance objectives? What changes, if any, should be considered?
- Is the length of the currently required $O_3$ monitoring seasons adequate to characterize concentrations in urban and non-urban areas? What changes, if any, should be considered?

**Data Reporting and Assessments**

The data interpretation of the primary and secondary NAAQS appendix describes the computations necessary for determining when the primary and secondary standards are met. The appendix addresses in detail, data completeness requirements, data reporting and handling conventions, the form of the standard, averaging times, and provides examples. As part of this review, the data interpretation appendix may need further revisions to ensure that EPA is providing the best protection of public health and welfare. This review will provide the opportunity to take advantage of the insights and newer concepts that have arisen in the recent review of other NAAQS pollutants.

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