



**EPA**

United States  
Environmental  
Protection Agency

---

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

*(This page intentionally left blank)*

EPA 452/R-11-006

April 2011

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

## **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 integrated review plan for the national ambient air quality standards (NAAQS) for ozone (O<sub>3</sub>) 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 plan may be modified to reflect information developed during the review of the O<sub>3</sub> NAAQS and to address advice and comments received from the Clean Air Scientific Advisory Committee and the public throughout this review. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

# TABLE OF CONTENTS

<b>LIST OF ACRONYMS/ABBREVIATIONS</b> .....	<b>IV</b>
<b>1 INTRODUCTION</b> .....	<b>1-1</b>
1.1 LEGISLATIVE REQUIREMENTS .....	1-2
1.2 OVERVIEW OF THE NAAQS REVIEW PROCESS .....	1-4
1.3 HISTORY OF O <sub>3</sub> NAAQS REVIEWS .....	1-8
1.4 RECONSIDERATION OF THE 2008 OZONE NAAQS .....	1-11
<b>2 STATUS AND SCHEDULE FOR NEW REVIEW</b> .....	<b>2-1</b>
<b>3 KEY POLICY-RELEVANT ISSUES</b> .....	<b>3-1</b>
3.1 ISSUES RELATED TO THE PRIMARY OZONE NAAQS .....	3-1
3.2 ISSUES RELATED TO THE SECONDARY OZONE NAAQS .....	3-3
<b>4 SCIENCE ASSESSMENT</b> .....	<b>4-1</b>
4.1 SCOPE AND ORGANIZATION .....	4-1
4.2 ASSESSMENT APPROACH .....	4-2
4.2.1 <i>Introduction</i> .....	4-2
4.2.2 <i>Literature Search and Identification of Relevant Studies</i> .....	4-2
4.2.3 <i>Criteria for Study Selection</i> .....	4-4
4.2.4 <i>Quality Assurance</i> .....	4-6
4.3 CONTENT AND ORGANIZATION OF THE ISA .....	4-6
4.4 CAUSAL DETERMINATIONS .....	4-13
4.5 SUPPLEMENTARY MATERIALS .....	4-14
4.6 SCIENTIFIC AND PUBLIC REVIEW .....	4-14
<b>5 HUMAN HEALTH RISK AND EXPOSURE ASSESSMENTS</b> .....	<b>5-1</b>
5.1 OVERVIEW .....	5-1
5.2 EXPOSURE AND HEALTH RISK ASSESSMENTS FROM THE LAST REVIEW .....	5-2
5.3 AIR QUALITY CONSIDERATIONS .....	5-4
5.4 POPULATION EXPOSURE ASSESSMENT APPROACH .....	5-5
5.5 HUMAN HEALTH RISK ASSESSMENTS .....	5-6
5.5.1 <i>Approach to Health Risk Assessment Based On Epidemiologic Studies</i> .....	5-7
5.5.2 <i>Approach to Health Risk Assessment Based on Controlled Human Exposure Studies</i> .....	5-8
5.5.3 <i>Uncertainty and Variability</i> .....	5-9
5.5.4 <i>Broader Risk Characterization</i> .....	5-9
5.6 SCIENTIFIC AND PUBLIC REVIEW .....	5-10
<b>6 VEGETATION AND OTHER WELFARE-RELATED ASSESSMENTS</b> .....	<b>6-1</b>
6.1 OVERVIEW .....	6-1
6.2 EXPOSURE, RISK, AND BENEFITS ASSESSMENTS FROM THE LAST REVIEW .....	6-1
6.2.1 <i>Exposure Assessment</i> .....	6-2
6.2.2 <i>Risk Assessment</i> .....	6-4
6.2.3 <i>Benefits Assessment</i> .....	6-5
6.3 AIR QUALITY CONSIDERATIONS .....	6-6
6.4 EXPOSURE ASSESSMENT APPROACH .....	6-7
6.5 RISK ASSESSMENT APPROACH .....	6-7

6.6	BENEFIT ASSESSMENT APPROACH.....	6-8
6.7	UNCERTAINTY AND VARIABILITY .....	6-9
6.8	SCIENTIFIC AND PUBLIC REVIEW .....	6-9
<b>7</b>	<b><i>POLICY ASSESSMENT/RULEMAKING</i></b> .....	<b>7-1</b>
7.1	POLICY ASSESSMENT .....	7-1
7.2	RULEMAKING.....	7-3
<b>8</b>	<b><i>AMBIENT AIR MONITORING</i></b> .....	<b>8-1</b>
8.1	OVERVIEW .....	8-1
8.2	CURRENT O <sub>3</sub> NETWORK STATUS .....	8-1
8.3	MONITORING ISSUES RELATED TO THE O <sub>3</sub> NAAQS.....	8-3
8.3.1	<i>Monitoring Methods</i> .....	8-4
8.3.2	<i>Network Design</i> .....	8-4
8.3.3	<i>Data Reporting and Assessments</i> .....	8-5
<b>9</b>	<b><i>REFERENCES</i></b> .....	<b>9-1</b>

## LIST OF ACRONYMS/ABBREVIATIONS

A/C	Air conditioning
APEX	EPA's Air Pollutants Exposure model, version 4
AQI	Air Quality Index
AQS	EPA's Air Quality System
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
CASTNET	Clean Air Status and Trends Network
CFR	Code of Federal Regulations
CHAD	EPA's Consolidated Human Activity Database
CMAQ	Community Multiscale Air Quality
CO	Carbon Monoxide
COPD	Chronic obstructive pulmonary disease
C-R	Concentration-response relationship
CRP	C-reactive protein
CSA	Consolidated Statistical Area
CV	Cardiovascular
CVD	Cardiovascular disease
ED	Emergency department
EPA	Environmental Protection Agency
FACE	Free-air exposures
FEM	Federal Equivalent Method
FEV <sub>1</sub>	Change in forced expiratory volume in one second
FIP	Federal Implementation Plan
FR	Federal Register
FRM	Federal Reference Method
HA	Hospital admissions
HEI	Health Effects Institute
HRV	Heart rate variability
IHD	Ischemic heart disease
IRP	Integrated Review Plan
ISA	Integrated Science Assessment
Km	Kilometer
ME	Microenvironment
MI	Myocardial infarction
MOA	Mode(s) or mechanism(s) of action
N	Nitrogen
NAAQS	National Ambient Air Quality Standards
NCEA-RTP	National Center for Environmental Assessment in Research Triangle Park
NCLAN	National Crop Loss Assessment Network
NEM	NAAQS Exposure Model
NERL	National Exposure Research Laboratory
NOAA	National Oceanic and Atmospheric Administration
NO <sub>2</sub>	Nitrogen dioxide

NO <sub>3</sub> <sup>-</sup>	Nitrate
NO <sub>x</sub>	Nitrogen oxides
NPS	National Park Service
NRC	National Research Council
O <sub>3</sub>	Ozone
OAQPS	Office of Air Quality Planning and Standards
OAR	Office of Air and Radiation
OMB	Office of Management and Budget
ORD	Office of Research and Development
OTC	Open Top Chambers
PA	Policy Assessment
PAMS	Photochemical Assessment Monitoring Station
PM	Particulate matter
PRB	Policy-Relevant Background
QA	Quality assurance
REA	Risk and Exposure Assessment
RR	Relative risk
SAB	Science Advisory Board
SoyFACE	Free air field based soybean study
SO <sub>2</sub>	Sulfur Dioxide
SO <sub>4</sub> <sup>2-</sup>	Sulfate
SO <sub>x</sub>	Sulfur Oxides
TB	Tracheobronchial
TREGRO	Tree growth model
TSP	Total suspended particulate
UV	Ultraviolet
VOC	Volatile organic compounds
W126	Cumulative, seasonal secondary ozone standard



# 1 INTRODUCTION

The U.S. Environmental Protection Agency (EPA) last completed a review of the primary (health-based) and secondary (welfare-based) national ambient air quality standards (NAAQS) for ozone (O<sub>3</sub>) 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 O<sub>3</sub> 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 O<sub>3</sub> standards to ensure they are scientifically sound and protective of public health and the environment as required by the Clean Air Act (CAA). The EPA published a proposed rule on the reconsideration of the 2008 O<sub>3</sub> NAAQS on January 19, 2010 (75 FR 2938-2999). Prior to the decision to reconsider the 2008 O<sub>3</sub> standards, EPA had initiated a new periodic review of the existing air quality criteria and standards for O<sub>3</sub> in September 2008.

This Integrative Review Plan (IRP) contains the plans for the new periodic review of the air quality criteria for O<sub>3</sub>-related effects on public health and public welfare and the current O<sub>3</sub> standards or any revised standards that may result from the reconsideration of the 2008 O<sub>3</sub> standards. This review will provide an integrative assessment of relevant scientific information for O<sub>3</sub> and related photochemical oxidants and will focus on the basic elements of the NAAQS: the indicator,<sup>1</sup> averaging time, form,<sup>2</sup> and level. These elements, which together serve to define each ambient air quality standard, must be considered collectively in evaluating the protection to public health and public welfare afforded by the standards.

This 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<sub>3</sub> NAAQS, and the Agency's plans to reconsider the 2008 O<sub>3</sub> NAAQS. Chapters 2 through 8 outline the Agency's plans for the new periodic review of the existing air quality criteria and the O<sub>3</sub> 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 and policy issues. Chapters 4 through 6 discuss the planned scope and organization of the key science and

---

<sup>1</sup> The "indicator" of a standard defines the chemical species or mixture that is to be measured in determining whether an area attains the standard.

<sup>2</sup> The "form" of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains the standard.

risk/exposure 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<sub>3</sub> NAAQS review. Finally, chapter 8 discusses the current ambient air monitoring network and monitoring issues related to the O<sub>3</sub> 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. section 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. The Administrator is to list those air pollutants that in her “judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;” “the presence of which in the ambient air results from numerous or diverse mobile or stationary sources;” and “for which . . . [the Administrator] plans to issue air quality criteria . . .” Air quality criteria are intended to “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air . . .” 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 are 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.”<sup>3</sup> 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.”<sup>4</sup> 42 U.S.C. § 7409(b)(2).

The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical

---

<sup>3</sup> 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, 91<sup>st</sup> Cong., 2d Sess. 10 (1970)].

<sup>4</sup> 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.”

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); *American Farm Bureau Federation v. EPA*, 559 F. 3d 512, 533 (D.C. Cir. 2009); *Association of Battery Recyclers v. EPA*, 604 F. 3d 613, 617-18 (D.C. Cir. 2010). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels, see *Lead Industries v. EPA*, 647 F.2d at 1156 n.51, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of 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*, 647 F.2d at 1161-62; *Whitman v. American Trucking Associations*, 531 U.S. 457, 495 (2001).

In setting primary and secondary standards that are "requisite" to protect public health and welfare, respectively, 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). Likewise, "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards." *American Petroleum Institute v. Costle*, 665 F. 2d at 1185.

Section 109(d)(1) requires that "not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards . . . and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate . . . ." Section 109(d)(2) requires that an independent scientific review committee "shall complete a review of the criteria . . . and the national primary and secondary ambient air quality standards . . . and shall recommend to the Administrator any new . . . standards and

revisions of existing criteria and standards as may be appropriate . . . .” Since the early 1980's, this independent review function has been performed by the Clean Air Scientific Review Committee (CASAC).<sup>5</sup>

## **1.2 OVERVIEW OF THE NAAQS REVIEW PROCESS**

Since completion of the last O<sub>3</sub> NAAQS review, the Agency has made a number of changes to the process for reviewing the NAAQS. The current process, which is being applied to this review of the NAAQS for O<sub>3</sub>, has four major phases: (1) planning, (2) science assessment, (3) risk/exposure assessment, and (4) policy assessment and rulemaking. An overview of the process is illustrated in Figure 1-1 below and each of these phases is described in this section.<sup>6</sup> The Agency maintains a web site on which key documents developed for NAAQS reviews are made available (<http://www.epa.gov/ttn/naaqs/>).

The planning phase of the NAAQS review process begins with a science policy workshop, which is intended to identify issues and questions to frame the review. Drawing from the workshop discussions, a draft IRP is prepared jointly by EPA's National Center for Environmental Assessment – Research Triangle Park (NCEA-RTP), within the Office of Research and Development (ORD), and EPA's Office of Air Quality Planning and Standards (OAQPS), within the Office of Air and Radiation (OAR). The draft IRP is made available for consultation with CASAC and for public comment. The final IRP is prepared in consideration of CASAC and public comments. This document presents the current plan and specifies the schedule for the entire review, the process for conducting the review, and the key policy-relevant science issues that will guide the review.

The second phase of the review, science assessment, involves the preparation of an Integrated Science Assessment (ISA) and supplementary materials. The ISA, prepared by NCEA-RTP, provides a concise review, synthesis, and evaluation of the most policy-relevant science, including key science judgments that are important to the design and scope of exposure and risk assessments, as well as other aspects of the NAAQS review. The ISA and its supplementary materials 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 in order to reflect the current state of knowledge. As such, the ISA forms the scientific foundation for each NAAQS review and is intended to provide

---

<sup>5</sup> Lists of CASAC members and of members of the CASAC O<sub>3</sub> Review Panel are available at: <http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CommitteesandMembership?OpenDocument>.

<sup>6</sup> Information on changes to the NAAQS review process since the last O<sub>3</sub> NAAQS review is available at: <http://www.epa.gov/ttn/naaqs/review.html>.

information useful in forming judgments about air quality indicator(s), form(s), averaging time(s) and level(s) for the NAAQS. Hence, the ISA and its associated materials function in the current NAAQS review process as the Air Quality Criteria Document (AQCD) did in the previous review process. The current review 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. Section 4 below provides a more detailed description of the planned scope, organization and assessment approach for the ISA and its supporting materials.

In the third phase, the risk/exposure assessment phase, OAQPS staff considers information and conclusions presented in the ISA, with regard to support provided for the development of quantitative assessments of the risks and/or exposures for health and/or welfare effects. As an initial step, staff prepares one or more planning documents that consider the extent to which newly available scientific evidence and tools/methodologies warrant the conduct of quantitative risk and exposure assessments. To the extent warranted, this document(s) outlines a general plan, including scope and methods, for conducting the assessments. This planning document(s) is generally prepared in conjunction with the first draft ISA and presented for consultation with CASAC and for public comment. As discussed in chapters 5 and 6 below, these planning documents for the current O<sub>3</sub> NAAQS review will focus on consideration of the newly available data, methods and tools in light of areas of uncertainty in the assessments conducted for the last review and of the potential for new or updated assessments to provide notably different exposure and risk estimates with lower associated uncertainty. Comments received on the planning document(s) are considered in the Agency's decision as to whether to conduct such assessments. When an assessment is performed, one or more drafts of each risk and exposure assessment document (REA) undergoes CASAC and public review, with the initial draft REA(s) generally being reviewed in conjunction with review of the second draft ISA, prior to completion of final REA(s). The REA provides concise presentations of methods, key results, observations, and related uncertainties. Chapters 5 and 6 discuss possible approaches being considered with regard to human health- and welfare-related assessments, respectively, for this review.

The review process ends with a policy assessment and rulemaking phase. Under the current NAAQS review process (Jackson, 2009), the EPA Administrator has reinstated the use of a Policy Assessment (PA). The PA, like the previous OAQPS Staff Paper, is a document that provides a transparent OAQPS staff analysis of the adequacy of the current standards and potential alternatives that are appropriate to consider prior to the issuance of proposed and final rules. The PA integrates and interprets the information from the ISA and REA(s) to frame policy options for consideration by the Administrator. Such an evaluation of policy implications is

intended to help “bridge the gap” between the Agency’s scientific assessments, presented in the ISA and REA(s), and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS. In so doing, the PA is also intended to facilitate CASAC’s advice to the Agency and recommendations to the Administrator on the adequacy of the existing standards or revisions that may be appropriate to consider, as provided for in the CAA. In evaluating the adequacy of the current standards and, as appropriate, a range of alternative standards, the PA considers the available scientific evidence and, as available, quantitative risk-based analyses, together with related limitations and uncertainties. The PA focuses on the information that is most pertinent to evaluating the basic elements of national ambient air quality standards: indicator, averaging time, form, and level. One or more drafts of a PA are released for CASAC review and public comment prior to completion of the final PA.

Following issuance of the final PA and consideration of conclusions presented therein, the Agency develops and publishes a notice of proposed rulemaking that communicates the Administrator’s proposed decisions regarding the standards review. A draft notice undergoes interagency review involving other federal agencies prior to publication.<sup>7</sup> Materials upon which this decision is based, including the documents described above, are made available to the public in the regulatory docket for the review. A public comment period, during which public hearings are generally held, follows publication of the notice of proposed rulemaking. Taking into account comments received on the proposed rule,<sup>8</sup> 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.

---

<sup>7</sup> Where implementation of the proposed decision would necessitate the implementation of emissions controls, EPA develops and releases a draft regulatory impact analysis (RIA) concurrent with the notice of proposed rulemaking. This activity is conducted under Executive Order 12866. The RIA is conducted completely independent of and, by statute, is not considered in decisions regarding the NAAQS.

<sup>8</sup> In the notice of final rulemaking, and generally also through the use of an accompanying document, the Agency responds to all significant comments on the proposed rule.

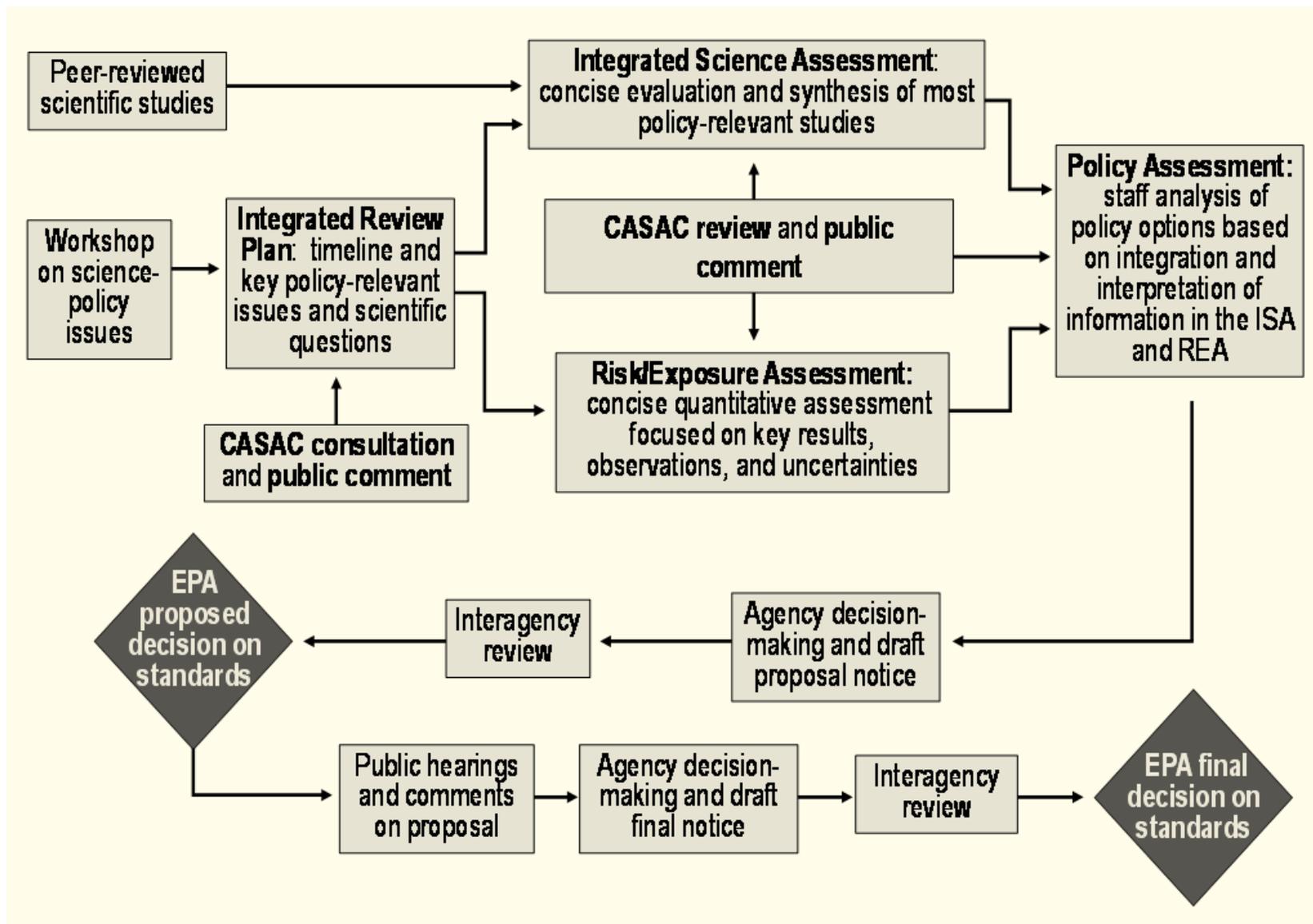


Figure 1.1. Overview of NAAQS Review Process

### 1.3 HISTORY OF O<sub>3</sub> NAAQS REVIEWS

Tropospheric (ground-level) O<sub>3</sub> is the indicator for the mix of photochemical oxidants (e.g., peroxyacetyl nitrate, hydrogen peroxide) formed from biogenic and anthropogenic precursor emissions. Naturally occurring O<sub>3</sub> in the troposphere can result from biogenic organic precursors reacting with naturally occurring nitrogen oxides (NO<sub>x</sub>) and by stratospheric O<sub>3</sub> intrusion into the troposphere. Anthropogenic precursors of O<sub>3</sub>, especially NO<sub>x</sub> and volatile organic compounds (VOCs), originate from a wide variety of stationary and mobile sources. Ambient O<sub>3</sub> concentrations produced by these emissions are directly affected by temperature, solar radiation, wind speed, and other meteorological factors.

Table 1-1 summarizes the O<sub>3</sub> 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 O<sub>3</sub> NAAQS Promulgated During the Period 1971 - 2008.**

Final Rule	Indicator	Averaging 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 <sub>3</sub>	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 <sub>3</sub>	8-hr	0.08	Annual fourth-highest daily maximum 8-hr concentration, averaged over 3 years
2008 (73 FR 16483)	O <sub>3</sub>	8-hr	0.075	Form of the standards remained unchanged relative to the 1997 standard

The 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 hour per year. The standards were based on scientific information contained in the 1970 Air Quality Criteria for Photochemical Oxidants (U.S. DHEW, 1970).

The first periodic review of the NAAQS for photochemical oxidants was initiated in 1977. Based on the 1978 Air Quality Criteria for Ozone and Other Photochemical Oxidants (U.S. EPA, 1978), 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<sub>3</sub>; 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, EPA announced plans to revise the 1978 Air Quality Criteria document (47 FR 11561), and in 1983 EPA initiated the second periodic review of the O<sub>3</sub> NAAQS (48 FR 38009). EPA subsequently published the 1986 Air Quality Criteria for Ozone and Other Photochemical Oxidants (U.S. EPA, 1986) and 1989 Staff Paper (U.S. EPA, 1989). Following publication of the 1986 Air Quality Criteria, document (AQCD) a number of scientific abstracts and articles were published that appeared to be of sufficient importance concerning potential health and welfare effects of O<sub>3</sub> to warrant preparation of a Supplement (U.S. EPA, 1992). Under the terms of a court order, on August 10, 1992 EPA published a proposed decision stating that revisions to the existing primary and secondary standards were not appropriate at the time (57 FR 35542). The notice explained that the proposed decision would complete EPA's review of information on health and welfare effects of O<sub>3</sub> assembled over a 7-year period and contained in the 1986 AQCD and its 1992 Supplement. 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<sub>3</sub> in light of emerging evidence of health effects related to 6- to 8-hour O<sub>3</sub> 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 EPA announced plans to initiate the third periodic review of the air quality criteria and O<sub>3</sub> NAAQS (57 FR 35542). On the basis of the scientific evidence contained in the 1996 Air Quality Criteria for Ozone and related Photochemical Oxidants (U.S. EPA, 1996a), the 1996 Staff Paper (U.S. EPA, 1996b), and related technical support documents, linking exposures to ambient O<sub>3</sub> to adverse health and welfare effects at levels allowed by the

then existing standards, EPA proposed to revise the primary and secondary O<sub>3</sub> standards on December 13, 1996 (61 FR 65716). The EPA proposed to replace the then existing 1-hour primary and secondary standards with 8-hour average O<sub>3</sub> 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-hour 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub>. 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> pollution in shielding the public from effects of solar (ultraviolet or UV) radiation, on November 14, 2001, EPA proposed to leave the 1997 8-hour 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-hour O<sub>3</sub> NAAQS set in 1997 (68 FR 614). Finally, on April 30, 2004, EPA announced the decision to make the 1-hour O<sub>3</sub> NAAQS no longer applicable to areas one year after the effective date of the designation of those areas for the 8-hour NAAQS (69 FR 23966). For most areas, the date that the 1-hour NAAQS no longer applied was June 15, 2005.

The EPA initiated the next periodic review of the air quality criteria and O<sub>3</sub> 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 Air Quality Criteria for Ozone and Other Photochemical Oxidants (US EPA, 2006) published in March 2006 and the Staff Paper (U.S EPA, 2007a) 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<sub>3</sub> 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 review with publication of a final decision on March 27, 2008 (73 FR 16436), revising the level of the 8-hour primary O<sub>3</sub> standard from 0.08 ppm to 0.075 ppm and revising the secondary standard to be identical to the revised primary standard.

#### **1.4 RECONSIDERATION OF THE 2008 OZONE NAAQS**

In May 2008, state, public health, environmental, and industry petitioners filed suit against EPA regarding the 2008 final decision on the O<sub>3</sub> NAAQS, 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<sub>3</sub> NAAQS to determine whether the standards established in the March 2008 O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> NAAQS set in March 2008 to ensure they are scientifically sound and protective of public health and the environment.<sup>9</sup> The EPA is basing this reconsideration on the scientific record from the 2008 review, including public comments and CASAC advice and recommendations. During the 2008 review, CASAC unanimously recommended a more health

---

<sup>9</sup> 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 proposed 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.

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<sub>3</sub> 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<sub>3</sub> NAAQS rule satisfy the requirements of the Clean Air Act.

The EPA is basing the reconsideration of the 2008 O<sub>3</sub> NAAQS decision on the scientific and technical information that was assessed during the 2008 review, including information in the 2006 Air Quality Criteria document (U.S. EPA, 2006), the 2007 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 Air Quality Criteria document is being 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 rulemakings, EPA has also conducted a provisional assessment (U.S. EPA, 2009c) of such "new" scientific information (published since review of the 2006 Air Quality Criteria document) and has concluded that the scientific literature would not materially change the conclusions reached in the 2006 Air Quality Criteria document, providing support for the determination that it was appropriate to proceed with the reconsideration rulemaking. The provisional assessment was subjected to internal EPA peer review, and the final provisional assessment (U.S. EPA, 2009c) was made available to CASAC and the public prior to the proposal (75 FR 2938). Consistent with EPA's approach in other NAAQS reviews, the Agency has not based its proposed decisions in the reconsideration on the new science but will instead review and consider the new science in the new review covered by this IRP.

Consistent with EPA's notice to the Court, this reconsideration of the 2008 O<sub>3</sub> NAAQS rule is being conducted through notice and comment rulemaking, with the notice of proposed rulemaking signed by the Administrator on January 6, 2010.<sup>10</sup> Following publication of the proposed rule (75 FR 2938) on January 19, 2010, the Agency provided for a 60-day public comment period, held public hearings in Arlington, Virginia and Houston, Texas on February 2, 2010 and in Sacramento, California on February 4, 2010, and solicited CASAC review of the

---

<sup>10</sup> This reconsideration will include review of the Air Quality Index (AQI) for O<sub>3</sub>, such that changes to the AQI will be proposed if the reconsideration results in a proposed change to the 2008 primary O<sub>3</sub> standard.

proposed rule on January 25, 2010. To ensure that the final decision on the reconsideration of the 2008 O<sub>3</sub> primary standard would be based on the most appropriate interpretation of the scientific evidence and exposure/risk information that was available in the 2008 review, in December 2010 the Administrator decided to ask the CASAC Ozone Reconsideration Panel to provide further advice about the strengths and limitations of the scientific evidence and the results of the exposure and health risk assessments to aid in her interpretation of this information. Public teleconferences with the CASAC Ozone Reconsideration Panel were held on February 18, March 3, and March 23, 2011 to respond to charge questions prepared by EPA. CASAC provided its response to the Administrator on March 29, 2011. EPA intends to issue a final decision on the reconsideration by July 29, 2011.

## **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<sub>3</sub> and related photochemical oxidants 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 Research Triangle Park, NC. The proceedings of that workshop have been considered and the issues discussed at the workshop have been incorporated into this IRP.

The development of this IRP was extended while the Agency reviewed the 2008 O<sub>3</sub> NAAQS rule for the purpose of determining whether it would reconsider the 2008 standards, as discussed above in section 1.4. A draft of this IRP was released on September 30, 2009, for the purpose of conducting a public teleconference consultation with CASAC, which was held on November 16, 2009, in order to discuss the Agency's plans for the continuation of this new review. This IRP reflects 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<sub>3</sub>-related effects on public health and public welfare. This involved updating the assessments presented in the 2006 Air Quality Criteria document (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, this new review will involve reviewing any O<sub>3</sub> standards that may be set in the July 2011 final rule that results from the reconsideration of the 2008 O<sub>3</sub> standards. While the Agency is reconsidering the 2008 O<sub>3</sub> standards, NCEA-RTP will continue the development of the ISA, the first draft of which was released to CASAC and the public in March 2011.

The schedule for the entire new review of the air quality criteria and standards is shown below in Table 2-1.

**Table 2-1. Schedule for the New Periodic O<sub>3</sub> NAAQS Review**

Stage of Review	Major Milestone	Target Dates
Integrated Review Plan (IRP)	Literature Search Federal Register Call for Information Workshop on Science/Policy Issues Draft IRP CASAC Consultation on Draft IRP Final IRP	Ongoing September 29, 2008 October 29-30, 2008 September 30, 2009 November 16, 2009 March 2011
Integrated Science Assessment (ISA)	First Draft ISA CASAC/Public Review of First Draft ISA Second Draft ISA CASAC/Public Review of Second Draft ISA Final ISA	March 2011 May 19-20, 2011 September 2011 November 2011 February 2012
Risk/Exposure Assessments (REAs)	Scope and Methods Plans CASAC Consultation on Scope and Methods Plans First Draft REAs CASAC/Public Review of First Draft REAs Second Draft REAs CASAC/Public Review of Second Draft REAs Final REAs	April 2011 May 19-20, 2011 October 2011 November 2011 May 2012 July 2012 October 2012
Policy Assessment (PA)/ Rulemaking	First Draft PA for CASAC/Public Review CASAC/Public Review of First Draft PA Second Draft PA for CASAC/Public Review CASAC/Public Review of Second Draft PA Final PA Proposed Rulemaking Final Rulemaking	June 2012 July 2012 November 2012 January 2013 March 2013 September 2013 June 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<sub>3</sub> that result from the Agency's reconsideration of the 2008 O<sub>3</sub> 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<sub>3</sub>.

### 3.1 ISSUES RELATED TO THE PRIMARY OZONE NAAQS

The first step in reviewing the adequacy of the primary O<sub>3</sub> 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 review regarding health effects related to exposure to O<sub>3</sub> and other photochemical oxidants (e.g., peroxyacetyl nitrate, hydrogen peroxide) in ambient air, with a particular emphasis on exposures and health risks in susceptible populations, such as children. 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<sub>3</sub>, 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<sub>3</sub> on at-risk populations, including those with potentially increased susceptibility such as children and disadvantaged populations?<sup>11</sup>
- 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<sub>3</sub> exposure?
- At what levels of O<sub>3</sub> 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<sub>3</sub> for the various health effects evaluated?

---

<sup>11</sup> *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<sub>3</sub>. *Vulnerability* refers to O<sub>3</sub>-related effects due to factors including socioeconomic status (e.g., reduced access to health care) or particularly elevated exposure levels.

- To what extent has new scientific information become available that alters or substantiates our understanding of non-O<sub>3</sub>-exposure factors that might influence the associations between O<sub>3</sub> 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<sub>3</sub>-related health effects are likely to occur with current ambient levels of O<sub>3</sub> or with levels that just meet the O<sub>3</sub> 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 review been addressed and/or have new uncertainties emerged?
- To what extent does newly available information reinforce or call into question any of the basic elements of the current O<sub>3</sub> standard?

Drawing upon the evidence and analyses presented in the ISA and REA, EPA will evaluate whether revisions to the primary O<sub>3</sub> standard might be appropriate, and, if so, how this standard might be revised. Specifically, we 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 standard 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 does 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<sub>3</sub> and other photochemical oxidants, and what are the uncertainties associated with the estimated exposure and risk reductions? What conclusions can be drawn regarding the health protection afforded susceptible populations?
- 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**

As with the review of the primary NAAQS, the first step in reviewing the adequacy of the secondary O<sub>3</sub> 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 review regarding welfare effects related to exposure to O<sub>3</sub> and other photochemical oxidants (e.g., peroxyacetyl nitrate, hydrogen peroxide) 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> that might influence the associations between O<sub>3</sub> 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<sub>3</sub> as low as or lower than those observed previously? What is the nature of the exposure-response relationships of O<sub>3</sub> for the various welfare effects evaluated?
- Given recognition in the last review that the significance of O<sub>3</sub>-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<sub>3</sub>-related welfare effects are likely to occur with current ambient levels of O<sub>3</sub> or with levels that just meet the O<sub>3</sub> 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 review been addressed and/or have new uncertainties emerged?
- To what extent does newly available information reinforce or call into question any of the basic elements of the current O<sub>3</sub> standard?

Drawing upon the information and assessments presented in the ISA and REA, EPA will evaluate whether revisions to the secondary O<sub>3</sub> 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<sub>3</sub> 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. 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.

The science assessment will consist of an ISA and supplementary materials 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<sub>3</sub> and related photochemical oxidants in ambient air. This document and its supplementary materials 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<sub>3</sub>. 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<sub>3</sub> 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 Air Quality Criteria document (U.S. EPA, 2006) and focus on peer reviewed literature published since the previous review of the air quality criteria for O<sub>3</sub>. The 2006 Air Quality Criteria document 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 may be more specifically discussed in detail to reinforce key concepts and conclusions and/or if they are open to reinterpretation in light of newer data. Older studies also may be the primary focus in some areas of the document where research efforts have subsided and these older studies remain the definitive works available in the literature. Emphasis will be placed on studies conducted at or near O<sub>3</sub>

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**

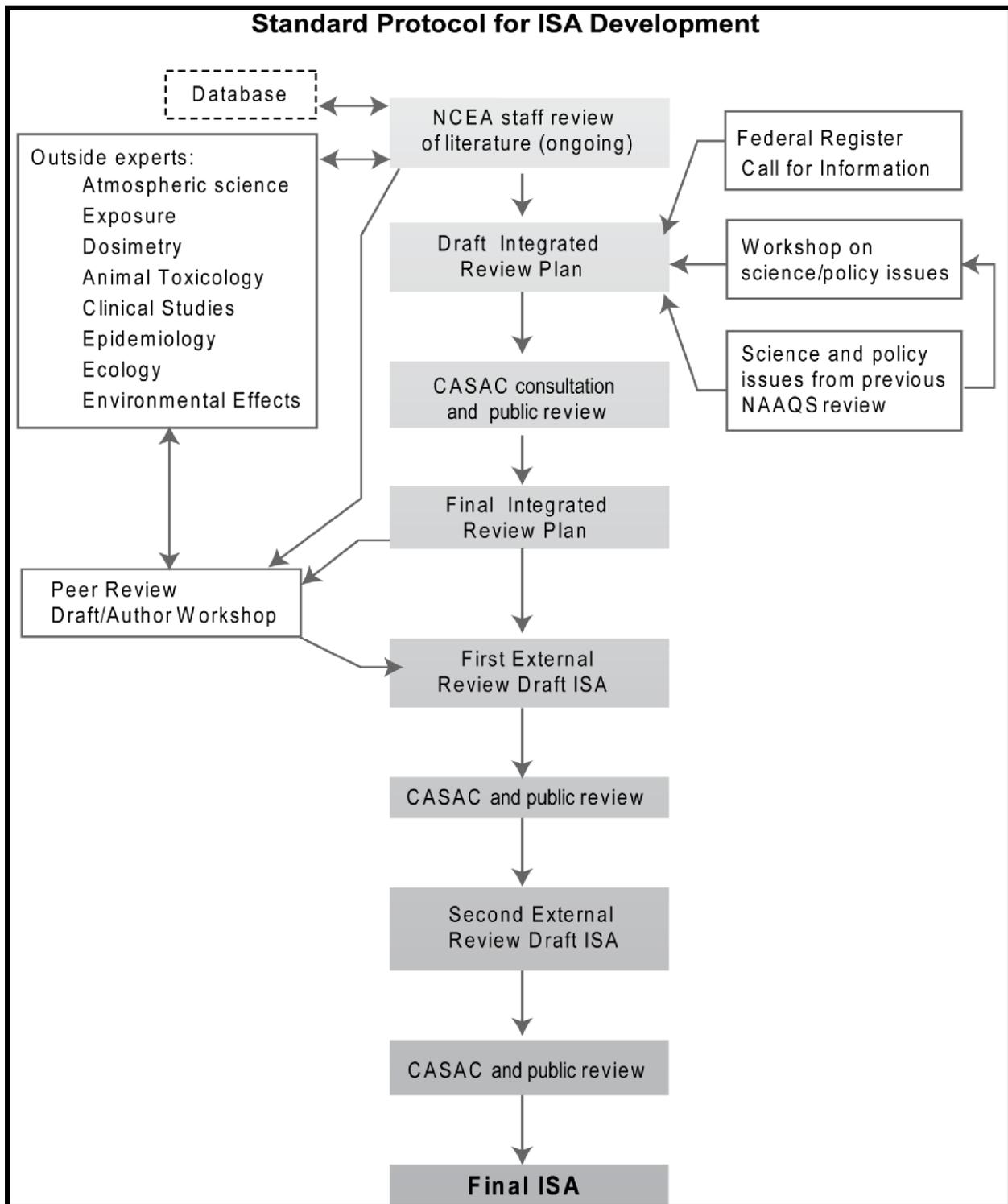
### **4.2.1 Introduction**

The EPA's NCEA-RTP is responsible for preparing the ISA and its supplementary materials for O<sub>3</sub>. 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 NAAQS review process is addressed in section 1.2.

### **4.2.2 Literature Search and Identification of Relevant Studies**

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 populations, 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<sub>3</sub> 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 approximately a month prior to the release of the second external review draft of the ISA (see Table 2-1). 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)**

### **4.2.3 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<sub>3</sub>; (2) health endpoints that repeat or extend findings from earlier assessments as well as those not previously extensively researched; (3) populations that are susceptible to O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> exposure within the respiratory tract. Consideration will be given mainly to animal studies conducted at less than 1 ppm O<sub>3</sub>. The necessity of such upper concentrations limits may be illustrated by rats, a key species used in O<sub>3</sub> 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<sub>3</sub> or other pollutants do not necessarily reflect effects in the most susceptible 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<sub>3</sub> uptake and effect or the

influence of photochemical oxidation processes that would otherwise be unavailable through in vivo studies. The appropriateness of O<sub>3</sub> concentrations will be evaluated as necessary.

For research evaluating controlled human exposures to O<sub>3</sub>, 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<sub>3</sub> separately and in combination with other pollutants such as PM and NO<sub>2</sub>; 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 research evaluating welfare effects, emphasis will 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<sub>3</sub> 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<sub>3</sub> effects on vegetation and the resulting consequences on growth and yield. These mechanisms will inform our considerations of O<sub>3</sub> effects on larger scale ecosystem structure, function and services. These and other welfare effects will be addressed in the ISA for both short- and long-term O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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 review.

#### **4.2.4 Quality Assurance**

NCEA participates in the Agency-wide Quality Management System, which requires the development of a Quality Management Plan (QMP). Implementation of the NCEA QMP ensures that all data generated or used by NCEA scientists are “of the type and quality needed and expected for their intended use” and that all information disseminated by NCEA adheres to a high standard for quality including objectivity, utility and integrity.

The NCEA QA staff is responsible for the review and approval of quality-related documentation. NCEA scientists are responsible for the evaluation of all inputs to the ISA, including primary (new) and secondary (existing) data, to ensure their quality is appropriate for their intended purpose. NCEA follows the Data Quality Objectives, which identify the most appropriate inputs to the science assessment, and provides QA instruction for researchers citing secondary information. The approaches utilized to search the literature and criteria for study selection were detailed in the two preceding subsections. Generally, NCEA scientists rely on scientific information found in peer-reviewed journal articles, books, and government reports. Where information is integrated or reduced from multiple sources to create new figures, tables, or summation, the data generated are considered to be new and subject to rigorous quality assurance measures to ensure their accuracy.

### **4.3 CONTENT AND ORGANIZATION OF THE ISA**

The organization of the ISA for O<sub>3</sub> will be consistent with that used in the ISA for particulate matter completed in December 2009 (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<sub>3</sub> 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<sub>3</sub> that stem from these issues will guide the content of the ISA. These questions were derived from the last O<sub>3</sub> NAAQS review, 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<sub>3</sub> 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<sub>3</sub>, and its potential associations with other photochemical oxidants and with other relevant atmospheric pollutants. New information concerning the mechanisms of formation of O<sub>3</sub> and other photochemical oxidants, such as peroxyacyl nitrates, and hydrogen peroxide and organic peroxides, and the physical properties governing their transport and lifetimes in the atmosphere will be considered. The ISA will evaluate relevant data concerning the origin, transformation and transport, and fate of atmospheric oxidants in addition to O<sub>3</sub>.

The assessment will also include information about the distribution of monitors in the regulatory O<sub>3</sub> 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<sub>3</sub>. New information on the distribution of ambient O<sub>3</sub> concentrations from in situ instruments, satellites, and other remote sensing tools will also be considered.

Since a key component of quantitative risk assessments has been the distribution of the policy-relevant background (PRB)<sup>12</sup> concentration of O<sub>3</sub> in the U.S., the ISA will evaluate methods for producing these concentrations and characterize O<sub>3</sub> PRB concentrations. In the last review, O<sub>3</sub> PRB concentrations were generated using the global scale, three dimensional, chemical transport model GEOS-CHEM, based on contributions from natural sources everywhere in the world and from anthropogenic sources outside continental North America. The ISA will evaluate relevant new studies and information on background concentrations. The assessment will include estimation of O<sub>3</sub> PRB concentrations based on the definition of PRB used in previous reviews, and it will also evaluate additional approaches to estimation of O<sub>3</sub> PRB concentrations, including consideration of alternative definitions of PRB. This may include evaluation of the use of models such as MOZART or CMAQ and approaches to the use of these models.

---

<sup>12</sup> "Policy-relevant background" has been defined by EPA historically as the O<sub>3</sub> concentrations that would be observed in the U.S. in the absence of anthropogenic emissions of O<sub>3</sub> precursors (e.g., VOC and NO<sub>x</sub>) 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).

The ISA will include evaluation of data on the effects of tropospheric O<sub>3</sub> on climate, including its role as a constituent greenhouse gas, i.e., in its role as a radiative forcing agent and its effects as an absorber of UV-B radiation in the troposphere. The potential effects of climate change on regional air quality are being assessed elsewhere by the Agency (<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=203459>).

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<sub>3</sub> concentrations and exposures to O<sub>3</sub> 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<sub>3</sub> 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 populations.

### **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<sub>3</sub>. 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<sub>3</sub> will be evaluated in epidemiologic, human clinical, and toxicological studies. The ISA will also integrate previous information on susceptible populations (e.g., asthmatics, children, outdoor workers) with new evidence for these and possibly other susceptible populations (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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> exposures?
- Do long-term exposures to O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub>? Is there evidence of coherence and plausibility for such effects?
- What new evidence is available on associations between O<sub>3</sub> and mortality (total, respiratory or cardiovascular)?
- To what extent is key evidence becoming available that could inform the understanding of populations and life stages that are particularly susceptible to O<sub>3</sub> exposures? What is known about genetic traits, metabolic syndrome, or other factors that affect susceptibility? What is known about susceptibility at various ages and developmental stages, including critical windows of exposure that result in different effects and/or effects at lower exposures? Are new animal models becoming available to better characterize susceptible populations?
- What O<sub>3</sub>-induced health effects are sufficiently characterized to be quantitatively compared across species?
- To what extent does exposure to O<sub>3</sub> contribute to health effects in other organ systems?
- What new evidence has become available to help discern health effects of multipollutant exposures (containing O<sub>3</sub>) versus O<sub>3</sub> 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<sub>2</sub>, SO<sub>2</sub>, and CO) influence the uncertainty of the evidence base for both short- and long-term O<sub>3</sub> exposures?
- To what extent are the observed health effects attributable to O<sub>3</sub> versus other oxidants that are associated with O<sub>3</sub>?
- 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<sub>3</sub> 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<sub>3</sub>.

- Is there new information related to the pathways and underlying biological mechanism(s) or modes of action for O<sub>3</sub>?
- What are the inherent interspecies differences in sensitivity to O<sub>3</sub> and in O<sub>3</sub> dosimetry in different regions of the respiratory tract? Are these likely to vary across age groups? Are there site-specific responses to O<sub>3</sub> in the respiratory tract that would better explain local and systemic effects of O<sub>3</sub> 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<sub>3</sub>-induced cellular and tissue injury, repair, and remodeling?

Susceptible Populations: The ISA will examine health outcome data to identify specific groups that have a greater likelihood of experiencing health effects related to O<sub>3</sub> exposure due to a variety of factors including, but not limited to: genetic or developmental factors, race, gender,

lifestage (e.g., children), lifestyle (e.g., smoking status, nutrition, outdoor work) or preexisting disease; as well as, population-level factors that can affect an individual's exposure to O<sub>3</sub> such as socioeconomic status (SES), which encompasses reduced access to health care, low educational attainment, residential location, and other factors. The host and environmental factors that are responsible for differential susceptibility to O<sub>3</sub> will be investigated.

- What do controlled human exposure, animal toxicological, and epidemiologic studies indicate regarding the relationship between acute exposures to O<sub>3</sub> 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<sub>3</sub> effects? What are the pathways and mechanisms through which O<sub>3</sub> 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)?
- How has new evidence increased our understanding of the potential susceptibility of children and older adults to effects from O<sub>3</sub> 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 susceptible populations?
- What evidence is available regarding susceptibility to O<sub>3</sub>-induced responses in population groups due to age, race, gender, or genetic makeup? How do the nature of the effects and exposure-response relationships differ between groups? Is there evidence of differing biological modes of action related to observed susceptibility?
- To what extent is susceptibility to the effects of short-term O<sub>3</sub> exposure is associated with long-term O<sub>3</sub> susceptibility?
- What factors (e.g., demographic and socioeconomic) affect susceptibility to short- and long-term O<sub>3</sub> exposures? Are there new data regarding population groups, such as disadvantaged populations with potentially greater susceptibility to effects of O<sub>3</sub>?

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).

### **Vegetation, Ecosystems and other Welfare Effects**

The ISA will evaluate the literature related to O<sub>3</sub> exposures on the growth of vegetation, visible foliar injury, ecosystem services and other welfare effects. This will include evaluation of O<sub>3</sub> exposures on productivity of ecosystems and crops systems and potential effects on ecosystem services. Other effects that will be evaluated include O<sub>3</sub> effects on materials and

climate. 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> effects on vegetation, there has been no common metric used across studies to describe the relationship between O<sub>3</sub> exposures and plant response. How can O<sub>3</sub> studies which use various O<sub>3</sub> metrics, plant species and methodologies be appropriately quantitatively synthesized and assessed?

Ecosystem Services: Some recent research has examined further how O<sub>3</sub> effects are potentially linked to ecosystem services and processes related to these services. Such linked ecosystem services and processes identified in recent studies include water supply and quality, N-cycling, bee pollination, and CO<sub>2</sub> sequestration.

- What is the nature of the information linking O<sub>3</sub> pollution and ecosystem services? What are the existing studies that make direct or indirect linkages between O<sub>3</sub> 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<sub>3</sub> on CO<sub>2</sub> sequestration in ecosystems?
- How does O<sub>3</sub> influence the biodiversity of ecological systems?
- Has O<sub>3</sub> altered nutritional content of forage for domestic animals or wildlife populations?

Materials Damage: Ozone and other photochemical oxidants react with many economically important man-made materials, decreasing their useful life and aesthetic appearance. Materials damaged by O<sub>3</sub> 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.

Climate: The ISA will include evaluation of data relevant to the issue of tropospheric O<sub>3</sub> as a constituent greenhouse gas, i.e., in its role as a radiative forcing agent and its effects as an absorber of UV-B radiation in the troposphere. The potential effects of climate change on regional air quality are being assessed elsewhere by the Agency (<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=203459>).

#### **4.4 CAUSAL DETERMINATIONS**

Since the last O<sub>3</sub> NAAQS review, EPA has developed a framework that is intended to provide a consistent and transparent basis for drawing conclusions on causal relationships between pollutant exposures and health or environmental effects. Use of this framework in the recent science assessment for particulate matter is described in chapter 1 of that ISA (EPA, 2009a). Briefly, the framework includes the following considerations for drawing conclusions of causality for specific endpoints: consistency of findings for an endpoint across studies in which it was examined, coherence of the results related to a specific endpoint among different study types or disciplines, the coherence of results with characterized mechanisms of action (biological plausibility), and evidence of a concentration- or dose-response relationship for an endpoint. In drawing judgments regarding causality for the criteria air pollutants, EPA focuses on evidence of effects at relevant pollutant exposures.

In the current ISA for O<sub>3</sub>, EPA will assess the results of recent relevant publications, building upon evidence available during the previous O<sub>3</sub> NAAQS review, to draw conclusions regarding the strength of the evidence for causal relationships between health and environmental effects associated with short- and long-term exposure periods. Evaluations of causality for ecological and welfare effects generally consider the probability of quantitative changes in response to exposure. Exposure-response relationships are often determined for a specific ecological system and scale, rather than at the national or even regional scale. In making determinations of causality for human health effects, evidence will be evaluated for broad health outcome categories, such as respiratory effects, and then conclusions drawn based upon the integration of evidence from across disciplines (e.g., epidemiology, clinical studies and toxicology) and also across the suite of related individual health outcomes. EPA will focus on

health outcome categories, rather than very specific endpoints, since the coherence of evidence across a spectrum of related endpoints (e.g., effects ranging from inflammatory effects to respiratory mortality) is an important aspect for drawing conclusions regarding causality.

#### **4.5 SUPPLEMENTARY MATERIALS**

Previous science assessments conducted to support NAAQS reviews included supplementary materials, which were designed to provide detailed supporting information and more comprehensive coverage of the research areas summarized in the ISA. NCEA intends to change the form, while maintaining the relevant content, of the materials that were formerly contained within the Annexes to the ISA.

As discussed previously, studies included in the text of the ISA will be those deemed informative to the NAAQS review process (e.g. policy-relevant) and of adequate quality. The ISA text, tables and figures will highlight and summarize key study details that are needed to understand and interpret the results of a study. This information, which was described in the text as well as reiterated in the annex tables of previous documents, includes: (1) the chemistry, physics, sources, emissions, and measurement of O<sub>3</sub>; (2) environmental concentrations and human exposure to O<sub>3</sub>; (3) dosimetry; (4) toxicological studies of O<sub>3</sub> health effects in laboratory animals and *in vitro* systems; (5) human clinical studies examining health effects following controlled exposure to O<sub>3</sub>; (6) epidemiologic studies of health effects from short- and long-term exposure to O<sub>3</sub>; (7) environmental studies on vegetation and ecosystem effects; and (8) materials damage and climate change related to O<sub>3</sub>. In addition, supplementary materials will be provided in the form of output from the Health and Environmental Research Online (HERO) database. A key function of the HERO output will be to document the base of evidence containing publications evaluated for the O<sub>3</sub> review, including any publications considered but not included in the ISA. This information will be presented as links to lists of references in the HERO database, which include bibliographic information and abstracts.

#### **4.6 SCIENTIFIC AND PUBLIC REVIEW**

Drafts of the ISA will be reviewed by the CASAC O<sub>3</sub> Review Panel and made available for public comment. The CASAC O<sub>3</sub> 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<sub>3</sub> 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 ozone ISA docket (Docket ID: EPA-HQ-ORD-2011-0050).

## 5 HUMAN HEALTH RISK AND EXPOSURE ASSESSMENTS

### 5.1 OVERVIEW

Characterizing health risks for the new periodic review of the primary NAAQS for O<sub>3</sub> will include conducting air quality analyses to support quantitative exposure and risk assessments in specific locations to the extent warranted by new information, taking into consideration available resources. The results of such assessments will be put into a broader public health perspective, with a particular emphasis on exposures and health risks in susceptible populations, such as children. 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<sub>3</sub>, but recognizes that O<sub>3</sub> serves as an indicator of the broader photochemical oxidant mix. Therefore, health effects reported to be associated with exposure to O<sub>3</sub> may not be due to O<sub>3</sub> 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 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 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 THE LAST REVIEW**

The exposure and health risk assessments conducted in the last review developed exposure and health risk estimates for 12 urban areas across the U.S. which were chosen based on the location of O<sub>3</sub> epidemiologic studies and to represent a range of geographic areas, population demographics, and O<sub>3</sub> climatology. These analyses were 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<sub>3</sub> 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<sub>3</sub> standard and several alternative 8-hr O<sub>3</sub> 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 populations, 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<sub>3</sub> 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<sub>3</sub> air quality, including counts of people exposed one or more times to a given O<sub>3</sub> 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<sub>3</sub> season.

As discussed in the Staff Paper and in section II.A of the 2008 O<sub>3</sub> NAAQS final rule (73 FR 16440 to 16442), of the uncertainties identified and evaluated, the most important uncertainties affecting the exposure estimates were related to modeling human activity patterns over an O<sub>3</sub> season, modeling of variations in ambient concentrations near roadways, and modeling of air exchange rates that affect the amount of O<sub>3</sub> 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<sub>3</sub> concentrations at or near 0.08 ppm.

The human health risk assessment conducted in the last review 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<sub>3</sub>-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<sub>3</sub> 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<sub>3</sub> risk assessment, in addition to important caveats and limitations, were addressed in section II.B of the 2008 O<sub>3</sub> NAAQS final rule notice (73 FR 16440 to 16443). In general, estimated risk reductions associated with going from current O<sub>3</sub> 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<sub>3</sub> concentrations. There was also noticeable city-to-city variability in estimated O<sub>3</sub>-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<sub>3</sub> 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 2008-2010 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 may also be conducted to place the results of the quantitative risk and exposure assessments into a broader public health context.

While incremental risk reductions may 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<sub>3</sub> concentrations that would be observed in the U.S. in the absence of anthropogenic (man-made) emissions of precursor emissions (e.g., VOC, NO<sub>x</sub>, 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 in past reviews included: (1) O<sub>3</sub> generated in the U.S. that arises from natural (biogenic) sources of emissions in the U.S., Canada, and Mexico and (2) O<sub>3</sub> in the U.S.

from the transport of O<sub>3</sub> 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, including alternative approaches for defining PRB, and will produce O<sub>3</sub> 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<sub>3</sub> levels observed in the U.S.) and to the extent warranted, evaluate alternative definitions of PRB and their implications on exposures and risk. This additional information will help inform policy considerations for this review of the O<sub>3</sub> NAAQS as well as more broadly inform efforts related to international efforts to reduce trans-boundary O<sub>3</sub> air pollution.

As part of the exposure and risk assessments, it will be necessary to adjust recent O<sub>3</sub> air quality data to simulate just meeting the current standard and any alternative O<sub>3</sub> standards that might be considered. In the last review, 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<sub>3</sub> levels and by analyzing changes in O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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 last review. Staff will consider performing the exposure assessment 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<sub>3</sub> 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 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<sub>3</sub>-season or year-long activity sequences for individuals from primarily cross-sectional activity data diaries.

As done in the last O<sub>3</sub> NAAQS review and other recent 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.

## **5.5 HUMAN HEALTH RISK ASSESSMENTS**

The goals of the O<sub>3</sub> 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<sub>3</sub> levels and with just meeting the current O<sub>3</sub> 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 in the last review. Staff will

consider performing the assessment 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<sub>3</sub> 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 supplementary materials. 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<sub>3</sub> 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<sub>3</sub> air quality estimated to occur when an area just meets a given O<sub>3</sub> 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 last review. 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<sub>3</sub> 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<sub>3</sub> concentrations are typically measured as the area-wide average of monitor-specific measurements, although personal exposures are occasionally measured. Health responses for O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> ISA infers the likelihood of a causal relationship between O<sub>3</sub> exposure and a given health effect category and the weight of the evidence for concluding that O<sub>3</sub> 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 last review. 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<sub>3</sub> 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  $\geq 10$ , 15, and 20% decrements in FEV<sub>1</sub>. In this new review, staff intends to investigate the possibility of using a model (McDonnell et al., 2007) that estimates FEV<sub>1</sub> responses associated with O<sub>3</sub> 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**

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 plans to 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<sub>3</sub> 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 review.

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<sub>3</sub> 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<sub>3</sub> 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 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<sub>3</sub> Review Panel will discuss its comments on the 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<sub>3</sub> 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**

Assessments being considered for this new review of the secondary O<sub>3</sub> NAAQS would focus on new information that has become available since the review completed in 2008. 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<sub>3</sub> standard. New information and methods available in this review have the potential to improve characterization of O<sub>3</sub> exposures and associated impacts, especially in non-urban areas, forests, and Class I protected lands. Recent information regarding direct O<sub>3</sub> effects on plants, including emerging evidence that O<sub>3</sub> 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 review, information regarding the interaction between O<sub>3</sub>, 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 THE LAST REVIEW**

The exposure, risk and benefits assessments conducted as part of the last review focused on O<sub>3</sub>-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<sub>3</sub> air quality for the years 2001 – 2004; (2) estimates of seedling growth loss under then current and alternative O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> outputs from the EPA/NOAA Community Multi-scale Air Quality (CMAQ)<sup>13</sup> model system (<http://www.epa.gov/asmdnerl/CMAQ>, Byun and Ching, 1999) were used to develop scaling factors to augment the monitor interpolation. In order to characterize uncertainty associated with the exposure estimates generated using the interpolation method, monitored O<sub>3</sub> concentrations were systematically compared to interpolated O<sub>3</sub> concentrations in areas where monitors were located. In general, the interpolation method performed well in many areas in the U.S. This approach was used to develop a national vegetation O<sub>3</sub> exposure surface.

---

<sup>13</sup> 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<sub>3</sub>, particulate matter, and nutrient deposition) holistically. The CMAQ model can generate estimates of hourly O<sub>3</sub> 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).

To evaluate changing vegetation exposures under selected air quality scenarios, a number of analyses were conducted. One analysis adjusted 2001 base year O<sub>3</sub> 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<sub>3</sub> air quality levels could result in significant O<sub>3</sub> exposures to vegetation in some areas; (2) overall 3-month 12-hr W126 O<sub>3</sub> 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 then proposed range for the primary O<sub>3</sub> standard) showed substantially improved O<sub>3</sub> 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<sub>3</sub> 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.<sup>14</sup> 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 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<sub>3</sub> average concentrations would reduce O<sub>3</sub> 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<sub>3</sub> concentrations in relation to plant response; and (3) the effects of attainment of a 8-hr

---

<sup>14</sup> The Staff Paper presented this analysis using then recent (2002-2004) county-level O<sub>3</sub> 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<sub>3</sub> levels for the counties in which they are located.

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 review 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<sub>3</sub>-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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> air quality scenarios from just meeting alternative

O<sub>3</sub> standards on the growth of mature trees.<sup>15</sup> 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<sub>3</sub>-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<sub>3</sub> (King et al., 2005); some mature trees such as red oak have shown an even greater sensitivity of photosynthesis to O<sub>3</sub> 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 (Andersen, et al, 1997).

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. The crop risk assessment, like the tree seedling assessment, combined NCLAN 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<sub>3</sub>-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.

---

<sup>15</sup> 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<sub>3</sub> and climate/meteorology interactions on tree growth. TREGRO has been used to evaluate the effects of a variety of O<sub>3</sub> 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).

### **6.3 AIR QUALITY CONSIDERATIONS**

Air quality analyses are necessary to inform and support welfare-related exposure, risk, and benefits assessments. The air quality analyses being considered for this review would build upon those of the ISA and would 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 federally designated Class I natural areas important to welfare effects assessment, (3) estimates of 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 would support quantitative exposure and risk assessments that may be considered in light of the new scientific information available for specific locations, as well as at regional and national scales.

In addition to updating air quality summaries since the last review, these air quality analyses may 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. Such air quality analyses would use monitor data from the AQS data base (which includes National Park Service monitors) and the CASTNET network. In addition, staff may explore the suitability of using other sources of O<sub>3</sub> concentration information that might be available, such as from portable monitors or satellites.

In the last review, 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 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<sub>3</sub> data, may be explored.

Estimates of the risks in excess of PRB remaining upon meeting the current or potential alternative standards require EPA to estimate PRB. As noted above in sections 4.2 and 5.3, EPA will be evaluating alternative definitions of PRB and the implications of those definitions for estimates of risk. This type of risk estimate is considered relevant to inform the EPA Administrator's decision on the adequacy of a given standard. The current approach to estimating O<sub>3</sub> 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 that would support any exposure, risk and benefits assessments that may be conducted, it would be necessary to adjust recent O<sub>3</sub> air quality data to

simulate just meeting the current standard and any alternative O<sub>3</sub> standards. In the last review, EPA used a quadratic air quality rollback approach (U.S. EPA, 2007a, section 4.5.8). Staff may 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 review, little has changed in terms of the extent of monitoring coverage in non-urban areas. We are planning to consider both past and alternative approaches for generating estimates of national O<sub>3</sub> exposures in an effort to continue enhancing our ability to characterize exposures in these non-monitored areas. It is expected that any vegetation exposure assessments that may be conducted will again include assessments of recent air quality, air quality associated with just meeting the current standard and any alternative standards that might be considered.

In addition, given the importance of providing protection for sensitive vegetation in areas afforded special protections, such as in federally designated Class I natural areas, we may also consider alternative sources of O<sub>3</sub> exposure information for those types of sites. For example, portable O<sub>3</sub> monitors are being deployed in some national parks and a current exploratory study is underway to measure O<sub>3</sub> concentration variations with gradients in elevation. Information from these monitors could potentially inform our understanding of uncertainties associated with assessing O<sub>3</sub> distribution patterns in complex terrain and high elevations.

#### **6.5 RISK ASSESSMENT APPROACH**

Since the last review, new scientific information on the direct and indirect effects of O<sub>3</sub> on vegetation and ecosystems, respectively, has become available. With respect to mature trees and forests, the information regarding O<sub>3</sub> impacts to forest ecosystems has continued to expand, including limited new evidence that implicates O<sub>3</sub> as an indirect contributor to decreases in stream flow through direct impacts on whole tree level water use. Long-term FACE (Free Air CO<sub>2</sub> enrichment) studies are continuing to provide additional evidence regarding chronic O<sub>3</sub> 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<sub>3</sub>. 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 available. In light of this new scientific information, we will consider whether additional analyses are warranted, such as combining the USFS data with recent county level air quality

data to determine the incidence of visible O<sub>3</sub> damage occurring across the U.S. at air quality levels that meet or are below the current standard, as was done in the last review. To the extent warranted, based on new information regarding O<sub>3</sub> effects on forest trees, both qualitative and quantitative assessments may be considered in an effort to place both the estimates of risk from more recent long-term studies and historic shorter-term studies in the context of Essential Services.

Additional information relevant to both tree and crop risk assessments expected to be available includes that regarding the interactions between elevated O<sub>3</sub> and CO<sub>2</sub> with respect to plant growth and how these interactions might be expected to be modified under different climatic conditions, and potential reactions of O<sub>3</sub> 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. To the extent warranted, staff also plans to consider any available information regarding potential risks to threatened or endangered species.

## **6.6 BENEFIT ASSESSMENT APPROACH**

To the extent warranted, qualitative and/or quantitative benefits assessments of ecosystem services impacted by O<sub>3</sub> will be considered to inform the current review. For example, benefits assessments in this review may include tree biomass and crop analyses, and when possible, may 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 crops. The impact of O<sub>3</sub> on limiting potential CO<sub>2</sub> sequestration is another important ecosystem services. New preliminary evidence of O<sub>3</sub> 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 for this assessment. This model jointly assesses the economic impacts of O<sub>3</sub> 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 use FASOM to model damage by O<sub>3</sub> to the agriculture and forestry sectors and quantify how O<sub>3</sub>-exposed vegetation impacts the ecosystem service of carbon sequestration.

A conclusion in the last review was that the science continued to support the use of an exposure index that reflects the effects of cumulative, seasonal O<sub>3</sub> exposures on plants. In light of new information on exposures, risks, non-plant effects, and ecosystem services, we will consider whether additional analyses are warranted to evaluate the relative risks associated with alternative cumulative, seasonal forms. 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 exposure, risk and benefits assessments that are being considered for this review, staff is considering a similar approach to that used in the previous review to characterize uncertainty and variability associated with these assessments. 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 CMAQ and FASOM 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 consider the impact of using different adjustment factors. As in the last review, every effort will be made to provide information on the uncertainties and variability associated with whatever exposure and risk assessments may be conducted. Uncertainties associated with empirical evidence due to exposure or research methods would be described.

## **6.8 SCIENTIFIC AND PUBLIC REVIEW**

A 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<sub>3</sub> Review Panel will discuss their comments on the 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<sub>3</sub> 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**

### **7.1 POLICY ASSESSMENT**

The Policy Assessment (PA), like the previous OAQPS Staff Paper, is a document that provides a transparent OAQPS staff analysis and staff conclusions regarding the adequacy of the current standards and potential alternatives that are appropriate to consider prior to the issuance of proposed and final rules. The PA integrates and interprets the information from the ISA and REA(s) to frame policy options for consideration by the Administrator. The PA is also intended to facilitate CASAC's advice to the Agency and recommendations to the Administrator on the adequacy of the existing standards or revisions that may be appropriate to consider, as provided for in the Clean Air Act. Staff conclusions will be based on the information contained in the ISA, and, as available, the REAs, and any additional staff evaluations and assessments discussed in the PA. In so doing, the discussion in the PA will be framed by consideration of a series of the policy-relevant questions drawn from those outlined in chapter 3, including the fundamental questions associated with the adequacy of the current standards and, as appropriate, 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 quantitative assessments for the adequacy of the current standards, and for any alternative standards under consideration. The PA will also describe a broad range of policy options for standard setting, identifying the broadest range for which the staff identifies support within the available information. In so doing, the PA will describe the underlying interpretations of the scientific evidence and risk/exposure information that might support such alternative policy options that could be considered by the Administrator in making decisions for the O<sub>3</sub> standards.

In identifying a range of primary standard options for the Administrator to consider, it is recognized that the final decision will be largely a public health policy judgment. A final decision must draw upon scientific information and analyses about health effects and risks, as well as judgments about how to deal with the range of uncertainties that are inherent in the scientific evidence and analyses. Staff's approach to informing these judgments is based on a recognition that the available health effects evidence generally reflects a continuum consisting of ambient levels at which scientists generally agree that health effects are likely to occur through lower levels at which the likelihood and magnitude of the response become increasingly

uncertain. This approach is consistent with the requirements of the NAAQS provisions of the Act and with how EPA and the courts have historically interpreted the Act. These provisions require the Administrator to establish primary standards that are requisite to protect public health and are neither more nor less stringent than necessary for this purpose. The provisions do not require that primary standards be set at a zero-risk level, but rather at a level that avoids unacceptable risks to public health, including the health of susceptible populations.<sup>16</sup>

In identifying a range of secondary standard options for the Administrator to consider, staff recognizes that the final decision will be largely a public policy judgment. A final decision must draw upon scientific evidence and analyses about effects on public welfare, as well as judgments about how to deal with the range of uncertainties that are inherent in the relevant information. This approach is consistent with the requirements of the NAAQS provisions of the Act and with how EPA and the courts have historically interpreted the Act. These provisions require the Administrator to establish secondary standards that are requisite to protect public welfare from any known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The provisions do not require that secondary standards be set to eliminate all welfare effects, but rather at a level that protects public welfare from those effects that are judged to be adverse.

Staff will prepare at least one draft of the PA document for CASAC review and public comment. The draft PA document will be distributed to the CASAC O<sub>3</sub> Review Panel for their consideration and provided to the public for review and comment. Review by the CASAC O<sub>3</sub> Review Panel will be discussed at public meetings that will be announced in the Federal Register. Based on past practice by CASAC, EPA expects that key advice and recommendations for revision of the document would be summarized by the CASAC in a letter to the EPA Administrator. In revising the draft PA document, OAQPS will take into account any such recommendations, and also consider comments received, from CASAC and from the public, at the meeting itself, and any written comments received. The final document will be made available on an EPA website, with its public availability announced in the Federal Register.

---

<sup>16</sup> The susceptible populations identified in a NAAQS review may be comprised of low income or minority groups. Where low income/minority groups are among the susceptible populations, the rulemaking decision will be based on providing protection for these and other susceptible populations. To the extent that low income/minority groups are not among the susceptible populations, a decision based on providing protection of the susceptible populations would be expected to provide protection for the low income/minority groups (as well as any other less sensitive population groups).

## 7.2 RULEMAKING

Following issuance of the final PA and EPA management consideration of staff analyses and conclusions presented therein, and taking into consideration CASAC advice and recommendations, the Agency will develop a notice of proposed rulemaking. The proposed rulemaking notice conveys the Administrator's proposed conclusions regarding the adequacy of the current standards and any revision that may be appropriate. A draft notice of proposed rulemaking will be submitted to the Office of Management and Budget (OMB) for interagency review, in which OMB and other federal agencies are provided the opportunity for review and comment. After the completion of interagency review, EPA will publish the notice of proposed rulemaking in the Federal Register. Monitoring rule changes associated with review of the O<sub>3</sub> standards, and drawing from considerations outlined in chapter 8 below, will be developed and proposed, as appropriate, in conjunction with this NAAQS rulemaking.

At the time of publication of the notice of proposed rulemaking, all materials on which the proposal is based are made available in the public docket for the rulemaking.<sup>17</sup> Publication of the proposal notice is followed by a public comment period, generally lasting 60 to 90 days, during which the public is invited to submit comments on the proposal to the rulemaking docket. Taking into account comments received on the proposed rule, the Agency will then develop a notice of final rulemaking, which again undergoes OMB-coordinated interagency review prior to issuance by EPA of the final rule. In the notice of final rulemaking, and generally also through the use of an accompanying document, the Agency responds to all significant comments on the proposed rule. Publication of the final rule in the Federal Register completes the rulemaking process.

---

<sup>17</sup> The rulemaking docket for the current O<sub>3</sub> review is identified as EPA-HQ-OAR-2008-0699. This docket has incorporated the ISA docket (EPA-HQ-ORD-2011-0050) by reference. Both dockets are publicly accessible at [www.regulations.gov](http://www.regulations.gov).

## **8 AMBIENT AIR MONITORING**

### **8.1 OVERVIEW**

The O<sub>3</sub> 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<sub>3</sub> 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 of O<sub>3</sub>.

To meet these multiple objectives, national O<sub>3</sub> sites are deployed in a 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<sub>3</sub> 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 review 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.<sup>18</sup> During this review, EPA intends to include any 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<sub>3</sub> NETWORK STATUS**

Presently, states and local air quality management agencies operate minimum numbers of EPA-approved O<sub>3</sub> monitors based on the population of each of their Metropolitan Statistical Area (MSA) and the most recently measured O<sub>3</sub> levels for each area. Currently, there are 369 MSAs in the U.S. subject to minimum O<sub>3</sub> monitoring requirements. In these areas, a total of 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

---

<sup>18</sup> The proposed rule, Ambient Ozone Monitoring Regulations: Revisions to Network Design Requirements, was published on July 16, 2009 (74 FR 34525).

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<sub>3</sub> monitors that were operated in excess of minimum requirements were sited to characterize the O<sub>3</sub> 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<sub>3</sub> minimum requirements do not account for the full breadth of additional factors that would be considered in designing a complete O<sub>3</sub> monitoring program for an area. Some of these additional factors include geographic size, population density, complexity of terrain and meteorology, presence of nearby O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> monitoring requirements in approved plans become the basis for state O<sub>3</sub> monitoring requirements for the 1-year period following plan approval.

Although there are currently no EPA requirements for O<sub>3</sub> monitoring other than in or adjacent to MSAs, there are at present about 200 state-operated O<sub>3</sub> monitors in counties that are not part of MSAs, and these monitors can be categorized in several ways. States commonly locate O<sub>3</sub> monitors both upwind and downwind of major urban areas to evaluate the spatial gradient or extent of transported O<sub>3</sub> pollution and the lag time typically associated with photochemical production. In some cases, these O<sub>3</sub> 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<sub>3</sub> concentration is outside the MSA.

As part of the Clean Air Status and Trends Network (CASTNET), the EPA operates 57 O<sub>3</sub> monitors, and the National Park Service (NPS) operates 23 monitors across the eastern and western U.S. The NPS also operates additional O<sub>3</sub> monitors independent of CASTNET stations. CASTNET O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub>, NO, and VOC in O<sub>3</sub> 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<sub>3</sub> nonattainment areas classified as serious, severe, or extreme. Design criteria for the PAMS network are based on locations relative to O<sub>3</sub> precursor source areas and predominant wind directions associated with high O<sub>3</sub> 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<sub>3</sub> and its precursors, and the photochemical processes related to O<sub>3</sub> nonattainment. EPA reduced PAMS requirements as part of the October 17, 2006 rulemaking. Current requirements include site-specific measurements for speciated VOC, carbonyls, NO<sub>x</sub>, NO<sub>y</sub>, CO, O<sub>3</sub>, surface meteorology, and upper air meteorology.

Unlike the ambient monitoring requirements for other criteria pollutants that mandate year-round monitoring, O<sub>3</sub> monitoring is currently only required during the seasons of the year that are conducive to O<sub>3</sub> formation. These seasons vary in length from place to place as the conditions that determine the likely O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> monitoring season for most sites continues all 12 months of the year.

### **8.3 MONITORING ISSUES RELATED TO THE O<sub>3</sub> NAAQS**

This new review of the O<sub>3</sub> NAAQS will explore a number of policy-relevant issues associated with measuring and characterizing O<sub>3</sub> 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<sub>3</sub>, including consideration of the available information on probe and siting criteria that could best support the current or alternative standards.

### 8.3.1 Monitoring Methods

The nation's O<sub>3</sub> 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<sub>3</sub> NAAQS have considered the implications of interferences in the response of UV and chemiluminescence-based instruments due to the effects of water vapor, VOC's, aromatic compounds and their oxidation products, and other organic and inorganic compounds.

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<sub>3</sub> 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?

### 8.3.2 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<sub>3</sub> 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 revisions to urban O<sub>3</sub> monitoring requirements necessary to improve characterization of O<sub>3</sub> 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 revisions to non-urban O<sub>3</sub> monitoring requirements necessary to improve characterization of O<sub>3</sub> concentrations outside of metropolitan areas? If so, what specific objectives should be 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<sub>3</sub> 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<sub>3</sub>-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<sub>3</sub> monitoring seasons adequate to characterize concentrations in urban and non-urban areas? What changes, if any, should be considered?

### **8.3.3 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.

## 9 REFERENCES

- Abt Associates Inc. (2007a). Ozone Health Risk Assessment for Selected Urban Areas. Prepared for Office of Air Quality Planning and Standards, U.S. Environmental Agency, Research Triangle Park, NC, July 2007. Available electronically on the internet at: [http://epa.gov/ttn/naaqs/standards/ozone/data/ozone\\_ra\\_final\\_tsd\\_7-2007.pdf](http://epa.gov/ttn/naaqs/standards/ozone/data/ozone_ra_final_tsd_7-2007.pdf).
- Abt Associates Inc, (2007b). Technical Report on Ozone Exposure, Risk and Impacts Assessments for Vegetation: Final Report. Prepared for Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC, January 2007. Available electronically on the internet at: [http://www.epa.gov/ttn/naaqs/standards/ozone/data/2007\\_01\\_environmental\\_tsd.pdf](http://www.epa.gov/ttn/naaqs/standards/ozone/data/2007_01_environmental_tsd.pdf).
- Adams, W.C. (2002). Comparison of chamber and face-mask 6.6-hour exposures to ozone on pulmonary function and symptoms responses. *Inhalation Toxicology*. 14:745-764.
- Adams, W.C. (2003). Comparison of chamber and face-mask 6.6-hour exposure to 0.08 ppm ozone via square-wave and triangular profiles on pulmonary responses. *Inhalation Toxicology*. 15: 265-281.
- Adams, W.C. (2006). Comparison of chamber 6.6-hour exposures to 0.04-0.08 ppm ozone via square-wave and triangular profiles on pulmonary responses. *Inhalation Toxicology*. 18: 127-136.
- Byun, D.W.; Ching, J.K.S. (1999). Science Algorithms of the EPA Models-3 Community Multiscale Air Quality (CMAQ) Modeling System: US Environmental Protection Agency, Office of Research and Development.
- Folinsbee, L.J.; McDonnell, W.F.; Horstman, D.H. (1988). Pulmonary function and symptom responses after 6.6-hour exposure to 0.12 ppm ozone with moderate exercise. *JAPCA*. 38: 28-35.
- Gregg, J.W.; Jones, C.G.; Dawson, T.E. (2003). Urbanization effects on tree growth in the vicinity of New York City. *Nature*. 424:183-187.
- Horstman, D.H.; Folinsbee, L.J.; Ives, P.J.; Abdul-Salaam, S.; McDonnell, W.F. (1990). Ozone concentration and pulmonary response relationships for 6.6-hr exposures with five hrs of moderate exercise to 0.08, 0.10, and 0.12 ppm. *Am Rev Respir Dis*. 142:1158-1163.
- Horst, R.; Duff, M. (1995). Concentration data transformation and the quadratic rollback methodology (Round 2, Revised). Unpublished memorandum to R. Rodriguez, U.S. EPA, June 8, 1995.

- Karnosky, D.F.; Pregitzer, K.S.; Zak, D.R.; Kubiske, M.E.; Hendrey, G.R.; Weinstein, D.; Nosal, M.; Percy, K.E. (2005). Scaling ozone responses of forest trees to the ecosystem level in a changing climate. *Plant Cell Environ.* 28:965-981.
- King, J.S.; Kubiske, M.E.; Pregitzer, K.S.; Hendrey, G.R.; McDonald, E.P.; Giardina, C. P.; Quinn, V.S.; Karnosky, D. F. (2005) Tropospheric O<sub>3</sub> compromises net primary production in young stands of trembling aspen, paper birch and sugar maple in response to elevated atmospheric CO<sub>2</sub>. *New Phytol.* 168:623-636.
- Laurence, J.A.; Kohut, R.J.; Amundson, R.G. (1993). Use of TREGRO to simulate the effects of ozone on the growth of red spruce seedlings. *Forest Sci.* 39:453-464.
- Laurence, J.A.; Retzlaff, W.A.; Kern, J.S.; Lee, E.H.; Hogsett, W.E.; Weinstein, D.A. (2001). Predicting the regional impact of ozone and precipitation on the growth of loblolly pine and yellow poplar using linked TREGRO and ZELG models. *For Ecol Manage.* 146:247-263.
- Langstaff, J.E. (2007). OAQPS Staff Memorandum to Ozone NAAQS Review Docket (OAR-2005-0172). Subject: Analysis of Uncertainty in Ozone Population Exposure Modeling. [January 31, 2007]. Available electronically on the internet at: [http://www.epa.gov/ttn/naaqs/standards/ozone/s\\_o3\\_cr\\_td.html](http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_cr_td.html).
- McDonnell, W.F. et al. (1991). Respiratory response of humans exposed to low levels of ozone for 6.6 hours. *Am Rev Respir Dis.* 147:804-810.
- Morgan M.G.; Henrion M. (1990). *Uncertainty: A Guide To Dealing with Uncertainty in Qualitative Risk and Policy Analysis.* Cambridge University Press.
- Retzlaff, W.A.; Arthur, M.A.; Grulke, N.E.; Weinstein, D.A.; Gollands, B. (2000). Use of a single-tree simulation model to predict effects of ozone and drought on growth of a white fir tree. *Tree Physiol.* 20:195-202.
- Rizzo, M. (2005). Evaluation of a quadratic approach for adjusting distributions of hourly ozone concentrations to meet air quality standards. November 7, 2005. Available electronically on the internet at: <http://epa.gov/ttn/naaqs/standards/ozone/data/rizzo-memo-11-05.pdf>.
- Rizzo, M. (2006). A distributional comparison between different rollback methodologies applied to ambient ozone concentrations. May 31, 2006. Available electronically on the internet at: [http://epa.gov/ttn/naaqs/standards/ozone/data/20060823\\_rizzo\\_rollback\\_evaluation.pdf](http://epa.gov/ttn/naaqs/standards/ozone/data/20060823_rizzo_rollback_evaluation.pdf).

- Taylor, G.E.; Owens, J.G.; Grizzard, T.; Selvidge, W.J. (1993). Atmosphere x canopy interactions of nitric acid vapor in loblolly-pine grown in open-top chambers. *J Environ Qual.* 22:70-80.
- Taylor, G.E., Jr.; Johnson, D.W.; Andersen, C.P. (1994). Air pollution and forest ecosystems: a regional to global perspective. *Ecol Appl.* 4:662-689.
- Tingey, D.T.; Laurence, J.A.; Weber, J.A.; Greene, J.; Hogsett, W.E.; Brown, S.; Lee, E.H. (2001). Elevated CO<sub>2</sub> and temperature alter the response of *Pinus ponderosa* to ozone: A simulation analysis. *Ecol Appl.* 11:1412-142.
- U.S. Department of Health, Education, and Welfare (1970). Air Quality Criteria for Photochemical Oxidants. Washington, DC: National Air Pollution Control Administration; publication no. AP-63. Available from: NTIS, Springfield, VA; PB-190262/BA.
- U.S. Environmental Protection Agency (1978). Air Quality Criteria for Ozone and other Photochemical Oxidants. Research Triangle Park, NC: Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office; report no. EPA-600/8-78-004. Available from: NTIS, Springfield, VA; PB80-124753.
- U.S. Environmental Protection Agency (1986). Air Quality Criteria for Ozone and other Photochemical Oxidants. Research Triangle Park, NC: Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office; report nos. EPA-600/8-84-020aF-eF. 5v. Available from: NTIS, Springfield, VA; PB87-142949.
- U.S. Environmental Protection Agency (1989). Review of the National Ambient Air Quality Standards for Ozone: Assessment of Scientific and Technical Information. OAQPS Staff Paper. Research Triangle Park, NC: Office of Air Quality Planning and Standards; report no. EPA-452/R-92-001. Available from: NTIS, Springfield, VA; PB92-190446.
- U.S. Environmental Protection Agency (1992). Supplement to the Air Quality Criteria for Ozone and other Photochemical Oxidants. Research Triangle Park, NC: Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office; report nos. EPA-600/8-88/105F. Available from: NTIS, Springfield, VA; PB92-235670.
- U.S. Environmental Protection Agency (1996a). Air Quality Criteria for Ozone and related Photochemical Oxidants. Research Triangle Park, NC: Office of Research and Development; report nos. EPA/600/AP-93/004aF-cF. 3v. Available from: NTIS, Springfield, VA; PB96-185582, PB96-185590, and PB96-185608. Available electronically on the internet at: <http://cfpub2.epa.gov/ncea/>.

- U.S. Environmental Protection Agency (1996b). Review of the National Ambient Air Quality Standards for Ozone: Assessment of Scientific and Technical Information. OAQPS Staff Paper. Research Triangle Park, NC: Office of Air Quality Planning and Standards; report no. EPA-452/R-96-007. Available from: NTIS, Springfield, VA; PB96-203435. Available electronically on the internet at: [http://www.epa.gov/ttn/naaqs/standards/ozone/s\\_o3\\_pr\\_sp.html](http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_pr_sp.html) .
- U.S. Environmental Protection Agency (2002). Project Work Plan for Revised Air Quality Criteria for Ozone and other Photochemical Oxidants. Research Triangle Park, NC: National Center for Environmental Assessment-RTP; report no. NCEA-R-1068.
- U.S. Environmental Protection Agency (2006). Air Quality Criteria for Ozone and other Photochemical Oxidants. Research Triangle Park, NC: Office of Research and Development; report no. EPA/600/R-05/004aB-cB. Available electronically on the internet at: <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=137307> .
- U.S. Environmental Protection Agency (2007a). Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information. OAQPS Staff Paper. Research Triangle Park, NC: Office of Air Quality Planning and Standards; report no. EPA-452/R-07-007a. Available electronically on the internet at: [http://www.epa.gov/ttn/naaqs/standards/ozone/s\\_o3\\_cr\\_sp.html](http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_cr_sp.html) .
- U.S. Environmental Protection Agency (2007b). Ozone Population Exposure Analysis for Selected Urban Areas. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. Available electronically on the internet at: [http://epa.gov/ttn/naaqs/standards/ozone/data/2007\\_07\\_o3\\_exposure\\_tsd.pdf](http://epa.gov/ttn/naaqs/standards/ozone/data/2007_07_o3_exposure_tsd.pdf) .
- U.S. Environmental Protection Agency (2008). Risk and Exposure Assessment to Support the Review of the NO<sub>2</sub> primary National Ambient Air Quality Standard. EPA-452/R-08-008a. Available electronically on the internet at: [http://www.epa.gov/ttn/naaqs/standards/nox/data/20081121\\_NO2\\_REA\\_final.pdf](http://www.epa.gov/ttn/naaqs/standards/nox/data/20081121_NO2_REA_final.pdf) .
- U.S. Environmental Protection Agency (2009a). Integrated Science Assessment for Particulate Matter (Second External Review Draft). Research Triangle Park, NC: Office of Research and Development; report nos. EPA/600/R-08/139B and EPA/600/R-08/139BA. Available electronically on the internet at: <http://cfint.rtpnc.epa.gov/ncea/prod/recordisplay.cfm?deid=210586> .
- U.S. Environmental Protection Agency (2009b). Risk and Exposure Assessment to Support the Review of the SO<sub>2</sub> Primary National Ambient Air Quality Standard. EPA- EPA-452/R-09-007. Available electronically on the internet at: <http://www.epa.gov/ttn/naaqs/standards/so2/data/200908SO2REAFinalReport.pdf> .

- U.S. Environmental Protection Agency (2009c). Provisional Assessment of Recent Studies on Health and Ecological Effects of Ozone Exposure. EPA/600/R-09/101. Available electronically at:  
<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=214003>.
- Weinstein, D.A.; Beloin, R.M.; Yanai, R.D. (1991). Modeling changes in red spruce carbon balance and allocation in response to interacting ozone and nutrient stresses. *Tree Phys.* 9:127-146.
- Weinstein, D.A.; Laurence, J.A.; Retzlaff, W.A.; Kern J.S.; Lee, E.H.; Hogsett, W.E.; Weber, J. (2005). Predicting the effects of tropospheric ozone on regional productivity of ponderosa pine and white fir. *Forest Ecol Manag.* 205:73-89.
- WHO (2008). Harmonization Project Document No. 6. Part 1: Guidance Document on Characterizing and Communicating Uncertainty in Exposure Assessment. Available electronically on the internet at:  
<http://www.who.int/ipcs/methods/harmonization/areas/exposure/en/>.

---

United States  
Environmental Protection  
Agency

Office of Air Quality Planning and Standards  
Health & Environmental Impacts Division  
Research Triangle Park, NC

Publication No. EPA-452/R-11-006  
April 2011

---