Plan for Review of the National Ambient Air Quality Standards for Ozone

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DISCLAIMER

This plan for the review of the national ambient air quality standards (NAAQS) for ozone (O_3) is an informational document that summarizes background information on EPA's NAAQS review process and the schedule for the ongoing review of the O_3 NAAQS. This document also includes staff views as to the planned organization and content of a key document, the *Ozone Staff Paper*, that will be prepared by OAQPS staff as part of this review. As such, some elements of this plan may be modified to reflect information developed during this review and to address advice and comments received from the Clean Air Scientific Advisory Committee and the public throughout this review.

Table of Contents

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1 INTRODUCTION

The U.S. Environmental Protection Agency (EPA) is presently conducting a review of the national ambient air quality standards (NAAQS) for ozone (O_3). This plan for the O_3 NAAQS review presents the schedule for key milestones in this review, and provides background information on the NAAQS review process, a brief summary of past O_3 NAAQS reviews, and the status of current review activities. This document also focuses on the development of a key document in the review process, the *Ozone Staff Paper: Policy Assessment of Scientific and Technical Information in the Review of the Ozone NAAQS* (O_3 Staff Paper), and discusses the planned organization and content of that document. As such, this plan is intended to serve as an informational document to help interested parties understand the status and plans for EPA's ongoing O_3 NAAQS review.

1.1 Overview of Review Process

Sections 108 and 109 of the Clean Air Act (Act) govern the establishment and periodic review of the NAAQS. These standards are established for pollutants that may reasonably be anticipated to endanger public health and welfare, and whose presence in the ambient air results from numerous or diverse mobile or stationary sources. The NAAQS are to be based on air quality criteria, which are to accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health or welfare which may be expected from the presence of the pollutant in ambient air.[1] The EPA Administrator is to promulgate and periodically review, at five-year intervals, "primary" (health-based) and "secondary" (welfare-based) NAAQS for such pollutants. Section 109(b)(1) of the Act 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." Section 109(b)(2) of the Act directs that a secondary standard is to "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air."[2]

Based on periodic reviews of the air quality criteria and standards, the Administrator is to make revisions in the criteria and standards and promulgate any new standards, as may be

[1] The cost of attaining the NAAQS is not to be taken into account in setting the standards, but rather is considered in the development of control strategies designed to implement the standards.

[2] Welfare effects, as defined in section 302(h) of the Act 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."

appropriate. The Act also requires that an independent scientific review committee advise the Administrator on the criteria and standards as part of this NAAQS review process. Since the early 1980's, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC), a standing committee of EPA's Science Advisory Board.

The process generally used by EPA for conducting periodic reviews of the criteria and NAAQS for a given pollutant includes the preparation of two key documents, an Air Quality Criteria Document (AQCD) and a Staff Paper, followed by the proposal and promulgation of decisions as to whether to retain or revise the existing standards. The AQCD, prepared by EPA's National Center for Environmental Assessment in Research Triangle Park (NCEA-RTP) within the Office of Research and Development (ORD), provides a critical assessment of the latest available scientific information upon which the NAAQS are to be based. Drawing upon the AQCD, staff in EPA's Office of Air Quality Planning and Standards (OAQPS) within the Office of Air and Radiation (OAR) prepares a Staff Paper that evaluates policy implications of the key studies and scientific information contained in the AQCD and presents the conclusions and recommendations of the staff for standard-setting options for the EPA Administrator to consider. The Staff Paper is intended to help "bridge the gap" between the scientific assessment contained in the AQCD and the judgments required of the Administrator in determining whether it is appropriate to retain or to revise the primary and secondary NAAQS. In conjunction with the Staff Paper, OAQPS staff conducts various policy-relevant assessments of air quality data and health and/or environmental effects to help inform staff's conclusions and recommendations. Drafts of the AQCD and the Staff Paper and related assessments are made available for public comment and CASAC review. The final versions of these documents incorporate changes made in response to CASAC advice and recommendations and public comments.

Based on the information in these documents, the Administrator proposes decisions on whether to retain or revise the NAAQS, taking into account CASAC advice and recommendations and public comments. The Administrator's proposed decisions are published in the *Federal Register*, with a preamble that presents the rationale for the decisions and solicits public comment. The Administrator makes final decisions after considering comments received on the proposed decisions. The Administrator's final decisions are promulgated in a *Federal Register* notice that addresses significant comments received on the proposal.

NAAQS decisions involve consideration of the four basic elements of a standard: indicator, averaging time, form, and level. The indicator defines the pollutant to be measured in the ambient air for the purpose of determining compliance with the standard. The averaging time defines the time period over which air quality measurements are to be obtained and averaged, considering evidence of effects associated with various time periods of exposure. The form of a standard defines the air quality statistic that is to be compared to the level of the standard (i.e., an ambient concentration of the indicator pollutant) in determining whether an area attains the standard. The form of the standard specifies the air quality measurements that are to be used for compliance purposes (e.g., the annual 4th highest daily maximum 8-hour concentration, averaged over three years), the monitors from which the measurements are to be obtained (e.g., one or more population-oriented monitors in an area), and whether the statistic is to be averaged across multiple years. These basic elements of a standard are the primary focus

of the staff conclusions and recommendations in the Staff Paper and in the subsequent rulemaking. These four elements taken together determine the degree of public health and welfare protection afforded by the NAAQS.

1.2 Scope of O_3 NAAQS Review Plan

The review of the O_3 criteria was initiated in September 2000 by NCEA-RTP with a general call for information published in the *Federal Register*. In November 2002, NCEA-RTP released a work plan for the review and revision of the O_3 AQCD (EPA, 2002). This O_3 NAAQS review plan is intended to update and go beyond the scope of the earlier O_3 AQCD work plan. That work plan focused on key issues to be addressed in the preparation of a revised O_3 AQCD, the organization and content of the revised AQCD, and the schedule for its preparation. Since the release of the O_3 AQCD work plan, a lawsuit was filed in March 2003 to compel EPA to complete the O_3 NAAQS review.[3] In resolving that lawsuit, EPA entered into a consent decree. The schedule for completion of the revised O_3 AQCD and the O_3 NAAQS review is now governed by that consent decree, as reflected in this plan.

Beyond updating the schedule for the preparation of the O_3 AQCD, this plan addresses the preparation of an O_3 Staff Paper and the subsequent rule making. Following a summary of past O_3 NAAQS reviews, this plan presents an updated schedule for key milestones through completion of the O_3 NAAQS review and the status of current review activities. The remainder of this plan then focuses on the development of the O_3 Staff Paper and related health and environmental assessments. The planned organization and content of the O_3 Staff Paper are outlined; key policy-relevant issues are identified; plans for preparing health and environmental assessments of scientific and technical information contained in the O_3 AQCD are briefly summarized; and general approaches are discussed for drawing upon the available evidence and assessments to develop staff recommendations on whether, and if so, how, it may be appropriate to revise the primary and secondary O_3 NAAQS.

Since this plan is being prepared prior to completion of the O_3 AQCD, it anticipates various issues that might emerge during the review of that document and allows for various approaches that might be appropriate for the health and environmental assessments planned in conjunction with the preparation of the O_3 Staff Paper. Thus, this plan represents current staff views and may be modified to reflect information developed during this review and to address advice and recommendations received from the CASAC and public comments.

1.3 Summary of Past O_3 NAAQS Reviews

On April 30, 1971, the EPA initially established primary and secondary NAAQS for photochemical oxidants under section 109 of the Act (36 FR 8186). Both primary and secondary

[3] The lawsuit filed by a group of plaintiffs representing national environmental organizations alleged that EPA had failed to perform its mandatory duty, under section 109(d)(1) of the Act, of completing the current review within the period provided by statute. *American Lung Association v. Whitman* (No. 1:03CV00778, D.D.C. 2003).

standards were set at a level of 0.08 parts per million (ppm), 1-hour average, total photochemical oxidants, not to be exceeded more than one hour per year.

On February 8, 1979, the first periodic review of the O_3 air quality criteria and standards was completed with the promulgation of revised standards (44 FR 8202). The level of the primary and secondary NAAQS was changed to 0.12 ppm; the indicator was changed to O_3; and the form of the standards was changed to be based on the expected number of days per calendar year with a maximum hourly average concentration above 0.12 ppm (i.e., attainment of the standard occurs when that number is equal to or less than one).

On March 9, 1993, EPA concluded its second periodic O_3 NAAQS review by deciding that revisions to the standards were not warranted at that time (58 FR 13008). The timing of this decision was required by a court order issued to resolve a lawsuit filed to compel EPA to complete its review of the criteria and standards for O_3 in accordance with the Act. This decision reflected EPA's review of relevant scientific information assembled since the last review, as contained in the 1986 O_3 AQCD and its Supplement and the 1989 O_3 Staff Paper, although it did not take into consideration a large number of more recently published studies on the health and welfare effects of O_3. The final decision emphasized the Administrator's intention to proceed as rapidly as possible with the next periodic review of the air quality criteria and standards to consider the more recent information.

Under a highly accelerated review process, EPA completed the last O_3 NAAQS review on July 18, 1997, revising the primary and secondary standards on the basis of the latest scientific evidence linking exposures to ambient O_3 to adverse health and welfare effects at levels allowed by the existing standards (62 FR 38856). The O_3 standards were revised by replacing the then existing primary 1-hour standard with an 8-hour average O_3 standard set at a level of 0.08 ppm. The form of the primary standard was changed to the annual fourth-highest daily maximum 8-hour average concentration, averaged over three years. The secondary O_3 standard was changed by making it identical in all respects to the revised primary standard.

On May 14, 1999, in response to challenges to EPA's 1997 decision filed by industry and others,[4] the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit Court) remanded the O_3 NAAQS to EPA, finding that section 109 of the Act, as interpreted by EPA, effected an unconstitutional delegation of legislative authority.[5] In addition, the D.C. Circuit Court directed that, in responding to the remand, EPA should consider the potential beneficial health effects of O_3 pollution in shielding the public from the effects of solar ultraviolet (UV) radiation. On January 27, 2000, EPA petitioned the U.S. Supreme Court for certiorari on the constitutional issue (and two other issues) but did not request review of the D.C. Circuit Court ruling regarding the potential beneficial health effects of O_3. On February 27, 2001, the U.S. Supreme Court unanimously reversed the judgment of the D.C. Circuit Court on the constitutional issue, holding that section 109 of the CAA does not delegate legislative power to the EPA in contravention of the Constitution, and remanded the case to the D.C. Circuit Court to

[4] *American Trucking Associations v. EPA*, No. 96-1441

[5] *American Trucking Associations v. EPA*, 175 F.3d 1027 (D.C. Cir., 1999)

consider challenges to the O_3 NAAQS that had not been addressed by that Court's earlier decisions.[6] On March 26, 2002, the D.C. Circuit Court issued its final decision, finding the 1997 O_3 NAAQS to be "neither arbitrary nor capricious," and denied the remaining petitions for review.[7]

On November 14, 2001, EPA proposed to respond to the Court's remand to consider the potential beneficial health effects of O_3 pollution in shielding the public from the effects of solar (UV) radiation by leaving the 1997 8-hour NAAQS unchanged (66 FR 52768). Taking into account public comment on the proposed decision, EPA published its final response to this remand on January 6, 2003, reaffirming the 8-hour O_3 NAAQS set in 1997 (68 FR 614).

2 OZONE NAAQS REVIEW SCHEDULE AND STATUS

Key milestones in the ongoing O_3 criteria and standards review are summarized below in Table 1. As noted above, the schedule for this review is now governed by a consent decree, as modified and entered by the court on December 16, 2004. The consent decree provides that EPA will meet the dates for the three milestones listed in Table 1 in bold type, which are premised on the expectation that the dates for other listed interim milestones will be met as well.

As shown in Table 1, EPA initiated this review in September 2000 with a call for information. A work plan for the preparation of the O_3 AQCD was released in November 2002 for CASAC and public review. EPA held a series of workshops on several draft chapters of the O_3 AQCD to obtain broad input from the relevant scientific communities in mid-2003. These workshops helped to inform the preparation of the first draft O_3 AQCD (EPA, 2005), which was released for CASAC and public review on January 31, 2005.

During the process of preparing the first draft O_3 AQCD, NCEA-RTP decided to make some revisions to the planned format of the O_3 AQCD that was described in the 2002 work plan. These decisions were made as part of a collaborative effort with OAQPS staff to modify the review process so as to enhance the Agency's ability to meet this and future NAAQS review schedules. As described in Chapter 1 of the first draft O_3 AQCD, emphasis is placed on interpretative evaluation and integration of evidence in the main body of the document, with more detailed descriptions of individual studies being provided in a series of accompanying annexes. This change is intended to streamline the document so as to facilitate timely CASAC and public review and to focus more clearly on issues most relevant to the policy assessment to be developed in the Staff Paper. The modified review process envisions that key policy-relevant issues will be identified earlier in the review process through enhanced collaboration between NCEA-RTP and OAQPS staff, leading to a more efficient linkage between the AQCD and the Staff Paper. Since this modified process was evolving during the later stages of the preparation of the first draft O_3 AQCD, the document does not fully reflect the revised format, especially those chapters that deal with welfare effects. It is intended that following the CASAC and public

[6] *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001)

[7] *American Trucking Associations v. EPA*, 283 F.3d 355, (D.C. Cir. 2002)

review meeting in early May, the revised format will be more consistently used throughout the second draft of the document.

Table 1. Key Milestones in the O_3 NAAQS review

Criteria Document and Staff Paper:	
• Call for information published in *Federal Register*	Sept. 2000
• Release draft O_3 AQCD Work Plan	Nov. 2002
• CASAC/public review and meeting on O_3 AQCD Work Plan	Feb. 2003
• Peer Review Workshops on draft chapters of O_3 AQCD	Mar. - Oct. 2003
• Release 1st draft O_3 AQCD	Jan. 31, 2005
• Release draft Health Assessment Plan (Exposure and Risk Assessment)	Apr. 2005
• CASAC/public review and meeting on 1st draft O_3 AQCD and CASAC consultation on draft Health Assessment Plan	May 4-5, 2005
• Release draft Environmental Assessment Plan	May 2005
• CASAC consultation on draft Environmental Assessment Plan	June 2005
• Release 2nd draft O_3 AQCD	Aug./Sept. 2005
• Release 1st drafts of O_3 Staff Paper and Health/Environmental Assessments	Sept. 2005
• CASAC/public review and meeting on 2nd draft O_3 AQCD and 1st drafts of O_3 Staff Paper and Health/Environmental Assessments	Dec 2005
• **Final O_3 AQCD**	**Feb 28, 2006**
• Release 2nd drafts of O_3 Staff Paper and Health/Environmental Assessments	Apr. 2006
• CASAC/public review and meeting on 2nd drafts of O_3 Staff Paper and Health/Environmental Assessments	July 2006
• Final O_3 Staff Paper and Health/Environmental Assessments	Sept. 2006
Rulemaking:	
• ***Federal Register*** **Notice of Proposed Rulemaking**	**Mar 28, 2007**
• ***Federal Register*** **Notice of Final Rulemaking**	**Dec 19, 2007**

Consistent with the above schedule, OAQPS staff is now preparing plans for the health and environmental assessments to be done in conjunction with the preparation of the O_3 Staff Paper. As discussed below, the health-related assessment plan will include discussions of the planned scope and methods to be used in conducting an exposure analysis and health risk assessment. The environmental-related assessment plan will focus on the scope and methods that could be used to conduct analyses of O_3-related impacts on vegetation, considering both agricultural crops and tree species. After consulting with the CASAC and considering public

comments on these plans, OAQPS staff will conduct the assessments and incorporate initial results into the first draft O_3 Staff Paper. The first draft O_3 Staff Paper will be released for CASAC review and public comment shortly after release of the second draft O_3 AQCD, and will be based on information in the second draft O_3 AQCD to the extent possible. The final O_3 Staff Paper and related assessments are not scheduled to be completed until several months following completion of the final O_3 AQCD, so as to ensure that those documents are based on information in the final O_3 AQCD.

3 OZONE STAFF PAPER DEVELOPMENT

3.1 Organization and Content

The policy assessment to be presented in the O_3 Staff Paper will be based on staff's evaluation of the policy implications of the scientific evidence contained in the O_3 AQCD and the results of quantitative analyses based on that evidence. Taken together, this information will inform staff conclusions and recommendations on the elements of the O_3 standards under review. While the O_3 AQCD focuses on new scientific information available since the last review, it appropriately integrates that information with scientific criteria from previous reviews. The quantitative analyses to be presented in the O_3 Staff Paper (and to be described in more detail in a number of technical support documents) are based on the most recently available air quality information, so as to provide current characterizations of O_3 air quality patterns and estimated health and welfare effects risks related to exposure to ambient O_3 concentrations.

Following an introductory chapter, the O_3 Staff Paper will be organized into three main parts: the characterization of ambient O_3 air quality data; O_3-related health effects and primary O_3 NAAQS; and O_3-related welfare effects and secondary O_3 NAAQS. The content of these parts is summarized here and discussed more fully below.

- The characterization of ambient O_3 air quality data will include information on O_3 properties, current O_3 air quality patterns, historic trends, and background levels, as well as providing a frame of reference for subsequent discussion of current and alternative O_3 NAAQS and alternative forms of O_3 standards.

- Health-based information will include an overview of key policy-relevant health effects evidence, major health-related conclusions from the O_3 AQCD, and an examination of issues related to the quantitative assessment of evidence from controlled human exposure and epidemiological studies. Results from the planned health assessment (i.e., an exposure analysis and risk assessment) will be presented. This part will conclude with a discussion of the adequacy of the current primary standard; staff conclusions as to potential alternative indicators, averaging times, levels, and forms; and staff recommendations on ranges of alternative primary standards for consideration by the Administrator.

- Welfare-based information will include an overview of key policy-relevant welfare effects evidence and major welfare-related conclusions from the O_3 AQCD. Results from the planned environmental assessment (i.e., exposure analyses and risk/benefit assessment) will be presented. This part will conclude with a discussion of the adequacy of the current secondary standard; staff conclusions as to potential alternative indicators, averaging times, levels, and forms; and staff recommendations on ranges of alternative secondary standards for consideration by the Administrator.

3.2 Air Quality Characterization and Analyses

Ambient O_3 air quality information, generally based on air quality data through 2004 available from EPA's Air Quality System database, and information in Chapters 2, 3, and 10 of the O_3 AQCD will be presented in Chapter 2. This chapter will summarize the chemical and physical properties of ambient ground-level O_3, including discussions of atmospheric processes that lead to the formation, removal, and transport of O_3 in the ambient air and radiative properties that affect the transmission of ultraviolet radiation to the earth's surface and global climate change processes. Urban and rural trends in O_3 concentrations and precursor emissions will be presented. The distributions of specific O_3 measures, including health-based indices such as daily maximum 1- and 8-hour averages, and vegetation-based indices such as the cumulative, seasonal SUM06 index,[8] will be characterized. Spatial patterns of O_3 over different geographic scales and temporal patterns over seasonal and diurnal time periods also will be characterized. Finally, background O_3 levels will be characterized, and issues pertaining to the international transport of O_3 and precursors, and various estimates of the impact of international transport will be discussed.

A key issue to be addressed in this chapter is the characterization of policy-relevant background[9] O_3 levels in the U.S. Policy-relevant background is an important input to the assessment of human health and environmental risks, since those assessments will focus on estimating risk associated with pollutant levels that can be controlled by U.S. regulations or through international agreements with border countries. Evaluation of the assessment provided in the draft O_3 AQCD concerning this issue and consideration of the results from 3-D global tropospheric O_3 model simulations will inform estimates of policy-relevant background, including consideration of regional and season differences in these estimates.

3.3 Ozone-Related Health Effects and Primary Standards

In presenting staff's review of the primary O_3 NAAQS, Chapter 3 will present a policy-relevant assessment of the health effects evidence evaluated in the O_3 AQCD. To put this information into a public health perspective, staff plans to conduct a quantitative assessment of public health impacts attributable to O_3, including an exposure analysis and health risk

[8] SUM06 is an index which sums all hourly O_3 concentrations at and above 0.06 ppm over a specified period of time; this index was proposed for consideration in the last review of the O_3 secondary standard.

[9] Policy-relevant background is defined as the distribution of O_3 concentrations that would be observed in the U.S. in the absence of anthropogenic (man-made) emissions of O_3 precursors in the U.S., Canada, and Mexico.

assessment, to be presented in Chapters 4 and 5, respectively. This assessment will provide quantitative estimates of human exposure to ambient O_3 and of the risk to public health associated with current O_3 levels, with attainment of the current standard, and with attainment of alternative O_3 standards. A Health Assessment Plan is being prepared that outlines the scope and methods being considered for use; staff intends to modify this plan, as appropriate, based on input received through a consultation with CASAC and from public comments. The complete assessment will be documented in an Exposure Analysis Report and a Risk Assessment Report; these technical support documents will include detailed descriptions of the assessment methods and results. Chapter 6 will present staff conclusions and recommendations on the various elements of the primary O_3 NAAQS and will also include a summary of key uncertainties and related staff research recommendations.

3.3.1 Policy-Relevant Assessment of Health Effects Evidence

An assessment of key policy-relevant health evidence on the known and potential health effects associated with exposure to ambient O_3, alone and in combination with other pollutants that are routinely present in ambient air, will be presented in Chapter 3. This chapter will discuss key policy-relevant findings on O_3-related health effects evaluated in Chapters 4 through 7 of the O_3 AQCD, placing particular emphasis on the integrative synthesis presented in Chapter 8 of that document. Various factors shown to modify human responses to O_3 inhalation will be identified, as will population groups that show increased sensitivity to O_3 exposure. The nature of identified physiological effects will be discussed, including consideration of when such effects might be judged to be adverse to the health of an individual. As in the last review, this assessment will draw upon the latest American Thoracic Society (ATS) guidelines as to what constitutes an adverse health effect. This issue of adversity of effects will be considered for both healthy individuals as well as for individuals with impaired respiratory systems. Consideration will be given to how these findings may change our understandings from the last review of the nature and/or significance of O_3 health effects and the O_3 exposure levels associated with such effects. In addition, based on information in Chapter 10 of the O_3 AQCD, indirect health effects associated with the role of changes in ground level O_3 in altering the flux of solar ultraviolet radiation and climate change processes will also be addressed.

This assessment will also address a number of key issues relevant to staff's interpretation and quantitative assessment of available toxicologic, controlled human exposure, and epidemiological evidence, so as to provide a foundation for a quantitative exposure analysis and health risk assessment. Such issues include, for example, considerations related to air quality measurements and data used in the health studies; interpretation and relevance of the wide range of inhalation effects identified in laboratory animal and controlled human exposure studies; judgments as to the adversity of health effects reported in these studies; and interpretation of epidemiological studies reporting associations between adverse health effects and ambient O_3 concentrations. In considering the epidemiological evidence, additional issues will be addressed, such as the specification of models used in epidemiologic studies; approaches used to evaluate the role of co-pollutants and potential confounding in O_3-effects associations; questions of temporality in associations between air quality and health effects, including lag periods used in short-term studies and the selection of time periods used to represent exposures in long-term

exposure studies; and questions related to the form of concentration-response relationships and potential threshold levels.

3.3.2 Human Exposure Analysis

Characterization of human exposures to ambient O_3 will be discussed in Chapter 4, drawing from information generally presented in Chapter 3 of the O_3 AQCD. This chapter will include discussions of factors that affect exposure to ambient O_3 and the use of central measurements of O_3 concentrations as a surrogate for population exposure in epidemiological studies. The central focus of this chapter will be on the exposure analysis being designed to estimate population exposure to ambient O_3 in a number of generally representative urban areas across the U.S.. This analysis will build upon the exposure analysis done in the last review and will incorporate current air quality data (i.e., 2002 through 2004) and enhancements made to exposure models and model inputs since the last review. Estimates will be generated for population exposures associated with current O_3 levels and with attainment of the current O_3 standard and potential alternative standards. Exposure estimates will be used as an input to the risk assessment for health endpoints for which exposure-response functions are available and will provide information on population exposures exceeding levels of concern that may be identified for various other health endpoints.

As will be discussed more fully in the Health Assessment Plan, staff is planning to model exposures in approximately 12 urban areas located throughout the U.S. These areas are being selected to represent a wide variety in population, geographic area, demographic makeup, climatology, and O_3 air quality. In addition, selection of urban areas will take into consideration the location of O_3 field and epidemiological studies reporting significant health effects that are to be included in the O_3 health risk assessment. Staff is now planning to develop exposure estimates for the general population as well as for subpopulations including school-age children and children with asthma.

A new version of EPA's Air Pollutants Exposure (APEX) model (also referred to as the Total Risk Integrated Methodology/Exposure (TRIM.Expo) model) will be used in this analysis. APEX simulates the movement of individuals through time and space and their exposure to O_3 in indoor, outdoor, and in-vehicle microenvironments. It is a Monte Carlo simulation model that will be used to simulate a large number of randomly sampled individuals within each urban area (e.g., 100,000) to represent area-wide population exposures. The development of appropriate distributions representing variability and uncertainty in various model inputs (e.g., air exchange rates, O_3 decay rates, physiological parameters) will be a key aspect of this modeling effort.

As part of this analysis, it is necessary to adjust recent O_3 air quality data to simulate just attaining alternative O_3 standards in each area. In the last review, EPA evaluated several procedures for simulating changes in O_3 air quality likely to result from attainment of the current or alternative standards based on analyzing changes in O_3 levels that have been observed historically. Staff and others are now giving further consideration to alternative air quality adjustment procedures for use in this analysis.

Human activity data needed for this analysis will be drawn from the Consolidated Human Activity Database (CHAD) developed and maintained by ORD's National Exposure Research Laboratory (NERL). Another key issue in this analysis is the development of an approach for creating O_3-season or year-long activity sequences for individuals based on a cross-sectional activity data base that includes 24-hour records.

This analysis will take 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 will be developed for several indicators of exposure to various levels of O_3 air quality, including counts of people exposed one or more times to a given O_3 concentration while at a specified breathing rate, and counts of person-occurrences which accumulate occurrences of specific exposure conditions over all people in the population of interest. The complete set of results and a detailed description of the methods used in this analysis will be presented in a separate Exposure Analysis Report.

3.3.3 Human Health Risk Assessment

The characterization of human health risks attributable to exposure to ambient O_3 levels will be presented in Chapter 5, based primarily on controlled human exposure and epidemiological studies evaluated in Chapters 6 and 7 of the O_3 AQCD. The human health risk assessment that will be presented in this chapter is now being designed to estimate population risks in a number of generally representative urban areas across the U.S., consistent with the scope of the exposure analysis described above. This risk assessment will build upon the assessment done in the last review, and will include additional health endpoints for which newly available studies have shown associations with exposure to ambient O_3. Risk estimates will be generated for public health risks associated with current O_3 levels and with attainment of the current O_3 standard and potential alternative standards. Particular attention will be given to providing a clear and quantitative characterization of the uncertainty and variability inherent in the assessment. Public health risks associated with health endpoints for which the available evidence is judged to be inadequate to support quantitative risk assessment will be characterized qualitatively.

As will be discussed more fully in the Health Assessment Plan, this assessment will include risk estimates based on both controlled human exposure studies and epidemiological and field studies. Staff is now planning to generate O_3-related risk estimates for lung function decrements based on probabilistic *exposure-response* relationships developed in controlled human exposure studies, together with probabilistic exposure estimates from the exposure analysis. For various other health endpoints, staff is now planning to generate O_3-related risk estimates based on *concentration-response* relationships developed in epidemiological or field studies, together with ambient air quality concentrations, baseline health incidence rates and population data for the various locations being included in the assessment. At this time, staff is considering inclusion of the following health endpoints in the assessment based on epidemiological or field studies: respiratory symptoms in asthmatic children, respiratory-related school absences, emergency department visits and hospital admissions for respiratory illness, and premature mortality. The inclusion of any particular health endpoint will depend in part on

the extent to which the O_3 AQCD infers the likelihood of a causal relationship between O_3 exposure and a given endpoint.

A number of issues related to the selection and application of appropriate concentration-response functions for use in this assessment will need to be addressed. For example, consideration will be given to the appropriate use of functions based on single- and multi-city studies, single- and multi-pollutant models, and models with different lag structures. Another important issue relates to the development of appropriate approaches for estimating risk in excess of policy-relevant background O_3 levels, consistent with the risk assessments that have been conducted in past NAAQS reviews. Particular attention will also be given to plans to conduct sensitivity analyses to characterize uncertainties in the assessment and the influence of various assumptions made to conduct the assessment. The complete set of results and a detailed description of the methods used in this risk assessment will be presented in a separate Risk Assessment Report.

3.3.4 Approach to Staff Review of Primary Standards

Chapter 6 will present staff conclusions and recommendations for the Administrator to consider in deciding whether the existing primary O_3 standard should be revised and, if so, what revised standards would be appropriate. Staff conclusions and recommendations on the primary standard will be based on the information contained in the O_3 AQCD, focusing particularly on the assessment and integrative synthesis of information presented in Chapter 8 of that document, and on the staff evaluations and assessments discussed in the preceding chapters of the O_3 Staff Paper.

In the last review, EPA's general approach to evaluating the primary standard focused on three areas. First, EPA examined the scientific literature to assess which acute and chronic health effects are associated with O_3, and where possible, identified exposure levels at which those effects occur. Second, EPA made judgments, based on advice from medical experts, as to when physiological effects become significant enough to be considered "adverse" to the health of individuals. Finally, EPA made public health policy judgments, informed by air quality, exposure, and risk analyses when possible, concerning the point at which risks would be reduced sufficiently to protect public health with an adequate margin of safety. Based on these considerations, EPA revised the primary standard to focus on acute adverse effects to public health associated with prolonged exposures to ambient O_3, based on an 8-hour averaging time.

In recommending 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.

In this review, a series of questions will frame staff's approach to reaching conclusions and recommendations, based on available evidence and information, as to whether consideration should be given to retaining or revising the current primary O_3 NAAQS. Staff's review of the adequacy of the current primary standard begins by considering whether the currently available body of evidence assessed in the O_3 AQCD suggests that revision of any of the basic elements of the standard would be appropriate. This evaluation of the adequacy of the current standard will involve addressing questions such as the following:

- To what extent does newly available information reinforce or call into question evidence of associations with effects identified in the last review?

- To what extent does newly available information reinforce or call into question any of the basic elements of the current O_3 standard?

- To what extent have important uncertainties identified in the last review been reduced and have new uncertainties emerged?

To the extent that the evidence suggests that revision of the current standard would be appropriate, staff will then consider whether the currently available body of evidence supports consideration of standards that are either more or less protective by addressing the following questions:

- Is there evidence that associations, especially likely causal associations, extend to air quality levels that are as low as or lower than had previously been observed, and what are the important uncertainties associated with that evidence?

- Are health risks estimated to occur in areas that meet the current standard; are they important from a public health perspective; and what are the important uncertainties associated with estimated risks?

To the extent that there is support for consideration of revised standards, staff will then identify ranges of standards (in terms of averaging times, levels and forms) that would reflect a range of alternative public health policy judgments, based on the currently available evidence, as to the degree of protection that is requisite to protect public health with an adequate margin of safety. In so doing, staff will address the following questions:

- Does the evidence provide support for considering different exposure indices or averaging times?

- What range of levels and forms of alternative standards is supported by the evidence, and what are the uncertainties and limitations in that evidence?

- To what extent do specific levels and forms of alternative standards reduce the estimated risks attributable to O_3, and what are the uncertainties in the estimated risk reductions?

Based on the evidence, estimated risk reductions, and related uncertainties, the staff will then make recommendations as to ranges of alternative standards for the Administrator's consideration in reaching decisions as to whether to retain or revise the primary O_3 NAAQS.

3.4 Ozone-Related Environmental Effects and Secondary Standards

In presenting staff's review of the secondary O_3 NAAQS, Chapter 7 will first discuss key policy-relevant findings on O_3-related welfare effects evaluated in the draft O_3 AQCD, including environmental effects on vegetation and ecosystems, effects on man-made materials, and indirect effects associated with O_3's role in altering the flux of solar ultraviolet radiation and climate change processes. Chapter 8 will then present staff's quantitative assessment of environmental impacts attributable to O_3, now being planned to include exposure and risk/benefits analyses for agricultural crops and possibly commercial forest tree species. An Environmental Assessment Plan is being prepared that outlines the scope and methods being considered for use; staff will finalize this plan based on input received through a consultation with CASAC and from public comments. The complete assessment will be documented in an Environmental Assessment Report; this technical support document will include a detailed description of the assessment methods and results. Chapter 9 will present staff conclusions and recommendations on the various elements of the secondary O_3 NAAQS, and will also include a summary of key uncertainties and related staff research recommendations.

3.4.1 Policy-Relevant Assessment of Ozone Environmental Impacts

An assessment of key policy-relevant evidence on the known and potential environmental effects associated with exposure to ambient O_3, alone and in combination with other pollutants and stressors that are routinely present in ambient air, will be presented in Chapter 7. This chapter will discuss key policy-relevant findings on O_3-related welfare effects evaluated in Chapters 9 through 11 of the O_3 AQCD. Various factors that modify plant responses to O_3 will be discussed, and species likely to have increased sensitivity to O_3 exposure will be identified. Consideration will be given to how newly available information change, if at all, our understandings from the last review of the nature and/or significance of O_3 welfare effects and the O_3 exposure levels associated with such effects. In addition, based on information in Chapter 10 of the O_3 AQCD, indirect environmental effects associated with the role of ground level O_3 in altering the flux of solar ultraviolet radiation and climate change processes will also be addressed.

Since the last review, research on O_3 effects on vegetation has continued to be published in the scientific literature as discussed in the draft O_3 AQCD. The majority of these studies have continued to use open-top chamber systems (OTCs) that were the standard O_3 exposure method

used in studies available in the last review. An alternate technology, FACE (Free Air CO_2 Enrichment), originally developed to expose vegetation to elevated levels of CO_2 in the field without using chambers, has more recently been employed to expose vegetation to O_3. Two major research studies ongoing in the U.S. are currently using this approach for O_3 exposure. One such study, referred to as SOY FACE, located in Illinois, is focusing on the effects of O_3 on soybeans. The other study, referred to as ASPEN FACE, is located in Wisconsin and includes effects of O_3 on aspen, birch, and red maple seedlings/saplings. These FACE studies report O_3 responses that are similar to those reported previously in OTC studies, without the alterations of microclimate that are an artifact of the use of such chambers.

In addition to new exposure techniques, the draft O_3 AQCD identifies several other important areas of research that will be discussed in this chapter. A number of new European studies have explored the application of the critical level concept with regard to O_3 exposures and vegetation response, and have evaluated the practicality of measuring O_3 flux as a way to establish dose-response functions for vegetation. These concepts will be considered by staff in the context of identifying appropriate forms for a distinct secondary standard for protection of vegetation.

3.4.2 Environmental Effects Analysis

Staff is planning a quantitative assessment of key policy-relevant information on the known and potential environmental effects associated with ambient O_3 exposure. This assessment, to be presented in Chapter 8, will draw upon the most relevant information contained in the O_3 AQCD and other significant research evaluated therein and will build upon the quantitative assessment performed during the last review. As will be discussed more fully in the Environmental Assessment Plan, staff is planning to focus on soybean crops based on their economic importance, O_3 sensitivity, and the availability of new information from recent studies using FACE technology. Other plant species, such as economically important trees, will be assessed if staff determines that sufficient new data are available to warrant updating the assessment of tree species conducted in the last review. Recent monitoring and atmospheric modeling data will be used to update current estimates of vegetation exposure to O_3. In addition to a quantitative assessment, the staff will discuss the potential qualitative risks to vegetation including risks to biodiversity, health of forest ecosystems, Class I areas, and aesthetic values.

Using O_3 monitoring data and the latest EPA models, exposure estimates will be modeled for soybean growing areas throughout the U.S. for several recent growing seasons. If other plant species are included, exposure estimates will be modeled for areas to cover the growing areas for those plants. The exposure estimates together with exposure-response relationships for soybean will be used to estimate yield losses based on yearly reports of county-level crop yield. Economic models, such as AgSim and other approaches discussed in the draft O_3 AQCD, will be evaluated for estimating economic losses due to current ambient O_3 levels. Additionally, the impact of attaining the current 8-hour O_3 NAAQS and alternative O_3 standards on economic losses will also be evaluated.

3.4.3 Approach to Staff Review of Secondary Standards

Staff conclusions and recommendations for the Administrator to consider in deciding whether the existing secondary O_3 standard should be revised and, if so, what revised standard would be appropriate will be presented in Chapter 9. Staff conclusions and recommendations on the secondary standard will be based on the information presented in chapters 9, 10, and 11 of the O_3 AQCD and on staff analyses and evaluations discussed in the preceding chapters of the O_3 Staff Paper.

In the last review, EPA concluded that under ambient O_3 exposure conditions existing at the time, adverse O_3 related effects were occurring to a number of commercially important crop species and tree species in the seedling stage and that additional protection against these effects was warranted. In considering what was known about the relationships between ambient O_3 concentrations and plant response, staff concluded that the best predictor of plant response to ambient O_3 levels would be measuring the amount of O_3 taken up by the plant as a result of stomatal conductance. Staff recognized, however, that using such a flux-based index as a basis for a national standard at that time was impractical, given the state of the science available, and focused instead on a number of biologically relevant seasonal cumulative, peak-weighted exposure indices as surrogates for a flux-based standard. Staff also considered the impact that alternative primary standard options being considered might have on improving ambient O_3 distributions in non-urban, agricultural and forested areas. Based on these considerations, EPA proposed to revise the secondary O_3 NAAQS by replacing the existing standard with either a standard defined in terms of a biologically relevant index (i.e., the SUM06 index), or a standard equal to a revised primary standard with an 8-hour averaging time. The final Agency decision made the secondary standard identical to the revised 8-hour primary standard.

In recommending 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. Staff's approach to informing these judgements is based on a recognition that the effects of O_3 on vegetation are the most widely recognized and thoroughly studied of the public welfare effects categories, that plants exhibit a wide range of O_3 sensitivities, both between and within species, and that O_3 impacts to vegetation are influenced by numerous and varied coexisting biotic and abiotic environmental stressors. Staff also recognizes that determinations of what is an adverse impact to vegetation may vary, depending on the associated value or intended use of the impacted species. 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.

In this review, a series of questions will frame staff's approach to reaching conclusions and recommendations, based on available evidence and information, as to whether consideration should be given to retaining or revising the current secondary O_3 NAAQS. The staff's review of the adequacy of the current standard begins by considering whether the currently available body of evidence assessed in the O_3 AQCD suggests that revision of any of the basic elements of the NAAQS would be appropriate. This evaluation is done for each category of O_3-related welfare effects identified in the O_3 AQCD as being associated with the presence of O_3 in the ambient air. Staff's review of the adequacy of the current O_3 standard for each effects category involves addressing questions such as:

- To what extent does the available information demonstrate or suggest that O_3-related effects are occurring at current ambient conditions or at levels that would meet the current standard?

- To what extent does the available information inform judgments as to whether any observed or anticipated effects are adverse to public welfare?

- To what extent is the current secondary standard likely to be effective in achieving protection against any identified adverse effects?

To the extent that the evidence suggests that revision of the current secondary O_3 NAAQS would be appropriate, staff then identifies ranges of standards (in terms of exposure indices, averaging times, levels, and forms) that would reflect a range of alternative policy judgments as to the degree of protection that is requisite to protect public welfare from known or anticipated adverse effects. In so doing, staff addresses questions such as:

- Does the available information provide support for considering different O_3 exposure indices?

- Does the available information provide support for considering different averaging times?

- What range of levels and forms of alternative standards is supported by the information, and what are the uncertainties and limitations in that information?

- To what extent do specific levels and forms of alternative standards reduce adverse impacts attributable to O_3, and what are the uncertainties in the estimated reductions?

Based on the available information, estimated reductions in adverse impacts, and related uncertainties, staff will make recommendations as to ranges of alternative standards for the Administrator's consideration in reaching decisions as to whether to retain or revise the secondary O_3 NAAQS.

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