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Introduction

The photochemical oxidants found in ambient air in the highest concentrations are ozone (O_3) and nitrogen dioxide (NO_2). Other oxidants, such as hydrogen peroxide (H_2O_2) and the peroxyacyl nitrates, also have been observed, but in lower and less certain concentrations. In 1971, the U.S. Environmental Protection Agency (EPA) promulgated National Ambient Air Quality Standards (NAAQS) to protect the public health and welfare from adverse effects of photochemical oxidants. The 1971 photochemical oxidant standards were promulgated on the basis of (1) commercially available measurement methodology,[1] (2) uncertainties over the concentrations of O_3 and non-O_3 photochemical oxidants in the atmosphere resulting from the nonspecificity of the measurement methodology, and (3) uncertainties regarding the health and welfare effects of the non-O_3 photochemical oxidants found in ambient air. After 1971, however, O_3-specific commercial analytical methods became available, as did additional information on concentrations and effects of the non-O_3 photochemical oxidants. As a result, the chemical designation of the standards was changed in 1979 from photochemical oxidants to O_3. This document focuses primarily on the scientific air quality criteria for O_3 and, to a lesser extent, on those for H_2O_2 and the peroxyacyl nitrates, particularly peroxyacetyl nitrate. The scientific air quality criteria for NO_2 are discussed in a separate document (U.S. Environmental Protection Agency, 1993).

The previous O_3 air quality criteria document (AQCD), *Air Quality Criteria for Ozone and Other Photochemical Oxidants* (U.S. Environmental Protection Agency, 1986) was released by EPA in August 1986 and a supplement, *Summary of Selected New Information on Effects of Ozone on Health and Vegetation* (U.S. Environmental Protection Agency, 1992), was released in January 1992. These documents were the basis for a March 1993 decision by EPA that revision of the existing 1-h NAAQS for O_3 was not appropriate at that time. That decision did not take into account some of the newer scientific data that became available after completion of the 1986 criteria document. The purpose of this document is to summarize the air quality criteria for O_3 available in the published literature through early 1995. This review was performed in accordance with provisions of the Clean Air Act (CAA) to provide the scientific basis for periodic reevaluation of the O_3 NAAQS.

[1]The term "photochemical oxidants" historically has been defined as those atmospheric pollutants capable of oxidizing neutral iodide ions (U.S. Environmental Protection Agency, 1978). A number of oxidants other than O_3 are measured, qualitatively if not quantitatively, by potassium iodide methods.

This chapter provides a general introduction to the legislative and regulatory background for decisions on the O_3 NAAQS, as well as a general summary of the organization, content, and major scientific topics presented in this document.

2.1 Legislative Background

Two sections of the CAA govern the establishment,review, and revision of the NAAQS. Section 108 (U.S. Code, 1991) directs the Administrator of EPA to identify certain ubiquitous pollutants that may reasonably be anticipated to endanger public health or welfare and to issue air quality criteria for them. These air quality criteria are to reflect the latest scientific information useful in indicating the kind and extent of all identifiable effects on public health or welfare that may be expected from the presence of the pollutant in ambient air.

Section 109(a) of the CAA (U.S. Code, 1991) directs the Administrator of EPA to propose and promulgate primary and secondary NAAQS for pollutants identified under Section 108. Section 109(b)(1) defines a primary standard as one the attainment and maintenance of which, in the judgment of the Administrator and based on the criteria and allowing for an adequate margin of safety, are requisite to protect the public health. The 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 and based on the criteria, are requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of the pollutant in ambient air.

Section 109(d) of the CAA (U.S. Code, 1991) requires periodic review and, if appropriate, revision of existing criteria and standards. Thus, the Administrator may find that EPA's review and revision of criteria make appropriate the proposal of new or revised standards. Alternatively, the Administrator may find that revision of the standards is inappropriate and conclude the review by leaving the existing standards unchanged.

2.2 Regulatory Background[2]

On April 30, 1971, EPA promulgated primary and secondary NAAQS for photochemical oxidants under Section 109 of the CAA (Federal Register, 1971). These standards were set at an hourly average of 0.08 ppm total photochemical oxidants not to be exceeded more than 1 h/year. On April 20, 1977, EPA announced (Federal Register, 1977) the first review and updating of the 1970 *Air Quality Criteria for Photochemical Oxidants* in accordance with Section 109(d) of the CAA. In preparing a revised AQCD, EPA made two external review drafts of the document available for public comment, and these drafts were peer reviewed by the Subcommittee on Scientific Criteria for Photochemical Oxidants of EPA's Science Advisory Board (SAB). A final revised AQCD for O_3 and other photochemical oxidants was published on June 22, 1978.

Based on the 1978 revised AQCD and taking into account the advice and recommendations of the Subcommittee and the comments received from the public, EPA announced (Federal Register, 1979) a final decision to revise the NAAQS for photochemical

[2]This text is excerpted and adapted from the *Proposed Decision on the National Ambient Air Quality Standards for Ozone* (Federal Register, 1992a).

oxidants on February 8, 1979. The final ruling revised the level of the primary standard from 0.08 to 0.12 ppm, set the secondary standard identical to the primary standard, changed the chemical designation of the standards from photochemical oxidants to O_3, and revised the definition of the point at which the standard is attained to "when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 ppm is equal to or less than one" (see Table 2-1).

Table 2-1. National Ambient Air Quality Standards for Ozone[a]

Date of Promulgation	Primary and Secondary NAAQS	Averaging Time
February 8, 1979	0.12 ppm[b] (235 $\mu g/m^3$)	1 h[c]

[a]See Appendix A for abbreviations and acronyms.
[b]1 ppm = 1,962 $\mu g/m^3$, 1 $\mu g/m^3 = 5.097 \times 10^{-4}$ ppm at 25 °C, 760 mm Hg.
[c]The standard is attained when the expected number of days per calendar year with a maximum hourly average concentration above 0.12 ppm (235 $\mu g/m^3$) is equal to or less than one.

On March 17, 1982, in response to requirements of Section 109(d) of the CAA, EPA announced (Federal Register, 1982) that it was undertaking plans to revise the existing 1978 AQCD for O_3 and other photochemical oxidants, and, on August 22, 1983, it announced (Federal Register, 1983) that review of the primary and secondary NAAQS for O_3 had been initiated. Public peer-review workshops on draft chapters of a revised AQCD were held December 15 through 17, 1982, and November 16 through 18, 1983. The EPA considered comments made at both workshops in preparing the first external review draft that was made available (Federal Register, 1984) on July 24, 1984, for public review.

On February 13, 1985 (Federal Register, 1985), and on April 2, 1986 (Federal Register, 1986), EPA announced two public meetings of the Clean Air Scientific Advisory Committee (CASAC) of EPA's SAB to be held March 4 through 6, 1985, and April 21 and 22, 1986, respectively. At these meetings, CASAC reviewed external review drafts of the revised AQCD for O_3 and other photochemical oxidants. After completion of this review, CASAC sent the EPA Administrator a closure letter, dated October 22, 1986, indicating that the document "represents a scientifically balanced and defensible summary of the extensive scientific literature." The EPA released the final draft document in August 1986.

The first draft of the Staff Paper "Review of the National Ambient Air Quality Standards for Ozone: Assessment of Scientific and Technical Information" was reviewed by CASAC at a public meeting on April 21 and 22, 1986. At that meeting, CASAC recommended that new information on prolonged exposure effects of O_3 be considered in a second draft of the Staff Paper prior to closure. The CASAC reviewed this second draft and also a presentation of new and emerging information on the health and welfare effects of O_3 at a public review meeting held on December 14 and 15, 1987. The CASAC concluded that sufficient new information existed to recommend incorporation of relevant new data into a supplement to the 1986 AQCD (O_3 supplement) and in a third draft of the Staff Paper.

A draft O_3 supplement, *Summary of Selected New Information on Effects of Ozone on Health and Vegetation: Draft Supplement to Air Quality Criteria for Ozone and Other Photochemical Oxidants,* and the revised Staff Paper were made available to CASAC and to the public for review in November 1988. The O_3 supplement reviewed and evaluated selected literature concerning exposure- and concentration-response relationships observed for health effects in humans and experimental animals and for vegetation effects. This literature appeared as peer-reviewed journal publications or as proceedings papers from 1986 through late 1988.

On December 14 and 15, 1988, CASAC held a public meeting to review these documents. The CASAC sent the EPA Administrator a closure letter dated May 1, 1989, indicating that the draft O_3 supplement, along with the 1986 AQCD, and the draft Staff Paper "provide an adequate scientific basis for the EPA to retain or revise the primary and secondary standards of ozone." The CASAC concluded that it would be some time before enough new information on the health effects of multihour and chronic exposure to O_3 would be published in scientific journals to receive full peer review and, thus, be suitable for inclusion in a criteria document. The CASAC further concluded that such information could better be considered in the next review of the O_3 NAAQS. A final version of the O_3 supplement has been published (U.S. Environmental Protection Agency, 1992).

On October 22, 1991, the American Lung Association and other plaintiffs filed suit to compel EPA to complete its review of the criteria and standards for O_3. On May 4, 1992, the U.S. District Court for the Eastern District of New York issued an order requiring the Administrator of EPA to sign a proposed decision on whether to revise the standards for O_3 by August 1, 1992, and to sign EPA's final decision by March 1, 1993.

On August 1, 1992, the Administrator signed a proposed decision not to revise the existing NAAQS for O_3 (Federal Register, 1992a), then, on March 1, 1993, signed EPA's final decision, concluding that revision of the NAAQS was inappropriate at that time (Federal Register, 1993a). For reasons indicated in the proposed and final decisions, the March 1993 decision did not take into consideration a number of recent studies on the health and welfare effects of O_3 that had been published since the last literature review in early 1989. The EPA estimated that approximately 3 years would be necessary to (1) incorporate the new studies into a revised criteria document, (2) complete mandated CASAC review, (3) evaluate the significance of the key information for regulatory decision-making purposes, and (4) publish a proposed decision on the O_3 NAAQS in the *Federal Register*.

The EPA intends to complete the current review of the criteria and standards for O_3 as rapidly as possible. Accordingly, the National Center for Environmental Assessment (formerly the Environmental Criteria and Assessment Office [ECAO]) of EPA's Office of Research and Development, located in Research Triangle Park, NC, has given very high priority to review and revision of the air quality criteria for O_3. The ECAO began by announcing the commencement of the review and identification of new information (Federal Register, 1992b). After assessing and evaluating pertinent new studies, ECAO prepared a preliminary draft of a revised AQCD that was reviewed in a series of expert peer reviewed workshops (Federal Register, 1993b,c). Comments received at the workshops were used to revise the preliminary draft for external review (Federal Register, 1994a). Public peer review meetings were held by CASAC to provide advice on the scientific and technical adequacy of the external review draft (Federal Register, 1994b) and the subsequent revised draft (Federal Register, 1995). The final document was prepared on the basis of comments received from the public and CASAC reviews and provides a scientific basis for review of the existing O_3 standards. The EPA's Office of Air Quality Planning and Standards

(OAQPS) is completing its preparation of a draft staff paper assessing the most significant information contained in this AQCD and presenting staff recommendations on whether revisions to the NAAQS for O_3 are appropriate. After reviews of the draft staff paper by the public and CASAC, the Administrator will decide whether to propose revisions to the O_3 NAAQS.

2.3 Summary of Major Scientific Topics Presented

A number of separate topics and issues are addressed in this O_3 criteria document. Some of the key questions addressed are highlighted below by document section.

2.3.1 Air Chemistry

- What concerns still exist regarding precision and accuracy of measurements of O_3 and its precursors?
- What is the order of magnitude of current estimates of natural emissions of O_3 precursors and emissions from anthropogenic sources and their relevance to tropospheric O_3 photochemistry?
- What new scientific information exists on the roles of meteorologic and climatologic factors in O_3 formation and transport?
- Are the reaction pathways of all major precursors to O_3 understood? Have all major reaction products been identified? How are the reactions and products represented in air quality models?
- What is the status of development, application, evaluation, and verification of air quality models?

2.3.2 Air Quality

- What are the trends and geographic differences in O_3 concentrations across the United States?
- What are diurnal and seasonal patterns of 1-h average O_3 concentrations for urban and nonurban sites and for attainment versus nonattainment areas?
- What is known about patterns of co-occurrence of O_3 with other pollutants in the atmosphere?
- What O_3 exposure assessment data are available for agricultural crops and forests?
- To what level and to what extent are humans typically exposed to O_3 in the course of normal, everyday activities?

2.3.3 Environmental Effects

- What are the effects of ambient O_3 concentrations on vegetation (i.e., agricultural and horticultural crops; urban landscape trees, shrubs, and flowers; forest tree species)?
- What characteristics of air quality (e.g., summary statistics) are relevant to these effects on vegetation?
- What are the long-term effects of O_3 exposures on natural ecosystems?
- Is there important new information on the effects of O_3 on nonbiological materials?

2.3.4 Health Effects

- What O_3 concentration and exposure duration relationships exist for effects on lung structure, function, and host defense mechanisms, and what are the important modifiers of these effects?
- What are the mechanisms of O_3-induced lung injury?
- Can dosimetry models predict human population responses to O_3 on the basis of laboratory animal data?
- Does long-term exposure to O_3 lead to the development of chronic lung disease or to an increased frequency or exacerbation of other chronic respiratory outcomes?
- What segments of the population are most susceptible to effects from exposure to O_3?

2.4 Organization and Content of the Document

This document critically evaluates and assesses scientific information on the health and welfare effects associated with exposure to the concentrations of O_3 and related photochemical oxidants present in ambient air. Although the document is not intended to be an exhaustive literature review, it is intended to selectively cover the pertinent literature through 1995. The references cited in the document should be reflective of the state of knowledge on those issues most relevant to review of the NAAQS for O_3, now set at 0.12 ppm for 1 h. Although emphasis is placed on the presentation of health and welfare effects data, other scientific data will be presented and evaluated in order to provide a better understanding of the nature, sources, distribution, measurement, and concentrations of O_3 and related photochemical oxidants in ambient air, as well as the characterization of population exposure to these pollutants.

To aid in the development of this document, summary tables of the relevant published literature have been provided to supplement a selective discussion of the literature. Most of the scientific information selected for review and comment in the text comes from the more recent literature published since completion of the previous O_3 criteria document (U.S. Environmental Protection Agency, 1986). Some of these newer studies were reviewed briefly in the supplement to that document (U.S. Environmental Protection Agency, 1992), but more intense evaluation of these studies has been included. Other studies, however, are included if they contain unique data, such as the documentation of a previously unreported effect or of a mechanism of an effect, or if they were multiple-concentration studies designed to provide exposure-response relationships. Emphasis is placed on studies conducted at or near O_3 concentrations found in ambient air. For animal toxicology studies, typically only those studies conducted at less than 1 ppm O_3 are considered. Studies that are presented in the previous criteria document and whose data were judged to be significant because of their usefulness in deriving the current NAAQS are discussed briefly in the text. Other, older studies also are discussed in the text if they were judged to be (1) open to reinterpretation because of newer data or (2) potentially useful in deriving revised standards for O_3. The reader should, however, consult the more extensive discussion of these "key" studies in the previous document. Generally, only published information that has undergone scientific peer review is included in the criteria document.

Certain issues of direct relevance to standard setting are not explicitly addressed in this document, but instead are analyzed in documentation prepared by OAQPS as part of its regulatory review process. Such issues include (1) determining what constitutes an "adverse

effect" and delineation of particular adverse effects that the primary and secondary NAAQS are intended to protect against, (2) exposure assessment, (3) assessment of consequent risks based on health and exposure analyses, and (4) factors to be considered in determining an adequate margin of safety. Key points and conclusions from such analyses are summarized in the Staff Paper prepared by OAQPS and reviewed by CASAC and the public. Although scientific data contribute significantly to decisions regarding the above issues, their resolution cannot be achieved solely on the basis of experimentally acquired information. Final decisions on items 1 and 4 are made by the EPA Administrator, as mandated by the CAA.

A fourth issue directly pertinent to standard setting is identification of populations at risk, which is basically a determination by EPA of the subpopulations to be protected by the promulgation of a given standard. This issue is addressed only partially in the criteria document. For example, information is presented on factors, such as preexisting disease, that biologically may predispose individuals and subpopulations to more severe effects from exposures to O_3. The identification of a population at risk, however, requires information above and beyond data on biological predisposition, such as information on levels of exposure, activity patterns, and personal habits. Such information is included in the Staff Paper developed by OAQPS.

Finally, the O_3 air quality document considers only the scientific and technical issues that are important for standard setting, not those issues relative to implementation of the O_3 NAAQS. For example, certain issues related to the control strategies for attainment of the standard and to possible atmospheric consequences of control strategy design are not discussed in this document. This limitation also includes discussion of impacts consequent to possible changes in the O_3 NAAQS. These issues would be better addressed in regulatory impact analyses or cost-benefit analyses that may be prepared as part of the O_3 NAAQS decision package.

This document is structured as follows: Chapter 1 (executive summary and conclusions) provides a concise presentation of key information and conclusions from all subsequent chapters. This is followed by this brief introduction (Chapter 2) containing information on the legislative and regulatory background for review of the O_3 NAAQS, as well as an overview of the organization of this document. Chapter 3 provides information on the chemistry, sources, emissions, measurement, and transport of O_3 and related photochemical oxidants and their precursors, and Chapter 4 covers environmental concentrations, patterns, and exposure estimates of O_3 and oxidant air quality. This is followed by Chapter 5, which deals with environmental effects of O_3 and related photochemical oxidants. Chapters 6, 7, and 8 discuss animal toxicological studies, human health effects, and extrapolation of animal toxicological data to humans, respectively. Finally, Chapter 9, provides an integrative and interpretive evaluation of health effects associated with exposure to O_3.

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