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**Part V**

**Environmental  
Protection Agency**

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**40 CFR Part 50  
National Ambient Air Quality Standards  
for Ozone; Final Rule**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 50

[ADA-95-58; FRL-5725-3]

RIN-2060-AE57

### National Ambient Air Quality Standards for Ozone

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This document describes EPA's decision to revise the national ambient air quality standards (NAAQS) for ozone (O<sub>3</sub>) based on its review of the available scientific evidence linking exposures to ambient O<sub>3</sub> to adverse health and welfare effects at levels allowed by the current O<sub>3</sub> standards. The current 1-hour primary standard is replaced by an 8-hour standard at a level of 0.08 parts per million (ppm) with a form based on the 3-year average of the annual fourth-highest daily maximum 8-hour average O<sub>3</sub> concentrations measured at each monitor within an area. The new primary standard will provide increased protection to the public, especially children and other at-risk populations, against a wide range of O<sub>3</sub>-induced health effects, including decreased lung function, primarily in children active outdoors; increased respiratory symptoms, particularly in highly sensitive individuals; hospital admissions and emergency room visits for respiratory causes, among children and adults with pre-existing respiratory disease such as asthma; inflammation of the lung, and possible long-term damage to the lungs. The current 1-hour secondary standard is replaced by an 8-hour standard identical to the new primary standard. The new secondary standard will provide increased protection to the public welfare against O<sub>3</sub>-induced effects on vegetation, such as agricultural crop loss, damage to forests and ecosystems, and visible foliar injury to sensitive species.

**EFFECTIVE DATE:** This rule is effective September 16, 1997.

**ADDRESSES:** A docket containing information relating to the EPA's review of the O<sub>3</sub> primary and secondary standards (Docket No. A-95-58) is available for public inspection in the Central Docket Section of the U.S. Environmental Protection Agency, South Conference Center, Room 4, 401 M St., SW., Washington, DC. This docket incorporates the docket from the previous review of the O<sub>3</sub> standards (Docket No. A-92-17) and the docket established for the air quality criteria document (Docket No. ECAO-CD-92-0786). The docket may be inspected between 8 a.m. and 3 p.m. on weekdays, and a reasonable fee may be charged for copying. The information in the docket constitutes the complete basis for the decision announced in this final rule. For the

availability of related information, see "SUPPLEMENTARY INFORMATION."

#### FOR FURTHER INFORMATION CONTACT:

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#### SUPPLEMENTARY INFORMATION:

##### Availability of Related Information

Certain documents are available from the U.S. Department of Commerce, National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. Available documents include:

(1) Air Quality Criteria for O<sub>3</sub> and Other Photochemical Oxidants ("Criteria Document") (three volumes, EPA/600/P-93-004aF through EPA/600/P-93-004cF, July 1996, NTIS # PB-96-185574, \$169.50 paper copy, \$58.00 microfiche).

(2) The Review of the National Ambient Air Quality Standards for O<sub>3</sub>: Assessment of Scientific and Technical Information ("Staff Paper")(EPA-452/R-96-007, June 1996, NTIS # PB-96-203435, \$67.00 paper copy and \$21.50 microfiche). (Add a \$3.00 handling charge per order.)

A limited number of copies of other documents generated in connection with this standard review, such as documents pertaining to human exposure and health risk assessments, and vegetation exposure, risk, and benefits analyses can be obtained from: U.S. Environmental Protection Agency Library (MD-35), Research Triangle Park, NC 27711, telephone (919) 541-2777. These and other related documents are also available for inspection and copying in the EPA docket identified under "ADDRESSES".

##### Electronic Availability

The Staff Paper and human exposure and health risk assessment support documents are now available on the Agency's Office of Air Quality Planning and Standards (OAQPS) Technology Transfer Network (TTN) Bulletin Board System (BBS) in the Clean Air Act Amendments area, under Title I, Policy/Guidance Documents. To access the bulletin board, a modem and communications software are necessary. To dial up, set your communications software to 8 data bits, no parity and one stop bit. Dial (919) 541-5742 and follow the on-screen instructions to register for access. After registering, proceed to choice "<T> Gateway to TTN Technical Areas", then choose "<E> CAAA BBS". From the main menu, choose "<1> Title I: Attain/Maint of NAAQS", then "<P> Policy Guidance Documents." To access these documents through the World Wide Web, click on "TTN BBSWeb", then proceed to the Gateway to TTN Technical areas, as above. If assistance is needed in accessing the system, call the help desk at (919) 541-5384 in Research Triangle Park, NC.

## Implementation Strategy for Revised Air Quality Standards

On Wednesday, July 16, 1997, President Clinton signed a memorandum to the Administrator specifying his goals for the implementation of the O<sub>3</sub> and PM standards. Attached to the President's memorandum is a strategy prepared by an interagency Administration group outlining the next steps that would be necessary for implementing these standards. The EPA will prepare guidance and proposed rules consistent with the President's memorandum. Copies of the Presidential document are available in paper copy by contacting the U.S. Environmental Protection Agency Library at the address under "Availability of Related Information" and in electronic form as discussed above in "Electronic Availability."

The following topics are discussed in this preamble:

- I. Background
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  - C. Review of Air Quality Criteria and Standards for O<sub>3</sub>
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### I. Background

#### A. Legislative Requirements

Two sections of the Act govern the establishment, review, and revision of NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify certain pollutants which "may reasonably be anticipated to endanger public health or welfare" and to issue air quality criteria for them. These air quality criteria are 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 \*\*\*.’’

Section 109 (42 U.S.C. 7409) directs the Administrator 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, based on [the] criteria and allowing an adequate margin of safety, are requisite to protect the public health.’’ The margin of safety requirement was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting, as well as to provide a reasonable degree of protection against hazards that research has not yet identified. 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, by selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that she finds may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The Act does not require the Administrator to establish a primary NAAQS at a zero-risk level but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator’s judgment. *Lead Industries Association v. EPA*. (647 F.2d 1130, 1161–62 (D.C. Cir. 1980)).

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 [the] criteria, [are] requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.’’ Welfare effects as defined in section 302(h) (42 U.S.C. 7602(h)) include, but are not limited to, ‘‘effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.’’

Section 109(d)(1) of the Act requires periodic review and, if appropriate, revision of existing air quality criteria and NAAQS. Section 109(d)(2) requires appointment of an independent scientific review committee to review criteria and standards and recommend new standards or revisions of existing criteria and standards, as appropriate. The committee established under section 109(d)(2) is known as the Clean Air Scientific Advisory

Committee (CASAC), a standing committee of EPA’s Science Advisory Board.

#### B. Related Control Requirements

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once EPA has established them. Under section 110 of the Act (42 U.S.C. 7410) and related provisions, States are to submit, for EPA approval, State implementation plans (SIP’s) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The States, in conjunction with EPA, also administer the prevention of significant deterioration programs (42 U.S.C. 7470–7479) for these pollutants. In addition, Federal programs provide for nationwide reductions in emissions of these and other air pollutants under Title II of the Act (42 U.S.C. 7521–7574), which involves controls for automobile, truck, bus, motorcycle, nonroad engine, and aircraft emissions; the new source performance standards under section 111 (42 U.S.C. 7411); and the national emission standards for hazardous air pollutants under section 112 (42 U.S.C. 7412).

#### C. Review of Air Quality Criteria and Standards for O<sub>3</sub>

The last review of O<sub>3</sub> air quality criteria and standards was completed in March 1993 with notice of a final decision not to revise the existing primary and secondary standards (58 FR 13008). The current primary and secondary standards are each set at a level of 0.12 ppm, with a 1-hour averaging time and a 1-expected-exceedance form, such that the standards are attained when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 ppm is equal to or less than 1, averaged over 3 years (as determined by 40 CFR part 50, Appendix H).<sup>1</sup>

The EPA initiated this current review of the air quality criteria and standards in August 1992 with the development of a revised Air Quality Criteria Document for O<sub>3</sub> and Other Photochemical Oxidants, henceforth the ‘‘Criteria Document.’’ Several workshops were held by EPA’s National Center for Environmental Assessment (NCEA) to discuss health and welfare effects information during the summer and fall of 1993. An external review draft of the Criteria Document made available to the public and to the CASAC in the spring of 1994 was reviewed at a public CASAC meeting held on July 20–21, 1994. Based on comments made at the meeting, NCEA staff prepared a second external review draft, which was reviewed at a public CASAC meeting on March 21–22, 1995. At the same meeting, the CASAC also

reviewed draft portions of a staff paper prepared by the OAQPS, Review of National Ambient Air Quality Standards for O<sub>3</sub>: Assessment of Scientific and Technical Information (henceforth, the ‘‘Staff Paper’’), focusing on health effects and the primary NAAQS.<sup>2</sup> Taking into account CASAC and public comments, staff revised both documents and made new drafts available for public and CASAC review during the summer of 1995. The OAQPS staff also prepared and made available draft portions of the Staff Paper focusing on welfare effects and the secondary standard.

A public CASAC meeting was held on September 19–20, 1995, at which time CASAC came to closure in its review of the draft Criteria Document and the primary standard sections of the draft Staff Paper. In a November 28, 1995 letter from the CASAC chair to the Administrator, CASAC advised that the final draft Criteria Document ‘‘provides an adequate review of the available scientific data and relevant studies of O<sub>3</sub> and related photochemical oxidants’’ (Wolff, 1995a). Further, in a November 30, 1995 letter, CASAC advised the Administrator that the primary standard portion of the draft Staff Paper ‘‘provides an adequate scientific basis for making regulatory decisions concerning a primary O<sub>3</sub> standard’’ (Wolff, 1995b). The final Criteria Document (U.S. EPA, 1996a) reflects CASAC and public comments received at and subsequent to the September 1995 CASAC meeting.

Based on comments on the Staff Paper from the September 1995 CASAC meeting, revisions were made to the secondary standard sections of the Staff Paper, which were reviewed at a public CASAC meeting held on March 21, 1996. At that meeting and in a subsequent letter to the Administrator, CASAC concluded that the secondary standard sections of the draft Staff Paper ‘‘provide an appropriate scientific basis for making regulatory decisions concerning a secondary O<sub>3</sub> standard’’ (Wolff, 1996). The final Staff Paper (U.S. EPA, 1996b) reflects CASAC and public comments received at and subsequent to the September 1995 and March 1996 meetings on the primary standard and secondary standard sections, respectively.

On November 27, 1996 EPA announced its proposed decision to revise the NAAQS for O<sub>3</sub> (61 FR 65716, December 13, 1996, hereinafter ‘‘proposal’’) as well as its proposed decision to revise the NAAQS for particulate matter (PM). In the proposal, EPA identified proposed revisions, based on the air quality criteria for O<sub>3</sub>, and solicited public comments on alternative primary and secondary standards and on the proposed forms of the standards.

<sup>1</sup> A more complete history of the O<sub>3</sub> NAAQS is presented in section II.B. of the Office of Air Quality Planning and Standards Staff Paper, Review of National Ambient Air Quality Standards for O<sub>3</sub>: Assessment of Scientific and Technical Information (U.S. EPA, 1996b).

<sup>2</sup> The Staff Paper evaluates policy implications of the key studies and scientific information in the Criteria Document, identifies critical elements that EPA staff believes should be considered, and presents staff conclusions and recommendations of suggested options for the Administrator’s consideration.

To ensure the broadest possible public input on the O<sub>3</sub> and PM proposals, EPA took extensive and unprecedented steps to facilitate the public comment process beyond the normal process of providing an opportunity to request a hearing and receiving written comments submitted to the rulemaking docket. The EPA established a national toll-free telephone hotline to facilitate public comments on the proposed revisions to the O<sub>3</sub> and PM NAAQS, and on related notices dealing with the implementation of revised O<sub>3</sub> and PM standards, as well as a system for the public to submit comments on the proposals electronically via the Internet. Over 14,000 calls and over 4,000 electronic mail messages were received through these channels. The public could also access key supporting documents (including the Criteria Document, Staff Paper, related technical documents and fact sheets) via the Internet.

The EPA also held several public hearings and meetings across the country to provide direct opportunities for public comment on the proposed revisions to the O<sub>3</sub> and PM NAAQS and to disseminate information to the public about the proposed standard revisions. On January 14 and 15, 1997, EPA held concurrent, 2-day public hearings in Boston, MA, Chicago, IL, and Salt Lake City, UT. A fourth public hearing, which focused primarily on PM monitoring issues, was held in Durham, NC on January 14, 1997. Over 400 citizens and organizations testified during these public hearings. EPA also held two national satellite telecasts to answer questions on the standards and participated in meetings sponsored by the Air and Waste Management Association on the proposed revisions to the standards at more than 10 locations across the country. Beyond that, several EPA regional offices held public meetings and workshops and participated in hearings that States and cities held around the country.

As a result of this intensive effort to solicit public input, over 50,000 written and verbal comments were received on the proposed revisions to the O<sub>3</sub> NAAQS by the close of the public comment period on March 12, 1997. The major issues raised in the comments are discussed throughout the preamble of this final rule. A comprehensive summary of all significant comments, along with EPA's response to such comments (hereafter "Response to Comments"), can be found in the docket for this rulemaking (Docket No. A-95-58).

The focus of this current review of the air quality criteria and standards for O<sub>3</sub> and related photochemical oxidants is on public health and welfare effects associated with exposure to ambient levels of tropospheric O<sub>3</sub>. Tropospheric O<sub>3</sub> is chemically identical to stratospheric O<sub>3</sub>, which is produced miles above the earth's surface and provides a protective shield from excess ultraviolet radiation. In contrast, tropospheric O<sub>3</sub> at sufficient concentrations has been associated

with harmful effects due to its oxidative properties and its presence in the air that people and plants take up during respiratory processes. Ozone is not emitted directly from mobile or stationary sources but, like other photochemical oxidants, commonly exists in the ambient air as an atmospheric transformation product. Ozone formation is the result of chemical reactions of volatile organic compounds (VOC), nitrogen oxides (NO<sub>x</sub>), and oxygen in the presence of sunlight and generally at elevated temperatures. A detailed discussion of atmospheric formation, ambient concentrations, and health and welfare effects associated with exposure to O<sub>3</sub> can be found in the Criteria Document and in the Staff Paper.

#### *D. Summary of Proposed Revisions to the O<sub>3</sub> Standards*

For reasons discussed in the proposal, the Administrator proposed to replace the current 1-hour primary standard for O<sub>3</sub> with an 8-hour standard set at 0.08 ppm, which would be met at an ambient air quality monitoring site when the 3-year average of the annual third-highest daily maximum 8-hour average O<sub>3</sub> concentration is less than or equal to 0.08 ppm. The proposal solicited comments on alternative 8-hour standards set at 0.09 ppm, which generally represents the continuation of the present level of protection, and 0.07 ppm, which would be highly precautionary in nature, as well as on retaining the current primary standard. The proposal also solicited comments on alternative forms of the standard, specific data handling and rounding conventions used in determining attainment with the standard, and issues related to the communication of public health information.

With regard to the secondary standard, the Administrator proposed to replace the current 1-hour secondary standard with one of two alternative standards: either one set identical to the proposed primary standard or a new seasonal standard expressed as a sum of hourly O<sub>3</sub> concentrations greater than or equal to 0.06 ppm, cumulated over 12 hours per day during the consecutive 3-month period of maximum concentrations during the O<sub>3</sub> monitoring season, set at a level of 25 ppm-hour. The proposal solicited comments on these two alternatives, as well as on specific issues related to the form of a seasonal standard and on an enhanced rural air quality monitoring network.

## **II. Rationale for the Primary Standard**

### *A. Introduction*

1. *Overview*. This notice presents the Administrator's final decision regarding the need to revise the current primary O<sub>3</sub> standard, and, more specifically, regarding the averaging time, level, and form of a new primary standard to replace the current 1-hour standard. This decision is based on a thorough review, in the Criteria Document, of the scientific information on human health

effects associated with exposure to ambient levels of O<sub>3</sub>, including evaluation of key studies published through 1995. This decision also takes into account:

(1) Staff Paper assessments of the most policy-relevant information in the Criteria Document and analyses of human exposure and risk, presented in the Staff Paper and supporting technical reports.

(2) CASAC advice and recommendations, as reflected in discussions of drafts of the Criteria Document and Staff Paper at public meetings, in separate written comments, and in CASAC's letters to the Administrator.

(3) Public comments received during the development of these documents, either in connection with CASAC meetings or separately.

(4) Extensive public comments received on the proposal regarding the primary O<sub>3</sub> standard.

After taking this information and comments into account and for the reasons discussed below in this unit, the Administrator concludes that revisions to the current primary standard to provide increased public health protection are appropriate at this time to protect public health with an adequate margin of safety. Further, the Administrator determines that it is appropriate to establish a revised 8-hour, 0.08 ppm primary standard with a form based on the 3-year average of the annual fourth-highest daily maximum 8-hour average O<sub>3</sub> concentrations measured at each monitor within an area.

As discussed more fully below in this unit, the rationale for the final decision regarding the O<sub>3</sub> primary NAAQS includes consideration of:

(1) Health effects information to inform judgments as to the likelihood that exposures to ambient O<sub>3</sub> result in adverse health effects for exposed individuals.

(2) Insights gained from human exposure and risk assessments to provide a broader perspective for judgments about protecting public health from the risks associated with O<sub>3</sub> exposure.

(3) Specific conclusions with regard to the elements of a standard (i.e., averaging time, level, and form) that, taken together, would be appropriate to protect public health with an adequate margin of safety.

(4) Alternative views of the significance of the effects and factors to be considered in policy judgments about the appropriate elements of the standard.

The health effects information and human exposure and risk assessments were summarized in the proposal and are only briefly outlined below. More fully discussed in the following units of this preamble is the Administrator's rationale, in light of key issues raised in public comments, for concluding that it is appropriate to revise the specific elements of the current standard including averaging time (Unit II.B.1.), level (Unit II.B.2.), and form (Unit II.B.3.). Finally, the related subject of the communication of

public health information, and the public comments received on this subject, are summarized in Unit II.C.

2. *Health effects information.* The last review of the air quality criteria for O<sub>3</sub> included an evaluation of key studies published through early 1989 and was the basis for EPA's 1993 decision not to revise the primary standard at that time. However, in recognition of the large number of new studies, particularly on 6- to 8-hour exposures to O<sub>3</sub>, that had become available since early 1989 but had not undergone rigorous assessment and review by CASAC, the EPA made clear in the 1993 final decision notice that it would proceed with the next review as rapidly as possible to consider this new information. Thus, the current review of health effects information focused on a large body of information published since 1989 that would lead to a more informed decision than was possible in 1993 as to whether an O<sub>3</sub> primary standard with a longer averaging time was appropriate to protect public health.

The proposal reviewed the human health effects associated with exposure to ambient levels of O<sub>3</sub> based on an integrative assessment of human clinical, epidemiological, and animal toxicological studies available through 1995, as assessed in the Criteria Document and Staff Paper. Based on this information, an array of health effects has been attributed to short-term (1 to 3 hours), prolonged (6 to 8 hours), and long-term (months to years) exposures to O<sub>3</sub>.

Acute health effects<sup>3</sup> are induced by short-term exposures to O<sub>3</sub> (observed at concentrations as low as 0.12 ppm), generally while individuals are engaged in moderate or heavy exertion, and by prolonged exposures to O<sub>3</sub> (observed at concentrations as low as 0.08 ppm), typically while individuals are engaged in moderate exertion. Moderate exertion levels are more frequently experienced by individuals than heavy exertion levels. The acute health effects include transient pulmonary function responses, transient respiratory symptoms, effects on exercise performance, increased airway responsiveness, increased susceptibility to respiratory infection, increased hospital admissions and emergency room visits, and transient pulmonary inflammation. Based in particular on new information available since the last review of the air quality criteria for O<sub>3</sub> was completed, such acute health effects have been observed following prolonged exposures at moderate levels of exertion at concentrations of O<sub>3</sub> as low as 0.08 ppm. Groups at increased risk of experiencing such effects include active children and outdoor workers who regularly engage in outdoor activities and individuals with preexisting respiratory disease (e.g.,

asthma, chronic obstructive lung disease). Further, it is recognized that some individuals are unusually responsive to O<sub>3</sub> and may experience much greater functional and symptomatic effects from exposure to O<sub>3</sub> than the average individual.

With regard to chronic health effects<sup>4</sup>, the collective data from studies of laboratory animals and human populations have many ambiguities, but provide suggestive evidence of such effects in humans. It is clear from toxicological data that O<sub>3</sub>-induced lung injury is roughly similar across species (including monkeys, rats, and mice) with responses that are concentration dependent. The currently available information provides at least a biologically plausible basis for considering the possibility that repeated inflammation associated with exposure to O<sub>3</sub> over a lifetime may result in sufficient damage to respiratory tissue such that individuals later in life may experience a reduced quality of life, although such relationships remain highly uncertain.

EPA's consideration of this health effects information necessarily included judgments with respect to when these physiological effects become so significant that they should be regarded as adverse to the health of individuals experiencing the effects. In making these judgments, the Administrator looked to guidelines published by the American Thoracic Society (1985) and the advice of CASAC. The proposal summarized the criteria and reasoning for EPA's judgments on this issue, upon which the CASAC panel expressed a consensus view that these "criteria for the determination of an adverse physiological response was reasonable" (Wolff, 1995b). The criteria take into account the degree of severity of the effects; the likelihood that the effects would interfere with normal activity for individuals with impaired respiratory systems or active healthy individuals; the likelihood that the effects would result in additional or more frequent use of medication, medical treatment, or emergency room visits for individuals with impaired respiratory systems; and the implications of single or repeated occurrences of the effects for an individual.

Some commenters raised concerns regarding the criteria used by EPA to make determinations as to when effects become adverse, citing CASAC's closure letter (Wolff, 1995b) stating that "there was considerable concern that the criteria for grading physiological and clinical responses to O<sub>3</sub> was confusing if not misleading." These concerns with the draft criteria were discussed at length during a public CASAC meeting, resulting in very specific agreements as to how to revise the draft criteria so as to be consistent with CASAC's advice (Transcript of CASAC meeting, September

19-20, 1995, pp. 242-248). Having reached such specific agreement, CASAC advised that further review of the final version of these criteria, subsequently incorporated in both the final Criteria Document and Staff Paper, was unnecessary.

Other commenters have questioned whether judgments made in this review are consistent with those made in the last review with regard to when physiological and clinical effects become adverse to individuals experiencing such effects. Specifically, the commenters focused on the judgment stated in the 1993 final decision notice (58 FR 13008, March 9, 1993) that "lesser effects associated with [1- to 3-hour] exposure to O<sub>3</sub> in the range of 0.12 ppm to 0.15 ppm observed in the controlled human studies did not constitute adverse effects for purposes of section 109 of the Act." The "lesser effects" referred to in that notice involved responses of a maximum decrease in lung function [as measured by forced expiratory volume in 1 second (FEV<sub>1</sub>)] of from 9 percent to 16 percent for the most sensitive individuals exposed in this range, with few, if any, symptoms. The EPA notes that this judgment is, in fact, consistent with judgments presented in the 1996 proposal, which identify moderate and large lung function decrements (as reflected in EPA's risk assessment by FEV<sub>1</sub> decreases of  $\geq 15$  percent and  $\geq 20$  percent, respectively, with the most sensitive individuals experiencing FEV<sub>1</sub> decreases as large as 40 percent to 50 percent at 6- to 8-hour exposures in the range of 0.08 ppm to 0.10 ppm in controlled human studies), and moderate to severe symptoms as being adverse.

3. *Exposure and risk assessments.* To put judgments about health effects that are adverse for individuals into a broader public health context, EPA conducted quantitative assessments to estimate O<sub>3</sub> exposures and related risks for the general population and two at-risk groups, "outdoor children" and "outdoor workers," living in nine representative U.S. urban areas. This broader context included consideration, to the extent possible, of the size of the particular population groups identified as at risk for various effects, the estimated number of people within at-risk groups likely to experience O<sub>3</sub>-related adverse effects, the estimated number of occurrences of such effects, and the estimated number of people who would experience exposures of concern<sup>5</sup> associated with various air quality scenarios representing attainment of the current and alternative 8-hour standards. Consideration was also given to the kind and degree of uncertainties inherent in assessing such exposures and risks. Such considerations provided a basis for judgments discussed in

<sup>3</sup> "Acute health effects" of O<sub>3</sub> are defined as those effects induced by short-term and prolonged exposures to O<sub>3</sub>. Examples of these effects are functional, symptomatic, biochemical, and physiologic changes.

<sup>4</sup> "Chronic health effects" of O<sub>3</sub> are defined as those effects induced by long-term exposures to O<sub>2</sub>. Examples of these effects are structural damage to lung tissue and accelerated decline in baseline lung function.

<sup>5</sup> "Exposures of concern" refer throughout to exposures at and above 0.08 ppm, 8-hour average, at which a range of health effects have been observed in controlled human studies, but for which data were too limited to allow for quantitative risk assessment.

the proposal about the levels of exposure and risk associated with the current and alternative standards, which helped inform judgments about the adequacy of public health protection afforded by the current and alternative standards.

Risk estimates were developed for those effects for which sufficient concentration-response information was available from studies evaluated in the Criteria Document, including adverse lung function and respiratory symptom responses. In a separate analysis, excess respiratory hospital admissions for individuals with asthma associated with attainment of alternative standards were also estimated, using a risk model for this health endpoint based on the results of an epidemiological study in New York City (Thurston et al., 1992) for which adequate air quality information was available to assess population risk<sup>6</sup>. These quantitative risk estimates (for that subset of O<sub>3</sub>-related effects for which information is sufficient to conduct such quantitative analyses) add to our understanding of the broader array of health effects that are associated with exposure to O<sub>3</sub> but for which quantitative risk estimates could not be developed.

The methodology, results, and key observations from these assessments were presented in the proposal. The EPA believes, and CASAC concurred, that the models selected to estimate exposure and risk were appropriate and that the methods used to conduct the health risk assessment for adverse lung function and respiratory symptom responses represent the state of the art. Nevertheless, the Administrator and CASAC recognized that there are many uncertainties inherent in such analyses, and that not all uncertainties inherent in such analyses could be quantified and reflected in ranges of risk estimates (Wolff, 1995b), as discussed in the proposal and the referenced technical support documents.

The exposure and risk assessments available at the time of proposal had been conducted to evaluate the O<sub>3</sub> exposures and risks associated with attainment of the current 1-hour standard and various alternative 8-hour standards under consideration early in the standards review process when the assessments were initiated. The EPA and CASAC recognized at that time that additional alternative standards might need to be analyzed later in the review process. Upon deciding to propose a standard with a concentration-based form in the Fall of 1996, EPA staff initiated supplemental analyses to estimate exposures and risks<sup>7</sup> for the specific

standard to be proposed and alternative standards on which the proposal solicited comment. In conducting these supplemental analyses, several technical changes were made based on insights gained from the initial analyses.<sup>8</sup> The supplemental assessment (Richmond, 1997) was placed in the docket and on the TTN on February 12, 1997, and its availability was announced in the **Federal Register** notice extending the public comment period on the proposal, providing the public the opportunity to comment on the supplemental assessment (61 FR 7743, February 20, 1997).

Key observations and results from the initial and supplemental exposure and risk assessments that are most pertinent to the decision to revise the current primary standard are highlighted in the following unit, together with discussion of the key issues raised in public comments on the methodology and public health implications of these assessments.

#### B. Elements of the Primary Standard

In selecting a primary standard for O<sub>3</sub>, the Administrator must specify: Averaging time, O<sub>3</sub> concentration (i.e., level), and form (i.e., the air quality statistic to be used as a basis for determining compliance with the standard).<sup>9</sup> All three of these elements are necessary to define a standard and to determine the degree of public health protection afforded by the standard. The proposal outlined the key factors considered in selecting each of these elements for the proposed standard, as well as the range of options for each element on which the EPA solicited comment. The factors reflect an integration of information on acute and chronic health effects associated with exposure to ambient O<sub>3</sub>; expert judgments on the adversity of such effects for individuals; and policy judgments, informed by air quality and exposure analyses and quantitative risk assessment when possible, as to the point at which risks would be reduced sufficiently to achieve protection of public health with an adequate margin of safety.

This approach to selecting a primary standard was endorsed by CASAC (Wolff, 1995b), particularly through its advice to the Administrator that "EPA's risk assessments must play a central role in identifying an appropriate level" and its recognition that "the selection of a specific level and [form] is a policy judgment." Further, it was the consensus view of CASAC that the ranges of 8-hour average levels (0.07 to 0.09 ppm) and

forms (concentration-based forms that generally allow for 1 to 5 exceedances) on which the proposal solicited comment were appropriate.

The following discussion focuses primarily on those considerations that were most influential in the Administrator's final decisions on these elements, taking into account the comments received on the range of options identified in the proposal.

1. *Averaging time.* In proposing to change the averaging time of the primary standard from 1 to 8 hours, the Administrator was concurring with the unanimous recommendation of CASAC (Wolff, 1995b) "that the present 1-hour standard be eliminated and replaced with an 8-hour standard," and that more research is needed to resolve uncertainties about potential chronic effects before appropriate consideration can be given to establishing a long-term (e.g., seasonal or annual) primary standard. The Administrator's proposed decision was supported by the following key observations and conclusions:

(1) The 1-hour averaging time specified in the current NAAQS was originally selected primarily on the basis of health effects associated with short-term (i.e., 1- to 3-hour) exposures, with qualitative consideration given to preliminary information on potential associations with longer exposure periods.

(2) Substantial new health effects information available for consideration in this review demonstrates associations between a wide range of health effects and prolonged (i.e., 6- to 8-hour) exposures below the level of the current 1-hour NAAQS.

(3) Results from the quantitative risk analyses show that attaining a standard with a 1-hour averaging time reduces the risk of experiencing health effects associated with both 1-hour and 8-hour exposures. Likewise, attaining an 8-hour standard reduces the risk of experiencing health effects associated with both 8-hour and 1-hour exposures. Thus, reductions in risks from both short-term and prolonged exposures can be achieved through a primary standard with an averaging time of either 1 or 8 hours. As a result, establishment of both 1-hour and 8-hour standards would not be necessary to reduce risks associated with the full range of observed acute health effects.

(4) The 8-hour averaging time is more directly associated with health effects of concern at lower O<sub>3</sub> concentrations than is the 1-hour averaging time. It was thus the consensus of CASAC "that an 8-hour standard was more appropriate for a human health-based standard than a 1-hour standard." (Wolff, 1995b)

(5) While there is a large animal toxicology database providing clear evidence of associations between long-term (e.g., from several months to years) exposures and lung tissue damage, with additional evidence of reduced lung elasticity and accelerated loss of lung function, there is no corresponding

<sup>6</sup> This study is one of several studies, mainly conducted in the northeastern portion of the United States and southeastern Canada, reporting excess daily respiratory-related hospital admissions associated with elevated O<sub>3</sub> levels within the general population and, more specifically, for individuals with asthma.

<sup>7</sup> The analyses were conducted for the at-risk population of outdoor children, the group with the highest exposures and risks. Outdoor children are the subset of children

between the ages of 6 and 18 years old who tend to be active outdoors, and include approximately over 30 percent to 45 percent of all children in this age group in the nine urban areas analyzed.

<sup>8</sup> These changes primarily focused on the air quality data used in the exposure analysis and on the air quality adjustment procedures used to simulate ambient O<sub>3</sub> concentrations upon attainment of alternative standards.

<sup>9</sup> This review focused only on a standard for O<sub>3</sub>, as the most appropriate surrogate for photochemical oxidants.

evidence for humans. Moreover, the state of the science has not progressed sufficiently to permit quantitative extrapolation of the animal-study findings to humans. Thus, the Administrator concluded that consideration of a separate long-term primary O<sub>3</sub> standard is not appropriate at this time. As discussed below, however, the Administrator considered the possibility of long-term effects in selecting the level of an 8-hour standard, which will provide protection against such effects to the extent they may occur in humans, by lowering overall air quality distributions and, thus, reducing cumulative long-term exposures.

The public comments reflect broad support for a standard with an 8-hour averaging time, either alone or in conjunction with a 1-hour standard. This support was typically based on references to:

(1) Evidence of health effects from 6- to 8-hour exposures to O<sub>3</sub> concentrations down to 0.08 ppm, which are lower than those concentrations that have induced such effects after 1- to 3-hour exposures, and which are lower than the 0.12 ppm level of the current standard.

(2) Analyses indicating that an 8-hour standard would limit both 1- and 8-hour exposures.

(3) CASAC's unanimous agreement that the current 1-hour standard should be replaced by an 8-hour standard. In considering the adequacy of the current 1-hour standard alone in light of the health effects evidence, some commenters have highlighted the statement in the Criteria Document that there is "strong evidence that ambient exposures to O<sub>3</sub> can cause significant exacerbations of preexisting respiratory disease in the general public at concentrations below 0.12 ppm." (U.S. EPA, 1996a, p. 7-171)

Commenters expressing support for an 8-hour averaging time included not only those who supported a level of public health protection consistent with or greater than that reflected by EPA's proposed standard, but also many who disagreed for various reasons with the need for increased public health protection beyond that provided by the current standard. Of those supporting an 8-hour averaging time but not supporting the need for increased protection, some expressed the view that the averaging time of a health-based standard should be consistent with the exposures of most concern, while others were simply neutral between the choices of retaining the current 1-hour standard and replacing it with an "equivalent" 8-hour standard.

The EPA agrees with the considerations raised by those commenters who favor an 8-hour standard. Further, in considering the appropriateness of an 8-hour standard as compared to a 1-hour standard, EPA also notes the results of its exposure and risk assessments which show variability across the nine urban areas analyzed with regard to the

extent to which the current 1-hour standard, and alternative 8-hour standards, limit 8-hour exposures of concern and associated risks of adverse health effects. As noted in the proposal and in the supplemental risk assessment, there is much greater variability across urban areas, particularly in looking at the seven current nonattainment areas examined, in the extent to which the current 1-hour standard limits such exposures of concern and risks than for the alternative 8-hour standards. For example, the updated assessment estimates that the current 1-hour standard results in 8-hour exposures of concern at and above 0.08 ppm<sup>10</sup> that vary by almost two orders of magnitude across these areas. In contrast, alternative 8-hour standards at the proposed level of 0.08 ppm result in estimated 8-hour exposures of concern and risks that are much more consistent.<sup>11</sup> In EPA's view, the fact that an averaging time of 8 hours results in a significantly more uniformly protective national standard than the current 1-hour standard is an important public health policy consideration that supports the selection of an 8-hour averaging time.

Those commenters who did not support EPA's proposal for an 8-hour averaging time generally did not support any revision to the current standard. These commenters predominantly focused on two basic points: The generally improving trends in air quality under the current standard and associated air quality management programs, which, commenters argued, suggest that there is no need for EPA to adopt any more stringent standard; and observations made in CASAC's closure letter (Wolff, 1995b) with regard to EPA's risk assessment not demonstrating any "bright line" threshold of effects or acceptable risk. With regard to the first issue, EPA agrees that air quality trends are improving as a consequence of ongoing control programs designed to attain the current NAAQS. The EPA does not, however, believe that these trends relieve the Agency of its statutory mandate to review and, if appropriate, revise the NAAQS on the basis of the best available scientific evidence to establish standards that protect public health with an adequate margin of safety. The fact that current control programs are resulting in progress toward improving air quality does suggest that it is important to ensure that such

<sup>10</sup> More precisely, exposures at and above 0.08 ppm refers to estimates of exposures to O<sub>3</sub> concentrations ≥ 0.081 ppm from the exposure assessment.

<sup>11</sup> In terms of the percent of outdoor children estimated to be exposed to O<sub>3</sub> concentrations at and above 0.08 ppm while engaged in moderate exertion, the current 1-hour standard results in a range across the seven nonattainment areas of approximately 0.3 percent to 24 percent of such children, whereas alternative 8-hour standards, at the proposed level of 0.08 ppm, result in a significantly more uniform degree of protection, with ranges of approximately 2 percent to 9 percent, third-highest concentration form, and 3 percent to 11 percent, fifth-highest concentration form, across the areas.

progress is maintained during any transition to a revised standard.

With regard to the second issue, commenters very frequently quoted from the CASAC closure letter (Wolff, 1995b) stating "that there is no bright line" which distinguishes any of the proposed standards (either the level or the number of allowable exceedances) as being significantly more protective of public health" and that "the selection of a specific level and number of allowable exceedances is a policy judgment." These commenters have variously interpreted these statements as a CASAC consensus that the differences in the public health protection afforded by any of the alternative standards were too small to be important from a public health perspective, not statistically significantly different, or simply not different at all. Based on these interpretations, the commenters argued that it is not appropriate to revise the standard in any way, because a revised standard would result in disruption to ongoing programs, additional planning requirements, and increased implementation costs, but would provide no or only very little improvement in public health protection.

The EPA believes that these commenters have misconstrued or too narrowly interpreted CASAC's advice to the Administrator by not considering the entire range of views and recommendations included in its closure letter. Specifically, CASAC began its summary of recommendations to the Administrator (Wolff, 1995b) by stating that "[t]he Panel was in unanimous agreement that the present 1-hour standard be eliminated and replaced with an 8-hour standard." This agreement was based on "the consensus of the Panel that an 8-hour standard was more appropriate for a human health-based standard than a 1-hour standard." Thus, CASAC was unequivocal in its advice to the Administrator with regard to which averaging time the health effects evidence more strongly supports. While some commenters have also quoted statements by individual Panel members at CASAC meetings suggesting that choosing between a 1- or 8-hour averaging time is a "policy" choice, these individual statements during the course of CASAC's review do not contradict nor supersede the clear and unanimous agreement of CASAC on averaging time as conveyed to the Administrator in its closure letter.

In considering these comments, EPA also believes it is important to put into a public health perspective CASAC's observations about the differences among alternative standards in protecting the public from the health effects that were quantitatively estimated in EPA's risk assessment. In the closure letter (Wolff, 1995b), CASAC observed that "the differences in the percent of outdoor children \*\*\* responding between the present standard and the most stringent proposal \*\*\* are small and their ranges overlap for all health endpoints." Most importantly, EPA notes that the primary

standard would provide protection from a broader array of health effects than it was possible to consider in its quantitative risk assessment. This perspective is clearly shared in particular by those CASAC panel members who personally favored a level or range of levels that included the proposed level of 0.08 ppm, in that the closure letter characterizes their views as reflecting, in part, their "concern over the evidence for chronic deep lung inflammation from the controlled human and animal exposure studies." While the risk of this effect, as well as other effects related to 6- to 8-hour exposures in the Criteria Document and Staff Paper (including increased airway responsiveness, impairment of host defenses suggesting an increased susceptibility to respiratory infection, and increased emergency room visits, doctor visits, and frequency of medication use by individuals with impaired respiratory systems) could not be quantitatively estimated in EPA's risk assessment, EPA believes that consideration of these effects is nevertheless important in making public health policy judgments.

Further, in interpreting CASAC's statements on EPA's risk assessment report (Whitfield et al., 1996) that there is no "bright line" which distinguishes any of the standards as being "significantly" more protective, and that the "ranges overlap," EPA notes that there are statistically significant differences in the estimated risks for the standards analyzed with 1- and 5-exceedance forms. This information was presented to CASAC at its September 1995 meeting (CASAC meeting transcript, September 19-20, 1995, pp. 108-109). Further, EPA again notes that whether one judges the differences to be significant or small can depend on whether one focuses on percentages, as CASAC's letter did, or on total numbers of times that children or other at-risk individuals experience such effects. The overlap in the ranges of risk referred to in the CASAC letter reflect differences among urban areas used in EPA's risk analysis (e.g., air quality, exposure patterns, environmental factors), not random uncertainties in risk estimates within any given urban area. Thus, the fact that the ranges overlap does not mean that there are no real or statistically significant differences in protection among alternative standards. To the extent that the quoted statements from CASAC's closure letter are read as implying that CASAC considered the differences not to be statistically significant (or that there are no differences at all in the protection afforded by the alternative standards), EPA disagrees with that reading.

Another group of commenters, while supporting an 8-hour standard, specifically opposed replacing the current 1-hour standard with an 8-hour standard, but favored instead both 8-hour and 1-hour standards. These commenters generally felt that a greater degree of public health protection than

that provided by the proposed standard was warranted, and that standards based on both averaging times were necessary to provide the requisite protection from 1- and 8-hour exposures of concern. These commenters generally argued that an 8-hour standard alone could still allow for high 1-hour exposures of concern, or that the retention of the current 1-hour standard was critical to maintaining current pollution control measures. As an initial matter, EPA is delaying revocation of the 1-hour standard to ensure an effective transition to the 8-hour standard, as discussed in Unit II.B.4 of this preamble. While EPA agrees that it is possible that an 8-hour standard alone could allow for high 1-hour exposures of concern, at and above 0.12 ppm,<sup>12</sup> EPA's exposure assessments estimate that alternative 8-hour standards, at the proposed level of 0.08 ppm but with different forms, would be very effective in limiting 1-hour exposures, and generally even more effective in limiting 1-hour exposures of concern than is the current 1-hour standard. More specifically, the updated assessment estimates that upon attainment of alternative 8-hour, 0.08 ppm standards, with forms ranging up to the fifth-highest concentration form, less than 0.1 percent of outdoor children are likely to experience any 1-hour exposures greater than 0.12 ppm while at heavy exertion levels in four to seven of the nine urban areas analyzed, whereas this is true for only two of the nine areas upon attainment of the current 1-hour standard. In all nine areas both the current and alternative 8-hour, 0.08 ppm standards are estimated to limit such exposures to less than 1 percent of the outdoor children. Thus, EPA concludes that an 8-hour averaging time does effectively limit both 1- and 8-hour exposures of concern.

For the reasons discussed above in this unit, and after taking into account the range of views expressed in the public comments, the Administrator finds that replacing the current 1-hour standard with an 8-hour standard, in combination with the decisions on level and form described below, is appropriate to provide adequate and more uniform protection of public health from both short-term (1 to 3 hours) and prolonged (6 to 8 hours) exposures to O<sub>3</sub> in the ambient air.

2. *Level.* Taken together, the level and form of the standard, for a given averaging time, determine the degree of public health protection afforded by the standard. Consideration of the level of the standard discussed in this unit of the preamble reflects a recognition of this linkage between level and form (discussed separately below in Unit II.B.3).

<sup>12</sup> The EPA recognizes this possibility exists especially in the very few areas with unusually "peaky" air quality patterns (i.e., in which the ratio of the 1- and 8-hour average design values for the current and proposed standards is greater than 1.5).

The Administrator's decision to propose the level of an 8-hour primary O<sub>3</sub> standard at 0.08 ppm, and to solicit comment on alternative levels, necessarily reflected a recognition, as emphasized by CASAC, that it is likely that "O<sub>3</sub> may elicit a continuum of biological responses down to background concentrations" (Wolff, 1995b). Thus, in the absence of any discernible threshold, it is not possible to select a level below which absolutely no effects are likely to occur. Nor does it seem possible, in the Administrator's judgment, to identify a level at which it can be concluded with confidence that no "adverse" effects are likely to occur. In such a case, as CASAC has advised, the traditional paradigm for standard-setting cannot be applied in the usual way, and assessments of risk "must play a central role in identifying an appropriate level" (Wolff, 1995b). Thus, the Administrator's task became one of attempting to select a standard level that would reduce risks sufficiently to protect public health with an adequate margin of safety, since a zero-risk standard is neither possible nor required by the Act. In this and other NAAQS reviews the CASAC has generally recognized that the selection of specific standards requires that the Administrator make public health policy judgments in addition to determinations of a strictly scientific nature. The Administrator's public health policy judgment on the level of the proposed standard was framed by the considerations discussed above in this unit and informed by the following key observations and conclusions:

(1) During the last review of the O<sub>3</sub> criteria and standards, CASAC concluded that the existing 1-hour standard set at 0.12 ppm O<sub>3</sub> provided "little, if any, margin of safety," and that the upper end of the range of consideration for a 1-hour standard should be 0.12 ppm (McClellan, 1989). In addition, several members of the CASAC panel recommended that consideration should be given to a lower 1-hour level of 0.10 ppm to offer some protection against effects for which there was preliminary information at that time of associations with 8-hour exposures to O<sub>3</sub>.

Regarding currently available evidence of O<sub>3</sub>-related effects:

(2) Based on a significant body of information available since the last review, there is now clear evidence from human clinical studies that O<sub>3</sub> effects of concern are associated with the 6- to 8-hour exposures tested. Studies were done at 6- to 8-hour exposure levels of 0.12, 0.10, and 0.08 ppm. This includes evidence of the following statistically significant responses at 6- to 8-hour exposures to the lowest concentration evaluated, 0.08 ppm O<sub>3</sub>, at moderate exertion: lung function decrements, respiratory symptoms (e.g., cough, pain on deep inspiration), nonspecific bronchial responsiveness, and biochemical indicators of pulmonary inflammation. Field studies

provide evidence of similar functional and symptomatic effects at ambient O<sub>3</sub> exposures that are consistent with the clinical findings. Laboratory animal studies provide supporting evidence of O<sub>3</sub>-induced biochemical indicators of inflammation and functional changes.

(3) Numerous epidemiological studies have reported excess hospital admissions and emergency department visits for respiratory causes (for asthmatic individuals and the general population) attributed primarily to ambient O<sub>3</sub> exposures, including O<sub>3</sub> concentrations below the level of the current standard, with no discernible threshold at or below this level. The biological plausibility of attributing such effects to ambient O<sub>3</sub> exposures is supported by human studies showing increased nonspecific bronchial responsiveness, laboratory animal studies showing pulmonary changes that decrease the effectiveness of the lung's defenses against bacterial respiratory infections, and the reasonable anticipation that O<sub>3</sub> exposures also increase the risk of respiratory infections in humans, based on the many similarities between animal and human defense mechanisms.

(4) Long-term laboratory animal studies suggest that changes in lung biochemistry and structure may, under certain circumstances, become irreversible, although it is unclear whether long-term exposures to ambient O<sub>3</sub> levels result in similar chronic health effects in humans.

Regarding the types and severity of O<sub>3</sub>-induced physiological effects that are considered to be adverse to the health status of individuals experiencing such effects:

(5) With regard to lung function decrements and respiratory symptoms, the Administrator recognized that these O<sub>3</sub>-induced effects are transient and reversible, and concluded that the extent to which such effects are adverse to the health status of an individual depends upon the severity, duration, and frequency with which an individual experiences such effects throughout the O<sub>3</sub> season. While group mean responses in clinical studies at the lowest exposure level tested of 0.08 ppm are typically small or mild in nature, responses of some sensitive individuals are sufficiently severe and extended in duration to be considered adverse. This would especially be true to the extent that those individuals likely to experience such effects would, on average, experience them several times a year.

(6) With regard to increased hospital admissions and emergency room visits, the Administrator judged that such effects are clearly adverse to individuals.

(7) With regard to pulmonary inflammation, the Administrator recognized that singular occurrences of inflammation are likely reversible and potentially of little health significance. On the other hand, based on laboratory animal studies, repeated inflammatory responses associated with

exposure to O<sub>3</sub> over a lifetime have the potential to result in damage to respiratory tissue such that individuals later in life may experience a reduced quality of life. Furthermore, there is the possibility that repeated pulmonary inflammatory responses could adversely affect asthmatic individuals by resulting in increased medication use, medical treatment, and/or emergency room visits and hospital admission. Such effects in asthmatics are of special concern particularly in light of the growing asthma problem in the United States and the increasing rates of asthma-related mortality and hospitalizations, especially among children in general and black children in particular. While O<sub>3</sub> has not been shown to cause asthma, the available evidence suggests that O<sub>3</sub> may exacerbate asthma. Accordingly, the Administrator judged that repeated exposures to O<sub>3</sub> levels that produce inflammation of the lungs are adverse to individuals likely to experience such exposures over long periods of time.

The Administrator considered the results of the exposure and risk analyses and the following key observations and conclusions from these analyses in putting effects considered to be adverse to individuals into a broader public health perspective and in making judgments about the level of a standard that would reduce risk sufficiently to protect public health with an adequate margin of safety:

(8) The median risk estimates for respiratory functional and symptomatic effects, as well as for excess hospital admissions of asthmatics for respiratory causes, are approximately the same or only marginally smaller for some of the 8-hour, 0.09 ppm standard options evaluated (including those with forms ranging from 1- to 3-expected-exceedances<sup>13</sup>) as compared to the current 1-hour, 0.12 ppm NAAQS (risk estimates are somewhat larger for an 8-hour, 0.09 ppm, 5-expected-exceedance standard as compared to those for the current NAAQS).

(9) Within any given urban area, statistically significant reductions in exposure and risk associated with respiratory functional and symptomatic effects result from alternative 8-hour standards as the level changes from 0.09 ppm to 0.08 ppm to 0.07 ppm. These reductions represent differences of hundreds of thousands of times that children in the nine urban areas included in the analysis would likely experience such effects under the range of alternative standards considered relative to the current standard. There are significant uncertainties in such quantitative estimates, however, and there is no break point or bright line that differentiates between acceptable and unacceptable risks within this range.

<sup>13</sup> The upper end of this range, 3-expected-exceedances, was based on air quality comparisons, since risk estimates were only available at the time of proposal for the 1- and 5-expected-exceedance forms of a 0.09 ppm standard. This range is consistent with the results of the updated risk assessment.

(10) Similarly, reductions in hospital admissions for respiratory causes for asthmatic individuals and the general population are estimated to occur with each change in the level of the standard from 0.09 ppm to 0.08 ppm to 0.07 ppm. However, hospital admissions for asthmatic individuals associated with ambient O<sub>3</sub> exposures within the range of standard levels under consideration represent a relatively small fraction of the total respiratory-related hospital admissions for asthmatics over the O<sub>3</sub> season.

(11) Estimated exposures to O<sub>3</sub> concentrations at and above 0.08 ppm (at which increased nonspecific bronchial responsiveness, decreased pulmonary defense mechanisms, and indicators of pulmonary inflammation have been observed in humans) while engaged in moderate exertion are essentially zero at the 0.07 ppm standard level (with a 1-expected-exceedance form) for the seven nonattainment areas evaluated in the exposure analyses for the at-risk population of outdoor children. Such exposures of outdoor children increase to approximately 0 to 1 percent at the 0.08 ppm standard level, while the estimated range at the 0.09 ppm standard level increases to approximately 3 to 7 percent of outdoor children for these areas.

(12) While recognizing that sensitive individuals may experience adverse but transient effects with a standard set at 0.08 ppm, no CASAC panel member supported selection of 0.07 ppm as the level of a primary standard. Of the members who expressed their personal views, three indicated a preference for a level of 0.08 ppm, one for a range of 0.08 to 0.09 ppm, three for a level of 0.09 ppm (with one of the three expressing a preference for selecting a form that would result in equivalent protection to the current standard), and one for a range of 0.09 to 0.10 ppm, associated with public advisories for O<sub>3</sub> levels at and above 0.07 ppm. Other CASAC panel members also expressed support for such public notices or advisories reflecting potential effects for extremely sensitive individuals associated with O<sub>3</sub> levels as low as 0.07 ppm.

These observations and conclusions resulted in the Administrator focusing in particular on the alternative levels of 0.08 ppm and 0.09 ppm, having placed great weight on the fact that none of the CASAC panel members expressed support for a standard set below 0.08 ppm. In deciding between these two levels, the Administrator took into account quantitative estimates of the risks associated with attaining standards set at these levels for those effects for which such quantitative risk estimates could be developed. Other factors that were important in the Administrator's proposed decision include:

(1) Quantitative estimates of 8-hour exposures of concern (i.e., at and above 0.08 ppm) associated with these standard levels.

(2) The consistency of the clinical, field, and epidemiological studies, in which effects were seen not only from controlled exposures to 0.08 ppm, but also in ambient environments in which 8-hour average O<sub>3</sub> concentrations ranged from above to below the 0.08 ppm level.

(3) The importance of increased protection for those sensitive individuals who may experience respiratory symptomatic and functional effects at lower O<sub>3</sub> concentrations than the population as a whole.

(4) The uncertainties in considering the potentially more serious but as yet uncertain chronic effects.

As discussed above in Unit II.A.3., EPA completed and made available for public comment supplemental exposure and risk assessments subsequent to the proposal. For any of the alternative standards considered in the assessment, the new estimates of exposures at and above 0.08 ppm are somewhat higher than those available at the time of proposal, while the new estimates of risks, for adverse effects including moderate and large decreases in lung function, moderate to severe respiratory symptoms, and hospital admissions for asthmatics, are lower. However, the relative differences in estimated exposures and risks between alternative standard levels remain about the same as at the time of proposal. Thus, while the Administrator's final decision takes into account the more recent assessments, the differences in the quantitative results between the initial and supplemental assessments do not fundamentally alter the basis for the judgments expressed at the time of proposal.

To aid in comparing the public health protection associated with 8-hour standards at the 0.08 ppm and 0.09 ppm levels, observations from the updated exposure and risk assessments for all nine urban areas evaluated are summarized below (assuming the third-highest concentration form, which was the upper end of the range of consideration for forms for the 0.09 ppm level).

(1) The percentages of outdoor children exposed to O<sub>3</sub> concentrations at and above 0.08 ppm (at which increased nonspecific bronchial responsiveness, decreased pulmonary defense mechanisms, and indicators of pulmonary inflammation have been observed in humans) while engaged in moderate exertion are estimated to be approximately 3 percent at the 0.08 ppm standard level, ranging from approximately 2 percent to 10 percent in the nine areas, increasing to approximately 11 percent at a standard level of 0.09 ppm, ranging from approximately 7 percent to 29 percent in the nine areas.

Updated risk estimates in terms of the percentages<sup>14</sup> and numbers of outdoor

children estimated to experience various health effects, and the total numbers of occurrences of these effects in outdoor children, upon attainment of these two alternative standards for all nine urban areas combined<sup>15</sup> are as follows:

(2) For moderate lung function (FEV<sub>1</sub>) decreases  $\geq 15$  percent, approximately 6 percent of outdoor children (180,000 children) would experience this effect one or more times per year (650,000 occurrences) at the 0.08 ppm standard level, increasing to approximately 8 percent of outdoor children (250,000 children and 1,100,000 occurrences) at the 0.09 ppm standard level.

(3) For large lung function (FEV<sub>1</sub>) decreases  $\geq 20$  percent, approximately 2 percent of outdoor children (58,000 children) would experience this effect one or more times per year (100,000 occurrences) at the 0.08 ppm standard level, increasing to approximately 3 percent of outdoor children (97,000 children and 220,000 occurrences) at the 0.09 ppm standard level.

(4) For moderate or severe pain on deep inspiration, approximately 0.9 percent of outdoor children (27,000 children) would experience this effect one or more times per year (120,000 occurrences) at the 0.08 ppm standard level, increasing to over 1 percent of outdoor children (41,000 children and 220,000 occurrences) at the 0.09 ppm standard level.

Many public commenters supported EPA's proposed level of 0.08 ppm for an 8-hour standard, including most public health associations and groups of medical professionals, many citizens, and some States and regional associations. There were also large numbers of commenters who expressed strong views in opposition to the proposed level. Of those who did not support the proposed 8-hour level, almost all commenters representing businesses and industry associations, many local governmental groups and private citizens, and some States either supported no change to the current standard or, if EPA were to replace the current 1-hour standard with an 8-hour standard, supported a level of 0.09 ppm directly or simply one that would be "equivalent" to the current standard. On the other hand, environmental groups, many citizens, and some medical professionals and researchers supported a level of 0.07 ppm for an 8-hour standard.

In general, the issues raised by these groups of commenters can be addressed in three categories: Comments on the strength and adequacy of the health effects evidence upon which the proposed decision was based, comments on the quantitative exposure and risk assessments and the extent to which the assessments either over- or under-predict exposures and risks among sensitive

populations, and judgments as to whether the differences in public health protection provided by alternative standards are significant from a public health perspective. Each of these categories of key issues is discussed separately below.

With regard to the first category of comments, on the strength and adequacy of the health effects evidence, commenters who did not support the need for any increased protection beyond that provided by the current standard questioned the adequacy or highlighted the limitations of the various types of health effects studies that have related O<sub>3</sub> exposures to adverse effects. For example, some commenters questioned the controlled human exposure studies, arguing that: Many such studies used patterns of exposures and exercise levels that are not representative of normal population exposures to ambient O<sub>3</sub>; some exposure chambers using artificially generated O<sub>3</sub> may have been contaminated with other pollutants that could have accounted for some of the observed effects; and responses to elevated O<sub>3</sub> levels were compared to responses to air with essentially no O<sub>3</sub> rather than to background levels typical of ambient air. Some commenters argued that these flaws in the study designs would result in overestimating responses to non-background levels of ambient O<sub>3</sub> or in erroneous findings of statistical significance. In contrast, others commented that because the chambers did not contain other pollutants and natural pulmonary irritants (e.g., pollens, dust) or a full range of environmental conditions (e.g., high temperatures and humidity) typical of ambient air, the results may underestimate the true impact of O<sub>3</sub> in the ambient air.

Some commenters also questioned the summer camp and other field studies and epidemiological studies reporting increased hospital admissions and emergency room visits, arguing that: The responses in these studies were inherently confounded by exposures to other pollutants, the camp studies did not differentiate activity levels of the participants, and linear regression down to or below background levels was unjustifiably used to analyze the results of the hospital admission studies. These commenters expressed the view that these and other flaws call into question any conclusions about whether the reported associations are causal. In contrast, other commenters argued that the hospital admissions reported in these studies are indicative of a pyramid of adverse health effects, including increased mortality, increased visits to emergency and outpatient departments and physicians, increased numbers of asthma attacks resulting in increased medication use, and increased numbers of restricted activity days and acute respiratory symptom days, that EPA has not adequately taken into account. The EPA notes that these comments are consistent with statistics published by the U.S. Department of Health and Human Services, which indicate

<sup>14</sup> These updated risk estimates in terms of the percentage of outdoor children in the nine urban areas are roughly comparable to the range of original estimates

presented in Table 1 of the proposal for 1- and 5-expected-exceedance forms of the standards.

<sup>15</sup> Approximately 3.1 million outdoor children reside in these nine urban areas.

that for every hospital admission of an individual with asthma for respiratory causes, there are more than five emergency and outpatient department visits and more than 20 office-based physician visits (U.S. DHHS, 1996).

With regard to studies related to pulmonary inflammation and chronic respiratory damage, some commenters argued that the linkage between repeated inflammatory responses and chronic respiratory damage was merely speculation, and, therefore, should not be considered as part of the basis for decisions on the primary standard. In contrast, others commented that animal studies had demonstrated that repeated pulmonary inflammation leads to degenerative or irreversible lung damage, that these studies are consistent with observations in human exposure studies, and, therefore, that they should be considered in decisions on the standard.

The EPA notes that many of these comments did not reflect an integrative assessment of the evidence—the approach CASAC has historically urged EPA to follow—but rather a piecemeal look at each individual study or type of study, which tends to miss the strength of the entire body of evidence taken together. Other commenters did consider the body of evidence in a more integrative manner, and many of these commenters expressed the view that the body of evidence as a whole provided clear evidence of O<sub>3</sub>-related effects at and below O<sub>3</sub> concentrations allowed by the current standard. Some commenters highlighted the large number of studies that demonstrate evidence of effects for prolonged exposures at and below 0.08 ppm, and criticized EPA for giving too little weight to those studies which reported serious effects, but for which the data were not sufficient to do quantitative risk assessments.

With regard to the second category of comments, on the exposure and risk assessments, a number of commenters raised concerns about key aspects of the assessments, including the exposure model, the development of concentration-response functions, the application of the risk model, and the measures of risk used to characterize the results of the assessments. With regard to the exposure model, a number of commenters claimed that: The model overestimates the exertion level that can be achieved by most children and outdoor workers and the fraction of time that these groups spend in moderate or heavy exertion; the model overestimates outdoor ambient exposures because fixed-site monitors overestimate outdoor personal exposures; and the air quality adjustment procedures used to simulate attainment of the standards are inappropriate or highly uncertain. Other commenters expressed concern that the exposure model may be significantly underestimating exposures for children and outdoor workers who repeatedly

exercise due to limitations in the available human activity pattern data.

As discussed in the proposal, EPA recognizes that the exposure model necessarily contains many sources of uncertainty, although every effort has been made to account for such uncertainties to the extent possible. In particular, the model incorporates and is sensitive to analytical procedures used to simulate spatial and temporal distributions of O<sub>3</sub> concentrations that would occur as a result of an area just attaining any of the alternative standards addressed in the exposure assessment. These air quality adjustment procedures are based on generalized models intended to reflect the patterns of changes in distributions of O<sub>3</sub> concentrations that have historically been observed in areas implementing control programs designed to attain the O<sub>3</sub> NAAQS. The EPA recognizes that future changes in air quality distributions are area-specific, and will be affected by whatever specific control strategies are implemented in the future to attain the revised NAAQS. Thus, generalized models are expected to be more uncertain for any given area than when exposure results are aggregated across many areas (as was done across the nine urban areas analyzed in EPA's exposure assessment).

Some commenters questioned the specific air quality adjustment procedure used in the initial and supplemental assessment<sup>16</sup>, and a few of these commenters recommended revisions or alternative procedures that they believed would be more representative of historical or projected future air quality patterns. As discussed in more detail in the Response to Comments, EPA acknowledges that both procedures used in the assessments result in projections of air quality that deviate to some degree from historical patterns of air quality changes observed in specific urban areas, and that other procedures may be more representative of air quality patterns in specific areas. While EPA will take these comments into account as future refinements are made to the air quality adjustment procedures used in the exposure model, EPA believes, and CASAC concurred, that the procedures used in the assessments conducted as part of this review are reasonable given the uncertainties inherent in projecting future changes in air quality patterns.

In commenting on the air quality adjustment procedure used in the supplemental assessment, some commenters particularly focused on the results for two of the nine areas analyzed in which, contrary to results from the initial assessment, lower risks

were estimated for the current standard as compared to the proposed standard. As discussed more fully in the Response to Comments, EPA believes that these results for each area cannot be distinguished within the sensitivity of the alternative air quality adjustment procedures used in the initial and supplemental assessments. Further, EPA notes that these two areas have much higher ratios of peak 1-hour to 8-hour O<sub>3</sub> concentrations than the vast majority of areas in which O<sub>3</sub> is monitored<sup>17</sup>, and it is thus reasonable to expect that generalized air quality adjustment procedures would be particularly uncertain for such areas.

Comments focusing on the development of concentration-response functions for use in the risk model have included a number of claims. Some commenters claimed that EPA inappropriately selected studies for developing the functions by excluding studies that reported lower response rates and by using only studies conducted by EPA scientists. Some commenters asserted that contaminants in the controlled exposure chambers may be responsible for some of the effects incorporated into the concentration-response functions for O<sub>3</sub>. Further, some commenters asserted that it was inappropriate to extrapolate the concentration-response functions to background levels or to develop concentration-response functions for symptomatic responses in children based on studies of such responses in adults.

Of the comments focusing on the application of the risk model, some commenters claimed that the aggregate risk results were overstated because of: Many of the methodological problems noted in the above summary of comments, the failure to take into account the known attenuation of effects, and the assumption of an inappropriately low background concentration in calculating risks attributable to non-background sources of O<sub>3</sub>. On the other hand, other commenters claimed that aggregate risk results were understated because of: Methodological problems, noted above, that underestimate exposures, limiting the analyses to only a subset of adverse health effects rather than estimating the full range of effects that have been attributed to O<sub>3</sub>, and by focusing only on nine urban areas rather than projecting risk reductions from alternative standards nationally.

While EPA has included comprehensive responses to these comments in the Response to Comments, most of the issues and concerns raised by commenters concerning the health effects evidence and the methods used in the exposure and risk assessments are essentially restatements of concerns raised during the review of the Criteria Document and the development and review of these quantitative assessments as part of the preparation and

<sup>16</sup> The initial risk assessment used both "Weibull" and "proportional" air quality adjustment procedures, whereas the supplemental risk assessment used a "proportional" air quality adjustment procedure for all nine urban areas. In responding to comments on the air quality adjustment procedures, EPA also evaluated an alternative "quadratic" procedure (as discussed in the Response to Comments), which generally resulted in risk estimates between those from the Weibull and proportional procedures.

<sup>17</sup> The two areas are Houston and parts of Los Angeles county, which are two of only six areas nationwide with peak 1- to 8-hour design value ratios greater than 1.5.

review of the Staff Paper. EPA presented and the CASAC reviewed in detail the approaches used to assess exposure and health risk, the studies and health effect categories selected for which concentration-response functions were estimated, and the presentation of the exposure and risk results summarized in the Staff Paper. As stated in the proposal, EPA believes and CASAC concurred, that the general models selected to estimate exposure and risk are appropriate and that the methods used to conduct the exposure and risk assessments represent the state of the art. EPA does not believe that the exposure or risk assessments are fundamentally biased in one direction or the other as claimed in some of the comments.

The Administrator and CASAC have recognized, however, that there are many uncertainties inherent in such assessments and that the resulting ranges of quantitative risk estimates do not reflect all of the uncertainties associated with the numerous assumptions inherent in such analyses (Wolff, 1995b). EPA summarized some of the most important caveats and limitations concerning both the exposure analyses and the risk assessments for lung function changes, respiratory symptoms, and hospital admissions in the proposal. A more complete discussion of assumptions and uncertainties is contained in the Staff Paper and technical support documents (Johnson et al., 1996 a,b; Whitfield et al., 1996; Richmond, 1997).

With regard to the third category of comments, reflecting commenters' judgments as to whether the differences in public health protection of alternative standards are significant from a public health perspective, EPA notes that highly divergent judgments were expressed by different groups of commenters. A large number of commenters who expressed the view that the differences in public health protection were not significant or important enough to warrant any standard more stringent than the current standard used CASAC as the basis for their position, as discussed above in Unit II.B.1. on averaging time. Others cited small percentages of outdoor children and other sensitive groups likely to be affected based on EPA's assessment, or even smaller percentages as modified by analyses conducted by the commenter to correct perceived errors in the analyses. In contrast, other commenters cited large total numbers of children likely to be affected, not only for the subset of O<sub>3</sub>-related effects and the nine areas analyzed in EPA's assessments, but also for a broader array of related effects projected nationally.

The core issue in this review of the primary O<sub>3</sub> standard, as stated by the Administrator at the time of proposal, is who is to be protected, and from what. Clearly, for pollutants, such as O<sub>3</sub>, that have no discernible thresholds for health effects, no standard can be risk-free. The Administrator's task is to select a standard level that will

reduce risks sufficiently to protect public health with an adequate margin of safety since a zero-risk standard is neither possible nor required by the Act. As CASAC and the Administrator recognize, the selection of a specific standard level for such pollutants requires public health policy judgments in addition to determinations of a strictly scientific nature.

In making such judgments, the Administrator rejects the notion that because standards cannot be risk-free they should not be revised to provide increased protection for sensitive populations, particularly including children in this case, when available evidence points to greater impacts on public health than had previously been demonstrated. In carefully reassessing both those risks to public health that can be quantified as well as those for which quantitative risk information is more limited, the Administrator has focused on the following comparisons between the degree of public health protection likely to be afforded by an 8-hour standard at the proposed level of 0.08 ppm and an alternative standard set at a level of 0.09 ppm (assuming the same third-highest concentration form):

(1) Based on EPA's updated analyses of estimated moderate or large decreases in lung function and moderate to severe pain on deep inspiration in outdoor children in nine urban areas (Richmond, 1997), a standard set at 0.09 ppm would allow approximately 40 percent to 65 percent more outdoor children to experience such effects than would a 0.08 ppm standard, and approximately 70 percent to 120 percent more occurrences of such effects in outdoor children per year.

(2) While only relatively small percentages of outdoor children are estimated to experience such effects, the differences in these percentages between the two standard levels represent tens of thousands more children, and hundreds of thousands more occurrences of adverse effects in these children, in these nine urban areas alone, for a 0.09 ppm standard as compared to a 0.08 ppm standard.

(3) Based on EPA's updated risk assessment of increased hospital admissions in New York City (Richmond, 1997), a standard set at 0.09 ppm would allow approximately 40 more excess hospital admissions of asthmatics within an O<sub>3</sub> season in New York City for respiratory causes as compared to a 0.08 ppm standard, which represents approximately a 40 percent increase in excess O<sub>3</sub>-related admissions, but only approximately a 0.3 percent increase in total admissions of asthmatics. The EPA believes that while these numbers of hospital admissions are relatively small from a public health perspective, they are indicative of a pyramid of much larger numbers of related O<sub>3</sub>-induced effects, including respiratory-related hospital admissions among the general population, emergency and outpatient department visits, doctors visits, and asthma

attacks and related increased use of medication that are important public health considerations.

(4) Based on EPA's exposure analyses in the nine urban areas, a standard set at 0.09 ppm would allow more than three times as many children to experience 8-hour average exposures of concern as would a 0.08 ppm standard, with the number of outdoor children likely to experience such exposures increasing from approximately 100,000 to more than 300,000 in the nine urban areas alone, representing an increase from approximately 3 percent to approximately 11 percent of the outdoor children likely to experience such exposures.

(5) These exposures of concern are judged by EPA to be an important indicator of the public health impacts of those O<sub>3</sub>-related effects for which information is too limited to develop quantitative estimates of risk, but which have been observed in humans at a level of 0.08 ppm for 6- to 8-hour exposures. Such effects include the following: increased nonspecific bronchial responsiveness (related, for example, to aggravation of asthma), decreased pulmonary defense mechanisms (suggestive of increased susceptibility to respiratory infection), and indicators of pulmonary inflammation (related to potential aggravation of chronic bronchitis or long-term damage to the lungs).

(6) To put these risks and exposures into broader perspective, EPA notes that approximately 46 million more people, including approximately 13 million more children and 3 million more individuals with asthma, live in areas that would not attain a 0.08 ppm standard compared to a 0.09 ppm standard. The general population as well as children and asthmatics would breathe cleaner air as a direct result of control measures designed to bring areas into attainment with the proposed standard.<sup>18</sup>

While recognizing the inherent uncertainties in these estimates, and after taking into account the range of views and judgments expressed in the public comments, the Administrator finds the public health impacts described in the proposal, as updated above, to be important and sufficiently large as to warrant a standard set at a level of 0.08 ppm, as proposed.

The Administrator recognizes the views of those who argue that similarly large improvements in public health protection would result from a standard set at 0.07 ppm as compared to the proposed standard, such that, based on the same reasoning, the evidence warrants a standard set at 0.07 ppm. In considering these views, the Administrator gives significant weight to the following considerations:

(1) No member of the CASAC panel of experts supported a standard set lower than

<sup>18</sup> The EPA anticipates that additional people would be protected through regional measures adopted for purposes of an 8-hour, 0.08 ppm standard.

0.08 ppm, specifically after considering a range of alternative standards that included 0.07 ppm.

(2) The most certain O<sub>3</sub>-related effects, while judged to be adverse, are transient and reversible (particularly at O<sub>3</sub> exposures below 0.08 ppm), and the more serious effects with greater immediate and potential long-term impacts on health are less certain, both as to the percentage of individuals exposed to various concentrations who are likely to experience such effects and as to the long-term medical significance of these effects.

(3) As many commenters have noted, based on information in the Criteria Document with regard to ambient concentrations of O<sub>3</sub> from background sources, an 8-hour standard set at a 0.07 ppm level would be closer to peak background levels that infrequently occur in some areas due to nonanthropogenic sources of O<sub>3</sub> precursors, and thus more likely to be inappropriately targeted in some areas on such sources.

After taking into account the public comments, and for the reasons outlined above, the Administrator finds that a standard set at a level of 0.07 ppm is not requisite to protect public health with an adequate margin of safety.

3. *Form.* The form of the current 1-hour, 0.12 ppm standard is a "1-expected-exceedance" form. That is, the current standard is based on the expected<sup>19</sup> number of days per year, on average over 3 years, on which the level of the standard is exceeded, and limits that number of expected exceedances to be less than or equal to 1.0.

In evaluating alternative forms for the primary standard, the adequacy of the public health protection provided was the Administrator's foremost consideration. The Administrator also recognized, however, that concerns have been raised with the current form since it was promulgated in 1979 due to the inherent lack of year-to-year stability in the measure of air quality on which the 1-expected-exceedance form is based.<sup>20</sup> The CASAC specifically took such concerns into account in recommending that the current form be revised and in noting that a more robust, concentration-based form would minimize such instability and provide some insulation from the impacts of extreme meteorological events that are conducive to O<sub>3</sub> formation (Wolff, 1995b). Such instability can have the effect of reducing public health protection by disrupting ongoing implementation plans and associated control programs.

As discussed in the proposal, based on information presented in sections IV. and V.I

<sup>19</sup> The term "expected" means that the numbers of exceedances per year are averaged over 3 years and may be calculated using specific adjustments to account for missing data.

<sup>20</sup> The 1-expected-exceedance form essentially requires the fourth-highest air quality value in 3 years, based on adjustments for missing data, to be less than or equal to the level of the standard for the standard to be met at an air quality monitoring site.

of the Staff Paper and the advice of CASAC, the Administrator focused her consideration on the following alternatives:

(1) Revising the current 1-expected-exceedance form of the standard to allow for multiple (up to five) expected exceedances per year, averaged over 3 years. A multiple-exceedance form would be based on a less extreme air quality statistic and, thus, would increase the stability of the expected-exceedance form.

(2) Adopting a concentration-based statistic, such as the 3-year average of the nth-highest daily maximum 8-hour average O<sub>3</sub> concentration, as an alternative to an expected exceedance statistic. Air quality analyses presented in the Staff Paper indicate that the 3-year averages of the annual third-, fourth-, and fifth-highest daily maximum 8-hour concentrations would provide approximately the same health protection as the 3-, 4-, and 5-expected-exceedance forms averaged over the same period, respectively.

It was the consensus of the CASAC Panel that this range of allowable exceedances (i.e., up to 5 exceedances), and the consideration of comparable concentration-based forms, was appropriate. Further, CASAC acknowledged that selecting from within this range of alternative forms is a policy judgment, especially given the nature of the health effects and the absence of a "bright line" that clearly differentiates between acceptable and unacceptable risks within this range. All 10 CASAC Panel members who expressed specific opinions on the form of the standard favored one that would allow for multiple exceedances (Wolff, 1995b).

In reaching her proposed decision on the form of an 8-hour standard set at 0.08 ppm, the Administrator had to choose a specific form within the range of up to 5 allowable exceedances or up to the comparable fifth-highest concentration, and either an exceedance-based or a concentration-based form. As discussed in the proposal, in considering possible forms within the range of 1 to 5 exceedances (or their concentration-based counterparts) the Administrator took into consideration aggregate risk estimates for those health effects for which quantitative risk analyses have been done; estimated exposures associated with those effects for which no quantitative risk estimates could be developed; and the magnitude of peak measurements of 8-hour average O<sub>3</sub> concentrations, and the number of days on which the level of the standard would likely be exceeded, based on an analysis of historical air quality data (Freas, 1996). In considering exposure and risk estimates available at the time of proposal for 1- and 5-expected-exceedance forms, the Administrator noted that the level of the standard is a more dominant factor in determining the degree of exposure and risk reductions achieved, with the form being associated with smaller differences in risk estimates within a continuum of risk. In

considering air quality comparisons for standards across the range of forms considered, the Administrator focused in particular on the extent to which alternative forms would limit the number of days in which the level of the standard would be exceeded in areas that just attain the standard<sup>21</sup>, and the magnitude of peak 8-hour average O<sub>3</sub> concentrations<sup>22</sup> that would occur in such areas.<sup>23</sup> More specifically, the Administrator took into consideration the percentage of monitoring sites just attaining an 8-hour, 0.08 ppm standard that would have 8-hour peak O<sub>3</sub> concentrations above a benchmark level of 0.09 ppm. This benchmark level is the upper end of the range of levels endorsed by CASAC for an 8-hour O<sub>3</sub> standard. The Administrator believes, given the uncertainties associated with this kind of complex health decision, that it is an appropriate goal to limit the percentages of areas experiencing such daily peaks.

In choosing to propose a concentration-based form, the Administrator recognized the advantages of a concentration-based form over an exceedance-based form. As discussed in the proposal, the principal advantage of a concentration-based form is that it is more directly related to the ambient O<sub>3</sub> concentrations that are associated with health effects. That is, given that there is a continuum of effects associated with exposures to varying levels of O<sub>3</sub>, the extent to which public health is affected by exposure to ambient O<sub>3</sub> is related to the actual magnitude of the O<sub>3</sub> concentration, not just whether the concentration is above a specified level. With an exceedance-based form, days on which the ambient O<sub>3</sub> concentration is well above the level of the standard are given equal weight to those days on which the O<sub>3</sub> concentration is just above the standard (i.e., each day is counted as 1 exceedance), even though the public health impact on the two days is significantly different. With a concentration-based form, days on which higher O<sub>3</sub> concentrations occur would weigh proportionally more than days with lower O<sub>3</sub> concentrations, since the actual concentrations

<sup>21</sup> Areas that "just attain the standard" are defined as those whose design value falls between 0.075 and 0.084 ppm.

<sup>22</sup> Peak 8-hour average concentrations are defined in terms of the fourth-highest daily maximum concentration in 3 years (i.e., the design value for the current 1-expected-exceedance form of the standard).

<sup>23</sup> The results of these air quality analyses are presented in Freas (1996) and summarized in the proposal for the third- and fifth-highest concentration forms and the 3- and 5-expected-exceedance forms. Based on these considerations, and the air quality comparisons in particular, the Administrator judged that the middle of the range of exceedances considered, three expected exceedances, or the comparable third-highest concentration, represented a reasonable policy choice, and proposed the 3-year average of the annual third-highest daily maximum 8-hour average O<sub>3</sub> concentrations as the form of the standard. In recognition of a range of views on the degree of health protection that would be appropriate, she also solicited comment on other concentration-based forms, including the second-, fourth-, and fifth-highest concentration forms.

are used directly in determining whether the standard is attained. A concentration-based form also has greater temporal stability than the expected-exceedance form and, thus, would facilitate the development of more stable implementation programs by the States.

As discussed above in Units II.A.3. and II.B.2., EPA completed and made available for public comment supplemental exposure and risk assessments subsequent to the proposal. These updated assessments, which specifically analyzed the third- and fifth-highest concentration-based forms, aid in comparing the differences in public health protection among alternative concentration-based forms within the range considered in the proposal for 8-hour, 0.08 ppm standards. Based on these updated assessments, the Administrator again notes that the level of the standard is the more dominant factor in determining the degree of risk reduction achieved, with these alternative forms being associated with much smaller differences in risk estimates within a continuum of risk. For example, within the nine urban areas included in the risk assessment, approximately 180,000 outdoor children would experience moderate lung function ( $FEV_1$ ) decreases  $\geq 15$  percent upon attainment of an 8-hour, 0.08 ppm standard with a third-highest concentration form, compared to approximately 200,000 outdoor children with a fourth-highest concentration form and 220,000 outdoor children with a fifth-highest concentration form.

The public comments include a large number that specifically addressed the form of the standard. Those commenters who expressed views on the form of the standard can be divided into three groups, according to the level of 8-hour standard and the relative degree of public health protection that the commenter supported. These groups include: Commenters who supported an 8-hour, 0.08 ppm standard to provide increased public health protection relative to the current standard; commenters who supported either an 8-hour, 0.09 ppm standard, or simply an 8-hour standard "equivalent" to the current standard; and commenters who supported an 8-hour, 0.07 ppm standard to provide a greater margin of safety than that afforded by the proposed standard.

The first group included many private citizens, some medical professionals and researchers, and some States and local governmental groups. While a number of commenters in the first group specifically supported the proposed third-highest concentration form, generally for the reasons presented in the proposal, others supported either a 1-expected-exceedance form or a concentration-based form in the upper part of the range (i.e., the fourth- or fifth-highest forms). The second group of commenters, which included many local governmental groups and private citizens, some States, and most commenters representing businesses and industry associations, almost exclusively

supported a concentration-based form in general, and a form in the upper part of the range (or above the range) in particular. In sharp contrast, the third group of commenters, which included environmental groups, many private citizens, and some medical professionals and researchers, almost exclusively supported a 1-expected-exceedance form in conjunction with an 8-hour, 0.07 ppm standard to provide the largest margin of safety within the range of alternative standards considered.

To the extent that the second and third groups of commenters argued for a different level than the Agency adopts today, the Administrator disagrees with their comments for the reasons set forth in the discussion of the standard level above in Unit II.B.2. To the extent that they argued for more than 5 exceedances (or the concentration-based equivalent), the Administrator disagrees with their views because such forms fall outside the range recommended by CASAC and would provide less public health protection than she deems appropriate. To the extent that the second and third groups of commenters addressed the merits of particular forms within the range of forms considered in the proposal, they raised points similar to those raised by commenters in the first group. These points are discussed below.

Among the commenters in the first group (i.e., those supporting an 8-hour, 0.08 ppm standard to provide increased public health protection), many felt that there was no compelling basis for selecting the third-highest rather than the fourth- or fifth-highest concentration-based form. These commenters frequently quoted CASAC's closure letter (Wolff, 1995b) as stating "that there is no bright line" which distinguishes any of the proposed standards (either the level or the number of exceedances) as being significantly more protective of public health," and that "the selection of a specific level and number of allowable exceedances is a policy judgment." In general, these commenters did not give weight to the air quality comparisons that were a major consideration in the Administrator's decision to propose the third-highest concentration form. Some commenters seem to view such air quality comparisons, particularly with regard to pollutants such as  $O_3$  that have no discernible threshold of effects, as relating more to people's perceptions of how well air pollution is controlled than to any objective measure of actual risks to public health.

These commenters made a number of points in questioning the need to specify an 8-hour, 0.08 ppm standard in terms of the third-highest rather than the fourth- or fifth-highest concentration form. Many noted that a change to an 8-hour averaging time in and of itself would appropriately focus air quality management programs on prolonged exposures of most concern. Further, many noted that a level of 0.08 ppm, regardless of the form within the range of forms considered

in the proposal, would provide significantly increased protection from  $O_3$ -related risks to public health associated with acute effects (i.e., those resulting from short-term and prolonged exposures) for which they believe there is sufficient evidence to be used as a basis for a standard at this time. Some of these commenters expressed the view that the potential for chronic effects (i.e., those resulting from long-term exposures) would be better addressed through continued research, rather than by adding a greater margin of safety to a revised standard based primarily on effects of short-term and prolonged exposures. Many of these commenters recognized, as did EPA in the proposal, that there is a continuum of risks associated with  $O_3$  exposures, that no standard can therefore be risk-free, and that there are large uncertainties in any estimates of the degree of protection associated with alternative forms. In general, these commenters also noted that, for the same reasons, CASAC advised that the selection of a form from within the range considered in the proposal was a policy judgment, not one that could be decided on the basis of science alone. In essence, these commenters argued that a more restrictive form than the upper part of the range endorsed by CASAC is not requisite to protect public health.

In contrast, other commenters in the first group (i.e., those supporting an 8-hour, 0.08 ppm standard) supported either the proposed third-highest or second-highest concentration form or a 1-expected-exceedance form. These commenters generally gave greater weight to limiting the magnitude of peak  $O_3$  concentrations and the number of days on which the standard level would be exceeded in areas meeting such a standard, and, in some cases, to providing a greater margin of safety to account for potential chronic effects. Such views suggest that limiting the number of days on which the standard level would be exceeded, for example, is an important factor in risk communication and in the public's understanding of the degree to which a standard protects people from exposures to  $O_3$  that may interfere with their ability to engage in normal activities or may result in the need for increased medication or medical treatment, especially for those individuals with asthma or other respiratory diseases. As discussed above in this unit, although some of these commenters felt that the third-highest concentration form would protect public health while also providing increased stability, others expressed concern that public health could be compromised by any form that allowed for multiple exceedances of the standard. The advantages of forms that allow for multiple exceedances, thus providing increased stability as discussed in the proposal, and the views of the CASAC panel members who expressed opinions, all of whom favored such forms, were not given

weight by commenters within this group who supported a 1-expected-exceedance form.

The Administrator has carefully reassessed the relative risks to public health of specific forms within the range of the second- to fifth-highest concentration forms or their exceedance-based equivalents, taking into account the public comments summarized above, and the advice from CASAC Panel members that the current form be replaced by a form that allows multiple exceedances. In doing so, the Administrator focused on the following considerations:

(1) The CASAC advised that concentration-based forms, within the range considered up to the fifth-highest concentration form, are appropriate for a health-based primary O<sub>3</sub> standard, and that selection from within this range is a policy judgment that cannot be based on science alone. This advice reflects CASAC's recognition that O<sub>3</sub> exhibits a continuum of effects, such that there is no discernible threshold above which public health protection requires that no exposures be allowed or below which all risks to public health can be avoided. The CASAC also recognized that a concentration-based form would increase the stability of the standard by providing some insulation from the impacts of extreme meteorological events (Wolff, 1995b).

(2) Estimates of the differences in risk to public health, for those effects that could be considered quantitatively, within a range of alternative forms from the second- to fifth-highest concentrations (for an 8-hour, 0.08 ppm standard) are relatively small compared to the differences between alternative levels. In other words, the choice of level is substantially more important to the degree of public health protection afforded by the standard than the choice of form from within this range of forms.

(3) Measures that distinguish between the alternatives within the range of the second- to fifth-highest forms, based on air quality analyses, reflect considerations related to how some individuals understand the degree to which an air quality standard protects public health. These considerations are a distinct aspect of risk communication to individual citizens even though the days on which exceedances occur are accounted for in EPA's quantitative assessments of risks to public health.

(4) To assess the comparative effect of all forms within the range of the second- to fifth-highest concentration forms, EPA considered air quality comparisons for all such forms (Freas, 1996). These comparisons (based on 1993 to 1995 data) show that 8-hour, 0.08 ppm second- and third-highest concentration standards are very similar in that each standard limits the percent of monitoring sites that would experience peak days above the benchmark level of 0.09 ppm to 1 percent of such sites, and the number of days on which the standards would likely be exceeded in the

worst of 3 years would be no more than 6 and 7, respectively. While less restrictive than either of these standards, an 8-hour, 0.08 ppm fourth-highest concentration standard would be significantly more restrictive than a fifth-highest standard. For example, the 8-hour, 0.08 ppm fourth-highest concentration standard would limit the percent of monitoring sites that would experience peak days about the benchmark level of 0.09 ppm to 8 percent of such sites, and the number of days on which the standards would likely be exceeded in the worst of 3 years would be no more than nine. In comparison, the fifth-highest concentration standard would limit the percent of monitoring sites that would experience peak days about the benchmark level of 0.09 ppm to 17 percent of such sites, and the number of days on which the standards would likely be exceeded in the worst of 3 years would be no more than 11.

(5) The extent to which the alternatives within the range of the second- to fifth-highest concentration forms provide protection against the more serious, but less certain effects that have been associated with exposure to O<sub>3</sub>, including potential chronic effects, cannot be quantitatively assessed at this time. Given that all such forms would result in significant reductions in exposures to O<sub>3</sub> at and above 0.08 ppm (the level where suggestive evidence of such effects is available), any form within this range would provide some margin of safety against these effects.

Based on these considerations, the available health effects evidence, the quantitative assessments contained in the Criteria Document, Staff Paper, and supplemental analyses and supporting documents, and the range of views and judgments expressed in the public comments on the appropriate form, the Administrator has reconsidered the form of the standard that is requisite to protect public health with an adequate margin of safety. As an initial matter, the Administrator has decided to adopt a concentration-based form which allows for more than one exceedance. While the Administrator understands the views of the many citizens who are concerned about a standard that would allow for multiple days on which the level of the standard may be exceeded, the Administrator concludes that such concerns are more relevant for pollutants that exhibit a clear threshold of effects than for pollutants such as O<sub>3</sub> that exhibit a continuum of effects. The Administrator believes that the public health risks associated with such pollutants can be appropriately addressed through a standard that allows for multiple exceedances to provide increased stability, but that also significantly limits both the number of days on which the level may be exceeded and the magnitude of such exceedances. This approach recognizes that exposures associated with such exceedances are already reflected in the exposure and risk assessments that were an important

consideration in selecting a 0.08 ppm level for the primary O<sub>3</sub> standard, and that increased stability in the standard is important to avoid disruption to ongoing control programs, and thus to maintain ongoing public health protection.

Having again concluded that a concentration-based O<sub>3</sub> standard that allows for multiple exceedances is appropriate, the Administrator considered the extent to which the form of an 8-hour standard should be selected so as to provide a margin of safety against possible, but uncertain chronic effects. The Administrator carefully considered the views of the many commenters who emphasized the uncertainties in the evidence, primarily from laboratory animal studies, that was available in this review of the criteria and standards to relate long-term exposures to ambient levels of O<sub>3</sub> to possible chronic effects in humans. These commenters, as did CASAC, advised that further research into potential chronic effects in humans should be continued, and the results considered in the next review of the O<sub>3</sub> standard. The Administrator is persuaded that the difference between the margins of safety for these potential chronic effects afforded by the alternatives within the range of the second- to fifth-highest concentration forms is not well enough understood at this time to use as the basis for choosing the most restrictive forms (i.e., the second- or third-highest concentration form). On the other hand, the Administrator also judges that the relatively large percentage of sites that would experience O<sub>3</sub> peaks above a benchmark level of 0.09 ppm even when attaining a fifth-highest concentration standard and the number of days on which the level of a fifth-highest concentration standard may be exceeded argue against choosing that form, which is the least restrictive within the range considered.

For the reasons outlined above, and taking into account the range of views in the public comments, the Administrator concludes that an intermediate form, the fourth-highest concentration form, would serve to appropriately balance these public health considerations in conjunction with the 8-hour averaging time and 0.08 ppm level selected, as discussed above in Units II.B.1. and II.B.2., that are of primary importance in determining the degree of public health protection afforded by the standard. In addition, the Administrator notes that based on an analysis of air quality in counties that would attain an 8-hour, 0.08 ppm fourth-highest concentration standard (based on 1993-1995 data), over 99 percent of such counties would be expected to have four or fewer days on which the level of the standard is exceeded in an average year (Freas, 1997). This number of exceedances is clearly within the range of multiple exceedances that CASAC judged to be appropriate for a health-based primary O<sub>3</sub> standard. Thus, in the Administrator's judgment, based on the

information currently available, an 8-hour, 0.08 ppm standard with a fourth-highest concentration form will protect public health with an adequate margin of safety.

In the proposal, which maintained the current approach of using air quality data from the monitor measuring the highest O<sub>3</sub> concentrations in an area to determine whether the primary standard for O<sub>3</sub> is attained, the Administrator solicited comment on the alternative of using some form of averaging across monitors. As discussed in the proposal, EPA recognized that during the review of the Staff Paper, a number of commenters suggested that averaging across monitors might be appropriate to increase the degree to which monitoring data used in determining attainment of the standard reflects population exposure and aggregate population health risk. Further, these commenters suggested that averaging data from multiple monitors in an area would produce a more stable measure of air quality and would take into account broader population exposure patterns across an area than would the current approach of considering data from each monitor independently.

The Administrator did not propose the use of spatial averaging because of concerns outlined in the proposal including: The difficulty in determining an appropriate level for a spatially averaged primary standard given that the bulk of the human health effects evidence supporting a decision on an appropriate O<sub>3</sub> standard is based on controlled human exposure studies that relate known O<sub>3</sub> exposures directly to responses in individuals; and questions as to whether adequate health protection would be provided to individuals within the populations that live or work in communities that routinely experience higher O<sub>3</sub> concentrations within a broad metropolitan area.

To address these two concerns, it would be necessary to define criteria for geographic locations or communities (e.g., spatial averaging zones) within which the use of spatially averaged O<sub>3</sub> data would be acceptable. Such criteria would be important since O<sub>3</sub> air quality concentrations can vary significantly across most urban areas. The lowest concentrations typically occur in the urban center and in locations near O<sub>3</sub> precursor sources, mid-range concentrations in neighborhoods and locations surrounding the urban center, and peak concentrations are typically measured downwind along the outermost suburban regions of the urban area. Also, the location of residences, schools, parks, and other places where individuals might be exposed more frequently to ambient O<sub>3</sub> concentrations of concern would be an important consideration. Unless the O<sub>3</sub> concentration gradients within each spatial averaging zone were relatively homogeneous, there may be significant numbers of sensitive individuals exposed to high O<sub>3</sub> concentrations

in areas where the spatial average indicates that the overall air quality is acceptable.

In the proposal, EPA also noted the need to help State and local governments devise different O<sub>3</sub> monitoring networks by revising relevant regulations and guidance, should spatial averaging be adopted. This would likely involve defining general criteria for monitoring network design, siting, and spatial averaging zones in nationally implementable terms, with case-by-case evaluation of each monitoring network. The EPA recognized that this activity would place additional burdens on State and local air quality management districts.

In soliciting comment on whether it would be desirable to adopt some form of spatial air quality averaging for O<sub>3</sub>, the Administrator also solicited comment on specific alternative approaches that could be used to address the issues of concern. In particular, the Administrator was interested in analyses that inform questions about monitoring network design, siting requirements, and approaches for specification of spatial averaging zones; the distribution of public health protection that would result from such alternative approaches; and the extent to which the level of the standard would need to be adjusted, if any, to provide public health protection consistent with the level of protection contemplated in the proposal.

The EPA received many comments on the subject of using spatially averaged data to determine when the primary standard for O<sub>3</sub> is attained. Commenters from business and industry associations frequently supported the use of spatially averaged data, as did many local governments and a small number of States, principally because it would provide a more stable air quality indicator and would better represent population exposure and risk. Some of these commenters felt that the use of spatial averaging would be consistent with the use of risk assessment as a policy tool for standard setting. Many of these commenters agreed that the heterogeneity of O<sub>3</sub> concentrations across geographic areas would need to be addressed by network design, with a few expressing the opinion that this would not be an insurmountable problem given that there is continual movement of monitors within existing networks. Some commenters suggested averaging approaches that included the use of population weighting of monitored data, and some supported the use of a public health information system to allow individuals residing in "hot spot" areas to reduce their exposures to O<sub>3</sub> concentrations of concern.

In contrast, environmental associations, public health professionals, most States, and many individuals voiced strong concerns that the use of spatially averaged data would routinely allow individuals who live or work in communities with consistently higher O<sub>3</sub> levels than those occurring across the broader urban area to be exposed to concentrations of concern. Many of these commenters raised

the issue of environmental equity, expressing the view that communities with consistently higher O<sub>3</sub> concentrations typically are composed predominantly of individuals of lower socioeconomic status, or are composed of a predominantly minority population. The EPA notes that this view is not consistent with the air quality data discussed earlier in this unit, in that O<sub>3</sub> concentrations are typically lower in urban centers than in locations surrounding or downwind of urban centers. Some commenters also raised concerns about the complexity and burdens associated with redesigning existing monitoring networks.

Taking into account the comments received, the Administrator does not find that the issues of concern, as outlined in the proposal and above, have been adequately addressed in this review of the O<sub>3</sub> standard. In particular, while EPA strongly agrees with the importance of public health advisories in addition to adequately protective standards, relying on the use of public health advisories to provide information for at-risk populations who may consistently be exposed to localized O<sub>3</sub> concentrations of concern is considered by the Administrator to be an insufficient approach to protecting public health with an adequate margin of safety. Further, the suggested use of population weighting of monitored data may, in many cases, be insufficiently sensitive to local O<sub>3</sub> variations to ensure adequate protection of these populations from localized O<sub>3</sub> concentrations. Thus, the revised O<sub>3</sub> standard will maintain the current approach of using air quality data from the monitor measuring the highest O<sub>3</sub> concentrations in an area to determine whether the standard is attained within an area.

The EPA has also considered spatial averaging in the context of the decision to revise the PM NAAQS, in part, by adopting a form of an annual standard for fine particles (i.e., PM<sub>2.5</sub>) that allows for spatial averaging within appropriate criteria. It is important to note that different considerations apply in these two cases. One principal difference is the nature of the health effects evidence for O<sub>3</sub> and PM<sub>2.5</sub>. When considering averaging approaches for O<sub>3</sub>, it should be recognized that much of the human health effects evidence supporting the O<sub>3</sub> standard is based on controlled human exposure studies that relate individual O<sub>3</sub> exposures directly to responses in individuals, whereas the health effects evidence supporting the PM<sub>2.5</sub> standards is from epidemiological studies relating community measures of PM<sub>2.5</sub> concentrations to population-wide responses. Thus, information available for determining an appropriate level of a standard in these two cases is predominantly individual-oriented in the case of O<sub>3</sub> and community-oriented in the case of PM<sub>2.5</sub>. As a consequence, additional research and exposure and risk assessments beyond those available in this review would be necessary to provide a basis for further

consideration of a spatially averaged standard for O<sub>3</sub>. The EPA will continue to explore this approach.

Another important difference between the O<sub>3</sub> and PM standards is that the suite of annual and 24-hour PM<sub>2.5</sub> standards permits the use of the 24-hour PM<sub>2.5</sub> standard, which would not be spatially averaged, as a backstop to control localized "hot spots," whereas a single O<sub>3</sub> standard does not allow for such a dual approach. Also, EPA notes that the existence of an established, extensive O<sub>3</sub> monitoring network would require substantial redesigning and relocation of monitors for the purpose of spatial averaging, in contrast to the current absence of such a network for PM<sub>2.5</sub> which can be newly designed to address community-oriented monitoring from the outset.

As discussed in the proposal, the Administrator recognizes that no standard within the range of levels and forms considered in this review, including the selected standard, is risk free, due to the continuum of risk likely posed by exposures to ambient O<sub>3</sub> potentially down to background levels. Accordingly, consistent with CASAC advice, the Administrator solicited comment in the proposal on elements of an enhanced public health advisory system. The Administrator believes that the information that could be made available through such a public health advisory system would be particularly useful to extremely sensitive individuals in making personal decisions about avoiding exposures with the potential to cause transient adverse effects on days when 8-hour average O<sub>3</sub> concentrations are predicted to be at or near the level of the standard. Approaches to developing an enhanced system, and comments received on such approaches, are discussed in Unit II.C. of this preamble.

4. *Final decision on the primary standard.* After carefully considering the information presented in the Criteria Document and the Staff Paper, the advice and recommendations of CASAC, public comments received on the proposal, and for the reasons discussed above, the Administrator is replacing the existing 1-hour, 0.12 ppm primary standard with a new 8-hour, 0.08 ppm primary standard. The new 8-hour standard will become effective September 16, 1997.

The 8-hour, 0.08 ppm primary standard will be met at an ambient air quality monitoring site when the 3-year average of the annual fourth-highest daily maximum 8-hour average O<sub>3</sub> concentration is less than or equal to 0.08 ppm. Data handling conventions are specified in a new Appendix I to 40 CFR part 50 as discussed in Unit VI below.

In the proposal, EPA proposed that the revocation of the existing 1-hour O<sub>3</sub> standard be delayed for certain purposes until EPA had approved State Implementation Plans to implement the new 8-hour O<sub>3</sub> standard. EPA had proposed continuing the applicability of the 1-hour standard in this way in order to

facilitate continuity in public health protection during the transition to a new standard. (See Memorandum from John S. Seitz to Mary D. Nichols, November 20, 1996; Docket No. A-95-58, item II-B-3.) Also, at the time of the proposal of the new O<sub>3</sub> standard, EPA had proposed an interpretation of the Act in the proposed Interim Implementation Policy (61 FR 65764, December 13, 1996) under which the provisions of subpart 2 of part D of Title I of the Act would not apply to existing O<sub>3</sub> nonattainment areas once a new O<sub>3</sub> standard becomes effective.

In light of comments received regarding the interpretation proposed in the Interim Implementation Policy, EPA has reconsidered that interpretation and now believes that the Act should be interpreted such that the provisions of subpart 2 continue to apply to O<sub>3</sub> nonattainment areas for purposes of achieving attainment of the current 1-hour standard. As a consequence, the provisions of subpart 2, which govern implementation of the 1-hour O<sub>3</sub> standard in O<sub>3</sub> nonattainment areas, will continue to apply as a matter of law for so long as an area is not attaining the 1-hour standard. Once an area attains that standard, however, the purpose of the provisions of subpart 2 will have been achieved and those provisions will no longer apply. However, the provisions of subpart 1 of part D of Title I of the Act would apply to the implementation of the new 8-hour O<sub>3</sub> standards.

To facilitate the implementation of those provisions and to ensure a smooth transition to the implementation of the new 8-hour standard, the 1-hour standard should remain applicable to areas that are not attaining the 1-hour standard. Therefore, the 1-hour standard will remain applicable to an area until EPA determines that it has attained the 1-hour standard, at which point the 1-hour standard will no longer apply to that area.

#### C. Communication of Public Health Information

Information on the public health implications of ambient concentrations of criteria pollutants is currently made available primarily through two EPA programs. The first program is designed to prevent ambient pollutant concentrations from reaching the significant harm level (i.e., an exposure level that constitutes an imminent and substantial endangerment to public health). The second program is the Pollutant Standards Index (PSI),<sup>24</sup> which is a health advisory system. The proposal focused on the potentially expanded use of the PSI in regard to allowing sensitive individuals to reduce their risk of exposure. Currently, EPA and local officials use the PSI as a public information tool to advise the public about the general health effects associated with different pollution levels and to describe whatever precautionary

steps may need to be taken if air pollution levels rise into the unhealthful range. By notifying the public when a PSI value exceeds 100 (which corresponds to the NAAQS for each criteria pollutant)<sup>25</sup>, citizens are given the opportunity to take appropriate steps to avoid exposures of concern. This use of the PSI could be expanded to provide more specific health information for O<sub>3</sub> concentrations close to the level of the primary standard. Given the continuum of risks associated with exposure to O<sub>3</sub>, this information, while perhaps of interest to all citizens, would be particularly useful to those individuals who are extremely sensitive to relatively low O<sub>3</sub> concentrations. As an example, the proposal mentioned the possibility of expanding the PSI to include two new descriptive categories in the Index, one including concentrations within a range somewhat below the level of the new primary standard (with a possible descriptor of "moderately good"), the other including concentrations within a range somewhat above the level of the standard (with a possible descriptor of "moderately unhealthful"). Such an approach could better reflect the increased understanding of health effects associated with O<sub>3</sub> exposure developed during this review, and would be consistent with the recommendation of a number of CASAC panel members "that an expanded air pollution warning system be initiated so that sensitive individuals can take appropriate 'exposure avoidance' behavior" (Wolff, 1995b).

The proposal also discussed the use of forecasting in combination with this expanded use of the PSI. For a health advisory system to be effective, citizens need to be notified as early as possible to be able to avoid exposures of concern. The notice indicated that if the current 1-hour primary NAAQS for O<sub>3</sub> is replaced with an 8-hour standard, there would clearly be increased value in using forecasted O<sub>3</sub> concentrations in providing cautionary statements to the public. Currently, when a health advisory indicates that the 1-hour O<sub>3</sub> PSI value of 100 has been exceeded, citizens generally have time to avoid exposures of concern because O<sub>3</sub> levels tend to remain elevated for several hours during the day. With the new 8-hour standard, however, this would likely not be the case, since by the time a PSI value is reported, the potential for prolonged exposures of concern would likely have passed for that day. Forecasting 8-hour maximum O<sub>3</sub> concentrations would facilitate the risk-reduction function of the PSI by giving citizens more time to limit or avoid exposures of concern.

The EPA did not formally propose revisions to the PSI in the proposal. Instead, the Administrator requested comment, and

<sup>25</sup> Currently, a PSI value of 100 for O<sub>3</sub> corresponds to an ambient concentration of 0.12 ppm, averaged over 1 hour.

<sup>24</sup> For a discussion of these programs, see the proposal.

indicated that the Agency might propose revisions to the PSI in conjunction with future proposals associated with the implementation of a revised NAAQS.

The EPA received a large number of comments from a wide variety of commenters on the usefulness of both an expanded health advisory system and the forecasting of 8-hour ambient O<sub>3</sub> concentrations. Commenters representing State and local agencies, business and industry associations, as well as environmental associations overwhelmingly endorsed the use of an expanded public health advisory system and many noted the importance of forecasting 8-hour O<sub>3</sub> concentrations in conjunction with the PSI, while recognizing a number of issues that would need to be addressed.

Comments from environmental associations endorsed increasing the specificity of warnings with regard to the health effects that could occur as a result of exposure, and noted that citizens are capable of dealing with complex information. These commenters also took exception to describing O<sub>3</sub> levels around the level of the standard that have been shown to result in decreased lung function and increased respiratory symptoms, as "moderately good," stating that this descriptor is misleading and might not be heeded by people who could, if they fully understood the nature of the health risk, take action to minimize their exposures. Other commenters felt that the descriptors "moderately good" and "moderately unhealthful" were unnecessarily confusing.

Industry commenters were uniformly supportive of enhancing the risk reduction function of the PSI by issuing health advisories with specific health information at and above the level of the standard. Several industry commenters also recommended that the function of the PSI be combined with the function of an O<sub>3</sub> action system, which would recommend voluntary actions to reduce ambient O<sub>3</sub> concentrations when the level of the standard is forecasted to be exceeded. This would result in a system that not only could provide accurate health effects information specific to the members of the population likely to experience effects, but also could help prevent exposures to levels of O<sub>3</sub> at or above the level of the standard.

Commenters from State and local air pollution control authorities strongly endorsed expanding the use of the PSI and the utilization of forecasted 8-hour O<sub>3</sub> concentrations. These commenters encouraged EPA to develop any such approaches to revise the PSI in consultation with State and local agencies, specifically in the areas of sharing real-time O<sub>3</sub> monitoring data among neighboring States, risk communication with the public, and coordination of a national program. States also expressed the need for flexibility in the implementation of such approaches and for guidance from EPA on technical aspects such as forecasting.

The EPA will take all of these comments into consideration when developing a proposal to revise the PSI (40 CFR 58.50) for O<sub>3</sub>. The EPA plans to propose these revisions, as well as revisions to the significant harm level program (40 CFR 51.16), at a later date.

### III. Rationale for the Secondary O<sub>3</sub> Standard

#### A. Introduction

1. *Overview.* This notice presents the Administrator's final decision regarding the need to revise the current secondary O<sub>3</sub> standard, and more specifically, to replace the existing 1-hour, 0.12 ppm O<sub>3</sub> secondary NAAQS with a secondary standard equal in form, level, and averaging time to the new 8-hour, 0.08 ppm primary standard. This decision is based on a thorough review of the scientific information on vegetation effects associated with exposure to ambient levels of O<sub>3</sub> as assessed in the Criteria Document. This decision also takes into account:

(1) Staff Paper assessments of the most policy-relevant information in the Criteria Document and staff analyses of air quality, vegetation exposure and risk, and economic values presented in the Staff Paper, upon which staff recommendations for a new O<sub>3</sub> secondary standard were based.

(2) Consideration of the degree of protection to vegetation potentially afforded by the new 8-hour, 0.08 ppm primary standard compared to alternative secondary standards.

(3) CASAC advice and recommendations as reflected in discussion of drafts of the Criteria Document and Staff Paper at public meetings, in separate written comments, and in CASAC's letter to the Administrator (Wolff, 1996).

(4) Public comments received during development of these documents either in conjunction with CASAC meetings or separately.

(5) Extensive public comments received on the proposed decision regarding the secondary O<sub>3</sub> standard.

After taking this information into account and for the reasons discussed in this Unit, the Administrator concludes that revisions to the current secondary standard are appropriate at this time to provide increased protection against adverse effects to public welfare, and that it is appropriate to set the new secondary standard identical to the new primary standard.

This review has focused on O<sub>3</sub> effects on vegetation since these public welfare effects are of most concern at O<sub>3</sub> concentrations typically occurring in the United States. By affecting commercial crops and natural vegetation, O<sub>3</sub> may also indirectly affect natural ecosystem components such as soils, water, animals, and wildlife. Based on the scientific literature assessed in the Criteria Document, the Administrator believes it is

reasonable to conclude that a secondary standard that protects the public welfare categories of commercial crops and natural vegetation from known or anticipated adverse effects would also afford increased protection to these other related public welfare categories. With regard to O<sub>3</sub> effects on manmade materials and deterioration of property, the scientific literature assessed in the Criteria Document contains little new information since the last review. Accordingly, EPA again concludes for the reasons set forth in 1993 (58 FR 13008, March 9, 1993) that O<sub>3</sub>-related effects on materials do not provide a basis for selecting an averaging time and level for a secondary standard. In addition, since the effects of O<sub>3</sub> on personal comfort and well-being (e.g., nose and throat irritation, chest discomfort, and cough) have been accounted for in the review of the primary standard, these effects are not considered in this review of the secondary standard.

The vegetation effects information, exposure and risk assessment, and economic analyses presented in the Staff Paper and proposal are briefly outlined in the remainder of Unit III.A. of this preamble. The key issues raised in public comments with regard to: Whether revisions to the current secondary standard are requisite to protect public welfare from adverse effects and the specific elements of a revised secondary standard are discussed in Unit III.B. along with the Administrator's rationale for concluding that it is appropriate to revise the current secondary standard to be identical to the new primary standard.

#### 2. *Vegetation effects information.*

Exposures to O<sub>3</sub> have been associated quantitatively and qualitatively with a wide range of vegetation effects such as visible foliar injury, growth reductions and yield loss in annual crops, growth reductions in tree seedlings and mature trees, and effects that can have impacts at the forest stand and ecosystem level. Summarized below are key findings for each of the above effects categories that are discussed in more detail in the Criteria Document, Staff Paper, and proposal.

Visible foliar injury can represent a direct loss of the intended use of the plant, ranging from reduced yield and/or marketability for some agricultural species to impairment of the aesthetic value of urban ornamental species. On a larger scale, foliar injury is occurring on native vegetation in national parks, forests, and wilderness areas, and may be degrading the aesthetic quality of the natural landscape, a resource important to public welfare.

Ozone can interfere with carbon gain (photosynthesis) and allocation of carbon with or without the presence of visible foliar injury. As a result of decreased carbohydrate availability, remaining carbohydrates may be allocated to sites of injured tissue or employed in other repair or compensatory

processes, thus reducing the carbohydrates available for plant growth and/or yield. Growth and yield effects of O<sub>3</sub> have been well documented for numerous species, including commodity crops, fruits and vegetables, and seedlings of both coniferous and deciduous tree species.

Due to a number of differences between seedlings and mature trees in their responses to O<sub>3</sub> exposures, data from tree seedling studies cannot, at this time, be extrapolated to quantify responses to O<sub>3</sub> in mature trees. However, long-term observational studies of mature trees have shown growth reductions in the presence of elevated O<sub>3</sub> concentrations. Where these growth reductions are not attributed to O<sub>3</sub> alone, due to the presence of many other environmental variables, it has been reported that O<sub>3</sub> is a significant contributor that potentially exacerbates the effects of other environmental stresses (e.g., pests). In addition, studies show that sensitivity to O<sub>3</sub> with respect to visible foliar injury and growth and yield effects can vary significantly within and between species for both crops and trees.

Growth reductions can indicate that plant vigor is being compromised such that the plant can no longer compete effectively for essential nutrients, water, light, and space. When many O<sub>3</sub>-sensitive individuals make up a population, the whole population may be affected. Changes occurring within sensitive populations, or stands, if they are severe enough, ultimately can change community and ecosystem structure. Structural changes that alter the ecosystem functions of energy flow and nutrient cycling can alter ecosystem succession.

In the CASAC closure letter, all CASAC panel members agreed that "damage is occurring to vegetation and natural resources at concentrations below the present 1-hour national ambient air quality standard (NAAQS) of 0.12 ppm," and the vegetation experts agreed that "plants appear to be more sensitive to O<sub>3</sub> than humans" (Wolff, 1996). Further, the CASAC panel agreed "that a secondary NAAQS, more stringent than the present primary standard, was necessary to protect vegetation from O<sub>3</sub>" (Wolff, 1996). The Administrator concurred in the proposal with the unanimous view of CASAC that the current standard of 0.12 ppm, 1-hour average, does not provide adequate protection to vegetation from the adverse effects of O<sub>3</sub>, based on the following specific observations that were taken from key studies and other biological effects information reported in the O<sub>3</sub> Criteria Document and Staff Paper:

(1) O<sub>3</sub> concentrations  $\geq$  0.10 ppm can be phytotoxic to a large number of plant species, and can produce acute foliar injury responses and reduced crop yield and biomass production.

(2) O<sub>3</sub> concentrations within the range of 0.05 to 0.10 ppm have the potential over a longer duration of creating chronic stress on vegetation that can result in reduced plant

growth and yield, shifts in competitive advantages in mixed populations, decreased vigor leading to diminished resistance to pest and pathogens, and injury from other environmental stresses. Some sensitive species can experience foliar injury and growth and yield effects even when concentrations never exceed 0.08 ppm.

The Administrator further concluded that the available scientific information supports the conclusion that a cumulative seasonal exposure index, such as the proposed SUM06 index,<sup>26</sup> is more biologically relevant than a single event or mean index.

3. *Vegetation exposure and risk analyses.* In reaching a judgment in the proposal as to a standard requisite to protect crops and vegetation against the adverse effects of O<sub>3</sub>, the Administrator took into account several additional considerations including the extent of exposure of O<sub>3</sub>-sensitive species, potential risks of adverse effects to such species, and monetized and nonmonetized categories of increased vegetation protection associated with reductions in O<sub>3</sub> exposures. In so doing, the Administrator recognized that markedly improved air quality, and thus significant reductions in O<sub>3</sub> exposures would result from attainment of the alternative 0.08 ppm, 8-hour primary standards within the range of 1- and 5-expected exceedance forms. Thus, as a matter of policy, the Agency estimated the increased protection from O<sub>3</sub>-related effects on vegetation associated with attainment of alternative 8-hour, 0.08 ppm primary standards, and then considered the incremental protection associated with attainment of a seasonal secondary standard.

The ability of EPA to characterize O<sub>3</sub> air quality in rural and remote sites was limited by the available rural O<sub>3</sub> monitoring network. Therefore, EPA conducted national analyses using geographic information systems (GIS) and data from existing air quality monitoring sites to estimate seasonal O<sub>3</sub> air quality for the year 1990, in terms of the 3-month, 12-hour, SUM06 exposure index. The year 1990 was selected because it was a fairly typical year in terms of O<sub>3</sub> air quality. The estimated 1990 air quality was then used as a baseline from which to roll back O<sub>3</sub> concentrations to project O<sub>3</sub> air quality that would be expected to occur when alternative standards were just attained.

The regulatory scenarios examined included just attaining the existing 1-hour secondary standard, alternative 8-hour primary standards in the range of 0.07 to 0.09 ppm, including standards set at 0.08 ppm, with 1- and 5-expected-exceedance forms, and a range of seasonal standards using the SUM06 index, based on a single year of data. Estimates of air quality associated with alternative 8-hour primary standards with 1- and 5-expected-exceedance forms were used

to roughly bound air quality estimates for 8-hour standards with concentration-based forms ranging from the annual second- to the fifth-highest concentration-based forms, and including the proposed third-highest concentration-based form.

By comparing these projected air quality scenarios for alternative standards with maps showing the growing regions for O<sub>3</sub>-sensitive crops and tree seedling species, estimates of exposures of concern and risks of adverse effects for various species were developed for alternative standards. Taking into account the body of information concerning O<sub>3</sub> effects on vegetation, as presented in the Criteria Document and Staff Paper and summarized in the proposal, EPA considered both quantifiable risks (when exposure-response functions were available) as well as those risks that could only be qualitatively characterized.

The Administrator concluded in the proposal that attaining a 8-hour, 0.08 ppm primary standard within the range of forms under consideration would provide substantially improved protection of vegetation from seasonal O<sub>3</sub> exposures of concern. The Administrator recognized, however, that some areas may continue to have elevated seasonal exposures, including forested park lands and other natural areas and Class I areas that are federally mandated to preserve certain air quality related values.

In its discussions of uncertainties, described in the proposal, the CASAC Panel members expressed concerns about the use of the GIS methodology to project national O<sub>3</sub> air quality and exposures of O<sub>3</sub>-sensitive species. As is the case with other analytic methods (e.g., Kriegering, inverse distance weighting), the GIS methodology contains numerous assumptions and uncertainties, and incorporates various databases each with their own set of uncertainties. As noted in the Staff Paper and proposal, the EPA and CASAC recognized that the uncertainties in exposure and risk estimates derived from the GIS methodology are large and unquantifiable, but that the method provides useful information that is appropriate to consider in comparing the relative protection afforded by alternative standards. Further, EPA noted in the Staff Paper and proposal that the GIS-generated air quality estimates compare reasonably well with the limited available O<sub>3</sub> monitoring data. In taking the results from these analyses into account, the Administrator recognized these inherent limitations and primarily considered the comparative results in assessing the degree of protection afforded by alternative standards.

While the analyses discussed above indicated that an 8-hour, 0.08 ppm primary standard within the range of alternatives considered, would provide increased protection for commercial and natural vegetation, it remained uncertain as to the extent to which air quality improvements designed to reduce 8-hour O<sub>3</sub> concentrations

<sup>26</sup> The SUM06 exposure index cumulates over a given time period and diurnal window all hourly O<sub>3</sub> concentrations greater than or equal to 0.06 ppm.

would reduce O<sub>3</sub> exposures measured by a seasonal SUM06 index. To further explore this question, EPA also examined the design values for alternative 8-hour, 0.08 ppm standards, within the range of 1- and 5-expected exceedances, averaged over 3 years, and a 3-month, 12-hour SUM06 standard for 581 counties (those having sufficient monitoring data for the period 1991 – 1993). As discussed in the Staff Paper and proposal, this analysis revealed that almost all areas that are within or above a SUM06 range of 25–38 ppm-hours would also have an 8-hour daily maximum design value of greater than 0.08 ppm. Thus, in those areas in which air quality monitoring is being conducted, areas that would likely be of most concern for effects on vegetation, as measured by the SUM06 exposure index, would also be addressed by an 8-hour primary standard set at a 0.08 ppm level.

4. *Monetized estimates of vegetation protection.* As discussed in section VII.F. of the Staff Paper and in the proposal, EPA developed monetized estimates of increased protection associated with several alternative standards for economically important commodity crops nation-wide<sup>27</sup> and for fruit and vegetable crops in California.<sup>28</sup> These analyses were based on the GIS-generated projections of O<sub>3</sub> air quality for various alternative standards. Monetized estimates of increased protection could not be developed for other important categories of vegetation, such as urban ornamentals, Class I areas, and commercial and other forests because of a lack of available concentration-response functions and appropriate economic valuation models. The available data suggested, however, that reductions in ambient O<sub>3</sub> concentrations resulting from attainment of alternative standards would confer increased protection for these categories as well by reducing biomass loss, protecting functional, aesthetic, and existing values, and by preserving biodiversity and native habitats.

As summarized in the proposal, most of the monetized estimates of increased protection would accrue from attainment of an 8-hour, 0.08 ppm primary standard, with a smaller incremental improvement obtained by the addition of a seasonal secondary standard. In contrast, the incremental protection obtained from the addition of a seasonal secondary standard would be considerably more significant when compared to an alternative 8-hour primary standard at a level of 0.09 ppm.

<sup>27</sup> Including 15 species, representing approximately 75% of the U.S. sales of agricultural crops, evaluated in the National Crop Loss Assessment Network (NCLAN) studies undertaken in the early to mid-1980's, which provide the largest, most uniform database on the effects of O<sub>3</sub> on agricultural crop species.

<sup>28</sup> These fruit and vegetable crops constitute approximately 50% of the Nation's fruits and vegetable markets.

#### *B. Need for Revision of the Current Secondary Standard*

Based on the above considerations and the rationale in the proposal, the Administrator proposed and sought comment on two alternative standards, either of which in her judgment would be appropriate to protect public welfare from known or anticipated adverse effects given the available scientific knowledge. The two alternatives were setting the revised secondary standard identical to the proposed 8-hour, 0.08 ppm primary standard, or establishing a 3-month, 12-hour, SUM06 seasonal secondary standard at the level of 25 ppm-hours. The Administrator recognized that it would be a reasonable policy choice to set the revised secondary standard identical to an 0.08, 8-hour ppm primary standard, but also recognized that a SUM06 seasonal standard is more biologically relevant and, therefore, was also appropriate to consider.

In reaching her final decision on a revised secondary standard, the Administrator has taken into account several factors. First, she again concludes based on information presented in the Criteria Document and Staff Paper, and summarized in the proposal and in this preamble, that the existing secondary standard does not provide adequate protection for vegetation against the adverse welfare effects of O<sub>3</sub>.

Second, she has considered the comments made by the CASAC Panel members during their reviews of these documents and in CASAC's closure letter, "that a secondary NAAQS, more stringent than the present primary standard, was necessary to protect vegetation from O<sub>3</sub>" (Wolff, 1996). These statements provide strong support to the Administrator's judgment that the body of scientific evidence on O<sub>3</sub> effects on vegetation provides sufficient and compelling evidence that the current secondary standard is not adequately protective and should be revised.

Third, the Administrator recognizes that significant uncertainties remain with respect to exposure dynamics, air quality relationships, and estimates of increased vegetation protection which are important factors in selecting an appropriate secondary standard, as described more fully in the Criteria Document, Staff Paper and proposal. The CASAC closure letter highlighted key uncertainties that hampered the Panel's ability to make any recommendations as to an appropriate form or level for a secondary standard that would be protective against adverse effects on vegetation from exposure to ambient levels of O<sub>3</sub>. The Panel stated that "agreement on the level and form of such a standard is still elusive" and "\*\*\*\*there remain important limitations to our understanding of the extent of the response of vegetation to O<sub>3</sub> under field conditions" (Wolff, 1996). These uncertainties are largely a result of inadequate rural and remote O<sub>3</sub> air quality data that would allow with greater

certainty determination of the relationships between O<sub>3</sub>-related effects being observed in the field and ambient O<sub>3</sub> exposures.

Nevertheless, the alternative standards proposed by the Administrator are consistent with the range of views expressed by the CASAC panel members, and CASAC recognized that choosing between the two alternatives is a policy decision that cannot be based solely on science (Wolff, 1996).

Fourth, the Administrator recognized that just attaining the 8-hour, 0.08 ppm, 1- and 5-expected exceedance alternatives results in markedly improved air quality when compared to just attaining the existing secondary standard, with only slight improvements associated with going from a 5- to 1-expected exceedance form.

Fifth, the Administrator has carefully considered the information and views provided in the public comments. Though these comments yielded no new scientific information relevant to choosing between the two alternative proposed standards, many commenters repeated the CASAC's concerns over the significant uncertainties remaining in the database. Many of these commenters expressed the view that EPA should wait to set a seasonal secondary standard until better rural air quality data were available, which would allow for better characterization of the magnitude of improvements in public welfare protection likely to be afforded by such a standard compared to a revised primary standard.

In sharp contrast, other commenters expressed the view that the available data were sufficient to demonstrate a need to set a seasonal secondary standard to protect vegetation against the adverse effects of O<sub>3</sub>, and many such commenters recommended the proposed SUM06 form for such a standard. A significant number of these commenters also made recommendations on the appropriate level for a seasonal SUM06, generally recommending levels lower than the proposed 25 ppm-hours, ranging from 8 to 20 ppm-hours. The key source frequently cited in support of these recommendations is an article by Heck and Cowling (1997) which summarizes the outcome of a consensus-building workshop sponsored by the Southern Oxidant Study group on the secondary standard held in January 1996.

This workshop was attended by 16 scientists with backgrounds in agricultural, managed forest, natural systems, and air quality, all of whom are leaders in their fields and whose research formed the basis of much of the research examined in the Criteria Document. These scientists expressed their judgements on what standard level(s) would provide vegetation with adequate protection from O<sub>3</sub>-related adverse effects.

Though the report identified no new data in support of the scientists' recommendations, the Administrator believes that the report lends important support to the view that the current secondary standard is not adequately

protective of vegetation. Further, the Administrator believes that the report foreshadows the direction of future scientific research in this area, the results of which could be important in future reviews of the O<sub>3</sub> secondary standard.

As the results of such research become available, EPA will be in a better position to characterize rural air quality and the improvements in vegetation protection that would result from a seasonal secondary standard, and to select a standard level that would provide adequate protection for vegetation. However, given the present limits of the scientific evidence of O<sub>3</sub>-related effects and of rural air quality data, as discussed in the Criteria Document, Staff Paper, the proposal, and by CASAC, the Administrator has decided that it is not appropriate to move forward with a seasonal secondary standard at this time for the reasons described below. In coming to this conclusion, the Administrator specifically considered the significant improvements in public welfare protection that are expected to be afforded by the new 8-hour primary standard, as well as the value of obtaining additional information to better characterize O<sub>3</sub>-related effects on vegetation under field conditions.

### C. Final Decision on the Secondary Standard

Based on the scientific evidence, CASAC advice and recommendations, comments received on the proposal, and the considerations summarized above, the Administrator is replacing the current secondary O<sub>3</sub> standard with an 8-hour standard, set at a level of 0.08 ppm, identical in all respects to the new primary standard. The Administrator judges that this standard will provide substantially improved protection for vegetation from O<sub>3</sub>-related adverse effects as compared to that provided by the current 1-hour, 0.12 ppm secondary standard, while allowing time for additional research and the development of a more complete rural monitoring network and air quality database from which to evaluate the elements of an appropriate seasonal secondary standard.

The decision not to set a seasonal secondary standard at this time is based in large part on the Administrator's recognition that the exposure, risk, and monetized valuation analyses presented in the proposal contain substantial uncertainties, resulting in only rough estimates of the increased public welfare protection likely to be afforded by each of the proposed alternative standards. These uncertainties were discussed in the proposal and the Staff Paper and were noted by CASAC (Wolff, 1996). In light of these uncertainties, the Administrator has decided it is not appropriate at this time to establish a new separate seasonal secondary standard given the potentially small incremental degree of public welfare protection that such a standard may afford. Instead, the Administrator finds it a reasonable policy choice to set a new secondary standard

identical to the new primary standard, while focusing additional research on key areas for consideration in the next review of the O<sub>3</sub> criteria and standards.

Continued research on the effects of O<sub>3</sub> on vegetation under field conditions and on better characterizing the relationship between O<sub>3</sub> exposure dynamics and plant response will be important in the next review because:

(1) The available biological database highlights the importance of cumulative, seasonal exposures as a primary determinant of plant responses.

(2) The association between daily maximum 8-hour O<sub>3</sub> concentrations and plant responses has not been specifically examined in field tests.

(3) The impacts of attaining an 8-hour, 0.08 ppm primary standard in upwind urban areas on rural air quality distributions cannot currently be characterized with confidence due to limited monitoring data and air quality modeling in rural and remote areas.

Setting the secondary standard equal to the primary standard will allow EPA the opportunity to evaluate more specifically the improvement in rural air quality and in O<sub>3</sub>-related vegetation effects resulting from measures designed to attain the new primary standard. This information in turn will allow for better evaluation of the incremental need for a separate seasonal secondary standard in the next review of the O<sub>3</sub> criteria and standards.

In the proposal, the Administrator solicited comment on the appropriate spatial scale of an expanded rural monitoring network. Relatively few comments were received regarding an expanded rural monitoring network, but those who did submit comments were generally in favor of an expanded network to allow for improved modelling of long-range transport of O<sub>3</sub> and its precursors and for better characterization of O<sub>3</sub> air quality in rural and remote areas. Those comments will serve to inform EPA's development of revised air quality surveillance requirements (40 CFR part 58) that will be proposed at a later date.

With respect to the proposed seasonal secondary standard only, the proposal sought comment on whether O<sub>3</sub> concentrations from several monitors should be spatially integrated when determining compliance with the standard. Only a few comments were received, with some supporting and some opposing spatial integration of O<sub>3</sub> concentrations from several monitors.

In view of the Administrator's decision to replace the current secondary standard with a secondary standard which is identical in form, level, and averaging time to the new 8-hour, 0.08 ppm primary standard, rather than with a seasonal standard, EPA is not adopting the use of spatial averaging for the new secondary standard.

To decrease some of the uncertainties discussed above and to remedy the lack of air quality data in rural and remote areas of

commercial or ecological importance for vegetation, the Administrator reiterates her intention, expressed in the proposal, to expand the rural O<sub>3</sub> monitoring network. The EPA will propose revised O<sub>3</sub> air quality surveillance requirements (40 CFR part 58) at a later date. The EPA is exploring opportunities to work with other Federal agencies to develop a coordinated and long-term rural monitoring network.

### IV. Other Issues

Several commenters raised key legal and procedural issues that are discussed below. These include: (1) Whether EPA must give consideration to costs and similar factors in setting NAAQS; (2) whether EPA erred in its selection of a methodology for determining the level of a NAAQS that protects public health with an adequate margin of safety; (3) whether EPA committed a procedural error by not extending the comment period; and (4) whether the 1990 amendments to the Act preclude EPA from revising the O<sub>3</sub> NAAQS to establish a new 8-hour standard. Responses to other legal and procedural issues are included in the Response-to-Comments Document.

#### A. Cost Considerations

For more than a quarter of a century, EPA has interpreted section 109 of the Act as precluding consideration of the economic costs or technical feasibility of implementing NAAQS in setting them. As indicated in the proposal, a number of judicial decisions have confirmed this interpretation. *Natural Resources Defense Council v. Administrator*, 902 F.2d 962, 972-73 (D.C. Cir. 1990)(PM NAAQS)("PM10"), vacated, in part, dismissed, 921 F.2d 326 (D.C. Cir.), cert. denied, 498 U.S. 1075, and cert. denied, 498 U.S. 1082 (1991); *Natural Resources Defense Council v. EPA*, 824 F.2d 1146, 1157-59 (D.C. Cir. 1987)(en banc)(CAA section 112 standards for vinyl chloride)("Vinyl Chloride"); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1185-86 (D.C. Cir. 1981)(ozone NAAQS)("Ozone"), cert. denied, 455 U.S. 1034 (1982); *Lead Industries Ass'n v. EPA*, 647 F.2d 1130, 1148-51 (D.C. Cir.)(lead NAAQS)("Lead Industries"), cert. denied, 449 U.S. 1042 (1980).

Some commenters have argued that costs and similar factors should, nonetheless, be considered, both in this rulemaking and in the rulemaking on proposed revisions to the NAAQS for particulate matter. Although most of the commenters' arguments are inconsistent with the judicial decisions cited above, several commenters have argued that those decisions are not dispositive. For reasons discussed below and in the Response-to-Comments Document, EPA disagrees with these comments and maintains its longstanding interpretation of the Act as precluding consideration of costs and similar factors in setting NAAQS.

1. *Background.* Given the nature of the points raised, a brief review of the issue seems useful before addressing the comments. The requirement that EPA establish national ambient air quality standards for certain pollutants, to be implemented by the States, was enacted in 1970 as part of a set of comprehensive amendments that established the basic framework for Federal, State, and local air pollution control. When EPA promulgated the original NAAQS in 1971, its first Administrator, William D. Ruckelshaus, concluded that costs and similar factors could not be considered in that decision.<sup>29</sup> This conclusion was not challenged in litigation on the original NAAQS. It has been confirmed since then, however, by every judicial decision that has considered the issue.

As discussed below, EPA's interpretation rests primarily on the language, structure, and legislative history of the statutory scheme adopted in 1970. It is also supported by the judicial decisions cited above, as well as by legislative developments since 1970 that reaffirm Congress' original approach to the issue.

Without cataloguing all relevant aspects of the 1970 amendments and their legislative history, several basic points should be noted. Under section 109(b) of the Act, NAAQS are to be "based on" the air quality criteria issued under section 108. Under section 108(a)(2), the kind of information EPA is required to include in criteria documents is limited to information about health and welfare effects "which may be expected from the presence of [a] pollutant in the ambient air \*\*\*." There is no mention of the costs or difficulty of implementing the NAAQS, nor of "effects" that might result from implementing the NAAQS (as opposed to effects of pollution in the air).<sup>30</sup> By contrast, Congress explicitly provided for consideration of costs and similar factors in decisions under other sections of the Act.<sup>31</sup> Moreover, States were permitted to consider economic and technological feasibility in developing plans to implement the NAAQS to the extent such consideration did not interfere with meeting statutory deadlines for attainment of the standards.<sup>32</sup> Finally, the legislative history indicated that Congress had considered the issue and had deliberately

chosen to mandate NAAQS that would protect health regardless of concerns about feasibility.<sup>33</sup>

The first judicial decision on the issue came in the Lead Industries case. An industry petitioner argued that EPA should have considered economic and technological feasibility in allowing a "margin of safety" in setting primary standards for lead. Based on a detailed review of the language, structure, and legislative history of the statutory scheme, the U.S. Court of Appeals for the District of Columbia Circuit concluded that:

This argument is totally without merit. [The petitioner] is unable to point to anything in either the language of the Act or its legislative history that offers any support for its claim \*\*\*. To the contrary, the statute and its legislative history make clear that economic considerations play no part in the promulgation of ambient air quality standards under section 109.

647 F.2d at 1148.

The Court cited a number of reasons for this conclusion. *Id.* at 1148–50. Among other things, it noted the contrast between section 109(b) and other provisions in which Congress had explicitly provided for consideration of economic and technological feasibility, as well as the requirement that NAAQS be based on air quality criteria defined without reference to such factors. *Id.* at 1148–49 & n.37. The Court also noted that, in developing plans to implement NAAQS, States may consider economic and technological feasibility only to the extent that this does not interfere with meeting the statutory deadlines for attainment of the standards; and that EPA may not consider such factors at all in deciding whether to approve State implementation plans. *Id.* at 1149 n.37 (citing *Union Electric Co. v. EPA*, 427 U.S. 246, 257–58, 266 (1976)).<sup>34</sup>

As to the legislative history of the 1970 amendments, the Court observed that:

[T]he absence of any provision requiring consideration of these factors was no accident; it was the result of a deliberate decision by Congress to subordinate such concerns to the achievement of health goals.

*Id.* at 1149. Citing several leading Supreme Court decisions, as well as the Senate report quoted above, the Court noted that Congress

had intended a drastic change in approach toward the control of air pollution in the 1970 amendments and was well aware that sections 108–110 imposed requirements of a "technology-forcing" character. *Id.*<sup>35</sup>

The Court also noted that Congress had already acted, in further amendments adopted in 1977, to relieve some of the burdens imposed by the 1970 amendments. *Id.* at 1150 n.38. Observing that Congress had, however, declined to amend section 109(b) to provide for consideration of costs and similar factors as requested by industrial interests, *id.* n.39, the Court concluded:

A policy choice such as this is one which only Congress, not the courts and not EPA, can make. Indeed, the debates on the [1970 amendments] indicate that Congress was quite conscious of this fact\*\*\*.

\*\*\* [I]f there is a problem with the economic or technological feasibility of the lead standards, [the petitioner], or any other party affected by the standards, must take its case to Congress, the only institution with the authority to remedy the problem.

*Id.* at 1150.

After the decision in Lead Industries, Supreme Court review was sought on the question whether costs and similar factors could be considered in setting NAAQS, among other issues. The Supreme Court declined to review the decision. *Lead Industries Ass'n v. EPA*, 449 U.S. 1042 (1980). The subsequent decisions in Ozone, Vinyl Chloride, and PM<sub>10</sub>, cited above, strongly reaffirmed the interpretation adopted in Lead Industries.<sup>36</sup> Supreme Court review of the Ozone and PM<sub>10</sub> decisions was sought but denied. *American Petroleum Institute v. Gorsuch*, 455 U.S. 1034 (1984); *American Iron and Steel Institute v. EPA*, 498 U.S. 1082 (1991).

The Lead Industries opinion focused largely, though not exclusively, on the 1970 amendments and their legislative history. Perhaps as a result, it did not canvass all the factors that, in fact, supported its conclusions at the time. For example, when Congress enacted major amendments to the Act in 1977, it was clearly aware that some areas of the country had experienced difficulty in

<sup>29</sup> 36 FR 8186, Apr. 30, 1971. EPA has maintained this interpretation consistently since then.

<sup>30</sup> That consideration of such factors was not intended in NAAQS decisions is also supported by section 109(a)(1). For pollutants for which air quality criteria had been issued prior to the 1970 amendments, that provision required EPA to propose NAAQS within 30 days after enactment and to take final action 90 days later. The criteria issued previously did not include information on costs and similar factors, and it would have been difficult if not impossible for EPA to supplement them in time to include meaningful consideration of such factors in NAAQS proposed 30 days after enactment.

<sup>31</sup> See, e.g., sections 110(e)(1), 111(a)(1), 231(b) (1970 Act); see also, e.g., sections 113(d)(4)(C)(ii), 125(a)(3), 202(a)(3)(C), 317 (1977 Act).

<sup>32</sup> *Union Electric Co. v. EPA*, 427 U.S. 246, 257–58 (1976).

<sup>33</sup> The Senate report on the 1970 amendments stated: "In the Committee discussions, considerable concern was expressed regarding the use of the concept of technical feasibility as the basis of ambient air standards. The Committee determined that (1) the health of people is more important than the question of whether the early achievement of ambient air quality standards protective of health is technically feasible; and, (2) the growth of pollution load in many areas, even with application of available technology, would still be deleterious to public health."

"Therefore, the Committee determined that existing sources of pollutants either should meet the standard of the law or be closed down \*\*\*."

S. Rep. No. 91–1196, at 2–3 (1970).

<sup>34</sup> These limitations would, of course, make little sense if such factors could be considered in setting the NAAQS themselves.

<sup>35</sup> Such requirements "are expressly designed to force regulated sources to develop pollution control devices that might at the time appear to be economically or technologically infeasible." *Id.* (quoting *Union Electric Co. v. EPA*, 427 U.S. at 257).

<sup>36</sup> In the PM<sub>10</sub> case, for example, the Court considered an argument that EPA should have considered potential health consequences of unemployment that might result from revision of the primary NAAQS for PM:

"This claim is entirely without merit. In three previous cases, this court has emphatically stated that section 109 does not permit EPA to consider such costs in promulgating national ambient air quality standards \*\*\*. It is only health effects relating to pollutants in the air that EPA may consider. \*\*\* Consideration of costs associated with alleged health risks from unemployment would be flatly inconsistent with the statute, legislative history and case law on this point."

902 F.2d at 973 (emphasis in original; citations omitted).

attempting to attain some of the NAAQS.<sup>37</sup> It was also aware that there might be no health-effects thresholds for the pollutants involved, and that significant uncertainties are inherent in setting health-based standards under the Act.<sup>38</sup> In response, Congress made significant changes in the provisions for implementation of the NAAQS, including changes intended to ease the burdens of attainment. It also amended sections 108 and 109 in several ways; for example, by requiring periodic review and, if appropriate, revision of air quality criteria and NAAQS and by establishing a special scientific advisory committee (CASAC) to advise EPA on such reviews. Notably, Congress recognized that implementation of NAAQS could cause "adverse public health, welfare, social, economic, or energy effects" and charged CASAC with advising EPA on such matters.<sup>39</sup> Yet it made no changes in sections 109(b) or 108(a)(2); that is, in the substantive criteria for setting or revising NAAQS. In other words, Congress chose to address economic and other difficulties associated with attainment of the NAAQS by adjusting the scheme for their implementation, rather than by changing the instructions for setting them.<sup>40</sup>

Congress enacted major amendments to the Act again in 1990, well after the Lead Industries and Ozone decisions that interpreted section 109 as precluding consideration of costs in NAAQS decisions.<sup>41</sup> In doing so, Congress was clearly aware of intervening developments such as EPA's decision to revise the PM NAAQS in 1987—the result of an elaborate review in which the

Administrator strongly underscored the scientific uncertainties involved<sup>42</sup>—and the Vinyl Chloride case drawing a sharp distinction between sections 109 and 112 with regard to consideration of costs and similar factors.<sup>43</sup> Indeed, the legislative history of the 1990 amendments reflects Congress' understanding that primary NAAQS were to be based on protection of health "without regard to the economic or technical feasibility of attainment."<sup>44</sup> Again, however, Congress chose to respond to severe, widespread, and persistent problems with attaining the NAAQS by adjusting the scheme for their implementation rather than by changing the basis for setting them. See, e.g., sections 181–192.

2. *Public comments.* As noted previously, a number of commenters have argued that costs and similar factors should be considered in EPA's final decisions on revision of both the ozone and particulate NAAQS. Aside from arguments that are simply inconsistent with the judicial decisions cited above, some of the commenters argue that those decisions are not dispositive for a variety of reasons. One commenter submitted a particularly comprehensive version of this argument in the rulemaking on proposed revisions to the particulate NAAQS; the following discussion focuses primarily on points raised by that commenter, among others.<sup>45</sup>

As a general matter, the commenter acknowledges that Congress intended to preclude consideration of economic costs and similar factors in setting NAAQS. The commenter argues, however, that this is so only when the scientific basis for NAAQS is "clear and compelling" or "unambiguous." From that premise, the commenter advances three key assertions:

<sup>42</sup> As the Administrator indicated in EPA's proposal to revise the PM standards:

"[T]hat review has revealed a highly limited data base—particularly where quantitative studies are concerned—and a wide range of views among qualified professionals about the exact pollution levels at which health effects are likely to occur. The setting of an 'adequate margin of safety' below these levels calls for a further judgment—in an area for which the scientific data base is even more sparse and uncertain\*\*\*."

"[L]ong and expert review of public health issues has to date revealed no scientific method of assessing exactly what level of standards public health requires. The scientific review indicates substantial uncertainties concerning the health risks associated with lower levels of particulate matter."

49 FR 10408, 10409, Mar. 20, 1984.

<sup>43</sup> Congress was clearly aware of the 1987 decision to revise the PM NAAQS, which among other things involved changing the indicator for particulate matter from "total suspended particulate" to PM<sub>10</sub>, because it enacted special nonattainment provisions, as well as provisions for PSD increments, applicable to PM<sub>10</sub>. Sections 188–190; section 166(f). It was clearly aware of the Vinyl Chloride decision because it amended section 112 in response to that decision, essentially creating a new scheme for setting emission standards for hazardous pollutants.

<sup>44</sup> H.R. Rep. No. 101–490, pt. 1, at 145 (1990). See also S. Rep. No. 101–228, at 5 (1989).

<sup>45</sup> Additional responses to points raised by this commenter and others are included, as appropriate, in the Response-to-Comments document.

(1) Where non-threshold pollutants are involved and the health evidence is ambiguous, section 109 must be interpreted to allow consideration of all relevant factors, including the practical consequences of EPA's decisions;

(2) To the extent the judicial decisions cited above are read as precluding this, they rest on a faulty analysis that pre-dates and cannot survive scrutiny under *Chevron*, *U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837 (1984);<sup>46</sup> and

(3) Because EPA has discretion to consider costs and similar factors where the health evidence is ambiguous, it must do so in light of Executive Order 12866, 58 FR 51735, Oct. 4, 1993, and two recent statutes, the Unfunded Mandate Reform Act of 1995, 2 U.S.C. secs. 1501–1571 (UMRA), and the Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104–121, 110 Stat. 857 (SBREFA), which in part amended the Regulatory Flexibility Act, 5 U.S.C. secs. 601–808.

EPA believes all three assertions are clearly incorrect. Regarding the first point, it should be evident, both from previous NAAQS decisions and from the court opinions upholding them, that the scientific basis for NAAQS decisions has never pointed clearly and unambiguously to a single "right answer."<sup>47</sup> This is inherent in the statutory scheme for the establishment and revision of NAAQS, which in effect requires them to be based on the "latest scientific knowledge" on potential health and welfare effects of the pollutant in question. See sections 109(b), 108(a)(2). Although advances in science increase our understanding of such effects, they also raise new questions. For this reason, the key studies for any given decision on revision of a NAAQS are, almost by definition, "at the very 'frontiers of scientific knowledge.'"<sup>48</sup> That is, studies that call into question the adequacy of a standard are always those that go beyond previous

<sup>46</sup> Several other commenters argue that the cited decisions are not dispositive because they held only that EPA is not required to consider costs and similar factors in setting NAAQS. As discussed below in connection with *Chevron*, however, the decisions clearly concluded that Congress intended to preclude consideration of such factors, and that EPA is not free to alter that congressional choice. Although these conclusions are technically dicta, nothing in the Court's opinions suggests that it would have interpreted section 109 differently had EPA claimed authority to consider costs and similar factors in NAAQS decisions. Indeed, the tone of the opinions argues to the contrary. See, e.g., PM<sub>10</sub>, 902 F.2d at 973. Cf. *Ethyl Corp. v. EPA*, 51 F.3d 1053 (D.C. Cir. 1995).

<sup>47</sup> See, e.g., *Lead Industries*, 647 F.2d at 1146–47, 1153–56, 1160–61, 1167 n.106. In enacting the 1970 amendments, Congress was aware that there were gaps in the scientific information available then as a basis for establishing the original NAAQS. See, e.g., S. Rep. No. 91–1196, at 9–11 (1970). If anything, Congress had an even greater understanding of the point when it enacted that 1977 amendments without changing the substantive criteria for setting NAAQS. See H.R. Rep. No. 95–294, at 43–51, 181–82 (1977).

<sup>48</sup> *Lead Industries*, 647 F.2d at 1147 (quoting *Ethyl Corp. v. EPA*, 541 F.2d 1, 24–27 (D.C. Cir.) (en banc), cert. denied, 426 U.S. 941 (1976)).

<sup>37</sup> See, e.g., H.R. Rep. No. 95–294, at 207–17 (1977).

<sup>38</sup> See, e.g., *id.* at 110–12; *id.* at 43–51.

<sup>39</sup> Section 109(d)(2)(C)(iv). Some commenters have argued that this provision requires EPA to consider such effects in setting NAAQS. From the language and structure of section 109(d), however, it is clear that CASAC's responsibility to advise on these factors is separate from its responsibility to review and recommend revision of air quality criteria and NAAQS, and that the advice pertains to the implementation of NAAQS rather than to setting them. The legislative history confirms this view, indicating that the advice was intended for the benefit of the States and Congress. See H.R. Rep. No. 95–294, at 183 (1977).

<sup>40</sup> The 1977 amendments also required EPA to prepare economic impact assessments for specified actions but limited the requirement to non-health-based standards, excluding decisions under sections 109 and 112. Section 317; H.R. Rep. No. 95–294, at 51–52 (1977). In this and other respects, Congress continued the approach it took in the 1970 amendments, making careful choices as to when consideration of costs and similar factors would be required and giving paramount priority to protection of health. See 123 Cong. Rec. H8993 (daily ed. Aug. 4, 1977) (Clean Air Conference Report (1977)); Statement of Intent; Clarification of Select Provisions), reprinted in 3 Senate Committee on Environment and Public Works, 95th Cong., A Legislative History of the Clean Air Act Amendments of 1977, at 319 (1978).

<sup>41</sup> In the interim, the National Commission on Air Quality had also submitted its report to Congress as required by a provision of the 1977 amendments. Among other things, the Commission recommended that the statutory approach of requiring NAAQS to be set at levels necessary to protect public health, without consideration of economic factors, be continued without change. National Commission on Air Quality, *To Breathe Clean Air* 55 (1981).]

studies—by reporting new kinds of effects, for example, or effects at lower concentrations than those at which effects have been reported previously.

As with pioneering work in other fields, such studies may have a variety of strengths and limitations.<sup>49</sup> As a result, the validity and implications of such studies may be both uncertain and highly controversial. Given the precautionary nature of section 109,<sup>50</sup> however, it is precisely these kinds of studies that the Administrator must grapple with when advances in science suggest that revision of a NAAQS is appropriate.

As a result, the EPA staff typically recommends for consideration, and the Administrator may propose for comment, a range of alternatives based on what the commenter would call “ambiguous” science. In this respect, the current reviews of the NAAQS for ozone and particulate matter are not unusual and do not differ, for example, from the review that led to adoption of the PM<sub>10</sub> NAAQS in 1987.<sup>51</sup> Indeed, the NAAQS that were upheld in the Lead Industries, Ozone, and PM<sub>10</sub> decisions were all based on highly controversial health evidence; the Lead Industries decision took note of congressional statements recognizing that there may be no thresholds for criteria pollutants; and the Ozone and PM<sub>10</sub> decisions noted the Administrator’s findings that clear thresholds could not be identified for ozone and particulate matter, respectively.<sup>52</sup> Thus, the present decisions on revision of the NAAQS for ozone and particulate matter cannot be distinguished from those past decisions in terms of the nature of the health evidence or pollutants involved.<sup>53</sup>

Regarding the second of the commenter’s key assertions, EPA believes it is clear that the judicial decisions cited above were correctly decided and continue to be good law under Chevron. In Chevron, the Supreme Court essentially reaffirmed the principle that courts must defer to reasonable agency

interpretations of the statutes they administer where Congress has delegated authority to them to elucidate particular statutory provisions. Where the intent of Congress on an issue is clear, however, it must be given effect by the agency and the courts. See 467 U.S. at 842–45. Thus, the first question on review of an agency’s interpretation under Chevron is “whether Congress has directly spoken to the precise question at issue.” If the court determines that it has not, the remaining question for the court is “whether the agency’s answer is based on a permissible construction of the statute.” 467 U.S. at 842–43 (footnote omitted). In determining whether Congress “had an intention on the precise question at issue,” a court employs “traditional tools of statutory construction.” *Id.* at 843 n.9.<sup>54</sup>

In essence, the commenter’s argument here is that the Lead Industries decision did not address whether Congress had “spoken directly” to the precise issue posed by the commenter; that is, whether section 109 must be interpreted differently for NAAQS decisions involving non-threshold pollutants and “ambiguous” health evidence. The Lead Industries opinion, which pre-dated Chevron, did not pose the question in those terms. Its focus, however, was clearly on what Congress intended to be the basis for NAAQS decisions, in a context the Court understood to involve considerable uncertainty and debate about the health evidence, as well as the possibility that there was no threshold for health effects of the pollutant.<sup>55</sup> In short, the health evidence was hardly “unambiguous,” yet the Court interpreted section 109 as precluding consideration of costs and similar factors even in allowing a margin of safety. Nothing in the Lead Industries decision or in the subsequent cases suggests in any way that section 109 should be interpreted differently based on the nature of the pollutants or health evidence involved, and the Court’s findings on congressional intent admit of no exceptions:

[T]he statute and its legislative history make clear that economic considerations play no part in the promulgation of ambient air quality standards under section 109.

647 F.2d at 1148.

Alternatively, the commenter argues that the Lead Industries case decided the issue incorrectly in light of the principles announced subsequently in Chevron. In this context, the commenter essentially argues that the Lead Industries decision rested on two factors that are no longer probative: (1) That there was no indication that Congress meant to allow consideration of costs in NAAQS decisions, and (2) that Congress specifically provided for such consideration in other sections of the Act but not in section 109. On

<sup>54</sup> In practice, analysis of this question is sometimes referred to as a “Chevron step one” analysis.

<sup>55</sup> See, e.g., 647 F.2d at 1148–51, 1152–53 & n.43, 1160–61.

the first point, the commenter argues that EPA is free under Chevron to consider costs and similar factors (by reinterpreting section 109) unless there is evidence that Congress intended to restrict its discretion. As to the second point, the commenter argues that similar reasoning was rejected in Vinyl Chloride.

In Vinyl Chloride, however, an en banc decision that post-dated Chevron, the Court essentially underscored the point that such issues cannot be decided mechanically but must turn, instead, on more analytical attention to relevant indicia of congressional intent. See, e.g., 824 F.2d at 1157 n.4; *id.* at 1157–63. With reference to NAAQS decisions in particular, the Court concluded that there were concrete indications of congressional intent to preclude consideration of costs and similar factors; for example, the fact that section 108 “enumerate[s] specific factors to consider and pointedly exclude[s] feasibility.” 824 F.2d at 1159. In a later case, moreover, the same Court held that EPA could not consider certain factors, in decisions under section 211(f)(4) of the Act, for reasons exactly parallel to those that the commenter criticizes in Lead Industries. See *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1057–63 (D.C. Cir. 1995).

Beyond this, the commenter’s characterization of the Lead Industries decision ignores or discounts much of the key evidence cited by the Court, including the language, structure, and legislative history of the statutory scheme established in 1970, for its conclusion that Congress intended to preclude consideration of costs and similar factors in NAAQS decisions.<sup>56</sup> As indicated above, the Vinyl Chloride and PM<sub>10</sub> cases, both of which post-dated Chevron, reached the same conclusion.

Moreover, this series of decisions went far beyond mere deference to an agency interpretation. As indicated in the Vinyl Chloride case, the Lead Industries court found “clear evidence” of congressional intent, which was to limit the factors EPA may consider under section 109. 824 F.2d 1159. Consistent with Chevron, these findings were based on traditional tools of statutory construction. See *id.* at 1157–59; Lead Industries, 647 F.2d at 1148–51. In terms of the analytical framework later established by Chevron, these were Chevron step one findings, meaning that the statute spoke

<sup>56</sup> See 647 F.2d at 1148–51. By contrast, the commenter’s argument that Congress actually intended EPA to consider such factors relies heavily on (1) statements made in subsequent legislative history, most of which were made in floor debate, that sought to justify controversial amendments to establish a different program than the NAAQS and did not involve any proposed changes in section 109 or related provisions; and (2) statements in early judicial decisions involving programs under other statutory provisions. In context, EPA believes these and other statements cited by the commenter are consistent with and do not alter the conclusion that Congress intended to preclude consideration of costs and similar factors under section 109.

<sup>49</sup> They may have methodological flaws, for example, but nonetheless report effects that are of serious medical significance; or they may be of impeccable quality but involve effects of uncertain significance. Others may involve results that are striking but hard to explain in terms of previous knowledge, or results that seem plausible and important but are not yet replicated by other studies.]

<sup>50</sup> See, e.g., Lead Industries, 647 F.2d at 1155–56; H.R. Rep. No. 94–295, at 43–51 (1977).

<sup>51</sup> As previously discussed, the Administrator strongly emphasized the uncertainties involved in that review. As a result of the uncertainties, he proposed “relatively broad” ranges for comment, though he focused on lower levels within the ranges as providing greater margins of safety against the health risks involved. See 49 FR 10408, 10409, Mar. 20, 1984.

<sup>52</sup> See, e.g., Lead Industries, 647 F.2d at 1152–53 & n.43, 1159–60; Ozone, 665 F.2d at 1185, 1187; PM<sub>10</sub>, 902 F.2d at 969–71, 972.

<sup>53</sup> Indeed, the present decisions on the NAAQS for PM and ozone are based on some of the best scientific information the Agency has ever been able to rely on in NAAQS decision-making. In particular, the science underlying these decisions is much more extensive and of much better quality than the science underlying the existing NAAQS for PM and ozone.

directly to the issue and that the courts, as well as the agency, must give effect to Congress' intent as so ascertained. See 467 U.S. at 842-43.<sup>57</sup> Thus, absent a more recent legislative enactment overriding that intent, EPA has no discretion to alter its longstanding interpretation that consideration of costs and similar factors is precluded in NAAQS decisions under section 109.<sup>58</sup>

As to the commenter's third key assertion, Executive Order 12866 (58 FR 51735, October 4, 1993) UMRA sections 202 and 205, and the Regulatory Flexibility Act (RFA), as amended by SBREFA, do not conflict with this interpretation or require a different result. Basically, the commenter argues that the Executive Order, UMRA, and the RFA (as amended by SBREFA) require agencies to use cost (or similar factors) as a decisional criterion in making regulatory decisions, and that this modifies the Clean Air Act's directive that EPA is precluded from considering costs when setting a NAAQS. The commenter's argument is flawed on a number of grounds. First, UMRA and the RFA (as amended by SBREFA) do not conflict with section 109 because they do not apply to this decision, as discussed in Unit VIII of this preamble. Second, the Executive Order and both statutes are quite clear that they do not override the substantive provisions in an authorizing statute. Third, the commenter's premise that UMRA and the RFA (as amended by SBREFA) establish substantive decisional criteria that agencies are required to follow is wrong.

<sup>57</sup> The commenter argues that the post-Chevron cases accepted the Lead Industries analysis uncritically rather than re-examining it under Chevron. Clearly, this elevates form over substance. It is true that neither case referred to Chevron in discussing the point at issue. In Vinyl Chloride, however, the Court retraced the steps in the Lead Industries analysis in some detail, characterized some of the key evidence reviewed in that analysis in terms going beyond mere rote repetition (e.g., "a far clearer statement than anything in the present case that Congress considered the alternatives"), and used Chevron-like language in discussing the significance of that evidence; that is, that it demonstrated congressional intention on the point at issue. E.g., 824 F.2d at 1159. Given that the Vinyl Chloride case was decided 3 years after Chevron, that it was an en banc decision of the D.C. Circuit involving interpretation of statutory language very similar to that in Lead Industries, and that the Court cited Chevron twice in analyzing the language and history of section 112, it seems highly unlikely that the Court was unmindful of Chevron principles in concluding that Congress intended to preclude consideration of costs under section 109 but not under section 112.

In the PM<sub>10</sub> decision, the Court confirmed the sharp distinction it had drawn, based on such evidence of congressional intent, between sections 109 and 112 in Vinyl Chloride. 902 F.2d at 972-73. Although discussion of the point was brief and did not mention Chevron, the industry petitioner raising the point had cited Chevron in arguing that the Lead Industries interpretation was not binding, and that EPA's decision on the PM<sub>10</sub> standards should be reversed on the ground that it rested on a legal position that EPA unjustifiably believed was mandated by Congress. Reply Brief of the American Iron and Steel Institute at 11 & n.10, *Natural Resources Defense Council v. Administrator*, 902 F.2d 962 (D.C. Cir. 1990) (Nos. 87-1438 et al.). Thus, Chevron issues were properly before the Court and were brought squarely to its attention.

<sup>58</sup> See also 52 FR 24854, July 1, 1987.

As a matter of law, the Executive Order cannot (and does not purport to) override the Clean Air Act. The Executive Order does not conflict with section 109 because the requirement that agencies "select approaches that maximize net benefits" does not apply if a "statute requires another regulatory approach." EO 12866, sec. (1)(a), 58 FR 51735, Oct. 4, 1993. More generally, the Executive Order provides that agencies are to adhere to its regulatory principles only "to the extent permitted by law." *Id.*, sec. (1)(b).

UMRA sections 202 and 205 do not apply to this decision, as discussed in Unit VII of this preamble. Even when they do apply to a regulatory action, they do not establish decisional criteria that an agency must follow, much less override decisional criteria established in the statute authorizing the regulatory action. UMRA does not require an agency to select any particular alternative. Rather, an agency can select an alternative that is not the least costly, most cost-effective or least burdensome if the agency explains why, sec. 205(b)(1). Such an explanation is not required if the least costly, most cost-effective or least burdensome alternative would have been "inconsistent with law," sec. 205(b)(2), and the only alternatives that an agency should consider are ones that "achieve[] the objectives of the rule," sec. 205(a). The UMRA Conference Report confirms that UMRA does not override the authorizing statute. "This section [202] does not require the preparation of any estimate or analysis if the agency is prohibited by law from considering the estimate or analysis in adopting the rule." 141 Cong. Rec. H3063 (daily ed. March 13, 1995).

The RFA (as amended by SBREFA) also does not apply to this decision, as discussed in Unit VII of this preamble. As is the case with UMRA, even when the RFA (as amended by SBREFA) does apply to a regulatory action, it does not establish decisional criteria that an agency must follow, much less override the underlying substantive statute. When the RFA was adopted in 1980, Congress made clear that it did not alter the substantive standards contained in authorizing statutes: "The requirements of section 603 and 604 of this title [to prepare initial and final regulatory flexibility analyses] do not alter in any manner standards otherwise applicable by law to agency action." Section 606 of the RFA. The legislative history further explains that section 606 "succinctly states that this bill does not alter the substantive standard contained in underlying statutes which defines the agency's mandate."<sup>59</sup> When Congress passed SBREFA in 1996 and amended parts of the RFA, it did not amend section 606.

Even when a regulatory decision is subject to sections 603 and 604 and an agency is

<sup>59</sup> 126 Cong. Rec. 21452, 21455 (1980) (Description of Major Issues and Section-By-Section Analysis of Substitute for S. 299).

therefore required to analyze alternatives that minimize significant economic impacts on small entities, the RFA (as amended by SBREFA) does not establish decisional criteria that an agency is required to follow. Both section 603 and 604 provide that the alternatives an agency should consider are to be "consistent with the stated objectives of applicable statutes." Sec. 603 and 604(a)(5). Furthermore, although the RFA (as amended by SBREFA) requires agencies to consider alternatives that minimize impacts on small entities subject to the rules' requirements and to explain their choice of regulatory alternatives, it does not require agencies to select such alternatives. For these reasons, the RFA (as amended by SBREFA) does not conflict with or override the Clean Air Act's preclusion of considering costs and similar factors in setting NAAQS.

3. *Conclusion.* In summary, EPA believes that the judicial decisions cited above are both correct and dispositive on the question of considering costs in setting NAAQS, and that the Agency is not free to reinterpret the Act on that question.

#### B. Margin of Safety

Several commenters questioned the approach used by the Administrator in specifying O<sub>3</sub> standards that protect public health with an adequate margin of safety. Rather than the integrative approach applied by the Administrator, these commenters maintained that EPA must employ a two-step process. The line of argument was that the Administrator must first determine a "safe level" and then apply a margin of safety taking into account costs and societal impacts. It was argued that this was the only approach that would enable the Administrator to reach a reasoned decision on a standard level that protects public health against unacceptable risk of harm, such that any remaining risk was "acceptable." In effect, these commenters argued that the Administrator must adopt the two-step methodology endorsed in Vinyl Chloride, 824 F.2d 1146, for setting hazardous air pollutant standards under section 112.

In recognition of the complexities facing the Administrator in determining a standard that protects public health with an adequate margin of safety, the courts have declined to impose any specific requirements on the Administrator's methodological approach. Thus, in Lead Industries the court held that the selection of any particular approach to providing an adequate margin of safety "is a policy choice of the type Congress specifically left to the Administrator's judgment. This court must allow him the discretion to determine which approach will best fulfill the goals of the Act." 647 F.2d at 1161-62. As a result, the Administrator is not limited to any single approach to determining an adequate margin of safety and may, in the exercise of her judgment, choose an integrative approach, a two-step approach,

or perhaps some other approach, depending on the particular circumstances confronting her in a given NAAQS review.

With respect to the approach advanced in comment, the PM<sub>10</sub> case made clear that the two-step process endorsed in Vinyl Chloride was necessary because of the need under section 112 of the Act to "sever determinations that must be based solely on health considerations from those that may include economic and technical considerations." 902 F.2d at 973. Because the Administrator may not consider cost and technological feasibility under section 109, however, the court concluded that "the rationale for parsing the Administrator's determination into two steps is inapposite." *Id.*

Because such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, the types of health information available, and the kind and degree of uncertainties that must be addressed will vary from one pollutant to another, the most appropriate approach to establishing a NAAQS with an adequate margin of safety may be different for each standard under review. Thus, no generalized paradigm such as that imbedded in EPA's cancer risk policy can substitute for the Administrator's careful and reasoned assessment of all relevant health factors in reaching such a judgment. As noted above, both Congress and the courts have left to the Administrator's discretion the choice of analytical approaches and tools, including risk assessments, rather than prescribing a particular formula for reaching such determinations. Because of the inherent uncertainties that the Administrator must address in margin of safety determinations, they are largely judgmental in nature, particularly with respect to non-threshold pollutants, and may not be amenable to quantification in terms of what risk is "acceptable" or any other metric. In view of these considerations, the task of the Administrator is to select an approach that best takes into account the health effects and other information assessed in the air quality criteria for the pollutant in question and to apply appropriate and reasoned analysis to ensure that the scientific uncertainties are taken into account in an appropriate manner.

In this instance, the Administrator has clearly articulated the factors she has considered, the judgments she has had to make in the face of uncertain and incomplete information, and alternative views as to how such information should be interpreted, in reaching her decision on standard specifications that will protect public health with an adequate margin of safety. See Unit II of this preamble. Her conclusions on these matters are fully supported by the record.

### C. Comment Period

A number of commenters maintained that EPA erred by not extending the comment

period for the review of the O<sub>3</sub> standards by at least 60 days. The commenters further maintained there was no justification for keeping the O<sub>3</sub> standard review on the same schedule as the PM NAAQS, since the O<sub>3</sub> review is not subject to a court-ordered deadline as is PM.

The EPA believes that there are benefits to reviewing the O<sub>3</sub> and PM NAAQS on the same schedule, for the reasons set forth in the proposal, and that the period available for public comment was sufficient. All interested parties have had ample notice that EPA intended to complete this review of the O<sub>3</sub> standards on an expedited basis. The EPA first announced its intention in a March 9, 1993, **Federal Register** notice (58 FR 13008) when the Administrator announced her commitment to expedite the review in light of new scientific evidence of the effects of O<sub>3</sub> on human health. In a February 3, 1994, **Federal Register** notice (59 FR 5164), the Administrator announced a schedule for completion of the scientific assessment and review of the standards, including opportunities for public comment. This schedule called for proposal in mid-1996 and a final decision as to whether to revise the O<sub>3</sub> standard by mid-1997. On June 12, 1996, in an advance notice of proposed rulemaking (61 FR 29719), the Administrator announced her decision to delay the O<sub>3</sub> proposal schedule in order to place it on the same schedule as the PM standard review. In that notice, she explained her rationale for reviewing the O<sub>3</sub> and PM NAAQS on the same schedule and pointed to the benefits of developing integrated implementation strategies. She also provided advance notice of the kinds of revisions to the primary and secondary O<sub>3</sub> NAAQS that she was considering proposing. In effect, the delay of the O<sub>3</sub> proposal provided interested parties an additional 5 months to review EPA's assessments of the scientific and technical information, as well as staff and CASAC recommendations as to whether revisions were appropriate. With this background, EPA believes all interested parties had ample opportunity to develop specific comments on the O<sub>3</sub> proposal during the 89 days allotted for public comment.<sup>60</sup>

Another commenter raised a more specific issue in requesting a 60-day extension of the public comment period. This commenter maintained that such an extension was necessary because EPA did not make publicly available certain O<sub>3</sub> exposure and health risk assessment reports and an explanatory memoranda in a timely manner. In response, EPA notes that the documents in question were entered into the docket on February 12, 1997, and placed on the OAQPS Technology Transfer Bulletin Board on February 13, 1997, so that they would have wide public

circulation. Because this commenter's organization was aware that the reports were under preparation and had expressed interest in receiving them, copies were sent directly to the responsible staff person on February 12, 1997. Given that these reports build on analyses and methodologies that were available to the public during the scientific phase of the O<sub>3</sub> NAAQS review, well in advance of the proposal, and that the new analyses and explanatory memorandum were only 120 pages in length, EPA believes that this commenter had sufficient time to review the material and prepare comments before the close of the comment period on March 12, 1997.

### D. 1990 Act Amendments

Contrary to the view expressed in some public comments, EPA maintains that the provisions of subpart 2 of Part D of Title I of the Clean Air Act, enacted in 1990, do not preclude EPA from revising the O<sub>3</sub> standard. The provisions of subpart 2 simply do not limit EPA's clear authority under section 109 to revise the standard.

The basic contention of the commenters is that because the provisions of subpart 2 are linked to the current 1-hour, 0.12 ppm O<sub>3</sub> standard, they prohibit EPA from revising the O<sub>3</sub> standard. These provisions, however, do not lead to such a conclusion. Moreover, the view expressed in these comments ignores provisions indicating that Congress believed that EPA could revise the O<sub>3</sub> NAAQS.

At the outset, it should be noted that Congress expressly authorized EPA to revise any ambient air quality standard in section 109. That section, which requires EPA to review and revise, as appropriate, each NAAQS every 5 years, contains no language expressly or implicitly prohibiting EPA from revising a NAAQS. If Congress had intended to preclude EPA from reviewing and revising a NAAQS, which is one of EPA's fundamental functions, Congress would have specifically done so. Clearly, Congress knew how to preclude EPA from exercising otherwise existing regulatory authority and did so in other instances. See section 202(b)(1)(C) (expressly precluding EPA from modifying certain motor vehicle standards prior to model year 2004); section 112(b)(2) (preventing EPA from adding to the list of hazardous air pollutants any air pollutants that are listed under section 108(a) unless they meet the specific exceptions of section 112(b)(2)); section 249(e)(3), (f) and section 250(b) (limiting EPA's authority regarding certain clean-fuel vehicle programs). No such language was included in either section 109 or elsewhere in the Act and no such implication may properly be based on the provisions of subpart 2 of Part D of Title I.

Second, other provisions of the Act expressly contemplate EPA's ability to revise any NAAQS, and provide no indication that such ability is limited to standards other than

<sup>60</sup> This comment period reflects an extension of 22 days beyond the 67-day comment period originally announced in the proposal.

those whose implementation is the subject of subparts 2, 3 and 4 of Part D. For example, section 110(a)(2)(H)(i) provides that SIPs are to provide for revisions "from time to time as may be necessary to take account of revisions of such national primary or secondary ambient air quality standard \*\*\*." Section 107(d)(1)(A) provides a process for designating areas as attainment, nonattainment, or unclassifiable "after promulgation of a new or revised standard for any pollutant under section 109 \*\*\*." Section 172(e) addresses modifications of national primary ambient air quality standards. Finally, section 172(a)(1) expressly contemplates that EPA may revise a standard in effect at the time of enactment of the 1990 Clean Air Act Amendments. Section 172(a)(1)(A) provides EPA with authority to classify nonattainment areas on or after the designation of an area as nonattainment with respect to "any revised standard, including a revision of any standard in effect on the date of the enactment of the Clean Air Act Amendments of 1990." Plainly, Congress had no intention of prohibiting EPA from revising any of the ambient standards in effect at the time of the enactment of the 1990 amendments.

Third, the provisions of subpart 2 of Part D do not support the contention that they somehow preclude EPA from exercising its authority to revise the NAAQS under section 109. The fact that Congress laid out an implementation program for the O<sub>3</sub> standard existing at the time of the 1990 amendments in no way suggests that Congress intended to preclude EPA from exercising the authority it provided EPA to revise the NAAQS when the health data on which EPA bases such decisions warranted a change in the standard. Contrary to this contention, section 181(a) does not preclude the designation of areas as nonattainment for O<sub>3</sub> that have design values less than 0.121 ppm. EPA has designated as nonattainment numerous areas whose design value was less than 0.121 ppm, but which violated the existing 1-hour, 0.12 ppm O<sub>3</sub> standard. These areas, referred to as "nonclassifiable nonattainment areas," include "submarginal" areas (i.e., O<sub>3</sub> nonattainment areas with design values below 0.121 ppm), (See 57 FR 13498, 13524-27, April 16, 1992). These areas include areas that were designated nonattainment prior to the 1990 amendments and whose nonattainment designation Congress required to be continued after 1990. See section 107(d)(1)(C)(i). Clearly, Congress did not prohibit the designation of areas as nonattainment for O<sub>3</sub> with design values below 0.121 ppm; in fact, in some cases, Congress required it. Furthermore, the position advanced by the commenters would mean that, in effect, Congress in the 1990 amendments legislatively revised the then-existing 1-hour, 0.12 ppm O<sub>3</sub> standard to a

0.121 ppm standard. There is no indication that Congress intended to do that.

In addition, the fact that Congress directed EPA to use "the interpretation methodology issued by the Administrator most recently" before the date of the enactment of the Clean Air Act Amendments of 1990 in the context of subpart 2 does not add any support to the commenters' position; it merely shows that Congress intended the existing 1-hour, 0.12 ppm standard to be implemented in a specified way, not that Congress intended to preclude EPA from using its otherwise applicable authority to revise the standard.

The EPA also disagrees with the contention that sections 172(a)(1)(C) and (a)(2)(D), which provide that the general classification and attainment date provisions of section 172 do not apply to areas for which classifications or attainment dates "are specifically provided under other provisions of this part," support the conclusion that Congress intended to prohibit EPA from revising the O<sub>3</sub> standard. These provisions simply mean that where Congress elsewhere provided for specific classifications and attainment dates, as in the case of subpart 2 regarding the 1-hour, 0.12 ppm standard, EPA is not to modify those classifications or dates. The EPA is not purporting to do this. These provisions do not lead to the conclusion that because Congress established them for the O<sub>3</sub> standard in effect at the time of the 1990 amendments, Congress meant that EPA could not revise that standard in order to appropriately protect public health.

EPA does not accept the thesis that revising the O<sub>3</sub> standard forces EPA to violate other provisions of the Act and, therefore, is not an "appropriate" revision of the standard under section 109. Revising the O<sub>3</sub> standard in accordance with the language of section 109 does not result in EPA violating any provision of the Act. On the other hand, a determination by EPA that the O<sub>3</sub> standard should not be revised, even though EPA concludes that it needs to be revised to protect public health with an adequate margin of safety, would violate section 109.

Also, EPA does not believe that carrying out the provisions of section 109 to set a new O<sub>3</sub> standard to protect public health with an adequate margin of safety somehow "risks undermining both perceptions and reality of the functioning of our democratic form of government." EPA is merely implementing the words of the Clean Air Act, a statute passed by the Congress and signed by the President. To refuse to revise the standard notwithstanding the need to protect public health as enunciated in section 109 would thwart the objectives of those who passed and signed the Clean Air Act on behalf of the American public.

Finally, for the reasons stated above, EPA's analysis of its ability to implement the revised O<sub>3</sub> standard under the provisions of subpart 1 of Part D of Title I does not support

the view that Congress prohibited EPA from revising the standard. Congress clearly specified an approach to the implementation of the 1-hour, 0.12 ppm O<sub>3</sub> standard in the provisions of subpart 2 of Part D. EPA believes that the clear and express linkage of that approach to the 1-hour, 0.12 ppm standard indicates that it may implement a revised O<sub>3</sub> standard in accord with the general principles of subpart 1 of Part D, as informed by the no-backsliding principle embodied in section 172(e). That Congress directed specifically how EPA and the States should implement the 1-hour, 0.12 ppm O<sub>3</sub> standard does not carry with it the implication that Congress intended to prohibit EPA from exercising its otherwise clear and express authority to revise that standard in order to carry out one of its fundamental missions, the establishment of ambient air quality standards to protect public health with an ample margin of safety. If Congress had intended to prohibit EPA from exercising such a fundamental authority it would have clearly specified (as it did in other instances) that EPA could not do so.

The EPA also disagrees with the contention that a revised O<sub>3</sub> standard may not be implemented for so long as the current 1-hour, 0.12 ppm O<sub>3</sub> standard remains in effect. The fact that the provisions of subpart 2 of Part D are focused on the implementation of the current standard does not mean that, if a new or revised O<sub>3</sub> standard is promulgated pursuant to section 109, the new standard could not simultaneously be implemented under the provisions of section 110 and subpart 1 of Part D, which apply regardless of the criteria pollutant of concern. There is no language in sections 181 or 182 that precludes the implementation of a different standard under other authority; those provisions simply govern the implementation of the 1-hour, 0.12 ppm O<sub>3</sub> standard. EPA further notes that it has historically had more than one primary standard for criteria pollutants (e.g., annual and 24-hour PM<sub>10</sub> and sulfur dioxide standards, and 8-hour and 1-hour CO standards) and believes that had Congress wanted to preclude EPA from implementing two primary O<sub>3</sub> standards simultaneously it would have expressly precluded EPA from doing so. Thus, EPA does not believe that it must repeal the 1-hour, 0.12 ppm O<sub>3</sub> standard before it can promulgate and implement a new primary O<sub>3</sub> standard.

## V. Technical Changes to Part 50

In the proposal, the EPA proposed two alternative secondary standards: (1) A secondary standard set identical to the proposed 0.08 ppm, 8-hour primary standard; or (2) a seasonal secondary standard expressed in the SUM06 form. For the reasons discussed in Unit III, the EPA has decided to promulgate a secondary ambient air quality standard for O<sub>3</sub> that is identical to the primary ambient air quality standard.

Accordingly, the language adopted in the final regulation (40 CFR 50.10) has been revised to reflect this change.

In the proposal, the regulatory text in § 50.9 inadvertently included language about what it means when the standard is not met, that should have been discussed in 40 CFR part 50, Appendix H. Therefore this sentence has been removed from § 50.10(b), and the discussion moved to the new Appendix I to 40 CFR part 50, which now provides additional clarification on calculations for sites with less than complete data, as discussed in Unit VI. of this preamble.

## VI. Revisions to Appendices D, E, and H

The EPA is finalizing the changes to Appendices D and E to 40 CFR part 50, that were proposed and described in the proposal. No adverse comments were received on these changes.

Because the revocation of the existing 1-hour standard will become effective at a later date (as discussed above in Unit II.B.4.), EPA is retaining Appendix H in its current form. A new Appendix I explains the computations necessary for determining when the new 8-hour primary and secondary standards are met.

The new Appendix I addresses data completeness requirements, data reporting, handling, and rounding conventions, and example calculations. The discussion in this unit sometimes refers to the contents of the new Appendix I as revisions to Appendix H, so as to highlight how the new Appendix I differs from the current Appendix H. For example, the example calculations in Appendix I differ from those in Appendix H to reflect the final form of the new 8-hour primary standard.

In the proposal, two alternative secondary standards were proposed, and the proposed changes to Appendix H addressed both alternatives: A secondary standard set identical to the proposed 0.08 ppm, 8-hour primary standard; or a seasonal secondary standard expressed in the SUM06 form. For the reasons discussed above, the Administrator has decided to set the secondary standard identical to the primary standard as reflected in Appendix I.

Key elements of Appendix I, particularly as they differ from those of Appendix H, are outlined below.

### A. Data Completeness

One key change to Appendix H, incorporated into Appendix I, for the new 0.08 ppm, 8-hour primary and secondary standards is that no numerical adjustment is made to the measured 8-hour concentrations to account for missing or incomplete data as was the case with the 1-hour standard. Instead, the EPA has decided to replace the methodology used to adjust the computation of estimated exceedances for missing data under the 1-hour standard with new data

completeness requirements for the 8-hour standards.

The EPA proposed that, in order to determine that the 8-hour standards have been met at a monitoring site during the current 3-year period, revisions to Appendix H would require 90 percent data completeness, on average, with no single year at the site having less than 75 percent data completeness. A site could be found not to have met the standards with less than complete data. Almost all commenters supported deleting the estimated exceedances missing data adjustment procedure of the current 1-hour standard and replacing it with minimum data completeness requirements. Several commenters felt that the proposed data completeness requirement might be too stringent and would be difficult to attain. Other commenters recommended that some consideration be made for hours lost due to instrument calibration. A few commenters thought that EPA should establish higher minimum data completeness requirements.

Based on its analysis of available air quality data, the EPA believes that, with the changes to the proposal described below, the data completeness requirement in Appendix I is reasonable given that 90 percent of all monitoring sites that currently operate on a continuous basis meet this objective. The EPA believes that a missing hour during the day resulting from instrument calibration should not negatively impact the ability of a monitoring site to meet the data completeness requirements because data completeness is based on the number of days with valid daily maximum 8-hour concentrations, not on the number of non-missing hours.

In the proposal, the EPA sought comment on whether meteorological data could provide an objective basis for determining, on a day for which there is missing data, that the meteorological conditions were not conducive to high O<sub>3</sub> concentrations, and therefore, that the day could be assumed to have an 8-hour daily maximum O<sub>3</sub> concentration less than 0.08 ppm. Under the 0.12 ppm 1-hour standard, a missing day is assumed less than the level of the standard only if the two adjacent days are non-missing, and the daily maximum 1-hour concentration on each of those days is less than or equal to 0.09 ppm. In the proposal, the EPA specifically requested comment on the appropriateness of using data on meteorological conditions, as well as on other information that would permit better definition of those necessary conditions likely to result in peak 8-hour O<sub>3</sub> concentrations in the ranges of concern. Most commenters expressing an opinion supported the use of meteorological data, as well as ambient data from nearby monitoring sites to establish that missing hours could be assumed less than the level of the standard. Days assumed less than the level of the standard would be counted as non-missing when computing whether the data completeness requirements have been met at the site.

Taking these comments into account, EPA has revised the proposed revisions to Appendix H, as reflected in Appendix I, to count missing days assumed less than the standard when computing whether the data completeness requirement has been met. EPA will develop guidance on methodologies necessary for using meteorological data and ambient measurements to make such determinations.

Several commenters expressed concerns about the possibility that stratospheric O<sub>3</sub> intrusion from aloft or forest fires may lead to exceedances of the level of the standard, particularly within the context of peak O<sub>3</sub> concentrations that have been observed at background sites. Commenters expressed concern that such events could lead to violations of the 8-hour standard and, therefore, they questioned the attainability of the proposed standard. Consistent with a forthcoming update to EPA's policy on natural events for the new 8-hour standard, EPA has revised Appendix H to specifically address this concern by stating that whether to use data affected by stratospheric O<sub>3</sub> intrusion or other natural events when determining if the standards have been met is subject to the approval of the appropriate Regional Administrator.

### B. Data Handling and Rounding Conventions

For the reasons cited above, and taking into account the advice of CASAC, the Administrator has set the level of the new 8-hour primary and secondary standards at 0.08 ppm. As EPA explained in the proposal, the level of the 8-hour standard is expressed to the second decimal place, 0.08 ppm, with the support of CASAC and in part to reflect uncertainties in the health effects evidence upon which the proposed standard is based. More specifically, these uncertainties include the measurement uncertainty and representativeness inherent in the reported ambient O<sub>3</sub> concentrations used in field and epidemiological studies and the uncertainty in the exposure estimates upon which quantitative risk assessments have been based. In the proposal, EPA stated its belief that expressing the proposed standard to the second decimal place is also consistent with the quality assurance guidelines that indicate the precision<sup>61</sup> for such O<sub>3</sub> measurements shall be within ± 15 percent.

To determine whether the standard is met, EPA proposed that the calculated value of the third-highest maximum 8-hour average concentrations, averaged over 3 years, is compared to the level of the standard. It is the level of the standard, 0.08 ppm, expressed to two decimal places that determines the number of significant digits to be used when comparing air quality measurements to the

<sup>61</sup> The term precision is used to denote both the reproducibility of a measurement under a constant set of conditions, as well as other components of measurement uncertainty such as instrument drift and relative bias.

standard. The EPA proposed that, for hourly data, 8-hour average O<sub>3</sub> concentrations computed from such hourly data, and the 3-year averages of the third highest maximum 8-hour average concentrations, that the third decimal place is carried forward as the rounding digit, and the insignificant digits are truncated. To compare the calculated 3-year average O<sub>3</sub> concentration to the level of the standard, the third decimal place of the calculated value is rounded. The current rounding convention is to round up digits equal to or greater than 5.

In the proposal, EPA recognized that the level of public health protection afforded by the use of the current rounding convention could be increased by replacing the current rounding convention with a convention that defined the smallest increment above the level of the standard to be 0.001 ppm for the purposes of determining whether the standard has been met. The EPA solicited comment on the use of such an alternative rounding convention, with regard to potential increased public health protection, as well as to potential effects on the probability of attainment misclassifications and on the stability of the standard.

Of the many States that commented specifically on the rounding convention, most State agencies cited concerns by their monitoring staffs about the precision and accuracy of measured O<sub>3</sub> concentrations in ambient environments and recommended maintaining the current rounding convention. A tribal association also supported the current rounding convention. Other State agencies felt that newer instruments were capable of supporting a rounding convention set at 0.001 ppm. Of those environmental and health associations that commented, all supported replacing the current rounding convention with the alternative 0.001 ppm convention.<sup>62</sup> All industry and trade associations that commented on rounding recommended that EPA retain the current rounding convention.

After taking these comments into account, EPA has decided that the current rounding approach is appropriate for comparing monitoring data to the level of the standard expressed to two decimal places. The current rounding procedure has the effect of reducing the probability of misclassifying an attainment area as nonattainment and of producing a more stable attainment test. The EPA believes that measures that promote a stable control program will lead to greater long-term health protection and risk reduction. For the reasons stated above, and taking into account the uncertainty in the exposure estimates upon which quantitative

risk assessments have been based, measurement uncertainty, data representativeness, and the desirability of these resulting effects, EPA is retaining the current rounding convention and finalizing the data handling and rounding conventions, in Appendix I, as proposed.

## VII. Regulatory and Environmental Impact Analyses

As discussed in Unit IV of this preamble, the Clean Air Act and judicial decisions make clear that the economic and technological feasibility of attaining ambient standards are not to be considered in setting NAAQS, although such factors may be considered in the development of State plans to implement the standards. Accordingly, although, as described below, a Regulatory Impact Analysis (RIA) has been prepared, neither the RIA nor the associated contractor reports have been considered in issuing this final rule.

### A. Executive Order 12866

Under Executive Order 12866, 58 FR 51735 (October 4, 1993), the Agency must determine whether a regulatory action is "significant" and, therefore, subject to Office of Management and Budget (OMB) review and other requirements of the Executive Order. The order defines "significant regulatory action" as any regulatory action that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency.

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

In view of its important policy implications, this action has been judged to be a "significant regulatory action" within the meaning of the Executive Order. As a result, under section 6 of the Executive Order, EPA has prepared an RIA, entitled "Regulatory Impact Analysis for Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule (July 1997)." This RIA assesses the costs, economic impacts, and benefits associated with potential State implementation strategies for attaining the PM and O<sub>3</sub> NAAQS and the proposed Regional Haze Rule. Changes made in response to OMB suggestions or recommendations will be documented in the

public docket and made available for public inspection at EPA's Air and Radiation Docket Information Center (Docket No. A-95-58). The RIA will be publicly available in hard copy by contacting the U.S. Environmental Protection Agency Library at the address under "Availability of Related Information" and in electronic form as discussed above in "Electronic Availability."

### B. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., provides that, whenever an agency is required to publish a general notice of rulemaking for a proposed rule, the agency must prepare an initial regulatory flexibility analysis for the proposed rule unless the head of the agency certifies that the rule "will not, if promulgated, have a significant economic impact on a substantial number of small entities" (section 605(b)). The EPA certified each of the proposed NAAQS rules based on its conclusion that the rule would not establish requirements applicable to small entities and therefore would not have a significant economic impact on small entities within the meaning of the RFA. See 61 FR 65638, 65668 (PM proposal); 61 FR 65716, 65746 (ozone proposal), both published on December 13, 1996. Accordingly, the Agency did not prepare an initial regulatory flexibility analysis for the proposed rule, but it did conduct a more general analysis of the potential impact on small entities of possible State strategies for implementing any new or revised NAAQS.

At the heart of EPA's certification of the proposed NAAQS rule was the Agency's interpretation of the word "impact" as used in the RFA. Is the "impact" to be analyzed under the RFA a rule's impact on the small entities that will be subject to the rule's requirements, or the rule's impact on small entities in general, whether or not they will be subject to the rule? In the case of NAAQS rules, the question arises because of the congressionally-designed mixture of Federal and State responsibilities in setting and implementing the NAAQS.

As EPA explained in the proposal, NAAQS rules establish air quality standards that States are primarily responsible for meeting. Under section 110 and part D of Title I of the CAA, every State develops a State Implementation Plan (SIP) containing the control measures that will achieve a newly promulgated NAAQS. States have broad discretion in the choice of control measures. As the U.S. Supreme Court noted in *Train v. NRDC*:

[P]rimary [NAAQS] deal with the quality of outdoor air and are fixed on a nationwide basis at a level which the agency determines will protect the public health. It is the attainment and maintenance of these standards which section 110(a)(2)(A) requires that State plans provide. In complying with this requirement, a State's plan must include "emission limitations" which are regulations of the composition of substances

<sup>62</sup> One individual commenter provided an analysis of current monitoring technology and suggested that the precision and accuracy data supported setting the standard to three decimal places and rounding the annual average third-highest 8-hour average concentration up at 0.001 ppm. EPA believes that the precision and accuracy data cited by the commenter does not capture all of the uncertainty inherent in ambient air quality measurements.

emitted into the ambient air from such sources as power plants, service stations and the like. They are the specific rules to which operators of pollution sources are subject and which, if enforced, should result in ambient air which meets the national standards.

The Agency is plainly charged by the Act with the responsibility for setting the national ambient air standards. Just as plainly, it is relegated to a secondary role in the process of determining and enforcing the specific, source-by-source emission limitations which are necessary if the national standards are to be met. Under 110(a)(2), the Agency is required to approve a State plan which provides for the timely attainment and maintenance of the ambient air standards, and which also satisfies that section's other general requirements. The Act gives the agency no authority to question the wisdom of a State's choices of emission limitations if they are part of a plan which satisfies the standards of 110(a)(2) and the Agency may devise and promulgate a plan of its own only if the state fails to submit an implementation plan which satisfies those standards. Section 110(c).

421 U.S. 60, at 78–79 (1975) (emphasis in original). In short, NAAQS rules themselves do not establish any control requirements applicable to small entities. State rules implementing the NAAQS may establish such requirements and the extent to which they do depends primarily on each State's strategy for meeting the NAAQS.<sup>63</sup>

To determine the proper interpretation of "impact" under the RFA, EPA considered the RFA's stated purpose, its requirements for regulatory flexibility analyses, its legislative history, the amendments made by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)(Pub. L. 104–121), and caselaw. The EPA concluded that all of these traditional tools of statutory construction point in one direction—that an agency is required to assess the impact of a rule on the small entities that will be subject to the rule's requirements, because the purpose of a regulatory flexibility analysis is to consider ways of easing or even waiving a rule's requirements as they will apply to small entities, consistent with the statute authorizing the rule. That purpose cannot be served in the case of the rules like the NAAQS that do not have requirements that apply to small entities.

More specifically, EPA noted that its interpretation of "impact" flows from the express purpose of the RFA itself. As the RFA's "Findings and Purposes" section (Pub. L. 96–354, section 2) makes clear, Congress enacted the RFA in 1980 out of concern that agencies were writing one-size-fits-all regulations that in fact did not fit the size and resources of small entities. Congress

noted that it is generally easier for big businesses to comply with regulations, and that small businesses are therefore at a competitive disadvantage in complying with uniform rules. Congress also noted that small entities' relative contribution to the problem a rule is supposed to solve may not warrant applying the same requirements to large and small entities alike. In the RFA itself, Congress therefore stated:

It is the purpose of this Act to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.

[Pub. L. 96–354, section 2(b).]

The EPA further noted that the RFA sections governing initial and final regulatory flexibility analyses reflect this statement of purpose. RFA sections 603 and 604 require that initial and final regulatory flexibility analyses identify the types and estimate the numbers of small entities "to which the proposed rule will apply" (sections 603(b)(3) and 604(a)(3)). Similarly, they require a description of the "projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement" (sections 603(b)(4) and 604(a)(4)). At the core of the analyses is the requirement that agencies identify and consider "significant regulatory alternatives" that would "accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities" (section 603(c) and 604(a)(5)). Among the types of alternatives agencies are to consider are the establishment of different "compliance or reporting requirements or timetables" for small entities and the exemption of small entities "from coverage of the rule, or any part" of the rule (section 603(c)(1) and (4)). The RFA thus makes clear that regulatory flexibility analyses are to focus on how to minimize rule requirements on small entities.

As EPA further explained, since regulatory flexibility analyses are not required for a rule that will not have a "significant economic impact on a substantial number of small entities," it makes sense to interpret "impact" in light of the requirements for such analyses. Regulatory flexibility analyses, as described above, are to consider how a rule will apply to small entities and how its requirements may be minimized with respect to small entities. In this context, "impact" is appropriately interpreted to mean the impact of a rule on the small entities subject to the rule's requirements.

The Agency cited two Federal court cases in support of its interpretation. In *Mid-Tex Elec. Co-op v. FERC*, 773 F.2d 327, 342 (D.C. Cir. 1985), petitioners claimed that the

RFA required an agency to analyze the effects of a rule on small entities that were not regulated by the rule but might be indirectly impacted by it. Petitioners noted that the Small Business Administration (SBA) also interpreted the RFA to require analysis of a rule's impact on small entities not regulated by the rule, and argued that the court should defer to the SBA's position in light of its compliance monitoring role under the RFA. After reviewing the RFA's "Findings and Purposes" section, its legislative history, and its requirements for regulatory flexibility analyses, the Mid-Tex court rejected petitioners' interpretation. As the court explained:

The problem Congress stated it discerned was the high cost to small entities of compliance with uniform regulations, and the remedy Congress fashioned—careful consideration of those costs in regulatory flexibility analyses—is accordingly limited to small entities subject to the proposed regulation. \*\*\* [W]e conclude that an agency may properly certify that no regulatory flexibility analysis is necessary when it determines that the rule will not have a significant economic impact on a substantial number of small entities that are subject to the requirements of the rule.

*Id.* at 342. Notably, Congress let this interpretation stand when it recently amended the RFA in enacting the SBREFA.

The EPA also cited a recent case affirming the Mid-Tex court's interpretation. In *United Distribution Companies v. FERC*, 88 F.3d 1105, 1170 (D.C. Cir. 1996), the court noted that the Mid-Tex court:

\*\*\* conducted an extensive analysis of the RFA provisions governing when a regulatory flexibility analysis is required and concluded that no analysis is necessary when an agency determines "that the rule will not have a significant economic impact on a substantial number of small entities that are subject to the requirements of the rule".

*Id.*, citing and quoting Mid-Tex (emphasis added by United Distribution court).

The Agency went on to explain that given the Federal/State partnership for attaining healthy air, the proposed NAAQS, if adopted, would not establish any requirements applicable to small entities. Instead, any new or revised standard would establish levels of air quality that States would be primarily responsible for achieving by adopting plans containing specific control measures for that purpose. The proposed NAAQS rule was thus not susceptible to regulatory flexibility analysis as prescribed by the amended RFA. Since it would establish no requirements applicable to small entities, it afforded no opportunity for EPA to fashion for small entities less burdensome compliance or reporting requirements or timetables, or exemptions from all or part of the rule. For these reasons, EPA certified that the proposed rule "will not, if promulgated, have a significant economic impact on a substantial number of small entities," within the meaning of the RFA. Because EPA was not required to prepare an initial regulatory

<sup>63</sup> It is worth noting that Federal rules that apply nationally also play a role in reducing emissions governed by NAAQS. For instance, EPA rules under Title II of the CAA require reductions in ozone-forming emissions from on and off-road vehicles and the fuels that power them. When EPA issues such rules, it conducts the analysis required under the RFA. For example, EPA performed regulatory flexibility analyses for the reformulated gasoline rule issued under section 211(k) of the CAA. See 59 FR 7716, February 16, 1994.

flexibility analysis for the rule, it was also not required to convene a Small Business Advocacy Review Panel for the rule under RFA section 609(b) as added by SBREFA.

Notwithstanding its certification of the proposed rule, EPA recognized that the proposed NAAQS, if adopted, would begin a process of State implementation that could eventually lead to small entities having to comply with new or different control measures, depending on the implementation plans developed by the States. EPA also recognized that the CAA does not allow EPA to dictate or second-guess how States should exercise their discretion in regulating to attain any new or revised NAAQS. Under those circumstances, EPA concluded that the best way to take account of small entity concerns regarding any new or revised NAAQS was to work with small entity representatives and States to provide information and guidance on how States could address small entity concerns when they write their implementation plans.

In line with this approach, as part of the RIA it prepared for the proposed NAAQS, EPA analyzed how hypothetical State plans for implementing the proposed rule might affect small entities. The analysis was necessarily speculative and limited, since it depended on projections about what States might do several years in the future and did not take into account any new strategies that might be developed and recommended by the FACA subcommittee formed to help devise potential strategies for implementing a new or revised NAAQS (see discussion of RIA and FACA process in the previous Unit of this notice). Nevertheless, the analysis provided as much information on potential small entity impacts as was reasonably available at the time of the proposed rule.

The Agency also took steps to ensure that small entities' voices were heard in the NAAQS rulemaking itself. With Jere Glover, Chief Counsel for Advocacy of the SBA, EPA convened outreach meetings modeled on the SBREFA panel process to solicit and convey small entities' concerns with the proposed NAAQS. Two meetings were held as part of that process, on January 7 and February 28, 1997, with a total attendance of 41 representatives of small businesses, small governments and small nonprofit organizations. Both meetings were attended by representatives of SBA and the Office of Management and Budget, as well as of EPA. The key concerns raised by small entities at those meetings related to the scientific foundation of the proposed NAAQS and the potential cost of implementing it, the same concerns raised by other industry commenters on the proposed rule. The Agency produced a report on the meetings to ensure that small entity concerns were part of the rulemaking record when EPA made its final decision on the proposal.

In light of States' pivotal role in NAAQS implementation, EPA also undertook a

number of additional activities to assist and encourage the States to be sensitive to small entity impacts as they implement any new or revised NAAQS. With the SBA, EPA began an interagency panel process to collect advice and recommendations from small entity representatives on how States could lessen any impacts on small entities. The EPA plans to issue materials in two phases to help States develop their implementation plans. In view of States' discretion in implementing the NAAQS, these materials will mostly take the form of guidance, which is not subject to the RFA's requirement for initial regulatory flexibility analysis. (Under RFA section 603, that requirement applies only to binding rules that are required to undergo notice-and-comment rulemaking procedures.) But regardless of the form such materials take, EPA is employing panel procedures to ensure that small entities have an opportunity to raise any concerns prior to the materials being issued in draft form.

To supplement the input the Agency receives from the ongoing CAAAC process (described earlier in this Unit of this preamble), EPA also added more small entity representatives to the subcommittee on implementation of any new or revised NAAQS. These representatives have formed a small entity caucus to develop and bring to the subcommittee a focused approach to small entity issues. These new subcommittee members are also part of the group in the aforementioned panel process. By means of these various processes, EPA hopes to promote the consideration of small entity concerns and advice throughout the NAAQS implementation process.

In response to the proposed rule, a number of commenters questioned EPA's decision to certify that the proposed NAAQS will not have a significant impact on a substantial number of small entities. Some commenters disagreed with EPA's view that the proposed NAAQS would not establish regulatory requirements applicable to small entities. These commenters argued that a number of control requirements applicable to small entities would automatically result from promulgation of the proposed NAAQS, such as new reasonable further progress, SIP and Federal Implementation Plan (FIP) requirements. Other commenters stated that it is possible for EPA to assess the impacts of the NAAQS revision on small entities and that, to a limited extent, EPA has already done so. Further, a number of commenters argued that EPA has a legal obligation under the RFA, as amended by SBREFA, to choose a NAAQS alternative that minimizes the impact on small entities. Some commenters questioned EPA's interpretations of the Mid-Tex and United Distribution cases. In addition, other commenters stated that EPA's position regarding the NAAQS and the RFA is inconsistent with its past practice and the legislative history of the RFA. Finally, a few commenters noted that the panel process EPA

conducted for the proposed NAAQS did not satisfy the requirements of SBREFA.

EPA disagrees that promulgation of the NAAQS will automatically result in control requirements applicable to small entities that EPA can and must analyze under the RFA. As noted previously, a NAAQS rule only establishes a standard of air quality that other CAA provisions call on States (or in case of State inaction, the Federal government) to achieve by adopting implementation plans containing specific control measures for that purpose. Following promulgation of a new or revised NAAQS, section 110 of the CAA requires States and EPA to engage in a designation process to determine what areas within each State's borders are attaining or not attaining the NAAQS. Under section 110 and parts C and D of Title I of the CAA, States then conduct a planning process to develop and adopt their SIPs. Depending on an area's designation for the particular NAAQS, these and other Title I provisions require a State's SIP to contain certain control programs in addition to the control measures that the State decides are also needed to attain and maintain the NAAQS.

The fact that the CAA requires SIPs to contain certain control programs under certain circumstances does not mean that EPA either can or must conduct a regulatory flexibility analysis of a rule establishing a NAAQS. Just from the standpoint of feasibility, EPA cannot know which areas will be subject to what mandatory SIP programs until after the designation process is completed. Beyond that, any mandatory SIP programs are still implemented by the States, and States have considerable discretion in how they implement them. For instance, the reasonable further progress requirement under section 172 leaves States broad discretion to determine the rate of progress and the control measures to achieve that progress.<sup>64</sup> As a result, EPA cannot be certain where and how any mandatory programs will be implemented with respect to small (or large) entities. Much less can EPA know about how States will exercise their discretion to develop additional controls needed to attain and maintain the NAAQS.

Even if EPA could know exactly how any mandatory SIP programs would apply to small entities, the purpose of the RFA is not served by attempting a regulatory flexibility analysis of State implementation of those

<sup>64</sup> Contrary to what some commenters assumed, the SIP requirements of subpart 2 of part D of Title I will not apply to SIPs to implement the revised ozone NAAQS. Those requirements were enacted by Congress in 1990 to address nonattainment of a 0.12 ppm 1-hour ozone NAAQS. To the extent those requirements remain in effect, they apply only to SIPs for areas still in nonattainment with that standard; they do not apply to SIPs for areas in nonattainment only with respect to the ozone NAAQS adopted today. Further, to the extent SIPs for areas in nonattainment with the previous ozone standard remain subject to subpart 2 requirements, there will be no incremental change in the impact on sources regulated by the States' SIPs pursuant to the requirements as a result of today's promulgation.

programs. As explained previously, the RFA and the caselaw interpreting it clearly establish that the purpose of the RFA is to promote Federal agency efforts to tailor a rule's requirements to the scale of the small entities that will be subject to it. That purpose cannot be served in the case of a NAAQS rule since the rule does not establish requirements applicable to small entities. In promulgating a NAAQS, the only choice before EPA concerns the level of the standard, not its implementation. While mandatory SIP programs may ultimately follow from promulgation of the NAAQS, there is nothing EPA can do in setting the NAAQS to tailor those programs as they apply to small entities. Whether and how the programs will apply in particular nonattainment areas is beyond the scope of the NAAQS rulemaking and, indeed, beyond EPA's reach in any rulemaking to the extent the applicability and terms of the programs are prescribed by statute.<sup>65</sup> Moreover, any mandatory SIP programs are supplemented by discretionary State controls that EPA has no power to tailor under the RFA or the CAA (see *Train v. NRDC*, quoted previously).

The commenters' suggestions for minimizing the potential impact of the NAAQS rule on small entities run afoul of both the RFA and the CAA. Some suggested that EPA set a less stringent standard (or no standard at all in the case of PM<sub>2.5</sub>) to reduce the chance that small entities would become subject to new or tighter SIP requirements. Others suggested that EPA require States to exempt small entities from new or tighter SIP requirements. However, as explained in a previous Unit of this notice addressing the Agency's authority to consider factors other than public health in setting primary NAAQS, the RFA neither requires nor authorizes EPA to set a less stringent NAAQS than the applicable CAA provisions allow in order to reduce potential small entity impacts. Indeed, the RFA provides that any means of providing regulatory flexibility to small entities be consistent with the statute authorizing the rule. Moreover, even if EPA set a less stringent standard, States could still exercise their discretion to obtain any needed emission reductions from small entities. As the Supreme Court in *Train v. NRDC* made clear, EPA has no authority to forbid States from obtaining reductions from any particular category of stationary sources, including small entities. See also, *Virginia v. EPA*, No. 108 F.3d 1397, 1408 (D.C. Cir. 1997), quoting *Union Electric v. EPA*, 427 U.S. 246, 269 (1976) ("section 110 left to the states the power to determine which sources would be burdened by regulations and to what extent").

EPA's approval of SIPs for the new or revised NAAQS also will not establish new

requirements, but will instead simply approve requirements that a State is already imposing. And again, EPA does not have authority to disapprove a State's plan except to the extent that the plan fails to demonstrate attainment and maintenance of the NAAQS as required by Title I of the CAA. In cases where EPA promulgates a FIP, EPA might establish control requirements applicable to small entities, and in such a circumstance, EPA would conduct the analyses required by the RFA.

Some commenters argued that under the RFA as amended by SBREFA, EPA now has an obligation to choose the alternative that minimizes the impact on small entities when setting the NAAQS. As indicated above, EPA disagrees with the commenters' argument for the reasons stated in the Unit of this notice discussing the Agency's authority to consider costs and other factors not related to public health in setting and revising primary NAAQS. In a nutshell, both the text and legislative history of the RFA make clear that the RFA does not override the substantive provisions of the statute authorizing the rule, but only requires agencies to identify and consider ways of minimizing the economic impact on small entities subject to the rule in a manner consistent with the authorizing statute.

Some commenters disagreed with EPA's interpretation of the Mid-Tex and United Distribution cases. In particular, these commenters noted that in those cases the relevant regulatory agency, FERC, wholly lacked jurisdiction to regulate the small entities at issue. According to these commenters, EPA does have the ability and jurisdiction to regulate small entities in the case of the NAAQS, and therefore EPA's reliance on Mid-Tex and United Distribution is misplaced.

The commenters' attempt to distinguish the FERC cases from the NAAQS rulemaking wholly overlooks the courts' reasoning, which in fact fully supports EPA's certification of the proposed NAAQS. As described above, the Mid-Tex court exhaustively reviewed the relevant sections of the RFA and its legislative history. Its analysis revealed that Congress passed the RFA out of concern with one-size-fits-all regulations and fashioned a remedy limited to regulations that apply to small entities. This principle is fully applicable to the NAAQS, which creates no rule requirements that apply to small entities.

The fact that FERC had no regulatory authority over the small entities indirectly affected by its rules played no essential role in the court's rationale. FERC could (and apparently did in the Mid-Tex rulemaking) estimate the potential indirect impact of its rules on small entities. Presumably, FERC could have also mitigated any indirect impact by changing some aspect of the rule (or else the small entities would have had no incentive to sue the agency). The court nevertheless found it unnecessary for FERC

to do either, based on its reading of the RFA as limited to analysis of a rule's impact on the small entities subject to the rule's requirements. In reaching its decision, the court noted that requiring agencies to "consider every indirect effect that any regulation might have on small businesses \*\*\* is a very broad and ambitious agenda, \*\*\* that Congress is unlikely to have embarked on \*\*\* without airing the matter." *Mid-Tex*, 773 F.d. at 343.

The commenters also overstate EPA's regulatory authority over small entities with respect to the regulation of criteria pollutants. Various CAA provisions authorize EPA to regulate various types of sources at the Federal level to accomplish specified goals. However, EPA's authority to more generally regulate sources, including small entities, in the manner of SIPs is limited to instances of State default of SIP responsibilities. When that occurs, EPA may issue a FIP containing specific control measures, and to the extent a proposed FIP would establish control measures applicable to small entities, EPA would analyze the small entity impact of those measures as required by the RFA. In 1994, for example, EPA prepared an initial regulatory flexibility analysis when it proposed a FIP for Los Angeles. See 59 FR 23264, May 5, 1994.

As noted above, Congress let the Mid-Tex interpretation stand when it recently amended the RFA in enacting SBREFA. If it had disagreed with the court's decision, it would have revised the relevant statutory provisions or otherwise indicated its disagreement when it enacted SBREFA. Instead, Congress actually reinforced the Mid-Tex court's interpretation of the RFA in enacting section 212(a) of SBREFA. That section requires that an agency issue a "small entity compliance guide" for "each rule \*\*\* for which an agency is required to prepare a final regulatory flexibility analysis under section 604" of the RFA. The guide is "to assist small entities in complying with the rule" by "explain[ing] the actions a small entity is required to take to comply" with the rule (SBREFA section 212(a)). Obviously, it makes no sense to prepare a small entity compliance guide for a rule that does not apply to small entities. SBREFA thus stands as further confirmation that Congress intended regulatory flexibility analyses to address only rules that establish requirements small entities must meet. Since SBREFA's passage, the United Distribution court has affirmed the Mid-Tex court's interpretation.

Some commenters noted that EPA's informal panel process did not comply with the requirements of SBREFA. The EPA did not convene a SBREFA panel because such a panel is not required for rules like the NAAQS that do not apply to small entities. Under the RFA as amended by SBREFA, since the Agency certified the proposal, it was not required to convene a panel for it. Nevertheless, EPA conducted the voluntary

<sup>65</sup> If and when the Agency issues any rules addressing State implementation of any statutorily required actions, EPA would analyze and address the impact of those rules on small entities as appropriate under the RFA.

panel process described above, as well as other voluntary small business outreach efforts. The process could not comply with the analytical requirements of the RFA for the reasons given above. However, it could and did ensure that EPA heard directly from small entities about the NAAQS proposals.

A few commenters stated that EPA's view of the NAAQS and the RFA is inconsistent with EPA's past positions regarding the RFA and NAAQS revisions. Some commenters also cited the Regulatory Impact Analysis for the proposed NAAQS and noted that this analysis demonstrates EPA's ability to estimate the impact of the NAAQS on small entities, thereby undercutting EPA's argument that it is not able to perform a regulatory flexibility analysis when setting the NAAQS.

Past **Federal Register** notices make clear that the nature of the NAAQS makes a regulatory flexibility analysis inapplicable to NAAQS rulemakings. For instance, in 1984, EPA stated that a "NAAQS for NO<sub>x</sub> by itself has no direct impact on small entities.

However, it forces each State to design and implement control strategies for areas not in attainment." 49 FR 6866, 6876, February 23, 1984; see also, 50 FR 37484, 37499, September 13, 1985; 50 FR 25532, 25542, June 19, 1985 (NAAQS for NO<sub>2</sub> do not impact small entities directly). EPA stated again in 1987 that the NAAQS "themselves do not contain emission limits or other pollution controls. Rather, such controls are contained in State implementation plans." 52 FR 24634, 24654, July 1, 1987.

EPA has typically performed an analysis to assess, to the extent practicable, the potential impact of retaining or revising the NAAQS on small entities, depending on possible State strategies for implementing the NAAQS. These analyses have provided as much insight into the potential small entity impacts of implementing revised NAAQS as could be provided at the NAAQS rulemaking stage. In some instances, these preliminary "analyses" were described as "regulatory flexibility analysis[es]" or as analyses "pursuant to this [Regulatory Flexibility] Act." See, e.g., 52 FR 24634, 24654, July 1, 1987; 50 FR 37484, 37499, September 13, 1985.

However, these analyses were based on hypothetical State control strategies, and EPA made the point on various occasions that any conclusions to be drawn from such analyses were "speculative," given that the NAAQS themselves do not impose requirements on small entities. Although these past analyses reflected the Agency's best efforts to evaluate potential impacts, they were not regulatory flexibility analyses containing the necessary elements required by the RFA. These analyses, for example, did not describe the "reporting, recordkeeping and other compliance requirements" of the proposed NAAQS rules that would apply to small entities, since the NAAQS rules did not apply to small entities. Nor did they determine how the proposed NAAQS rules could be eased or

waived for small entities. Such an analysis is not possible in the case of the NAAQS. To the extent EPA labeled these analyses regulatory flexibility analyses in the past, that label was inappropriate. EPA's current practice is to describe such an analysis more accurately as a "general analysis of the potential cost impacts on small entities." See, e.g., 61 FR 65638, 65669, 65747, December 13, 1996 (current O<sub>3</sub> and PM NAAQS proposals).<sup>66</sup> EPA's analytical approach to small entity impacts of the NAAQS has thus remained consistent over time.

One commenter noted that the legislative history of the RFA suggests that the RFA was intended to apply to the NAAQS. As noted previously, EPA's reading of both the RFA and SBREFA, based on the language of the statute as amended and its legislative histories and applicable caselaw, is that the RFA requirements at issue do not apply to the NAAQS. The legislative history cited by the commenter does not change this conclusion.

In fact, the statement by Senator Culver on which the commenter relies does not indicate that the NAAQS should be subject to regulatory flexibility analyses. Rather, Senator Culver uses the NAAQS as an example of the type of standard that agencies would not change as a result of the Regulatory Flexibility Act. According to Senator Culver, Section 606 "succinctly states that this bill does not alter the substantive standard contained in underlying statutes which defines the agency's mandate." 126 Cong. Rec. S 21455 (Aug. 6, 1980) daily ed. After citing CAA section 109, Senator Culver goes on to describe EPA's bubble policy (which addresses the limits on emissions from a particular facility) as the type of flexible regulation that agencies should consider, once EPA has set a NAAQS. "The important point for purposes of this discussion is that the 'bubble concept', a type of flexible regulation, in no manner altered the basic statutory substantive standard of the EPA \*\*\*. No regulatory flexibility analysis alters the substantive standard otherwise applicable by law to agency action." Id. Thus, contrary to the suggestion of the commenter, Senator Culver's statement actually confirms that the time to consider regulatory flexibility is when regulations

applicable to sources are being established, not when a NAAQS itself is being set.

Under section 604 of the RFA, whenever an agency promulgates a final rule under section 553 of the Administrative Procedure Act, after being required by that section or any other law to publish a general notice of proposed rulemaking (NPRM), the agency is required to prepare a final regulatory flexibility analysis. RFA section 605(b) provides, however, that section 603 (re initial regulatory flexibility analyses) and section 604 do not apply if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities and publishes such certification at the time of publication of the NPRM or at the time of the final rule.

As noted above, EPA certified today's rule at the time of the NPRM. After considering the public comments on the certification, EPA continues to believe that today's rule will not have a significant economic impact on a substantial number of small entities for the reasons explained above and that it therefore appropriately certified the rule. Further, as required by the CAA, EPA is promulgating today's rule under CAA section 307(d). For all the foregoing reasons, EPA has not prepared a final regulatory flexibility analysis for the rule. The Agency has nonetheless analyzed in the final RIA for the rule the potential impact on small entities of hypothetical State plans for implementing the NAAQS. The Agency also plans to issue guidance to the States on reducing the potential impact on small entities of implementing the NAAQS.

### C. Impact on Reporting Requirements

There are no reporting requirements directly associated with the finalization of ambient air quality standards under section 109 of the Act (42 U.S.C. 7409). There are, however, reporting requirements associated with related sections of the Act, particularly sections 107, 110, 160, and 317 (42 U.S.C. 7407, 7410, 7460, and 7617).

### D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year. This requirement does not apply if EPA is prohibited by law from considering section 202 estimates and analyses in adopting the rule in question. Before promulgating an EPA rule for which a written statement is needed, section 205 of the

<sup>66</sup> As commenters pointed out, the RIA for the proposed PM NAAQS does state that "[t]he screening analysis \*\*\* provides enough information for an initial regulatory flexibility analysis (RFA) if such an analysis were to be done." That statement was mistaken and was not made in the RIA for the proposed ozone NAAQS. While both RIAs attempted to gauge the potential impact on small entities of State implementation of the proposed NAAQS, neither could or did identify any specific control or information requirements contained in the NAAQS rule that would apply to small entities. Indeed, both RIAs made clear that the impact being analyzed was that of potential State measures to attain the NAAQS, and that such an analysis was inherently speculative and uncertain. Thus, the RIAs actually confirm EPA's statement in the preambles for the proposed NAAQS that conducting a complete regulatory flexibility analysis is not feasible for rules setting or revising a NAAQS.

UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. These requirements do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation of why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements. Section 204 of UMRA requires each agency to develop "an effective process to permit elected officers of State, local and tribal governments \*\*\* to provide meaningful and timely input" in the development of regulatory proposals containing a significant Federal intergovernmental mandate.<sup>67</sup>

The EPA has determined that the provisions of sections 202 and 205 of the UMRA do not apply to this decision. "Unless otherwise prohibited by law," EPA is to prepare a written statement under Section 202 of UMRA that is to contain assessments and estimates of the costs and benefits of a rule containing a Federal mandate. Congress clarified that "unless otherwise prohibited by law" referred to whether an agency was prohibited from considering the information in the rulemaking process, not to whether an agency was prohibited from collecting the information. The Conference Report on UMRA states, "This section [202] does not require the preparation of any estimate or analysis if the agency is prohibited by law from considering the estimate or analysis in adopting the rule." 141 Cong. Rec. H3063 (daily ed. March 13, 1995). Because the Clean Air Act prohibits EPA, when setting

the NAAQS, from considering the types of estimates and assessments described in section 202, UMRA does not require EPA to prepare a written statement under section 202.<sup>68</sup> The requirements in section 205 do not apply because those requirements only apply to rules "for which a written statement is required under section 202 \*\*\*."

The EPA has determined that the provisions of section 203 of UMRA do not apply to this decision. Section 203 only requires the development of a small government agency plan for requirements with which small governments might have to comply. Since setting the NAAQS does not establish requirements with which small governments might have to comply, section 203 does not apply. The EPA acknowledges, however, that any corresponding revisions to associated State implementation plan requirements and air quality surveillance requirements, 40 CFR part 51 and 40 CFR part 58, respectively, might result in such effects. Accordingly, EPA will address unfunded mandates as appropriate when it proposes any revisions to 40 CFR parts 51 and 58.

With regard to the outreach described in UMRA section 204, EPA did follow a process for providing elected officials with an opportunity for meaningful and timely input into the proposed NAAQS revisions, although EPA did not describe this process in the proposal. The EPA conducted a series of pre-proposal outreach meetings with State and local officials and their representatives that permitted these officials to provide meaningful and timely input on issues related to the NAAQS and the monitoring issues associated with them. Beginning in January, 1996, EPA briefed State and local air pollution control officials at national meetings with State and Territorial Air Pollution Program Administrators (STAPPA)/ Association of Local Air Pollution Control Officials (ALAPCO) in Washington DC, North Carolina, Chicago and Nevada. The EPA also held briefings for the Washington DC representatives of several State and local organizations, including National Conference of State Legislators, U.S. Conference of Mayors, National Governors Association, and National League of Cities, and STAPPA/ALAPCO. EPA also held separate briefings and discussions with State and local officials at meetings set up by the National Governors Association, the U.S. Conference of Mayors and the Council of State Governments. The

EPA also conducted in-depth briefings at each EPA regional office and regional staff also had several meetings and discussions with their State counterparts about the standards. The efforts described above, which provided elected officials with opportunity for meaningful and timely input into the proposed NAAQS revisions, met any requirements imposed by section 204. The docket will contain a written statement describing these outreach efforts, including a summary of the comments and concerns presented by State, local, and tribal governments and a summary of EPA's evaluation of those comments and concerns.

Several commenters disagreed with EPA that UMRA sections 202, 203 and 205 do not apply to this decision. These commenters argued that EPA is not prohibited from considering costs in setting NAAQS under the Clean Air Act and applicable judicial decisions. Some commenters also expressed the view that there is no conflict between UMRA and the Clean Air Act with regard to the NAAQS. These commenters argued that UMRA and the NAAQS can be "harmonized" by reading UMRA as an information gathering statute and that EPA should therefore perform the analyses required by UMRA, regardless of whether costs may be considered. Finally, at least one commenter argued that in past NAAQS reviews, EPA did not dispute its UMRA obligations.

As discussed more fully in Unit IV of this preamble, EPA is prohibited from considering cost in setting the NAAQS. Given that fact (as noted in Unit IV preamble), sections 202 and 205 do not apply.<sup>69</sup> As the Conference Report clarifies, UMRA itself states that the section 202 estimates and analyses are not required in cases such as the NAAQS, where an agency is prohibited by law from considering section 202 estimates and analyses. Reading UMRA in the manner suggested by the commenters would effectively read this provision out of UMRA; UMRA contains an exception for rules like the NAAQS, it must be given effect.

With regard to EPA's position regarding UMRA in previous NAAQS review exercises, EPA simply made plain in those situations that because it did not plan on revising the NAAQS, it determined, without further

<sup>67</sup> As noted in Unit VII.B. of this preamble, a NAAQS rule only establishes a standard of air quality that other provisions of the Act call on States (or in the case of State inaction, the Federal government) to achieve by adopting implementation plans containing specific control measures for the purpose. Thus, it is questionable whether the NAAQS itself imposes an enforceable duty and thus whether it is a significant Federal mandate within the meaning of UMRA. EPA need not and does not reach this issue today. For the reasons given in this unit, even if the NAAQS were determined to be a significant Federal mandate, EPA does not have any obligations under sections 202 and 205 of UMRA, and EPA has met any obligations it would have under section 204 of UMRA.

<sup>68</sup> In addition to the estimates and assessments described in section 202 of UMRA, written statements are also to include an identification of the Federal law under which the rule is promulgated (section 202(a)(1) of UMRA) and a description of outreach efforts under section 204 of UMRA (section 202(a)(5) of UMRA). Although these requirements do not apply here because a written statement is not required under section 202 of UMRA, this preamble identifies the Federal law under which this rule is being promulgated and a written statement describing EPA's outreach efforts with State, local, and tribal governments will be placed in the docket.

<sup>69</sup> One commenter argued that in reviewing the SO<sub>2</sub> NAAQS, EPA determined that it need not revise the SO<sub>2</sub> NAAQS, but could instead pursue an alternative regulatory program under other authority. This commenter argued that EPA has similar flexibility in reviewing the PM and Ozone NAAQS, and thus UMRA requires EPA to identify the least burdensome alternative (such as retaining the current NAAQS) as part of that process. As discussed more fully above at Unit IV of this preamble, EPA does not agree that it has flexibility to choose such an alternative; nor does EPA agree with the commenter's characterization of the action it took in deciding not to revise the SO<sub>2</sub> NAAQS. In fact, in deciding not to revise the SO<sub>2</sub> NAAQS, EPA determined, for reasons independent of section 303 of the Clean Air Act that a NAAQS revision was not warranted. See 61 FR 25566, 25575, May 22, 1996.

review, that UMRA sections 202, 203 and 205 did not apply. EPA thus stated that:

Because the Administrator has decided not to revise the existing primary NAAQS for SO<sub>2</sub>, this action will not impose any new expenditures on governments or on the private sector, or establish any new regulatory requirements affecting small governments. Accordingly, EPA has determined that the provisions of section 202, 203 and 205 do not apply to this final decision.

61 FR 25566, 25577, May 22, 1996; See also 61 FR 52852, 52856, October 8, 1996 (Same statement for NO<sub>2</sub> NAAQS). As this statement makes clear, EPA only determined that UMRA sections 202, 203 and 205 did not apply to the NAAQS when EPA fails to revise the standard. Having made that determination, EPA had no reason to catalogue additional bases for finding UMRA inapplicable. Nothing in that statement was intended to preclude EPA, or precludes EPA, from concluding for other reasons (such as those discussed above) that UMRA also does not apply when EPA in fact revises an applicable NAAQS.

#### E. Environmental Justice

Executive Order 12848 requires that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. These requirements have been addressed to the extent practicable in the RIA cited above.

#### F. Submission to Congress and the Comptroller General

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in today's **Federal Register**. This rule is a "major rule" for purposes of SBREFA.

### VIII. Response to Petition for Administrator Browner's Recusal

On March 13, 1997, the Washington Legal Foundation (WLF), filed a petition with EPA asking that I, Carol Browner, disqualify myself in rulemaking regarding the NAAQS for PM and O<sub>3</sub>. The petition claims that my public statements indicate a "clear and convincing showing" that I had "already decided to revise the NAAQS for PM and ozone" and that I therefore "could not give meaningful consideration" to comments adverse to the proposed rule. On May 12, 1997, EPA's General Counsel, Jonathan Z. Cannon, sent a letter to WLF regarding the petition. This letter and the WLF petition were then placed in the dockets for the proposed O<sub>3</sub> and PM standards pending

"consideration and final response in connection with the Agency's final actions."

Contrary to WLF's assertions, I have maintained an open mind throughout these proceedings, and have based today's decisions on the rulemaking record—including consideration of comments opposed to the proposal. The law does not require the Administrator of EPA to disqualify herself merely for expressing views on a proposed regulation; in fact, it is part of my responsibility to engage in the public debate on the proposals. Moreover, the assertions in WLF's petition do not accurately represent my views. The petition takes quotes out of context and repeatedly misinterprets my statements. For example, WLF quotes a statement that I made at the Children's Environmental Health Network Research Conference as an indication that I had "prejudged the issue." However, my statement that "I will not be swayed" did not refer to adopting the NAAQS as proposed. Instead, as is clear from reviewing the entire speech, I was addressing my broader concern about children's health and the range of EPA standards affecting children's health. I also appeared at several congressional hearings and testified before members of Congress, some of whom were strongly opposed to the proposals. At those hearings, I explained the basis for the proposals and put forward the reasons why I concluded the proposals were appropriate, given the information before me at the time. At the same time, I made clear that I took very seriously my obligation to keep an open mind, and to consider fully and fairly all significant comments that the Agency received. For these reasons and others, as set forth in Mr. Cannon's May 12, 1997 response to WLF, which I adopt in full, I have decided not to recuse myself from any aspect of considering revisions to the NAAQS for O<sub>3</sub> and PM. Accordingly, I am hereby denying WLF's petition.

### IX. References

- (1) American Thoracic Society. (1985) Guidelines as to what constitutes an adverse respiratory health effect, with special reference to epidemiologic studies of air pollution. *American Review of Respiratory Disease*. 131: 666-668.
- (2) Freas (1996) Ambient air quality relationships among alternative ozone air quality standards. Internal memorandum from Warren P. Freas to file, U.S. EPA, EMAD/OAQPS/OAR, RTP, NC, dated October 30, 1996. Docket No. A-95-58 Item II-B-6.
- (3) Freas (1997) Ambient air quality relationships for counties meeting alternative air quality standards. Internal memorandum from Warren P. Freas to file, U.S. EPA, EMAD/OAQPS/OAR, RTP, NC, dated July 1, 1997. Docket No. A-95-58 Item xxx.
- (4) Heck, Walter W. And Ellis B. Cowling. January, 1997. EM Journal. "The Need for a Long Term Cumulative Secondary Ozone Standard - An Ecological Perspective." Air and Waste Management Association, Pittsburgh, PA.; pp. 23-33.

(5) Johnson, T.; Capel, J.; Mozier, J.; McCoy, M. (1996a) Estimation of ozone exposures experienced by outdoor children in nine urban areas using a probabilistic version of NEM. Prepared by IT/Air Quality Services for U.S. EPA, OAQPS; Research Triangle Park, NC, August.

(6) Johnson, T.; Capel, J.; McCoy, M.; Mozier, J. (1996b) Estimation of ozone exposures experienced by outdoor workers in nine urban areas using a probabilistic version of NEM. Prepared by IT/Air Quality Services for U.S. EPA, OAQPS; Research Triangle Park, NC, August.

(7) McClellan, R. O. (1989) Letter from Chairman of Clean Air Scientific Advisory Committee to the EPA Administrator, dated May 1, 1989. EPA-SAB-CASAC-LTR-89-019.

(8) Richmond (1997) Supplemental ozone exposure and health risk analyses. Internal memorandum from Harvey M. Richmond to Karen M. Martin, U.S. EPA, AQSSD/OAQPS/OAR, RTP, NC, dated February 11, 1997. Docket No. A-95-58 Item IV-A-1.

(9) Seitz (1996) Revocation date for the existing 1-hour ozone standards. Internal memorandum from John S. Seitz to Mary D. Nichols, U.S. EPA, OAQPS/OAR, RTP, NC, dated November 20, 1996. Docket No. A-95-59 Item II-B-3.

(10) Thurston, G.D.; Ito, K.; Kinney, P.L.; Lippmann, M. (1992) A multi-year study of air pollution and respiratory hospital admissions in three New York State metropolitan areas: results for 1988 and 1989 summers. *Journal of Exposure Analysis and Environmental Epidemiology*. 2:429-450.

(11) U.S. Department of Health and Human Services (1996) Vital and health statistics: current estimates from the national health interview survey, 1994. Hyattsville, MD: Public Health Service, National Center for Health Statistics; DHHS publication no. (PHS) 96-278.

(12) U.S. Environmental Protection Agency (1996a) Air quality criteria for Ozone and related photochemical oxidants. Research Triangle Park, NC: Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office; EPA report nos. EPA/600/AP-93/004a-c.

(13) 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; EPA report no. EPA-452/R-96-007. Available from: NTIS, Springfield, VA; PB96-203435.

(14) Whitfield, R.G.; Biller, W.F.; Jusko, M.J.; Keisler, J.M. (1996) A probabilistic assessment of health risks associated with short-term exposure to tropospheric ozone. Report prepared for U.S. EPA, OAQPS, Argonne National Laboratory; Argonne, IL, June. (For copies, contact Harvey M. Richmond, U.S. Environmental Protection Agency, OAQPS, MD-15, Research Triangle Park, N.C. 27711, (919) 541-5271.)

(15) Wolff, G. T., (1995a) Letter from Chairman of Clean Air Scientific Advisory Committee to the EPA Administrator, dated November 28, 1995. EPA-SAB-CASAC-LTR-96-001.

(16) Wolff, G. T., (1995b) Letter from Chairman of Clean Air Scientific Advisory Committee to the EPA Administrator, dated November 30, 1995. EPA-SAB-CASAC-LTR-96-002.

(17) Wolff, G. T., (1996) Letter from Chairman of Clean Air Scientific Advisory Committee to the EPA Administrator, dated April 4, 1996. EPA-SAB-CASAC-LTR-96-006.

### List of Subjects in 40 CFR Part 50

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

Dated: July 16, 1997.

Carol M. Browner,

Administrator.

Therefore, for the reasons set forth in the preamble, title 40, chapter I, part 50 of the Code of Federal Regulations is amended as follows:

### PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

1. The authority citation for part 50 continues to read as follows:

**Authority:** Secs. 109 and 301(a), Clean Air Act, as amended (42 U.S.C. 7409, 7601(a)).

2. Section 50.9 is revised to read as follows:

#### § 50.9 National 1-hour primary and secondary ambient air quality standards for ozone.

(a) The level of the national 1-hour primary and secondary ambient air quality standards for ozone measured by a reference method based on Appendix D to this part and designated in accordance with part 53 of this chapter, is 0.12 parts per million (235  $\mu\text{g}/\text{m}^3$ ). The standard is attained when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 parts per million (235  $\mu\text{g}/\text{m}^3$ ) is equal to or less than 1, as determined by Appendix H to this part.

(b) The 1-hour standards set forth in this section will no longer apply to an area once EPA determines that the area has air quality meeting the 1-hour standard. Area designations are codified in 40 CFR part 81.

3. Section 50.10 is added to read as follows:

#### § 50.10 National 8-hour primary and secondary ambient air quality standards for ozone.

(a) The level of the national 8-hour primary and secondary ambient air quality standards for ozone, measured by a reference method based on Appendix D to this part and designated in accordance with part 53 of this chapter, is 0.08 parts per million (ppm), daily maximum 8-hour average.

(b) The 8-hour primary and secondary ozone ambient air quality standards are met at an ambient air quality monitoring site when the average of the annual fourth-highest daily maximum 8-hour average ozone concentration is less than or equal to 0.08 ppm, as determined in accordance with Appendix I to this part.

4. Appendix D is amended by revising references 8 and 9 and by removing all of the

text and figures immediately following "Figure 2, Schematic Diagram of a Typical UV Photometric Calibration System (Option 1), through the end of Appendix D.

### Appendix D to Part 50—Measurement Principle and Calibration Procedure for the Measurement of Ozone in the Atmosphere

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#### 6. References.

\* \* \* \* \*

8. Transfer Standards for Calibration of Ambient Air Monitoring Analyzers for Ozone, EPA publication number EPA-600/4-79-056, EPA, National Exposure Research Laboratory, Department E, (MD-77B), Research Triangle Park, NC 27711.

9. Technical Assistance Document for the Calibration of Ambient Ozone Monitors, EPA publication number EPA-600/4-79-057, EPA, National Exposure Research Laboratory, Department E, (MD-77B), Research Triangle Park, NC 27711.

\* \* \* \* \*

### Appendix E [Removed and Reserved]

5. Appendix E is removed and reserved.

6. Appendix H is amended by revising the appendix heading to read "Appendix H To Part 50—Interpretation of The 1-Hour Primary and Secondary National Ambient Air Quality Standards for Ozone".

7. Appendix I is added to read as follows:

### Appendix I to Part 50—Interpretation of the 8-Hour Primary and Secondary National Ambient Air Quality Standards for Ozone

#### 1. General.

This appendix explains the data handling conventions and computations necessary for determining whether the national 8-hour primary and secondary ambient air quality standards for ozone specified in § 50.10 are met at an ambient ozone air quality monitoring site. Ozone is measured in the ambient air by a reference method based on Appendix D of this part. Data reporting, data handling, and computation procedures to be used in making comparisons between reported ozone concentrations and the level of the ozone standard are specified in the following sections. Whether to exclude, retain, or make adjustments to the data affected by stratospheric ozone intrusion or other natural events is subject to the approval of the appropriate Regional Administrator.

#### 2. Primary and Secondary Ambient Air Quality Standards for Ozone.

##### 2.1 Data Reporting and Handling Conventions.

2.1.1 *Computing 8-hour averages.* Hourly average concentrations shall be reported in parts per million (ppm) to the third decimal place, with additional digits to the right being truncated. Running 8-hour averages shall be computed from the hourly ozone concentration data for each hour of the year and the result shall be stored in the first, or start, hour of the 8-hour period. An 8-hour average shall be considered valid if at least 75% of the hourly averages for the 8-hour period are available. In the event that only 6 (or 7) hourly averages are available, the 8-hour average shall be

computed on the basis of the hours available using 6 (or 7) as the divisor. (8-hour periods with three or more missing hours shall not be ignored if, after substituting one-half the minimum detectable limit for the missing hourly concentrations, the 8-hour average concentration is greater than the level of the standard.) The computed 8-hour average ozone concentrations shall be reported to three decimal places (the insignificant digits to the right of the third decimal place are truncated, consistent with the data handling procedures for the reported data.)

##### 2.1.2 *Daily maximum 8-hour average concentrations.*

(a) There are 24 possible running 8-hour average ozone concentrations for each calendar day during the ozone monitoring season. (Ozone monitoring seasons vary by geographic location as designated in part 58, Appendix D to this chapter.) The daily maximum 8-hour concentration for a given calendar day is the highest of the 24 possible 8-hour average concentrations computed for that day. This process is repeated, yielding a daily maximum 8-hour average ozone concentration for each calendar day with ambient ozone monitoring data. Because the 8-hour averages are recorded in the start hour, the daily maximum 8-hour concentrations from two consecutive days may have some hourly concentrations in common. Generally, overlapping daily maximum 8-hour averages are not likely, except in those non-urban monitoring locations with less pronounced diurnal variation in hourly concentrations.

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

2.2 *Primary and Secondary Standard-related Summary Statistic.* The standard-related summary statistic is the annual fourth-highest daily maximum 8-hour ozone concentration, expressed in parts per million, averaged over three years. The 3-year average shall be computed using the three most recent, consecutive calendar years of monitoring data meeting the data completeness requirements described in this appendix. The computed 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations shall be expressed to three decimal places (the remaining digits to the right are truncated.)

2.3 *Comparisons with the Primary and Secondary Ozone Standards.* (a) The primary and secondary ozone ambient air quality standards are met at an ambient air quality monitoring site when the 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentration is less than or equal to 0.08 ppm. The number of significant figures in the level of the standard dictates the rounding convention for comparing the computed 3-year average annual fourth-highest daily maximum 8-hour average ozone concentration with the level of the standard. The third decimal place of the computed value is rounded, with values equal to or greater than 5 rounding up. Thus, a computed 3-year average ozone concentration of 0.085 ppm is the smallest value that is greater than 0.08 ppm.

(b) This comparison shall be based on three consecutive, complete calendar years of air quality monitoring data. This requirement is met for the three year period at a monitoring site if daily maximum 8-hour average concentrations are

available for at least 90%, on average, of the days during the designated ozone monitoring season, with a minimum data completeness in any one year of at least 75% of the designated sampling days. When computing whether the minimum data completeness requirements have been met, meteorological or ambient data may be sufficient to demonstrate that meteorological conditions on missing days were not conducive to concentrations above the level of the standard. Missing days assumed less than the level of the standard are counted for the purpose of meeting the data

completeness requirement, subject to the approval of the appropriate Regional Administrator.

(c) Years with concentrations greater than the level of the standard shall not be ignored on the ground that they have less than complete data. Thus, in computing the 3-year average fourth maximum concentration, calendar years with less than 75% data completeness shall be included in the computation if the average annual fourth maximum 8-hour concentration is greater than the level of the standard.

(d) Comparisons with the primary and secondary ozone standards are demonstrated by examples 1

and 2 in paragraphs (d)(1) and (d) (2) respectively as follows:

(1) As shown in example 1, the primary and secondary standards are met at this monitoring site because the 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations (i.e., 0.084 ppm) is less than or equal to 0.08 ppm. The data completeness requirement is also met because the average percent of days with valid ambient monitoring data is greater than 90%, and no single year has less than 75% data completeness.

**EXAMPLE 1. AMBIENT MONITORING SITE ATTAINING THE PRIMARY AND SECONDARY OZONE STANDARDS**

Year	Percent Valid Days	1st Highest Daily Max 8-hour Conc. (ppm)	2nd Highest Daily Max 8-hour Conc. (ppm)	3rd Highest Daily Max 8-hour Conc. (ppm)	4th Highest Daily Max 8-hour Conc. (ppm)	5th Highest Daily Max 8-hour Conc. (ppm)
1993 .....	100%	0.092	0.091	0.090	0.088	0.085
1994 .....	96%	0.090	0.089	0.086	0.084	0.080
1995 .....	98%	0.087	0.085	0.083	0.080	0.075
Average .....	98%				0.084	

(2) As shown in example 2, the primary and secondary standards are not met at this monitoring site because the 3-year average of the fourth-highest daily maximum 8-hour average ozone

concentrations (i.e., 0.093 ppm) is greater than 0.08 ppm. Note that the ozone concentration data for 1994 is used in these computations, even though the data capture is less than 75%, because the

average fourth-highest daily maximum 8-hour average concentration is greater than 0.08 ppm.

**EXAMPLE 2. AMBIENT MONITORING SITE FAILING TO MEET THE PRIMARY AND SECONDARY OZONE STANDARDS**

Year	Percent Valid Days	1st Highest Daily Max 8-hour Conc. (ppm)	2nd Highest Daily Max 8-hour Conc. (ppm)	3rd Highest Daily Max 8-hour Conc. (ppm)	4th Highest Daily Max 8-hour Conc. (ppm)	5th Highest Daily Max 8-hour Conc. (ppm)
1993 .....	96%	0.105	0.103	0.103	0.102	0.102
1994 .....	74%	0.090	0.085	0.082	0.080	0.078
1995 .....	98%	0.103	0.101	0.101	0.097	0.095
Average .....	89%				0.093	

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

The air quality design value at a monitoring site is defined as that concentration that when reduced to the level of the standard ensures that the site

meets the standard. For a concentration-based standard, the air quality design value is simply the standard-related test statistic. Thus, for the primary and secondary ozone standards, the 3-year average annual fourth-highest daily maximum 8-hour

average ozone concentration is also the air quality design value for the site.

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