federal register

Friday
December 13, 1996

Part III

Environmental Protection Agency

40 CFR Part 50

National Ambient Air Quality Standards for Ozone; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[AD–FRL–5659–4]

RIN 2060–AE57

National Ambient Air Quality Standards for Ozone: Proposed Decision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In accordance with sections 108 and 109 of the Clean Air Act (Act), EPA has reviewed the air quality criteria and national ambient air quality standards (NAAQS) for ozone (O_3) and particulate matter (PM). Based on these reviews, the EPA proposes to change the standards for both classes of pollutants.

This document describes EPA's proposed changes with respect to the NAAQS for O_3. The EPA's proposed actions with respect to PM are being proposed elsewhere in today's Federal Register. Nonetheless, EPA has concluded that the effects and control of each are in many instances linked and will be affected by the other. For this reason, EPA intends to review and, as appropriate, modify both standards on a similar schedule, with promulgation of revised O_3 standards in June of 1997, concurrent with promulgation of revised standards for PM. Doing so will permit States, localities and industry to address the control of these and related pollutants on a more consistent basis.

Ozone and related pollutants have long been recognized, in both clinical and epidemiological research, to affect public health. The proposed revised standard would provide protection for children and other at-risk populations against a wide range of O_3-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.

With respect to O_3, EPA proposes to change the current primary standard (last modified in 1979) in several respects:

1. Since longer exposure periods are of greater concern at lower O_3 concentrations, attainment of the standard would no longer be based upon 1-hour averages, but instead on 8-hour averages. This improvement was unanimously recommended by EPA's Clean Air Scientific Advisory Committee (CASAC).

2. As a result of this change in averaging time, the level of the standard would be lowered from the present 0.12 parts per million (ppm). The EPA solicits comment on alternative levels of 0.09 ppm, which generally represents the continuation of the present level of protection, and 0.08 ppm, an increased level of protection. Based upon its review, EPA is proposing the 0.08 ppm standard to provide increased protection for children and asthmatics. The EPA also solicits comment on retaining the current primary standard and on an alternative 8-hour standard at a level of 0.07 ppm.

3. In addition, EPA proposes to change the test for attainment (i.e., the form) of the new standard. Currently, the test of attainment is whether a site exceeds the 1-hour standard on an average of no more than once per year, averaged over three years. Given the natural variation in hourly O_3 levels, this ''one expected exceedance'' test can result in relatively unstable attainment/nonattainment designations. The CASAC recommended a change to a more stable form; consistent with this recommendation, EPA proposes a form based on a 3-year average of 8-hour O_3 concentrations. The EPA solicits comment on a range of such concentration-based forms.

The EPA proposes to replace the current secondary standard with one of two alternative standards: one set identical to the proposed new primary standard or, alternatively, a new seasonal standard expressed as a sum of hourly O_3 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_3 monitoring season, set at a level of 25 ppm-hour. Either of the proposed alternative secondary standards would provide increased protection against O_3-induced effects, such as agricultural crop loss, damage to forests and ecosystems, and visible foliar injury to sensitive species.

DATES: Written comments on this proposed rule must be received by February 18, 1997.

ADDRESSES: Submit comments (in duplicate if possible) on the proposed rule to: Office of Air and Radiation Docket and Information Center (6102) Attn: Docket No. A–95–58, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Public Hearing: The EPA will announce in a separate Federal Register document the date, time, and address of the public hearing on this proposed rule.

FOR FURTHER INFORMATION CONTACT: Dr. David McKee, MD–15, Air Quality Standards and Strategies Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, Telephone: (919) 541–5288.

SUPPLEMENTARY INFORMATION:

Docket

Docket No. A–95–58 incorporates by reference 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 8:00 a.m. and 5:30 p.m. on weekdays, and a reasonable fee may be charged for copying.

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: Air Quality Criteria for O_3 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); and the Review of the National Ambient Air Quality Standards for O_3: 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 above.

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 Activities

When the proposed revisions to the primary and secondary standards are implemented by the States, utility, automobile, petroleum, and chemical industries are likely to be affected, as well as other manufacturing concerns that emit volatile organic compounds or nitrogen oxides. The extent of such effects will depend on implementation policies and control strategies adopted by States to assure attainment and maintenance of the proposed standards.

The EPA is developing appropriate policies and control strategies to assist States in the implementation of the proposed revisions to both the primary and secondary O_3 NAAQS. The resulting implementation strategies will then be published for public comment in the future.

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The following topics are discussed in today's preamble:

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 pollutants which ''may reasonably be anticipated to endanger public health and 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.

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 program (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 through the Federal Motor Vehicle Control Program under title II of the Act (42 U.S.C. 7521–7574), which involves controls for automobile, truck, bus, motorcycle, 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_3

The last review of O_3 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 existing 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).[1]

The EPA initiated this current review in August 1992 with the development of a revised Air Quality Criteria Document for O_3 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 30–31, 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 20–21, 1995. At the same meeting, the CASAC also reviewed draft portions of a staff paper prepared by the Office of Air Quality Planning and Standards (OAQPS), Review of National Ambient Air Quality Standards for Ozone: Assessment of Scientific and Technical Information (henceforth, the ''Staff Paper''), focusing on health effects and the primary NAAQS. 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_3 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_3 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_3 standard'' (Wolff, 1996).

The focus of this current review of the air quality criteria and standards for O_3 and related photochemical oxidants is on public health and welfare effects associated with exposure to ambient levels of tropospheric O_3. *Tropospheric* O_3 is chemically identical to *stratospheric* O_3, which is produced miles above the earth's surface and provides a protective shield from excess ultraviolet radiation. In contrast, tropospheric O_3 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_X), 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_3 can be found in the final Criteria Document (U.S. EPA, 1996a) and in the final Staff Paper (U.S. EPA, 1996b).

This review of the scientific criteria for O_3 has occurred simultaneously with the review of the criteria for particulate matter (PM). These criteria reviews, as well as related implementation strategy activities to date, have brought out important linkages between PM and O_3. A number of community epidemiological studies have found similar health effects to be associated with exposure to PM and O_3, including, for example, aggravation of respiratory disease (e.g., asthma), increased respiratory symptoms, and increased hospital admissions and emergency room visits for respiratory causes. Laboratory studies have suggested potential interactions between O_3 and various constituents of PM. Other key similarities relating to exposure patterns and implementation strategies exist between PM, specifically fine particles, and O_3. These similarities include: (1) Atmospheric residence times of several days, leading to large urban and regional-scale transport of the pollutants; (2) similar gaseous precursors, including NO_X and VOC, which contribute to the formation of both O_3 and fine particles in the atmosphere; (3) similar combustion-related source categories, such as coal and oil-fired power generation and industrial boilers and mobile sources, which emit particles directly as well as gaseous precursors of particles (e.g., sulfur oxides (SO_X), NO_X, VOC) and O_3 (e.g., NO_X, VOC); and (4) similar atmospheric chemistry driven by the same chemical reactions and intermediate chemical species that form both high fine particle and O_3 levels. High fine particle levels are also associated with significant impairment of visibility on a regional scale.

These similarities provide opportunities for optimizing technical analysis tools (i.e., monitoring networks, emission inventories, air quality models) and integrated emission reduction strategies to yield important co-benefits across various air quality management programs. These co-benefits could result in a net reduction of the regulatory burden on some source category sectors that would otherwise be impacted by separate O_3, PM, and visibility protection control strategies.

In recognition of the multiple linkages and similarities in effects and the potential benefits of integrating the Agency's approaches to providing for appropriate protection of public health and welfare from exposure to PM and O_3, EPA is conducting the reviews of the NAAQS for both pollutants on the same schedule. Accordingly, today's Federal Register contains a separate notice announcing proposed revisions to the PM NAAQS. Linking the PM and O_3 review schedules provides an important

[1] A more complete history of the O_3 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_3: Assessment of Scientific and Technical Information (U.S. EPA, 1996b).

opportunity for more effective and efficient air quality management—both in terms of communicating a more complete description of the health and welfare effects associated with the major components of urban and regional air pollution, and by helping the States and local areas to plan jointly to address both PM and O_3 air pollution at the same time with one process, and to work jointly with industry to address common sources of air pollution. The EPA believes this integrated approach will lead to more effective and efficient protection of public health and the environment.

II. Rationale for Proposed Decision on the Primary Standard

This notice presents the Administrator's proposed decision to replace the existing 1-hour O_3 primary NAAQS with a new 8-hour standard, based on a thorough review, in the Criteria Document, of the latest scientific information on human health effects associated with exposure to ambient levels of O_3, including evaluation of key studies published through 1995. This decision also takes into account and is consistent with: (1) Staff assessments of the most policy-relevant information in the Criteria Document and staff analyses of human exposure and risk, presented in the Staff Paper, upon which staff recommendations for a new O_3 primary standard are based; (2) 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 letters to the Administrator; and (3) public comments received during the development of these documents, either in connection with CASAC meetings or separately.

The rationale for the proposed revisions of the O_3 primary NAAQS includes consideration of: (1) Health effects information to inform judgments as to the likelihood that exposures to ambient O_3 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_3 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; and (4) alternative views of the significance of the effects and factors to be considered in policy judgments about the appropriate level of the standard.

A. Health Effects Information

The following summary of human health effects associated with exposure to ambient levels of O_3 is based on integrative information from human clinical, epidemiological, and animal toxicological studies, as presented 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_3. Acute health effects[2] induced by short-term exposures to O_3, generally while individuals were engaged in heavy exertion, include transient pulmonary function responses, transient respiratory symptoms, and effects on exercise performance. The current O_3 primary NAAQS is generally based on these acute effects associated with heavy exercise and short-term exposures. Other health effects associated with short-term or prolonged O_3 exposures include increased airway responsiveness, susceptibility to respiratory infection, increased hospital admissions and emergency room visits, and transient pulmonary inflammation.

Since the last review of the air quality criteria for O_3 was completed, available information has increased substantially on effects associated with prolonged and long-term exposures. Based on this new information, similar acute health effects have been observed following prolonged exposures at concentrations of O_3 as low as 0.08 ppm and at moderate levels of exertion.[2] Although chronic effects[3] such as structural damage to pulmonary tissue and carcinogenicity have been investigated in a substantial number of laboratory animal studies, these effects have not been adequately established in human studies to draw any conclusions at this time.

This array of effects is briefly summarized below for short-term and prolonged O_3 exposures, and for long-term O_3 exposures. Further, judgments are presented 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.

1. Effects of Short-term and Prolonged O_3 Exposures

a. Pulmonary Function Responses

Transient reductions in pulmonary function have been observed in healthy individuals and those with impaired respiratory symptoms (e.g., asthmatic individuals) as a result of both short-term and prolonged exposures to O_3. The strongest and most quantifiable exposure-response information on such pulmonary function responses to O_3 has come from controlled human exposure studies. The evidence from such studies clearly shows that reductions in lung function are enhanced by increased levels of activity involving exertion, typically reported as ''exercise'' in clinical studies, and by increased O_3 concentrations. Pulmonary function decrements generally tend to return to baseline levels shortly after short-term exposure, and effects are typically attenuated upon repeated short-term exposures over several days.

As discussed in section V.C.1 of the Staff Paper, numerous experimental studies of exercising adults have demonstrated decrements in lung function both for exposures of 1–3 hours at ≥0.12 ppm O_3 and for exposures of 6.6 hours at ≥0.08 ppm O_3. These studies provide conclusive evidence that O_3 levels commonly monitored in the ambient air induce lung function decrements in exercising adults. The extent of lung function decrements varies considerably among individuals. Further, numerous summer camp studies provide an extensive and reliable database on lung function responses to ambient O_3 and other pollutants in children and adolescents living in the Northeastern U.S., southern California, and Southern Canada. Lung function changes reported at ambient O_3 concentrations in these studies are comparable to those reported in children and adults exposed under controlled experimental conditions, although direct comparisons are difficult to make because of differences in experimental design and analytical approach.

b. Respiratory Symptoms and Effects on Exercise Performance

As discussed in section V.C.2 of the Staff Paper, various transient human respiratory symptoms, including cough, throat irritation, chest pain on deep inspiration, nausea, and shortness of breath, have been induced by O_3 exposures of both healthy individuals and those with impaired respiratory systems. Increasing O_3 exposure durations and levels have been shown to elicit increasingly more severe

[2] ''Acute health'' effects of O_3 are defined as those effects induced by short-term and prolonged exposures to O_3. Examples of these effects are functional, symptomatic, biochemical, and physiologic changes.

[3] ''Chronic health'' effects of O_3 are defined as those effects induced by long-term exposures to O_3. Examples of these effects are structural damage to lung tissue and accelerated decline in baseline lung function.

symptoms that persist for longer periods in increasingly larger numbers of individuals. Symptomatic and pulmonary function responses follow a similar time course during an acute exposure and the subsequent recovery, as well as over the course of several days during repeated exposures. As with pulmonary function responses, the severity of symptomatic responses varies considerably among subjects. For some outdoor workers or active people who are highly responsive to ambient O_3, respiratory symptoms may cause reduced productivity or may curb the ability or desire to engage in normal activities. Furthermore, O_3-induced interference with exercise performance, either by reducing maximal sustainable levels of activity or reducing the duration of activity that can be tolerated at a particular work level, is likely related to such symptomatic responses.

c. Increased Airway Responsiveness

Increased airway responsiveness is an indication that the airways are predisposed to bronchoconstriction which can be induced by a wide variety of external stimuli (e.g., pollens, dust, cold air, sulfur dioxide (SO_2), etc.). A high level of bronchial responsiveness is characteristic of asthma. Ozone exposure causes increased responsiveness of the pulmonary airways to subsequent challenge with bronchoconstrictor drugs such as histamine or methacholine. Changes in airway responsiveness tend to resolve somewhat more slowly than pulmonary function changes, typically disappearing after 24 hours, and appear to be less likely to attenuate with repeated exposure.

As a result of increased airway responsiveness induced by O_3 exposure, human airways may be more susceptible to a variety of stimuli, including antigens, chemicals, and particles. For example, as cited in section V.C.3 of the Staff Paper, healthy subjects after being exposed to O_3 concentrations as low as 0.20 ppm for 1 hour and 0.08 ppm for 6.6 hours have experienced small increases in nonspecific bronchial responsiveness, which usually resolve within 24 hours. Asthmatic subjects typically have increased airway responsiveness at baseline. Whereas the differences in baseline nonspecific bronchial responsiveness between healthy individuals and sensitive asthmatics may be as much as 100-fold, changes induced by O_3 exposure are usually only 2- to 4-fold. With regard to O_3-induced increases in airway responsiveness (e.g., to specific inhaled antigens, cold air, and SO_2) ongoing studies will need to be completed and evaluated before conclusions can be drawn. Because enhanced response to antigens in asthmatics could lead to increased morbidity (i.e., medical treatment, emergency room visits, hospital admissions) or to more persistent alterations in airway responsiveness, these health endpoints raise concern for public health, particularly for individuals with impaired respiratory systems.

d. Increased Susceptibility to Respiratory Infection

When functioning normally, the human respiratory tract, like that of other mammals, has numerous closely integrated defense mechanisms that provide protection from the adverse effects of a wide variety of inhaled particles and microbes. To the extent that these defense mechanisms can be broken down or impaired by the inhalation of O_3, as discussed in section V.C.4 of the Staff Paper, O_3 exposures can result in increased susceptibility to respiratory infection and related respiratory dysfunction. Evidence of such effects has come primarily from a very large number of laboratory animal studies with generally consistent results. One of the few studies of moderately exercising human subjects exposed to 0.08 ppm O_3 for 6.6 hours reported decrements in alveolar macrophage function, the first line of defense against inhaled microorganisms and particles in the lower airways and air sacs.

No single experimental human study or group of animal studies conclusively demonstrates that human susceptibility to respiratory infection is increased by exposure to O_3. However, taken as a whole, the data suggest that acute O_3 exposures can impair the host defense capability of both humans and animals, possibly by depressing alveolar macrophage function and perhaps also by decreasing mucociliary clearance of inhaled particles and microorganisms. This suggests that humans exposed to O_3 may be predisposed to bacterial infections in the lower respiratory tract. The seriousness of such infections may depend on how quickly bacteria develop virulence factors and how rapidly mechanisms are mobilized to compensate for depressed alveolar macrophage function.

e. Hospital Admissions and Emergency Room Visits

Increased summertime hospital admissions and emergency room visits for respiratory causes have been associated with ambient exposures to O_3 and other environmental factors. As cited in section V.C.5 of the Staff Paper, numerous studies conducted in various locations in the Eastern United States (U.S.) and Canada consistently have shown a relationship between ambient O_3 levels and increased incidence of emergency room visits and hospital admissions for respiratory causes, even after controlling for modifying factors, as well as when considering only concentrations <0.12 ppm O_3. Such associations between elevated ambient O_3 during summer months and increased hospital admissions have a plausible biological basis in the human and animal evidence of functional, symptomatic, and physiologic effects discussed above and in the increased susceptibility to respiratory infections observed in laboratory animals.

Individuals with preexisting respiratory disease (e.g., asthma, chronic obstructive pulmonary disease) may generally be at increased risk of such effects, and some individuals with respiratory disease may have an inherently greater sensitivity to O_3. On the other hand, individuals with more severe respiratory disease are less likely to engage in the level of exertion associated with provoking responses to O_3 exposures in healthy humans. On balance, it is reasonable to conclude that evidence of O_3-induced increased airway resistance, nonspecific bronchial responsiveness, susceptibility to respiratory infection, increased airway permeability, airway inflammation, and incidence of asthma attacks suggests that ambient O_3 exposure could be a cause of increased hospital admissions, particularly for asthmatics.

f. Pulmonary Inflammation

Respiratory inflammation can be considered to be a host response to injury and indicators of inflammation as evidence that respiratory cell damage has occurred. Inflammation induced by exposure of humans to O_3 may have several potential outcomes: (1) Inflammation induced by a single exposure (or even several exposures over the course of a season) could resolve entirely; (2) repeated acute inflammation could develop into a chronic inflammatory state; (3) continued inflammation could alter the structure and function of other pulmonary tissue, leading to disease processes such as fibrosis; (4) inflammation could interfere with the body's host defense response to particles and inhaled microorganisms, particularly in potentially vulnerable populations such as children and older individuals; and (5) inflammation could amplify the lung's response to other agents such as allergens or toxins. For humans, only the first of these potential outcomes has been demonstrated in the laboratory. However, this is expected because regulations concerning human experimental studies require that long-term damage be avoided. Hence, study protocols only involved brief exposures.

Exposures of laboratory animals to O_3 for periods ≤8 hours have been shown to result in cell damage, inflammation, and increased leakage of proteins from blood into the air spaces of the respiratory tract. In general, higher O_3 concentrations are required to elicit a response equivalent to that of humans. This may partly result from study design differences, in which humans were exposed while exercising, whereas most animal studies were done at rest, resulting in differences in effective ventilation rates. Laboratory animals studies done at night, during the animals' active period, or in which ventilation rates were increased with coexposure to carbon dioxide (CO_2) tend to support this view. The extent and course of inflammation and its constitutive elements has been evaluated by using bronchoalveolar lavage (BAL) to sample cells and fluid from the lung and lower airways of humans exposed to O_3. Several such studies cited in section V.C.7 of the Staff Paper have shown that exercising humans exposed (1 to 4 hours) to 0.2 to 0.6 ppm O_3 had O_3-induced markers of inflammation and cell damage. The lowest concentration of prolonged O_3 exposure tested in humans, 0.08 ppm for 6.6 hours with moderate exercise, also induced small but statistically significant increases in these endpoints.

Thus, it is reasonable to conclude that repeated acute inflammatory response and cellular damage discussed above is potentially a matter of public health concern; however, it is also recognized that most, if not all, of these effects begin to resolve in most individuals within 24 hours if the exposure to O_3 is not repeated. Of possibly greater public health concern is the potential for chronic respiratory damage which could be the result of repeated O_3 exposures occurring over a season or a lifetime. Evidence for these chronic effects is discussed below.

2. Potential Effects of Long-term O_3 Exposures

Epidemiologic studies that have investigated potential associations between long-term O_3 exposures and chronic respiratory effects in humans thus far have provided only suggestive evidence of such a relationship. Most studies investigating this association have been cross-sectional in design and have been compromised by incomplete control of confounding variables and inadequate exposure information. Other studies have attempted to follow variably exposed groups prospectively. As cited in Section V.C.8 of the Staff Paper, studies conducted in southern California and Canada have compared lung function changes over several years between populations living in communities with high and low ambient O_3 levels. The findings suggest small, but consistent, decrements in lung function among inhabitants of the more highly polluted communities; however, associations between O_3 and other copollutants and problems with study population loss have reduced the level of confidence in these conclusions.

In a large number of animal toxicology studies, ''lesions'' [4] in the centriacinar regions of the lung (i.e., the portion of the lung where the region that conducts air and the region that exchanges gas are joined) are well established as one of the hallmarks of O_3 toxicity. Studies have been conducted using rats, mice, and primates. In one study in which rats were exposed to an urban pattern of O_3 exposure, changes indicative of cell and tissue damage were reported, although post-exposure damage was mainly reversible. A similar study of identically exposed groups of rats found: (1) Increases in expiratory resistance suggesting central airway narrowing after 78 weeks of exposure, (2) reduced tidal volumes at all evaluation times during the exposure, and (3) generally reduced breathing frequency, although no single evaluation time was statistically significant. Another related study with a similar protocol reported reduced lung volume, which is consistent with a ''stiffer'' lung (i.e., restrictive lung disease). A recent multicenter chronic study illustrates some of the complex interrelationships among the structural, functional, and biochemical effects. The three types of health endpoints mentioned above were evaluated in a collaborative project using rats exposed for 20 months. Lung biochemistry and structure were affected at 0.5 ppm and 1.00 ppm O_3, but not at 0.12 ppm O_3, although no effects on pulmonary function were observed at any exposure level.

In summary, the collective data on long-term exposure to O_3 garnered in studies of laboratory animals and human populations have many ambiguities. It is clear from toxicology data that the distribution of O_3 ''lesions'' is roughly similar across species (including monkeys, rats, mice) with responses that are concentration dependent (and perhaps time or exposure-pattern dependent). Under certain conditions, some of these structural changes may become irreversible. It is unclear, however, whether ambient exposure scenarios encountered by humans result in similar ''lesions'' or whether there are resultant functional or impaired health outcomes in humans chronically exposed to O_3. The epidemiologic lung function studies generally parallel those of the animal studies, but these studies lack good information on individual O_3 exposure history and are frequently confounded by personal or copollutant variables. Thus, the Administrator recognizes that there is a lack of a clear understanding of the significance of repeated, long-term inflammatory responses, and that there is a need for continued research in this important area. Nevertheless, the currently available information provides at least a biologically plausible basis for considering the possibility that repeated inflammation associated with exposure to O_3 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.

Studies of laboratory animals exposed to O_3 have been relatively inconclusive with regard to genotoxicity and carcinogenicity, particularly at lower O_3 concentrations. Only long-term exposure of laboratory animals to a high concentration of O_3 (1.0 ppm) has been shown to evoke a limited degree of carcinogenic activity in one strain of female mice, whereas rats were unaffected. Furthermore, there was no concentration response relationship established, perhaps due to the limited scope of the studies, and there is inadequate information from other research to provide mechanistic support for the finding in mice. (For further discussion, see section V.C.9 in the Staff Paper.)

Several epidemiologic studies cited in Section V.C.6 of the Staff Paper have attempted to find associations between daily mortality and O_3 concentrations in various cities around the U.S. Although an association between ambient O_3 exposure in areas with very high O_3 levels and daily mortality has been suggested by these studies, the data are limited.

3. Adversity of Effects for Individuals

Some population groups have been identified as being sensitive to effects

[4] Differing views have been expressed by CASAC panel members regarding the use of the term ''lesion'' to describe the O_3-induced morphological (i.e., structural) abnormalities observed in toxicological studies. Section V.C.8 of the Staff Paper describes and discusses these degenerative changes in more detail.

associated with exposures to ambient O_3 levels, such that individuals within these groups are at increased risk of experiencing the above effects. Such groups at increased risk include active children and outdoor workers who regularly engage in outdoor activities that involve heavy levels of exertion during short-term periods of elevated ambient O_3 levels or moderate levels of exertion during prolonged periods of elevated ambient O_3 levels. Exertion increases the amount of O_3 entering the airways and can cause O_3 to penetrate to peripheral regions of the lung where lung tissue is more likely to be damaged. Secondly, individuals characterized as having preexisting respiratory disease (e.g., asthma or chronic obstructive lung disease), while not necessarily more responsive than healthy individuals in terms of the magnitude of pulmonary function decrements or symptomatic responses, may be at increased risk. That is, the impact of O_3-induced responses on already-compromised respiratory systems may more noticeably impair an individual's ability to engage in normal activity or may be more likely to result in increased self-medication or medical treatment. It is recognized that limitations on using such individuals in experimental studies have prevented a more complete assessment of the full range of potential responses to O_3 or their health significance in such individuals. Finally, some individuals are unusually responsive to O_3 relative to other individuals with similar levels of activity or with a similar health status and may experience much greater functional and symptomatic effects from exposure to O_3 than the average individual response. The mechanisms and characteristics responsible for increased sensitivity to O_3 exposure have not been defined; thus, it is not clear whether these ''hyperresponders'' constitute a population subgroup with a specific risk factor or simply represent the upper end of the O_3 response distributions within the general and at-risk populations.

In making judgments as to when the effects discussed above become significant enough that they should be regarded as adverse to the health of individuals in these sensitive populations, the Administrator has looked to guidelines published by the American Thoracic Society (ATS) and the advice of CASAC. While recognizing that perceptions of ''medical significance'' and ''normal activity'' may differ among physicians, lung physiologists, and experimental subjects, the ATS (1985) defined adverse respiratory health effects as ''medically significant physiologic or pathologic changes generally evidenced by one or more of the following: (1) Interference with the normal activity of the affected person or persons, (2) episodic respiratory illness, (3) incapacitating illness, (4) permanent respiratory injury, and/or (5) progressive respiratory dysfunction.'' Human health effects for which clear, causal relationships with exposure to O_3 have been demonstrated (e.g., functional and symptomatic responses) fall into the first category listed in the ATS definition. Human health effects for which statistically significant associations have been reported in epidemiology studies fall into the second and third categories. These more serious effects include respiratory illness that may require medication (e.g., asthma), but not necessarily hospitalization, as well as emergency room visits and hospital admissions for acute occurrences of respiratory morbidity. Human health effects for which associations have been suggested but not conclusively demonstrated fall primarily into the last two categories. Evidence of these most serious health endpoints for O_3 comes from studies of effects in laboratory animals, which can be extrapolated to humans only with a significant degree of uncertainty, and from human epidemiological studies.

Application of these guidelines, in particular to the least serious category of effects related to ambient O_3 exposures, involves judgments about which medical experts on the CASAC panel and public commenters have expressed a diversity of views. To help frame such judgments, the EPA staff defined gradations of individual functional responses (e.g., decrements in forced expiratory volume (FEV_1), increased airway responsiveness) and symptomatic responses (e.g., cough, chest pain, wheeze), together with judgments as to the potential impact on individuals experiencing varying degrees of severity of these responses. These gradations and impacts, summarized below, are discussed in the Criteria Document (Chapter 9) and Staff Paper (section V.F, Table V–4a, 4b, 4c for individuals with impaired respiratory systems and Table V–5a, 5b, 5c for healthy individuals) and incorporate significant input from the CASAC panel of medical experts. The CASAC panel expressed a consensus view that these ''criteria for the determination of an adverse physiological response was reasonable'' (Wolff, 1995b).

For individuals with impaired respiratory systems, small functional responses (e.g., FEV_1 decrements of 3% to ≤10%, increased nonspecific bronchial responsiveness <100%, lasting less than 4 hours) and/or mild symptomatic responses (e.g., cough with deep breath, discomfort just noticeable on exercise or deep breath, lasting less than 4 hours) would likely interfere with normal activity (and, therefore, be considered adverse under the ATS guidelines) for relatively few such individuals and would likely result in the use of normal medication as needed. Moderate functional responses (e.g., FEV_1 decrements ≤10% but <20%, increased nonspecific bronchial responsiveness ≤300%, lasting up to 24 hours) and/or moderate symptomatic responses (frequent spontaneous cough, marked discomfort on exercise or deep breath, wheeze accompanied by shortness of breath, lasting up to 24 hours) would likely interfere with normal activity for many such individuals and would likely result in additional or more frequent use of medication. Large functional responses (e.g., FEV_1 decrements ≥20%, increased nonspecific bronchial responsiveness >300%, lasting longer than 24 hours) and/or severe symptomatic responses (e.g., persistent uncontrollable cough, severe discomfort on exercise or deep breath, persistent wheeze accompanied by shortness of breath, lasting longer than 24 hours) would likely interfere with normal activity for most such individuals and would likely increase the likelihood of seeking medical treatment or visiting an emergency room.

For active healthy individuals, it is judged that moderate levels of functional responses (e.g., FEV_1 decrements >10% but <20% lasting up to 24 hours) and/or moderate symptomatic responses (e.g., frequent spontaneous cough, marked discomfort on exercise or deep breath, lasting up to 24 hours) would likely interfere with normal activity (and, therefore, be considered adverse under the ATS guidelines) for relatively few sensitive individuals in the at-risk populations of concern (active children and outdoor workers). Further, it is judged that large functional responses (e.g., FEV_1 decrements >20% lasting longer than 24 hours) and/or severe symptomatic responses (e.g., persistent uncontrollable cough, severe discomfort on exercise or deep breath, lasting longer than 24 hours) would likely interfere with normal activity for many sensitive individuals.

In judging the extent to which such impacts represent effects that should be regarded as adverse to the health status of individuals, an additional factor that the Administrator has considered is whether such effects are experienced repeatedly by an individual during the course of a year or only on a single occasion. While some experts would judge single occurrences of moderate responses to be a ''nuisance,'' especially for healthy individuals, a more general consensus view of the adversity of such moderate responses emerges as the frequency of occurrence increases. Thus, the Administrator agrees with the judgments presented in the Staff Paper that repeated occurrences of moderate responses, even in otherwise healthy individuals, may be considered to be adverse since they could well set the stage for more serious illness.

B. Human Exposure and Risk Assessments

To put judgments about health effects that are adverse for individuals into a broader public health context, the Administrator has taken into account the results of human exposure and risk assessments. This broader context includes consideration, to the extent possible, of the size of particular population groups at risk for various effects, the likelihood that exposures of concern will occur for individuals in such groups under varying air quality scenarios, and the kind and degree of uncertainties inherent in assessing the risks involved. Such considerations provide a basis for judgments about the various levels of risk and the adequacy of public health protection afforded by the current NAAQS and alternative standards.

1. Exposure Analyses

The EPA conducted exposure analyses to estimate O_3 exposures for the general population and two at-risk populations, ''outdoor children'' and ''outdoor workers,'' living in nine representative U.S. urban areas. The areas include a significant fraction of the U.S. urban population, 41.7 million people, the largest areas with major O_3 nonattainment problems, and areas that are in attainment with the current NAAQS. Exposure estimates were developed for a recent year, as well as for modeled air quality that simulated conditions associated with attainment of the current NAAQS and various alternative standards. The exposure analyses provide estimates of the size of at-risk populations exposed to various concentrations under different regulatory scenarios, as presented in section V.G of the Staff Paper and summarized below. These estimates are an important input to the risk assessment summarized in the next section.

The probabilistic NAAQS exposure model for O_3 (pNEM/O_3) used in these analyses builds on earlier deterministic versions of NEM by modeling random processes within the exposure simulation. The pNEM/O_3 model takes into account the most significant factors contributing to total human O_3 exposure, including the temporal and spatial distribution of people and O_3 concentrations throughout an urban area, the variation of O_3 levels within each microenvironment, and the effects of exertion (which is represented by ventilation rate) on O_3 uptake in exposed individuals. A more detailed description of pNEM/O_3 and its application is presented in section V.G of the Staff Paper and associated technical support documents (Johnson et al., 1994; Johnson et al., 1996 a,b; McCurdy, 1994a).

The regulatory scenarios examined in the exposure analyses include 1-hour O_3 standards of 0.12 ppm (the current NAAQS) and 0.10 ppm, and 8-hour standards of 0.07, 0.08, and 0.09 ppm, the range of alternative 8-hour standards recommended in the Staff Paper and supported by CASAC as the appropriate range for consideration in this review. These analyses used 1- and 5-expected-exceedance forms of the standards and are based on use of a single year of data. These estimates were also used to roughly bound exposure estimates for other concentration-based forms of the standard under consideration (e.g., the second- and fifth-highest daily maximum 8-hour average O_3 concentration, averaged over a 3-year period) by using air quality analyses that compare alternative forms of the standard, as presented in Section IV and Appendix A of the Staff Paper. The estimated exposures reflect what would be expected in a typical or average year in an area just attaining a given standard over a 3-year compliance period. Additional air quality and exposure analyses were done to estimate the exposures that would be expected in the worst year of a 3-year compliance period.

The exposure estimates were done in terms of both ''people exposed'' (i.e., the number of people who experience a given level of air pollution, or higher, at least one time during the time period of analysis) and ''occurrences of exposure'' (i.e., the number of times a given level of pollution is experienced by the population of interest). Individual exposures were estimated in terms of dose, where dose is defined as the product of O_3 concentration and ventilation rate over a defined period. Distributions of exposure estimates over the entire range of actual or simulated ambient O_3 concentrations were developed as important input to the risk analysis, although results also were developed in terms of the frequency of exposures to ambient O_3 concentrations above the lowest O_3 concentrations at which health effects have been clearly associated with exposure to O_3 in controlled human exposure studies (i.e., 0.12 ppm, 1-hour average, and 0.08 ppm, 8-hour average, respectively).

Key observations important in comparing estimated exposures associated with attainment of the current NAAQS and alternative standards under consideration include:

(1) Children who are active outdoors (representing approximately 7% of the population in the study areas) appear to be the at-risk population group examined with the highest percentage and number of individuals exposed to O_3 concentrations at and above which there is evidence of health effects, particularly for 8-hour average exposures at moderate exertion to O_3 concentrations ≥0.08 ppm.

(2) On both an absolute number and a percentage basis, exposure estimates are higher for the 8-hour average effects level of 0.08 ppm at moderate exertion than for the 1-hour average effects level of 0.12 ppm at heavy exertion.

(3) Estimated exposures above these effects cutpoints, even on a percentage basis, vary significantly across the urban areas examined in this analysis. However, general patterns of exposure can be seen in comparing the current NAAQS and alternative standards, particularly in looking at the seven current nonattainment areas examined. For example, for estimates of the mean percent of outdoor children exposed to 8-hour average O_3 concentrations ≥0.08 ppm while at moderate exertion, the following patterns are seen: the range of estimates associated with the current 1-hour NAAQS is approximately 1–21%, dropping to approximately <3% for a 0.10 ppm 1-hour standard. For alternative 8-hour standards (of the same 1-expected-exceedance form as the current NAAQS), the estimated ranges of mean percentages of outdoor children exposed are approximately 3–7% for a 0.09 ppm standard, 0–1.3% for a 0.08 ppm standard, and from essentially 0 in most areas to <0.1% for a 0.07 ppm standard.

(4) In general, there are relatively small differences in comparing the distributions of 8-hour exposure estimates for outdoor children associated with 1- and 5-expected exceedance forms of any given alternative standard, although at particular cutpoints on the distribution,

differences between these two forms can appear to be significant in some areas.

(5) Based on comparisons of air quality distributions, estimated exposures are generally comparable for 8-hour standards with 5-expected-exceedance and fifth highest daily maximum concentration forms. In either case, exposure estimates for the worst year of a 3-year compliance period would be higher than for the average or typical year, with the magnitude of the difference varying across areas. For example, for an 8-hour, 0.08 ppm standard of either form, about 95% of current nonattainment areas would have 10 or fewer exceedances of the 0.08 ppm level in the worst year, compared to an average of less than 5 exceedances in the typical year. Exposures estimated for a year in which there were 10 exceedances of the 0.08 ppm level would be roughly comparable to the exposures estimated to occur upon attainment in a typical year of a 0.09 ppm, 8-hour standard, with 1- to 5-expected-exceedance forms.

In taking these observations into account, the Administrator and CASAC recognize the uncertainties and limitations associated with such analyses, including the considerable, but unquantifiable, degree of uncertainty associated with a number of important inputs to the exposure model. A key uncertainty in model inputs results from the availability of only a limited human activity database, with regard to both the number of subjects who contributed daily activity diary data and the short time periods over which subjects recorded their daily activity patterns. These limitations may not adequately account for day-to-day repetition of activities common to children, such that the number of people who experience multiple occurrences of high exposure levels may be underestimated. Small sample size also limits the extent to which ventilation rates associated with various activities may be representative of the population group to which they are applied in the model. In addition, the air quality adjustment procedure used to simulate air quality distributions associated with attaining alternative standards, while based on statistical analyses of empirical data, incorporates significant uncertainty, especially when applied to areas requiring very large reductions in air quality to attain the alternative standards examined or to areas that are now in attainment with the current NAAQS. A more complete discussion of these uncertainties and limitations is presented in the Staff Paper and the technical support documents (Johnson et al., 1996a,b).

2. Risk Assessment

The EPA conducted an assessment of health risks for several categories of respiratory effects associated with attainment of alternative 1- and 8-hour O_3 NAAQS and under a recent year of air quality (''as is'' air quality). The O_3 health risk assessment considers the same alternative air quality scenarios and the same nine urban areas that were examined in the human exposure analyses described above.

The objective of the risk assessment was to estimate the magnitude of risks to population groups believed by EPA and CASAC to be at greatest risk either due to increased exposures (i.e., outdoor children and outdoor workers) or increased susceptibility (e.g., asthmatics) while characterizing, as explicitly as possible, the range and implications of uncertainties in the existing scientific database. While the risk estimates are subject to uncertainties as discussed below and should not be viewed as demonstrated health impacts, EPA believes they do represent reasonable estimates as to the possible extent of risk for these effects given the available information. Although it does not cover all health effects caused by O_3, the risk assessment was intended as a tool, together with other information presented in the Staff Paper and in the revised Criteria Document, to aid the Administrator in judging which alternative O_3 NAAQS would reduce risks sufficiently to protect public health with an adequate margin of safety.

The health risk assessment builds upon the earlier O_3 NAAQS health risk assessment work developed during the previous review of the standard. The health risk model takes into account (1) concentration-response or exposure-response relationships used to characterize various respiratory effects of O_3 exposure, (2) distributions of O_3 1-hour and 8-hour daily maximum concentrations upon attainment of alternative NAAQS obtained from the pNEM/O_3 analyses described above, and (3) distributions of population exposure, in terms of both the number of individuals in the general population, outdoor workers, and outdoor children exposed and the number of occurrences of exposure, upon attainment of alternative O_3 NAAQS, obtained from the O_3 exposure analyses. A more detailed description of the risk assessment methodology and its application is presented in Section V.H of the Staff Paper and associated technical support document (Whitfield et al., 1996).

a. Adverse Lung Function and Respiratory Symptom Responses

Risk estimates have been developed for several of the respiratory effects observed in controlled human exposure studies to be associated with O_3 exposure. These include lung function decrements (measured as changes in FEV_1) and moderate or severe pain on deep inspiration (PDI). Each of the effects is associated with a particular averaging time and, for most of the acute (1- to 8-hour) responses, effects also are estimated separately for specific ventilation ranges [measured as equivalent ventilation rate (EVR)] that correspond to the EVR ranges observed in the health studies used to derive exposure-response relationships.

An effect, or endpoint, can be defined in terms of a measure of biological response and the amount of change in that measure thought to be of concern. For lung function decrements, estimates are provided for the lower end, midpoint, and upper end of the range of response that might be considered an adverse health effect (i.e., $\geq$10, 15, or 20% FEV_1 decrements) as discussed in II.A.3 above. For acute symptomatic effects, estimates are provided for responses that EPA considers to be of most concern (e.g., moderate and severe PDI). Due to limitations in the available data, the risk assessment provides estimates only for each individual health endpoint rather than various combinations of functional and symptomatic responses.

The acute exposure-response relationships developed were based on the clinical studies and were applied to ''outdoor children,'' ''outdoor workers,'' and the general population. While these specific clinical studies only included adults aged 18–35, findings from other clinical studies and summer camp field studies in at least six different locations in the northeast United States, Canada, and Southern California indicate changes in lung function in healthy children similar to those observed in healthy adults exposed to O_3 under controlled chamber conditions.

While different risk measures are provided by the O_3 health risk assessment, EPA has focused on ''headcount risk'' estimates. Headcount risk provides estimates of both the number of people affected and the number of incidences of a given health effect, considering individuals' personal exposures as they go about their daily activities (e.g., from indoors to outdoors, moving from place to place, and engaging in activities at different exertion levels).

A major input to the headcount risk model is the series of population exposure distributions for the alternative NAAQS analyzed. Using available exposure estimates, risk estimates were calculated for the nine urban areas examined in the exposure analysis. For 8-hour exposures under moderate exertion, outdoor children represent the population group experiencing the greatest exposure, and, therefore, this population also has the highest risk estimates in terms of the percent of the population estimated to respond. Therefore, this summary of results focuses on the risk estimates for outdoor children. Whitfield et al. (1996) presents results of the headcount risk estimates for each of the nine urban areas for outdoor children and outdoor workers.

Table 1 presents a summary of risk estimates for 8-hour and 1-hour health endpoints for outdoor children upon attainment of alternative 8-hour, 1- and 5-expected exceedance standards and the current 0.12 ppm, 1-hour standard. The risk estimates in Table 1 are for effects associated with exposure under moderate exertion. These risk estimates represent an aggregate estimate for the nine urban areas examined; an aggregate estimate is presented since there is significant variability in this risk measure across the areas. The uncertainty in these risk estimates associated with sample size considerations is characterized by the 90 percentile credible intervals shown.

TABLE 1.—PERCENT OF OUTDOOR CHILDREN ESTIMATED TO EXPERIENCE VARIOUS HEALTH EFFECTS 1 OR MORE TIMES PER YEAR ASSOCIATED WITH 8- AND 1-HOUR OZONE EXPOSURES UPON ATTAINING ALTERNATIVE STANDARDS*

Alternative standards		Pulmonary function decrements, FEV_1 ≥15% associated with 8-hour exposures	Pulmonary function decrements, FEV_1 ≥20% associated with 8-hour exposures	Moderate or severe pain on deep inspiration associated with 1-hour exposures
Level	Averaging time and form			
0.07 ppm	8-hour, 1 expected exceedance	3.0 **(1.0–6.6)	0.4 (0.1–1.8)	0.3 (0.01–1.9)
0.08 ppm	8-hour, 1 expected exceedance	5.1 (2.2–9.6)	1.4 (0.5–3.7)	0.6 (0.05–2.7)
	8-hour, 5 expected exceedances	6.7 (3.3–11.9)	2.3 (0.8–5.3)	0.8 (0.1–3.2)
0.09 ppm	8-hour, 1 expected exceedance	7.7 (3.3–13.3)	2.7 (1.0–6.1)	0.9 (0.1–3.5)
	8-hour, 5 expected exceedances	9.5 (5.1–15.9)	3.8 (1.5–7.9)	1.3 (0.2–4.2)
0.12 ppm	1-hour, 1 expected exceedance	8.3 (8.2–14.2)	3.0 (1.1–6.6)	1.0 (0.1–3.6)

* Estimates represent aggregate results for 9 urban areas examined. The total number of outdoor children residing in the 9 urban areas was 3.1 million.

** 90% credible interval.

Key observations important in comparing estimated health risks associated with attainment of the current NAAQS and alternative standards under consideration include:

(1) On both an absolute number and a percentage basis, risk estimates are higher for effects associated with 8-hour exposures under moderate exertion than for effects associated with 1-hour exposures under heavy exertion.

(2) Reflecting a continuum of risk, there is a decreasing trend in the median estimates of the population estimated to experience the lung function and symptomatic responses as one moves along the range of alternative 8-hour average, 1-expected exceedance standards under consideration. For example, based on the aggregate risk estimates summarized in Table 1, the median percent of outdoor children estimated to experience FEV_1 decrements greater than 15% is reduced from about 7.7% for a 0.09 ppm, 8-hour standard to about 5.1% for a 0.08 ppm, 8-hour standard. Attaining a 0.07 ppm, 8-hour standard results in a further reduction to about 3.0% of outdoor children estimated to experience this effect.

(3) In general, the differences in risk estimates for outdoor children associated with 1- and 5-expected exceedance standards set at the same standard level are relatively modest within the continuum of risk. For example, the risk estimates for lung function decrements ≥15% associated with a 5-expected exceedance standard set at 0.08 ppm fall between the risk estimates for the 0.08 and 0.09 ppm, 1-expected exceedance, 8-hour standards. Similarly, the risk estimates for a 5-expected exceedance standard set at 0.09 ppm fall between the risk estimates for the 0.09 and 0.10 ppm, 1-expected exceedance, 8-hour standards. The risk estimates for the current 0.12 ppm, 1-hour standard fall between the risk estimates for the 0.09 ppm, 1- and 5-expected exceedance standards.

(4) Multiple occurrences of lung function decrements ≥15% and ≥20% associated with 8-hour exposures under moderate exertion are estimated to occur for outdoor children upon attainment of any of the alternative 1- or 8-hour standards analyzed. The average seasonal numbers of occurrences per responder across the urban areas included in the analysis range from four to about nine for lung function decrements ≥15% and from two to about five for lung function decrements >20%, such that some individuals will experience more frequent occurrences of effects during the O_3 season, whereas others will experience fewer occurrences than the average in any given area.

(5) Based on comparisons of air quality distributions, risk estimates are generally comparable between 8-hour standards with 5-expected exceedances or fifth-highest daily maximum concentration forms. As noted in the previous discussion of the exposure estimates, for either form the worst year of a 3-year compliance period would be higher than for the average or typical year. For example, about 95% of current nonattainment areas meeting either form of an 8-hour, 0.08 ppm standard would have 10 or fewer exceedances in the worst year, compared to an average of less than five exceedances in a typical year. Risk estimates for a year in which there were 10 exceedances of 0.08 ppm, 8-hour average vary from urban area to urban area but fall between the risk estimates for a 5-expected exceedance standard of 0.08 ppm and a 5-expected exceedance standard set at 0.09 ppm.

The EPA believes, and CASAC concurred, that the models selected to estimate exposure and risk are appropriate and that the methods used to conduct the health risk assessment represent the state of the art. Nevertheless, the Administrator and CASAC recognize that there are many uncertainties inherent in such analyses. 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). Some of the most important caveats and limitations concerning the health risk assessment for lung function and respiratory symptom endpoints include: (1) The uncertainties and limitations associated with the exposure analyses discussed above, (2) the extrapolation of exposure-response functions below the lowest-observed-effects levels to an estimated background level of 0.04 ppm, and (3) the inability to account for some factors which are known to affect the exposure-response relationships (e.g., assigning children the same symptomatic response rates as observed for adults and not adjusting response rates to reflect the increase and attenuation of responses that have been observed in studies of lung function and symptoms upon repeated exposures). A more complete discussion of assumptions and uncertainties is contained in the Staff Paper and in the technical support document (Whitfield et al., 1996).

b. Excess Respiratory-Related Hospital Admissions

As discussed earlier in this notice, several epidemiology studies, mainly conducted in the northeastern portion of the U.S. and southeastern Canada, have reported excess daily respiratory-related hospital admissions associated with elevated O_3 levels during the O_3 season. To gain insight into the possible impact of just attaining alternative 1- and 8-hour O_3 standards, EPA has developed a risk model for this endpoint. The model is based on the regression coefficient (and the corresponding standard error) developed by Thurston et al. (1992) for New York City and estimated daily maximum hourly average O_3 levels over an entire season at various monitors in New York City upon attainment of alternative standards (as developed for the pNEM/O_3 analysis). The regression coefficient (11.7 admissions/ppm $O_3/10^6$ people) and its standard error (4.7 admissions/ppm $O_3/10^6$ people) were used to define a probabilistic concentration-response relationship. The model is described in more detail in Whitfield et al. (1996). One-hour daily maximum O_3 concentrations for one O_3 season under various alternative air quality standards were used to estimate the number of excess respiratory-related admissions of asthmatics (i.e., those attributable to O_3 concentrations higher than background). The O_3 concentration-response relationship developed by Thurston et al. (1992) was based on air quality data from the Queens monitor. Therefore, the risk estimates based on the Queens County monitor most closely represent the air quality index used in the original study and are summarized below. In each analysis, the air quality was adjusted to just attaining a particular standard at the monitor with the highest O_3 levels for the New York area, and the O_3 levels were adjusted at the other monitors using the procedures described in Johnson et al. (1996a).

Based on Table V–20 in the Staff Paper, the hospital admissions model results in a median estimate of excess respiratory-related admissions for asthmatic individuals attributable to O_3 exposure of approximately 390 (with a 90% credible interval of approximately 130–640) per year for the New York City area based on ''as is'' air quality using 1991 data. Just attaining the current 0.12 ppm, 1-hour standard is estimated to reduce excess hospital admissions to about 210 (with a 90% credible interval of 70–340), which is approximately a 50% decrease in O_3-induced admissions due to concentrations in excess of the estimated 0.04 ppm estimated background level. Upon attaining the 0.08 ppm, 8-hour, 1 expected exceedance standard, for example, the median estimate for excess respiratory-related hospital admissions attributable to O_3 exposure is further reduced to approximately 115 (with a 90% credible interval of approximately of 40–190). This represents a 70% decrease in O_3-induced hospital admissions from the ''as is'' scenario and about a 45% decrease from the current 1-hour standard.

It should be recognized that the O_3-induced excess hospital admissions represent a relatively small fraction of the overall respiratory-related hospital admissions for asthmatics over the seven month O_3 season. Based on an estimated 15,000 admissions per year during the O_3 season, the reduction in hospital admissions for asthmatics for any respiratory-related reason in going from ''as is'' air quality to attaining a 0.08 ppm, 8-hour, 1-expected exceedance standard is about 2%. Similarly, the reduction from attaining the current 1-hour standard to attaining a 0.08 ppm, 8-hour, 1-expected exceedance standard represents about a 0.6% decrease in total respiratory admissions for asthmatics due to all causes.

Key observations important in comparing hospital admission risk estimates associated with attainment of the current NAAQS and alternative standards under consideration include:

(1) Risk estimates for excess hospital admissions for asthmatics attributable to O_3 exposures in excess of an estimated background level of 0.04 ppm are projected to be significantly reduced (about 45%) under a 0.08 ppm, 8-hour, 1-expected exceedance standard compared to the current 1-hour NAAQS.

(2) The excess hospital admissions risk estimates associated with 1- and 5-expected exceedance standards set at 0.08 ppm are very similar.

(3) When viewed from the perspective of respiratory-related admissions for asthmatics due to all causes, the excess hospital admissions attributable to O_3 exposures in excess of an estimated background concentration of 0.04 ppm constitute a relatively small portion of total admissions. For example, comparing the risk estimates associated with the current 1-hour NAAQS and a 0.08 ppm, 8-hour, 1-expected exceedance standard results in only about a 0.6% reduction in respiratory hospital admissions for asthmatics due to all causes.

In taking these observations into account, the Administrator recognizes the uncertainties and limitations associated with the hospital admission risk assessment. These include: (1) The inability at this time to quantitatively extrapolate the risk estimates for the New York City area to other urban areas, (2) uncertainty associated with the underlying epidemiological study that served as the basis for developing the concentration-response relationship used in the analysis, and (3) uncertainties associated with the air quality adjustment procedure used to simulate attainment of alternative standards for the New York City area. A more complete discussion of these uncertainties and limitations is presented in the Staff Paper and technical support document (Whitfield et al., 1996).

c. Conclusions on the Elements of the Primary Standard

In selecting a primary standard for O_3, the Administrator must specify: (1) Averaging time, (2) O_3 concentration (i.e., level), and (3) form (i.e., the air quality statistic to be used as a basis for determining compliance with the standard).[5] All three of these elements are necessary to define a standard. Based on the assessment of relevant scientific and technical information in the Criteria Document, section VI of the Staff Paper outlines a number of key factors to be considered in specifying each of these elements, as well as recommendations to focus consideration on a discrete range of options for each

[5] This review focused only on a standard for O_3, as the most appropriate surrogate for photochemical oxidants.

element. The factors reflect an integration of information on acute and chronic health effects associated with exposure to ambient O_3; expert judgments on the adversity of such effects for individuals; and policy judgments, informed by air quality 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 proposed primary standard was endorsed by members of CASAC (Wolff, 1995b), particularly through their advice to the Administrator that ''EPA's risk assessments must play a central role in identifying an appropriate level'' and their recognition that the selection of a specific concentration and form ''is a policy judgment.'' Further, it was the consensus view of CASAC that the ranges of levels (0.07 to 0.09 ppm) and forms (1 to 5 exceedances) recommended in the Staff Paper were appropriate.

Thus, the Administrator has focused her consideration on the recommended options and key factors outlined in the Staff Paper. The considerations that were most influential in the Administrator's selection of each specific element of the proposed standard are outlined below.

1. Averaging Time

The Administrator concurs with the unanimous recommendation of CASAC (Wolff, 1995b) ''that the present 1-hr standard be eliminated and replaced with an 8-hr 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) standard. These judgments are 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-hours) 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_3 concentrations than is the 1-hour averaging time. It was thus the consensus of CASAC ''that an 8-hr standard was more appropriate for a human health-based standard than a 1-hr 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 not corresponding 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 concludes that consideration of a separate long-term O_3 standard is not appropriate at this time. As discussed below, however, the Administrator has considered the possibility of long-term effects in selecting the level of the 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.

2. Level

The Administrator's consideration of an appropriate level for an 8-hour standard to protect public health with an adequate margin of safety necessarily reflects a recognition, as emphasized by CASAC, that it is likely that ''O_3 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 becomes one of attempting 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. Consequently, as CASAC recognized, ''the selection of a specific level * * * is a policy judgment'' (Wolff, 1995b). The Administrator's policy judgment on the level of the proposed standard is framed by the above considerations and informed by the following key observations and conclusions:

(1) During the last review of the O_3 criteria and standards, the CASAC concluded that the existing 1-hour standard set at 0.12 ppm O_3 provided ''little, if any, margin of safety,'' and 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_3.

Regarding currently available evidence of O_3-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_3 effects of concern are associated with the 8-hour exposures tested. Studies were done at 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_3, 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_3 exposures that are consistent with the clinical findings. Laboratory animal studies provide supporting evidence of O_3-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_3 exposures, including O_3

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_3 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_3 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_3 levels result in similar chronic health effects in humans.

Regarding the types and severity of O_3-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 recognizes that these O_3-induced effects are transient and reversible, and concludes 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_3 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 extremely 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 judges that such effects are clearly adverse to individuals.

(7) With regard to pulmonary inflammation, the Administrator recognizes that singular occurrences of inflammation are likely reversible and potentially of little health significance. On the other hand, repeated inflammatory responses associated with exposure to O_3 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.

Accordingly, the Administrator judges that repeated exposures to O_3 levels that produce inflammation of the lungs are adverse to individuals likely to experience such exposures over long periods of time.

The Administrator has 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 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 functional and symptomatic effects, as well as for excess hospital admissions and emergency room visits due to respiratory causes, are approximately the same or only marginally smaller for some of the 0.09 ppm 8-hour standard options evaluated (including those with forms ranging from 1- to 3-expected-exceedances[6]) as compared to the current 0.12 ppm 1-hour NAAQS (risk estimates are somewhat larger for a 0.09 ppm 8-hour 5-expected-exceedance form as compared to the current NAAQS).

(9) Within any given urban area, statistically significant reductions in exposure and risk associated with 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 would likely experience such effects under the range of alternative standards considered relative to the current standard.[7] 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.

(10) Similarly, reductions in hospital admissions and emergency room visits for asthmatic individuals 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_3 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_3 season.

(11) Estimated exposures to O_3 concentrations ≥0.08 ppm (at which increased nonspecific bronchial responsiveness, decreased pulmonary defense mechanisms, and indicators of pulmonary inflammation have been observed in humans) are essentially zero at the 0.07 ppm standard level for most areas evaluated in the exposure analyses for the at-risk population of outdoor children. Such exposures of outdoor children increase to approximately 0 to 1.3% at the 0.08 ppm level, while the estimated range at the 0.09 ppm level rises to 3–7% for the areas evaluated.

(12) While recognizing that extremely 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_3 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_3 levels as low as 0.07 ppm.

[6] Based on air quality comparisons, since risk estimates are only currently available for the 1- and 5-expected-exceedance forms of a 0.09 ppm standard.

[7] With regard to these risk analyses, CASAC concluded ''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 noted that the differences in percent of outdoor children responding between the present standard and the most stringent standard ''are small and their ranges overlap for all health endpoints.'' (Wolff, 1995b) To address any apparent differences between EPA's and CASAC's conclusions, it is important to note that EPA's risk analysis report (Whitfield et al., 1996) makes clear that there are *statistically significant* differences in estimated risk for alternative standard levels; 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* cities used in EPA's risk analysis (e.g., air quality, esposure patterns, environmental factors), not *random uncertainties in risk estimates within any given city*. Thus, the fact that the ranges overlap does not mean that there are no real or statistically significant differences in protection among alternative standards.

After carefully assessing the key observations and conclusions drawn from the available scientific evidence and analyses, and taking into account the advice of CASAC and comments from the public, the Administrator focused her consideration on two policy options for the level of the primary O_3 standard: 0.08 ppm and 0.09 ppm. A standard set at a level of 0.09 ppm (within the middle of the range of forms discussed below) would result in approximately equivalent public health protection as that afforded by the current standard; a 0.08 ppm level would provide greater protection. In her judgment, the selection of either level could properly take into account the available scientific and technical information and would be consistent with the views expressed by her scientific advisors, since none of the CASAC panel members expressed the view that the standard level should be set below 0.08 ppm. On the other hand, the Administrator is aware of alternative views that place great weight on margin of safety considerations, leading to support by some commentors for a standard level option of 0.07 ppm, as discussed further below.

In deciding between the 0.08 ppm and 0.09 ppm alternatives, the Administrator took into account several factors including: (1) Estimates of risk, in terms of the percentage of children likely to experience respiratory symptoms and decreases in lung function of concern; (2) estimates of exposures to the lowest concentration at which other, more uncertain effects have been observed; and (3) the body of health effects evidence as a whole.

In considering risk estimates, she noted that there is a continuum of increasing risk reduction in going from the upper end of the range of consideration (0.09 ppm, with a 5-expected-exceedance form) down to the lower end of this range (0.08 ppm, with a 1-expected-exceedance form) and below, and that the current 1-hour standard provides a level of protection within but near the top of this range. These quantitative risk estimates are summarized in Table 1 above, showing the varying percentages of children estimated to experience these symptomatic and functional effects of concern for the alternative 0.08 and 0.09 ppm 8-hour standards. Quantitative risks could be estimated for these effects because studies are available that allow for a determination of how the percentages of individuals likely to experience such effects vary as a function of the O_3 concentrations to which they are exposed.

With respect to exposure estimates, she noted that these alternative standards provide differing degrees of protection from exposures to O_3 concentrations that have been associated with other potentially adverse, but more uncertain effects, including nonspecific bronchial responsiveness (related, for example to aggravation of asthma) and inflammation of the lungs (related to potential chronic aggravation of bronchitis or long-term damage to the lungs). For these effects, the evidence is not sufficient to conduct a quantitative risk assessment, but the relative protection of the alternative standards can be considered in terms of the percentages of outdoor children who would be exposed one or more times to the lowest concentration at which evidence of these effects has been observed (i.e., 0.08 ppm). As noted above, in summarizing key observations from the exposure assessment, the percentages of outdoor children likely to be exposed to the level are approximately 3 to 7% for a 0.09 ppm standard (with a 1-expected-exceedance form) and approximately 0 to 1.3% for a 0.08 ppm standard with the same form. For comparison, these exposures range from approximately 1 to 21% for the current 1-hour standard of 0.12 ppm,[8] dropping to essentially 0% for a 0.07 ppm 8-hour standard. While the public health risks associated with these effects are uncertain and cannot be assessed definitively, the Administrator finds these different exposures to be an important factor in making this policy choice.

Both the quantitative risk estimates for respiratory symptoms and decreased lung function and the exposure estimates associated with bronchial responsiveness and inflammation of the lung provide an important perspective in assessing the public health implications of effects observed in individuals exposed to various O_3 concentrations. Nonetheless, the Administrator believes that these estimates alone do not provide a clear basis for making a policy choice between the 0.09 and 0.08 ppm levels for an 8-hour standard.

Finally, the Administrator noted that in a number of clinical studies examining all of the effects discussed above in human subjects, various researchers have consistently reported statistically significant effects at an exposure level of 0.08 ppm. This exposure level reflects the lowest level that researchers have chosen to conduct the relevant studies, and it does provide a strong point of consistency in the currently available scientific evidence. Effects at this level observed in clinical studies are also consistent with the results of epidemiological and summer camp studies reporting similar symptomatic and functional effects associated with exposures to ambient levels of O_3 that broadly span this clinical lowest-observed-effects level.

The Administrator has weighed the importance of increased protection for those extremely sensitive individuals who may experience symptomatic and functional effects at lower O_3 concentrations than the population as a whole, the uncertainties in considering the potentially more serious but as yet uncertain chronic effects. For all these reasons, the Administrator is proposing to set the level of an 8-hour O_3 standard at 0.08 ppm.

However, as noted above, in making this judgment, the Administrator is mindful that a range of views has been expressed as to the appropriate policy choice between 0.08 ppm and 0.09 ppm for an 8-hour standard level. For example, while some CASAC members supported the choice of the proposed 0.08 ppm, fully half or more of the CASAC panel members expressing views on a specific level supported a specific level or range of levels that include 0.09 ppm.

Those that favored a 0.09 ppm standard did so on the basis of several kinds of judgments. As the CASAC noted, it is unclear whether there is a threshold level for the various health effects discussed above. For this reason, some CASAC members and others have suggested that it is difficult to determine if a margin of safety exists for any particular level and therefore, in their opinion the differences in health protection may not be significant enough to justify a change from the current standard.

Others may support a 0.09 ppm standard on the basis of uncertainties about: (1) The medical significance of the reported effects of O_3 exposure at these levels for individuals experiencing such effects; (2) the public health significance of the degree of exposure and risk reduction likely to be achieved by moving from 0.09 ppm O_3 to 0.08 ppm O_3; (3) the appropriate weight to be given to the health endpoints that could not be addressed in the quantitative risk assessment; and 4) how to address the various uncertainties in the scientific evidence on health effects and in the exposure and risk estimates in making a policy decision on a standard level

[8] The wide range of exposures for this 1-hour standard (compared to the narrower ranges for the 8-hour standards) reflects much greater variability across cities in the extent to which a 1-hour standard limits 8-hour exposures.

that will protect public health with an adequate margin of safety.

A policy decision to set a 0.09 ppm 8-hour standard would place more weight on the transient and reversible nature of reported decrements in lung function, increased respiratory symptoms, and lung inflammation, and would call into question the medical significance of moderate levels of such effects, particularly for healthy individuals. This view would also emphasize the relatively small fraction of the overall respiratory-related hospital admissions for asthmatics that are estimated to be linked to O_3 exposures over the O_3 season. Thus, it could be reasonable to judge that any incremental reduction in such risk achieved by levels below 0.09 ppm O_3 would be of little consequence when viewed from a broader public health perspective. Further, this view would note the lack of evidence linking O_3-induced markers of inflammation and cell damage with chronic respiratory damage in humans. In this view, while the potential for O_3-induced chronic respiratory damage would be a matter of public health concern, additional research would be needed before such concerns should be reflected in margin of safety considerations. These interpretations of the evidence and judgments as to the nature and significance of the reported O_3-induced health effects, could justify a judgement that an 8-hour standard set at 0.09 ppm O_3 protects public health with an adequate margin of safety. Thus, the Administrator solicits public comment on this alternative of a 0.09 ppm level for an 8-hour standard.

In sharp contrast, the Administrator also notes that others would make a different set of judgments as to the significance of O_3-induced health effects and the appropriate public health policy response. To reflect these views, the Administrator is also requesting comment on the alternative of establishing the level of an 8-hour standard at 0.07 ppm. A standard set at this level, within a range of forms (as discussed in the next section), would be highly precautionary in nature. A policy decision to select such a standard would reflect an emphasis on (1) The many studies that have reported observed effects in humans at moderate levels of exercise at an exposure level of 0.08 ppm; (2) judgments that the reported decrements in lung function, increased respiratory symptoms, and indicators of inflammation, even when transient and reversible at moderate levels, are adverse effects; and (3) judgments that even the most sensitive responders should be afforded protection against the occurrence of such effects through national ambient air quality standards. This view would judge that even a relatively small number of O_3-induced excess hospital admissions do pose a significant public health problem, especially considering that for every hospital admission, there are likely many more patients visiting physicians and an increasing use of medication. Further, even though no clear linkage has been established between the O_3-induced markers of inflammation, cell damage, and chronic respiratory damage shown in animal toxicological studies and similar effects in humans, this view would hold that the possibility of such a link suggests the need for a wide margin of safety.

Based on these judgments as to the nature and significance of the reported O_3-induced health effects, some commentors would reach the policy judgment that an 8-hour standard should be set at 0.07 ppm to protect public health with an adequate margin of safety. In recognition of this view, the Administrator also solicits public comment on an 0.07 ppm level for an 8-hour standard.

Based on the comments received and the accompanying rationale, the Administrator may choose at the time of final promulgation to adopt a standard from within the range of alternatives on which she is requesting comment, with further specification of the form of such a standard (as discussed in the next section), in lieu of the 0.08 ppm level of the 8-hour O_3 standard she is proposing today.

3. Form

The current primary NAAQS is expressed in a ‘‘1-expected-exceedance’’ form. That is, the standard is formulated on the basis of the expected number of days per year, on average, on which the level of the standard will be exceeded. More specifically, the test for determining attainment of the standard specifies that the expected number of days per year on which the level is exceeded is to be less than or equal to 1.0 (values equal to or greater than 1.05 round up), averaged over a three year period, and that specific adjustments are to be made for missing data. The current NAAQS is applied on a site-by-site basis; data from multiple air quality monitoring sites are not combined.

Since promulgation of the current NAAQS in 1979, a number of concerns have been raised about the 1-expected-exceedance form. These include, in particular, the year-to-year stability of the number of exceedances, the stability of attainment status of an area, the data handling conventions, including the procedures for adjusting for missing data, and the evaluation of air quality on a site-by-site basis rather than some form of averaging across monitoring sites. These issues are discussed in some detail in section V.I of the Staff Paper, and alternative forms that would address such issues are recommended for consideration.

In evaluating alternative forms for the primary standard, the adequacy of the public health protection provided is of foremost consideration. However, consistent with the advice of CASAC, the Administrator is also interested in considering alternative forms that provide increased stability and thereby reduce the likelihood of areas ‘‘flip-flopping’’ in and out of attainment simply as a result of natural variability in meteorological conditions that are conducive to O_3 formation. Such instability can have the effect of reducing public health protection by disrupting ongoing implementation plans and associated control programs.

Based on information presented in sections IV and V.I of the Staff Paper and the advice of CASAC, the Administrator has 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 three 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 three-year average of the nth-highest daily maximum 8-hour average O_3 concentration, as an alternative to an expected exceedance statistic. Air quality analyses presented in the Staff Paper indicate that, for example, the 3-year average of the annual third highest daily maximum 8-hour concentration provides approximately the same health protection as the 3-expected-exceedance form averaged over the same period. Similarly, the 3-year average of the annual fifth-highest daily maximum 8-hour average concentration approximately corresponds to an expected-exceedance form that allows five expected exceedances averaged over three years.

The CASAC acknowledged that selecting from 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. However, CASAC did recommend that a more robust, concentration-based form (one that would allow for multiple exceedances) be adopted to provide additional stability in control programs, and thus in public health protection, by insulating an area from the impacts of extreme meteorological events (Wolff, 1995b).

In reaching her proposed decision on the form of the standard, the Administrator first assessed the degree of health protection that would be provided by alternative expected-exceedance forms of the standard. Having decided to propose a level of 0.08 ppm for an 8-hour primary standard, as discussed above, the Administrator focused on the degree of risk reduction that would be achieved by a 1-expected-exceedance form as compared to a 5-expected-exceedance form. Examination of the quantitative risk assessment results discussed above revealed that, within the range of one to five expected exceedances, the dominant factor in determining the degree of risk reduction achieved is the level of the standard, with the number of expected exceedances being associated with smaller differences in risk estimates within a continuum of risk.

In considering possible forms within the range of one to five expected exceedances, the Administrator took into account as the foremost consideration the adequacy of public health protection provided. This includes consideration of (1) aggregate risk for those health effects for which quantitative risk analyses have been done; (2) consideration of exposures associated with those effects for which no quantitative risk estimates could be developed; and (3) the magnitude of peak measurements of 8-hour average O_3 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). Based on these considerations, the Administrator judges that the middle of the range, three expected exceedances, would represent a reasonable policy choice. Relative to a standard set at the upper end of the range (i.e., a 5-expected-exceedance standard), a 3-expected-exceedance standard would serve to better limit the number of days in which the level of the standard would be exceeded in areas that just attain the standard [9], as well as limiting the magnitude of peak measurements of 8-hour average O_3 concentrations that would occur in such areas.[10] A 3-expected-exceedance standard would also provide significantly increased stability relative to a standard set at the lower end of the range (i.e., the current 1-expected-exceedance form [11]). The Administrator believes that such a policy choice would appropriately reflect the advice of CASAC.

The Administrator also considered whether the form should be expressed in terms of expected exceedances or generally equivalent concentration-based statistics. As discussed in the Staff Paper, a concentration-based statistic has certain advantages over the expected-exceedance form. The principal advantage is that a concentration-based form is more directly related to the ambient O_3 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_3, the extent to which public health is affected by exposure to ambient O_3 is related to the actual magnitude of the O_3 concentration, not just whether the concentration is above a specified level. With an exceedance-based form, days on which the ambient O_3 concentration is well above the level of the standard are given equal weight to those days on which the O_3 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_3 concentrations occur would weigh proportionally more than days with lower O_3 concentrations, since the actual concentrations are used directly in determining whether the standard is attained. Further, based on analyses of historical air quality data (Freas, 1996), concentration-based forms control peak measures of O_3 concentrations somewhat better than the corresponding exceedance-based forms [12], although exceedance-based forms tend to limit the numbers of days on which the level of the standard is exceeded somewhat better than concentration-based forms [13]. 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.

Taking the factors discussed above into account, as well as the advice of CASAC and the observations and conclusions discussed in the Staff Paper, the Administrator believes that the primary standard should be expressed in terms of concentrations rather than expected exceedances. As indicated above, the 3-year average of the annual third-highest daily maximum 8-hour average O_3 concentration would provide approximately the same degree of health protection as the 3-expected-exceedance form averaged over the same period. Accordingly, the Administrator proposes to express an 8-hour primary standard of 0.08 ppm as the 3-year average of the annual third-highest maximum 8-hour average O_3 concentration, so as to reduce risk sufficiently to protect at-risk populations, including outdoor children, outdoor workers, and persons with preexisting respiratory disease, against adverse health effects with an adequate margin of safety. Such a standard would also provide a more stable basis upon which the States can design and implement their O_3 control programs. Given the range of views discussed in the above section on level of the standard, however, the Administrator also solicits comment on other concentration-based forms within the range of the second- to the fifth-highest daily maximum 8-hour average O_3 concentrations.

[9] Areas that "just attain the standard" are defined as those whose design value falls between 0.075 and 0.084 ppm. Based on 1993–1995 air quality data, 95% of monitoring sites that just attain a 0.08 ppm standard with a 3-expected-exceedance form would have 6 or fewer days on which the standard would be exceeded, in the worst of the three years, as compared to 10 days or fewer days with a 5-expected-exceedance form (Freas, 1996).

[10] Based on 1993–1995 air quality data, 4% of monitoring sites that just attain a 0.08 ppm standard with a 3-expected-exceedance form would have 8-hour peak O_3 concentrations (in terms of the 4th highest daily maximum concentration in three years) above a benchmark level of 0.09 ppm, as compared to 22% of such sites with a 5-expected exceedance form (Freas, 1996).

[11] In comparing alternative 8-hour standards to the current standard (0.12 ppm, 1-hour average) with a 1-expected-exceedance form, 77% of monitoring sites that just attain the current standard would have 8-hour peak O_3 concentrations (in terms of the 4th highest daily maximum concentration in three years) above a benchmark level of 0.09 ppm.

[12] For example, whereas 4% of monitoring sites that just attain a 0.08 ppm standard with a 3-expected-exceedance form would have 8-hour peak O_3 concentrations above the benchmark of 0.09 ppm, only 1% of such sites with a 3rd (or 2nd) highest daily maximum concentration form would do so. Similarly, whereas 22% of just-attain sites with a 5-expected-exceedance form would have peak concentrations above the 0.09 ppm benchmark, 17% of such sites with a 5th highest daily maximum concentration form would do so.

[13] For example, whereas 95% of monitoring sites that just attain a 0.08 ppm standard with a 3-expected-exceedance form would have 6 or fewer days on which the standard would be exceeded, in the worst of the three years, with a 3rd highest concentration form 95% of such sites would have 7 or fewer such days. Similarly, with a 5-expected-exceedance form, 95% of such sites would have 10 or fewer such days, as compared to 11 or fewer days with a 5th highest concentration forms (Freas, 1996).

The Administrator has also considered whether the above conclusions on the form of a standard would be affected if she selected one of the alternative levels of a standard discussed in the previous section. During the last review of the O_3 criteria and standards the CASAC concluded that the existing 1-hour standard of 0.12 ppm O_3 provides little, if any, margin of safety, and during this review the new evidence focuses on effects below the level of the current NAAQS. In general, the risks projected (based on air quality analyses) for a 3-expected-exceedance form of a 0.09 ppm standard are only marginally below those estimated to occur upon attainment of the current NAAQS. Taking these factors into account, the Administrator judges that consideration of a form for an alternative 0.09 ppm 8-hour standard should be limited to the third-highest daily maximum 8-hour average O_3 concentration, averaged over 3 years, so as not to relax the level of protection afforded by the current standard. With regard to the alternative of a possible 0.07 ppm 8-hour standard, the Administrator judges that the conclusions discussed above with respect to the 0.08 ppm level are applicable, such that consideration of the 3-year average of the annual third-highest daily maximum 8-hour average O_3 concentration is appropriate, with comment solicited on forms within the range of the second to the fifth highest.

The Administrator recognizes that none of the levels and forms under consideration would provide a risk-free standard, due to the continuum of risk likely posed by exposures to ambient O_3 potentially down to background levels. Accordingly, the Administrator believes, consistent with the advice of CASAC, that it would be appropriate to provide additional information to the public about the nature of risks associated with exposures to ambient O_3. Such information could 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_3 concentrations are predicted to be at or near the level of the proposed standard. As discussed in Section III below, one way to provide such information might be in conjunction with the Pollutant Standards Index already in use in many metropolitan areas.

A number of commentors have raised the issue of whether data from multiple monitoring sites, rather than data from the highest monitor might be used to determine when the primary standards for O_3 are attained.[14] These commentors have suggested that some form of averaging across monitors might be appropriate in order to increase the degree to which monitoring data used in determining attainment of the standard reflects population exposure and aggregate population health risk. Averaging data from multiple monitors in an area would produce a more stable measure of air quality, and could take into account broader population exposure patterns across an area than would the current approach of considering data from each monitor independently. When considering averaging approaches for O_3, it should be recognized that the bulk of the human health effects evidence supporting the decision on an appropriate O_3 standard is based on controlled human exposure studies that relate known O_3 exposures directly to responses in individuals.[15] Moreover, as discussed previously in this notice, the O_3 exposure analysis and the lung function and respiratory symptoms components of the health risk assessments, which were considered in developing this proposal, reflect the movement of people through time and space within an urban area and incorporate air quality data from the various monitors within each urban area in estimating population exposure and health risk for various population groups. For these reasons, it would be considerably more difficult to determine an appropriate level for a spatially averaged primary standard.

In any case, the Administrator does not believe it would be appropriate to consider averaging monitors across broad areas [e.g., a Consolidated Metropolitan Statistical Area (CMSA) or a Metropolitan Statistical Area (MSA)] because such averaging would not be reflective of the variability of O_3 concentrations across larger metropolitan areas. However, it may be appropriate to consider averaging monitors across smaller geographic areas within a CMSA/MSA if zones can be defined that better reflect the gradient of O_3 concentrations and associated population exposure. Any approach to averaging across monitors within an urban area must take into account not only the desirability of providing better characterizations of overall population exposure, where possible, but also concerns about whether adequate health protection would be provided to individuals within the populations that live or work in areas within a CMSA that routinely experience higher O_3 concentration levels.

In defining smaller geographic areas within which EPA might permit spatially averaged O_3 data (hereafter referred to as ‘‘spatial averaging zones’), it would be necessary to consider the variability of O_3 concentrations across the broader metropolitan area as reflected in the monitoring data. Ozone air quality concentrations vary significantly across most urban areas; the lowest concentrations typically occur in the urban center and in locations near O_3 precursor sources, mid-range concentrations in neighborhoods and areas 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 areas where individuals might be exposed more frequently to ambient O_3 concentrations of concern should be considered. In order for a spatially averaged value to represent potential individual exposures within the spatial averaging zone, the O_3 pollution concentration gradients within each of these spatial averaging zones would need to be relatively homogeneous. Otherwise, there may be significant numbers of sensitive individuals exposed to high O_3 concentrations in areas where the spatial average indicates that the overall air quality is acceptable.

Spatial averaging would also have implications for the existing O_3 monitoring infrastructure. Although a number of larger metropolitan areas have extensive O_3 monitoring networks, more than half of the 234 MSA’s with O_3 monitoring networks have only 1 or 2 O_3 monitoring sites. If a spatially averaged form of the O_3 NAAQS were to be adopted, EPA expects that the density of most O_3 monitoring networks would have to be increased, and/or that relocation of some O_3 monitoring sites might be necessary.

To help State and local governments devise different O_3 monitoring networks, the EPA would revise the 40

[14] Spatial averaging of monitoring data is also discussed in the notice of a proposed decision on the PM NAAQS published today, specifically with regard to an annual $PM_{2.5}$ standard. Different considerations apply in the two cases principally because of differences between (1) the nature of the health effects evidence for O_3 and $PM_{2.5}$; (2) a single proposed O_3 standard, in contrast to the proposed suite of annual and 24-hour $PM_{2.5}$ standards; and (3) the existence of an established, extensive O_3 monitoring network, in contrast to the absence at present of such a network for $PM_{2.5}$.

[15] In contrast, estimates of excess hospital admissions associated with O_3 and all of the human health effects evidence relating particulate matter to various responses are based on relationships between responses in population groups and pollutant concentrations observed at ambient fixed site monitors.

CFR Part 58 Ambient Air Quality Surveillance regulation and associated guidelines. In so doing, EPA would most likely define general criteria for monitoring network design, siting, and spatial averaging zones in nationally implementable terms; however, because of the variability of the O_3 pollution problem across the nation, a locally conducted case-by-case evaluation of each O_3 monitoring network, and the identification of appropriate zones for spatial averaging, would be necessary. This activity would place additional burdens on State and local air quality management agencies.

The Administrator believes that before such an averaging approach could be given appropriate consideration, the above concerns would need to be addressed. Thus, the Administrator solicits comment on whether it would be desirable to adopt some form of spatial air quality averaging for O_3 and on specific alternative approaches that might be adopted. In particular, the Administrator is 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 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 this proposal.

D. Proposed 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, and for the reasons discussed above, the Administrator proposes to replace the existing 1-hour primary standard with a new 8-hour, 0.08 ppm primary standard. The new 8-hour standard would become effective 30 days after the date of promulgation. 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), the Administrator also proposes except for two limited purposes (attainment demonstrations and reclassifications) that the revocation of the existing 1-hour standard would become effective at the time EPA determines that an area's State implementation plan provides for the achievement of the proposed new 8-hour standard. The EPA's plans for assuring an effective transition from the existing 1-hour standard to the proposed new 8-hour standard are proposed in the Interim Implementation Policy notice published elsewhere in today's Federal Register.

The proposed 0.08 ppm, 8-hour primary standard 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_3 concentration is less than or equal to 0.08 ppm. Data handling conventions are specified in proposed revisions to Appendix H, as discussed in Section V below.

The EPA solicits comments on alternative levels of 0.09 ppm, which generally represents the continuation of the present level of protection, as well as its proposed level of 0.08 ppm, an increased level of protection. The EPA also solicits comment on an alternative 8-hour standard at a level of 0.07 ppm and on retaining the current primary standard.

III. 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. Under section 303 of the Act, EPA identifies exposure levels that constitute ''an imminent and substantial endangerment to the health of persons.'' The EPA regulations (40 CFR 51.16) require the States to adopt contingency plans to prevent ambient pollutant concentrations from reaching these significant harm levels (SHLs). The SHL for O_3 is that level of O_3 at which serious and widespread health effects occur among the general population. With respect to the existing 1-hour O_3 NAAQS of 0.12 ppm, the SHL is 0.60 ppm, averaged over 2 hours. In developing strategies for implementing the proposed revision of the existing NAAQS, EPA will consider corresponding changes in the SHL and propose revisions as appropriate in conjunction with other proposed revisions to the 40 CFR Part 51.

Another program, known as the Pollutant Standards Index (PSI) has long been in use to provide accurate, timely, and easily understandable information about daily levels of pollution (40 CFR 58.50). The PSI establishes a uniform system of indexing pollution levels for O_3, carbon monoxide, nitrogen dioxide, particulate matter and sulfur dioxide. Reported PSI values [16] enable the public to know whether air pollution levels in a particular location are characterized by EPA as good, moderate, unhealthful, or worse. The PSI converts pollutant concentrations in a community's air to a number on a scale of 0 to 500. On that scale, the number 100 corresponds to the NAAQS for each particular pollutant. For the current O_3 NAAQS, a 1-hour average reading of 0.12 ppm is translated into a PSI value of 100. A PSI value in excess of 100 has meant that a pollutant is in the ''unhealthful'' (or worse) range on a given day; a PSI value at or below 100 has meant that a pollutant reading is in the satisfactory (moderate or good) range. Should the current 1-hour O_3 NAAQS be replaced by an 8-hour NAAQS as proposed, the PSI index would likely be revised to reflect 8-hour average concentrations.

In addition, 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, 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_3 concentrations close to the level of the primary standard. Given the continuum of risks associated with exposure to O_3, this information, while perhaps of interest to all citizens, would be particularly useful to those individuals who are extremely sensitive to relatively low O_3 concentrations. More specifically, the PSI could be expanded to include two new descriptive categories in the Index, one including concentrations within a range somewhat below the level of the new primary standard, the other including concentrations within a range somewhat above the level of the standard. Such an approach could better reflect the increased understanding of health effects associated with O_3 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).

For example, for concentrations somewhat below the level of the proposed standard, a new PSI category could be created with a descriptor such as ''moderately good.'' This category could be defined to correspond to 8-hour O_3 levels such as 0.07 to 0.08 ppm. Eight-hour average O_3 concentrations in this range potentially induce functional

[16] PSI values are reported in all metropolitan areas of the U.S. with populations ≥200,000.

and symptomatic responses that are small and mild, respectively, for most individuals, but could limit activity for a very small number of individuals within the subpopulation of those with impaired respiratory systems or who are otherwise extremely sensitive to O_3 exposure. An expanded warning system thus could include a caution to such individuals to consider reducing prolonged moderate to heavy exertion outdoors on days with O_3 concentrations in this range.

Further, at concentrations somewhat above the level of the proposed standard, for example, a new PSI category could be created with a descriptor such as ''moderately unhealthful.'' This category could be defined to correspond to 8-hour O_3 levels such as 0.09 to 0.10 ppm. Exposures to 8-hour average O_3 concentrations in this range are associated with an increase in the number of individuals who could potentially experience effects, including moderate or greater functional (e.g., 10 to 20% or greater decrements in FEV_1) and symptomatic (e.g., cough, chest discomfort) responses. An expanded warning system thus could include a stronger caution, of interest to all citizens and, in particular, to individuals with impaired respiratory systems and especially sensitive individuals in the at-risk populations of active outdoor children and workers to consider limiting prolonged moderate to heavy exertion outdoors on such days.

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. Should the current 1-hour primary NAAQS for O_3 be replaced with an 8-hour standard, there would clearly be increased value in using forecasted O_3 concentrations in providing cautionary statements to the public. When a health advisory indicates that the current 1-hour O_3 PSI value of 100 has been exceeded, citizens generally have time to avoid exposures of concern because O_3 levels tend to remain elevated for several hours during the day. With an 8-hour standard, however, this may 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_3 concentrations would facilitate the risk-reduction function of the PSI by giving citizens more time to limit or avoid exposures of concern.

Several State and local air pollution control agencies are already issuing health advisories based on forecasted O_3 concentrations. Methodologies currently used for forecasting 1-hour maximum O_3 concentrations include both the use of sophisticated empirical meteorological models as well as photochemical models that combine emissions inventory data and predicted meteorological conditions. These two modeling approaches could be adapted for use in estimating the expected 8-hour average maximum O_3 concentration value for the same or next day.

By using historical O_3 monitoring data and meteorological data, empirical meteorological models using various statistical regression techniques could be constructed that would provide an estimate of the expected same or next day's maximum 8-hour average O_3 concentration, given current and projected conditions. Input model parameters could be defined in the course of the construction of such a statistical model, and would involve those parameters providing the most predictive capability, such as current and expected mixing depth, current and expected boundary layer wind speeds and temperatures, and O_3 monitoring data for the last several days.

Alternatively, by using an existing photochemical modeling emissions inventory, current and projected meteorological conditions could be used to simulate the next day's (or several days') O_3 concentrations. Cities and areas already experiencing high O_3 concentrations would likely have the needed emissions inventory data and experience with relevant photochemical models. New capabilities are rapidly advancing in providing meso-scale [17] meteorological forecasts that might prove useful in augmenting or supporting the development of either of these modeling approaches. For instance, the National Oceanic Atmospheric Administration is currently refining its ability to provide operational meso-scale forecasts of meteorological conditions on a 48 kilometer grid that covers all of the United States.[18]

Another possible approach to enhance forecasting relates to the development of a program to facilitate the sharing of real-time O_3 data among neighboring States. Further, data from O_3 air quality monitoring networks show that O_3 concentrations across large urban areas can be highly variable. Thus, issuing geographically-targeted forecasts, to reflect these spatial variations in O_3 concentrations, could more appropriately limit the focus of a health advisory to locations in which individuals are likely to be at risk. Such programmatic enhancements to the PSI could better reflect both a change to an 8-hour averaging time and the temporal and spatial variations in air quality that occur across urban areas.

The EPA is not formally proposing to revise the PSI at this time. However, the Administrator requests comment on the potential usefulness of health effects information of the type discussed above, and the appropriateness of using the PSI as a mechanism to convey such information to the public, as well as comment on potential new PSI categories and associated descriptors, levels, and cautionary statements. Comment is also requested on related issues such as the practicality of adopting forecasting methods and geographically-targeted forecasts. The EPA may propose such revisions to the PSI in conjunction with future proposals associated with the implementation of a revised NAAQS.

IV. Rationale for Proposed Decision on the Secondary Standard

This notice presents the Administrator's proposed decision to replace the existing 1-hour O_3 secondary NAAQS with one of two alternative new standards: a standard that is identical to the proposed 0.08 ppm, 8-hour primary standard or, alternatively, a new seasonal standard expressed as a sum of hourly concentrations greater than or equal to 0.06 ppm, cumulated over 12 hours per day during the maximum 3-month period during the O_3 monitoring season, set at a level of 25 ppm-hour.

As noted in the Background section of this notice, this Act defines public welfare effects as including but not limited to ''effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility and climate, as well as *effects on economic values* and on personal comfort and well-being.'' (Emphasis added) The explicit inclusion of economic values in the list of potential public welfare effects of the presence of criteria pollutants in the ambient air has led to the suggestion by some that EPA may consider a broad array of economic values, including both the potential disbenefit as well as the benefits associated with reducing air pollution in making decisions with regard to secondary standards.

A broad construction of disbenefits might include costs of control. EPA's longstanding view of the Clean Air Act is that the statute precludes the Agency from considering costs in making such decisions. Section 109 directs that any secondary standard specify a level of air

[17] Meso-scale is a scale larger than the largest thunderstorm clusters (3 kilometers) and smaller than roughly 3000 kilometers.

[18] See Internet web page, http://nic.fb4.noaa.gov:8000/research/mesoscale2.html.

quality that, ''based on [the air quality] criteria [provided for under section 108], is requisite to protect the public welfare from *any* known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air.'' Section 108, in turn, states that those criteria must ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health *or welfare* * * *.'' (Emphasis added.) Nothing in this language provides any indication that EPA may base its decision on the secondary standards on factors other than the effects of the pollutant at issue on welfare. This contrasts with other provisions of the Act, in which Congress explicitly directed the Administrator to consider costs in making her decision (e.g., section 111). Beyond that, the parallel structure of section 109's provisions on primary and secondary standards, combined with the exclusive emphasis on the effects of the pollutant itself in both of those provisions, suggests that Congress did not intend a different treatment of cost in relation to setting secondary standards from what would apply for primary standards.

The relevant case law confirms this. In *Lead Industries Assn.* v. *EPA,* 647 F.2d 1130 (D.C. Cir. 1980), which involved a challenge to EPA's failure to consider costs in setting the primary standard for lead, the Court rejected industry's claim that EPA must consider costs in setting primary standards. The court's rationale applied equally to secondary standards. Specifically, the Court held that:

> [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. (Emphasis added.) The Court later declared:

> Where Congress intended the Administrator to be concerned about economic and technological feasibility, it expressly so provided. [Citation to Section 111 as an example.] In contrast, Section 109(b) speaks only of protecting the public health *and welfare.*

Id. See also, Natural Resources Defense Council v. *Administrator,* 902 F.2d 962 (D.C. Cir. 1990).

A closely related issue is whether and how EPA may consider, in setting secondary standards, any alleged negative effect that reducing ambient concentrations of the relevant pollutant or its precursors may have on public welfare. For example, it has been suggested that reductions of NO_x, a precursor of O_3, could result in both positive and negative benefits. Lower NO_x emissions would reduce the adverse effects of nitrogen deposition on sensitive aquatic and terrestrial systems, but in some localities such reductions could result in a possible disbenefit of reduced fertilization of nitrogen deficient soils. Notwithstanding EPA's view of the law, or any particular finding as to the potential disbenefits outlined above, EPA solicits comment on the view that economic values be broadly construed to include the possible disbenefits and benefits resulting from implementation of standards for the purpose of establishing secondary standards.

The proposal is based on a thorough review of the latest scientific information, as assessed in the Criteria Document, on vegetation effects associated with exposure to ambient levels of O_3. It also takes into account and is consistent with: (1) Staff 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_3 secondary standard are based; (2) consideration of the degree of protection to vegetation potentially afforded by the proposed new 0.08 ppm, 8-hour primary standard; (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); and (4) public comments received during development of these documents either in conjunction with CASAC meetings or separately.

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 ozone 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 ozone,'' although ''agreement on the level and form of such a standard is still elusive'' (Wolff, 1996).

This review has focused on O_3 effects on vegetation, including agricultural crops, since these effects are of most concern at O_3 concentrations typically occurring in the United States. By affecting crops and native vegetation, O_3 may also indirectly affect natural ecosystem components such as soils, water, animals, and wildlife, although such impacts are not quantifiable at this time. Based on the scientific literature assessed in the Criteria Document, the Administrator believes it is reasonable to conclude that a secondary standard protecting the public welfare categories of crops and vegetation from known or anticipated adverse effects would also afford increased protection to the other related public welfare categories. With regard to O_3 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_3 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_3 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 the review of the secondary standard.

The rationale for proposing to revise the O_3 secondary NAAQS, presented below, includes consideration of: (1) vegetation effects information to inform judgments as to the likelihood that exposures to ambient O_3 result in adverse public welfare effects, (2) information on biologically relevant measures of exposure, (3) insights gained from air quality, exposure, risk, and economic benefits assessments that provide a broader perspective for judgments about protecting public welfare from any known or anticipated adverse effects, and (4) specific conclusions with regard to the elements of a standard (i.e., averaging time, form, and level) that, taken together, would be appropriate to protect public welfare.

A. Effects on Vegetation

Exposures to O_3 have been associated quantitatively and qualitatively with a wide range of vegetation effects including: (1) visible foliar injury, (2) growth reductions and yield loss in annual crops, (3) growth reductions in tree seedlings and mature trees, and (4) effects that can have impacts at the forest stand and ecosystem level. Since the last review, new information has been published in the scientific literature and assessed in the Criteria Document on the effects of O_3, particularly with respect to forest tree species, both seedlings and mature trees, as well as with respect to the dynamics of exposure. Discussed below are key findings for each of the above effects categories drawn from section VII.D of the Staff Paper.

1. Visible Foliar Injury

Visible foliar injury can be an effect of concern either when it directly represents loss of the intended use of the plant, ranging from reduced yield and marketability to impairment of the aesthetic value of individual plants and natural landscapes, or when it serves as an indicator of the presence of concentrations of O_3 in the ambient air that are associated with more serious effects. Visible foliar injury cannot serve as a reliable surrogate measure for other O_3-related vegetation effects because other effects have been reported with or without visible injury.

Both the concentration and the duration of O_3 exposures are important factors in eliciting visible foliar injury. For example, as cited in the Staff Paper, to protect public welfare from visible foliar symptoms for crops, O_3 concentrations in the range 0.10 to 0.25 ppm for a duration of 1 hour were identified as a limiting value, which decreased to 0.04 ppm to 0.09 ppm when duration of exposure was increased to 4 hours. For trees, the ranges of concentrations were slightly higher, including 0.06 to 0.17 ppm at the 4-hour duration. Flower size was significantly reduced in three species of flowering ornamentals when exposed to O_3 for 6 hours/day for periods of days to weeks, at concentrations from 0.10 to 0.12 ppm, and flower color was reduced at the same or lower concentration without visible injury to plant leaves. Ozone concentrations of 0.10 ppm for 3.5 hours/day for 5 days or 0.20 ppm for 2 hours were high enough to elicit injury in most turf grasses.

On a larger scale, foliar injury is occurring on native vegetation in natural parks, forests, and wilderness areas, and may be degrading the aesthetic quality of the natural landscape, a resource important to public welfare. For example, in the east, injury to white pine has been observed in the Jefferson and George Washington National Forests and throughout the Blue Ridge, including areas of the Shenandoah National Park, that experienced an average of five episodes (i.e., any day with a 1-hour concentration > 0.08 ppm) during the growing season, with episodes lasting from 1 to 3 consecutive days. In the Great Smoky Mountains National Park, surveys in the summers of 1987 to 1990 found that 95 plant species exhibited foliar injury symptoms consistent with O_3 damage. During this period, O_3 monitoring data indicated both elevated concentrations and prolonged exposures to O_3, especially at the higher elevation sites.

At western sites, in the Sierra Nevada and Sequoia National Forests, appearance of chlorotic mottle of pines increased from approximately 20% in 1977 to 55% in the high O_3 year of 1988. Sequoia National Forest and Sequoia-Kings Canyon National Park experience high O_3 levels of concern, with mean hourly averages ranging from 0.018 to 0.076 ppm, and annual hourly maxima of 0.11 to 0.17 ppm for 1987. Since 1991, there has been an annual survey of the amount of crown injury by O_3 to the same trees in approximately 33 sample plots located in several National Parks and Forests in the Sierra Nevada Mountains. Injury symptoms are still being observed in ponderosa and Jeffrey pine as well as the less sensitive big cone Douglas fir.

2. Growth/Yield Reductions in Annual Crops

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 reductions can indicate that plant vigor is being compromised which can lead to yield reductions in commercial crops.

As discussed in the Staff Paper, the National Crop Loss Assessment Network (NCLAN) studies undertaken in the early to mid-1980's provide the largest, most uniform database on the effects of O_3 on agricultural crop species. The NCLAN protocol was designed to produce crop exposure-response data representative of the areas in the U.S. where the crops were typically grown. In total, 15 species accounting for greater than 85% of U.S. agricultural acreage planted were studied. Of these 15 species, 13 species including 38 different cultivars were combined in 54 cases representing unique combinations of cultivars, sites, water regimes, and exposure conditions.

Crops were grown under typical farm conditions and exposed in open-top chambers to ambient O_3 and increased O_3 above ambient (i.e., modified ambient). The modified ambient treatments contained numerous high peaks (hourly O_3 concentrations above 0.10 ppm), occurring more frequently than in typical ambient air quality distributions. Such exposure patterns have raised questions among some researchers as to the relative importance of large numbers of high O_3 peaks versus cumulative mid-level exposures in associations between reported effects and various measures of O_3 exposures. Exposure durations in these studies were species dependent but typically went from stand establishment to harvest (an average 28 days) and some crops were grown in more than one geographical region and repeated over years. In addition, baseline controls were exposed to approximately 0.025 ppm O_3, which is lower than typical background levels in some crop areas. These aspects of the NCLAN protocols contribute to the uncertainty inherent in extrapolating controlled field study results of percentage yield reductions to non-chambered ambient field conditions and crop regions having different O_3 air quality distributions. Despite these uncertainties, a major advantage of the NCLAN approach compared to other study designs is that it allows for the use of regression analyses to develop exposure-response functions, allowing for prediction of yield loss as a function of O_3 exposure levels across the range of treatment levels, cultivars, and growing conditions used in the studies.

Based on regression of NCLAN analyses, at least 50% of the species/cultivars tested exhibited a 10% yield loss (relative to a 0.025 ppm baseline concentration) at a 7-hour seasonal mean O_3 concentration of 0.05 ppm or more. These findings have also been reported in terms of various cumulative exposure indices that address better the varying patterns of exposure. Using one particular exposure index, the 3-month, 12-hour SUM06 index [19], 50% of species/cultivars tested were predicted to exhibit between 10 and 20% yield loss (relative to a baseline SUM06 concentration of 0 ppm-hour) across the range of 25 to 38 ppm-hour.

Other studies cited in the Staff Paper examined effects of O_3 on agricultural crops using different methodologies. One methodology used ethylene diurea (EDU) as a control to study O_3 effects under ambient conditions. These studies indicate that yields were reduced by 18 to 41% relative to the chemically protected controls when ambient O_3 concentrations exceeded 0.08 ppm during the day for 5–18 days over the growing season.

3. Growth Reductions in Tree Seedlings and Mature Trees

Since preparation of the 1986 Criteria Document, a number of new studies

[19] The SUM06 exposure index cumulates over a given time period and diurnal window all hourly O_3 concentrations greater than or equal to 0.06 ppm.

have been published relating O_3 exposure to effects on deciduous and evergreen seedlings and mature trees. These studies help to address a significant gap in O_3 effects data identified by EPA in the last review.

The relationship between the responses of seedlings and those of mature trees to O_3 exposure is not well understood. Several studies cited in the Staff Paper describe a number of differences between seedlings and mature trees including stomata number on the leaves, photosynthetic rate, water use efficiency, nutritional needs, recycling capacities, and canopy effects (e.g., sun vs. shade, wind speed, CO2 concentrations) that may explain the varying sensitivities of seedling and mature trees to O_3 exposures. As a result, data from tree seedling studies cannot, at this time, be extrapolated to quantify responses to O_3 in mature trees.

A study, cited in the Staff Paper, conducted in Shenandoah National Park compared the growth of seedlings and productivity of herbaceous vegetation grown in charcoal-filtered air in open-top chambers to that in open plots and found that tulip poplar, green ash, sweet gum, black locust, several evergreen species (e.g., Eastern hemlock, Table mountain pine, pitch pine and Virginia pine), common milkweed, and common blackberry all demonstrated growth suppression. Except for the last two species, almost no visible injury symptoms accompanied the growth reduction.

The EPA's National Health and Environmental Effects Research Laboratory—Western Ecology Division initiated a research program to address the effects of O_3 on forest tree seedlings. Using the same open-top chamber methodology as NCLAN, this program developed exposure-response functions for six deciduous species, including aspen, red alder, black cherry, red maple, sugar maple, and tulip poplar and five evergreen species, including douglas fir, ponderosa pine, loblolly pine, eastern white pine, and Virginia pine. Similar to crops, these studies showed that sensitivity to O_3 varied significantly between tree type and growth strategy and between species and types within species.

When the distribution of the relative biomass losses for various percentiles of the deciduous and evergreen studies are aggregated (see Table VII–3 of the Staff Paper), a 12-hour SUM06 exposure of 33.3 ppm-hours over 92 days is associated with less than 10% biomass reduction (relative to a baseline SUM06 concentration of 0 ppm-hour) in 50% of the seedling cases studied. When evaluated separately, deciduous seedlings exhibited somewhat greater sensitivity than evergreen seedlings, on average.

When compared to the yield reductions in NCLAN studies, the seedlings show less biomass loss, on average, than the yield reductions exhibited by crops at any given exposure level. Such comparisons (e.g., yield loss in annuals vs. biomass loss in perennials) should be viewed with caution given the absence of more complete information on other aspects of plant response. Moreover, other studies cited in the Staff Paper report that very sensitive black cherry seedlings and aspen clones experienced 10% biomass loss (relative to a baseline SUM06 concentration of 0 ppm-hour) when exposed to much lower SUM06 exposures regimes (9 to 13 ppm-hour). These data suggest that, given the mean 3-month SUM06 value at monitored sites over the 10 year period 1982–1991 of 29.5 ppm-hour (shown in Table VII–1 of the Staff Paper), the potential for biomass loss in such sensitive seedling species could be significant.

In assessing the seedling studies, it should be further recognized that the influence of multiple environmental factors (e.g., drought, nutrient level, site factors, pest/pathogen interactions) were not taken into account because the seedlings were grown under optimal growing conditions and the genomes studied may not represent the complete range of sensitivities within a given species. These factors make it problematic when trying to predict effects on perennial species growing in an ecosystem context.

Long-term observational studies of mature trees have also been conducted. In both the Cumberland Plateau in Tennessee and San Bernardino National Forest, significant reductions in growth in white pine individuals and ponderosa pine respectively have been reported. While these growth reductions are not attributed to O_3 alone, it is reported that O_3 was a significant contributor that potentially exacerbated the effects of other environmental stresses.

Several other field studies cited in the Staff Paper reported growth reduction in mature eastern white pine. A comparison of growth rates of mature eastern white pine in the Blue Ridge Mountains of Virginia from periods 1955–1959 with those in 1974–1978 indicates decreases of 26, 37, and 51% for trees characterized as O_3 tolerant, intermediate, and sensitive, respectively. Because no significant change in seasonal precipitation occurred over the same time period, the effects on growth were attributed to O_3, which during the later period reached peaks frequently in excess of 0.12 ppm and monthly averages of 0.05—0.07 ppm on a recurring basis. Monitoring in the same area revealed peak hourly averages > 0.08 ppm for the months April-September in 1979 and 1980. As early as 1979, it was concluded by researchers that the most sensitive eastern white pine were so severely injured by O_3 exposure that they were probably being removed from the population.

Growth rate changes in O_3-stressed ponderosa and Jeffrey pine have been evaluated in the western United States. Major decreases in growth were reported to have occurred for both symptomatic (i.e., visible O_3 injury) and asymptomatic trees during the 1950's and 1960's. The percentage of trees exhibiting growth decreases at any given site never exceeded 25% in a given decade, and mean annual radial increment in trees with visible symptoms of O_3 injury was 11% less than at sites where trees showed no O_3 injury. Larger trees and trees older than 100 years showed greater decreases in growth than smaller and younger trees.

The responses of a number of fruit and nut trees to O_3 exposure were also reported in the Staff Paper. Almond has been identified as the most sensitive, but peach, apricot, pear, and plums have also been affected. Growth reductions were observed in almond, peach, and apricot when exposed once weekly for four months to 0.25 ppm-hour O_3 for 4 hours (a high level of exposure generally experienced only in fruit and nut tree growing areas in California). Other studies examined O_3 effects on citrus and avocado. Valencia orange trees (during a production year) exposed to a seasonal 12-hour mean of 0.04 and 0.075 ppm O_3 had 11 and 31% lower yield respectively than trees grown in filtered air with a very low O_3 seasonal 12-hour mean concentration of 0.012 ppm. Avocado growth was reported to be reduced by 20 or 60% by exposure to 12-hour seasonal means of 0.068 and 0.096 ppm O_3, respectively, during two growing seasons.

4. Forest and Ecosystem Effects

Plant populations can be affected by O_3 exposures, particularly when they contain many sensitive individuals. Changes 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 arrest or reverse ecosystem development.

The San Bernardino forest ecosystem, which has experienced chronic O_3 exposures over a period of 50 or more years, is the only known example of the above sequence of events in which O_3 exposures have been determined to be a fundamental stressor. From 1968 to 1972, the average daily maximum for total oxidants for each month was measured at Rim Forest (5,640 ft.), in the San Bernardino Region, where the highest concentrations are usually recorded. For the months of May through August, the average daily maximum for total oxidants went from a low of 0.14 ppm in 1969 to approximately 0.28 ppm in 1971, with concentrations rarely going below 0.05 ppm at night at this elevation. Ozone concentrations exhibited a cyclic diurnal pattern, with the monthly average of hourly values ranging from 0.07 to 0.10 ppm at 10:00 am and from 0.15 to 0.22 ppm at 4:00 pm. The primary effect of O_3 at these high levels was that the most susceptible members of the forest community, ponderosa and Jeffrey pine, could no longer compete effectively for essential nutrients, water, light and space. As a consequence, there was a decline in the sensitive species and an increase in more tolerant ones.[20]

Beginning with injury to the ponderosa and Jeffrey pine, other major changes in the San Bernardino ecosystem were observed in surveys during the period 1973 and 1978. Foliar injury, premature senescence, and needle fall decreased the photosynthetic capacity of stressed pines and reduced the production of carbohydrates resulting in a decrease in radial growth and in the height of stressed trees. Numerous other organisms and processes were also affected either directly or indirectly, including successional patterns of fungal microflora and relationship to the decomposer community. Nutrient availability was influenced by the heavy litter and thick needle layer under stands with the most severe needle injury and defoliation. The composition of lichens was significantly reduced.

For the period 1974 to 1988 there was an improvement shown in the injury index used to describe chronic injury to crowns of ponderosa and Jeffrey pines attributable to lower O_3 levels in the San Bernardino region. It was observed, however, that ponderosa and Jeffrey pines with slight to severe crown injury lost basal area in relation to competing species that are more tolerant to O_3. In effect, stand development was reversed and the development of the normal fire climax mixture dominated by ponderosa and Jeffrey pines was altered.

Ozone has also been reported to be a selective pressure among sensitive tree species (e.g., eastern white pine) in the east. The nature of community dynamics in eastern forests is different, however, than in the west, consisting of a wider diversity of species and uneven aged stands, and the O_3 levels are less severe. Therefore, lower level chronic O_3 stress in the east is more likely to produce subtle long-term forest responses such as shifts in species composition, rather than wide-spread community degradation. Dieback of the spruce-fir forests has occurred in the Appalachian mountains. Though these high elevation forests are exposed to a broad range of air pollution stresses including O_3, the loss of spruce-fir has been attributed principally to insect attack. It has not been determined whether there is a link between the insect damage cited as the cause of the tree death and the role of O_3 in predisposing trees to insect attack.

B. Biologically Relevant Exposure Indices

The specification of an exposure index for vegetation must include an appropriate averaging time, diurnal window (i.e., the hours during the day), and form. Key observations, based on the information presented in section VII of the Staff Paper, regarding each aspect of an exposure index for vegetation are summarized below.

An appropriate averaging time to protect against vegetation effects of O_3 should take into account the cumulative impact of repeated peak and mid-level O_3 exposures over the entire growing season. There is, however, significant variability in growth patterns and lengths of growing seasons among the wide range of vegetation species that may experience adverse effects associated with O_3 exposure. Because of this, the selection of any single averaging time for a national standard will of necessity be a compromise relative to the range of growing seasons for all vegetation species of concern. Based on an assessment of the available information in the Staff Paper, the Administrator believes that the consecutive 3-month period with maximum O_3 concentrations in the O_3 season is a reasonable surrogate for the various periods of plant sensitivity to O_3 identified in vegetation effects research and most likely covers adequately the periods of greatest plant sensitivity.

The second aspect related to specifying an appropriate exposure index is the diurnal window over which O_3 concentrations are cumulated in computing a seasonal average. While studies assessed in the Staff Paper have reported that increasing the diurnal window from 7 to 12 to 24 hours captures more of the peak and mid-level O_3 concentrations that occur in some environments, the associated reductions in growth or yield and increases in foliar injury have not been observed to increase proportionally with the increasing diurnal period. This observation is consistent with other findings that growth and yield reductions are in large part the result of decreases in carbohydrate production through photosynthesis, which only occurs in daylight hours, and that the majority of plants, although not all, have significantly reduced stomatal conductance at night. As a result, the Administrator judges that the potential for significant impacts from night time O_3 exposures is very low.

Based on the above considerations, the Administrator judges that an exposure index that is based on the consecutive 3-months with maximum O_3 concentrations in the O_3 season with a 12-hour diurnal window, including the daylight hours from 8:00 am to 8:00 pm, would capture biologically relevant exposures for the wide range of vegetation growing in environmental conditions found across the United States. The Administrator recognizes, however, the differing views among the experts on the CASAC panel on these characteristics of an appropriate index.

Specifying the form of a seasonal exposure index intended to correspond to the relationship between vegetation response and O_3 exposure is complicated by the many biological variables that influence the uptake of O_3 by the plant and plant responses to such uptake. In spite of the large number of studies that have been conducted to evaluate the effects of O_3 on vegetation, only a few studies assessed in the Staff Paper can be used directly to evaluate the differential effects of specific ranges or patterns of O_3 concentrations on plant responses.

Based on an assessment of these key studies as well as other biological effects information reported in the Criteria Document and Section VII of the Staff Paper, the Administrator concurs with the unanimous view of CASAC that the current standard of 0.12 ppm, 1-hour average, does not provide adequate protection, based on the following observations: (1) Peak O_3 concentrations ≥ 0.10 ppm can be phytotoxic to a large number of plant species, and can produce acute foliar injury responses, reduced crop yield and biomass production, and (2) mid-range O_3

[20] Subsequent to this time period, based on data from 1976 to 1991, O_3 levels in this area have declined from these high concentrations.

concentrations (0.05 to 0.09 ppm) have 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 the upper end of the mid-range concentrations. Because the relative importance of peak concentrations and mid-range concentrations in predicting plant response depends on numerous factors controlling stomatal conductance and other regulators of plant sensitivity, the Administrator believes, consistent with CASAC's views, that no one concentration-weighted exposure index can be characterized as best accounting for the complex relationship between O_3 concentrations and plant responses across a wide range of species.

With this limitation in mind, the EPA focused its assessments on two particular concentration-weighted indices, the SUM06 and W126,[21] that have been reported to perform about equally well as exposure measures to predict the exposure-response relationships observed in the NCLAN crop studies. In the absence of other effects studies designed to examine the differences in predictive power between these two forms under different exposure regimes and plant growing conditions, the Administrator recognizes that the available science alone cannot provide an adequate basis for selecting between these cumulative concentration-weighted indices. The Administrator, therefore, took into account policy considerations in comparing the relative advantages of these indices for use in establishing a national air quality standard to address seasonal effects of O_3 on vegetation.

The W126 exposure index incorporates a weighting function that gives increasing value to all concentrations between 0.00 ppm and 0.10 ppm, with a weight of 1 applied to all concentrations > 0.10 ppm. In assessing this form, the Administrator notes that there is insufficient scientific information at this time to judge the biological relevance of this weighting function, especially at concentrations below 0.05 ppm that are within the estimated range of background O_3 concentrations.[22] In contrast, the SUM06 form does not include O_3 concentrations below the cut-point of 0.06 ppm, such that it would not be influenced by background concentrations under typical air quality distributions.

In selecting between these two alternatives, in the absence of biological evidence to distinguish between the forms, the Administrator, as a matter of policy, judges that a SUM06 index would be the more appropriate index for a seasonal secondary standard. In reaching this judgment, the Administrator recognizes that there is no biological evidence of an effects threshold, and that the effects studies we see do not establish that the SUM06 index best accounts for all of the biologically relevant exposures. The adoption of a SUM06 index would, in the Administrator's judgment, provide an appropriate complement to the proposed 0.08 ppm, 8-hour primary standard by better accounting for the vegetation effects associated with exposures within the mid-range concentrations. Because it would not be unduly influenced by background concentrations, it would also provide a more appropriate target for air quality management programs designed to reduce emissions from anthropogenic sources contributing to O_3 formation.

C. Vegetation Exposure and Risk Analyses

In reaching judgments as to the requisite degree of protection needed to protect crops and vegetation against the effects of O_3, the Administrator has taken into account several additional considerations, including the extent of exposure of O_3-sensitive species, potential risks to such species, and monetized and nonmonetized benefits associated with reductions in O_3 exposures. Such considerations help inform judgments as to the degree of protection that a secondary NAAQS should provide, and, thus, an appropriate level and form for a secondary standard that would provide such protection.

In considering the change in risk to vegetation and potential welfare benefits associated with reductions in O_3 exposure, the Administrator recognizes that significant reductions in O_3 exposures would result from attainment of the proposed primary standard discussed above in Section II. Thus, as a matter of policy, she believes it is appropriate to evaluate welfare benefits estimated to accrue, respectively, from attainment of the 0.08 ppm, 8-hour primary standard (as well as alternative 0.09 ppm and 0.07 ppm primary standards) as a baseline for the estimation of *incremental* benefits from attainment of alternative seasonal secondary standards.

1. Exposure Characterization

Though numerous effects of O_3 on vegetation have been documented as discussed above, it is important in considering risk to examine O_3 air quality patterns in the U.S. relative to the location of O_3 sensitive species in order to predict whether or not effects are occurring and whether they are likely to occur under alternative standards. To address these questions, the EPA assessed the available air quality data and conducted national modeling analyses since insufficient monitoring data are available for such assessments at a national level.

Because the national air quality surveillance network for O_3 was designed principally to monitor O_3 exposure in populated areas, there is very limited measured data available to characterize O_3 air quality in rural and remote sites. For the West, Bohm (1992) presents data for the years 1980 through 1988 for all O_3 monitoring sites near Western forests and includes examples of the dominant patterns in daily O_3 concentrations. Sites located far from urban or point source areas experience O_3 patterns with little hourly variation and few hourly concentrations above 0.06 ppm. However, sites on the fringe of urbanized centers or valleys experience patterns with some variation in hourly concentrations and typically higher O_3 concentrations (> 0.10 ppm). In California, for example, Yosemite and Sequoia National Parks, which receive pollutants transported from highly urbanized areas, had 24-hour means ranging from 0.036 to 0.085 ppm on 75% of summer days. Lake Gregory, a forested area in the western section of the San Bernardino Mountains and situated on the eastern fringe of the Los Angeles Basin, California, had diurnal means ranging from 0.085 to 0.10 ppm during 49% of summer days. Means decreased with altitude and distance from the source. Urban sites have fluctuating diurnal patterns, with high afternoon concentrations. Marked scavenging of O_3 at night contributes to lower diurnal means. Outside of California, the patterns are similar, with the frequency of occurrence of high O_3 levels relating to the size of the city and the air pollution potential of the area. The observed O_3 concentrations

[21] The W126 exposure index cumulates over a given time period and diurnal window all hourly O_3 concentrations weighted by a specific sigmoidal weighting function.

[22] At sea level, annual average background values are estimated to be between 0.02 and 0.035 ppm O_3. Persistent and episodic natural sources contribute to background hourly O_3 concentrations in the range of 0.03–0.05 ppm (U.S. EPA, 1996b, p. 21).

discussed here are within the ranges associated with vegetation injury.

In the Eastern United States, studies have been undertaken to relate O_3 exposure patterns to elevation. As reported in the Staff Paper, several sites were monitored in western Virginia from May to December 1982 ranging in elevation from 457 m to 1067 m. In general, the high elevation site, Big Meadows, in the Shenandoah National Park, had higher monthly O_3 concentrations than the lower elevation sites, yet the number of peak O_3 occurrences (≥ 0.10 ppm) did not necessarily increase with altitude, suggesting that higher monthly averages were associated more with the lack of night time scavenging than with a large number of peak hourly concentrations. Another study cited in the Staff Paper compared sites for the period 1988–1992 located in West Virginia, Virginia and Pennsylvania, and found the 6 sites with the highest exposures were also the highest elevation sites (> 500m). The highest elevation sites were also observed to have large numbers of O_3 episodes, with a number of hourly peaks ≥ 0.10 ppm ranging from only a few in 1992 (a more typical O_3 year) to over 100 in 1988 (a high O_3 year). In 1988, all 11 sites exceeded the 3-month W126 level (21.0 ppm-hours) estimated to result in greater than 10% biomass loss in 50% of the tree seedling cases. In other years, except for 1992, more than half the sites exceeded this level. While these studies were conducted using a W126 exposure indicator rather than the SUM06 form discussed above, EPA believes the result would not be substantially different if a SUM06 indicator had been used. Similar exposure patterns have also been reported in the Great Smokies National Park.

Because of the lack of monitoring data, national air quality typical of agricultural crop growing areas has not been characterized. Since agricultural sites typically occur at relatively flat, low elevation areas, often downwind of large urban areas, they would be expected, unlike the high elevation sites discussed above, to experience a fluctuating diurnal O_3 pattern with O_3 levels starting low in the early morning and building to a peak in the early to late afternoon, before falling to almost background levels at night if scavenging agents are present. To characterize exposure patterns nationally, EPA conducted analyses using geographic information systems (GIS) and data from existing air quality monitoring sites to estimate seasonal O_3 air quality for the year 1990. The year 1990 was selected because it was a typical O_3 year (not extremely high or low). The estimated seasonal air quality, in terms of the 3-month, 12-hour, SUM06 exposure index, was used to estimate the potential risk to vegetation under 1990 air quality conditions, as well as that predicted to occur under alternative standards.

In taking the results from such analyses into account, the Administrator recognizes that there are many sources of uncertainties inherent in such analyses. Some of the most important caveats and uncertainties concerning the GIS exposure and risk assessments for crop yield and biomass loss in seedlings include: (1) Extrapolating from exposure-response functions generated in open-top chambers to ambient conditions, (2) the lack of a performance evaluation of the national air quality extrapolation, (3) the methodology to adjust modeled air quality to reflect attainment of various alternative standard options, and (4) inherent uncertainties in models to estimate economic values associated with attainment of alternative standards. A description of the GIS and air quality adjustment methodologies used, as well as the associated uncertainties, are discussed in the Staff Paper and related technical support documents (Horst and Duff, 1995a,b; Lee and Hogsett, 1996; Rodecap et al., 1995).

The regulatory scenarios examined include just attaining the existing 1-hour secondary standard, as well as alternative 8-hour primary standards, including standards set at 0.08 ppm, with 1- and 5-expected-exceedance forms, based on a single year of data (1990). These estimates of protection provided by the alternative 8-hour, primary standards were also used to roughly bound exposure estimates for other concentration-based forms under consideration (e.g., the second- and fifth-daily maximum 8-hour average O_3 concentrations, averaged over a 3-year period) by using air quality analyses that compare alternative forms of the standard.

Key observations important in comparing estimated 3-month, 12-hour SUM06 exposures under 1990 conditions, with just attaining the existing 0.12 ppm, 1-hour standard, and the 0.08 ppm, 8-hour alternatives include:

(1) Under 1990 air quality, a large portion of California and a few localized areas in North Carolina and Georgia are projected to have seasonal O_3 levels above those reported to produce greater than 20% yield loss in 50% of NCLAN crops and 17% biomass loss in seedlings. At least a third of the country, again mostly in the Eastern U.S., would most likely have seasonal exposures levels which could allow up to 10% yield loss in 50% of NCLAN crops and studied seedlings.

(2) When 1990 air quality is adjusted to simulate attaining the current 0.12 ppm, 1-hour secondary standard, the overall seasonal 12-hour SUM06 exposures improve, but not dramatically. Under this attainment scenario, there are still areas of the country judged to have seasonal O_3 levels sufficient to cause greater than (California) or equal to (multistate region in East) 20% and 17% yield or biomass loss in crops and trees seedlings, respectively.

(3) Just attaining the 0.08 ppm, 8-hour, 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. The only area projected to exhibit seasonal exposures high enough to result in 20% yield loss for crops is a portion of southern California, while seasonal exposures in the majority of the southeast would be estimated to drop to levels that could allow up to 10% yield and biomass loss in 50% of NCLAN crops, and studied tree seedlings, respectively.

These results suggest that the proposed 0.08 ppm, 8-hour primary standard would provide significantly improved protection of vegetation from seasonal O_3 exposures of concern. The Administrator recognizes, however, that some areas may continue to have elevated seasonal exposures, including forested park lands and other natural areas, and Class I areas which are federally mandated to preserve certain air quality related values.

To further bound these analyses, EPA also examined 8-hour daily maximum and 3-month, 12-hour SUM06 design values for 581 counties (those having sufficient monitoring data for the period 1991–1993). As discussed in the Staff Paper, 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 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 would also be addressed by an 8-hour primary standard set at a 0.08 ppm level.

While these analyses indicate that the adoption of an 8-hour, 0.08 ppm primary standard would provide increased protection, it remains uncertain as to the extent to which air quality improvements designed to reduce 8-hour O_3 concentrations would reduce O_3 exposures measured by a SUM06 index. The Administrator judges this to be an important consideration because: (1) The biological database stresses the importance of cumulative, seasonal exposures in determining plant response; (2) plants have not been specifically tested for the importance of daily maximum 8-hour O_3 concentrations in relation to plant response; and (3) the effects of attainment of a 8-hour standard in upwind urban areas on rural air quality distributions cannot be characterized with confidence due to the lack of monitoring data in rural and remote areas. These factors are important considerations in determining whether a separate seasonal secondary standard should be adopted.

2. Assessment of Risk to Vegetation

The EPA has undertaken both quantitative and qualitative assessments of O_3 risk to vegetation. As discussed in the Staff Paper, these assessments predicted that crop loss, under 1990 air quality conditions, of greater than 10% (relative to the baseline of yield at O_3 levels of 0.025 ppm used in the NCLAN studies) would occur in some production areas for soybean, kidney bean, wheat, cotton, and peanut, with lower yield losses estimated for barley, corn, and sorghum. Economic benefits were estimated for the quantifiable effects associated with reductions in O_3 exposures through attainment of alternative standards for agricultural crops as well as California fruit and vegetation, as summarized below.

The persistence of O_3 in crop growing regions may also result in currently nonquantifiable effects such as reduction in the genetic diversity of crop cultivars available, as well as the loss of other beneficial traits that may be linked genetically with O_3 sensitivity as a result of breeding programs designed to increase yield. Such indirect effects may also occur in plants used in urban landscapes and gardens.

Examination of tree seedlings revealed significant variability in projected seedling biomass loss, under 1990 air quality conditions. For the most sensitive species studied, black cherry seedling biomass loss is projected to be greater than 30% for over half its geographic range. The less sensitive white pine and aspen seedlings biomass losses have been projected to be up to 10% for 10% of the growing region, but only 2–3% losses are projected over 50% of their geographic range. Less sensitive species studied are projected to have less than 2% seedling biomass loss in all areas. Given the uncertainties associated with such projections, as discussed in the Staff Paper, these estimates of biomass loss represent a potential risk that species may experience at least for seedling establishment, reforestation, or natural regeneration.

While it is not possible at this time to scale biomass loss effects in seedlings to mature trees, field observations of seedling health and mortality can provide information relevant to assessing risk to mature trees and forests. Studies cited in the Staff Paper suggest that O_3 can stress seedlings sufficiently to reduce root growth, thus affecting the seedlings' growth, competitiveness, and survivability both immediately after germination and in subsequent years.

The importance of below-ground effects on trees, forests, and ecosystems is often overlooked when evaluating responses to O_3 exposure. As discussed in Section VII.B of the Staff Paper, O_3 stress inhibits photosynthesis and reduces the amounts of sugars available for transfer to the roots that can alter mycorrhizal colonization and compatibility, reducing mycorrhizal formation and root growth. Significant reduction and deterioration in feeder roots have been observed in O_3 damaged white pine and ponderosa pine.

Beyond biomass loss and impact on root systems, other risks to vegetation associated with O_3 include shifts in the relationship between tree species and insect or pathogens, which can result in imbalances within communities that may have long-term effects such as those observed in the San Bernardino forests. Ozone effects can also reduce biodiversity by selectively impacting particularly sensitive O_3 species/individuals and by reducing the ability of affected areas to provide habitats for other plants or animal species. Moreover, O_3-sensitive vegetation exists over much of the U.S. including National Parks and other Class I areas. The National Park Service has reported that sensitive vegetation is being injured by O_3 transported into the parks, affecting not only vegetation of ecological importance but also aesthetic and existence values.

3. Economic Benefits Assessment

As discussed in Section VII.F of the Staff Paper, EPA developed estimates of monetized benefits associated with several standard alternatives. The analyses focused on commodity crops studied in the NCLAN project, representing approximately 75% of the U.S. sales of agricultural crops, and California fruits and vegetables that constitute approximately 50% of the Nation's fruits and vegetable markets. Monetized benefits could not be estimated for other important categories such as urban ornamentals, Class I areas, and commercial forests because of the lack of concentration response functions and appropriate economic valuation models. The available data suggest that reductions in ambient O_3 levels obtained by the alternative standards would confer benefits to these categories as well by reducing biomass loss, protecting functional, aesthetic, and existence values, and by preserving biodiversity and native habitat.

Benefits associated with attaining the current NAAQS and a new 8-hour, 0.08 ppm primary standard, as well as the incremental benefits associated with the lowest seasonal secondary standard under consideration were estimated. The combined benefits for commodity crops and California fruits and vegetables for attaining a new 8-hour, 0.08 ppm primary standard were reported in terms of a 1-expected-exceedance form.[23] The key findings from these analyses are:

(1) Total estimated annual benefits associated with attaining the current NAAQS include approximately \$160–\$340 M in monetized benefits from the commodity crops and California fruits and vegetables analyzed, as well as some level of benefits from the other benefits categories for which no quantitative estimates could be made.

(2) Total estimated annual benefits associated with attaining a new 8-hour primary standard of 0.08 ppm, 1-expected-exceedance, include approximately \$490–\$1,420 M in monetized benefits from the commodity crops and California fruits and vegetables analyzed, as well as some level of benefits from the other benefits categories for which no quantitative estimates could be made, although directionally these benefits would be expected to be greater than those associated with attaining the current NAAQS.

(3) *Incremental* annual benefits associated with attaining the lowest seasonal secondary standards analyzed include approximately \$300–\$580 M in monetized benefits relative to the current NAAQS, compared to approximately \$40–\$80 M relative to a new 8-hour, 0.08 ppm, 1-expected-exceedance standard. Additional incremental benefits would be obtained for the other benefits categories shown,

[23] As noted in the Staff Paper, there were small differences in the forms of the alternative standards analyzed.

although no quantitative estimates of these additional benefits could be made.

To project monetized benefits nationwide, the above reported estimates were scaled upward, by proportionately scaling the monetized estimates to the entire market, since the commodity crops included in the analyses account for only 75% of the U.S. sales of all agricultural crops and the California fruits and vegetables include only approximately 50% of the nation's fruit and vegetable markets. The EPA recognizes, however, that factors such as the sensitivity to O_3 of crops and fruits and vegetables not formally analyzed, regional air quality, and regional economics introduce considerably uncertainty to any such approach to developing a national estimate. Application of the scaling approach to the ranges given above results in the following rough approximations to national monetized benefits associated with the categories of commodity crops and fruits and vegetables:

(1) National approximation of annual monetized benefits associated with attaining the current NAAQS: $270–$530 M.

(2) National approximation of annual monetized benefits associated with attaining a new 8-hour primary standard of 0.08 ppm, 1-expected-exceedance: $970–$2,270 M.

(3) National approximation of *incremental* annual monetized benefits associated with attaining the lowest seasonal secondary standards analyzed: $490–$910 M relative to the current NAAQS, compared to approximately $70–$130 M relative to a new 8-hour, 0.08 ppm, 1-expected-exceedance standard.

An examination of the monetized benefits reported above indicates that most of the estimated benefits accrue from attainment of the 8-hour, 0.08 ppm primary standard with a smaller incremental improvement obtained by the addition of a seasonal secondary standard. The projected national approximations for commodity crops and fruits and vegetables suggest that benefits on the order of 1 to more than 2 billion dollars would result from the proposed 8-hour, 0.08 ppm primary standard, alone or in combination with a seasonal secondary standard. The EPA also examined the monetized benefits estimates that would result from the attainment of either a 0.07 ppm or a 0.09 ppm, 8-hour primary standard.[24] These estimates suggest that if a 0.07 ppm 8-hour primary standard were to be attained, only a very small incremental improvement in monetized benefits ($40–$80 M) would be realized by the addition of the lowest seasonal secondary standard analyzed. In contrast, if a 0.09 ppm, 8-hour primary standard were to be attained, the incremental benefits to be obtained from the addition of the lowest seasonal secondary standard analyzed would be considerably more significant ($230–$430 M). The qualitative information summarized above also suggests that the monetized benefits alone do not fully reflect the public welfare benefits that would be obtained from the adoption of the alternative primary standards alone or in combination with a new seasonal secondary standard.

D. Conclusions on Elements of the Secondary Standard

Based on the assessments of relevant scientific and technical information in the Criteria Document, sections VII and VIII of the Staff Paper, the views of CASAC, and for the reasons discussed above, the Administrator has made the following observations and judgments:

(1) The existing 1-hour, 0.12 ppm secondary standard does not adequately protect vegetation against the adverse effects of O_3. Peak O_3 concentrations >0.10 ppm, but less than the existing standard, can be phytotoxic to a large number of plant species, and can produce acute foliar injury responses, crop yield loss and reduced biomass production. The available scientific information also indicates that mid-range concentrations (0.05 to 0.09 ppm) have the potential to produce chronic stress on vegetation, resulting in reduced plant growth and yield, shifts in competitive advantages in mixed populations, decreased vigor leading to diminished resistance to pests, pathogens, injury from other environmental stresses, and foliar injury in some sensitive species. The quantitative exposure and benefits analysis indicate that the risk of such adverse effects would persist even upon attainment of the existing standard. The CASAC is unanimously in agreement with this conclusion (Wolff, 1996).

(2) Based on the results of the quantitative exposure and benefits analyses, the attainment of the proposed 0.08 ppm, 8-hour primary standard would provide substantially improved protection against adverse effects of O_3 on vegetation. The Administrator recognizes that these analyses contain substantial uncertainties, resulting in only rough estimates of the benefits associated with alternative standards. Nonetheless, the Administrator believes, consistent with advice from CASAC (Wolff, 1996), that these analyses can be of use in identifying the relative incremental benefits associated with the alternative standards. Based on these analyses, a reasonable policy choice would be to set the secondary standard identical to the proposed 0.08 ppm, 8-hour primary standard.

(3) The Administrator also recognizes, however, that the available scientific information on exposure dynamics and their role in producing plant response clearly supports the conclusion that a cumulative seasonal exposure index is more biologically relevant than a single event or mean index. Therefore, for the reasons discussed in section B above, the Administrator believes that consideration should also be given to establishing a new seasonal secondary standard.

Having reached these conclusions, the Administrator is proposing two alternatives for public comment: (1) Setting the revised secondary standard identical to the proposed 0.08 ppm, 8-hour primary standard, or (2) establishing a new seasonal secondary standard. These alternatives are consistent with the range of views expressed by CASAC panel members (Wolff, 1996). The Administrator and CASAC (Wolff, 1996) recognize that choosing between these alternatives, as well as selecting a specific seasonal exposure index, are policy decisions, and that such decisions cannot be based solely on science.

In specifying the averaging time, form, and level of a new seasonal secondary standard, as outlined below, the Administrator has focused her consideration on the recommended ranges and key factors outlined in the Staff Paper. Such an approach was generally supported by most CASAC panel members.

1. Averaging Time

The Administrator believes that an averaging time for a proposed seasonal secondary should be specified as the consecutive 3-month period of maximum concentrations in the O_3 season with a 12-hour diurnal window, including the daylight hours from 8:00 a.m. to 8:00 p.m local standard time. In her judgment, such an averaging time will adequately address the most biologically relevant periods of exposure for both annual and perennial vegetation.

[24] The national approximation of annual monetized benefits associated with attaining a 8-hour, 0.07 ppm primary standard alone would be $1,120–$3,100 M. This contrasts to $970–$2,270 M for a 0.08 ppm, 8-hour primary standard alone, and $530–$1,220 M for a 0.09 ppm, 8-hour primary standard alone.

2. Form

The Administrator believes that a SUM06 exposure index is a reasonable policy choice for a seasonal secondary standard to protect against the effects of O_3 on vegetation. In reaching this determination, the Administrator is particularly mindful that the protection provided by the secondary standard should supplement the protection provided by the primary standard. A SUM06 form would, in her judgement, provide such supplemental protection by cumulating exposure over a season reflective of the cumulative nature of O_3 effects on plants and giving relatively more weight to mid-range exposures of concern than to the peak exposures addressed by the proposed 0.08 ppm, 8-hour primary standard, without being influenced by estimated background concentrations that are beyond the scope of control intended by a NAAQS.

3. Level

The level at which a seasonal secondary standard should be set depends on policy judgments by the Administrator as to the level of air quality the attainment and maintenance of which is requisite to protect the public welfare from any known or anticipated adverse effects associated with the pollutant in the ambient air. As discussed above and in Section VII of the Staff Paper, the EPA undertook a series of analyses to examine the incremental improvements in terms of modelled exposure potential, monitored air quality, and quantifiable economic and other benefits that would accrue from a seasonal secondary standard. These analyses indicate that, beyond those achieved by 0.08 ppm, 8-hour, 1- to 5-expected-exceedance primary standard alternatives, relatively smaller incremental improvements would result from the adoption of a SUM06 seasonal standard within the range of levels under consideration, 38–25 ppm-hour.[25] Again, the Administrator acknowledges the significant uncertainties in the analyses and recognizes that these benefits should be regarded as rough approximations.

Based on these observations, it is the Administrator's judgment, taking into account the protection provided by both primary and secondary standards, that in the selection of the level for a seasonal secondary standard the focus should be on the lower end of the SUM06 (38–25 ppm-hours) range where a greater degree of incremental protection would more likely be expected. Although it was judged that this degree of incremental protection may be relatively small at the national level, such incremental improvement could be potentially significant at regional and local levels where it would be expected to provide additional protection for the most sensitive commercial crops and tree species, while directionally providing increased protection against the more subtle impacts of O_3 on vegetation and ecosystem resources in Class I and other regions. Thus, the Administrator decided to propose a level of 25 ppm-hour for a SUM06 secondary standard.

E. Proposed Decision on the Secondary Standard

As discussed more fully above, the Administrator took into account several factors in reaching her proposed decision on the secondary standard. First, she concluded based on information presented in the Criteria Document and Staff Paper and discussed above, that the existing secondary standard does not provide adequate protection for vegetation against the effects of O_3. Having reached this conclusion, the Administrator next considered: (1) The degree of protection afforded by the proposed 8-hour, 0.08 ppm primary standard; (2) the incremental protection associated with a SUM06, 25 ppm-hour secondary standard; and (3) the value of establishing a seasonal form for the secondary standard that is more representative of biologically relevant exposures. In weighing these factors, the Administrator recognized, as did CASAC, that reaching a decision on revising the secondary standard requires a blend of scientific and policy considerations.

Based on the quantitative analyses discussed above and presented in detail in Section VII of the Staff Paper, a reasonable policy choice could be to set the revised secondary standard identical to the proposed 8-hour, 0.08 ppm primary standard. Attainment of such a secondary standard would, in the Administrator's judgment, provide substantial protection against the effects of O_3 on vegetation. The Administrator also recognizes, however, that a SUM06 seasonal secondary standard would have a stronger scientific basis in that it would better account for cumulative, seasonal exposure. The Administrator also notes the growing body of evidence, assessed in the Criteria Document and Staff Paper, that suggests more subtle impacts of O_3 acting in synergy with other natural and man-made stressors on individual plants, populations and whole systems. While both the Staff Paper and CASAC concluded that there is insufficient information as yet to estimate the severity of these impacts quantitatively, the Administrator is concerned that the available information be given proper weight in considering the extent to which a secondary standard should be precautionary as to such effects. Given the potential significance of the effects, particularly at the regional scale and in Class I areas, coupled with the views of many in the scientific community that a SUM06 seasonal standard would be more representative of biologically relevant exposures, the Administrator believes it is important to air these issues fully. Therefore, the Administrator is proposing two alternatives for public comment: (1) Setting the revised secondary standard identical to the proposed 0.08 ppm, 8-hour primary standard in all respects; or (2) establishing a 3 month, 12-hour, SUM06 seasonal secondary standard, set at the level of 25 ppm-hour.

As discussed previously, the Administrator has also requested comment on two alternative levels for the 8-hour primary standard. Accordingly, she has examined the implications for her decision on the secondary standard of adopting either of the alternative levels for the primary standard. Based on the economic benefits assessment and other factors discussed above, adoption of a secondary standard identical to a 0.09 ppm, 8-hour standard would provide appreciably less protection against vegetation effects than would an 0.08 ppm, 8-hour secondary standard. For that reason, the Administrator would be more inclined to set a 25 ppm-hour SUM06 seasonal secondary standard if a 0.09 ppm, 8-hour primary standard were to be selected. On the other hand, if a 0.07 ppm, 8-hour primary standard were to be selected, appreciably more benefits would result as compared to those associated with attainment of the proposed 0.08 ppm, 8-hour primary standard. In such a case, the Administrator would most likely establish a secondary standard identical to a 0.07 ppm, 8-hour primary standard. The EPA solicits comments on the implications that the possible selection of one of the alternative 8-hour primary standards (i.e., 0.09 or 0.07 ppm) would have on the selection of an appropriate secondary standard.

The Administrator also recognizes the importance of enhancing the existing O_3 monitoring network to provide better coverage in rural areas of agricultural or ecological importance irrespective of the final alternative chosen. Because expanding the O_3 monitoring network

[25] Roughly corresponding to the 20 percent and 10 percent yield loss protection levels for 50 percent of the NCLAN crops, respectively.

would impose additional cost burdens, EPA specifically requests public comment on the appropriate spatial scale for an enhanced monitoring network intended to provide adequate air quality surveillance in more rural areas in a cost-effective manner. Such 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, EPA is also seeking comment on whether O_3 concentrations from several monitors should be spatially integrated when determining compliance with the standard. Such an approach could provide a more representative indication of vegetation exposures over a given area than O_3 concentrations measured at a single monitor. To help inform consideration of this approach, EPA specifically requests comment on the spatial scale that should be considered for such integration (e.g., averaging) and the number of monitors that would be needed to determine representative vegetation exposures for a given spatial scale.

V. Revisions to Appendix H—Interpretation of the NAAQS for Ozone

The EPA is proposing to revise Appendix H to 40 CFR part 50 to reflect the proposed revisions to the primary and secondary standards discussed above. The proposed revisions to Appendix H would explain the computations necessary for determining when the proposed primary and secondary standards are met. More specifically, the proposed revisions address data completeness requirements, data reporting, handling, and rounding conventions, and example calculations. Because two alternative secondary standards are proposed, the proposed changes to Appendix H address both alternatives: (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. Depending on the final decision on the secondary standard, the proposed revisions to Appendix H will be modified accordingly.

Key elements of the proposed revisions to Appendix H are outlined below.

A. Data Completeness

One key change to Appendix H is that the data completeness requirements for the proposed 0.08 ppm, 8-hour primary standard (and the secondary standard if it is set identical to the primary standard) would not include an adjustment to the concentration statistic to account for missing data. Instead, the proposal would require 90% data completeness, on average, during the 3-year period, with no single year within the period having less than 75% data completeness. This data completeness requirement would have to be satisfied in order to determine that the standard(s) have been met at a monitoring site. A site could be found not to have met the standard(s) with less than complete data.

Based on its analysis of available air quality data, the EPA believes that the proposed data completeness requirement is reasonable given that 90% of all monitoring sites that are operated on a continuous basis routinely meet this objective. The EPA is seeking comment, however, on whether meteorological data would 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_3 concentrations, and therefore, that the day could be assumed to have an O_3 concentration less than 0.08 ppm. The EPA specifically requests comment on the appropriateness of permitting adjustments for missing data based on meteorological conditions, as well as on information that would permit better definition of those necessary conditions likely to result in peak 8-hour O_3 concentrations in the ranges of concern.

For a secondary standard expressed in a 3-month, 12-hour, SUM06 form, a site would be required to have 75% data completeness in a given year and adjustments would be made for missing data. Because this alternative is a seasonal cumulative index, representing a distribution of O_3 values under a range of meteorological conditions, rather than a peak statistic, the EPA is proposing a missing data procedure that would multiply the unadjusted SUM06 value by the ratio of the number of possible daylight hours (8:00 am to 8:00 pm) during the O_3 monitoring season to the number of hours with valid ambient hourly concentrations.

B. Data Handling and Rounding Conventions

Almost all State agencies now report hourly O_3 concentrations to three decimal places, in ppm, since the typical incremental sensitivity of currently used O_3 monitors is 0.001 ppm. In calculating 8-hour average O_3 concentrations from such hourly data, and in calculating 3-year averages of the third highest maximum 8-hour average concentrations, the calculated fourth decimal place digit would be rounded (with 0.0005 rounded up) to preserve the number of significant digits in the reported data.

To determine whether the proposed standard is met, the calculated value of the third highest maximum 8-hour average concentrations, averaged over three years, would be compared to the level of the standard. The proposed standard of 0.08 ppm is expressed to the second decimal place, reflective of the quantitative uncertainties in the health effects evidence upon which the proposed standard is based. More specifically, these uncertainties include the measurement uncertainty inherent in the reported ambient O_3 concentrations used in field and epidemiological studies and in the exposure estimates upon which quantitative risk assessments have been based. The EPA believes that expressing the proposed standard to the second decimal place is consistent with the quality assurance guidelines that indicate the precision[26] for such O_3 measurements shall be within ±15%.

To compare the calculated 3-year average O_3 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. Rounding has the effects of reducing the probability of misclassifying an attainment area as nonattainment and of producing a more stable attainment test. Taking into account measurement uncertainty and the desirability of these resulting effects, EPA has historically deemed the current rounding convention to be appropriate.

On the other hand, EPA recognizes that this current rounding convention directionally results in less public health protection than that which would be associated with a convention that defined the smallest increment of 0.001 ppm to be above the level of the standard for the purposes of determining whether the standard has been met.[27] Thus, EPA solicits comment on the use of an alternative rounding convention defined as low as 0.001 ppm, with regard to potential increased public health protection as well as to potential effects on the probability of

[26] 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.

[27] Based on 1993–1995 air quality data, approximately 13 million more people would live in areas for which the alternative rounding convention would result in improvements in air quality as compared to the current rounding convention. This population difference corresponds to an increase of 66 counties that would not meet the proposed primary standard based on the alternative rounding convention.

attainment misclassifications and on the stability of the standard.

VI. Technical Changes to Appendices D and E

A. Appendix D to Part 50—Measurement Principle and Calibration Procedure for the Measurement of O_3 in the Atmosphere

Minor revisions to the references listed within Appendix D are proposed to provide the reader with the most recent information on obtaining reference materials to support the O_3 monitoring methodology. Specifically, these changes include updating the EPA addresses and adding EPA document reference numbers.

Appendix D also contains information on the ''Temporary Alternative Calibration Procedure—(Boric Acid-Potassium Iodide)'' for the O_3 federal reference method. This alternative calibration procedure was considered to be a valid alternative to the ultraviolet photometry procedure for direct calibration of O_3 analyzers for a period between the promulgation of the original O_3 federal reference method and 18 months after promulgation (from February 1979 through August 1980). Since this period has expired, it is no longer necessary to include the alternative calibration procedure in Appendix D; therefore, EPA proposes to remove it.

B. Appendix E to Part 50—Reference Method for Determination of Hydrocarbons Corrected for Methane

Appendix E specifies a reference method that was used when EPA established a total hydrocarbon National Ambient Air Quality Standard. The total hydrocarbon NAAQS was revoked on January 5, 1983 (48 FR 628), and the inclusion of a total hydrocarbon reference method within Appendix E is no longer appropriate. Accordingly, the EPA proposes to remove it.

Several sources of information on the current techniques used for the measurement of hydrocarbons are available. Two that are widely used are the ''Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air, Method TO–12, Method for the Determination of Non-Methane Organic Compounds (NMOC) in Ambient Air Using Cryogenic Preconcentration and Direct Flame Ionization Detection (PDFID),'' EPA–600/4–89–017, National Exposure Research Laboratory, U.S. EPA; and ''Photochemical Assessment Monitoring Stations Implementation Manual,'' Appendix N, EPA–454/B–93–051, March 1994, available through the National Technical Information Services (NTIS publication number PB 94 187 382), 5825 Port Royal Road, Springfield, VA 22161.

VII. Implementation Program

Recognizing that adoption of new NAAQS for O_3, together with new particulate matter (PM) NAAQS, as well as potential new regulations for regional haze, could have profound implications for existing State implementation programs, EPA established a subcommittee under the Clean Air Act Advisory Committee (CAAAC) in 1995. The Subcommittee, comprised of some 58 members representing environmental organizations, State and local air pollution control agencies, Federal agencies, academia, industry, and other public interests, is to provide advice and recommendations to EPA on developing new, integrated approaches for implementing the potential new NAAQS for O_3 and PM, as well as a potential new regional haze reduction program. The Subcommittee, through several work groups made up of Subcommittee members and other designees recommended by the Subcommittee, is in the process of examining key aspects of the existing implementation programs for O_3 and PM, to provide for more effective implementation of the potential new NAAQS, as well as to provide new approaches to better integrate broad regional and national control strategies with more localized efforts.

Upon completion of its work, the Subcommittee will present its findings and recommendations to the CAAAC. These recommendations will then assist EPA's development of appropriate policies and regulations for implementing the potential new O_3 and PM NAAQS and regional haze regulations in the most efficient and environmentally effective manner. These policies and regulations will then be published in the Federal Register for further input from the public.

VIII. Regulatory Impacts

The EPA has judged this proposal to be a significant action, and has prepared a draft Regulatory Impact Analysis (RIA) for it as discussed below. Neither the draft RIA nor the associated contractor reports have been considered in issuing this proposal. Judicial decisions make clear that the economic and technological feasibility of attaining ambient standards are not to be considered in setting them, although such factors may be considered to a degree in the development of State plans to implement the standards.

As discussed above, EPA has established a Subcommittee of the CAAAC to examine the existing implementation programs for O_3 and PM, and provide advice and recommendations to assist EPA in developing new, integrated approaches for implementing potential new or revised NAAQS for O_3 and PM, as well as a potential new regional haze reduction program. Because the work of the Subcommittee is still in progress, the draft RIA and associated regulatory flexibility assessment that accompany this notice do not reflect its advice and recommendations or any resulting implementation strategies for O_3. The EPA anticipates that such strategies will be more efficient and environmentally effective than the ones analyzed. While the draft RIA and flexibility assessment should be useful in generally informing the public about potential costs and benefits associated with implementation of the proposed revisions, they do not reflect any new implementation or monitoring requirements or policies that may be proposed after consideration of the Subcommittee's advice and recommendations. As EPA develops and elaborates such requirements or policies, it will continue to consult with the Subcommittee and will prepare further regulatory analyses as appropriate.

A. Executive Order 12866

Under Executive Order 12866, 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 one 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 or recipients thereof; or

(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 proposal has been judged to be a ''significant regulatory action'' within the meaning of the Executive Order, and EPA has submitted it to OMB for review. 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 EPA has prepared and entered into the docket a draft regulatory impact analysis (RIA) entitled ''Regulatory Impact Analysis for Proposed Ozone National Ambient Air Quality Standard (November 1996)''. This draft RIA assesses the costs, economic impacts, and benefits associated with the implementation of the current and several alternative NAAQS for ozone. As discussed in the draft RIA, there are an unusually large number of limitations and uncertainties associated with the analyses and resulting cost impacts and benefit estimates. Because judicial decisions make clear that cost can not be considered in setting NAAQS, the results of the draft RIA have not been considered in developing this proposal.

COMPARISON OF BENEFITS AND COSTS—REGIONAL CONTROL STRATEGY BASELINE (BILLIONS OF 1990$)

[Estimates are incremental from the current standard]

Alternative ozone NAAQS	Monetized annual benefits of partial attainment	Annual costs of partial attainment
80 ppb, 8 hour, 4 AX	$0–0.6	$0.6
80 ppm, 8 hour, 1 AX	0.1–1.5	2.5

As discussed in the RIA itself, there are a large number of limitations and uncertainties inherent in estimating these national costs and benefits over extended periods of time. Results are limited by the inability to monetize certain health or welfare benefits for comparison with projections of control costs that are usually more complete, but are sometimes overstated due to an inability to forecast advances in pollution prevention and control. The approaches used for the RIA did not attempt to take advantage of flexibilities and savings possible in consideration of combined air quality management program for the PM and O_3. Further, they were limited by availability of emissions, air quality monitoring, and related information. Indeed, the suite of control measures available to be considered in the cost analysis was not sufficient to achieve full attainment in 2007. It is for this reason we have only presented the costs and benefits for this ''partial attainment'' scenario. In the partial attainment scenario, there would be 8 to 20 residual nonattainment areas representing 14 to 32 million people, respectively, in 2007. These areas would need approximately 120,000 to 750,000 additional tons of emission reductions in order to attain the standards. One implication of this scenario is that more time will be needed to attain the standards in the areas remaining in nonattainment. Moreover, based on past experience, improvements in technologies and creative implementation programs are likely to result in more effective programs than can now be forecasted. The EPA is planning to improve and expand its analysis of the integrated costs and benefits of attaining both the PM and ozone standards in association with developing implementation guidance.

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 regulatory flexibility analyses for the proposed and final rule unless the head of the agency certifies that it will not have a significant economic impact on a substantial number of small entities. In judging what kinds of economic impacts are relevant for this determination, it is appropriate to consider the purposes and requirements of the RFA. *Mid-Tex Electrical Co-op* v. *FERC*, 773 F.2d 327, 341–42 (D.C. Cir. 1985).

Review of the findings and purposes section of the RFA makes clear that Congress enacted the RFA to address the economic impact of rules on small entities *subject to the rule's requirements.* Pub. L. 96–354, section 2 (1980); *see also* 126 Cong. Rec. 21,452, 21,453 (1980). In explaining the need for the RFA, Congress generally expressed concern about the problematic consequences of applying regulations uniformly to large and small entities. Specifically, Congress stated that ''laws and regulations designed for application to large scale entities have been applied uniformly to small [entities] even though the problems that gave rise to government action may not have been caused by those small entities, that ''uniform Federal regulatory and reporting requirements have in numerous instances imposed unnecessary and disproportionately burdensome demands * * * upon small [entities] with limited resources,'' that ''the failure to recognize differences in the scale and resources of regulated entities has in numerous instances adversely affected competition in the marketplace,'' and that ''the practice of treating all regulated [entities] as equivalent may lead to inefficient use of regulatory agency resources.'' *Id.* To address these concerns, Congress enacted the RFA ''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 [entity] *subject to regulation*'' (emphasis added). *Id.*

The statutory requirements for regulatory flexibility analyses confirm that the economic impact to be analyzed is the impact of the rule on small entities that will have to comply with the rule's requirements. In both initial and final regulatory flexibility analyses, for example, the agency issuing the rule is required to describe and (where feasible) estimate the number of small entities ''to which the proposed rule will apply''; describe the reporting, recordkeeping and other ''compliance requirements'' of the proposed rule; and estimate the classes of small entities that ''will be subject to the requirement.'' *See* RFA sections 603 and 604. The agency must also discuss and address significant regulatory alternatives that are consistent with the applicable statutes and would minimize any significant economic impact on small entities. Among the possible alternatives listed by the RFA are the establishment of differing compliance and reporting requirements that take into account the resources available to small entities and partial or total exemptions from the rule for small entities. *See* RFA section 603(c). The RFA's requirements for regulatory flexibility analyses thus establish that the focus of such analyses are the regulatory requirements small entities will be required to meet as a result of the rule and ways to tailor those requirements to reduce the burden on small entities. *Mid-Tex Electrical Co-op*, 773 F.2d at 342 (''[I]t is clear that Congress envisioned that the relevant ''economic impact'' was the impact of compliance with the proposed rule on regulated small entities').

The scope of regulatory flexibility analyses in turn informs the scope of the analysis necessary to support a certification that a rule will not have ''a significant economic impact on a substantial number of small entities.'' Thus, ''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.* (emphasis added); *see also United Distribution Companies* v. *FERC*, 88 F.3d 1105, 1170 (D.C. Cir. 1996).

In view of the RFA's purposes and the requirements it establishes for regulatory flexibility analyses, EPA believes that today's proposal to revise the O_3 NAAQS will not have a significant economic impact on small entities within the meaning of the RFA. The proposed rule, if promulgated, will not establish requirements applicable to small entities. Instead, it will establish a standard of air quality that other Act provisions will call on states (or in case of state default, the federal government) to achieve by adopting implementation plans containing specific control measures for that purpose. In other words, state (or federal) regulations implementing the NAAQS might establish requirements applicable to small entities, but the NAAQS itself would not.[28] For these reasons, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

While the statutory requirements for regulatory flexibility analyses are thus inapplicable to NAAQS standard-setting, EPA is nonetheless interested in assessing to the extent possible the potential impact on small entities of implementing a revised O_3 NAAQS. EPA has accordingly conducted a more general analysis of the potential cost impacts on small entities of control measures that states might adopt to attain and maintain a revised NAAQS, and has included that analysis in the RIA cited above.

That analysis examines industry-wide cost and economic impacts for those sectors likely to be affected when the proposed revisions to the O_3 NAAQS are implemented by States. As part of the draft RIA, the EPA has analyzed various industries for the existence of small entities to ascertain whether small entities within a given industry category are likely to be differentially affected when compared to the industry category as a whole. This information will serve to inform potentially affected small entities, thus enabling them to participate more effectively in EPA's review and potential revision of existing implementation requirements and policies and in development of any necessary State implementation plan revisions. As indicated previously, EPA will prepare further analyses as appropriate as it develops new implementation requirements or policies.

The EPA's finding that today's proposal will not have a significant economic impact on small entities also entails that the new small-entity provisions in Section 244 of the Small Business Regulatory Enforcement Fairness Act (SBREFA) do not apply. Nevertheless, EPA intends to fulfill the spirit of SBREFA on a voluntary basis. To accomplish this, following the proposal of new air quality standards for ozone and particulate matter, EPA intends to work with the Small Business Administration (SBA) to hold two separate panel exercises to collect comments, advice and recommendations from representatives of small businesses, small governments, and other small organizations. The first panel, soliciting comments on the new standards themselves, will be held shortly after proposal. The second panel, covering implementation of the standards, will be held a few months later. Both panel exercises will be carried out using a panel process modeled on the ''Small Business Advocacy Review Panel'' provisions in Section 244 of SBREFA. We are also adding a number of small-entity representatives to our Federal advisory committee focusing on NAAQS implementation; we expect the small-entity advice from this committee will help the aforementioned implementation panel accomplish its purpose.

C. Impact on Reporting Requirements

There are no reporting requirements directly associated with an ambient air quality standard proposed under section 109 of the Act (42 U.S.C. 7400). 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). If EPA proposes revisions to the air quality surveillance requirements (40 CFR part 58) for O_3, the associated RIA will address the Paperwork Reduction Act requirements through an Information Collection Request.

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 to State, local, and tribal governments, in the aggregate, or to 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 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.

As indicated previously, EPA cannot consider in setting a NAAQS the economic or technological feasibility of attaining ambient air quality standards, although such factors may be considered to a degree in the development of State plans to implement the standards. Accordingly, EPA has determined that the provisions of sections 202, 203, and 205 of the UMRA do not apply to this proposed decision. 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.

E. Environmental Justice

Executive Order 12848 requires that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as

[28] Because the proposed rule would not establish requirements applicable to small entities, EPA can not in fact perform the analyses contemplated by the RFA.

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 draft RIA cited above.

List of Subjects in 40 CFR Part 50

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

Dated: November 27, 1996.

Carol M. Browner,

Administrator.

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For the reasons set forth in the preamble, chapter I of title 40 of the Code of Federal Regulations is proposed to be 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 primary and secondary ambient air quality standards for O_3.

(a) The level of the national primary ambient air quality standard for O_3, 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) 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 six (or seven) hourly averages are available, the 8-hour average shall be computed on the basis of the hours available, using six (or seven) as the divisor. The 8-hour averages shall be stated in parts per million to three decimal places.

(c) The primary O_3 ambient air quality standard is met at an ambient air quality monitoring site when the 3-year average of the annual third-highest daily maximum 8-hour average O_3 concentration is less than or equal to 0.08 ppm. The primary standard is not met when the 3-year average of the annual third-highest daily maximum 8-hour average O_3 concentration is greater than 0.08 ppm. Computations for comparisons with the primary standard and data handling conventions are specified in Appendix H to this part.

(d) The national secondary ambient air quality standard for O_3 is based on a 3-month cumulative index that sums all ambient hourly concentrations greater than or equal to 0.06 ppm during the hours 8:00 am to 8:00 pm local standard time (LST). The secondary O_3 standard is met at an ambient air quality monitoring site when the cumulative index value (SUM06) based on a consecutive 3-month period of maximum concentrations is less than or equal to 25 ppm-hours. Computations for comparisons with the level of the secondary standard and data handling conventions are specified in Appendix H to this part.

3. Appendix D is amended as follows:

a. References 8 and 9 are revised.

b. After Figure 2, Schematic Diagram of a Typical UV Photometric Calibration System (Option 1), all remaining text included within the ‘‘Temporary Alternative Calibration Procedure—

(Boric Acid-Potassium Iodide)'' section is removed.

c. Figure 1, Schematic Diagram of a Typical BAKI Calibration System, Figure 2, KI Sampling Train, and Figure 3, Schematic Diagram of a Typical BAKI Calibration System (Option 1), are removed.

Appendix D to Part 50—Measurement Principle and Calibration Procedure for the Measurement of O_3 in the Atmosphere

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References

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8. Transfer Standards for Calibration of Ambient Air Monitoring Analyzers for O_3, 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.

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Appendix E [Removed and Reserved]

4. Appendix E is removed and reserved.

5. Appendix H is revised in its entirety to read as follows:

Appendix H to Part 50—Interpretation of the Primary and Secondary National Ambient Air Quality Standards for O_3

1. General

This appendix explains the data handling conventions and computations necessary for determining whether the national primary and secondary ambient air quality standards for O_3 specified in part 50.9 of this chapter are met at an ambient O_3 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 O_3 concentrations and the level of the O_3 standard are specified in the following sections.

2. Primary Ambient Air Quality Standard for O_3

2.1 Data Reporting and Handling Conventions

a. *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 O_3 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 six (or seven) hourly averages are available, the 8-hour average shall be computed on the basis of the hours available using six (or seven) as the divisor. The 8-hour average O_3 concentrations shall be rounded to three decimal places (with 0.0005 rounded up) to preserve the number of significant digits in the reported data. The insignificant digits are truncated.

b. *Daily maximum 8-hour average concentrations.* There are 24 possible running 8-hour average O_3 concentrations for each calendar day during the O_3 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 O_3 concentration for each calendar day with ambient O_3 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.

c. An O_3 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 Standard-Related Summary Statistic

The standard-related summary statistic is the annual third-highest daily maximum 8-hour O_3 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 third-highest daily maximum 8-hour average O_3 concentrations shall be rounded to three decimal places (with 0.0005 rounded up) to preserve the number of significant digits in the reported data. The insignificant digits are truncated.

2.3 Comparisons With the Primary O_3 Standard

a. The primary O_3 ambient air quality standard is met at an ambient air quality monitoring site when the 3-year average of the annual third-highest daily maximum 8-hour average O_3 concentration is less than or equal to 0.08 ppm. The primary standard is not met at an ambient air quality monitoring site when the 3-year average of the annual third-highest daily maximum 8-hour average O_3 concentration is greater than 0.08 ppm. Thus, the 3-year average annual third-highest daily maximum 8-hour average O_3 concentration is also the design value for the site. The number of significant figures in the level of the standard dictates the rounding convention for comparing the computed 3-year average annual third-highest daily maximum 8-hour average O_3 concentration with 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 O_3 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 O_3 monitoring season, with a minimum data completeness in any one year of at least 75% of the designated sampling days.

c. Although three complete years of data are required to demonstrate attainment of the standard, years with high concentrations shall not be ignored on the ground that they have less than complete data. Thus, in computing the 3-year average third-highest maximum concentration, calendar years with less than 75% data completeness shall be included in the computation if the annual third-highest maximum 8-hour concentration is greater than the level of the standard.

EXAMPLE 1.—AMBIENT MONITORING SITE ATTAINING THE PRIMARY O_3 STANDARD

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	0.090	0.085	0.083	0.080
1994	96	0.084	0.083	0.075	0.074	0.074
1995	98	0.080	0.079	0.073	0.068	0.065
Average	98			0.078		

The primary standard is met at this monitoring site because the 3-year average of the annual third-highest daily maximum 8-hour average O_3 concentrations (i.e., 0.078 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 monitoring is greater than 90%, and no single year has less than 75% data completeness.

EXAMPLE 2.—AMBIENT MONITORING SITE FAILING TO MEET THE PRIMARY O_3 STANDARD

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	0.104	0.103	0.092	0.091	0.088
1995	98	0.103	0.101	0.101	0.097	0.095
Average	89			0.099		

The primary standard is not met at this monitoring site because the 3-year average of the third-highest daily maximum 8-hour average O_3 concentrations (i.e., 0.099 ppm) is greater than 0.08 ppm. Note that the O_3 concentration data for 1994 is used in these computations, even though the data capture is less than 75%, because the third-highest daily maximum 8-hour average concentration for that year is greater than 0.08 ppm.

3. Secondary Ambient Air Quality Standard for O_3

3.1 Data Reporting and Handling Conventions

a. *Computing the daily index value (D.I.).* The secondary O_3 standard is based on a seasonal index that accumulates all hourly O_3 concentrations greater than or equal to 0.060 ppm for each hour of the day between 8:00 a.m. to 8:00 p.m. local standard time (LST). The reporting requirements are the same as described above for the primary standard. The hourly average ambient O_3 concentrations shall be reported in parts per million (ppm) to three decimal places, with additional digits to the right being truncated. The first step, computing the daily index value, D.I., for the daylight hours is illustrated below:

EXAMPLE 3.—SAMPLE DAILY INDEX CALCULATION FOR AN AMBIENT OZONE MONITORING SITE

Start hour (a.m.)	Concentration (ppm)	Start hour (p.m.)	Concentration (ppm)
12	0.034	12	0.079
1	0.027	1	0.082
2	0.016	2	0.085
3	0.014	3	0.088
4	0.010	4	0.083
5	0.009	5	0.081
6	0.014	6	0.065
7	0.025	7	0.056
8	0.045	8	0.051
9	0.060	9	0.038
10	0.075	10	0.039
11	0.080	11	0.034

Daily index (D.I.) = 0.060 + 0.075 + 0.080 + 0.079 + 0.082 + 0.085 + 0.088 + 0.083 + 0.081 + 0.065 = 0.78 ppm-hours

b. *Computing the monthly cumulative index (SUM06).* The daily index is computed at each monitoring site for each calendar day in each month during the O_3 monitoring season designated in part 58, Appendix D to this chapter. At an individual monitoring site, a month is counted as a valid O_3 monitoring month if ambient O_3 concentrations are available for at least 75% of possible index hours in the month. For months with greater than 75% data completeness, the monthly total index value shall be adjusted for incomplete sampling by multiplying the unadjusted SUM06 cumulative index value by the ratio of the number of possible daylight hours to the number of hours with valid ambient hourly concentrations.

Example 4. Adjusting the monthly SUM06 for missing data.

$$\text{M.I.} = \sum_{j=1}^{n} (\text{D.I.}) * (n * 12)/v$$

where,

M.I. = the monthly sum of the daylight hours greater than or equal to 0.060 ppm,

D.I. = the daily sum of the daylight hours greater than or equal to 0.060 ppm,

n = the number of days in the calendar month,

v = the number of daylight hours (8:00 a.m.—8:00 p.m. LST) with valid hourly O3 concentrations.

3.2 Secondary Standard-related Summary Statistic

The standard-related summary statistic is the annual maximum 3-month SUM06 value expressed in ppm-hours. Specifically, the annual SUM06 value is computed on a calendar year basis using the three highest, consecutive monthly SUM06 values.

3.3 Comparisons with the Secondary O_3 Standard

The secondary O_3 standard is met when the annual maximum SUM06 value based on a consecutive 3-month period at an O_3 air quality monitoring site is less than or equal to 25 ppm-hours. Values of 0.5 or greater shall be rounded up.

EXAMPLE 5.—SAMPLE CALCULATION OF THE MAXIMUM 3-MONTH SUM06 VALUE AT AN AMBIENT AIR QUALITY MONITORING SITE

	April	May	June	July	August	September	October
Monthly SUM06	4.442	9.124	12.983	16.153	13.555	4.364	1.302
3–Month Total	na	na	26.549	38.260	42.691	34.072	19.221

The maximum consecutive 3-month SUM06 value for this site is 43 ppm-hours. Because 43 is greater than 25, the secondary O_3 ambient air quality is not met at this ambient air quality monitoring site.

[FR Doc. 96–30903 Filed 12–12–96; 8:45 am]

BILLING CODE 6560–50–P