ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[FRL–7428–7]

RIN 2060–ZA11

National Ambient Air Quality Standards for Ozone: Final Response to Remand

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final response to remand.

SUMMARY: On July 18, 1997, in accordance with sections 108 and 109 of the Clean Air Act (Act), EPA completed its review of the national ambient air quality standards (NAAQS) for ozone (O_3) by promulgating revised primary and secondary standards (62 FR 38856; henceforth, ''1997 final rule''). On May 14, 1999, the United States Court of Appeals for the District of Columbia Circuit (''D.C. Circuit'') remanded the O_3 NAAQS to EPA to consider, among other things, any potential beneficial health effects of O_3 pollution in shielding the public from the ''harmful effects of the sun's ultraviolet rays.'' 175 F.3d 1027 (D.C. Cir., 1999). Today's action provides EPA's final response to that aspect of the Court's remand. Based on its review of the air quality criteria and NAAQS for O_3 completed in 1997, its additional assessment of potential beneficial effects of tropospheric O_3, and taking into account public comments, EPA has determined that information linking (a) changes in patterns of ground-level O_3 concentrations likely to occur as a result of programs implemented to attain the 1997 O_3 NAAQS to (b) changes in relevant patterns of exposures to ultraviolet (UV–B) radiation of concern to public health is too uncertain at this time to warrant any relaxation in the level of public health protection previously determined to be requisite to protect against demonstrated direct adverse respiratory effects of exposure to O_3 in the ambient air. Further, it is the Agency's view that associated changes in UV–B radiation exposures of concern, using plausible but highly uncertain assumptions about likely changes in patterns of ground-level ozone concentrations, would likely be very small from a public health perspective. As a result, the revised O_3 NAAQS will remain set at a level of 0.08 parts per million (ppm), with a form based on the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentrations measured at each monitor within an area. No other issues related to the 1997 O_3 NAAQS remain before the Court, and other remanded issues related to implementation of the O_3 NAAQS are not addressed by today's action.

EFFECTIVE DATE: March 7, 2003.

ADDRESSES: A docket containing information relating to EPA's review of the O_3 primary and secondary standards and this response to the D.C. Circuit remand (Docket No. A–95–58) is available for public inspection at the EPA's Air Docket Center, 1301 Constitution Avenue, N.W., Room B108, Washington, DC 20460, Mail code 6102T. This docket incorporates the docket from the previous review of the O_3 standards (Docket No. A–92–17) and the docket established for the ozone air quality criteria document (Docket No. ECAO–CD–92–0786). The docket may be inspected between 8:30 a.m. and 4:30 p.m. on weekdays, excluding legal holidays. A reasonable fee may be charged for copying. The information in the docket constitutes the complete basis for the decision announced in this final response to the remand. For the availability of related information, see **SUPPLEMENTARY INFORMATION.**

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SUPPLEMENTARY INFORMATION:

Availability of Related Information

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

(1) The Review of the National Ambient Air Quality Standards for Ozone: 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).

(2) Air Quality Criteria for Ozone 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 and $58.00 microfiche).

A limited number of copies of other documents generated in connection with the review of the standard, such as documents pertaining to human exposure and health risk assessments and the relationships between ground-level O_3, UV–B radiation, and health effects, can be obtained from: U.S. Environmental Protection Agency Library (C267–01), 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.

Electronic Availability

The Staff Paper and documents pertaining to human health risk and exposure assessments are available on the Office of Air and Radiation, Policy and Guidance Web site at: *http://www.epa.gov/ttn/oarpg/t1sp.html.* The O_3 NAAQS 1996 proposal and 1997 final rule are available at the same Web site, at: *http://www.epa.gov/ttn/oarpg/t1pfpr.html.*

Children's Environmental Health

This final response to the Court's remand, reaffirming the 1997 8-hour O_3 NAAQS, specifically takes into account children as the group most at risk to the direct inhalation-related effects of O_3 exposure, and was based on studies of effects on children's health (U.S. EPA, 1996a; U.S. EPA, 1996b) and assessments of children's exposure and risk (Johnson, 1994; Johnson *et al.,* 1996 a,b; Whitfield *et al.*, 1996; Richmond, 1997). The 8-hour O_3 primary standard protects children's health with an adequate margin of safety from the direct adverse effects associated with inhalation exposures to ground-level O_3, after considering potential indirect beneficial effects of ground-level O_3 related to its attenuation of UV–B radiation and any associated adverse health effects.

Implementation Activities

When the 8-hour primary and secondary O_3 standards are implemented by the States, the power generation, automobile, petroleum, and chemical industries are likely to be affected, as well as other manufacturing concerns that emit volatile organic compounds (VOC) or nitrogen oxides (NO_X). The extent of such effects will depend on implementation policies and control strategies adopted by States to assure attainment and maintenance of the standards.

The EPA is now developing appropriate policies and control strategies to assist States in the implementation of the 8-hour primary and secondary O_3 NAAQS. The EPA now expects to propose an implementation strategy for public comment early in 2003.

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The following topics are discussed in today's preamble:

I. Background

A. 1997 Revision of the O_3 NAAQS

On July 18, 1997, in accordance with sections 108 and 109 of the Act, EPA completed its review of the NAAQS for O_3 by promulgating revised primary and secondary standards (1997 final rule). These standards were based on EPA's review of the available scientific evidence linking direct exposures to ambient O_3 to adverse health and welfare effects at levels allowed by the then current O_3 standards. The revised primary and secondary standards were each set at a level of 0.08 ppm, with an 8-hour averaging time and a form based on the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentrations measured at each monitor within an area.[1] The new primary standard was established to provide increased protection to the public, especially children and other at-risk populations, against a wide range of O_3-induced respiratory health effects due to inhalation exposures, including decreased lung function, primarily in children active outdoors; increased respiratory symptoms, particularly in highly sensitive individuals; hospital admissions and emergency room visits for respiratory causes, among children and adults with pre-existing respiratory disease such as asthma; inflammation of the lung; and possible long-term damage to the lungs. The new secondary standard was established to provide increased protection to the public welfare against direct O_3-induced effects on vegetation, such as agricultural crop loss, damage to forests and ecosystems, and visible foliar injury to sensitive species.

1. Legislative Requirements

Two sections of the Act govern the establishment, review, and revision of NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify certain pollutants which ''may reasonably be anticipated to endanger public health or welfare'' and to issue air quality criteria for them. These air quality criteria are to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air * * *.''

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate ''primary'' and ''secondary'' NAAQS for pollutants identified under section 108. Section 109(b)(1) defines a primary standard as one ''the attainment and maintenance of which, in the judgment of the Administrator, based on [the] criteria and allowing an adequate margin of safety, are requisite to protect the public health.'' 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.''[2]

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.

2. Review of Air Quality Criteria and Standards for O_3

An overview of the last review of the O_3 air quality criteria and standards is presented in section I.C of the preamble to the 1997 final rule. In summary, the 1997 review was initiated in August 1992 with the development of a revised Air Quality Criteria Document for Ozone and Other Photochemical Oxidants (henceforth, the ''Criteria Document''). Multiple drafts of the Criteria Document were reviewed by CASAC and the public, resulting in a final Criteria Document (U.S. EPA, 1996a) that reflected CASAC and public comments.[3] The EPA also prepared a staff paper, Review of National Ambient Air Quality Standards for Ozone: Assessment of Scientific and Technical Information (henceforth, the ''Staff Paper'').[4] Multiple drafts of the Staff Paper were also reviewed by CASAC and the public, resulting in a final Staff Paper (U.S. EPA, 1996b) that reflected CASAC and public comments.[5]

On November 27, 1996 EPA announced its proposed decision to

[1] The form of a standard refers to the air quality statistic that is used to determine whether an area attains the standard.

[2] Welfare effects as defined in section 302(h) (42 U.S.C. 7602(h)) include, but are not limited to, ''effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.''

[3] 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 ozone and related photochemical oxidants'' (Wolff, 1995a).

[4] The Staff Paper evaluates policy implications of the key studies and scientific information in the Criteria Document, identifies critical elements that EPA staff believes should be considered, and presents staff conclusions and recommendations of suggested options for the Administrator's consideration.

[5] In separate letters from the CASAC chair to the Administrator, CASAC advised that the primary standard and secondary standard sections of the final draft Staff Paper provide ''an adequate scientific basis for making regulatory decisions'' concerning the O_3 standards (Wolff, 1995b, 1996).

revise the NAAQS for O_3 (61 FR 65716, December 13, 1996; henceforth, ''1996 proposal''), as well as its proposed decision to revise the NAAQS for particulate matter (PM). To ensure the broadest possible public input on these proposals, EPA took extensive and unprecedented steps to facilitate the public comment process, including the establishment of a national toll-free telephone hotline and provisions for electronic submission of comments. The EPA also held several public hearings, participated in numerous meetings across the country, and held two national satellite telecasts to provide direct opportunities for public comment and to disseminate information to the public about the proposed standard revisions. As a result of this intensive effort to solicit public input, more than 50,000 comments were received on the proposed revisions to the O_3 NAAQS by the close of the public comment period on March 12, 1997.

The final rule, published on July 18, 1997, presented EPA's rationale for its final decision, and addressed the major issues raised in comments on the 1996 proposal. A comprehensive summary of all significant comments, along with EPA's response to such comments (U.S. EPA, 1997; henceforth, ''Response to Comments''), can be found in the docket for the 1997 rulemaking (Docket No. A–95–58).[6] The 1997 final rule presented EPA's decision to replace the existing 1-hour primary and secondary standards [7] (each set at a level of 0.12 ppm, with a 1-expected-exceedance form, averaged over 3 years [8] with 8-hour standards, each set at a level of 0.08 ppm, with a form based on the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentrations measured at each monitor within an area (as determined by 40 CFR part 50, appendix I).

B. Ozone NAAQS Litigation and Remand

1. Litigation Summary

Following promulgation of the revised 8-hour O_3 NAAQS, numerous petitions for review of the standards were filed in the D.C. Circuit. *American Trucking Associations* v. *EPA,* No. 97–1441. Oral argument was held on December 17, 1998 and the Court rendered its opinion on May 14, 1999. *American Trucking Associations* v. *EPA* (''ATA I''), 175 F.3d 1027 (D.C. Cir., 1999). A divided panel found that section 109 of the Act, 42 U.S.C. § 7409, as interpreted by EPA in setting the revised O_3 (and PM) NAAQS, effected an unconstitutional delegation of legislative authority. *Id.* at 1033–1040. The Court remanded the O_3 standards with instructions that EPA should articulate an ''intelligible principle'' for determining the degree of residual risk to public health permissible in setting revised NAAQS. *Id.* In addition, the Court also directed that, in responding to the remand, EPA should consider the potential beneficial health effects of O_3 pollution in shielding the public from the ''harmful effects of the sun's ultraviolet rays.'' *Id.* at 1051–1053.

In 1999, EPA petitioned the D.C. Circuit for rehearing *en banc* on several aspects of that Court's decision in *ATA I.* Although the petition for rehearing was granted in part and denied in part, the Court declined to review its ruling with regard to the potential beneficial effects of O_3 pollution. *American Trucking Associations* v. *EPA* (''*ATA II*''), 195 F.3d 4, 10 (D.C. Cir., 1999). The Court did note, however, that it ''expressed[ed] no opinion, of course, upon the effect, if any, that studies showing the beneficial effects of tropospheric ozone * * * might have upon any ozone standards * * *'' *Id.*

On January 27, 2000, EPA petitioned the U.S. Supreme Court for *certiorari* on the constitutional issue and two other issues, but did not request review of the D.C. Circuit ruling regarding the potential beneficial health effects of O_3. The EPA's petition for *certiorari* was granted on May 22, 2000; oral argument was subsequently held on November 7, 2000; and an opinion was issued on February 27, 2001. *Whitman* v. *American Trucking Associations* (''*Whitman*''), 531 U.S. 457 (2001). The U.S. Supreme Court reversed the judgment of the D.C. Circuit on the constitutional issue, holding that section 109 of the Act does not delegate legislative power to the EPA in contravention of the Constitution, and remanded the case to the D.C. Circuit to consider challenges to the O_3 (and PM) NAAQS that had not been addressed by that Court's earlier decisions.

Oral argument was held on December 18, 2001, and on March 26, 2002, the D.C. Circuit issued its final decision finding the 1997 O_3 (and PM) NAAQS to be ''neither arbitrary nor capricious,'' and denied the remaining petitions for review. *American Trucking Associations* v. *EPA* (''*ATA III*''), 283 F.3d 355, (D.C. Cir. 2002). Thus, today's final response to the Court's 1999 remand regarding the potential beneficial health effects of O_3 constitutes EPA's final response to challenges to the 1997 O_3 NAAQS. Other remanded issues, relating to implementation of the O_3 NAAQS, are not addressed by today's action.

2. Remand on Health Benefits Issue

The D.C. Circuit's 1999 ruling concludes that ''EPA cannot ignore the possible health benefits of ozone.'' [9] *ATA I*, 175 F.3d at 1033. According to the Court ''[p]etitioners presented evidence that, according to them, shows the health benefits of tropospheric ozone as a shield from the harmful effects of the sun's ultraviolet rays—including cataracts and both melanoma and non-melanoma skin cancer.'' *Id.* at 1051. In rejecting EPA's view that Congress did not intend it to consider potential indirect beneficial effects of tropospheric O_3 in shielding the public from potentially harmful, but naturally occurring, UV–B radiation from the sun, the Court concluded that ''legally * * * EPA must consider the positive identifiable effects of a pollutant's presence in the ambient air in formulating air quality criteria under section 108 and NAAQS under section 109.'' *Id.* at 1052. As a result, the Court directed EPA to ''determine whether * * * tropospheric ozone has a beneficent effect and, if so, then to assess ozone's net adverse health effect.'' *Id.* at 1053. Today's action sets forth EPA's final response in that regard.

C. Atmospheric Distribution of O_3 and UV–B Radiation

The focus of the 1997 review of the air quality criteria and standards for O_3 and related photochemical oxidants was on public health and welfare effects associated with direct exposure to ambient levels of O_3 in the lower troposphere, essentially at ground level. People are directly exposed to ground-level O_3 simply by breathing ambient air; similarly, plants are directly exposed through their respiratory processes. Ground-level O_3 is not emitted directly from mobile or stationary sources but, like other photochemical oxidants, commonly exists in the ambient air as an

[6] This docket incorporates by reference the docket from the previous O_3 NAAQS review (Docket No. A–92–17) and the docket established for the Criteria Document (Docket No. ECAO–CD–92–0876).

[7] These 1-hour O_3 standards were originally set in 1979 (44 FR 8202, February 8, 1979) and reaffirmed in 1993 (58 FR 13008, March 9, 1993).

[8] The 1-hour 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 one, averaged over 3 years (as determined by 40 CFR part 50, appendix H).

[9] For the reasons discussed in the Response to Comments (U.S. EPA, 1997, pp. 128–135), EPA did not consider in the 1997 review adverse health effects that might be caused by the potential increase in UV–B radiation that could result from reductions in ground-level O_3 brought about by control programs implemented to attain a revised O_3 NAAQS.

atmospheric transformation product. Ground-level O_3 formation is the result of chemical reactions of VOC, NO_X, and oxygen in the presence of sunlight and generally at elevated temperatures. As a principal ingredient in photochemical smog, elevated episodic concentrations of ground-level O_3 typically occur in the summertime. High concentrations may be found in and downwind of major urban centers as well as across broad regions of elevated precursor emissions. A detailed discussion of atmospheric formation, ambient concentrations, and health and welfare effects associated with direct exposure to O_3 can be found in the Criteria Document and Staff Paper.

Naturally occurring O_3 is found in two sections of the earth's atmosphere, the stratosphere and the troposphere. The demarcation between these two layers varies between about 8 and 18 kilometers (km) above the earth's surface. As illustrated in Figure 1, depicting the vertical profile of O_3, most naturally occurring O_3 (> 90 percent) resides in the stratosphere, with the remaining O_3 (< 10 percent) in the troposphere. The band of O_3 between about 15 and 30 km is commonly known as the ''ozone layer.''

Man-made air pollution has significantly perturbed the natural distribution of O_3 in both layers. It is now widely accepted that emissions of long-lived chlorofluorocarbons (CFCs) and other compounds can deplete the natural O_3 layer in the stratosphere. And, as summarized above, much shorter lived emissions of VOC and NO_X can markedly increase ''smog'' O_3 in the lowest portion of the troposphere, which is termed the planetary boundary layer. This fluctuating planetary boundary or ''mixing'' layer of the troposphere can extend as high as 1 to 3 km above the ground. Assuming a fairly high summertime O_3 pollution reservoir of 65 parts per billion (ppb) in a typical 1 km mixing layer, Cupitt (1994) estimated that pollution would add less than 1 percent to the expected total vertical profile of tropospheric and stratospheric O_3 (*i.e.*, ''total column'' O_3) that would occur in the natural environment.

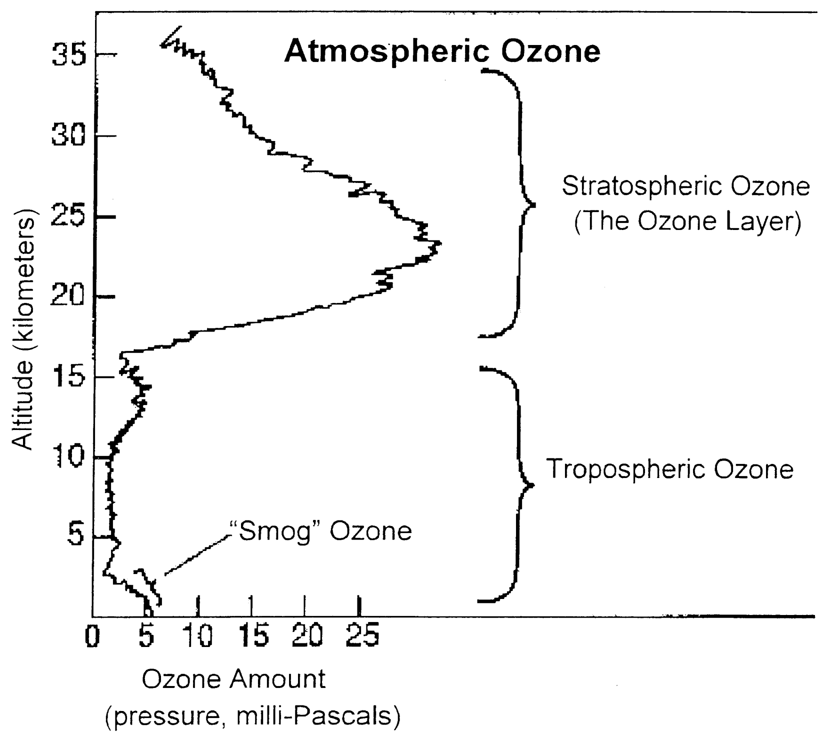

Figure 1. Distribution of Ozone in the Atmosphere (adapted from World Meteorological Organization, 1994, p. 20)

Ozone at ground level and throughout the troposphere is chemically identical to stratospheric O_3. Stratospheric O_3 occurs far too high to present any threat of direct respiratory-related adverse effects to people or plants from ambient ground-level exposures, but is known to provide a natural protective shield from excess radiation from the sun by absorbing UV–B radiation [10] before it penetrates to ground level. Recognizing that exposure to UV–B radiation has been associated with adverse health and welfare effects, EPA and international scientific, regulatory, and legislative organizations have for some time focused on understanding the effects of UV–B radiation and on controlling the man-made pollution that is causing the depletion of the O_3 layer in the stratosphere, as discussed in section I.D below.[11]

During the 1997 review, EPA recognized that tropospheric O_3 also absorbs UV–B radiation (U.S. EPA, 1996a, p. 5–79), such that ground-level O_3 formed by man-made pollution has the potential to provide some degree of additional shielding beyond the natural

[10] UV–B radiation refers to the region of the solar spectrum within the range of wavelengths generally from 280–290 nanometers (nm) at the lower end, to 315–320 nm at the upper end.

[11] For example, in 1977 and again in 1990, Congress added provisions to the Act to address stratospheric O_3 depletion and the resultant increase in exposure to UV–B radiation.

levels that would otherwise occur in the absence of man-made pollution. The relationship between ground-level O_3 and UV–B radiation, as well as the health effects associated with exposure to UV–B radiation and consideration of the UV–B radiation-related health risks associated with changes in ground-level O_3 are discussed in section II.B below. In response to the remand on the health benefits issue, EPA's assessment of the net adverse health effects of ground-level O_3 is discussed in section II.C below, as a basis for today's decision on the primary O_3 NAAQS, summarized in section II.D below.

D. Related Stratospheric O_3 Program

In the 1970s, scientists first grew concerned that certain chemicals could damage the earth's protective stratospheric O_3 layer, and these concerns were validated by the discovery of thinning of the O_3 layer over Antarctica in the southern hemisphere. Because of the risks posed by stratospheric O_3 depletion and the global nature of the problem, leaders from many countries decided to work together to craft a workable solution. Since 1987, over 175 nations have signed a landmark environmental treaty, the Montreal Protocol on Substances that Deplete the Ozone Layer. The Protocol's chief aim is to reduce and eventually eliminate the production and use of man-made O_3 depleting substances, such as CFCs. By agreeing to the terms of the Montreal Protocol, signatory nations ratifying the Protocol—including the United States—commit to take actions to protect the stratospheric O_3 layer and to reverse the damage due to the use of O_3 depleting substances.

In 1990, Congress amended the Act by adding title VI (sections 601–618) to address the issue of stratospheric O_3 depletion.[12] Most importantly, the amended Act required the gradual end to the production of certain chemicals that deplete the O_3 layer.[13] In addition, the Act requires EPA to develop and implement regulations for the responsible management of O_3 depleting substances in the United States. The EPA has developed several regulatory programs under these authorities that include: ending the production and import of O_3 depleting substances (57 FR 33754, July 30, 1992) and identifying safe and effective alternatives (59 FR 13044, March 18, 1994), ensuring that refrigerants and halon fire extinguishing agents are recycled properly (58 FR 28660, May 14, 1993), banning the release of O_3 depleting refrigerants during the service, maintenance, and disposal of air conditioners and other refrigeration equipment (60 FR 40420, August 8, 1995), and requiring that manufacturers label products either containing or made with the most harmful O_3 depleting substances (58 FR 8136, February 11, 1993). Because of their relatively high O_3 depletion potential, several man-made compounds, including CFCs, carbon tetrachloride, methyl chloroform, and halons were targeted first for phaseout. The EPA continues to develop additional regulations for the protection of public health and the environment from effects associated with the depletion of the stratospheric O_3 layer.

Besides implementing and enforcing stratospheric O_3 protection regulations in the U.S., EPA continues to work with other U.S. government agencies and international governments to pursue ongoing changes to the Montreal Protocol and other treaties. These refinements to the Protocol and other treaties are based on ongoing scientific assessments of O_3 depletion that are coordinated by the United Nations Environment Programme (UNEP) and the World Meteorological Organization (WMO), with cooperation from EPA and other agencies around the globe (UNEP, 1998; and WMO, 1998).

In addition to these regulatory and scientific activities, EPA maintains several education and outreach projects to help protect the American public from the health effects of overexposure to ultraviolet (UV) radiation. Chief among these projects is the UV Index, a tool that provides a daily forecast of the next day's likely UV levels across the United States.[14] The UV Index, which EPA launched in partnership with the National Weather Service, serves as the cornerstone of EPA's SunWise School Program, the goal of which is to educate young children and their caregivers about the health effects of overexposure to the sun, as well as simple steps that people can take to avoid overexposure.[15]

E. Summary of Proposed Response to Remand

On November 14, 2001, EPA proposed a response to the D.C. Circuit remand (66 FR 52768; henceforth, ''proposed response'') to consider any potential beneficial effects of ground-level O_3 in shielding the public from potentially harmful, but naturally occurring, UV–B radiation from the sun. *ATA I,* 175 F.3d at 1051–53. Based on its review of the air quality criteria and NAAQS for O_3 completed in 1997, and its additional assessment of potential beneficial effects of ground-level O_3, EPA provisionally determined that the information linking (a) Changes in patterns of ground-level O_3 concentrations likely to occur as a result of programs implemented to attain the 1997 O_3 NAAQS to (b) changes in relevant patterns of exposure to UV–B radiation of concern to public health is too uncertain at this time to warrant any relaxation in the level of public health protection previously determined to be requisite to protect against the demonstrated adverse respiratory effects of direct inhalation exposure to O_3 in the ambient air.[16] Further, the proposed response presented the Agency's view that even when using plausible but highly uncertain assumptions about likely changes in patterns of ground-level O_3 concentrations, associated changes in UV–B radiation exposures of concern would likely be very small from a public health perspective. Thus, EPA proposed not to change the O_3 NAAQS set in 1997 at a level of 0.08 ppm, with a form based on the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentrations measured at each monitor within an area.

The proposed response solicited public comments on EPA's proposed decision not to change the 1997 O_3 NAAQS, and on various specific aspects of EPA's review and rationale. The EPA received ten comments on the proposed response from industry, public interest groups, and local and State governments. Significant comments are addressed throughout section II below and more fully in a separate Response to Comments (U.S. EPA, 2002).

II. Rationale for Final Response To Remand on the Primary O_3 Standard

Today's action presents the Administrator's final response to the remand, in which the Court directed EPA to determine ozone's net adverse effect on public health and not

[12] Title VI replaced the provisions regarding stratospheric O_3 depletion enacted in 1977. 42 U.S.C. 7671.

[13] Both the Act and the Montreal Protocol, however, provide for limited ''essential use exemptions'' for the continued production and import of very small quantities of CFCs and other O_3 depleting substances needed for certain essential uses, for example, for metered dose inhalers used by people with asthma and other respiratory diseases.

[14] Information about the UV Index is available from the EPA Stratospheric Ozone Hotline at (800) 296–1996 or at *http://www.epa.gov/sunwise/uvindex.html*.

[15] Information about EPA's SunWise School Program is available at *http://www.epa.gov/sunwise/*.

[16] The D.C. Circuit upheld EPA's determination that the 1997 O_3 NAAQS was requisite to protect against demonstrated adverse respiratory effects in *ATA III.*

''disregard the studies'' upon which the petitioners primarily relied in their challenge. *ATA I,* 175 F.3d at 1053. Today's action reaffirms the 8-hour O_3 primary standard promulgated in 1997, based on:

(1) Information from the 1997 criteria and standards review that served as the basis for the 1997 primary O_3 standard, including the scientific information on health effects associated with direct inhalation exposures to O_3 in the ambient air, consideration of the adversity of such effects for individuals, and human exposure and risk assessments (section II.A below);

(2) A review of scientific information in the record of the 1997 review (but not considered as part of the basis for the 1997 standard) on potential health effects associated with changes in UV–B radiation, the association between changes in ground-level O_3 and potential changes in UV–B radiation, and predictions of changes in ground-level O_3 levels likely to result from attainment of alternative O_3 standards (section II.B below);

(3) Consideration of the net adverse effects of ground-level O_3, taking into account both direct adverse inhalation-related health effects and potential indirect beneficial health effects associated with the shielding of UV–B radiation by ground-level O_3 (section II.C below); and

(4) Consideration of the comments received on the proposed response.

A number of commenters focused on various aspects of EPA's decision-making process and the timing of EPA's final response. A few such commenters expressed the view that EPA's proposed response to the remand was procedurally inadequate in that in reviewing information in the record on ozone's potential beneficial effects, EPA did not supplement the air quality criteria or consult with CASAC. These commenters also asserted that EPA should reopen the record to include new studies and analyses regarding ozone's potential beneficial effects that were not available for inclusion in the 1997 rulemaking record. These commenters thus argued that EPA should supplement the air quality criteria with information on ozone's potential beneficial effects, including both new and record information, consult with CASAC, and re-propose a response to the remand.[17]

Other commenters expressed the opposite view, agreeing with EPA's reliance on the rulemaking record that was before the Court in the *ATA* litigation as the basis for EPA's proposed response, and urging EPA to conclude its response as expeditiously as possible. These commenters argued that to reopen the record would require consideration not only of new information on potential beneficial effects, but also new information on adverse respiratory effects, and that to do so would effectively erase the previous review cycle. These commenters also asserted that the analyses of ozone's potential beneficial effects that were included in the record fail to meet minimum standards of reliability and scientific adequacy, that failure by EPA to expeditiously conclude the review that began in 1992 would represent unreasonable delay, and that any associated delay in implementing the 1997 O_3 NAAQS would be at the expense of public health.

Having considered these procedural comments, EPA continues to believe it is appropriate to base its response to the remand on the large amount of relevant information in the 1997 rulemaking record that was before the Court in *ATA I,* taking into account as well the substantive comments received on the proposed response. The EPA also believes it is unnecessary to supplement the air quality criteria with the draft, preliminary analyses relied on by commenters and by some petitioners in the *ATA I* litigation, or to undertake a more formal CASAC review. As more fully discussed in the Response to Comments, EPA took note of the following in reaching these conclusions:

(1) This action responds to a remand from the D.C. Circuit and addresses the only remaining issue regarding the setting of the 1997 O_3 standard.[18] It is not a new, separate review of air quality criteria and NAAQS under sections 108 and 109. In these circumstances, it is appropriate for EPA to base its response on the record associated with the prior NAAQS review and court decisions. The EPA recognizes that new studies and related information relevant to further assessment of ozone's net adverse effects may now be available that were not part of the 1997 rulemaking record.

Such information is likely available not only on indirect potentially beneficial effects of O_3, but also on direct adverse respiratory-related effects of O_3. Taking into account the 5-year periodic review requirements of section 109 of the Act, and noting that this review already extended a decade since it was initiated (57 FR 38832; August 27, 1992), EPA believes that any such new information should be considered in the next periodic review. The EPA has already initiated the next periodic review. Preparation of a revised O_3 Criteria Document that will incorporate all such relevant information is well underway (65 FR 57810; September 26, 2000).

(2) Limiting its consideration to information that was part of the 1997 record, as well as comments on the proposed response, is consistent with EPA's prior exercise of its discretion to decide whether new studies or analyses cited during a public comment period are of such potential significance that a final decision should be postponed so they can be assessed in supplemental air quality criteria and considered before concluding a NAAQS review. *See* 58 FR 12008, 13014 n.2 (1993) (ozone NAAQS). In prior reviews, after an extended review of relevant scientific information, EPA has been aware of yet additional relevant information, but determined that the information would be more appropriately considered in its next periodic review.[19] *See, e.g.,* 62 FR 38652, 38662 (1997) (PM NAAQS).

(3) The record includes relevant information on indirect potentially beneficial effects of O_3. The public has been afforded two opportunities to submit comments and relevant information on this issue, through EPA's solicitation of public comments on both the 1996 proposal and the 2001 proposed response.

(4) The documents in the 1997 record cited by some commenters—and upon which certain petitioners primarily relied in their challenge of EPA's 1997 decision—(Cupitt, 1994; DOE, 1995; Lutter and Wolz, 1997) do not generally meet the minimum standards that EPA and CASAC have historically maintained for inclusion of health-related information in air quality criteria. The documents in question are either draft, unpublished analyses or, in the case of the one paper that was published, characterized by the authors as a ''preliminary analysis,'' which generally relied upon the assumptions in the other unpublished analyses. Consistent with its practice in other NAAQS reviews, the EPA judges these

[17] Some commenters also expressed the view that EPA's proposed response to the remand was premature since the D.C. Circuit had not yet decided other related issues. These comments are now moot since the D.C. Circuit issued its final opinion on March 26, 2002, denying all remaining challenges to the 1997 O_3 NAAQS.

[18] As noted earlier, this action does not address implementation of the O_3 NAAQS.

[19] As in other instances where EPA has received additional studies during public comment, EPA provisionally examined a 1997 draft analysis conducted by Madronich and determined that it did not warrant supplementing the air quality criteria at this time. *See, e.g.,* 62 FR 38652, 38662 (1997) (PM NAAQS).

draft, unpublished or preliminary analyses to be inappropriate for inclusion in air quality criteria, and concludes that supplementing the 1996 O_3 criteria is not warranted.

(5) As discussed in more detail in section II.B.2, EPA also determined that it was not in a position to supplement the air quality criteria by developing its own more extensive analysis because information essential to the development of such an analysis (*e.g.,* behavioral patterns related to potential UV–B radiation exposure) is not available at this time.

(6) The EPA has appropriately consulted CASAC by providing for its review and comment the proposed response, as well as the key documents from the record upon which EPA's response is based.[20] The CASAC has expressed no concern with this procedure nor indicated that any further CASAC involvement was necessary or appropriate. Indeed, only one member of CASAC chose to comment at all, and that member likewise expressed no concern with the method by which EPA consulted with CASAC on the response to the remand. Finally, the commenters have not provided any reason to believe that additional review by CASAC would have affected the outcome of this action in any way.

In view of the above factors, in particular the quality and type of analyses relied on by commenters and the fact that CASAC had the opportunity to review those analyses as well as other information in the record, EPA believes its approach to this response represents a reasonable exercise of its discretion to decide when to supplement the review process and fulfills the Agency's responsibilities under the Act. The EPA's response fully complies with the direction of the Court that EPA determine ozone's net adverse effect on public health and not ''disregard the studies'' upon which the petitioners primarily relied in their challenge. *ATA I,* 175 F.3d at 1053. Nothing in the Court's remand purports to require EPA to reopen the air quality criteria, or indeed the entire review process, before concluding this aspect of the 1997 review. For the reasons discussed above, EPA also believes it would be inappropriate to do so.

Accordingly, the EPA concludes that any further extension of this review, through reopening the rulemaking record or review process, would represent an unwarranted delay in completing this review cycle, which began in 1992 and originally concluded in 1997. Any further extension of this review would also delay Agency and State actions to implement the 8-hour O_3 NAAQS, which EPA believes would be inappropriate and contrary to the purpose of the Act, in that it would impede the important public health protections afforded by the 8-hour ozone NAAQS.

A. Direct Adverse Health Effects From Breathing O_3 in the Ambient Air

This section briefly summarizes information on the direct adverse health effects from breathing O_3 in the ambient air, information as to when those effects become adverse to individuals, and insights gained from human exposure and risk assessments intended to provide a broader perspective for judgments about protecting public health from the risks associated with direct O_3 inhalation exposures.[21]

1. Health Effects Associated With O_3 Inhalation Exposures

Based on information from human clinical, epidemiological, and animal toxicological studies, 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. Long-established acute health effects[22] 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.[23] The 1997 review included substantial new information on similar effects associated with prolonged exposures at concentrations as low as 0.08 ppm and at moderate levels of exertion. 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. The 1997 review also included new information on chronic health effects[24] associated with long-term exposures. This array of effects is briefly summarized below, followed by considerations as to when these physiological effects could become medically significant such that they should be regarded as adverse to the health of individuals experiencing them.

a. Effects of Short-term and Prolonged O_3 Exposures

(i) Pulmonary function responses. Transient reductions in pulmonary function have been observed in healthy individuals and those with impaired respiratory systems (*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 responses has come from controlled human exposure studies, which clearly show that reductions in lung function are enhanced by increased levels of activity involving exertion and by increased O_3 concentrations. Numerous such 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, providing conclusive evidence that O_3 levels commonly monitored in the ambient air induce lung function decrements in exercising adults. Further, numerous summer camp studies provide an extensive and reliable data base on comparable lung function responses to ambient O_3 and other pollutants in children and adolescents. The extent of pulmonary function decrements varies considerably among individuals, pulmonary function generally tends to return to baseline levels shortly after short-term exposure, and effects are typically attenuated upon repeated short-term exposures over several days.

(ii) Respiratory symptoms and effects on exercise performance. Various transient respiratory symptoms, including cough, throat irritation, chest pain on deep inspiration, 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 symptoms that persist for longer periods

[20] The EPA's request for comments, together with copies of the proposed response and key documents, was transmitted to CASAC in a letter to Dr. Philip Hopke from Dr. Karen Martin, January 14, 2002, which is available in the docket. The EPA had previously provided an earlier draft of the proposed response, together with copies of key documents, to CASAC members in January 2001, ten months before the proposed response was published. *See* letter to Dr. Philip Hopke from Dr. Karen Martin, January 22, 2001 (available in the docket).

[21] See the 1996 proposal and 1997 final rule for more complete summaries and the Criteria Document and Staff Paper for more detailed discussion.

[22] ''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.

[23] The 1-hour O_3 primary NAAQS set in 1979 was generally based on these acute effects associated with heavy exercise and short-term exposures.

[24] ''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.

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, may curb the ability or desire to engage in normal activities, and may interfere with maximal exercise performance.

(iii) Increased airway responsiveness. Increased airway responsiveness is an indication that the airways are predisposed to bronchoconstriction, with a high level of bronchial responsiveness being characteristic of asthma. 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. 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.

(iv) 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. Evidence that inhalation of O_3 may break down or impair these defense mechanisms comes 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. While 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, taken as a whole, the data suggest that acute O_3 exposures can impair the host defense capability of both humans and animals, potentially resulting in a predisposition to bacterial infections in the lower respiratory tract.

(v) 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. Numerous studies consistently have shown such a relationship, even after controlling for modifying factors, as well as when considering only O_3 concentrations < 0.12 ppm. 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.

(vi) 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. 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 humans, the extent and course of inflammation and its constitutive elements have been evaluated by using bronchoalveolar lavage (BAL) to sample cells and fluid from the lung and lower airways. Several such studies 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, with the lowest concentration of prolonged O_3 exposure tested in humans, 0.08 ppm for 6.6 hours with moderate exercise, inducing small but statistically significant increases in these endpoints. Thus, it is reasonable to conclude that repeated acute inflammatory response and cellular damage 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 that could be the result of repeated O_3 exposures occurring over a season or a lifetime.

b. 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. The findings from such studies conducted in southern California and Canada 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. Other epidemiologic studies have attempted to find associations between daily mortality and O_3 concentrations in various cities around the United States. 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.

In a large number of animal toxicology studies, "lesions" [25] in the

[25] 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

Continued

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. Under certain conditions, some of the structural changes seen in these studies 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 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. In summary, the collective data on long-term exposure to O_3 garnered in studies of laboratory animals and human populations have many ambiguities. Nevertheless, the currently available information provides at least a biologically plausible basis for considering 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.

c. Adversity of Effects for Individuals

Some population groups have been identified as being sensitive to effects associated with exposures to ambient O_3 levels, such that individuals within these groups are at increased risk of experiencing such effects. Population groups at increased risk include: (1) Active children and outdoor workers who regularly engage in outdoor activities; [26] (2) individuals with preexisting respiratory disease (*e.g.*, asthma or chronic obstructive lung disease); [27] and (3) some individuals, referred to as ''hyperresponders,'' who 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.

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. Based on these guidelines, with CASAC concurrence, 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) were defined, together with judgments as to the potential impact on individuals experiencing varying degrees of severity of these responses.[28]

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 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, EPA has concluded 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.

2. Human Exposure and Risk Assessments

To put judgments about respiratory 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.[29] This broader context includes consideration, to the extent possible, of the particular population groups at risk for various health effects, the number of people in at-risk groups likely to be exposed to O_3 concentrations shown to cause health effects, the number of people likely to experience certain adverse health effects under varying air quality scenarios, and the kind and degree of uncertainties inherent in these assessments. These quantitative assessments add to our understanding of the overall body of evidence linking O_3 inhalation exposures to adverse health effects. The models used in these assessments were appropriate and the methods used represent the state of the art.

a. Exposure Analyses

The EPA conducted exposure analyses to estimate O_3 exposures for the general population and two at-risk populations, active children who regularly engage in outdoor activity (*i.e.*, ''outdoor children'') and ''outdoor workers,'' living in nine representative U.S. urban areas.[30] Exposure estimates were developed for a baseline year (*e.g.*, 1993, 1994), using monitored O_3 air quality data (*i.e.*, the ''as is'' scenario), as well as for simulated air quality conditions reflecting attainment of the 1-hour NAAQS and various alternative standards. The exposure analyses provide: (1) Estimates of the number of people exposed in each of these population groups to various O_3 concentrations, and the number of occurrences of such exposures, under different regulatory scenarios,[31] which are an important input to the risk assessment conducted for certain adverse health effects (summarized in the next section); and (2) estimates of the frequency of occurrences of O_3 ''exposures of concern,'' [32] which help

Paper describes and discusses these degenerative changes in more detail.

[26] 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.

[27] While not necessarily more responsive than healthy individuals in terms of the magnitude of pulmonary function decrements or symptomatic responses, these individuals may be at increased risk since 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.

[28] These gradations and impacts are summarized in the 1996 proposal and discussed in the Criteria Document (Chapter 9) and Staff Paper (section V.F, Tables V–4 and V–5).

[29] See the 1996 proposal (61 FR 65723–6) and 1997 final rule (62 FR 38860–1) for a more complete summary of these assessments. A detailed description of the exposure and risk models and their application at the time of the 1996 proposal are presented in the Staff Paper and associated technical support documents (Johnson, 1994; Johnson *et al.*, 1996 a,b; Whitfield *et al.*, 1996). Following proposal, supplemental exposure and risk analyses were done to analyze the specific standard proposed and alternative standards on which comment was solicited, as well as to refine the procedures used to simulate O_3 concentrations upon attainment of alternative standards (Richmond, 1997).

[30] The areas include a significant fraction of the U.S. urban population, 41.7 million people, the largest urban areas with major O3 nonattainment problems, and two large urban areas that are in attainment with the 1-hour NAAQS.

[31] Estimates of ''people exposed'' reflect the number of people who experience exposures to a given concentration of O_3, or higher, at least one time during the period of analysis, and estimates of ''occurrences of exposure'' reflect the number of times a given O_3 concentration is experienced by the population of interest.

[32] ''Exposures of concern'' refer throughout to O_3 exposures at and above 0.08 ppm, 8-hour average, at moderate exertion. Such exposures are particularly relevant to a consideration of a number of health effects, discussed in section I.A.1 above, that have been observed in controlled human studies under these exposure conditions, but for which data were too limited to allow for

to put into broader perspective other O_3-related health effects that could not be included in the risk assessment (summarized below).

The computer model used in these analyses, the probabilistic NAAQS exposure model for O_3 (pNEM/O_3), combines information on O_3 air quality with information on patterns of human activity to produce estimates of O_3 inhalation exposures. This model has been developed to take into account the most significant factors contributing to total O_3 inhalation exposure including: The temporal and spatial patterns of ground-level O_3 concentrations throughout an urban area; the variations of O_3 levels within a comprehensive set of ''microenvironments;'' [33] the temporal and spatial patterns of the movement of people throughout an urban area; and the effects of variable exertion levels (represented by ventilation rates), associated with a range of activities that people regularly engage in, on O_3 uptake in exposed individuals. The analysis of these key factors incorporated extensive data bases, including, for example, data from ground-level O_3 monitoring networks in these areas, data from numerous research studies that characterized the activity patterns of the general population and at-risk groups 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),[34] and census data on relevant factors such as age, work status, home location and type of air conditioning system present, and work place location.

The regulatory scenarios examined in the exposure analyses include both 1-hour O_3 standards, at levels of 0.12 ppm (the 1979 NAAQS) and 0.10 ppm, and 8-hour standards, at levels of 0.07, 0.08, and 0.09 ppm, with 1- and 5-expected exceedance forms, *i.e.*, 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 estimates were also used to roughly bound exposure estimates for concentration-based forms of the standards under consideration (*e.g.*, the second- and fifth-highest daily maximum 8-hour average O_3 concentration, averaged over a 3-year period).[35] The estimated exposures are based on a single year of air quality data and 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 analyses were done to estimate exposures that would be expected in the worst year of a 3-year compliance period.

Based on the results of the exposure analyses, children who are active outdoors (representing approximately 7 percent of the population in the study areas) appear to be the at-risk population group examined with the highest percentage and number of individuals likely to experience exposures of concern. Estimated exposures of concern varied significantly across the urban areas examined in this analysis, with far greater variability associated with the 1-hour NAAQS in contrast to the more consistent results associated with alternative 8-hour standards.[36] Despite this variability across areas, general patterns can be seen in comparing alternative standards. For example, for aggregate estimates of the mean percent of outdoor children likely to experience exposures of concern within the seven nonattainment areas: The range of estimates associated with the 1-hour NAAQS is approximately 0.3–24 percent, whereas for alternative 8-hour standards (of the same 1-expected-exceedance form as the 1-hour NAAQS), the ranges are approximately 3–7 percent for a 0.09 ppm standard, 0–1 percent for a 0.08 ppm standard, and essentially zero for a 0.07 ppm standard. Within any given urban area, these differences in estimated exposures of concern between alternative standards are statistically significant.

In looking more specifically at a comparison between 8-hour standards at the 0.09 ppm and 0.08 ppm levels, aggregate estimates of the mean percentage of outdoor children likely to experience exposures of concern are estimated to be approximately 3 percent at the 0.08 ppm level (ranging from 2–10 percent in the nine areas), increasing to approximately 11 percent at the 0.09 ppm level (ranging from 7–29 percent in the nine areas).[37] Thus, based on these analyses, a standard set at 0.09 ppm would allow more than three times as many children to experience exposures of concern as would a 0.08 ppm standard, with the number of children likely to experience such exposures increasing from approximately 100,000 to more than 300,000 in these nine areas alone. These exposures of concern are judged by EPA to be an important indicator of the public health impacts of those O_3-related effects for which information is too limited to develop quantitative estimates of risk, but which have been observed in humans at a level of 0.08 ppm for 6- to 8-hour exposures. Such effects include increased nonspecific bronchial responsiveness (related, for example, to aggravation of asthma), decreased pulmonary defense mechanisms (suggestive of increased susceptibility to respiratory infection), and indicators of pulmonary inflammation (related to potential aggravation of chronic bronchitis or long-term damage to the lungs).

In taking these observations into account, the Administrator and CASAC recognized 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 limitations in the human activity data base that 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 generalized models intended to reflect patterns of air quality changes that have historically been observed, contains significant uncertainty, especially when applied to areas requiring very large reductions in air quality to attain alternative standards

quantitative risk assessment. Exposures at and above 0.12 ppm, 1-hour average, at heavy exertion, are also of concern; however, the focus here is on 8-hour average exposures since 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.

[33] The five indoor and two outdoor microenvironments included in this exposure model account for the highly localized variations in O_3 concentrations to which people are exposed that are not directly reflected in the concentrations measured at ambient ground-level O_3 monitoring sites.

[34] See, for example, Tables V–8 and V–9 in the Staff Paper, pp. 83–84.

[35] As discussed in section IV and appendix A of the Staff Paper.

[36] The observed area-to-area variability reflects differences in the shape of air quality distributions and differences in the relationships between 1-hour and 8-hour peak concentrations across urban areas, as well as differences in the percentage of homes with air conditioning (which impacts exposure estimates when individuals are indoors) and the frequency of warm versus cool days (which impacts exposure estimates because different sets of human activity patterns are used for warm versus cool days in the exposure model) across the nine urban areas (Richmond, 1997).

[37] Based on the supplemental analyses that used the third-highest concentration-based form of the standards (Richmond, 1997).

or to areas that are now in attainment with the 1-hour NAAQS.[38]

b. Risk Assessments

The EPA conducted an assessment of health risks for several categories of respiratory effects considering the same population groups, alternative air quality scenarios, and urban areas that were examined in the human exposure analyses described above. The objective of the risk assessment was to estimate to the extent possible the magnitude of risks to population groups believed 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 uncertainties inherent in the assessment. While different risk measures are provided by the assessment, EPA has focused on ''headcount risk'' estimates which include: (1) Estimates of the number of people likely to experience a given health effect and (2) estimates of the number of incidences of a given health effect likely to be experienced by the population group of interest (n.b., some individuals likely experience that given health effect more than once in a year). While the estimates of numbers of people and incidences of effects are subject to uncertainties and should not be viewed as demonstrated health impacts, EPA believes they do represent reasonable estimates of the likely extent of these effects on public health given the available information.

This risk assessment builds upon earlier O_3 risk assessment approaches developed during the previous O_3 NAAQS review. The risk models produce estimates of risk by taking into account: (1) Exposure-response or concentration-response relationships used to characterize various respiratory effects of O_3 exposure; (2) distributions of population exposures upon attainment of alternative standards resulting from the exposure analyses described above; and (3) distributions of 1-hour and 8-hour daily maximum O_3 concentrations upon attainment of alternative standards, developed as part of the exposure analyses. The assessment addresses a number of adverse lung function and respiratory symptom effects as well as increased hospital admissions, as discussed below.

(i) Adverse lung function and respiratory symptom effects. Risk estimates have been developed for several of the respiratory effects observed in controlled human exposure studies to be associated with O_3 exposure for which sufficient quantitative dose-response information was available. These effects include lung function decrements (measured as changes in FEV_1) and pain on deep inspiration (PDI).[39] More specifically, these effects, or health endpoints, are defined not only in terms of physiological responses, but also the amount of change in that response judged to be of medical significance (as discussed in section II.A.3 above). For decrements in FEV_1 responses, risk estimates are provided for the lower end, midpoint, and upper end of the range of response considered to be an adverse health effect (*i.e.,* ≥ 10, 15, or 20 percent FEV_1 decrements), while for PDI responses, risk estimates are provided for moderate and severe responses. Although some individuals may experience a combination of responses, risk estimates could only be provided for each individual health endpoint rather than various combinations of functional and symptomatic responses.

The exposure-response relationships used to characterize these functional and symptomatic effects were based on the controlled human exposure studies, and were applied to ''outdoor children,'' ''outdoor workers,'' and the general population.[40] These exposure-response relationships were combined with the results of the exposure analyses, which provided distributions of population exposures estimated to occur upon attainment of alternative standards, 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.

Following from the results of the exposure analyses showing outdoor children to be the population group experiencing the greatest exposures, this population group also has the highest estimated risk in terms of the percent of the population, and the numbers of children, likely to experience the health effects included in the assessment. As expected, the risk estimates exhibit the same general patterns in comparing alternative standards as was observed in the results of the exposure analyses. Estimated risk varied significantly across the urban areas examined, with greater variability associated with the 1-hour NAAQS than with alternative 8-hour standards, and, within any given urban area, the differences in risk estimated for the various 1-hour and 8-hour standards analyzed were statistically significant.

In looking more specifically at a comparison between 8-hour standards at the 0.09 ppm and 0.08 ppm levels, aggregate estimates of the number of outdoor children in the nine areas likely to experience moderate (≥ 15 percent) and large (≥ 20 percent) FEV_1 decreases and moderate or severe PDI are summarized in the 1997 final rule.[41] For example, for large FEV_1 decreases (≥ 20 percent), approximately 2 percent of outdoor children (58,000 children) would likely experience this effect one or more times per year (100,000 occurrences) at the 0.08 ppm standard level, increasing to approximately 3 percent of outdoor children (97,000 children and 220,000 occurrences) at the 0.09 ppm standard level. Based on this assessment, a standard set at 0.09 ppm would allow approximately 40–65 percent more outdoor children to experience these functional and symptomatic effects than would a 0.08 ppm standard, and approximately 70–120 percent more occurrences of such effects in outdoor children per year.

In considering these observations, the Administrator and CASAC have recognized that there are many uncertainties inherent in such assessments, not all of which can be quantified. Some of the most important caveats and limitations in this assessment include: (1) The uncertainties and limitations associated with the exposure analyses discussed above; (2) the extrapolation of exposure-response functions, consistent with CASAC's recommendation, that projects some biological responses 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

[38] A more complete discussion of uncertainties and limitations is presented in the Staff Paper and technical support documents (Johnson *et al.,* 1996a,b; Richmond, 1997).

[39] 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 studies used to derive exposure-response relationships.

[40] While these studies only included adults aged 18–35, findings from other clinical studies and summer camp field studies in several locations across the U.S. and Canada indicate changes in lung function in healthy children similar to those observed in healthy adults exposed to O_3 under controlled laboratory conditions.

[41] Based on the supplemental analyses that used the third-highest concentration-based form of the standards (Richmond, 1997).

observed in studies of lung function and symptoms upon repeated exposures).[42]

(ii) Excess respiratory-related hospital admissions. A separate risk assessment was done for increased respiratory-related hospital admissions as reported in several epidemiologic studies.[43] The assessment looked only at one urban area, New York City, for which adequate air quality information also was available to assess population risk. Increased respiratory-related hospital admissions for individuals with asthma were modeled using a probabilistic concentration-response function based on the results of an epidemiologic study in New York City (Thurston *et al.*, 1992) and estimated distributions of daily maximum 1-hour average O_3 concentrations upon attainment of alternative standards at various monitors in New York City (developed as part of the exposure analysis discussed above).[44] The resulting risk estimates are for excess respiratory-related hospital admissions (*i.e.*, those attributable to O_3 concentrations above an estimated background O_3 level of 0.04 ppm) for asthmatic individuals over an O_3 season.

Similar to the risk assessment discussed above for lung function and respiratory symptom effects, reductions in hospital admissions for respiratory causes for asthmatic individuals and the general population are estimated to occur with each change in the level of alternative 8-hour standards from 0.09 ppm to 0.07 ppm. In looking more specifically at a comparison between 8-hour standards at 0.09 ppm and 0.08 ppm levels, a standard set at 0.09 ppm is estimated to allow approximately 40 more excess hospital admissions of asthmatics within an O_3 season in New York City for respiratory causes as compared to a 0.08 ppm standard, which represents approximately a 40 percent increase in excess O_3-related admissions, but only approximately a 0.3 percent increase in total admissions of asthmatics. The EPA believes that while these numbers of hospital admissions are relatively small from a public health perspective, they are indicative of a pyramid of much larger numbers of related O_3-induced effects, including respiratory-related hospital admissions among the general population, emergency and outpatient department visits, doctors visits, and asthma attacks and related increased use of medication that are important public health considerations.

In taking these observations into account, the Administrator recognizes the uncertainties and limitations associated with this assessment. These include: (1) The inability at this time to quantitatively extrapolate the risk estimates for New York City to other urban areas; (2) uncertainty associated with the underlying epidemiologic study from which the concentration-response relationship used in the analysis was drawn; and (3) uncertainties associated with the air quality adjustment procedure used to simulate attainment of alternative standards for the New York City area.[45]

B. Potential Indirect Beneficial Health Effects Associated with Ground-level O_3

This section is drawn from information in the record of the 1997 review with regard to the effect of ground-level O_3 on the attenuation of UV–B radiation and potential associated health benefits. All relevant record information was reviewed, including EPA documents, published articles, oral testimony at public meetings, and written comments submitted during the rulemaking and on the proposed response. This section summarizes information on the health effects associated with UV–B radiation exposure (section B.1) and the relationship between ground-level O_3 and UV–B radiation (section B.2), and evaluates estimates of UV–B radiation risks that have been attributed to reductions in ground-level O_3 projected to result from attainment of the 1997 O_3 NAAQS (section B.3). This section also responds to a number of technical comments on the proposed response relating to (i) the distinctions that EPA has drawn between assessing the public health impacts of changes in stratospheric versus ground-level O_3, (ii) the distinctions between assessing the public health impacts of changes in inhalation-related exposures to ground-level O_3 versus the impacts of changes in dermal-related exposures to UV–B radiation as mediated by changes in ground-level O_3, and (iii) the appropriate weight to give to analyses in the record that provide quantitative estimates of the public health impacts of changes in dermal-related exposures to UV–B radiation as mediated by changes in ground-level O_3.

1. Health Effects Associated with UV–B Radiation Exposure

The following short summary of information[46] on the adverse human health effects associated with exposure to UV–B radiation focuses on the three major organ systems whose tissues are commonly exposed to solar radiation: the skin, eyes, and immune system.[47] It is these three systems that are potentially subject to damage from increased UV–B radiation as a result of the absorption of solar energy by molecules present in the cells and tissues of these organs. The biologically effective dose of radiation that actually reaches target molecules generally depends on the duration of exposure at particular locations, time of day, time of year, behavior (*i.e.*, ''sun avoidance'' and ''sun seeking'' behavior[48]), and, for the skin, characteristics that include pigmentation and temporal variations (*e.g.*, changes in the pigmentation due to tanning).

a. Effects on the Skin

The most common form of solar damage to the skin is sunburn. Susceptibility to sunburn and the ability to tan are the basis for a classification system of six skin phenotypes. The most sensitive individuals (skin type I) are very light-skinned, with red or blonde hair and blue or green eyes (U.S. EPA, 1987, ES–33). The most resistant individuals (skin type VI) are darkly pigmented even without exposure to solar radiation. Susceptibility to sunburn may be a risk factor for skin cancer.

Among light-skinned populations, skin cancer is among the most common kinds of cancer. The three types of skin cancer that have been associated with exposure to solar radiation include two common types of nonmelanoma skin cancers (NMSC), squamous cell carcinoma (SCC) and basal cell carcinoma (BCC), and melanoma, a far less common form of cancer.

[42] A more complete discussion of assumptions and uncertainties is presented in the Staff Paper and the technical support documents (Whitfield *et al.*, 1996; Richmond, 1997).

[43] Several studies, mainly conducted in the northeastern U.S. and southeastern Canada have reported excess daily respiratory-related hospital admissions associated with elevated O_3 levels within the general population and, more specifically, for individuals with asthma.

[44] The model is described in more detail in Whitfield *et al.* (1996) and results from the supplemental analysis are presented in Richmond (1997).

[45] A more complete discussion of these uncertainties and limitations is presented in the Staff Paper and technical support documents (Whitfield *et al.*, 1996; Richmond, 1997).

[46] More detailed information about the health effects associated with UV–B radiation exposure may be found in the proposed response to the remand (66 FR 57278–57280).

[47] The reference document available in the record for the information in this section is the EPA document ''Assessing the Risk of Trace Gasses that Can Modify the Stratosphere'' (U.S. EPA, 1987).

[48] Sun avoidance is an intentional decrease in exposure, for example, by using clothing, sunscreens, and sunglasses to shield the body from solar radiation. Sun seeking behavior is an intentional increase in exposure to solar radiation, for example, by sunbathing.

Prolonged exposure to the sun is considered to be the dominant risk factor for NMSC (U.S. EPA, 1987, ES–33). It has been observed that NMSC tends to develop on sites that are most frequently exposed to the sun (*e.g.*, head, face, and neck). Outdoor workers, who are subject to greater exposure to solar radiation, tend to have higher incidence rates of NMSC. A latitudinal gradient exists for the flux of UV–B radiation (*i.e.*, the amount of radiation transmitted through the atmosphere), with fluxes generally higher in lower latitudes. A similar latitudinal gradient is generally seen in incidence rates of NMSC. Skin pigmentation provides a protective barrier that reduces the risk of developing NMSC, such that light-skinned individuals, who are more susceptible to sunburn and have blue or green eyes, are more likely to develop NMSC.

Both types of NMSC result from the malignant transformation of keratinocytes, the major structural cells of the skin. Cumulative long-term exposure to UV radiation is the exposure of concern for both types of NMSC. More specifically, the incremental increase in cumulative lifetime exposure to UV–B radiation is the metric used to estimate the risk of increased incidence of NMSC (U.S. EPA, 1987, ES–3). Epidemiological evidence, however, also indicates that exposure to solar radiation may play different roles in the etiology of SCC and BCC. In particular, SCC is more likely to develop on sites receiving the highest cumulative UV radiation doses (*e.g.*, nose), and the development of SCC is more strongly associated with cumulative exposure to UV radiation. Relative to SCC, BCC is more likely to develop on sites that are not normally exposed to the sun, such as the trunk. For a given cumulative level of exposure to solar radiation, the risk of developing SCC may be greater than the risk of developing BCC.

Dose-response relationships for NMSC are generally estimated in terms of a biological amplification factor (BAF), which is defined as the percent change in tumor incidence that results from a 1 percent change in UV–B radiation. While there is considerable uncertainty in such estimates, results from several studies have produced an overall BAF range that is 1.8 to 2.85 for all nonmelanoma skin tumors (U.S. EPA, 1987, ES–34). The BAF estimates are generally higher for males than females and for SCC than BCC, and generally increase with decreasing latitude. Key uncertainties in these estimates include, for example, uncertainties in the actual doses of UV–B radiation received and in the underlying baseline incidence rates in populations. Additional uncertainty is introduced in estimating the change in mortality from NMSC associated with changes in UV–B radiation, reflecting in part discrepancies of reporting between death certificates and hospital diagnoses. Based on published estimates, rates of metastasis among SCCs and BCCs varied by one to two orders of magnitude, with rates estimated to be approximately 2 to 20 percent for SCC and 0.0028 to 0.55 percent for BCC. The overall fatality rate for NMSC has been estimated to be approximately 1 to 2 percent, with three-fourths to four-fifths of the deaths attributable to SCC (U.S. EPA, 1987, ES–34).[49]

Melanoma is a serious, life-threatening skin cancer that is far rarer and generally much more aggressive than NMSC. The relationship between exposure to UV–B radiation and melanoma is not as clear as the relationship between exposure to UV–B radiation and NMSC. The EPA (1987) noted limitations in the evidence linking solar radiation to melanoma. For example, no animal models were identified in which exposure to UV–B radiation experimentally induces melanoma, and no *in vitro* models for malignant transformation of melanocytes. Despite these limitations, EPA (1987) recognizes that a large array of evidence does support the conclusion that solar radiation is one of the causes of melanoma. Melanin, the principal pigment in the skin, effectively absorbs UV radiation, such that darker skin provides more protection from UV radiation. Lighter-skinned individuals, whose skin contains less protective melanin, have higher incidence and mortality rates from melanoma than do darker-skinned individuals.

Sun exposure seems to induce freckling, which is an important risk factor for melanoma, and sun exposure leading to sunburn apparently induces melanocytic moles, which are also a risk factor for melanoma. Additional evidence suggests that melanoma risk may be associated with childhood sunburn. However, other evidence suggests that childhood sunburn may be a surrogate for an individual's pigmentation characteristics or be related to mole development, rather than being a separate risk factor (U.S. EPA, 1987, ES–37).

Most studies that have used latitude as a surrogate for sunlight or UV–B exposure have found an increase in melanoma incidence or mortality correlated with proximity to the equator. Other evidence, however, creates uncertainty about the relationship between solar radiation and melanoma. Some ecologic epidemiology studies, conducted primarily in Europe or in countries close to the equator, have failed to find a latitudinal gradient for melanoma. In addition, outdoor workers generally have lower incidence and mortality rates from melanoma than indoor workers, which appears to be incompatible with the hypothesis that the cumulative dose from exposure to solar radiation causes melanoma. Unlike NMSC, most melanoma occurs on sites of the body that are not habitually exposed to sunlight. This evidence suggests that exposure to solar radiation, or UV–B, is not solely responsible for variations in the incidence and mortality from melanoma (U.S. EPA 1987, ES–37).

Considering the available evidence, EPA (1987) concluded that UV–B radiation is a likely component of solar radiation that causes melanoma, either through the initiation of tumors or through suppression of the immune system. The EPA (1987) also recognized that significant uncertainties exist in characterizing associations between solar radiation and melanoma, including the appropriate action spectrum to be used in estimating doses, the best functional form for a dose-response relationship, and the best way to characterize dose (*e.g.*, peak value, cumulative summer exposure).

b. Effects on the Eyes

Evidence suggests that adverse effects on the eye are associated with exposure to UV–B radiation. Effects likely include increases in cataract incidence or severity and increased incidence of retinal disorders and retinal degeneration. Cataracts are characterized by the gradual loss of transparency of the lens due to the accumulation of oxidized lens proteins. Many possible mechanisms exist for the formation of cataracts, and UV–B radiation may play an important role in some mechanisms. Therefore, while epidemiological studies indicate that the prevalence of human cataracts varies with latitude and UV radiation in general (U.S. EPA, 1987, ES–40), significant uncertainty exists about the action spectrum to be used in any estimation of dose associated with variations in solar radiation. Epidemiological and laboratory evidence indicates that the exposure of

[49] More recent estimates of mortality rates from NMSC may be found on the American Cancer Society's Web site *http://www.cancer.org,* under cancer type ''Skin, Nonmelanoma,'' then under ''Nonmelanoma Skin Cancer—Overview.''

concern in the development of cataracts is the cumulative lifetime exposure to UV–B radiation.

c. Effects on the Immune System

Information on the effects of UV–B radiation on the immune system comes primarily from laboratory animal studies. High doses of UV radiation cause a depression in systemic hypersensitivity reactions, whereas relatively lower doses cause a depression in local contact hypersensitivity. Both of these immunosuppressive effects of UV radiation have been found to reside almost entirely in the UV–B portion of the solar spectrum (U.S. EPA, 1987, ES–39).

Information about the effects of UV radiation on the human immune system, however, is very limited. Without more complete information from laboratory or epidemiological studies, the nature of an exposure of concern cannot be estimated. Immunologic studies have not assessed the effects of long-term, low-dose UV–B irradiation, such that the magnitude of risk from this type of exposure cannot be assessed (U.S. EPA, 1987, ES–40).

2. Relationship Between Ground-level O_3 and UV–B Radiation Exposure

a. Relevant Atmospheric Factors

The relationships between ground-level O_3 and UV radiation occur in the context of a much larger dynamic of the earth's atmospheric systems. The sun is, of course, overwhelmingly the main source of a wide band of electromagnetic radiation, including the ultraviolet. The total atmosphere blocks a significant portion of the range of this incoming solar radiation before it reaches ground level, including much of the more energetic wavelengths that are shorter than visible light (400–900 nm). The UV spectrum (100–400 nm) is comprised of UV–C (100–280 nm), UV–B (280–320 nm), and UV–A (320–400 nm). Ultraviolet -B radiation is efficiently but not completely absorbed by total column O_3. Wavelengths above 350 nm, including visible light, are not absorbed by oxygen (O2) or O_3 (U.S. EPA, 1987, ES 35). Because the amount of atmospheric O_3 traversed by sunlight varies with the sun angle, atmospheric absorption is more complete in winter months and both early and late in the day, as compared to the absorption around mid-day near the summertime solar zenith. Therefore, a decrease in total column O_3 from naturally occurring conditions is of greater concern during times of higher sun angles, and for the more energetic portion of the UV–B range.

The underlying annual and diurnal patterns of UV–B penetration to the ground layer are driven primarily by three factors: (1) The change in apparent sun angle with the surface that occurs as the earth travels around the sun; (2) the diurnal change in apparent sun angle caused by the earth's rotation; and (3) the solar/meteorologically driven annual change in the amount of O_3 in the stratosphere. Stratospheric O_3 over U.S. latitudes shows a characteristic peak in the spring months, falling steadily thereafter through summer and fall (Fishman *et al.*, 1990; Frederick *et al.*, 1993). The combination of the annual sun cycle and the stratospheric O_3 cycle means that peak UV–B radiation reaching the troposphere tends to occur in late June to early July, and falls steadily thereafter (Frederick *et al.*, 1993). The annual peak in ground-level O_3 concentrations, which extends in most areas from May through September, generally overlaps the UV–B radiation peak (*e.g.*, U.S. EPA, 1996a, Figure 4–23). Diurnal patterns of ground-level O_3 vary, but in urban areas, summertime peaks tend to occur between noon and 4 pm (U.S. EPA, 1996a, section 4.4). This obviously overlaps with peak incoming UV–B radiation. The pattern of vertical mixing in the atmosphere is such that morning ground-level measurements probably do not accurately reflect ''mixing-layer'' concentrations (U.S. EPA, 1996a, p. 3–44).[50]

The relationship between ground-level O_3 and solar radiation, including UV–B radiation, is complex and mediated by a number of atmospheric factors. It is not limited to the simple absorption of energy. At a fundamental level, the variation in apparent solar radiation is a primary cause of meteorological fluctuations that strongly influence the build-up and transport of anthropogenic air pollution. Further, as discussed in Chapter 3 of the Criteria Document, UV–B radiation that penetrates the stratosphere to the mixing layer plays a key role in the processes leading to the formation of photochemical smog, including the formation of ground-level O_3. In fact, increased penetration of UV–B radiation to the troposphere due to stratospheric O_3 depletion would likely increase ground-level concentrations of O_3 in most urban and many rural areas of the U.S. (U.S. EPA, 1996a, p. 3–5). The chain of indirect events triggered by increased penetration of UV–B radiation can result in both increases and decreases in aerosol and acid rain formation (U.S. EPA, 1996a; pp. 3–38 to 39), with attendant further feedbacks through heterogeneous chemistry and aerosol scattering of UV–B radiation. All of these complex processes could, under varying conditions, increase or decrease the amount of UV–B radiation that actually reaches ground level relative to an unperturbed case. The reactions can further affect the concentrations of radiatively important substances such as methane, O_3, and particles, and could affect local, regional, and global climate.

Setting aside the direction and magnitude of these complex indirect effects of UV–B radiation penetration on ground-level air pollution, and assuming appropriate sun angles and cloud density, the marginal effect of ground-level O_3 on the absorption of UV–B radiation by the earth's atmosphere can be considered separately. Because of increased scattering of incident UV–B radiation by the denser layer air molecules, droplets, and particles nearer the surface, tropospheric O_3 can absorb somewhat more UV–B radiation than an equal amount of O_3 in the stratosphere (Brühl and Creutzen, 1989). The extent to which this increase in unit effect occurs depends on the relative concentrations and character of aerosols in the troposphere as compared to the stratosphere.

A further consideration is the relative effectiveness of ground-level O_3 in absorbing those spectra of UV–B radiation wavelengths most likely to cause health effects. The ''effective dose'' of UV–B radiation can be expressed as a function of two factors, the intensity of radiation (by wavelength) reaching the earth's surface and the action spectrum. The wavelength-dependent effect of O_3 on reducing the intensity of radiation in the UV–B range is summarized above. The action spectrum describes how effective radiation at particular wavelengths is at causing a particular biological effect or a response in an instrument. Action spectra allow the estimation of the potential effects of simultaneously changing radiation at different wavelengths by different amounts, as happens with changing O_3 levels. Laboratory and field studies have been used to estimate and adopt action spectra conventions for various biological endpoints (*e.g.*, Madronich, 1992). As noted above, uncertainty exists about the action spectra as well as how to specify appropriate dose metrics for particular health endpoints. Even estimates of the range of wavelengths

[50] The mixing layer (relevant to the vertical ''thickness'' of ground-level O_3) develops and grows in height through the day.

considered to be generally biologically active vary within the UV–B radiation spectrum. These different action spectra have different sensitivities to changes in total column O_3, which are formalized as numerical radiation amplification factors (RAF).[51] In general, a 1 percent change in total column O_3 will produce greater than a 1 percent change (*e.g.*, 1.1 to 1.8 percent) in effective radiation dose for particular effects.

Nevertheless, as noted above, typical summertime ground-level O_3 pollution in the eastern U.S. is less than 1 percent of total column O_3. Even considering the relative effectiveness of ground-level O_3 in reducing UV–B radiation and the amplification of effective dose, such pollution could add a few percent at most to naturally occurring biologically effective UV–B radiation shielding.[52] Viewed from one perspective and holding all other factors constant, the assumed typical O_3 pollution level is providing some ''improvement'' or incremental UV–B radiation shielding above the natural conditions that would otherwise exist in the mixing layer. It should also be noted that, if typical summertime O_3 levels were assumed to approximate the estimated continental background of about 40 ppb for daylight hours (U.S. EPA, 1996b, p.p. 20–21), this too would represent an ''improvement'' over the natural conditions that would exist in the mixing layer without the influence of international transport of O_3.[53]

The extent to which changes in ground-level O_3 concentrations would translate into changes in UV–B radiation-related health effects in various locations cannot, however, be adequately viewed by reference to uniform assumptions applicable for specific sun angle, latitude, time of day, cloud cover, and the presence of other pollutants.[54] In the real world, all of these factors vary with location, season, meteorology, and time of day. Moreover, the complex causal relationships noted above among all of these factors mean that neither static calculations holding other factors constant (*e.g.*, Cupitt, 1994) nor simple empirical associations between measured ground-level O_3 and UV–B radiation (*e.g.*, Frederick *et al.*, 1993) provide an adequate basis for assessing the ''net'' shielding associated with control strategy driven changes in ground-level pollution in various locations over an extended time period. Moreover, as for the direct effects of O_3, the extent of resultant UV–B radiation-related health effects is also heavily dependent on the variation of these physical changes superimposed on the activity patterns and other factors that determine population exposures and sensitivities to UV–B radiation, and on the extent to which significant biological responses can be attributed in part to episodic peak exposures as well as to long-term cumulative exposures.

Assessing the effective O_3 layer shielding is considerably more difficult for ground-level O_3 than for stratospheric O_3 because of its far greater spatial and temporal variability and the much smaller contribution to the total O_3 column made by ground-level O_3. Some insights into the relative variability of these two layers are provided in Fishman *et al.* (1990), which compares satellite measurements of stratospheric O_3 with ''residual'' tropospheric O_3, a measure that actually excludes the lowest portion of the ground-layer O_3 in the mixing layer. For the summer months, the long-term spatial variability in the amount of O_3 in the stratosphere across the lower 48 U.S. States is about 7 percent (Figure 8c), while the variability in the tropospheric ''residual'' is nearly 4 times greater, at about 25 percent (Figure 9c). By comparison, the spatial variability in ground-level O_3 measurements across regions and cities in the U.S. is far greater (U.S. EPA, 1996a, Chapter 4) reaching 200 percent and higher for comparable long-term measurements. Within an area as small as the Los Angeles basin alone, for example, the median ground-level 8-hour O_3 values in different locations varied by more than a factor of 2 (Table 28; Johnson *et al.*, 1996c). The satellite information also shows a marked contrast in the seasonal variations in O_3 for these two layers. The variation in the summer/winter stratospheric O_3 column over the U.S. is only about 2 to 4 percent, while the variation in seasonal ''residual'' tropospheric O_3 is about 50 to 80 percent (Figures 8a,c;9a,c; Fishman *et al.*, 1990). Again, the variability is even greater for ground-level measurements (*e.g.*, U.S. EPA, 1996a, Figure 4–23; Frederick *et al.*, 1993).

Although Fishman *et al.* (1990) do not compare daily variations in stratospheric O_3 above the U.S., it is reasonable to conclude that the spatial and annual/seasonal temporal stability evidenced by this large stratospheric reservoir would result in far more stable day-to-day and diurnal patterns as compared to ground-level O_3. The high variability of daytime O_3 concentrations for these temporal scales is amply documented in the Criteria Document (U.S. EPA, 1996a, Figure 4–23).

The spatial and temporal stability of the expansive and deep stratospheric O_3 reservoir means that assessments of the effects of long-term declines or restoration can reasonably assume that short-term and local-scale variations in important factors such as cloud cover, other pollutants, temperature, population demographics and activity patterns beneath this layer will tend to ''even out'' over time, permitting more confidence in the magnitude and direction of such assessments. In contrast to the stability of the stratospheric O_3 layer, the large spatial and day-to-day variability outlined above for ground-level O_3 means that geographical or temporal variations in other factors such as weather, other pollutants, sensitive population subgroups and human activity patterns may not ''even out'' in particular areas under assessment. Moreover, it is reasonable to assume that the variations in ground-level O_3 are not independent of the variations in many of these other factors. Such variability may have a substantial impact on the outcome of any assessment of the relative effects of a change in ground-level O_3 strategies or standards. This, combined with the many local- and regional-scale interactions among all of these factors, would complicate any such ground-level O_3 assessment.

A few commenters expressed the view that since EPA, and other agencies such as UNEP, have developed quantitative estimates of the public health impacts of relatively large increases in incident UV–B radiation associated with projected changes in the global reservoir of stratospheric O_3, it is necessarily the case that EPA can now develop credible estimates of the public health impacts associated with the relatively very small increases in incident UV–B radiation that could result from changes in ground-level O_3 likely to occur as a

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[51] The RAF is defined as the percent increase in effective dose divided by the percent decrease in total column O_3 (Madronich, 1992).

[52] For reasons discussed below, any such shielding would vary widely from day-to-day, even in the summer O_3 season.

[53] This estimated continental background is due in part to natural sources of emissions in North America and in part to the long-range transport of emissions from both anthropogenic and natural sources outside of North America.

[54] Adding to the complexity of understanding this relationship are the results of high-dose animal toxicology studies that suggest more research is needed into the direct effects of ground-level O_3 on the skin. Tests by Thiele *et al.* (1997) suggest that long-term exposure to O_3 can deplete vitamin E in the skin, and this could make the skin more susceptible to the effects of UV–B radiation (U.S. EPA, 1997). Therefore, reducing long-term ground-level O_3 exposure might serve to reduce skin problems. Even a relatively small O_3 effect here could partially or completely offset any small UV–B radiation mediated effect estimated based on O_3—UV–B interactions alone.

result of programs implemented to attain an 8-hour O_3 NAAQS. These commenters further suggest that EPA, in concluding that such estimates can not now be developed with sufficient credibility to serve as a basis for setting a less stringent 8-hour O_3 NAAQS, is treating scientific uncertainty differently than it did when regulating substances that deplete O_3 in the stratosphere. The EPA believes that these commenters are ignoring fundamental differences, discussed above, in the nature and relative magnitude of the temporal and spatial variability of O_3 levels in the stratosphere and at ground-level in the troposphere. The EPA remains convinced that it is entirely reasonable to use available information to make estimates of broad-scale public health impacts in the context of the stratospheric O_3 program, while concluding that such broad-scale analytic approaches necessarily obscure and assume away the localized and highly variable factors that are central to credibly estimating public health impacts in the context of programs designed to attain the O_3 NAAQS.

More specifically, EPA notes that quantitative estimates of public health impacts associated with projected changes in stratospheric O_3 are based primarily on epidemiological studies designed to evaluate impacts of long-term UV–B radiation exposures over broad geographic regions (defined in terms of latitude bands) within which stratospheric O_3 levels exhibit relatively little variability. These types of epidemiological studies are not designed to discern impacts associated with much smaller, and much more highly variable, localized changes in ground-level O_3 that will likely result from programs implemented to attain an 8-hour O_3 NAAQS—such local variations are simply averaged out in these studies that compare average UV–B radiation penetration over broad geographic regions with regional average incidence rates of UV–B radiation-related effects. The EPA believes that in choosing not to apply the same type of approach used to assess stratospheric O_3 impacts to its assessment of NAAQS-related changes in ground-level O_3, that it is treating scientific uncertainty in an appropriate and consistent manner. To do otherwise, as some commenters urge, would be to disregard the uncertainties associated with localized and highly variable changes in UV–B radiation exposure patterns that are central to an assessment of NAAQS-related changes, but that are not relevant to the long-term, regional assessment of stratospheric O_3 impacts. Therefore, EPA rejects the notion advanced by these commenters that the simple application of a stratospheric O_3-type assessment would produce credible quantitative estimates of NAAQS-related impacts for the purpose of weighing against the adverse respiratory-related impacts of ground-level O_3, for which EPA has applied state-of-the-art assessments that appropriately take into account the relevant, highly variable patterns of changes in exposures of concern to ground-level O_3 (as discussed more fully in the following section).

b. Factors Related to Area-Specific Assessment

An enumeration of factors that would be important in assessing the potential UV–B radiation-related consequences of a more stringent O_3 NAAQS in any geographical area serves to illustrate the complexities discussed above. Such UV–B radiation-related factors are analogous, but not equivalent to the factors that were important in the respiratory effects exposure and risk assessments discussed above in section II.A.2. These UV–B radiation-related factors include: the temporal and spatial patterns of ground-level O_3 concentrations throughout a geographic area where reductions are likely to occur, and the variations in O_3 concentrations within a comprehensive set of ''microenvironments'' relevant to UV–B radiation exposures (which are generally different from the microenvironments relevant to O_3 inhalation exposures); the associated temporal and spatial patterns of UV–B radiation flux in such microenvironments; the temporal and spatial patterns of movement of people throughout the UV–B radiation-related microenvironments within the geographic area; and the effects of variable behaviors (*e.g.*, the use of sunscreen, hats, sunglasses) within the range of activities that people regularly engage in, on the effective dose of UV–B radiation that reaches target organs such as the skin.

While analogous to the respiratory-related factors, there are a number of important differences between these sets of factors that arise, for example, due to: (1) The indirect nature of the relationship between changes in ground-level O_3 and UV–B radiation-related health effects (in contrast to the direct relationship between ground-level O_3 and inhalation-related health effects); (2) the long-term nature of the relevant exposures that are associated with UV–B radiation's chronic health effects (in contrast to the short-term exposures associated with acute inhalation effects); (3) the different types of parameters that are relevant to assessing dermal exposures (in contrast to those that are important in assessing inhalation exposures); and (4) the importance of skin type in characterizing the sensitive populations (in contrast to characterizing sensitive populations in terms of activity levels and respiratory health status). Further, as was done in EPA's assessment of respiratory effects, it is important to characterize the exposure-related factors specifically to address the relevant at-risk sensitive population groups. As noted in section II.B.1, the sensitivity to UV–B radiation effects varies among U.S. demographic groups, such that it would be important to incorporate census data on relevant characteristics (*e.g.*, age at time of exposure, skin pigmentation) that affect an individual's susceptibility.

Aspects of each of these factors (including areas where current information or modeling tools are insufficient to address these factors at this time), significant comments received on these factors, and EPA's general responses are discussed briefly below.

(i) Estimation of area-specific and microenvironment changes in ground-level O_3. Implementation of a more stringent O_3 standard would, over time, further reduce O_3 concentrations across many areas within the U.S., but would affect various areas in different ways. Depending on the strategies adopted, in some locations peak concentrations would be reduced significantly during the O_3 season, while the lower concentrations that occur on far more numerous days could increase. In such areas, the long-term cumulative effect could be little net change, or even a small increase in cumulative shielding. In other areas, the entire distribution of O_3 could be reduced. The assessment of the acute respiratory health effects of O_3 appropriately focused on the higher portion of this distribution, using a simple roll-back approach discussed above (section II.A.2.a) to simulate changes in air quality patterns during the O_3 season based on available air quality monitoring data. For assessment of chronic effects such as those associated with UV–B radiation, however, where long-term cumulative exposures are of central importance, the mid to lower portion of the distribution would also be important. Also the distribution across the entire year, for which O_3 monitoring data is not generally available in many parts of the country, could potentially be important. The mid to lower portion of the

distribution is much more strongly influenced by complex atmospheric chemistry and nonanthropogenic sources, such that more sophisticated, area-specific modeling may be needed to estimate changes in this part of the distribution likely to occur as a result of programs designed to attain a more stringent O_3 NAAQS.

In addition, although not relevant to assessing direct respiratory effects, the vertical distribution of O_3 concentrations up through the mixing layer becomes important in assessing the effect of O_3 in shielding UV–B radiation. The current lack of routine vertical profile measurements means that little is known about the relative effect of ground-level control strategies on O_3 in the mixing layer.

With regard to characterizing changes in O_3 concentrations within microenvironments relevant to UV–B radiation exposure, it is clear that this set of microenvironments would differ in some respects from the set of microenvironments that were relevant for respiratory effects. For example, while indoor microenvironments can reduce exposure to both ambient O_3 and UV–B radiation, outdoor microenvironments that are relevant for inhalation exposure do not reflect the characteristics that are important for UV–B radiation exposure. Further, while not relevant to inhalation exposure, microenvironments shaded by the presence of trees, buildings, and other structures in many heavily occupied areas would be important to characterize for UV–B radiation analyses because these microenvironments would tend to have greatly reduced UV–B radiation exposures even when at the same ground-level O_3 concentration as a sunny microenvironment.

A few commenters expressed the view that estimating area-specific changes and microenvironment changes in ground-level O_3 is just as important in conducting exposure and risk assessments for direct respiratory-related effects of ground-level O_3 as it would be in conducting such assessments for UV–B radiation-related effects mediated by changes in ground-level O_3. These commenters further asserted that since EPA was able to estimate area-specific changes and microenvironment changes in ground-level O_3 to conduct the respiratory-related exposure and risk assessments discussed above (section II.A.2), then EPA should also be able to estimate such changes as part of an assessment of UV–B radiation-related exposure and risk. While EPA agrees that these factors are relevant for both types of assessments, EPA does not agree that the same information on area-specific and microenvironment changes is relevant for both types of assessments. The EPA believes that these commenters are ignoring both the important differences, discussed above, in the information needed on area-specific and microenvironment factors to conduct the two types of exposure and risk assessments, and the limitations in the available information.

In particular, EPA's 9-city exposure and risk assessment of acute respiratory health effects of O_3 appropriately focused on the higher portion of the distribution of ground-level O_3 concentrations during the O_3 season, in contrast to an area-specific assessment of chronic UV–B radiation-related effects that would need to focus on the entire distribution of O_3 concentrations, not only at ground-level but extending up throughout the vertical mixing layer, across the entire year. While EPA has available air quality monitoring data sufficient for simulating changes in ground-level O_3 concentrations within the O_3 season associated with attaining a more stringent O_3 NAAQS, data are not generally available for simulating changes throughout the vertical mixing layer (necessary for calculating changes in UV–B radiation penetration to the earth's surface as a function of changes in ground-level O_3 concentration patterns) or for simulating changes beyond the O_3 season (which is only 4 to 5 months in many parts of the country). Further, while data are available on microenvironments relevant to direct inhalation-related exposures, data are not yet available on the different microenvironments relevant to dermal UV–B radiation exposures. Thus, while methodologically analogous, sufficient information is simply not yet available to address these factors as part of an area-specific assessment of UV–B radiation-related exposure and risk mediated by changes in ground-level O_3 associated with programs designed to attain a more stringent O_3 NAAQS.

(ii) Estimation of temporal and spatial patterns of UV–B radiation flux. Relative to the assessment of direct respiratory effects, the assessment of the indirect effect of O_3 shielding on UV–B radiation-related health effects requires the additional step of estimating how changes in the temporal and spatial patterns of O_3 concentrations result in changes in the patterns of UV–B radiation. Given a three-dimensional pattern of O_3 levels, a first-order approximation of UV–B penetration to the earth's surface can be readily made. The factors that influence radiation flux through the stratosphere are fairly well characterized, and most are directly related to the modest changes in stratospheric O_3 and large variations in sun angle that depend on latitude, time of year, and time of day (U.S. EPA, 1987). Nevertheless, beyond these factors, and in addition to changes in ground-level O_3, a number of other (second-order) factors in the boundary layer and the rest of the troposphere can affect the amount of UV–B radiation reaching potentially affected populations. One such factor is cloud cover, which can reduce UV–B radiation reaching the earth's surface by 50 percent or more (Cupitt, 1994). Another such factor is the presence of UV–B radiation scattering and absorbing aerosols. Depending on local circumstances and the NAAQS implementation strategy chosen, aerosol-related UV–B radiation exposure might increase or decrease as a result of ground-level O_3 reductions (U.S. EPA, 1996a, Chapter 3). Both O_3 and aerosols can affect local climate as well as UV–B radiation, and this could affect cloud cover as a further indirect consequence of a reduction strategy. While any such indirect effects might be expected to be small for modest O_3 changes, it is not currently possible to predict the magnitude or the sign of their net effect on UV–B radiation penetration.

A few commenters expressed the view that these types of uncertainties do not preclude a quantitative assessment of exposure and risk related to UV–B radiation, because assessments of environmental risks always include simplifying assumptions. While EPA agrees that simplifying assumptions could be made about these types of second order uncertainties, EPA notes that there is little information available for judging whether any such assumptions were realistic or even plausible. Thus, EPA continues to maintain that having relevant information on these factors would be important in judging the credibility of any area-specific assessment of UV–B radiation-related exposure and risk mediated by changes in ground-level O_3.

(iii) Estimation of temporal and spatial patterns of movement of people throughout microenvironments. While population densities are high in areas with the highest ground-level O_3 concentrations, people may not receive their highest exposure to UV–B radiation in such locations. Reductions in O_3 shielding would presumably be most significant in outdoor recreational areas such as the beach or rural open areas where many people likely receive a disproportionate share of their cumulative sun exposure. Local or

regional meteorological factors can, however, cause ground-level O_3 concentrations to be lower in many such areas, particularly in the western United States. For example, O_3 concentrations in the heavily populated Los Angeles area tend to be lowest at the coast and increase inland; in this case, smog-related O_3 would be providing the least shielding where the potential for exposure to UV–B radiation is the highest. The extensive data base on human activity patterns, which was used in the assessment of respiratory effects, does not generally include parameters that relate to people's movement through the types of outdoor microenvironments that are relevant to the assessment of UV–B radiation exposure.

One comment referenced specific EPA data bases that now contain activity pattern data for limited types of outdoor recreation locations, such as tennis courts and golf courses, suggesting that data are now available to better address human activity patterns in microenvironments relevant to assessing UV–B radiation-related exposures and risk. While EPA recognizes that data bases have recently expanded to include additional relevant human activity information, it also notes that the expanded data bases still fall far short of what would be needed to comprehensively project population activity patterns over time and space—in shaded, partially-shaded, and sunny environments. Additional data are still needed to conduct an exposure analysis that could account for the fraction of UV–B radiation exposure that is incurred, for example, during outdoor recreational activities in various non-shaded or partially-shaded microenvironments. The EPA continues to believe that sufficient data on relevant activity patterns are still not currently available, and that reliable estimation of the change in UV–B radiation exposure associated with reducing ground-level O_3 would be significantly hindered by not taking such factors into account.

(iv) Effects of variable behaviors on effective dose of UV–B radiation. Another important factor to be considered in assessing the potential UV–B radiation-related effects of a change in ground-level O_3 is that human behavior affects UV–B radiation exposures. When people choose to shield themselves from UV–B radiation exposure with clothing and sunscreens, and by timing their outdoor activities to avoid peak sun conditions, they are affecting a parameter that is important in assessing UV–B radiation-related effects. The generally well-known risks associated with too much sun exposure are such that many people limit their own as well as their children's exposure through such measures, regardless of the status of the protective stratospheric O_3 layer or variable amounts of ground-level O_3 pollution. While some sun exposure is generally beneficial to health, limiting excessive sun exposure would remain important for a person's health even if the stratospheric O_3 layer were fully restored to its natural state.[55]

Since sun-seeking or sun-avoidance behaviors can tend to maximize or minimize exposure to UV–B radiation, not factoring such behavioral data into an area-specific exposure assessment would hinder reliable estimation of the increased exposure associated with reducing ground-level O_3. Changes in behavior in the past, specifically increases in sun-seeking behaviors, are believed to be the primary reason for the increases in skin cancer incidence and mortality observed in the U.S. by the 1980's (U.S. EPA, 1987). Conversely, future rates of skin cancer could be reduced to the extent that people choose to change their behavior by increasing sun-avoidance behaviors.

Public awareness of the risks associated with overexposure to UV radiation seems to be having an effect on behavior. In 1987, EPA noted that behaviors causing increased UV–B radiation exposure were apparently reaching an upper limit (U.S. EPA, 1987, ES–35). The effect of increased awareness of the health consequences of UV–B radiation exposure on decreasing the number of harmful exposures is not likely to show up, in terms of reducing the incidence and mortality rates of skin cancers, for many years. Nevertheless, ignoring its effects would tend to bias exposure estimates in an area-specific assessment of the UV–B radiation-related effects of smog reduction strategies.

A few commenters noted that variable behaviors would also affect the assessments of respiratory-related exposure and risk, and that not having such information to assess exposure and risk of UV–B radiation-related effects would not introduce any additional uncertainty beyond what is incorporated in the assessments of respiratory effects. The EPA believes that these commenters are not taking into account the extent to which EPA's respiratory-related exposure and risk analyses did incorporate effects of variable respiratory-related behaviors of people as they move through space and time, and through different microenvironments, in that such behaviors are part of the human activity pattern data base used in those assessments. The human activity pattern data base incorporates respiratory-related parameters derived from human activity studies in which subjects report the types of activity they engage in as a function of location and time throughout the day, which are then linked to variable breathing rates that affect the likelihood that specific O_3 exposures are likely to result in adverse respiratory effects.[56] In contrast, the available human activity pattern data base does not include parameters related to dermal exposures to UV–B radiation, such as time spent in sunny, partially shaded, and shaded locations, nor does it include parameters related to the likelihood that people in sensitive groups exhibit sun-avoidance or sun-seeking behaviors while in such microenvironments. Thus, EPA disagrees with comments asserting either that its respiratory-related exposure and risk analyses did not take into account relevant variable behavior patterns or that there is now sufficient information available on UV–B radiation-related variable behaviors to take such factors into account in an area-specific assessment of UV–B radiation-related exposure and risk mediated by changes in ground-level O_3.

In the proposed response to the remand, EPA specifically solicited comment on the factors related to area-specific assessments of UV–B radiation-related effects that are discussed above (66 FR 57284). Beyond the specific comments on each factor noted above, commenters did not generally challenge the appropriateness of these factors in the development of such area-specific assessments, or the importance of

[55] Because of the high baseline risk of effects under natural conditions, as well as the increased risk posed by stratospheric O_3 depletion, medical authorities and governmental bodies have developed campaigns to effect such changes in behavior. The EPA and the National Weather Service (NWS) developed the UV Index. The Index provides a forecast of the expected risk of overexposure to the sun and indicates the degree of caution that should be taken when working, playing, or exercising outdoors. The EPA also developed the SunWise School Program to be used in conjunction with the UV Index. This program is designed to educate the public, especially children and their care givers, about the health risks associated with overexposure to UV radiation and encourage simple and sensible behaviors that can reduce the risk of sun-related health problems later in life (U.S. EPA, 1995a, b).

[56] The EPA recognizes that these data bases may not contain the most current information on respiratory-related avoidance behaviors that may now be occurring in response to EPA's new Air Quality Index health advisories or local community ozone action day programs. Any such updated information appropriately will be included in analyses conducted as part of the periodic review of the O_3 NAAQS that is now underway.

conducting area-specific assessments. However, as noted above, a few commenters expressed the view that since EPA conducted area-specific quantitative assessments for the inhalation exposure and respiratory effects risk assessments discussed above (section II.A.2), it necessarily has sufficient information about these same factors to conduct such exposure and risk assessments of the potential UV–B radiation-related consequences of a more stringent O_3 NAAQS. These commenters also expressed the view that to the extent that EPA has incorporated these factors in quantitative area-specific assessments of respiratory effects, it should be possible to use the same information on these factors to conduct similar assessments of UV–B radiation-related effects.

While EPA clearly recognizes that the factors that are important in the inhalation exposure and respiratory effects risk assessments are analogous to the factors that would be important to conducting similar assessments of the UV–B radiation-related effects, as discussed above, EPA believes that these commenters are ignoring the important differences between these sets of factors. Although substantial information has been gathered over time regarding factors related to respiratory effects, no such similar research has as yet been done that would provide comparable information related to dermal exposure factors. For the reasons discussed above, EPA rejects the notion advanced by these commenters that simply because there is sufficient information to conduct area-specific quantitative assessments for the inhalation exposure and respiratory effects risk assessment, that such information would be sufficient to conduct exposure and risk assessments of the UV–B radiation-related effects of a more stringent O_3 NAAQS.

Based on the discussion of factors above and consideration of the comments received, EPA continues to believe that more information is needed before credible area-specific quantitative analyses of potential UV–B radiation-related consequences of a more stringent O_3 NAAQS could be conducted.

3. Evaluation of UV–B Radiation-Related Risk Estimates for Ground-level O_3 Changes

As should be clear from the discussion above, a full risk assessment of UV–B radiation-related effects resulting from a moderate change in ground-level O_3 would be an extremely challenging enterprise that appears to be beyond current data and modeling capabilities. Nevertheless, three analyses (Cupitt, 1994; U.S. DOE, 1995; Lutter and Wolz, 1997) have developed estimates that attempt to bound the potential indirect UV–B radiation related effects associated with replacing the former 1-hour O_3 NAAQS with an 8-hour O_3 standard. All three analyses essentially reflect a static comparison of two separate O_3 concentrations on a national basis, and include, either explicitly or implicitly, numerous assumptions needed while excluding the important area-specific issues and factors outlined above.

The most thoroughly documented calculations are those provided in Cupitt (1994), an EPA white paper developed as an initial scoping analysis of the issues, in preparation for potential consideration in the Regulatory Impact Analysis (RIA) that would accompany the O_3 NAAQS regulatory package. This paper discusses many of the important factors and uncertainties outlined above, summarizes key background information to provide perspective, and includes a discussion and table summarizing the many simplifying assumptions that were needed to permit the development of quantitative estimates. Cupitt's analysis evaluates changes resulting from cumulative exposures under two scenarios, including one that compares estimates of NMSC incidence associated with an assumed reduction of daytime summer O_3 of 10 ppb that would occur uniformly throughout 30 eastern States and the District of Columbia and within an assumed atmospheric mixing layer that ranged up to 2 km in altitude. Assuming no other relevant factors changed over the several decade exposure period that would be required, the resulting increase in NMSC incidence for this extreme scenario was estimated eventually to reach ''between 0.6% and 1%.'' While these percentages are small—indeed too small to be measurable (Cupitt, 1994)—if taken at face value, they would not necessarily be judged as trivial because of the large baseline of NMSC. For reasons outlined below, however, even these small percentage estimates appear to be substantially overstated and cannot be considered reliable.

The Cupitt paper was never formally published, but it was subjected to internal agency peer review and commentary by experts at EPA's Office of Research and Development (ORD) (Childs, 1994; Altshuller, 1994). While finding the exposition, including recognition of the difficulties in such an approach, to be ''very acceptable,'' the reviewers noted substantial uncertainties in basic data and expressed concerns about the numerous simplifying assumptions that called the numerical results into significant question. Examples of data uncertainties noted by the reviewers include: (1) The accuracy of column O_3 (in Dobson units) and UV measurements used; (2) the fact, recognized in Cupitt (1994), that the predicted UV–B radiation flux changes are at the ''noise'' level and could not be reliably detected statistically or attributed to the change in ground-level O_3 concentration; (3) data on effects of aerosols are limited, yet ignoring such effects in estimating the O_3—UV–B radiation relationship was ''erroneous;'' and (4) data to permit dynamic assessment of the feedback between increased UV radiation and increased O_3 is limited to uncertain models, and this potential feedback mechanism was ignored in the analysis (Childs, 1994).

Reviewers also questioned a number of the simplifying assumptions that could have ''substantial impact'' on the resulting risk estimates. Among these were: (1) The assumed mixing height of 2 km, which reviewers considered too high on average, especially for the eastern United States—by overstating the thickness of the pollution-related layer of the atmosphere that is the focus of the control strategies designed to attain the NAAQS, this factor would bias the estimates upwards by as much as a factor of 2; (2) the assumption that the O_3 mixing ratio is the same at the earth's surface as it is at 2 km, when the vertical profile varies through the diurnal cycle—because vertical mixing increases through the day, this assumption would be most important in the earlier portion of daylight hours; (3) the assumption that neither aerosols nor O_3 production cycles themselves exert either positive or negative feedback on UV–B penetration—as noted in the previous section, a dynamic consideration of these factors could change the direction of the result in particular areas; (4) the assumption that NMSC might result from episodic exposures, when, in fact, NMSC results from cumulative doses—this assumption affects only separate and far smaller estimates Cupitt made for episodic changes, essentially invalidating those results; (5) the assumption that all people would be susceptible to NMSC based on assumed exposure factors; and (6) the assumption that behavioral patterns, demographic patterns, and meteorological factors and other factors related to actual exposures remain constant over time (Childs, 1994; Altschuller, 1994).

These reviewers capsulized their conclusions regarding the quantitative results of this analysis as follows:

In summary, (1) the numbers resulting from these calculations are quite small, and (2) the limitations of the accuracy and reliability of the input to the calculations produces numbers that cannot be defended, whether large or small. (Childs, 1994).

As noted in the discussion above, this is not simply a matter of uncertain and small risk estimates. On balance, several of the problems noted above served to inflate the overall estimates, and, depending upon local conditions and the implementation strategy assumed, could even call the direction of the results into question for some locations. Further, a significant bias, not highlighted in the cited reviews, is how well the assumed 10 ppb change in daytime O_3 levels averaged over an entire summer season (and over half the U.S.) reflects what might occur in response to the revised O_3 NAAQS.[57] In fact, this assumed change, as well as the assumptions regarding its spatial and vertical extent, are significantly larger than could reasonably be expected based on the revisions to the O_3 standard promulgated in 1997.

To provide a fair comparison, it is necessary to convert the 1-hour standard into its nearest 8-hour equivalent. As documented in the Staff Paper (U.S. EPA, 1996b), the nearest equivalent 8-hour standard would have a level of about 0.09 ppm. Superficially, this might appear to support a 10 ppb difference compared to the 0.08 ppm 8-hour standard set in 1997. The appropriateness of this comparison fades, however, when one considers that these standards are stated in reference to extreme high values in the distribution (*e.g.*, the average of the 4th-highest daily maximum concentrations). Cupitt's analysis assumed that a ''mixing layer'' up to 2 km deep over a very large geographical region would experience a change of 10 ppb in daylight average O_3 for an entire O_3 season. This scenario would require a challenging regional strategy that would, on average, reduce each day for the over 150 day O_3 season by 10 ppb. Yet, the 0.08 ppm 8-hour O3 standard would require that only the fourth-highest day of the O_3 season be reduced by about 10 ppb, as compared to the previous standard. Based on available O_3 trends information, strategies that reduce peak O_3 days would have far less effect on the far more numerous days toward the middle and lower-parts of the O_3 season distribution (*e.g.*, U.S. EPA, 1996a, Figures 4–2, 4–3). In fact, as reported in the Response to Comments document, based on earlier RIA projections of long-term O_3 reductions that might occur as a result of efforts to meet the 0.08 ppm 8-hour O_3 standard, the magnitude of the assumed average change appears to be overstated by more than a factor of 3 (U.S. EPA, 1997). When considered with the excessively high assumed mixing layer, the overly large geographical area requiring reductions (over 30 States), and the assumption that the entire population would be at the same risk as the more sensitive subpopulations, it is EPA's judgment, based on the record, that these readily identified biases could well be on the order of a factor of 10.

More subtle are the uncertainties and potential bias inherent in an essentially static comparison of two different O_3 values that are assumed to be uniform over a very large area. Dynamic, real-world implementation strategies would involve a number of alternative local and regional scale approaches that vary significantly in time and space, with a variety of possible outcomes with respect to the middle and lower portions of the O_3 distribution that are most relevant to estimating long-term summer averages over a period of decades into the future. An example of such local strategy-dependent outcomes would be control of NO_X emissions across a metropolitan area, which could reduce O_3 concentrations at downwind peak monitors, but also result in localized increases in lower concentrations in the center city area (National Academy of Sciences, 1991, Figure 11–2). As noted in section II.B.2 above and in Altshuller (1994), the interrelated indirect results from reduced O_3 and UV–B radiation could trigger feedbacks through increased O_3, aerosol, or cloud cover that could partially or fully offset the initial O_3 effects on UV–B radiation. Available data and assessment tools do not permit a reasonable quantitative assessment of these second- and third-order indirect effects (Altshuller, 1994; Childs, 1994).

Other potential problems associated with ignoring area-specific considerations in an O_3/UV–B risk analysis summarized in the previous section include: (1) The assessment of local physical factors (*e.g.*, buildings) that reduce UV–B radiation exposure in outdoor microenvironments, (2) meteorological conditions (*e.g.*, sea breeze) or local emissions patterns that reduce pollution in high UV–B radiation exposure microenvironments, (3) behavioral adjustments to information concerning UV–B radiation risk over time, and (4) local differences in the proportion of sensitive populations. Even Cupitt's assumption that 90 percent of exposure occurs during the summer O_3 season embeds an additional assumption about long-term personal behavior for which little empirical evidence exists.

In the proposed response, EPA solicited comment on the above discussion of the key assumptions used in the Cupitt analysis (66 FR 57285). None of the commenters disagreed with any specific aspect of EPA's evaluation of these assumptions as outlined in the proposed response, nor did any commenter disagree with EPA's judgement that the assumptions described above could introduce biases on the order of a factor of 10 to Cupitt's estimates of changes in UV–B radiation-related effects resulting from changes in ground-level O_3 projected to occur upon attainment of a more stringent O_3 NAAQS.

In summary, EPA continues to believe that the Cupitt (1994) white paper was useful for its intended purpose as a scoping analysis to identify the potential issues arising in any attempt to assess the potential shielding provided by changes in ground-level O_3. It established that any effects of even fairly large, long-term O_3 reductions in ground-level O_3 would be quite small, but as evidenced in the comments of the peer review and the discussion above, available data and modeling tools fall far short of permitting reliable quantitative risk estimates for consideration in standard setting or benefits assessments.

The analysis of this issue by U.S. Department of Energy (DOE) staff (1995) is summarized in a statement submitted as a part of public comments at a CASAC meeting. The exposition is far less complete than that of Cupitt, and it is quite difficult to reconcile the range of estimates for possible increased occurrences of NMSC, the lower bound of which are less than Cupitt, while the upper bound estimates are more than double his. The analysis apparently starts with the same assumptions regarding a constant change in summertime O_3 of 10 ppb through a 2 km mixing layer, but important information about the other assumptions is lacking. In any event, the paper does not appear to improve upon the methodology in the Cupitt analysis.[58] Given that the DOE

[57] Cupitt provides no rationale for the selection for this value where it first appears in a Table, which is characterized as addressing ''questions from OMB.''

[58] In addition to estimates for NMSC, the DOE statements also provided estimates for melanoma skin cancers and cataracts. As discussed above, the quantitative relationship between cumulative UV–B exposure and the latter effects are not as well established as for NMSC. Given the lack of documentation and the additional uncertainties over those for NMSC, neither the DOE estimates of

Continued

statement must share the limitations outlined above for Cupitt and the fact that the analytical approach is neither well documented nor peer reviewed, no reliance is placed on the quantitative results presented in the DOE submission.

The work of economic analysts Lutter and Wolz (1997) provides a self-described ''preliminary analysis'' of UV–B radiation screening by tropospheric O_3. Here, the exposition permits a more direct comparison with that of Cupitt, and it appears that many of the same simplifying assumptions were used—either explicitly or implicitly. This paper relied upon Cupitt's assumption that the NAAQS revision might bring about a summertime average of 10 ppb reduction in O_3 in areas not attaining the standard. As discussed above, based on the record, EPA believes this substantially overstates the likely effect of the NAAQS revision. Their assumption of a constant mixing ratio for the 10 ppb change that would extend well above the planetary boundary layer, up to 10 km, also introduces upward bias into their upper-bound risk estimates. The resultant apparent dose appears to be a factor of 4 larger than the upper bound used by Cupitt and DOE staff. The other quantitative inputs to the analysis differed to a more modest degree from those used by Cupitt. In the end, the upper bound estimate of possible increased occurrences of NMSC is more than double that of Cupitt, due largely to the unwarranted assumption of a 10 km mixing height.

Again, because the quantitative assessment shares most of the limitations cited above for Cupitt, and actually adds substantial bias in a key assumption, EPA has appropriately placed no reliance on the quantitative risk estimates for NMSC from Lutter and Wolz (1997) or to the secondary estimates derived in the DOE analyses.

In the proposed response to the remand, EPA solicited comment on its evaluation of the three analyses discussed above (66 FR 57286). No commenter offered specific challenges to any technical aspect of EPA's evaluations of the quantitative analyses by Cupitt (1994), DOE (1995), and Lutter and Wolz (1997), as discussed above. Some commenters, however, expressed the general view, presumably despite the limitations of these analyses, that EPA was not justified in ignoring or discounting such evidence of positive effects, or that such analyses could serve as an upper bound on estimated UV–B radiation-related impacts. In sharp contrast, other commenters expressed the view that these analyses were of questionable reliability and did not achieve minimum standards of scientific adequacy appropriate for information to be used as a basis for NAAQS decisions.

In taking all these comments into account, EPA rejects the notion that it has ignored or completely discounted these analyses. On the contrary, EPA has thoroughly reviewed these analyses by examining the methodologies used, the nature and validity of the underlying assumptions, and the resultant uncertainties inherent in the UV–B radiation-related impacts estimated by these analyses. In so doing, EPA has concluded that (1) the methodologies used in these analyses inherently ignore area-specific factors that are important in estimating the extent to which small, variable changes in ground-level O_3 mediate long-term exposures to UV–B radiation (in contrast to the appropriate application of such methodologies that EPA and others have done in estimating the impact of relatively large changes in the stratospheric O_3 reservoir attributable to emissions of O_3-depleting substances); (2) the studies likely substantially overestimate UV–B radiation-related impacts as a result of the biases introduced by the use of specific underlying assumptions, as discussed above; and (3) as a consequence of the first two conclusions, the analyses are not scientifically adequate to be relied upon as a basis for making NAAQS decisions, and they do not provide credible quantitative estimates of UV–B radiation-related impacts that can appropriately be compared to the quantitative estimates of direct adverse respiratory-related impacts that EPA used in part as a basis for its initial NAAQS decision. The EPA believes that its examination of these analyses and their underlying assumptions, together with its examination of the basic science dealing with the atmospheric distribution of O3 and UV–B radiation (section I.C above) and information on the health effects associated with UV–B radiation and the relationship between ground-level O_3 and UV–B radiation exposure (sections II.B.1 and 2 above), does support the conclusion that UV–B radiation impacts mediated by changes in ground-level O_3 associated with attaining a more stringent O_3 NAAQS are likely very small from a public health perspective.

Beyond the comments submitted on the three analyses discussed above, a few commenters also contended that EPA's proposed response was incomplete because it did not consider another draft analysis by Madronich, referred to as a 1997 ''EPA staff assessment'' of UV–B radiation-related health benefits, that had been submitted by EPA to the Office of Management and Budget (OMB) in conjunction with OMB's review of the draft RIA for the O_3 NAAQS. These comments expressed the view that this draft analysis represented a substantial improvement over the earlier analyses of Cupitt (1994), DOE (1995), and Lutter and Wolz (1997) in its approach to estimating potential increases in NMSC associated with State-specific average changes in O_3 concentrations between baseline levels (*i.e.*, ground-level O_3 concentrations current at the time of the analysis) and full attainment of the 1996 proposed O_3 NAAQS. These commenters assert that EPA should now consider the results of this draft analysis, or the results of a new analysis that incorporates further refinements and extensions to the methodology and scope of the Madronich analysis, in its response.

In considering this comment, EPA first notes that the Madronich analysis submitted with the comments has not been appropriately characterized in the comments. The Madronich analysis is not an ''EPA staff assessment,'' but rather it is a draft analysis prepared by a consultant at the request of EPA, to help inform EPA's preparation of the RIA. This draft analysis was not completed, published, or peer reviewed. Moreover, it was judged not to provide an adequate basis for quantifying potential UV–B radiation-related impacts as part of EPA's final RIA, a document that historically includes quantitative estimates of a more speculative nature than those thought to be adequate to consider as a basis for setting a NAAQS. In fact, the final RIA for the 1997 O_3 NAAQS, which was reviewed by other Federal agencies and approved for release by OMB, concluded that the available scientific and technical information, which included the Madronich draft analysis, would not permit reliable quantitative estimates of any potential impact of the more stringent O_3 NAAQS on UV–B radiation-related effects.[59] In summary, the Madronich draft analysis does not represent the type of peer-reviewed

such effects nor the uncritical reliance on them by Lutter and Wolz (1997) should be given quantitative credence.

[59] The EPA also notes that this draft analysis was appropriately not part of the rulemaking record upon which EPA is basing its response. The fact that OMB staff placed this draft analysis in OMB's docket, which includes information related to OMB's review of the RIA, in no way implies that the draft analysis was or should have been part of EPA's rulemaking record.

information that is appropriately relied upon as a basis for NAAQS rulemaking.

Although, for the reasons discussed above, EPA has not relied on the Madronich draft analysis in reaching this final response, the Agency nevertheless has conducted a provisional examination of this draft analysis to assess whether the results of the analysis call into question or are consistent with the conclusions reached in the proposed response. In this draft analysis, Madronich estimates the increases in NMSC that would result from changes in ground-level O_3 from 1997 baseline values to full attainment of the 1996 proposed O_3 NAAQS (*i.e.*, a standard set at 0.08 ppm O_3 with a form based on the 3-year average of the annual third-highest daily maximum 8-hour average concentrations). As an initial matter, and as recognized by some commenters, this draft analysis is based on an inappropriate comparison—then-current air quality versus attainment of the proposed NAAQS. The relevant comparison is between full attainment of the 1979 1-hour 0.12 ppm O_3 standard and full attainment of the 1997 final 8-hour O_3 NAAQS (with a somewhat less stringent form based on the fourth-highest daily maximum 8-hour average concentrations). Thus, the analysis by its design substantially overestimates the relevant projected decreases in O_3 levels likely to result from revising the 1979 O_3 standard (since baseline levels in some areas are substantially above levels that would attain the 1979 1-hour standard), and thus, substantially overestimates projected UV–B radiation-related impacts.

Looking beyond this initial matter, EPA notes that this analysis is based on estimated statewide average changes in O_3 concentrations. Thus, like the three other analyses discussed above, this draft analysis incorporates none of the area-specific factors, discussed in section II.B.2.b above, that EPA considers to be important in developing credible estimates of UV–B radiation-related impacts mediated by the localized and highly variable changes in ground-level O_3 likely to result from attainment of a more stringent O_3 NAAQS. The EPA does not dispute that the draft analysis uses assumptions and models that may well be appropriate for developing credible estimates of UV–B radiation-related impacts mediated by large-scale regional and relatively uniform changes in stratospheric O_3 likely to result from emissions of O_3-depleting substances.[60] But, EPA also recognizes and has fully explained (above in section II.B.2) the important differences in the factors that are central to analyses of UV–B radiation-related impacts that are mediated by changes in stratospheric O_3 versus ground-level O_3—differences that this analysis, and the commenters, simply ignore.

Apart from these area-specific methodological issues, EPA has also provisionally looked at the quantitative estimates of State-by-State annual incidences of NMSC that result from the Madronich draft analysis, yielding a nationwide aggregate estimate of an additional 696 NMSC cases annually, with over half of this estimate coming from the State of California alone.[61] Using the California estimate as an example, EPA has considered the potential impact of various assumptions used in the analysis on the estimated incidences. First, as discussed above, the use of a current baseline comparison would likely substantially overestimate incidences in California in particular, in light of the significant extent to which many areas in California continue to exceed the 1979 1-hour standard. That is, it is likely that decreases in ground-level O_3 from baseline levels to levels that would attain the 1979 1-hour standard would be greater, perhaps much greater, than the additional decreases needed to reach attainment of the 1997 8-hour standard. This bias would also likely affect estimates from other States that contribute a high proportion of the national incidence estimate and that have areas that exceed the 1-hour standard by a significant margin, including, for example, New Jersey, Georgia, and Texas, which together account for approximately 20 percent of the national estimate.

Second, as in the Cupitt analysis, the Madronich analysis assumes that the entire population would be equally susceptible to NMSC based on assumed exposure factors. This assumption would also lead to substantial overestimation of effects, however, based on demographic data from the 2001 Statistical Abstract of the United States and information on sensitive populations (discussed above in section II.B.1).[62]

Third, as noted above, the Madronich draft analysis assumes that attainment of a more stringent O_3 standard will decrease O_3 concentrations and increase UV–B radiation flux equally throughout the State, without taking into account the highly variable and localized patterns of changes in ground-level O_3 likely to result from attainment of the O_3 NAAQS, nor does it take into account the variable exposure patterns of people as they move through various microenvironments and exhibit varying degrees of sun-seeking and sun-avoidance behaviors. However, attainment of a more stringent O_3 standard will not reduce O_3 concentrations equally everywhere, and may not reduce O_3 concentrations at all in locations where people receive their highest exposure to UV–B radiation. As noted above in section II.B.2.b, in the heavily populated Los Angeles area, ground-level O_3 is at its lowest levels thus providing the least shielding along the coast, where the potential for exposure to UV–B radiation is the highest, and it is unlikely that programs designed to bring Los Angeles into attainment with a more stringent standard will result in any significant reductions in coastal O_3 levels. In this regard, some commenters also note that the analysis may also underestimate incidences since the analysis assumes that the entire population of a State will experience changes in O_3 concentrations, and presumably resultant changes in UV–B radiation-related impacts, that reflect a statewide average, thus potentially underestimating changes to the large segments of the population that live in urban areas that would likely experience larger than average changes in ground-level O_3 concentrations. However, given the variable and localized patterns of changes in ground-level O_3 that have been monitored in urban areas, including in some cases significantly lower concentrations in inner cities and higher concentrations in downwind suburban areas, it is not clear the extent to which ignoring such area-specific factors would bias resulting estimates for any given urban area either low or high. These considerations serve to demonstrate the

[60] The EPA notes that the draft analysis estimates changes in radiation levels using a radiative transfer model that has been previously used in a number of O_3 scientific studies and WMO/UNEP international assessments of stratospheric O_3 depletion, and NMSC incidences using information from epidemiologic studies and from studies of action spectrum for induction of skin cancer in mice. The draft analysis assumes national incidence rates of 500,000 BCC cases per year and 100,000 SCC cases per year for the baseline scenario.

[61] Only point estimates are presented in the analysis; no quantitative estimates or even qualitative discussion of the uncertainties in these estimates are presented.

[62] According to the 2000 Census (U.S. Census Bureau, 2001), approximately 47 percent of the population of California is designated as ''white alone.'' While not all ''white'' people are susceptible to skin cancer, this proportion is probably a better estimate of the fairer members of all races and ethnic groups in California that would be more susceptible to NMSC than the entire population.

importance of conducting area-specific assessments, as EPA did in evaluating the adverse respiratory-related impacts likely to result from attaining a more stringent O_3 standard.

Finally, one comment also notes that the Madronich draft analysis considers NMSC, but not other UV–B radiation-related effects, and that EPA should extend this quantitative analysis to estimate incidences of such other effects. The EPA believes that quantitative risk estimates to be used as a basis for NAAQS decision making should not be made based on back-of-the-envelope type approaches, as offered in the comment. Consistent with this view, EPA refrained from developing quantitative risk estimates for a range of adverse respiratory-related effects when it judged that information needed to make credible quantitative estimates was not available.[63] To do otherwise with regard to potential beneficial effects would be to apply a lower information standard than was used to assess adverse effects, which EPA declines to do, consistent with the direction from the Court in its remand to apply the ''same approach,'' including the same (neither higher nor lower) ''information threshold'' to either type of information.

Although the biases and uncertainties outlined above can not be reliably quantified, EPA believes that it is reasonable to presume that any increase in nationwide annual incidences of NMSC associated with attaining a more stringent O_3 standard would likely be substantially smaller than estimated by the draft Madronich analysis. Assuming that it's even as much as one-third of that estimated by Madronich, the EPA judges that a nationwide NMSC incidence rate of this approximate magnitude would be very small from a public health perspective, representing an increase of roughly 0.03 percent in the national baseline incidence rate assumed by Madronich.[64] As to other UV–B radiation-related effects, the Madronich draft analysis provides no basis for the development of credible quantitative estimates of such effects. Having chosen not to rely upon simple ratios to develop quantitative estimates of the ''pyramid of effects'' related to the estimated number of hospital admissions of asthmatics that EPA did quantify in its risk assessment,[65] EPA declines to use any lower information standard, as suggested by a few commenters, in its evaluation of potential beneficial effects.

In summary, EPA has conducted a provisional examination of the Madronich draft analysis, considering the underlying assumptions and methodology as well as the quantitative results and likely uncertainties and biases in the results. Based on this provisional examination, EPA does not believe that this analysis calls into question, but rather is generally consistent with the conclusions reached in its proposed response: That information is not available at this time that will allow for credible quantitative estimates of potential UV–B radiation-related impacts of attaining a more stringent O_3 standard, and that associated changes in UV–B radiation exposures of concern, using plausible but highly uncertain assumptions would likely be very small from a public health perspective.

C. Consideration of Net Adverse Health Effects of Ground-level O_3

In considering the net adverse health effects of ground-level O_3, EPA has focused on characterizing and weighing the comparative importance of the potential indirect beneficial health effects associated with the attenuation of UV–B radiation by ground-level O_3 (section II.B above) and the direct adverse health effects associated with breathing O_3 in the ambient air (section II.A above). The same key factors considered by EPA in its 1997 review of the O_3 standard, and in the proposed response, are again considered here in characterizing the information on potential beneficial effects in the record of the 1997 review and in comments received on the proposed response, and in comparatively weighing this information relative to the direct adverse effects. Beyond quantitative assessments of exposure and risk that were central to EPA's 1997 review, these factors include the nature and severity of the effects, the types of available evidence, the size and nature of the sensitive populations at risk, and the kind and degree of uncertainties in the evidence and assessments. Because of the complexity and multidimensional nature of such a comparison, and because many of the effects, both adverse and beneficial, could not be characterized in terms of quantitative risk estimates, EPA has made no attempt to characterize all the relevant effects or associated risks to public health with a common metric.[66]

The available record information on the potential indirect beneficial health effects associated with ground-level O_3 includes information from studies of health effects caused by exposure to UV–B radiation and studies that focus on the consequences of unnaturally high exposures to UV–B radiation due to depletion of the stratospheric O_3 layer, as well as analyses that attempt to focus specifically on the consequences of assumed changes in tropospheric O_3 levels. The nature and severity of the effects of UV–B radiation exposure on the skin, eye, and immune system are discussed above (section II.B.1), as is the nature of sensitive populations at risk for these effects. These effects, especially on the skin and eye, are generally understood to be associated with long-term cumulative exposure to UV–B radiation and to have long latency periods from cumulative exposures, especially those early in life. People with light skin pigmentation make up the primary at-risk population for effects on the skin, especially for NMSC, while at-risk populations for other effects are not as well understood. For NMSC, uncertainties in the evidence generally

[63] In the 1997 final rule (62 FR 38868), EPA specifically noted that for many O_3 inhalation-related risks to public health, information was too limited to develop quantitative estimates of risk, including: increased nonspecific bronchial responsiveness (related, for example, to aggravation of asthma), decreased pulmonary defense mechanisms (suggestive of increased susceptibility to respiratory infection), and indicators of pulmonary inflammation (related to potential aggravation of chronic bronchitis or long-term damage to the lungs).

[64] This judgment is consistent with the judgment made by EPA with regard to its estimate of the incidence rate of O_3-related hospital admissions of asthmatics in New York City, which was one of many adverse public health effects considered as part of the basis for its 1997 O_3 NAAQS decision. In its 1997 final rule, EPA judged that an annual increase of approximately 40 hospital admissions in New York City alone, representing an increase of about 0.3 percent in total hospital admissions of asthmatics, was ''relatively small from a public health perspective'' (62 FR 38868). An increase in NMSC incidence of roughly 0.03 percent is an order of magnitude lower than the estimated rate of O_3-related hospital admissions of asthmatics, and such hospital admissions would generally represent a more serious health effect than an incidence of NMSC, which can generally be treated in a doctor's office or outpatient facility. The EPA also notes that based on baseline incidence rates reported on the Skin Cancer Foundation Web site, *www.skincancer.org*, submitted by a commenter, this increase in NMSC incidence would be roughly only 0.02 percent.

[65] In its 1997 final rule (62 FR 38868), EPA noted that O_3-related hospital admissions of asthmatics are indicative of a pyramid of much larger numbers of related O_3-induced effects, including respiratory-related hospital admissions among the general population, emergency and outpatient department visits, doctors visits, and asthma attacks and related increased use of medication that are important public health considerations.

[66] A commenter asserted that the Court's direction to consider O_3's net adverse health effect in essence presumes the existence and use of a common metric. The EPA notes that while the Court identified the use of a common metric as one approach that EPA could use, in no way did the Court require EPA to use such an approach, nor does EPA believe that such an approach would provide a more meaningful basis on which to evaluate O_3's net effects.

relate to uncertainties in the relevant action spectra and BAFs, as well as in factors related to characterizing the severity of the different types of NMSC. Based on the record information, for the other effects, the role of UV–B radiation is less well understood (*e.g.,* as to relevant action spectra, BAFs, the nature of exposures of concern), although cumulative exposure to UV–B radiation is thought to play a causal role. These characterizations are derived from the large body of epidemiologic and toxicologic evidence that served as the basis for the reference document by EPA (1987).

The record includes a quantitative assessment conducted by EPA (1987, App. E) of the health risks associated with changes in exposure to UV–B radiation attributable to changes in the stratospheric O_3 layer. This assessment models the relationship between wide-scale changes in global/regional levels of stratospheric O_3, resulting from emissions of O_3 depleting substances with long-atmospheric lifetimes, and changes in UV–B radiation flux as a function of latitude for three broad regions across the United States.[67] As discussed above (section II.B.2), because changes in the stratospheric O_3 layer are relatively uniform across broad regions, varying across the U.S. primarily with latitude, information on localized spatial and temporal patterns of exposure-related variables (*e.g.,* changes in ground-level O_3, meteorological conditions, human activity patterns) are not relevant in producing credible estimates of risk associated with changes in stratospheric O_3. This is in sharp contrast to the nature of the information necessary to produce credible estimates of risk associated with changes in exposures to UV–B radiation projected to result from changes in ground-level O_3 that would be associated with attainment of alternative 8-hour standards for O_3.

An evaluation of the available analyses that have produced estimates of UV–B radiation-related health risks associated with changes in ground-level O_3 and the comments received on them, in section II.B.3 above, identifies major limitations in available information that resulted in the need for the analyses to incorporate broad and unsupportable assumptions. These limitations are particularly important with regard to information on spatial and temporal patterns of changes in ground-level O_3 (across the entire year and extending vertically up through the tropospheric mixing layer) likely to result from various future emission control strategies, relevant meteorological conditions and atmospheric chemistry leading to a cascade of broader indirect effects, and human demographic and activity patterns (*e.g.,* the degree of shading within outdoor microenvironments, and the prevalence of sun-seeking and sun-avoidance behaviors among sensitive groups) likely to affect UV–B radiation-related exposures of concern. For the reasons discussed above, these limitations are judged to be of central importance in any such analysis. Thus, in light of such limitations, and after careful consideration of the comments received, EPA continues to agree with internal and external reviewers, and some commenters, in concluding that the available scientific and technical information would not permit credible quantitative estimates of these potential beneficial effects.[68] Thus, EPA concludes that available analyses based on such limited information cannot serve as credible estimates of potential beneficial effects associated with the presence of ground-level O_3 due to man-made emissions of O_3-forming substances.

Beyond the specific technical comments discussed above in section II.B, several commenters expressed the general view that EPA had inappropriately applied a ''double standard'' in its evaluation of the scientific evidence because it failed to evaluate the protective shielding effects of ground-level O_3 using the same criteria by which it evaluated the adverse respiratory effects. This viewpoint was specifically expressed by one commenter in stating that ''EPA has accepted, often without reservation, scientific evidence purporting to establish the adverse effects of ground-level ozone on respiratory effects. At the same time it has often discounted proffered scientific evidence of the potential benefits of ground-level ozone in screening harmful UV–B radiation.'' (Docket No. A–95–58, VI–C–8, pg. 28) As discussed below, EPA strongly rejects both aspects of this comment. Other commenters expressed the opposite view, finding EPA's approach to be evenhanded in its evaluation of the scientific evidence for potential beneficial and adverse effects, with one commenter noting that EPA ''has never concluded that any allegation or ''evidence'' [of adverse effects], regardless of its preliminary or speculative nature or degree of uncertainty, must be factored into NAAQS decisionmaking.'' (Docket No. A–95–58, VI–C–6, pg. 2)

First, EPA believes that there is ample evidence in the record of the 1997 review of the O_3 NAAQS to invalidate the notion that the Agency uncritically accepts scientific evidence of adverse respiratory effects of ground-level ozone. For example, in considering evidence of adverse respiratory-related effects such as increases in bronchial responsiveness, decrements in alveolar macrophage function, and O_3-induced markers of inflammation and cell damage (as discussed in the 1996 proposed rule, 61 FR 65720–21), EPA judged that there was not sufficient information on dose-response relationships to develop quantitative risk estimates for these acute effects, even in light of the availability of peer-reviewed human exposure studies demonstrating indicators of these effects in humans at quantified exposure levels over quantified time periods (1997 final rule, 62 FR 38868). Similarly, EPA limited the scope of its quantitative risk assessment of acute respiratory-related hospital admissions of asthmatics to just one city (New York City), despite the availability of peer-reviewed studies showing increased admissions in other cities, because it judged that there was not adequate city-specific concentration-response information from epidemiological studies in other cities, that applying the New York City concentration-response information to other cities would introduce too much uncertainty into any such quantitative estimates, or that adequate ambient O_3 monitoring data were not available for other study areas to produce credible estimates of this risk for those cities (EPA, 1996b, pp. 111–112). Further, EPA did not rely on quantitative estimates of other adverse effects that have been related to hospital admissions of asthmatics in published documents submitted by commenters on the 1996 proposed rule (*e.g.,* the ''pyramid of effects'' including hospital admissions among the general population, visits to emergency departments and doctors'

[67] Since the EPA's 1987 risk assessment on stratospheric ozone depletion, numerous changes have been made to the model to reflect the commitments made since 1987 by the United States, under amendments to the Montreal Protocol, for reductions in production of various ozone depleting chemicals and to incorporate more accurately the latest scientific information.

[68] This conclusion was also reached by the Health and Ecological Effects Subcommittee of the Advisory Council on Clean Air Compliance Analysis, a part of EPA's Science Advisory Board, in conjunction with their review of ''The Benefits and Costs of the Clean Air Act 1990 to 2010'' (EPA, 1999b), noting that the relevant information ''was very weak and more information is required'' (EPA, 1999a). As one commenter noted, this SAB Council has more recently recommended that in EPA's next periodic prospective analysis of the Act, the Agency's analysis address this issue (Advisory Council for Clean Air Compliance Analysis, 2001).

offices, and increased asthma attacks and use of medication), due to the substantial uncertainties inherent in such ratio-of-effects-based approaches to quantifying risk. Finally, with regard to chronic effects, EPA declined to rely on available evidence, or develop quantitative estimates, of the risk of chronic O_3 respiratory-related morbidity or mortality effects in its 1997 final rule, judging that the evidence was too limited or uncertain, despite arguments by commenters on the 1996 proposed rule that such available, peer-reviewed evidence should be used as a basis for setting a lower 8-hour O_3 standard than the 0.08 ppm standard set by EPA in that rulemaking.

Second, far from discounting proffered scientific evidence of the potential ground-level ozone in screening harmful UV–B radiation, EPA has fully considered all the record evidence on the beneficial shielding effects of ground-level O_3, as well as information received in public comments, as discussed in section II.B above. Moreover, EPA has taken the additional step of provisionally considering the unpublished, Madronich draft analysis (section II.B.3), as submitted by commenters and characterized by them as an improvement over other analyses in the record. Having provisionally considered this analysis, for the reasons discussed above in section II.B, EPA has found that this analysis does not call into question the Agency's conclusions with regard to the lack of credibility of such available analyses or the likelihood that any such beneficial UV–B radiation-related effects are likely very small from a public health perspective. The fact that EPA does not agree with commenters' opinions on these issues does not in any way demonstrate that EPA has simply discounted their proffered evidence of the potential beneficial screening effects of ground-level O_3.

Therefore, EPA rejects the view of some commenters that it applied a double standard in reaching its conclusions about potential UV–B radiation-related effects that may result from a more stringent O_3 NAAQS. In fact, EPA believes that were it to rely upon the available evidence of UV–B radiation-related effects to conclude otherwise, as urged by these commenters, that it then would be applying the very type of double standard that these commenters argue against. If EPA were to have relied upon quantitative risk estimates from draft or preliminary analyses that did not utilize appropriate methods or information to take into account relevant area-specific factors, and that had not been peer-reviewed, it would then be inappropriately applying a double standard in comparing any such UV–B radiation-related risk estimates to the adverse respiratory-related risks estimated in peer-reviewed analyses that were appropriately designed and limited by the availability of credible information and assessment methods.

In setting aside the available quantitative risk analyses, EPA notes that our above evaluation of a number of critical factors in the analyses provides reasons for believing that the public health impacts of any potential beneficial effects associated with ground-level O_3 are likely very small, albeit unquantifiable at this time (sections II.B.2–3). In giving qualitative consideration to the available evidence on potential indirect beneficial effects of ground-level O_3, EPA believes it is appropriate to weigh this information in the context of the body of evidence on adverse effects caused by direct inhalation exposures to ground-level O_3 that formed the basis for the 1997 O_3 primary standard.

As an initial matter, as discussed in the 1997 final rule, the Administrator focused primarily on quantitative comparisons of risk, exposure, and air quality in selecting both the level (62 FR 38867–8) and form (62 FR 38869–72) of the 1997 O_3 primary standard. More specifically, she looked at comparisons of both those risks to public health that can be explicitly quantified in terms of estimated incidences and the size of the at-risk population (*e.g.,* children) likely to experience adverse effects, as well as those for which quantitative risk information is more limited, but for which quantitative estimates of the number of children likely to experience exposures of concern could be developed (as discussed in section II.A.2 above). In considering these comparisons, she recognized that although there were inherent uncertainties in these estimates, the underlying assessments took into account extensive data bases on the spatial and temporal patterns of air quality and directly relevant human activity patterns likely to result in inhalation exposures of concern. Further, the Administrator recognized that the assessment methods were appropriate and state-of-the-art, and that the results should play a central role in her decision.

Beyond the quantitative information on direct adverse effects, with regard to the qualitative evidence suggestive of potential serious, chronic adverse effects on public health associated with long-term inhalation exposures, EPA judged that such information was too uncertain and not well enough understood at the time to serve as the basis for establishing a more restrictive 8-hour standard in terms of either level (62 FR 38868) or form (62 FR 38871). In so doing, EPA understood that further research into potential chronic adverse effects in humans would be continued, and the results considered in the next review (62 FR 38871).

In weighing the available information on potential indirect beneficial effects of ground-level O_3, the EPA considers this information in the same light as the information on potential direct chronic adverse effects associated with long-term inhalation exposures to ground-level O_3. In both instances, the potential health effects are serious and likely to develop over many years, with important periods of exposure likely occurring in childhood. Different population groups are likely affected, however, by these potential adverse and beneficial effects. Urban populations and people with impaired respiratory systems (*e.g.,* people with asthma), who are disproportionately from certain minority groups, are most at-risk for the direct inhalation-related effects, whereas fair-skinned populations are most generally, but not exclusively, at-risk for the indirect beneficial effects related to exposure to UV–B radiation. Although different types of uncertainties are inherent in the record information on these effects, in both cases, the uncertainties related to ground-level O_3 are so great as to preclude the development of credible estimates of the size of the affected population or the probability of the occurrence of such effects.[69] In the case of indirect effects related to ground-level O_3, EPA believes that the use of plausible but unsubstantiated assumptions would likely lead to the conclusion that the potential impacts on public health are likely very small; no such conclusions have yet been drawn with regard to the public health impacts of potential direct chronic adverse effects related to inhalation exposures. After considering these factors and the public comments received, EPA now

[69] Two commenters expressed the view that EPA's analogy of UV–B radiation-related protective effects to chronic respiratory-related adverse effects is flawed because the nature of the uncertainties associated with these two types of effects are different. As discussed more fully in its response to comments (EPA, 2002), EPA explicitly recognizes here that there are different types of uncertainties inherent in the evidence of these effects, but disagrees with the commenter's characterization of these differences and with the view that any such differences in the nature of the uncertainties invalidate the weighing of these types of effects as EPA has done in reaching its conclusions.

concludes that, much like the qualitative evidence on direct adverse effects potentially associated with long-term inhalation exposures, the newly considered available evidence on potential indirect beneficial effects is not well enough understood at this time to serve as the basis for establishing a less restrictive 8-hour standard than was promulgated in 1997. Rather, EPA believes that the most recent evidence and credible analyses of potential long-term, indirect beneficial effects should be considered in the next review in conjunction with the most recent information on long-term, direct adverse effects.

D. Final Response To Remand on the Primary O_3 NAAQS

After carefully considering the scientific information available in the record on adverse effects on public health associated with direct inhalation exposures to O_3 in the ambient air and on the potential for indirect benefits to public health associated with the presence of ground-level O_3 and the resultant attenuation of naturally occurring UV–B radiation from the sun, taking into account the weight of that evidence in assessing the net adverse health effects of ground-level O_3, considering comments received on the proposed response, and for the reasons discussed above, the Administrator is now responding to the remand by reaffirming the 8-hour primary O_3 standard promulgated in 1997. In leaving unchanged the 1997 O_3 standard at this time, the Administrator has fully considered the available information in the record of the 1997 O_3 NAAQS review on potential beneficial health effects of ground-level O_3 using the same approach as for her consideration of the adverse respiratory-related effects, as directed by the Court's remand. Based on such consideration, she has determined that the information linking (a) changes in patterns of ground-level O_3 concentrations likely to occur as a result of programs implemented to attain the 1997 O_3 NAAQS to (b) changes in relevant exposures to UV–B radiation of concern to public health is too uncertain at this time to warrant any relaxation in the level of public health protection previously determined to be requisite to protect against the demonstrated direct adverse respiratory effects of exposure to O_3 in the ambient air.[70] Further, it is the Agency's view that even when using plausible but highly uncertain assumptions about likely changes in patterns of ground-level ozone concentrations, associated changes in UV–B radiation exposures of concern would likely be very small from a public health perspective.

In the past, the Administrator has been confronted with situations where there has been both quantifiable and unquantifiable evidence, and has moved forward with a NAAQS decision. The inability to quantify all related effects does not preclude the Agency from making a NAAQS decision, particularly in situations where there is strong quantifiable evidence of significant adverse health effects. Moreover, in this case, as noted above, EPA believes that while the potential beneficial effects are not quantifiable at this time, they are likely very small from a public health perspective. Accordingly, the Administrator believes it is inappropriate to wait for additional information on such effects prior to responding to this remand.

In determining now that the 0.08 ppm, 8-hour O_3 standard set in 1997 is requisite to protect public health with an adequate margin of safety, the Administrator is finding that such a standard is both necessary and sufficient. Consideration of the potential beneficial effects of ground-level O_3 did not, of course, call into question whether this standard was sufficient to protect against the adverse respiratory-related effects of O_3 addressed in EPA's 1997 final rule. However, it did raise the question as to whether this standard was still necessary to protect against O_3's net effects. Having determined that any potential UV–B radiation-related effects associated with this more stringent standard are likely very small from a public health perspective, and having judged that the evidence of any such effects should be weighed no more heavily in a determination of O_3's net effects than the record evidence on O_3's potential chronic adverse effects, the Administrator has concluded that O_3's net adverse effects necessitate a standard no less stringent than the standard set in EPA's 1997 final rule.[71]

The 0.08 ppm, 8-hour primary standard is met at an ambient air quality monitoring site when the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentration is less than or equal to 0.08 ppm. Data handling conventions are specified in a new appendix I to 40 CFR part 50, as discussed in the 1996 proposal and 1997 final rule.[72]

As discussed previously, the Administrator recognizes that relevant information on indirect potentially beneficial health effects of ground-level O_3 (as well as information on direct adverse health effects of ground-level O_3) is now available that was not part of the 1997 rulemaking record. In that regard, she notes that the next periodic review of the O_3 NAAQS is now well underway, having been formally initiated by EPA's Office of Research and Development with a call for information (65 FR 57810; September 26, 2000). To ensure that the current review of the O_3 criteria and standards now underway can be based on a comprehensive and current body of relevant scientific information, EPA continues to encourage the submission of new scientific information on the relationships between ground-level O_3, associated attenuation of UV–B radiation and other indirect effects of the presence of O_3 in the ambient air, and effects on public health such as those associated with changes in relevant exposures to UV–B radiation.

The EPA's ongoing review and revision of the O_3 Criteria Document is addressing a number of issues related to indirect potentially beneficial health effects of ground-level O_3. In particular, available information on the role of ground-level O_3 in attenuating solar UV–B radiation is being considered. Attention will be focused on the gaps in information, identified above in section II.B.2, that precluded the development of area-specific quantitative assessments of potential beneficial effects of ground-level O_3. For example, the review is considering the available information related to understanding relevant spatial and temporal patterns in changes in ground-level O_3, and associated spatial and temporal patterns in changes in solar UV–B radiation flux. The review will also consider available information on changes in human exposure to solar UV–B radiation as mediated by changes in ground-level O_3, including information related to characterizing how UV–B radiation exposures of sensitive populations may be affected by human activity patterns and variable sun-seeking and sun-avoidance behaviors. In addition, available information on the nature of health

[70] As noted above, the D.C. Circuit has already upheld EPA's determination that the 0.08 ppm 8-hour O_3 NAAQS was requisite to protect against adverse respiratory effects. *See ATA III,* 283 F.3d at 379.

[71] In so doing, EPA is applying the same decision making standard as it applied in its 1997 final rule, based on the plain meaning of the word ''requisite,'' consistent with the U.S. Supreme Court's decision in *Whitman,* 121 S. Ct. at 911–12, 914.

[72] Subsequent to the 1997 final rule, EPA has promulgated further revisions to 40 CFR part 50 with regard to the applicability of the 1-hour O_3 standards (65 FR 45182; July 20, 2000). In addition, EPA notes that recent legislation addresses the timing of future actions on nonattainment designations with regard to the 8-hour O_3 standards (Pub. L. 106–377, 114 Stat. 1441 (2000)).

effects associated with changes in exposure to UV–B radiation mediated by changes in ground-level O_3 concentrations is being considered. As part of the O_3 Criteria Document, this information will be presented to CASAC and the public for review and comment. Based on the revised O_3 Criteria Document, and taking into account CASAC advice and public comments, EPA will consider the extent to which the available information provides an adequate basis for developing credible quantitative estimates of potential beneficial health effects of ground-level O_3. All such relevant information will be considered in EPA's review of the primary O_3 NAAQS.

III. Rationale for Final Response To Remand on the Secondary O_3 Standard

This notice also presents the Administrator's final response to the remand, reaffirming the 8-hour O_3 secondary standard promulgated in 1997, based on:

(1) Information from the 1997 criteria and standards review that served as the basis for the 1997 secondary O_3 standard, including the scientific information on welfare effects associated with direct exposures to O_3 in the ambient air, with a focus on vegetation effects, and assessments of vegetation exposure, risk, and economic values;

(2) A review of the scientific information in the record of the 1997 review (but not considered as part of the basis for the 1997 standard) on the welfare effects associated with changes in UV–B radiation, the association between changes in ground-level O_3 and changes in UV–B radiation, and predictions of changes in ground-level O_3 levels likely to result from attainment of alternative O_3 standards; and

(3) Consideration of the comments received on the proposed response.

A. Direct Adverse Welfare Effects

As discussed in the 1997 final rule, direct exposures to O_3 have been associated quantitatively and qualitatively with a wide range of vegetation effects such as visible foliar injury, growth reductions and yield loss in annual crops, growth reductions in tree seedlings and mature trees, and effects that can have impacts at the forest stand and ecosystem level. Visible foliar injury can represent a direct loss of the intended use of the plant, ranging from reduced yield and/or marketability for some agricultural species to impairment of the aesthetic value of urban ornamental species. On a larger scale, foliar injury is occurring on native vegetation in national parks, forests, and wilderness areas, and may be degrading the aesthetic quality of the natural landscape, a resource important to public welfare. Growth and yield effects of O_3 have been well documented for numerous species, including commodity crops, fruits and vegetables, and seedlings of both coniferous and deciduous tree species. Although data from tree seedling studies could not be extrapolated to quantify responses to O_3 in mature trees, long-term observational studies of mature trees have shown growth reductions in the presence of elevated O_3 concentrations. Even where these growth reductions are not attributed to O_3 alone, it has been reported that O_3 is a significant contributor that potentially exacerbates the effects of other environmental stresses (*e.g.,* pests). In addition, growth reductions can indicate that plant vigor is being compromised such that the plant can no longer compete effectively for essential nutrients, water, light, and space. When many O_3-sensitive individuals make up a population, the whole population may be affected. Changes occurring within sensitive populations, or stands, if they are severe enough, ultimately can change community and ecosystem structure. Structural changes that alter the ecosystem functions of energy flow and nutrient cycling can alter ecosystem succession.

Based on key studies and other biological effects information reported in the Criteria Document and Staff Paper, it was recognized that peak O_3 concentrations equal to or greater than 0.10 ppm can be phytotoxic to a large number of plant species, and can produce acute foliar injury and reduced crop yield and biomass production. In addition, O_3 concentrations within the range of 0.05 to 0.10 ppm have the potential over a longer duration of creating chronic stress on vegetation that can result in reduced plant growth and yield, shifts in competitive advantages in mixed populations, decreased vigor leading to diminished resistance to pest and pathogens, and injury from other environmental stresses. Some sensitive species can experience foliar injury and growth and yield effects even when O_3 concentrations never exceed 0.08 ppm. Further, the available scientific information supports the conclusion that a cumulative seasonal exposure index is more biologically relevant than a single event or mean index.

To put judgments about these vegetation effects into a broader national perspective, the Administrator has taken into account the extent of exposure of O_3-sensitive species, potential risks of adverse effects to such species, and monetized and non-monetized categories of increased vegetation protection associated with reductions in O_3 exposures. In so doing, the Administrator recognized that markedly improved air quality, and thus significant reductions in O_3 exposures would result from attainment of the 0.08 ppm, 8-hour primary standard. In looking further at the incremental protection associated with attainment of a seasonal secondary standard, she recognized that areas that would likely be of most concern for effects on vegetation, as measured by the seasonal exposure index, would also be addressed by the 0.08 ppm, 8-hour primary standard.

B. Potential Indirect Beneficial Welfare Effects

This section is drawn from the limited information in the record of the 1997 review with regard to the effect of ground-level O_3 on the attenuation of UV–B radiation and potential associated welfare benefits.[73] While this information suggests the potential for effects on plants and aquatic organisms, EPA (1987, ES–40—ES–43) recognizes that relevant studies are limited and the uncertainties are great due in part to problems in study designs, such that quantitative conclusions cannot be drawn.

With regard to effects on vegetation, while some plant cultivars tested in the laboratory were determined to be sensitive to UV–B radiation exposure, these experiments have been shown to inadequately replicate effects in the field, such that they do not reflect the complex interactions between plants and their environment. The only long-term field studies of crops involved soybeans, producing suggestive evidence of reduced yields under conditions simulating changes in total column O_3 over an order of magnitude greater than those projected to occur as a result of changes in ground-level O_3 associated with attainment of the 1997 O_3 NAAQS. Beyond the limited studies of crops, EPA (1987, ES–41) notes that little or no data exist on UV–B radiation effects on trees and other types of natural vegetation, or on possible interactions with pathogens. While it is noted that changes in UV–B radiation levels could alter the results of competition in natural ecosystems, no evidence is available to evaluate this

[73] The information in this section is drawn primarily from the EPA document ''Assessing the Risk of Trace Gasses that Can Modify the Stratosphere'' (U.S. EPA, 1987).

effect. Further, it is recognized that UV–B radiation may both inhibit and stimulate plant flowering, depending on the species and growth conditions. Recognizing that interactions between UV–B radiation and other environmental factors are important in determining potential UV–B radiation effects on plants, EPA (1987, ES–42) notes that extensive, long-term studies would be required to address these interactions.

With regard to effects on aquatic organisms, EPA (1987, ES–42) notes that while initial experiments show that increased UV–B radiation has the potential to harm aquatic life, difficulties in experimental designs and the limited scope of the studies prevent the quantification of potential risks. Some study results suggest that most zooplankton show no effect due to increased exposure to UV–B radiation up to some threshold exposure level, with exposures above such threshold levels eliciting notable effects. For species under UV–B stress, such effects could include reduced time spent at the surface of the water, which is critical for breeding in some species, possibly leading to changes in species diversity. It is also noted that, as do all other living organisms, aquatic biota cope with exposure to UV–B radiation by avoidance, shielding, and repair mechanisms, although uncertainty exists as to the extent to which such mitigation mechanisms would occur (U.S. EPA, 1987, ES–43). It is recognized that determination of UV–B radiation exposure in aquatic systems is complex because of the variable attenuation of UV–B radiation in the water column, and that further research is needed to improve our understanding of how UV–B radiation exposure affects marine species, particularly given their world-wide importance as a source of protein.

With regard to EPA's characterization of UV–B radiation-related effects, one commenter noted that there is now more information about the welfare effects of UV–B radiation than there was in the record of the 1997 review,[74] and asserted that this information is sufficient for the Agency to reach ''rough'' quantitative conclusions about some of these effects. The commenter further expressed the view that the relevant information on UV–B radiation-related effects should be evaluated as part of EPA's air quality criteria and be made subject to CASAC review. Moreover, this commenter suggested that EPA's calling the risks ''potential'' effects in the proposed response is inconsistent with its concluding that such effects are ''real'' in the context of stratospheric O_3 depletion.

The EPA agrees that there is now more information on the effects of UV–B radiation on plants, aquatic ecosystems and materials than was available in the 1997 review, and notes that there is also more information available now on the direct adverse effects of O_3 on vegetation and ecosystems. While EPA agrees that relevant information about the welfare effects of ground-level O_3, including both potential UV–B radiation-related beneficial effects and direct adverse effects, should be evaluated as part of updated air quality criteria, EPA believes that all such updated information should be evaluated during the periodic review of the O_3 criteria and standards that is now underway. A fuller discussion of EPA's procedural approach to responding to the remand, especially with regard to incorporating new information in updated air quality criteria and CASAC review, can be found in the introduction to section II above.

Further, EPA strongly disagrees with the commenter's assertion that currently available information on the effects of stratospheric O_3 depletion is sufficient for developing credible quantitative estimates of UV–B radiation-related effects associated with changes in ground-level O_3 likely to result from attainment of a more stringent O_3 NAAQS. While EPA has developed quantitative estimates of the impacts of relatively large and broadly uniform increases in incident UV–B radiation associated with projected changes in the global reservoir of stratospheric O_3, it is not necessarily the case that EPA can now develop credible estimates of impacts associated with the relatively very small and locally variable increases in incident UV–B radiation that may result from future projected changes in ground-level O_3. The EPA believes that this commenter is ignoring both the fundamental differences in the nature and relative magnitude of the temporal and spatial variability of O_3 levels in the stratosphere and ground-level troposphere, and the importance of area-specific assessments for addressing impacts related to changes in ground-level O_3 that take into account relevant factors (as discussed in section II.B above). Area-specific factors that would be important in assessing the potential for UV–B radiation-related consequences of a more stringent O_3 NAAQS on plants, aquatic ecosystems, and materials in any geographical area are the same or analogous to factors that are important in assessing the impacts on human health. Such factors include the temporal and spatial patterns of ground-level O_3 throughout a geographic area where reductions are likely to occur, the associated temporal and spatial patterns in UV–B radiation flux, and the sensitivity and spatial and temporal exposure patterns of plants, aquatic systems and materials to the relatively very small and highly variable changes in UV–B radiation associated with relevant changes in ground-level O_3.

For example, the commenter specifically noted that new information on the effects of stratospheric O_3 depletion finds that solar UV–B radiation can affect marine ecosystems by damaging the early developmental stages of some marine organisms that, in turn, can result in significant reductions in the size of the populations of larger animals that feed on these animals. Thus for marine ecosystems, increased UV–B radiation is most likely to have an effect over specific geographic areas and during specific periods of time in the life cycles of some marine organisms. This geographic and temporal specificity is not important in estimating the impacts associated with changes in stratospheric O_3, given its relative spatial and temporal stability. Such assessments of the effects of long-term declines or restoration can reasonably assume that short-term and local-scale variations in important factors, such as developmental stages of marine organisms, will tend to ''even out'' over time, permitting more confidence in the magnitude and direction of such assessments. In contrast, such geographic and temporal factors would have a major influence in estimating impacts associated with the localized and highly variable changes in ground-level O_3 associated with attaining a more stringent O_3 NAAQS. In particular, as discussed above in section II.B.2, coastal areas tend to have much lower ground-level O_3 levels relative to inland areas, and there is little evidence to indicate that attaining a more stringent O_3 NAAQS would appreciably change O_3 levels, and associated UV–B radiation penetration, at ground-level over marine ecosystems. Further, the seasonality of ground-level O_3 levels, and efforts to reduce ground-level O_3 to attain a more stringent O_3 NAAQS, would be important to take in account in any credible assessment of impacts of changes in ground-level O_3 levels on the seasonal developmental stages of organisms in marine

[74] The commenter specifically cited an EPA Web site pertaining to stratospheric O_3 depletion (*http://www.epa.gov/ozone/science/effects.html*), with information on the effects of UV–B radiation on plant growth, aquatic organisms and materials of commercial interest.

ecosystems. This example illustrates why broad-scale analytic approaches appropriately used to estimate stratospheric O_3 impacts are not appropriate for developing credible estimates of the impacts on public welfare of changes in tropospheric O_3 likely to result from attaining a more stringent O_3 NAAQS. Thus, EPA believes that it is not inconsistent to conclude that such quantifiable effects are ''real'' in relation to large, relatively uniform changes in the stratospheric O_3 reservoir, and to characterize effects that can not be credibly quantified in relation to relatively very small and highly variable changes in tropospheric O_3 associated with attaining a more stringent O_3 NAAQS as ''potential'' effects at this time.

C. Final Response To Remand on the Secondary O_3 NAAQS

After considering the scientific information available in the record on adverse welfare effects associated with direct exposure to O_3 in the ambient air and on the potential indirect benefits to public welfare related to attenuation of naturally occurring UV–B radiation, and the relevant comments received, the Administrator again concludes that there is insufficient information available on UV–B radiation-related effects that may result from attaining the 1997 O_3 NAAQS to warrant any relaxation in the level of public welfare protection previously determined to be requisite to protect against the demonstrated direct adverse effects of exposure to O_3 in the ambient air. Thus, the Administrator responds to the remand by reaffirming the 8-hour secondary O_3 standard promulgated in 1997, which is identical to the 8-hour primary O_3 standard.

In determining now that the 0.08 ppm, 8-hour O_3 standard set in 1997 is requisite to protect public welfare, the Administrator is finding that such a standard is both necessary and sufficient. While consideration of the potential beneficial effects of ground-level O_3 clearly did not call into question whether this standard was sufficient to protect against the direct adverse welfare effects of ground-level O_3 addressed in EPA's 1997 final rule, it did raise the question as to whether this standard was still necessary in light of potential UV–B radiation-related beneficial effects. Having determined that any potential UV–B radiation-related welfare effects associated with attaining the 1997 O_3 standard are too uncertain to be given any appreciable weight in balancing against the demonstrated direct adverse effects of ground-level O_3 on vegetation, for which information was sufficient for both quantitative and qualitative assessments that provided the basis for the 1997 secondary O_3 standard, the Administrator has concluded that the weight of evidence of O_3's adverse effects necessitates a standard no less stringent than the standard set in EPA's 1997 final rule.[75]

As recognized in section II.D with regard to consideration of health effects, the Administrator also recognizes that relevant information on indirect potentially beneficial welfare effects of ground-level O_3 is now available that was not part of this rulemaking record. As previously noted, the next periodic review of the O_3 NAAQS has already been initiated by EPA's ORD and preparation of a revised O_3 Criteria Document that will incorporate such relevant information is now underway. Thus, to ensure that the next review of the O_3 criteria and standards can be based on a comprehensive and current body of relevant scientific information, EPA continues to encourage the submission of new scientific information on the relationships between ground-level O_3, associated attenuation of UV–B radiation and other indirect effects of the presence of O_3 in the ambient air, and effects on public welfare such as those associated with changes in relevant exposures to UV–B radiation.

As noted above in section II.D, EPA's ongoing review and revision of the O_3 Criteria Document is addressing a number of issues related to indirect potentially beneficial health effects of ground-level O_3. In addition to the issues noted above, EPA's review will also consider the available information on the nature of environmental effects associated with changes in solar UV–B radiation mediated by changes in ground-level O_3 concentrations. Based on the revised O_3 Criteria Document, and taking into account CASAC and public comments, EPA also will consider the extent to which the available information provides an adequate basis for developing credible quantitative estimates of potential beneficial environmental effects of ground-level O_3. All such relevant information will be considered in EPA's review of the secondary O_3 NAAQS.

[75] In so doing, EPA is applying the same decision making standard as it applied in its 1997 final rule, as noted above in section II.D on the primary standard, based on the plain meaning of the word ''requisite,'' consistent with the U.S. Supreme Court's decision in *Whitman,* 121 S. Ct. at 911–12, 914.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, the Agency must determine whether a regulatory action is ''significant'' and, therefore, subject to OMB review and the 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.

Pursuant to the terms of Executive Order 12866, it has been determined that this response is a ''significant regulatory action'' because of its important national policy implications. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record and made available for public inspection at EPA's Air Docket Center (Docket No. A–95–58).

Since today's final response to the remand is a reaffirmation of the revisions to the O_3 NAAQS previously promulgated in 1997, no new RIA has been prepared. The RIA (1997) prepared in conjunction with the 1997 revision to the O_3 NAAQS is available in the docket, from EPA at the address under ''Availability of Related Information,'' and in electronic form as discussed above in ''Electronic Availability.''

As a number of judicial decisions have made clear, the economic and technological feasibility of attaining ambient standards are not to be considered in setting NAAQS, although such factors may be considered in the development of State plans to implement the standards. *E.g., Whitman,* 531 U.S. at 471 (2001); *ATA I,* 175 F.3d at 1040–1043. Accordingly, although a RIA was prepared for the 1997 decision to revise the O_3 NAAQS, neither that RIA nor the associated contractor reports have been considered in issuing this final response.

B. Paperwork Reduction Act

This action does not impose an information collection burden under provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* because today's final response to the remand does not establish any new information collection requirements beyond those which are currently required under the Ambient Air Quality Surveillance Regulations in 40 CFR part 58 (OMB #2060–0084, EPA ICR No. 0940.16). Therefore, the requirements of the Paperwork Reduction Act do not apply to today's final action. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

C. Regulatory Flexibility Act

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) Any small business, based on the Small Business Administration's size standards; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. On May 14, 1999, the United States Court of Appeals for the District of Columbia Circuit (''D.C. Circuit'') remanded the O_3 NAAQS to EPA to consider, among other things, any potential beneficial health effects of O_3 pollution in shielding the public from the ''harmful effects of the sun's ultraviolet rays.'' 175 F.3d 1027 (D.C. Cir., 1999). Today's action provides EPA's final response to that aspect of the Court's remand and reaffirms the 1997 primary O_3 NAAQS. Therefore, this rule does not establish any new regulatory requirements affecting small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 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. 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. The provisions of section 205 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 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 noted above, 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. *See, e.g., Whitman,* 531 U.S. at 471; *ATA I,* 175 F.3d at 1040–43. Accordingly, and for the reasons discussed in the 1996 proposal and 1997 final rule, EPA has determined that the provisions of sections 202, 203, and 205 of the UMRA do not apply to this final action. 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. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

Today's final response to the remand does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The final response to the remand only reaffirms the previously promulgated ozone standard and would not alter the relationship that has existed under the Clean Air Act for 30 years, in which EPA sets NAAQS and the States implement them through submission of SIPs, in accordance with the requirements of the Clean Air Act. Thus, Executive Order 13132 does not apply to this action.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

This final response to the remand, which leaves unchanged the 1997 final rule, does not have tribal implications. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), requires Federal agencies to ensure that their policies, programs, activities, and standards identify and assess environmental health and safety risks that may disproportionately affect children. To respond to this order, agencies must explain why the regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency.

This final response is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866. However, today's final response to the remand, reaffirming the 1997 primary O_3 NAAQS, specifically takes into account children as the group most at risk to the direct inhalation-related effects of O_3 exposure, and was based on studies of effects on children's health (U.S. EPA, 1996a; U.S. EPA, 1996b) and assessments of children's exposure and risk (Johnson *et al.,* 1994; Johnson *et al.,* 1996a, b; Whitfield *et al.,* 1996; Richmond, 1997). The 1997 revision to the primary O_3 NAAQS was promulgated to provide adequate protection to the public, especially children, against a wide range of direct O_3-induced health effects, including decreased lung function, primarily in children who are active outdoors; increased respiratory symptoms, primarily in highly sensitive individuals; hospital admissions and emergency room visits for respiratory causes, among children and adults with respiratory disease; inflammation of the lung and possible long-term damage to the lungs. This final response to the remand affirming the 1997 primary O_3 NAAQS maintains the level of protection of children's health established by the standard set in 1997. Therefore, today's final action does comply with the requirements of Executive Order 13045.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This final response to the remand is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This is because this final response to the remand leaves unchanged the 1997 final rule. Thus, Executive Order 13211 does not apply to this rule.

I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 *note*) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. Today's final response to the remand does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2) because it is a reaffirmation of the O_3 NAAQS promulgated in 1997. Nonetheless, EPA will submit a report containing this response and other information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the response in the **Federal Register**. Although this final response is not a major rule, EPA will apply the ''major rule'' restrictions regarding the effective date; thus, the response will be effective 60 days after publication in the **Federal Register**.

V. References

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List of Subjects in 40 CFR Part 50

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

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Christine Todd Whitman,

Administrator.

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