

**Responses to Significant Comments on the
2001 Proposed Response to the Remand of the
National Ambient Air Quality Standards for Ozone**
(November 14, 2001; 66 FR 57268)

Docket Number A-95-58

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List of Acronyms

The following acronyms have been used for the sake of brevity in this document:

Act	Clean Air Act
Agency	U. S. Environmental Protection Agency
CASAC	Clean Air Scientific Advisory Committee
CAA	Clean Air Act
D.C. Circuit	United States Court of Appeals for the District of Columbia Circuit
DOE	U. S. Department of Energy
EPA	U. S. Environmental Protection Agency
NAAQS	National ambient air quality standards
NMSC	Nonmelanoma skin cancer
O ₃	Ozone
OMB	Office of Management and Budget
ORD	Office of Research and Development
UNEP	United Nations Environment Programme
U.S.	United States
UV	Ultraviolet
UV-B	Ultraviolet-B radiation

Frequently Cited Documents

The following documents are frequently cited throughout EPA's response to comments, often by means of the short names listed below:

1996 proposal	National Ambient Air Quality Standards for Ozone; Proposed Rule. 61 FR 65716, December 13, 1996.
1997 final rule	National Ambient Air Quality Standards for Ozone; Final Rule. 62 FR 38856, July 18, 1997.
EPA (1987)	U.S. EPA (1987) Assessing the Risk of Trace Gases That Can Modify the Stratosphere. Volume 1 Executive Summary, Docket A-95-58, IV-D-2694, Appendix B 4.
Proposed response to remand	National Ambient Air Quality Standards for Ozone; Proposed Response to Remand. 66 FR 57268, November 14, 2001.
Final response to remand	National Ambient Air Quality Standards for Ozone; Final Response to Remand; to be published in the <i>Federal Register</i> in October 2002.

Responses to Significant Comments on the 2001 Proposed Response to the Remand of the National Ambient Air Quality Standards (NAAQS) for Ozone

I. INTRODUCTION

This document, together with the preamble to the National Ambient Air Quality Standards for Ozone: Final Response to Remand (“final response to remand”) and several separate documents referred to below, presents the responses of the U.S. Environmental Protection Agency (EPA) to the comments received on the 2001 National Ambient Air Quality Standards for Ozone: Proposed Response to Remand (“proposed response to remand”). All significant issues raised in the public comments have been addressed.

As reflected in the table of contents for this document, responses are organized by subject area. Comments have been grouped into two primary subject areas: (1) comments on legal, policy or procedural topics, and (2) comments on technical topics. This document refers to various support documents, available in the docket, that have assisted in the development of EPA’s final response to the remand. A complete list of references, including these support documents, is presented at the end of this document.

The responses presented in this document are intended to augment the responses to comments that appear in the preamble to the final response to the remand or to address comments not discussed in that preamble. Although portions of the preambles to the proposed and final responses to the remand are paraphrased in this document where useful to add clarity to the responses, the basic rationale for EPA’s response to the remand is contained in the proposed and final responses to the remand.

In compliance with the June 1, 1998 Executive Memorandum on Plain Language in government writing, this document is written using plain language. Thus, the use of “we,” “us,” or “our” in this package refers to EPA. The use of “you” refers to the commenter or reader and may include industry groups, State or local agencies, environmental groups and other interested individuals.

II. RESPONSES TO SIGNIFICANT COMMENTS ON PROPOSED RESPONSE TO REMAND (Category VI-C Comments Received)

A. Comments Received on Legal, Policy or Procedural Topics

Comment 1: The process EPA undertook in responding to the remand was procedurally flawed.

1a: EPA should have reopened the record to consider information more recent than that in the 1997 rulemaking record.

Several commenters argued that EPA should have undertaken a different procedural approach to the remand. In particular, they argued, among other things, that EPA should reopen the record to consider information regarding health effects from UV-B exposure and possible changes to potential UV-B radiation exposure that could occur under different ozone standards that is more recent than what was before the court in the 1997 rulemaking record.

Response: 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 American Trucking Associations v. EPA (“ATA I”), 175 F.3d 1027 (D.C. Cir. 1999), taking into account as well the substantive comments received on the proposed response. This action responds to a remand from the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) and addresses the only remaining issue regarding the setting of the 1997 ozone (O₃) standard.¹ 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. 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 O₃, but also on direct adverse respiratory-related effects of O₃. Taking into account the 5-year periodic review requirements of section 109 of the Act, and noting that this review has 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, which EPA has already initiated. Preparation of a revised O₃ Criteria Document that will incorporate all such relevant information is well underway (65 FR 57810; September 26, 2000).

Moreover, 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

¹ As noted in the proposed response to remand, this action does not address *implementation* of the O₃ NAAQS.

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.²

Finally, the record includes relevant information on indirect potentially beneficial effects of O₃. 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 to the remand, and EPA has fully considered all information provided in the comments.

1b: EPA should have reopened the Criteria Document and Staff Paper and the formal CASAC and public review process.

In addition to arguing that EPA should have obtained new studies and analyses regarding potential UV-B-related health impacts from changes in tropospheric ozone levels that were not in the 1997 rulemaking record, several commenters argued that EPA should have (1) supplemented the air quality criteria with all available studies and analyses, including several analyses that were included in the 1997 record but not considered in setting the standard; (2) consulted with the Clean Air Scientific Advisory Committee (CASAC) and reconfigured the make-up of CASAC to include members with expertise in UV-B related health effects; (3) noticed drafts of the supplemental air quality criteria for public comment; (4) finalized the supplemental air quality criteria; and (5) re-proposed a response to the remand. Some commenters argued that this process was mandated by sections 108, 109 and 117 of the Clean Air Act. One commenter also alleged that EPA violated section 307(d) by not undertaking a more formal CASAC review of the proposed response, especially in light of the discussion on this issue in the earlier CASAC meetings.

Response: As noted above, we are responding to a remand to address the only remaining issue regarding the setting of the 1997 O₃ standard in this action, and not undertaking a new, separate review of air quality criteria and NAAQS under sections 108 and 109. The approach we took in response to the remand was appropriate and lawful for two main reasons – (1) the documents commenters believe necessitated supplementing the Criteria Document and Staff Paper and submitting such supplements to CASAC do not rise to the level of quality generally required for air quality criteria, and (2) we did consult with CASAC and provided its members everything needed to evaluate the proposed response to the remand.

² 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). See Response to Comment 9c for further discussion of the 1997 draft analysis.

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 peer-review and publication 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, EPA judges these draft, unpublished or preliminary analyses to be inappropriate for inclusion in air quality criteria, and concludes that supplementing the 1996 O₃ air quality criteria is not warranted.

In addition, as discussed in more detail in section II.B.2 of the preamble to the final response to remand, EPA also determined that it was not in a position to supplement the air quality criteria by developing its own more extensive area-specific analysis because information essential to the development of such an analysis (e.g., human activity patterns related to potential UV-B radiation exposure) is not available at this time. Importantly, commenters did not challenge either the appropriateness of the factors we set forth as necessary for adequate area-specific assessments, or the importance of conducting area-specific assessments in an analysis. Thus, EPA correctly determined that the documents relied on by commenters, which were not based on this type of information, did not warrant supplementing the Criteria Document or Staff Paper. Finally, because the documents did not warrant supplementing the air quality criteria, there was no supplemental criteria to provide to CASAC.

Moreover, commenters simply are wrong when they state that EPA failed to consult with CASAC, and therefore “violated” sections 108, 109 and 117 of the Act.³ As noted above, this action is in response to the limited remand on the last remaining issue regarding the 1997 O₃ standard; it is not a new, separate review of air quality criteria and NAAQS under sections 108 and 109. EPA appropriately consulted CASAC and provided for its review and comment the proposed response, as well as the key documents from the record upon which the proposed response is based. In two separate letters – one sent in January 2001, ten months before the proposed response was published,

³ Section 117(c) requires that EPA consult with the appropriate advisory committee prior to issuing air quality criteria for an air pollutant under section 108(a)(2) of the Act, which relates to the initial air quality criteria issued for pollutants newly listed under section 108(a)(1). Since the revised O₃ air quality criteria developed as part of the 1997 O₃ NAAQS review were issued under section 108(c), the consultation provision of section 117(c) does not apply in this instance. Moreover, the revised O₃ air quality criteria were reviewed by CASAC under the provisions of section 109(d). In addition, as discussed above, EPA reasonably decided not to supplement the revised O₃ air quality criteria for purposes of this response to the remand, such that no further consultation on the O₃ air quality criteria would be appropriate, even if section 117(c) were to apply.

and the other in January 2002 – we provided the proposed response to CASAC members, along with the key documents, in order to “facilitate [its] review of [the proposed response].”⁴ We provided CASAC everything its members needed to evaluate the proposed response to the remand and invited CASAC comments. Importantly, the CASAC did not recommend that the 1996 O₃ air quality criteria be revised based on the information provided, nor did it express any concern with this procedure or indicate 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, but rather offered a comment of a technical nature.

One commenter also incorrectly stated that EPA violated section 307(d) of the Act by failing to obtain and then respond to CASAC recommendations in the proposed response. As noted above, we did provide a copy of the proposed response and key documents to CASAC ten months before publication. Since CASAC made no recommendations prior to publication, no response to CASAC recommendations was required in the proposed response.⁵

Importantly, 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.

Comment 2: EPA’s process for responding to the remand was appropriate and EPA should conclude its response as expeditiously as possible.

Other commenters agreed with EPA’s approach to responding to the remand. In particular, they argued that it was appropriate for EPA to rely on the rulemaking record that was before the Court in the American Trucking Associations v. EPA (“ATA”), No. 97-1441, litigation as the basis for EPA’s proposed response, and urged 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

⁴ See Letter to Dr. Philip Hopke from Dr. Karen Martin, January 14, 2002; Letter to Dr. Philip Hopke from Dr. Karen Martin, January 22, 2001 (both available in the docket). The 2002 letter was sent to convey the new Administration’s proposed response, which essentially mirrored the package sent in 2001.

⁵ EPA did not “shut down” CASAC from making any recommendations on UV-B, as alleged by commenters. EPA’s statement in a 1995 meeting that CASAC did not have to consider UV-B-related health impacts at that time did not in anyway prevent CASAC from making any recommendations then, or subsequently. CASAC is an independent body and is free to provide advice on subjects it deems appropriate regardless of comments from EPA staff. To the extent CASAC had not considered UV-B effects prior to the decision in ATA I, CASAC was aware of the remand from this Court and could have provided recommendations anytime subsequently; it simply chose not 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 O₃ NAAQS would be at the expense of public health.

Response: EPA agrees with these commenters that the process we undertook in responding to the remand was lawful and met the direction of the Court. It would not be appropriate to reopen the record to consider only new information regarding UV-B, as suggested by other commenters. To consider the “net” impact of an ozone standard, as instructed by the Court in the remand, we would also have had to reopen the record to consider new respiratory impact studies as well. The process of evaluating new information on the net impact of an ozone standard is best reserved for the periodic NAAQS review we initiated in 2000. Our response to the remand was the appropriate method to conclude this NAAQS review, which began 10 years ago.

Comment 3: EPA does not apply, or even acknowledge, the decisional criteria to select a standard that is “not higher or lower than necessary to protect public health.”

As argued by petitioners in American Trucking Associations v. EPA (“ATA III”), 283 F.3d 355 (D.C. Cir. 2002), some commenters argued that EPA's decision on the remand must follow the “new” criteria described in Whitman v. American Trucking Associations (“Whitman”), 531 U.S. 457 (2001) – setting the NAAQS at a level that is “not lower or higher than is necessary.” They argue that EPA merely relied on the same “key factors” (the nature and severity of effects, the types of evidence available, the size and nature of the populations at risk, and the kinds and degrees of uncertainties in the evidence and assessments) that the D.C. Circuit in ATA I held neither require nor provide guidance for defining limits on NAAQS levels. Moreover, when setting the level for a pollutant which may have both adverse and beneficial impacts, these commenters argued that EPA cannot err on the side of a lower standard in order to create an adequate margin of safety. In addition, commenters argue that EPA should pursue the measurement of net public health benefits in a single metric in accordance with the advice of the Court (e.g., “quality adjusted life-years” or “willingness to pay”). Finally, one commenter argued that the Clean Air Act's federalism structure counsels in favor of a less stringent (i.e., higher numerically) NAAQS, in order to allow states the right to decide if they want a more stringent (i.e., lower numerically) NAAQS.

Response: As the Court in ATA III held, Whitman did not set a new standard and EPA properly weighs the appropriate information when setting the NAAQS. We are not required to follow a particular formula, criteria, or “metric” when setting the NAAQS at a level “requisite” to protect the public health and welfare with an adequate margin of safety. As for the argument that the federalism structure of the Act counsels that EPA set a less stringent NAAQS in order to allow States to adopt a more stringent standard if they deem it necessary to protect their population, Congress squarely placed the responsibility to weigh any competing adverse and beneficial health impacts with the EPA, not the states. Moreover, the commenter's argument assumes that EPA set the NAAQS at “a needlessly

stringent” level. For the reasons set forth in the preamble to the final response, we do not believe the information on the potential indirect effect of UV-B radiation warrants changing the levels set to protect the public from the direct adverse respiratory impacts of ground level ozone with an adequate margin of safety, and disagree with commenter’s statements that the NAAQS is “needlessly stringent.”

Comment 4: Proposed response to remand is premature because the D.C. Circuit has not yet decided other issues related to the validity of the 1997 O₃ NAAQS.

Some commenters argued that EPA should not reach a decision on this remand prior to the decision by the D.C. Circuit in the ATA case that was pending at the time commenters submitted their comments. They also argued that EPA should delay responding to the remand on UV-B until it has completed the remand on implementation issues. Moreover, they argued that Congress’s creation of subpart 2 demonstrates a Congressional bias in favor of retaining the 1979 O₃ NAAQS, or at least an 8-hour standard equivalent to the 1-hour 1979 standard.

Response: On March 26, 2002, the D.C. Circuit rendered its opinion in ATA III, finding for EPA on all issues. Thus, the comment on this issue is moot. As for postponing our response to the remand on UV-B until we have completed developing an implementation strategy, EPA disagrees that the Supreme Court’s opinion in Whitman even suggests such an approach. It is EPA’s opinion that resolution of the issues involved in setting the ozone *standard* can and should occur before development of an *implementation strategy* is completed – indeed, stakeholders will need to know what standard must be implemented in order to comment most effectively on an implementation strategy. Moreover, EPA does not believe that resolution of the implementation issues will address whether Congress evidenced a bias for retaining the 1979 1-hour O₃ NAAQS, or its 8-hour equivalent. Issues of implementation address how to implement the NAAQS, not whether the NAAQS are set at the appropriate level. Indeed, Congress’ clear mandate in section 109 to revisit, and when necessary revise, the NAAQS every five years, directly contradicts such a reading of the subpart 2 implementation requirements.

Comment 5: EPA used a “double standard” in developing the proposed response to the remand.

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 O₃ using the same approach as for its evaluation of adverse respiratory effects. These commenters offered various bases for this general viewpoint.

5a: EPA often discounted proffered scientific evidence of potential beneficial effects of ground-level O₃, whereas it has accepted, often without reservation, scientific evidence of adverse respiratory effects.

Response: First, there is ample evidence in the record of the 1997 review of the O₃ 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 O₃-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 O₃ 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’ 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 O₃ 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 O₃ standard than the 0.08 ppm standard set by EPA in that rulemaking.

Second, far from uncritically discounting proffered scientific evidence of the potential for 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 O₃, as well as information received in public comments. Moreover, EPA has taken the additional step of provisionally considering the unpublished, Madronich draft analysis, as submitted by commenters and characterized by them as an improvement over other analyses in the record. The fact that EPA’s detailed evaluation of the proffered evidence led it to conclusions that do not agree with commenters’ opinions about these analyses does not in any way demonstrate that EPA has simply discounted their proffered evidence of the potential beneficial screening effects of ground-level O₃.

5b: EPA made judgments regarding O₃'s potential beneficial effects without consultation with CASAC, whereas it consulted with CASAC on similar judgments regarding O₃'s adverse effects.

Response: EPA rejects this comment since, as discussed above in response to Comment 1b, it has appropriately consulted with CASAC on its judgments regarding O₃'s potential beneficial effects. As noted above, EPA has provided for CASAC review and comment on the proposed response to the remand, as well as on the key documents from the record upon which EPA's proposed response was based.

5c: EPA's analogy of O₃'s UV-B radiation-related protective effects to O₃'s chronic respiratory-related adverse effects is flawed.

Two commenters expressed this view, arguing that the analogy is flawed because the nature of the uncertainties associated with these two types of effects are different.

Response: EPA explicitly recognized that there are different kinds of uncertainties inherent in the evidence of these two types of effects, but in both cases the uncertainties are such that no reliable quantitative assessment of public health impacts associated with alternative O₃ standards could be made. Moreover, in the case of potential UV-B radiation-related effects of ground-level O₃, EPA concluded, based on plausible but highly uncertain assumptions, that any such effects would likely be very small from a public health perspective. On the other hand, no such conclusion has yet been drawn with regard to the public health impacts of potential chronic respiratory-related adverse effects; that is, to the extent that such effects do occur, the public health impacts could be important. Thus, EPA believes it is logical and appropriate to compare its current judgment that the evidence on potential beneficial effects of O₃ 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, with the judgment made at the time that standard was promulgated that the evidence on potential chronic respiratory-related adverse effects was not well enough understood to serve as the basis for establishing a *more restrictive* standard. Thus, EPA 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.

5d: EPA did not weigh transitory effects of sunburn caused by UV-B radiation similarly to the transitory adverse respiratory effects of O₃.

Response: While EPA recognizes that sunburns are caused mainly by the UV-B radiation in sunlight, there is no evidence to suggest that changes in UV-B radiation potentially associated with changes in ground-level O₃ projected to result from attainment of the O₃ NAAQS will lead to an increase in the incidence of sunburns. On the contrary, the 1998 Assessment of the Environmental Effects of Ozone Depletion conducted by the United Nations Environmental Programme (UNEP, 1998; see Health risks chapter, Longstreth et al., 1998) concludes that sunburns will not appreciably increase even with the much more significant increase in UV-B radiation resulting from the thinning of the stratospheric O₃ layer. As discussed in the UNEP assessment, this is due to the powerful adaptation of the skin, which protects the skin from significant seasonal changes in UV-B radiation. The UNEP assessment concludes that by far the most sunburns arise from lack of care in going through the adaptation process,

and that such sunburns will not increase with the significant changes in UV-B radiation associated with ozone depletion. Similarly, there is no reason to project any increase in sunburns would be associated with the much smaller changes in ground-level O₃ projected to result from attainment of the O₃ NAAQS. Since changes in ground-level O₃ have not been linked with increased incidence of sunburn, it is appropriate for EPA not to consider such an effect at all, nor to weigh such an effect against the demonstrated adverse respiratory effects of ground-level O₃.

Comment 6: EPA was evenhanded in its evaluation of the scientific evidence for potential beneficial and adverse effects.

Other comments expressed the view that EPA has never concluded that any evidence of adverse effects, regardless of its preliminary or speculative nature, must be used as a basis for NAAQS decision making.

Response: EPA agrees with this comment, and refers to the response to comment 5a above for examples showing that EPA applied similar judgments to the evidence of adverse effects as to evidence of potential beneficial effects. These examples include ones where EPA declined to quantitatively assess certain evidence of adverse effects, or limited the scope of its assessment, or declined to rely on available evidence (i.e., of the risk of chronic O₃ respiratory-related morbidity or mortality effects), 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 O₃ standard than the 0.08 ppm standard set by EPA in that rulemaking.

Comment 7: EPA did not respond adequately to the remand.

Commenters variously argued that EPA did not adequately respond to the remand because it failed to consider all available evidence of potential beneficial effects in developing its proposed response, it downplayed the evidence of adverse effects associated with UV-B radiation exposure, and it did not discuss the public health significance of UV-B radiation-related effects.

Response: For reasons discussed above in response to comment 1a, 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 ATAI, taking into account as well the substantive comments received on the proposed response. Thus, EPA believes that its response is based on all appropriate evidence.

EPA strongly disagrees that it downplayed the evidence of adverse effects associated with UV-B radiation exposure. EPA's response includes an extended discussion of information on the adverse health effects associated with exposure to UV-B radiation, including effects on the skin, eyes, and immune system. That discussion includes information on the nature of such effects, including the serious nature of some of the effects, the types of available evidence, the relevant sensitive populations, the nature of the UV-B radiation exposures that have been linked to such effects, available quantitative dose-response relationships and relative fatality rates for non-melanoma skin cancer, and important

uncertainties and limitations in the available evidence and analyses. This is the same type of information that EPA has presented in discussing the adverse respiratory-related effects associated with exposure to ground-level O₃.

EPA's response discusses the public health significance of changes in UV-B radiation-related effects associated with changes in ground-level O₃ likely to result from control strategies implemented by States to attain an O₃ NAAQS. For reasons discussed throughout the proposed and final responses, EPA concluded that such public health impacts could not be reliably quantified, and further concluded that based on plausible, but highly uncertain assumptions, such effects would likely be very small from a public health perspective. In addition, in its final response, EPA provisionally considered the draft Madronich analysis, concluding that nationwide estimates of public health impacts would likely be substantially smaller than estimated by that draft analysis and would similarly be very small from a public health perspective. Thus, EPA strongly believes that it has appropriately discussed the public health significance of the relevant potential UV-B radiation-related effects.

Comment 8: EPA failed to determine whether tropospheric ozone has a beneficial effect and failed to determine its net adverse health effect, if any.

Response: The final response makes clear that EPA has determined that any potential UV-B radiation-related effects associated with the O₃ standard set in 1997 are likely very small from a public health perspective. Further, the final notice also makes clear that the EPA has judged that the evidence of any such effects should be weighed no more heavily in a determination of O₃'s net effects than the record evidence on O₃'s potential chronic adverse effects. Thus, EPA has concluded that the information on O₃'s net adverse effects is such that it does not warrant any relaxation of the standard set in EPA's 1997 final rule. These determinations stop short of making any quantitative determinations as to any potential beneficial effects, in light of EPA's conclusion that O₃ potential beneficial can not be reliably quantified. Further, for reasons discussed in the final response and in the response to comment 3 above, EPA has determined that it need not, nor would it be appropriate to produce any quantitative estimate of "net adverse effects" using a single metric.

B. Comments Received on Technical Topics

Comment 9: UV-B radiation-related effects can and should be quantified.

Commenters variously argued that EPA can and should quantify the potential UV-B radiation-related beneficial effects of ground-level O₃ for a number of reasons.

9a: Such effects have already been quantified by EPA in support of its stratospheric O₃ program.

A few commenters note that the methodologies for estimating increases in skin cancer effects associated with UV-B radiation exposures are well established, and could be applied in conducting an analysis of UV-B radiation-related effects for the purposes of EPA's response to the remand. They

further note that EPA's regulatory impact analysis for its stratospheric O₃ program has estimated very substantial benefits, and that these benefits can be simply extrapolated to estimate the benefits associated with changes in ground-level O₃. One commenter asserted that such an extrapolation produces benefits that are greater than those estimated by EPA for its 1997 O₃ NAAQS rulemaking. These commenters further suggest that in concluding that such estimates can not now be developed with sufficient credibility to serve as a basis for setting a less stringent NAAQS, EPA is treating scientific uncertainty differently than it did when regulating substances that deplete stratospheric O₃.

Response: The EPA believes that these commenters are ignoring fundamental differences in the nature and relative magnitude of the temporal and spatial variability of O₃ levels in the stratosphere and at ground-level in the troposphere, as discussed in the proposed and final responses. 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 O₃ 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 O₃ NAAQS.

More specifically, EPA notes that quantitative estimates of public health impacts associated with projected changes in stratospheric O₃ 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 O₃ levels exhibit relatively little variability. These types of epidemiological studies of long-term exposures are not designed to discern impacts associated with much smaller, and much more highly variable, localized changes in ground-level O₃ that will likely result from programs implemented to attain an 8-hour O₃ 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. EPA believes that in choosing not to apply the same type of approach used to assess stratospheric O₃ impacts to its assessment of NAAQS-related changes in ground-level O₃ 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 O₃ impacts. Therefore, EPA rejects the notion advanced by these commenters that the simple application of a stratospheric O₃-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 O₃, 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 O₃.

9b: Such effects could be quantified using the same approach as EPA has used in assessing O₃'s adverse respiratory-related effects.

Some commenters argued that EPA has dealt with uncertainties surrounding spatial and temporal variability of O₃ levels after implementing the O₃ NAAQS and behavioral factors influencing human exposure levels in quantifying the adverse respiratory-related effects of the 1997 O₃ NAAQS. One commenter argued that three limitations (to quantifying risk) identified by EPA in its proposed response are invalid, including: (1) discerning spatial and temporal patterns of changes (e.g., area-specific and microenvironment changes) in ground-level ozone concentrations from a more stringent standard is as important to an assessment of reduced respiratory health risks as to estimates of increased UV-B health hazards; (2) the existence of second-order effects (e.g., relevant meteorological conditions and atmospheric chemistry leading to a broad cascade of indirect effects) does not preclude a quantitative risk assessment because analysts must make simplifying assumptions in any assessment of environmental risks; and (3) uncertainty over human activity patterns does not prevent the quantification of the health benefits of ozone because these uncertainties also apply to assessment of respiratory health effects. Further, this commenter asserted that by not conducting a quantitative assessment of potential beneficial effects, EPA is ignoring its own risk characterization policy.

Response: EPA recognizes that factors that are important in the inhalation exposure and respiratory effects risk assessments are analogous to factors that would be important in conducting area-specific assessments of potential UV-B radiation-related effects. However, EPA notes that while analogous, the factors are not the same for both types of analyses, and believes that these commenters are ignoring the important differences between these sets of factors, as discussed in the proposed and final responses. Although substantial information has been gathered over time regarding factors related to inhalation exposures, no such similar research has as yet been done that would provide comparable information related to dermal exposure factors. As discussed more specifically below, EPA rejects the notion advanced by these commenters that simply because there is sufficient information to conduct area-specific quantitative assessments for inhalation exposures and respiratory risks, there is also sufficient information to conduct exposure and risk assessments of the UV-B radiation-related effects of a more stringent O₃ NAAQS.

First, with regard to spatial and temporal patterns of changes in ground-level O₃, EPA agrees that such patterns are relevant for both types of assessments. However, 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 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 O₃ appropriately focused on the higher portion of the distribution of ground-level O₃ concentrations during the O₃ 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 O₃ 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 O₃ concentrations within the

O₃ season associated with attaining a more stringent O₃ NAAQS, data generally are not 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 O₃ concentration patterns) or for simulating changes beyond the O₃ 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 O₃ associated with programs designed to attain a more stringent O₃ NAAQS.

Second, with regard to second-order factors in the boundary layer and the rest of the troposphere that can affect the amount of UV-B radiation reaching potentially affected populations (which do not come into play in assessing ground-level O₃'s direct respiratory effects), EPA agrees that simplifying assumptions could be made. However, 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 O₃.

Third, with regard to human activity patterns, EPA notes that there is a substantial amount of available information on human activity patterns relevant to respiratory-related exposures, such that EPA's respiratory-related exposure and risk analyses could appropriately incorporate the effects of variable respiratory-related behaviors of people as they move through space and time, and through different microenvironments. More specifically, the human activity pattern database 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 O₃ exposures are likely to result in adverse respiratory effects.⁶ In contrast, the available human activity pattern database 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. Further, while EPA recognizes that databases have recently expanded to include additional human activity information related to outdoor recreation locations, it also notes that the expanded databases

⁶ The EPA recognizes that these databases 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 will be considered appropriately in analyses conducted as part of the periodic review of the O₃ NAAQS that is now underway.

still fall far short of what would be needed to comprehensively project UV-B radiation-related 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. Thus, EPA disagrees with comments asserting that because human activity patterns were taken into account in EPA’s respiratory-related exposure and risk analyses, such factors can be equivalently addressed in any such UV-B radiation-related assessments, 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 O₃.

Finally, EPA disagrees that by declining to conduct a quantitative assessment of potential beneficial effects, we are ignoring our own risk characterization policy (U.S. EPA, 2000). As the commenter noted, that policy, in part, recognizes that “risk characterization should be prepared in a manner that is clear, transparent, reasonable, and consistent with other risk characterizations of similar scope prepared across programs in the Agency.” As discussed above and in response to comment 5a, EPA believes that it has characterized the risks of potential beneficial effects in a manner that is consistent with its approach to characterizing the risks of the adverse effects. To the extent that EPA judged that information was sufficient to permit credible quantitative estimates of exposures of concern or of incidences of specific effects in sensitive populations, EPA included quantitative estimates in its risk characterization. Likewise, to the extent that EPA judged that information was not sufficient to permit credible quantitative estimates of exposures of concern or of incidences of specific effects in sensitive populations, EPA did not include quantitative estimates in its risk characterization, relying instead on qualitative characterization. EPA’s risk characterization policy does not direct that quantitative estimates of risk be prepared without regard to whether there is sufficient information available upon which such quantitative estimates can be credibly based.

9c: Such effects have been quantitatively assessed in a 1997 “EPA staff assessment,” and EPA should consider this assessment or the results of further refinements to this assessment.

Some commenters argued that EPA’s response is incomplete because it neglects an “EPA staff assessment” of UV-B radiation-related benefits that would be lost as a result of the 1997 standard. These commenters expressed the view that this assessment (i.e., a 1997 draft analysis by Madronich) represented a substantial improvement over earlier works by 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 O₃ concentrations between baseline levels (i.e., ground-level O₃ concentrations current at the time of the analysis) and full attainment of the 1996 proposed O₃ standard. One commenter further asserted that there are 3 areas requiring further refinement to the approach taken by Madronich (1997): (1) EPA should revise “current baseline” to be consistent with the baseline in its risk assessment (i.e., full attainment of the 1-hour 0.12 ppm standard), (2) EPA should revise its analysis to use county-specific data on population and ozone concentrations (rather than State-wide

averages), and (3) EPA should also develop quantitative estimates for UV-B related health effects other than non-melanoma skin cancer, including at least the health effects that it was able to quantify in its 1992 analysis of the benefits of stratospheric ozone.

Response: In considering this comment, EPA first notes that the Madronich analysis submitted with these comments has not been appropriately characterized in the comments. The Madronich analysis is not an “EPA staff assessment;” rather, it is a draft analysis prepared by a consultant at the request of EPA, to help inform EPA’s preparation of the Regulatory Impact Analysis (RIA) required by Executive Order 12866. 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 even for purposes of EPA’s final RIA, a document that historically includes quantitative estimates of a more speculative nature than those considered adequate as part of the basis for setting a NAAQS. In fact, the final RIA for the 1997 O₃ 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 O₃ NAAQS on UV-B radiation-related effects.⁷ In summary, the Madronich draft analysis simply does not represent the type of peer-reviewed 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 O₃ from 1997 baseline values to full attainment of the 1996 proposed O₃ NAAQS (i.e., a standard set at 0.08 ppm O₃ 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 O₃ standard and full attainment of the 1997 final 8-hour O₃ 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 O₃ levels likely to result from revising the 1979 O₃ 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.

⁷ 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.

Looking beyond this initial matter, EPA notes that this analysis is based on estimated state-wide average changes in O₃ concentrations. Thus, like the earlier analyses, this draft analysis incorporates none of the area-specific factors, discussed in section II.B.2.b of the final response, 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 O₃ likely to result from attainment of a more stringent O₃ 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 O₃ likely to result from emissions of O₃-depleting substances.⁸ But, EPA also recognizes, and has fully explained in section II.B.2 of the final response, the important differences in the factors that are central to analyses of UV-B radiation-related impacts that are mediated by changes in stratospheric O₃ versus ground-level O₃ – 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 nation-wide aggregate estimate of an additional 696 NMSC cases annually, with over half of this estimate coming from the state of California alone.⁹ 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 O₃ 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

⁸ 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 scientific studies and international assessments of stratospheric O₃ depletion conducted by the World Meteorological Organization and the United Nations Environmental Programme (WMO, 1998; UNEP, 1998), 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 basal cell carcinoma cases per year and 100,000 squamous cell carcinoma cases per year for the baseline scenario.

⁹ Only point estimates are presented in the analysis; no quantitative estimates or even qualitative discussion of the uncertainties in these estimates are presented.

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 in section II.B.1 of the final response.¹⁰

Third, as noted above, the Madronich draft analysis assumes that attainment of a more stringent O₃ standard will decrease O₃ 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 O₃ likely to result from attainment of the O₃ 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 O₃ standard will not reduce O₃ concentrations equally everywhere, and may not reduce O₃ concentrations at all in locations where people receive their highest exposure to UV-B radiation. As noted in section II.B.2.b of the final response, in the heavily populated Los Angeles area, ground-level O₃ 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 O₃ 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 O₃ concentrations, and presumably resultant changes in UV-B radiation-related impacts, that reflect a state-wide 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 O₃ concentrations. However, given the variable and localized patterns of changes in ground-level O₃ 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 importance of conducting area-specific assessments, as EPA did in evaluating the adverse respiratory-related impacts likely to result from attaining a more stringent O₃ standard.

Finally, one commenter 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 decisionmaking 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

¹⁰ 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.

make credible quantitative estimates was not available.¹¹ 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 O₃ 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.¹² 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

¹¹ In the 1997 final rule (62 FR 38868), EPA specifically noted that for many O₃ 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).

¹² This judgment is consistent with the judgment made by EPA with regard to its estimate of the incidence rate of O₃-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 O₃ 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 O₃-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. EPA also notes that based on baseline incidence rates reported on the Skin Cancer Foundation website, www.skincancer.org, submitted by a commenter, this increase in NMSC incidence would be roughly only 0.02 percent.

of asthmatics that EPA did quantify in its risk assessment,¹³ 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 O₃ 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.

9d: EPA's decision as to whether to quantify such effects should take into account the high value that such information might provide.

One commenter asserted that a decision about whether to quantify such effects is best considered not simply in terms of credibility, as EPA has done, but in terms of the value of the information such quantification might provide. The commenter expresses the view that the value of quantitative information about potential UV-B radiation-related O₃ benefits is high because a standard intended to protect public health, but set without due regard to the lost health benefits from lower O₃ concentrations, could fail to achieve its purpose.

Response: For reasons discussed in the final notice, EPA believes not only that any potential beneficial effects of O₃ pollution in shielding the public from solar UV-B radiation can not be credibly quantified, but also, using plausible but highly uncertain assumptions, that any such effects would likely be very small from a public health perspective. Further, as discussed in the response to comment 9c, the view that any potential beneficial effects would likely be very small is supported by EPA's provisional consideration of the results of a draft quantitative analysis submitted by this commenter. Thus, EPA does not agree with this commenter that there is necessarily a high value to developing quantitative estimates of such effects. In addition, EPA does not agree that even if there were likely to be a high value in having quantitative estimates of such effects, it would then be appropriate to attempt to develop such estimates without a due regard for the adequacy or quality of the information. EPA believes that information quality considerations are not appropriately disregarded. Whether the information might be valuable to a decision making process depends in large part on such information quality considerations. EPA did not disregard the adequacy or quality of the available quantitative

¹³ In its 1997 final rule (62 FR 38868), EPA noted that O₃-related hospital admissions of asthmatics are indicative of a pyramid of much larger numbers of related O₃-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.

information on various types of adverse respiratory-related effects of O₃ in deciding not to develop quantitative estimates for certain types of such adverse effects (as noted above in response to comment 5a); neither does EPA believe it would be appropriate to disregard the adequacy or quality of the available quantitative information on potential beneficial effects.

9e: The Advisory Council on Clean Air Compliance Analysis (ACCACA) recommended that EPA’s analysis of the costs and benefits of the Clean Air Act address the potential beneficial effects of tropospheric ozone.

Response: In the EPA’s first prospective analysis of the costs and benefits of the CAA, 1990 - 2010 (1999 Report to Congress, U.S. EPA, 1999a), the ACCACA of EPA’s Science Advisory Board (SAB) had little to say regarding quantification of UV-B radiation-related benefits of ground-level O₃. However, as referred to in the proposed response to the remand, in the minutes of a meeting of the Health and Ecosystem Effects Subcommittee of the ACCACA, there was a record that “there was no consensus on an issue raised by one discussant for the Agency to discuss potential risk-risk trade-offs associated with increased UV-b radiation due to lower tropospheric ozone, but it was stated that the information was very weak and more information is required.” (U.S. EPA, 1999b). In the most recent review of EPA’s draft analytical plan for the second prospective analysis of the costs and benefits of the CAA, 1990 - 2020, the ACCACA did comment that as a result of the ATA litigation, “the Council recommends that the Agency’s analysis address the issue of the potential beneficial effects of tropospheric ozone in reducing ultraviolet-B (UV-B) exposure” (U.S. EPA, 2001) It should be noted that the ACCACA offers its recommendations in the context of Section 812 of the CAA, which proscribes the use of a default assumption of zero value to any benefits unless supported by specific data in any case where numerical values are assigned to such benefits. The ACCACA has interpreted this as a broad mandate to attempt to quantify benefits when at all possible. This mandate contrasts sharply with EPA’s careful approach to quantifying exposure and risk in conjunction with our review of the NAAQS under sections 108 and 109 of the CAA, which has not been interpreted by EPA or the Court as requiring quantification of effects when available information does not support credible estimates. Thus, EPA does not consider the ACCACA’s advice in conjunction with analyses conducted under section 812 of the CAA as being necessarily applicable to our approach to analyses conducted in support of our review of the NAAQS.

Comment 10: EPA’s conclusion that UV-B radiation-related effects are likely very small is inappropriate, based on comparisons of beneficial and adverse effects of ground-level O₃.

One commenter asserts that beneficial effects of ground-level O₃ equal or outweigh the adverse inhalation-related effects, based on his “back-of-the-envelope” calculations using estimates in Madronich (1997) and DOE (1995). The commenter also asserts that a heuristic comparison of the generally temporary and reversible respiratory effects with the relatively persistent UV-B radiation-related health benefits that would be lost as the result of a more stringent standard illustrates the problem with EPA’s assertion that UV-B related health benefits are “very small.” The commenter

further notes that with the exception of ozone-related hospital admissions, the respiratory benefits of ozone reductions that EPA used to justify the 1997 standard were too small for EPA to quantify in its 1999 Report to Congress.

Response: As discussed above in response to comment 9c and in the final response to the remand, EPA does not agree that the type of “back-of-the-envelope” calculations suggested by this commenter are credible. On the contrary, we have discussed at length the reasons why the Madronich (1997) and DOE (1995) estimates do not provide a basis for making credible estimates, and why, in provisionally considering the Madronich draft analysis in light of alternative plausible assumptions, the quantitative estimates are quite small relative to just the estimates of hospital admissions associated with O₃'s adverse respiratory related effects. Further, in reaching the conclusion that beneficial effects of O₃ equal or outweigh the adverse respiratory-related effects, the commenter inappropriately compares nationwide beneficial effects estimates with adverse effects estimates developed for just 9 cities, or in the case of hospital admissions, for just 1 city. Such comparisons are clearly inappropriate and do not support the commenter's conclusion.

With regard to the commenter's “heuristic” comparison, the commenter distorts the characterizations of both the adverse effects and the potential beneficial effects. For example, the commenter characterizes all the adverse effects, which include not only respiratory symptoms and transient lung function decrements but also hospital admissions for asthmatics (and a related pyramid of effects that include increased emergency room visits and medication use) and potential chronic effects such as structural damage to lung tissue and an accelerated decline NAAQS baseline lung function, as being “generally temporary and reversible.” On the other hand, the commenter characterizes the potential beneficial effects, including nonmelanoma skin cancer, as being “relatively persistent.” Neither of these characterizations are adequate or appropriate given the broad range of demonstrated and potential effects, and they grossly oversimplify any such heuristic comparison.

With regard to the commenter's reference to EPA's quantification of the public health benefits associated with implementation of the 1997 O₃ NAAQS in its 1999 Report to Congress, the commenter confuses the issue of quantifying benefits in *monetary* terms with the quantification of benefits in terms of *non-monetary public health indicators*. While those effects for which EPA developed monetized estimates of O₃-related benefits (i.e., hospital admissions, gains in productivity for outdoor workers) are limited by available data and methods, EPA also quantified in non-monetary terms very significant public health benefits. For example, the 1999 Report to Congress included public health benefits (associated with the implementation of the 1997 O₃ and particulate matter standards) in terms of millions fewer occurrences of respiratory symptoms and minor restricted activity days and hundreds of thousands fewer asthma attacks. In addition, other respiratory-related O₃ benefits are qualitatively characterized. Thus, this comment mischaracterizes and significantly downplays the overall public health respiratory-related benefits associated with the implementation of the 1997 O₃ NAAQS.

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