

“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 O₃ 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 O₃ standard, including the scientific information on health effects associated with direct inhalation exposures to O₃ 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 O₃ and potential changes in UV-B radiation, and predictions of changes in ground-level O₃ levels likely to result from attainment of alternative O₃ standards (section II.B below);

(3) Consideration of the net adverse effects of ground-level O₃, 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 O₃ (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 O₃ 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 O₃ 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 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 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 O₃ 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 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.

(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 O₃ NAAQS.

¹⁸ As noted earlier, this action does not address implementation of the O₃ 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).