



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

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EPA-CASAC-07-001

Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Clean Air Scientific Advisory Committee's (CASAC) Peer Review of the Agency's 2nd Draft Ozone Staff Paper

Dear Administrator Johnson:

EPA is in the process of reviewing the national ambient air quality standards (NAAQS) for ozone (O₃) and related photochemical oxidants, which the Agency most recently revised in July 1997. As part of its ongoing review of the ozone NAAQS, EPA's Office of Air Quality Planning and Standards (OAQPS) developed a 2nd Draft Ozone Staff Paper, entitled, *Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information* (July 2006). At the request of the Agency, EPA's Clean Air Scientific Advisory Committee (CASAC or Committee), supplemented by subject-matter-expert panelists — collectively referred to as the CASAC Ozone Review Panel (Ozone Panel) — met in a public meeting in Durham, NC, on August 24-25, 2006, to conduct a peer review of this draft Ozone Staff Paper and three related draft technical support documents.

In its summary of EPA staff conclusions on the primary (health-related) ozone NAAQS found in Chapter 6 of the 2nd Draft Ozone Staff Paper, OAQPS set-forth two options with regard to revising the level and the form of the standard: (1) retain the current primary eight-hour (8-hr) NAAQS of 0.08 parts per million (ppm); or (2) consider a reduction in the level of the primary O₃ NAAQS within the range of alternative 8-hr standards included in Staff's exposure and risk assessments (which included a range from 0.064 to 0.084 ppm) with primary focus on an O₃ level of 0.07 ppm with a range of forms from third- through fifth-highest daily maximum. The Ozone Panel unanimously concludes that:

1. There is no scientific justification for retaining the current primary 8-hr NAAQS of 0.08 parts per million (ppm), and

2. The primary 8-hr NAAQS needs to be substantially reduced to protect human health, particularly in sensitive subpopulations.

Therefore, *the CASAC unanimously recommends a range of 0.060 to 0.070 ppm for the primary ozone NAAQS*. With regard to the secondary (welfare-related) ozone NAAQS, *the Ozone Panel is in strong agreement with the scientific and technical evidence presented in the summary of EPA staff conclusions on the secondary ozone NAAQS found in Chapter 8 of the draft Staff Paper in support of the alternative secondary standard of cumulative form that extends over an entire growing season*.

The Ozone Panel members agree that this letter adequately represents their views. The chartered Clean Air Scientific Advisory Committee fully endorses the Panel's letter and hereby forwards it to you as the Committee's consensus report on this subject. A discussion of each chapter in the 2nd Draft Ozone Staff Paper follows this letter, and the comments of individual Panel members on the 2nd Draft Ozone Staff Paper and three related draft technical support documents are attached as Appendix D.

1. Background

Section 109(d)(1) of the CAA requires that the Agency periodically review and revise, as appropriate, the air quality criteria and the NAAQS for the "criteria" air pollutants, including ambient ozone. Pursuant to sections 108 and 109 of the Act, EPA is in the process of reviewing the ozone NAAQS. OAQPS, within the Office of Air and Radiation (OAR), developed the 2nd Draft Ozone Staff Paper as part of this activity. In February 2006, the Agency's National Center for Environmental Assessment, Research Triangle Park, NC (NCEA-RTP), within the Agency's Office of Research and Development (ORD), released its final *Air Quality Criteria for Ozone and Related Photochemical Oxidants, Volumes I, II, and III*, (EPA/600/R-05/004aF-cF, Final Ozone Air Quality Criteria Document) for this current review cycle for the ozone NAAQS. The 2nd Draft Ozone Staff Paper evaluates the policy implications of the key scientific and technical information contained in the Final Ozone AQCD and identifies critical elements that the Agency believes should be considered in its review of the ozone NAAQS. The Ozone Staff Paper is intended to "bridge the gap" between the scientific review contained in the Ozone AQCD and the public health and welfare policy judgments required of the EPA Administrator in reviewing the ozone NAAQS.

The Ozone Panel met in a public meeting on December 8, 2005 to conduct a consultation on EPA's 1st Draft Ozone Staff Paper and two related technical support documents. However, given that the OAQPS' first draft Staff Paper did not contain Agency staff conclusions about whether to retain or revise the existing primary and secondary Ozone standards, the CASAC's activity only amounted to a technical assessment of that document. The Committee's letter to you from that meeting (EPA-CASAC-CON-06-003), dated February 16, 2006, is posted at URL: http://www.epa.gov/sab/pdf/casac_con_06_003.pdf.

2. CASAC Ozone Review Panel's Peer Review of the 2nd Draft Ozone Staff Paper and Related Technical Support Documents

The Ozone Panel reviewed the 2nd Draft Ozone Staff Paper and found it improved over the earlier version that had been reviewed as part of a consultation process. *However, the Panel did not agree with the EPA staff conclusions that it was appropriate to consider retaining the current NAAQS as an option that would be protective of public health and welfare.* The Ozone Panel's recommendations for reducing the level of the primary ozone standard, and its rationale for these recommendations, are provided immediately below. Following a detailed discussion on the primary and secondary NAAQS are the Panel's major, chapter-specific comments. Finally, the individual written comments of Ozone Panel members on the 2nd Draft Ozone Staff Paper and the three related draft technical support documents are attached in Appendix D. Panelists' responses to the Agency's charge questions are included in these individual review comments.

Primary Ozone NAAQS

New evidence supports and build-upon key, health-related conclusions drawn in the 1997 Ozone NAAQS review. Indeed, in the 2nd Draft Ozone Staff Paper, EPA staff themselves arrived at this same conclusion:

"Based on the above considerations and findings from the [Final Ozone AQCD], while being mindful of important remaining uncertainties, staff concludes that the newly available information generally reinforces our judgments about causal relationships between O₃ exposure and respiratory effects observed in the last review and broadens the evidence of O₃-related associations to include additional respiratory-related endpoints, newly identified cardiovascular-related health endpoints, and mortality. Newly available evidence also has identified increased susceptibility in people with asthma. While recognizing that important uncertainties and research questions remain, we also conclude that progress has been made since the last review in advancing our understanding of potential mechanisms by which ambient O₃, alone and in combination with other pollutants, is causally linked to a range of respiratory- and cardiovascular-related health endpoints." (Pages 6-6 and 6-7)

Several new single-city studies and large multi-city studies designed specifically to examine the effects of ozone and other pollutants on both morbidity and mortality have provided more evidence for adverse health effects at concentrations lower than the current standard. (See the numerous ozone epidemiological single-city studies shown in Figure 3-4 on page 3-53 of the 2nd Draft Staff Paper and, in addition, Appendix 3B of the staff paper, which contains the summary of effect estimates and air quality data for these studies and multi-city epidemiological studies.) These studies are backed-up by evidence from controlled human exposure studies that also suggest that the current primary ozone NAAQS is not adequate to protect human health (Adams, 2002; McDonnell, 1996).

Furthermore, we have evidence from recently reported controlled clinical studies of healthy adult human volunteers exposed for 6.6 hours to 0.08, 0.06, or 0.04 ppm ozone, or to filtered air alone during moderate exercise (Adams, 2006). Statistically-significant decrements in lung function were observed at the 0.08 ppm exposure level. Importantly, adverse lung function effects were also observed in some individuals at 0.06 ppm (Adams, 2006). *These*

results indicate that the current ozone standard of 0.08 ppm is not sufficiently health-protective with an adequate margin of safety. It should be noted these findings were observed in healthy volunteers; similar studies in sensitive groups such as asthmatics have yet to be conducted. However, people with asthma, and particularly children, have been found to be more sensitive and to experience larger decrements in lung function in response to ozone exposures than would healthy volunteers (Mortimer *et al.*, 2002).

Going beyond spirometric decrements, adverse health effects due to low-concentration exposure to ambient ozone (that is, below the current primary 8-hour NAAQS) found in the broad range of epidemiologic and controlled exposure studies cited above include: an increase in school absenteeism; increases in respiratory hospital emergency department visits among asthmatics and patients with other respiratory diseases; an increase in hospitalizations for respiratory illnesses; an increase in symptoms associated with adverse health effects, including chest tightness and medication usage; and an increase in mortality (non-accidental, cardiorespiratory deaths) reported at exposure levels well below the current standard. *The CASAC considers each of these findings to be an important indicator of adverse health effects.* As demonstrated in Chapter 5 of the 2nd Draft Ozone Staff Paper (specifically, Figures 5.5, 5.7, 5.8, and 5.9), a significant decrease in adverse effects due to ozone exposures can be achieved by lowering the exposure concentrations below the current standard, which is effectively 0.084 ppm. Beneficial effects in terms of reduction of adverse health effects were calculated to occur at the lowest concentration considered (*i.e.*, 0.064 ppm). (See also Figure 3-4, "Effect estimates (with 95% confidence intervals) for associations between short-term ozone exposure and respiratory health outcomes," on page 3-53.)

The justification provided in the 2nd Draft Ozone Staff Paper for retaining the current level of the primary ozone standard as an option for the Administrator was based on results of controlled human exposure studies measuring modest declines in FEV₁ after exposures to 0.08 ppm ozone. However, as stated in the Staff Paper (page 3-6), while average decrements in the FEV₁ were relatively small, 26% of the subjects had greater than 10% decrements, which can be clinically significant. Also, while measures of FEV₁ are quantitative and readily obtainable in humans, they are not the only measures — and perhaps not the most sensitive measures — of the adverse health effects induced by ozone exposure. As stated on page 6-32 of the Final Ozone AQCD, "Spirometric responses to ozone are independent from inflammatory responses and markers of epithelial injury (Balmes *et al.*, 1996; Bloomberg *et al.*, 1999; Hazucha *et al.*, 1996; Torres *et al.*, 1997). Significant inflammatory responses to ozone exposures that did not elicit significant spirometric responses have been reported (Holz *et al.*, 2005; McBride *et al.*, 1994)." Agency staff's analyses placed most emphasis on spirometric evidence and not enough emphasis on serious morbidity (*e.g.*, hospital admissions) and mortality observed in epidemiology studies (see page 6-44).

Therefore, on the basis of the large amount of recent data evaluating adverse health effects at levels at and below the current NAAQS for ozone, it is the unanimous opinion of the CASAC that the current primary ozone NAAQS is not adequate to protect human health. Furthermore, the Ozone Panel is in complete agreement both that: the EPA staff conclusion in Section 6.3.6 arguing that "consideration could be given to retaining the current 8-hr ozone standard" is not supported by the relevant scientific data; and that the current primary 8-hr

standard of 0.08 ppm needs to be substantially reduced to be protective of human health, particularly in sensitive subpopulations.

Additionally, we note that the understanding of the associated science has progressed to the point that *there is no longer significant scientific uncertainty regarding the CASAC's conclusion that the current 8-hr primary NAAQS must be lowered.* A large body of data clearly demonstrates adverse human health effects at the current level of the 8-hr primary ozone standard. Retaining this standard would continue to put large numbers of individuals at risk for respiratory effects and/or significant impact on quality of life including asthma exacerbations, emergency room visits, hospital admissions and mortality. (Scientific uncertainty does exist with regard to the lower level of ozone exposure that would be fully-protective of human health. The Ozone Panel concludes that it is possible that there is no threshold for an ozone-induced impact on human health and that some adverse events may occur at policy-relevant background.)

Moreover, EPA staff concluded that changes in the concentration-based form of the standard (*i.e.*, whether to use the third-, fourth-, or fifth-highest daily maximum 8-hr average concentration) should also be considered. The analysis found in the 2nd Draft Ozone Staff Paper indicates that modest changes in the form of the standard can have substantial impacts on the frequency of adverse health effects. Therefore, the CASAC recommends that the Agency conduct a broader evaluation of alternative concentration-based forms of the primary 8-hr ozone standard and the implications of those alternative forms on public-health protection and stability (*i.e.*, with respect to yearly variability to ensure a stable target for control programs).

The CASAC further recommends that the ozone NAAQS should reflect the capability of current monitoring technology, which allows accurate measurement of ozone concentrations with a precision of parts per *billion*, or equivalently to the third decimal place on the parts-per-million scale. In addition, given that setting a level of the ozone standard to only two decimal places inherently reflects upward or downward "rounding," *e.g.*, 0.07 ppm includes actual measurements from 0.0651 ppm to 0.0749 ppm, the CASAC chooses to express its recommended level, immediately below, to the third decimal place.

Accordingly, the CASAC unanimously recommends that the current primary ozone NAAQS be revised and that the level that should be considered for the revised standard be from 0.060 to 0.070 ppm, with a range of concentration-based forms from the third- to the fifth-highest daily maximum 8-hr average concentration. While data exist that adverse health effects may occur at levels lower than 0.060 ppm, these data are less certain and achievable gains in protecting human health can be accomplished through lowering the ozone NAAQS to a level between 0.060 and 0.070 ppm.

Secondary Ozone NAAQS

An important difference between the effects of acute exposures to ozone on human health and the effects of ozone exposures on welfare is that vegetation effects are more dependent on the *cumulative* exposure to, and uptake of, ozone over the course of the entire growing season (defined to be a minimum of at least three months). *Therefore, there is a clear need for a*

secondary standard which is distinctly different from the primary standard in averaging time, level and form. Developing a biologically-relevant ozone air quality index would be directly responsive to the 2004 National Research Council (NRC) recommendations on Air Quality Management in the United States (NAS, 1994) and will help support important new Agency initiatives to enhance ecosystem-related program tracking and accountability.

In its 1996 review of the ozone NAAQS, EPA staff proposed several cumulative seasonal ozone exposure indices, including SUM06, the concentration-weighted metric (*i.e.*, the seasonal sum of all hourly average concentrations > 0.06 ppm), and W126, the integrated exposure index with a sigmoidal weighting function, as candidates for a secondary standard. The Administrator considered a three-month, 12-hr SUM06 secondary standard at a level of 25 ppm-hr as an appropriate, biologically-relevant secondary standard, but ultimately rejected this option in favor of simply setting the secondary standard equal to the primary. It was rationalized that efforts to attain the new 8-hr primary standard would also eliminate most adverse effects on vegetation, and at that time there were uncertainties in how cumulative seasonal exposures would change with efforts to reduce peak 8-hour concentrations. Additionally, it was assumed that future ozone/vegetation effects research over the coming years would clarify the very uncertain quantitative relationships between ozone exposures and vegetation/ecological responses under ambient field conditions.

Unfortunately, however, the Agency has supported very little new vegetation/ecological ozone effects research over the past decade. The net result is that the quantitative evidence linking specific ozone concentrations to specific vegetation/ecological effects must continue to be characterized as having high uncertainties due to the lack of data for verification of those relationships. It is not surprising that substantial research needs remain, as indicated both in Chapter 8 and in individual reviewer comments. The quantitative evidence linking specific ozone concentrations to specific vegetation effects — especially at the complex ecosystem level — must continue to be characterized as having high uncertainties due to the lack of data for verification of those relationships. To a large extent, this is an unavoidable consequence of the inherent complexities of ecosystem structure and function, interactions among biotic and abiotic stressors and stimuli, variability among species and genotype, detoxification and compensatory mechanisms, *etc.* Nevertheless, the compelling weight of evidence provided in Chapter 7 of the 2nd Draft Ozone Staff Paper results from the convergence of results from many various and disparate assessment methods including chamber and free air exposure, crop yield and tree seedling biomass experimental studies, foliar injury data from biomonitoring plots, and modeled mature tree growth.

Despite limited recent research, it has become clear since the last review that adverse effects on a wide range of vegetation including visible foliar injury are to be expected and have been observed in areas that are below the level of the current 8-hour primary and secondary ozone standards. Such effects are observed in areas with seasonal 12-hr SUM06 levels below 25 ppm-hr (the lower end of the range of a SUM06 secondary standard suggested in the 1996 review and the upper end of the range suggested in Chapter 8 of the 2nd Draft Ozone Staff Paper). Seasonal SUM06 (or equivalent W126) ranges well below 25 ppm-hr were recommended for protecting various managed and unmanaged crops and tree seedlings in the 1997 workshop on secondary ozone standards (Heck and Cowling, 1997). The absence of clear-

cut lower effects thresholds for sensitive vegetation combined with the lower recent estimates of policy-relevant background (typical range of 0.015 to 0.035 ppm) emphasizes the importance of efforts to reduce low- to mid-range environmental exposures below 0.060 ppm.

Based on the Ozone Panel's review of Chapters 7 and 8, *the CASAC unanimously agrees that it is not appropriate to try to protect vegetation from the substantial, known or anticipated, direct and/or indirect, adverse effects of ambient ozone by continuing to promulgate identical primary and secondary standards for ozone. Moreover, the members of the Committee and a substantial majority of the Ozone Panel agrees with EPA staff conclusions and encourages the Administrator to establish an alternative cumulative secondary standard for ozone and related photochemical oxidants that is distinctly different in averaging time, form and level from the currently existing or potentially revised 8-hour primary standard.* The suggested approach to the secondary standard is a cumulative seasonal growing standard such as the indices SUM06 or W126 aggregated over at least the three summer months exhibiting the highest cumulative ozone levels and includes the ozone exposures from at least 12 daylight hours. The CASAC suggests a range of 10 to 20 ppm-hours for the three-month growing season SUM06 index for agricultural crops rather than the 15-25 ppm-hours proposed in Chapter 8.

However, the Ozone Panel views the three-month growing season W126 index as a potentially more biologically-relevant index than the 3-month growing season SUM06 index. This is because the W126 index has no absolute minimum ozone concentration threshold and only lightly weights the lower ozone concentrations. Therefore, a three-month seasonal W126 that is the approximate equivalent of the SUM06 at 10 to 20 ppm-hr is preferred. As shown by the references cited at the end of Chapter 8, the consensus view among expert persons in the ecological communities of both this country and elsewhere around the world is that *a secondary standard of cumulative form and extending over an entire growing season will be far more effective than a secondary standard that is not cumulative in form and does not include the whole growing season.*

In conclusion, the Clean Air Scientific Advisory Committee is pleased to provide its scientific advice and recommendations to the Agency on the primary and secondary ozone NAAQS. We recognize that our recommendation of lowering of the current primary ozone standard would likely result in a large portion of the U.S. being in non-attainment. *Nevertheless, we take very seriously the statutory mandate in the Clean Air Act not only for the Administrator to establish, but also for the CASAC to recommend to the Administrator, a primary standard that provides for an "adequate margin of safety ... requisite to protect the public health."*

Finally, as announced during the Ozone Panel's August meeting, once the Agency releases the Final Ozone Staff Paper in early January 2007, the CASAC intends to hold a public teleconference in late January or early February 2007 for the members of the Ozone Panel to review — and, prospectively, to offer additional, unsolicited advice to the Agency concerning — Chapter 6 (Staff Conclusions on Primary O₃ NAAQS) and Chapter 8 (Staff Conclusions on Secondary O₃ NAAQS) in that final Agency document. The purpose of such advice would be to

inform EPA's efforts as it develops the forthcoming, proposed rule for ozone and related photochemical oxidants. As always, the CASAC wishes EPA well in this important endeavor.

Sincerely,

/Signed/

Dr. Rogene Henderson, Chair
Clean Air Scientific Advisory Committee

Appendix A – Clean Air Scientific Advisory Committee Roster (FY 2006)

Appendix B – CASAC Ozone Review Panel Roster

Appendix C – Charge to the CASAC Ozone Review Panel

Appendix D – Review Comments from Individual CASAC Ozone Review Panel Members