

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR SCIENCE ADVISORY BOARD

March 26, 2007

EPA-CASAC-07-002

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) Review of the Agency's Final Ozone Staff Paper

Dear Administrator Johnson:

The Clean Air Scientific Advisory Committee (CASAC or Committee), augmented by subject-matter-expert Panelists — collectively referred to as the CASAC Ozone Review Panel (Ozone Panel) — completed its review of the Agency's 2nd Draft Ozone Staff Paper in October 2006 (EPA-CASAC-07-001). In that letter, dated October 24, 2006, the CASAC indicated it would review the Agency's Final Ozone Staff Paper and offer additional, unsolicited advice to the Agency on the chapters concerned with setting the primary and secondary National Ambient Air Quality Standards (NAAQS) for ozone.

On March 5, 2007, the Ozone Panel met via a public teleconference to review EPA's *Final Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information* (Final Ozone Staff Paper, January 2007). The Panel focused on Chapter 6 (The Primary O₃ NAAQS) and Chapter 8 (The Secondary O₃ NAAQS). The CASAC roster is attached as found in Appendix A, the Ozone Panel roster is provided as Appendix B, and Ozone Panel members' individual review comments are found in Appendix C.

Members of the CASAC Ozone Review Panel were pleased to review EPA's Final Ozone Staff Paper. The members of CASAC and the Ozone Panel were unanimous in their praise of both the responsiveness of the Agency to our previous recommendations and of the clarity of this document. While the CASAC recognizes that the Ozone Staff Paper is a final document, the Committee offers the following advice to aid the Administrator and Agency staff in developing EPA's proposed rule for ozone and related photochemical oxidants, to be published in June 2007.

Primary Standard

- The CASAC Ozone Review Panel agreed with the choice of indicator, statistical form and averaging time for the primary Ozone NAAQS suggested by Agency staff.
- The Final Ozone Staff Paper recommended that "consideration be given to a standard level within the range of somewhat below 0.080 ppm to 0.060 ppm," adding that "[s]tandard levels within this range that were considered in staff analyses of air quality, exposure, and risk include 0.074, 0.070, and 0.064 ppm, representative of levels within the upper, middle, and lower parts of this range, respectively." Reiterating what was stated in the CASAC's previous letter to you on this review (EPA-CASAC-07-001), *Ozone Panel members were unanimous in recommending that the level of the current primary ozone standard should be lowered from 0.08 ppm to no greater than 0.070 ppm.* The above-referenced CASAC letter (from October 24, 2006), in addition to EPA's own findings in the Final Ozone Air Quality Criteria Document (AQCD) and the Final Ozone Staff Paper, provide overwhelming scientific evidence for this recommendation. *Furthermore, the Ozone Panel recommends that the NAAQS should be specified to the third decimal place of the ppm scale to avoid any rounding issues* as indicated by the standard levels that the Agency itself considered in the Final Ozone Staff Paper.
- Pursuant to the Clean Air Act, the primary NAAQS for criteria air pollutants must be set to protect the public health with an adequate margin of safety. *Significantly, the Final Ozone Staff Paper does not address the issue of a margin of safety.* (On page 6-86, the authors conclude that the proposed standard would "...provide an appropriate degree of public health protection...;" however, there is no explicit mention of a margin of safety, *per se.*) Such a discussion should be added to the document and taken into consideration in setting the primary ozone standard.
- There is an underestimation of the affected population when one considers only twelve urban "Metropolitan Statistical Areas" (MSAs). The CASAC acknowledges that EPA may have intended to illustrate a range of impacts rather than be comprehensive in their analyses. However, it must be recognized that ozone is a regional pollutant that will affect people living outside these 12 MSAs, as well as inside and outside other urban areas.
- There is an urgent need to fund more research on the effects on sensitive subpopulations of low levels of the photochemical oxidant mixture for which ozone is used as a surrogate. In addition to the three field studies pointing to higher responses to the oxidant mixtures than to pure ozone that the Agency has already referenced in the Final Ozone AQCD (1–3), three other such studies are referenced below (4–6). More information on the effects of low levels of oxidant mixtures on public health is essential to inform the future decision-making process.
- Finally, with respect to policy-relevant background (PRB), the Ozone Panel wishes to point out that the Final Ozone Staff Paper does not provide a sufficient base of evidence from the peer-reviewed literature to suggest that the current approach to determining a PRB is the best method to make this estimation. One reason is that part of the PRB is not

controllable by EPA. It would require international cooperation beyond the bounds of North America. A better scientific understanding of the PRB and its relationship to intercontinental transport of air pollutants could serve as the basis for a more concerted effort to control its growth and preserve the gains in air quality achieved by control efforts within the U.S. In any case, there is no apparent need to define PRP in the context of establishing a health-based (primary) ozone NAAQS. The effects of inhaled ozone on decreases in respiratory function have been seen in healthy children exposed to ozone within ambient air mixtures in summer camps (1–6). Furthermore, the concentrationresponse functions above 40 ppb are either linear, or indistinguishable from linear. Thus, PRB is irrelevant to the discussion of where along the concentration-response function a NAAQS with an 8-hour averaging time that provides enhanced public health protection should be.

Secondary Standard

- The CASAC Ozone Review Panel members were unanimous in supporting the recommendation in the Final Ozone Staff Paper that protection of managed agricultural crops and natural terrestrial ecosystems requires a secondary Ozone NAAQS that is substantially different from the primary ozone standard in averaging time, level and form.
- The recommended metric for the secondary ozone standard is the (sigmoidally-weighted) W126 index, accumulated over at least the 12 "daylight" hours and over at least the three maximum ozone months of the summer "growing season."
- The Ozone Panel agrees with EPA Staff recommendations that the lowest bound of the range within which a seasonal W126 welfare-based (secondary) ozone standard should be considered is 7.5 ppm-hrs; however, it *does not* agree with Staff's recommendations that the upper bound of the range should be as high as 21 ppm-hours. Rather, the Panel recommends that the upper bound of the range considered should be no higher than 15 ppm-hour, which the Panel estimates is approximately equivalent to a seasonal 12-hour SUM06 level of 20 ppm-hours.
- Multi-year averaging to promote a "stable" secondary Ozone NAAQS is less appropriate for a cumulative, seasonal secondary standard than for a primary standard based on maximum eight-hour concentrations. If multi-year averaging is employed to increase the stability of the secondary standard, the level of the standard should be revised downward to assure that the desired threshold is not exceeded in individual years.
- There was an effective, Federally-funded program of ozone environmental effects research during the 1970s and 1980s, but such research support has been neglected in recent years. It is reasonable to conclude that changes in the distribution and genetic makeup of crop cultivars and naturally occurring plant species has and will take place over time along with modification of levels and distribution of ambient ozone exposures. Therefore, future refinements of the secondary Ozone NAAQS will require both: (1) a significant future investment in effects research to ensure that data for plant response to ozone are representative of the species and genetic composition of current crop and forest

species utilized by society; and (2) a clear understanding of the sources and propagation of uncertainty in the results of that research.

Additional details on the general recommendations listed above are provided in the comments of the individual members of the Ozone Panel that are included in Appendix C.

The CASAC appreciate this opportunity to work with the Agency is using science to help inform the setting of primary and secondary NAAQS to protect public health. While this is the last of a long series of Agency NAAQS-related staff papers, the Committee will continue to provide you with scientific advice related to setting criteria air pollutant standards protective of the public health and public welfare under EPA's revised NAAQS review process. As always, the CASAC wishes the Agency well in this important endeavor.

Sincerely,

/Signed/

Dr. Rogene Henderson, Chair Clean Air Scientific Advisory Committee

Appendix A - Roster of the Clean Air Scientific Advisory Committee

Appendix B – Roster of the CASAC Ozone Review Panel

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

References

- 1. Spector, D.M., Lippmann, M., Lioy, P.J., Thurston, G.D., Citak, K., James, D.J., Bock, N., Speizer, F.E., and Hayes, C. Effects of ambient ozone on respiratory function in active normal children. *Am. Rev. Respir. Dis.* 137:313-320 (1988).
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- 6. Lippmann, M. Health effects of tropospheric ozone: Implications of recent research findings to ambient air quality standards. *J. Exposure Anal. Environ. Epidemiol.* 3:103-129 (1993).

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* Members of the statutory Clean Air Scientific Advisory Committee (CASAC) appointed by the EPA Administrator

This appendix contains the written review comments of the individual members of the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Final Ozone Staff Paper who submitted such comments electronically. The comments are included here to provide both a full perspective and a range of individual views expressed by Panel members during the review process. These comments do not represent the views of the CASAC Ozone Review Panel, the CASAC, the EPA Science Advisory Board, or the EPA itself. The views of the CASAC Ozone Review Panel and the CASAC as a whole are contained in the text of the report to which this appendix is attached. Panelists providing review comments are listed on the next page, and their individual comments follow.

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Dr. Ellis Cowling

Dr. Ellis Cowling North Carolina State University March 2, 2007

Comments on Chapter 8 and Related parts of Chapters 2 and 7 in the "Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information – OAQPS Staff Paper" and the "Technical Report on Ozone Exposure, Risk, and Impacts Assessments for Vegetation"

What a delight it was to review Chapter 8 — *Staff Conclusions and Recommendations on the Secondary* O_3 *NAAQS* — with its firm conclusions and carefully reasoned staff recommendations to the Administrator of USEPA regarding the need for a secondary (public-welfare based) standard for ozone that is:

- a) Biologically relevant to vegetation including agricultural crops; seedling, sapling, and mature forest trees; and natural vegetation in natural ecosystems including natural grasslands in various parts of the United States,
- b) Distinct in form from the existing primary (public-health based) ozone standard, and also
- c) Distinct in form from the various alternative public-health-based primary standards for ozone that are proposed in Chapter 6 of this same Staff Paper!

These conclusions and carefully reasoned recommendations are soundly based on the available scientific literature summarized in the 2006 Criteria Document for ozone, its carefully prepared Integrative Synthesis Chapter, and also on information presented directly in Chapters 2, 7, and 8 of the present Staff Paper or its Appendixes, and the associated "Technical Report on Ozone Exposure, Risk, and Impacts Assessments for Vegetation."

It was especially satisfying to review the following conclusions with regard to the specific indicator, averaging time, statistical form, and range of levels of the secondary (public-welfare based) standard that EPA staff consider to be appropriate for consideration and implementation by the Administrator of EPA. This high degree of satisfaction was enhanced by the congruence between the following quoted paragraphs from pages 8-25 through 8-27 and the recommendations contained in CASAC's letter to Administrator Johnson dated October 26, 2006 — which was also printed as an attachment to this final OAQPS Staff Paper for ozone:

(1) "It is appropriate to continue to use O₃ as the indicator for a standard that is intended to address effects associated with exposure to O₃, alone or in combination with related photochemical oxidants. Based on the available [scientific] information, we conclude that there is no basis for considering any alternative indicator."

- (2) "It is not appropriate to continue to use an 8-hr averaging time for the secondary standard O₃ standard. The 8-hr average form should be replaced with a cumulative, seasonal, concentration weighted form. ... staff concludes that the W126 form is more appropriate than the SUM06 form recommended in the last review."
- (3) "It is appropriate to consider the maximum consecutive 3 month period within the O3 season as the seasonal averaging time over which cumulative O₃ exposures for the daily 12-hr daylight (8 am to 8 pm) window. Though the length of time in the growing season varies significantly between species, staff concludes that the 3-month of maximum O₃ exposure generally coincides with the maximum biological activity for most plants. Staff notes that for certain welfare effects of concern (e.g., foliar injury, yield loss for annual crops, growth effects on other annual vegetation and potentially tree seedlings), an annual standard form may be more appropriate, while for other welfare effects (e.g., mature tree biomass loss), a 3-year average form may be more appropriate [especially because of carry over effects from one year to the next]. Staff concludes it is appropriate to consider both the annual and 3-year average forms."
- (4) "It is appropriate to consider a range of levels when making a determination regarding what is requisite [for] public welfare protection. Staff concludes that an appropriate upper bound of this range is 21 ppm-hrs, expressed in terms of the W126 index, which is roughly equivalent to that proposed by the Administrator in the last review as able to provide a requisite level of protection to vegetation.

Our analyses indicate that this level will provide protection against O_3 -related adverse impacts on vegetation such as tree growth and crop yield beyond that afforded by the current 8-hr standard. In large part, the basis for selecting the level in the last review was a judgment as to what was an appropriate level of protection against crop yield loss. Though crop data are still useful as a potential indicator of risk to other sensitive herbaceous plants, staff recognizes that agricultural systems are heavily managed. In addition, the annual productivity of agricultural systems is vulnerable to disruption from many other stressors (e.g., weather, insects, disease), who's impact in any given year greatly outweigh the direct reduction in annual productivity resulting from elevated O_3 exposures.

On the other hand, O_3 can also more subtly impact crop and forage nutritive quality and indirectly exacerbate the severity of the impact from other stressors. ... Taking all of the above considerations into account, staff concludes that from a public welfare perspective, greater concern should be placed on the impacts of O_3 exposures on vegetation in less heavily managed and unmanaged ecosystems such as tree seedlings, mature trees, and forest ecosystems in general.

Thus staff concludes that the lower end of the range should incorporate the lower end of the range expressed by CASAC — a 3-month 12-hr W126 approximately equal to 7 ppm-hrs. This lower level will increase protection for the most sensitive tree species and the ecosystems where they are found."

- "Several additional factors should be considered when selecting an appropriate level for a secondary standard. These include:
- 1) The fact that O₃ effects are cumulative and have been shown to have carry over effects from one year to the next;
- 2) Some seedling tree species have sensitivities as great as annual crops and the importance of protecting against small percentages of biomass loss on an annual basis has been expressed by some within the scientific community;
- 3) Visible foliar injury impacts can occur within a growing season at very low levels of O₃ exposure; and
- The extent to which a secondary standard is precautionary in nature, given the possibility of O₃ impacts acting in synergy with other natural and manmade stressors.

Should a 3-year average of a 12-hr W126 be selected, the level chosen should reflect the fact that annual impacts are still a concern for visible foliar injury, tree seedling biomass loss, and crop yield loss, so that a potential lower level might be considered to reduce the potential of adverse impact from a single high O_3 year that could still occur while attaining a 3-year average."

Additional Comments on the Scientific Merit of a Secondary Standard for Ozone that is Distinct in Form from the Primary Standard

Ozone is a general metabolic poison. In the light of EPA's consistently strong emphasis on effects of ozone and related photochemical oxidants on human health, how interesting it is to realize that the injurious effects of ozone and other photochemical oxidants were first discovered on vegetable crops and forest trees and only later were discovered also to be injurious to human health and to be the principal cause of eye irritation in photochemical smog.

Ozone and other oxidants cause stress in plants and thus predispose both individual plants and whole ecosystems to attack by natural enemies that include disease- and injury-inducing bacteria, fungi, nematodes, viruses, and insects. In some cases, exposure to high concentrations of ozone also decreases the resistance of plants to injury and damage by abiotic stress factors such as drought and frost.

Different species and varieties of plants vary widely in susceptibility to ozone and other oxidants. Many species of crop plants, forest and shade trees, and some of the multiple-species of plants in natural ecosystems are more sensitive to injury and damage by ozone than most people. That is, many plants show visible symptoms of injury at concentrations of ozone that are considerably lower (40 to 60 ppb of ozone) than the 80 to 120 ppb of ozone that are generally recognized to cause ill-health in people.

The injurious effects of ozone and other oxidants on plants and ecosystems are CUMMULATIVE in their effects rather than acute or chronic in their effects as is found for most health effects of ozone on people. The important effects of ozone and other oxidants on human health occur in spite of the fact that most people spend most days of their lives inside home, school, office, and/or factory buildings where ozone exposures are a small faction of the ambient air concentrations of ozone that occur in the ambient air.

By contrast, almost all plants spend their entire lives in the great outdoors — where they are exposed to ambient concentrations of ozone 24 hours of every day, 7 days of every week, and in all seasons of the year; these continuous exposures occur for all the weeks, months, years, decades, or sometimes even centuries of the functional lives of the plant, animals, insects, and microorganisms that inhabit the managed or unmanaged ecosystems in all parts of the United States.

Thus, many plant pathologists, plant physiologists and ecologists like me are prone to assert, somewhat factiously, that:

"Plants do not worry about a bad Tuesday, but they do worry about bad ozone seasons."

Furthermore, we plant scientists also are well aware that the injurious effects of ozone often carry over from one year to the next.

For all of the above reasons, plant pathologists, physiologists, and ecologists concerned with the injurious effects of ozone and other photochemical oxidants on plants recommend that the "averaging time" of O_3 exposure necessary to avoid or decrease injury to crop plants, trees, and natural ecosystems should extend over the whole growing season rather than just a few hours. Hence the "ozone indices" recommended by EPA staff and CASAC to avoid or decrease injury or damage to plants have been of a cumulative form — such as W126 as was recommended by both EPA staff and CASAC in 2007 or SUM06 as was recommended by EPA staff and the Administrator of EPA as well as CASAC in 1997.

Significant injury and damage to vegetation continues to occur in many parts of the United States that are not in violation of the current 8-hr ozone standard.

The maps and charts shown on pages 7-28 of the staff paper and pages 7B-4 and 7B-5 of Appendices, as well as the discussion on pages 7-17 and 7-19 of the staff paper indicate the geographical locations and numbers of counties in which visible foliar injury and other welfare effects occur in areas that meet the current 8-hr standard for ozone.

On March 21, 1996, I presented the attached statement to the CASAC of that time regarding the need for a secondary standard for ozone that is different in form from the primary standard. That statement was titled "Avoiding the Necessity for a Second NRC Report on 'Rethinking the Ozone Problem in Urban and Regional Air Pollution' during the Years Between 2002 and 2017."

After careful study of Chapters 2, 7, and 8 in the current EPA Staff Paper on ozone, rereading again the 1991 NRC "Rethinking" report as mentioned above, and finally, once again rereading my 1996 statement to CASAC as shown on pages 5-9 of these comments, I am even more convinced (and for the same general and specific reasons outlined in all of these

documents) that the time has come for the Administrator of the USEPA to establish a biologically appropriate secondary (public-welfare based) National Ambient Air Quality Standard for ozone that is distinctly different in form from the primary (public-health based) standard for ozone and related photochemical oxidants.

Avoiding the Necessity for a Second NRC Report on "Rethinking the Ozone Problem in Urban and Regional Air Pollution" during the Years Between 2002 and 2017

Statement by Ellis B. Cowling University Distinguished Professor At-Large and Professor of Plant Pathology and Forest Resources at North Carolina State University to the Clean Air Act Scientific Advisory Committee (CASAC) EPA Auditorium Research Triangle Park, North Carolina March 21, 1996

The objective of this written statement is to provide additional justification to CASAC for recommending to the Administrator of EPA, that a secondary standard for ozone clearly different in form from the primary standard should be promulgated in 1997. This justification is based on three fundamental premises:

1) As discussed in the EPA Staff Paper on the secondary standard for ozone, a longer term seasonal standard, which is cumulative in form will provide an addition measure of protection against the harmful effects of ozone on the many different species of crop plants, forest trees, shade trees, ornamental plants, and the thousands of other plant, animal, insect, and microbial species that make up the living components of all the natural and managed ecosystems on which the quality of American life depends.

2) A secondary standard different in form from the primary standard will also accelerate and improve the processes of public education about many aspects of the tropospheric ozone problem. These aspects include, among others, the following general ideas:

— Contemporary ozone pollution causes significant harm to crops, forests, ornamental plants, and natural ecosystems in many parts of the United States.

— Ozone pollution is a serious threat to the welfare of people and ecosystems in many rural as well as urban areas of our country.

— Ozone and its chemical precursors are frequently transported from rural areas to urban areas and from urban areas to rural areas in many parts of the United States.

— The air concentrations of ozone and other oxidants that cause harm to crop plants, forests, and natural ecosystems are appreciably lower than the concentrations of ozone and other oxidants that cause harm to most people.

— Ozone pollution is not just an urban problem associated with high peak concentrations of ozone during exceptional weather episodes but also a problem of longer-term chronic exposures of plants to much lower, but still toxic, concentrations under persistent weather conditions.

3) A secondary standard clearly different in form from the primary standard will also have significant and pronounced effects on the nature, quality, and policy relevancy of ozone-related scientific research that will be undertaken during 1997 and beyond. A very important objective of that research should be to:

- fill the persistent gaps in available knowledge, and

— decrease the continuing scientific uncertainties

that have plagued ozone decision making in the past and,

if we do not change the way we think about the ozone problem, will continue to plague the periodic updates and CASAC reviews of the Ozone Criteria Documents that are now scheduled to occur in 2002, 2007, 2012, 2017, etc.

Every CASAC member is aware of the 10 principal findings of the 1991 NRC report entitled "Rethinking the Ozone Problem in Urban and Regional Air Pollution" and the call for reform of the precepts for decision making about tropospheric ozone that were advanced in Milton Russell's classic paper: Ozone Pollution: The Hard Choices (Science 241:1275-1276, 1988) — see attached reprint.

The title-words Rethinking in the NRC report and Hard Choices in Milton Russell's paper were chosen very deliberately. The intent in both cases was to encourage a significant change in the way American scientists, regulatory officials in industry and government, and the public at large think about ozone pollution and its management. Without a radical change in the quality of scientific, regulatory, and public thinking, both the NRC committee, and Milton Russell, former Assistant Administrator of EPA, were convinced, the United States will continue to fall short of its own objective — to develop robust, scientifically sound, and cost effective strategies and tactics by which to manage ozone pollution during the remainder of this century and beyond. The NRC report of 1991 indicated that despite 20 years of expensive and well-intentioned attempts, America's efforts to manage ozone near the ground "largely have failed." These attempts failed for two primary reasons:

1) Because the identical primary and secondary ozone standards established in 1970-71 and in 1978-79 were neither statistically robust nor founded on an adequate scientific understanding of the biological, chemical, and meteorological processes that lead to ozone accumulation near the ground, and

2) Because previous decisions about the kinds and quality of ozone-relevant biological-effects research and atmospheric-science research that was done were too often driven primarily by short-term regulatory deadlines, and, frequently, by incomplete scientific perceptions and policy assumptions.

The time has come for American scientists, leaders in industry and government, and people in general to understand that the problem of ozone pollution can not be managed by continuing to believe that the people in metropolitan areas like Atlanta, Chicago, New York, and other urban and regional ozone non-attainment areas can "solve the problem" of urban smog and regional ozone exposures without understanding the regionality and the seasonality of both the ozone problem itself and the regionality and seasonality of the management approaches that must be used if the nation is to learn how to manage ozone and other oxidants at reasonable cost.

This deficiency in understanding of the regionality and seasonality of the ozone problem was one of the most important points made in the NRC report and in Russell's "Hard Choices" paper. But these same deficiencies were driven home even more forcefully in November 1994, when 26 of the 29 states that were required to submit a State Implementation Plan for Ozone were unable to make an attainment demonstration following available guidelines.

As a result:

— Mary Nichols issued her now-famous "Memo of March 2, 1995,"

— The Environmental Commissioners of States (ECOS) joined together with EPA in creating the Ozone Transport Assessment Group (OTAG) involving more than 30 states east and some west of the Mississippi River, and

— The Federal Advisory Committee Act Subcommittee on Ozone, Fine Particulate Matter, and Regional Haze Implementation was created to look at at least three of the five or six air-pollution problems that are related to the general oxidative capacity of the atmosphere (the other problems being acidification of soils and surface and ground waters, nitrogen saturation of forest soils, and airborne-nitrogen-induced eutrophication of surface waters).

But even these more recent initiatives are driven by unrealistically short-term regulatory deadlines, and, frequently, by incomplete scientific perceptions and policy assumptions. Examples include:

— Use of specific exceptional ozone episodes rather than by both episodic and season-long ozone time periods of interest,

— Use of local and regional emissions inventories for natural and anthropogenic emissions that are of uneven quality for both rural and urban/suburban sources of ozone precursors,

— Use of emissions-based mathematical models rather than both emissions-based and observation-based air quality models, and

— Use of models that may "get the ozone peaks right" but are not skillful enough to "get the peaks, and the low ozone concentrations, and the natural and anthropogenic ozone precursors right" at the same time.

As CASAC makes its decisions about the closure letter that must now be written about the secondary standard for ozone, I hope all committee members will think very carefully about the nature, quality, pace, and intensity of research interactions that will occur as the result of the two choices you will help make today:

1) To recommend, once again, that identical primary and secondary standards be established for ozone in 1997, as was done in 1970-71 and in 1977-79, albeit, an 8-hour primary standard for which CASAC already has prepared a closure letter; or, alternatively,

2) To recommend that a secondary standard clearly different in form from the primary standard be established — an 8-hour primary standard of simple form, and a separate 3-month-long standard of cumulative form as recommended in the EPA Staff Paper.

I hope CASAC will reflect very carefully on the extent and thoroughness of rethinking of the ozone problem that will occur under these two alternative choices. How differently will the thinking and nature of communications be — both between and among the following kinds of expert- and non-expert persons who are interested in or have responsibilities for research and management decisions about ozone pollution:

- air pollution biologists,
- atmospheric chemists and physicists,
- air pollution meteorologists,
- air quality modelers,
- state and federal air-quality officials,
- air-quality leaders in industry and commerce including those in:
- the utility industry,
- the automobile industry,
- the petroleum industry,
- the printing, painting, solvents, and forest products industries, etc. and, perhaps most important of all,
- the public at large who will ultimately pay the bills for whatever decisions are made about ozone management during the years ahead?

In Summary:

Promulgation of a secondary standard for ozone that is clearly distinct in form from the primary standard will accomplish five important things:

1) It will provide an addition measure of protection against the harmful effects of ozone on the many different species of crop plants, forest trees, shade trees, ornamental plants, and the thousands of other plant, animal, insect, and microbial species that make up the living components of all the natural and managed ecosystems on which the quality of American life depends.

2) It will accelerate and improve the processes of public education about many aspects of the tropospheric ozone problem and its management.

3) It will enhance and improve the nature, quality, and policy relevancy of the scientific research that will be undertaken during 1997 and beyond.

4) It will enhance the quality and intensity of interactions that will occur between air pollution biologists concerned with the impact of ozone on crops and forests and atmospheric scientists

who are interested in the chemical, meteorological, biological, energy use, transportation, and industrial-development processes that undergird our future air-quality management policies; and

5) It will avoid the necessity for another NRC report on "rethinking the ozone problem in urban and regional air pollution" sometime during the years between 1997, 2002, 2007, 2012, and 2017 because we failed, once again in 1996 and 1997, to recognize the need for still further rethinking of the tropospheric ozone problem.

Dr. Douglas Crawford-Brown

Comments on Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information

Doug Crawford-Brown (3-9-07)

I begin by noting that I was not on the CASAC to review the previous drafts of this document, or to participate in the discussions surrounding that document. As a result, I cannot comment on whether the current draft is or is not a significant improvement over the earlier one. I also follow only the health effects side of this issue, and so comment only on that issue and its associated uncertainties.

Having said that, I note that this draft was quite easy to follow. Whether I agree with the final conclusions or not (and I basically do), I found the arguments and analyses in the draft simple to follow, despite the authors confronting a wide array of complex information. They are to be congratulated for selecting appropriate studies, drawing appropriate conclusions from those individual studies, and then looking for coherent summary conclusions across the studies.

It is clear from the data presented that the old standard is now problematic with respect to protection of health with an adequate margin of safety. My recommendation is that a standard in the vicinity of 0.70 ppm is consistent with the available data, and even this does not fully address the concerns over a margin of safety. There are, however, two ways to build in a margin of safety: through the exposure-response side of the assessment, or through the exposure assessment side. The staff may be contending that the ways in which exposures will be determined has conservatism built in, and therefore the margin of safety is included in that way. But as currently written, the document is curiously silent on the issue of margin of safety. I recommend it be made more explicit, with reference to either exposure-response conservatism or exposure assessment conservatism.

This leads me to my second consideration. The document contains some interesting discussions of how exposure assessment can be improved, presumably with the goal of better understanding exposure-response relationships. This includes a better ability to understand risks in subpopulations characterized by increased sensitivity or unusual activity patterns. One needs to think carefully through the ways in which highly detailed exposure information is used in health effects studies intended to establish acceptable exposure levels, and ensure that this use is not inconsistent with the ways in which compliance monitoring will eventually be done. Compliance monitoring does not reflect exposures at the levels of spatial and temporal resolution of the risk assessment studies, and so it quickly becomes possible for the exposure metric on an exposure-response function to fail to be equivalent to the exposure metric measured in compliance monitoring. I don't have an answer as to how this issue can be resolved, only to say that it is necessary to try to match as closely as possible the spatial and temporal scale of the exposure metric used in the health effects studies to the metric used in compliance monitoring. I don't believe this has yet been done in the draft document.

I am not sure how I feel about the use of measures of lung function as the basis for low exposure effects (realizing that there ARE data on more obviously significant measures such as hospital admissions). On the one hand, these could be precursors to more clinically significant effects. But they could also be sub-clinical effects with no evident relationship to quality or length of life. I don't believe the current document fully addresses this issue.

This is then related to another issue that appears throughout the health effects discussions in the document. The question is raised as to whether effects at low exposures, which one could take to be background, affect the exposure-response relationship at higher exposures. There is a point in the document at which the authors discuss the fact that the exposure-response relationships noted in clinical studies at EPA labs (e.g. here in the Research Triangle Park) might be compromised by the higher annual average ozone levels in the surrounding area. They suggest specifically that subjects may have been desensitized by the background exposures, depressing the exposure-response slope below that expected in other areas of the country, or at least those areas with lower policy relevant background levels. However, there is just as much evidence that low levels of exposure to pollutants don't cause adverse effects directly, but instead sensitize individuals to subsequent exposures to a range of risk factors. This would tend to inflate the exposure-response slopes in the study areas relative to other geographic areas with lower background. The authors just must be clear what they are assuming to be the case here, and provide the evidence to support that claim.

A minor quibble is that the authors refer at numerous points to "evidence based" conclusions. I know this is a fashionable phrase, and perhaps they are required to use it by current EPA procedures (although I can't find where this is true), but it leaves the reader wondering what the alterative to "evidence based" conclusions might be. In the medical field, "evidence based" is usually used in contrast to expert judgment by physicians. Is that the intent in this draft document?

Other than these points, I was quite pleased with the draft document.

Dr. Henry Gong

Post-Teleconference Comments on Chapter 6 – Staff Conclusions and Recommendations on the Primary O3 NAAQS, Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information. OAQPS Staff Paper, January 2007.

By Henry Gong, M.D., 3/5/07

I compliment the EPA Staff for an excellent Chapter 6. The chapter is not perfect but adequately and effectively summarizes the pertinent scientific information and presents informative exposure-risk estimates. The chapter is also an important product of thoughtful dialogues between the CASAC Review Panel and EPA Staff to achieve resolution and clarification and effective focusing of concepts and conclusions. As such, this iterative process (as well as the Staff Report) represents an important and necessary component of the scientific-policy-making procedures for developing appropriate NAAQS.

My only concern is that Chapter 6 does not discuss "adequate margin of safety" which is inherently part of public health protection and the Clean Air Act. I believe that the safety margin (especially for sensitive groups) needs to be included in both the Chapter discussion and in the final decision-making for the NAAQS for ozone.

Thus, I continue to strongly support CASAC's letter to the EPA Administrator (dated October 20, 2006). I support the range of 0.060 to 0.070 ppm for the primary 8-hour ozone NAAQS, since there is no scientific justification for retaining the current NAAQS of 0.08 ppm. I also support other considerations stated in the October 2006 letter, including CASAC's recommendations for the secondary ozone NAAQS.

Dr. Paul J. Hanson

Comments on Chapters 8 of the Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information OAQPS Staff Paper

Final Comments from Dr. Paul J. Hanson: 06 March 2007

I commend the EPA staff for their comprehensive modifications to both Chapters 7 and 8 of the Staff Paper and the attention they paid to panel comments submitted in August of 2006. In my opinion EPA staff has done a very good job of laying out the rationale and justifications for their recommendations for a change to the secondary NAAQS for ozone.

Good justification exists for the promulgation of a secondary standard for the protection of human welfare effects different from the primary standard designed to protect human health. The key change is the recommended alteration of the form of the secondary standard to a cumulative exposure index that better describes the true nature of tropospheric ozone's interaction with vegetation and materials in the natural world. The recommended averaging time (12 daylight hours and 3 month growing season) and levels for a W126-based secondary standard represent a logical choice driven by the need to propose a single standard representing a compromise across a wide range of sensitivities exhibited by important agricultural, forest, and natural species present throughout the United States. Mr. Richard L. Poirot's verbal and written comments on setting the level of the secondary standard offered during the 05 March 2007 teleconference provide additional logical input to be considered in selecting a specific level for the secondary ozone standard.

A few comments on the text of Chapters 7 and 8 are offered below for EPA's consideration:

Pages 7-40 to 7-43

I found the EPA Staff's justification of the extensive use of historical open-top chamber data for the analysis of crop responses to ozone (i.e., NCLAN results) to adequately address the CASAC-Ozone Panel's concerns about the utility of the methods and the applicability of those data to current crop varieties currently in use throughout the United States.

Page 7-62

The figure appears to have an unneeded subtitle -- "Is Foliar injury present or absent?, 2001".

Page 8-13 lines 3 and 4

I'm not certain that EPA Staff can adequately support the <u>general</u> statement that "the results of these impairments (e.g., loss in vigor) may be premature pant death". While this statement may be true for some sensitive species it is not likely to be a logical conclusion for all

plant species. As presented in the document I could not tell the intent of the authors.

Pages 8-27 and 8-29

I strongly agree with the plant species-level, ecosystem and methodological research needs outlined in the document. Without continued support for fundamental research on the mechanisms and quantitative measurement of ozone effects the NAAQS review process will suffer.

Dr. Allan Legge

Final Review Comments: Allan H. Legge

"Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information" OAQPS Staff Paper, January 2007, EPA-452/R-07-003.

Chapter 7: Policy-Relevant Assessment of Welfare Effects Evidence Chapter 8: Staff Conclusions and Recommendations on a Secondary O₃ NAAQS

Overall Comments:

The same underlying scientific assumptions used by Staff in the previous version of the Staff Paper (July, 2006) with respect to the secondary O_3 NAAQS are still being used in this version and are still seen as highly uncertain and as a result are still very problematic. While Staff has made an admirable effort to more fully identify where uncertainties exist, the matter of the propagation of error/uncertainty and its potential accumulative impact on their analysis still has not been addressed. However, it is clear that Staff recognizes the importance of the need to quantify these uncertainties, as some of these uncertainties are identified in their research recommendations (pp. 8-27 to 8-29).

It is important to note that Staff has been at a major disadvantage preparing this Staff Paper due to the fact that the state of the science regarding ambient ozone and vegetation/ecosystems has not changed very much since the last O_3 AQCD. Since the Agency has provided little or no support for research in this area in the intervening years from 1996 to the present to help remedy this problem by improving the state of the science and hence reducing the scientific uncertainties, the Agency must be strongly criticized for this lack of action. This is very unfortunate because it is clear that a scientifically defensible and protective secondary O_3 standard is needed especially when there is evidence of foliar injury from exposure to ambient ozone at the current primary standard.

Staff has attempted to get around the 'lack of adequate scientific information' problem by selectively using the results of a series of 'elegant and imaginative' mathematical analyses drawn from the revised technical document prepared for OAQPS by Abt Associates Inc. (2007)[see "Technical Report on Ozone Exposure, Risk, and Impact Assessment for Vegetation" - January 24, 2007]. The starting point of the analyses is the definition of the set of ozone metrics which will be used and which are all assumed to have a solid scientific foundation. The ambient ozone data which are modeled and/or monitored are the input data which are then used in the generation of the national potential O_3 exposure surface (POES) after which these data are subject to various 'rollback methodologies'. These data are then used to estimate crop and tree ozone exposures which ultimately lead to an economic benefits assessment for agricultural crops using AGSIM and tree growth simulation using TREGRO. Essentially, the results of each set of analyses forms the basis for the next set of analyses and so on. It is the results of these 'elegant and imaginative' mathematical analyses which provide much of the foundation for the conclusions drawn by Staff regarding the selected potential secondary O_3 standards. That being

said, Staff does not appear to appreciate the potential for propagation of error/uncertainty other than to qualitatively describe and identify where uncertainty exists. It is still my view that the analyses provided by Abt Associates Inc. (2006 and 2007) represent a "house of cards" with an unstable foundation.

Specific Comments:

1. The case has not been made by Staff that the results of ozone/vegetation exposure experiments carried out in open-top chambers (OTC) can be extrapolated to reflect what occurs in the ambient environment.

2. The case has not been made by Staff that one can use the same concentration-response (C-R) functions today which were developed in the 1980's using controlled ozone exposures in OTCs during the National Crop Loss Assessment Network (NCLAN) Program for selected agricultural crop species cultivars and the EPA's National Environmental Effects Research Laboratory-Western Ecology Division (NEERL-WED) for selected tree species seedlings.

3. The case is not made by Staff that the current crop species cultivars in use in 2002 have the same ozone sensitivity as the crop species cultivars used in NCLAN in the 1980's which were developed in the 1970's.

4. The case is not made by Staff that the ozone exposure indices SUM06 and W126 have a biological basis as has been implied. The only thing which can be said is that these two exposure indices are simply mathematical expressions of exposure which have been related to an endpoint such as yield in controlled ozone exposure OTC experiments.

Dr. Morton Lippmann

Final Review Comments – M. Lippmann Ozone Staff Paper – Jan. 2007 Draft

General Comments:

- 1) This Jan. 2007 "final" draft reflects the prior recommendations of CASAC, and is substantially improved.
- 2) Even though the Jan. 2007 Staff Paper is considered to be final, there are some technical defects in Chapters 2 and 3 that I think may warrant notation in an Errata. I also have some serious concerns about what is not in Chapter 6 that I feel should have been, and I recommend that they be addressed when the Notice of Intent to establish the next Ozone NAAQS is prepared. These are addressed below as some Specific Comments.

Specific Comments on Chapters 2 & 3.:

- 1) p. 2-6, Table 2-2: The entries for 2002, 2003, & 2004 are identical. This cannot be correct.
- 2) p. 3-3, Para. 3, line 6: change "a role for one or a group" to "a specific role for any one, or any group".
- 3) p. 3-22, Para. 1, line 1: insert "cross-sectional" before "study."
- 4) p. 3-22, Para. 1, lines 8-10: change to "116). In a longitudinal analysis of lung function development of 4th, 7th, and 10th grade students over four years, Gauderman et al., (2000) found no association with O3 exposure. Further longitudinal analyses by the same group".
- 5) [I cannot understand why previous requests to get this citation right have been ignored].
- 6) p. 3-37, Para. 2, lines 7-9: The labeling of the body of evidence on ozone-related mortality as being only "highly suggestive", and needing additional research on underlying mechanisms to become more fully established before it can be used in standard setting, sets the bar far higher than those used previously for ozone effects and, for that matter, for most, if not all, of the effects associated with other NAAQS pollutants. The only justification that I can see for this reluctance to use the evidence provided in this Staff Paper is that there are so many other effects to rely on that it is not needed in reaching the Staff recommendations in Chapter 6. The problem, at least for me, is that not considering the substantial evidence for short-term mortality attributable to ozone in ambient air sets a bad precedent for future NAAQS reviews.

Comments on Chapter 6:

1) What is included in this chapter, while prolix and repetitious, provides largely reasonable summations, conclusions and recommendations. However, in my view, Chapter 6 greatly understates the public health impacts of exposures that can be expected to occur at any of the exposure scenarios under the three levels options that were considered for this

"Final" Staff Paper draft. This is not only because the calculations are made for only those people living in 12 MSAs, but also because it ignores the people living outside of all of the MSAs in the U.S. The fact that ozone is regional in nature, and is often higher in concentration downwind of MSAs than within them, has not been considered in the risk assessment.

2) Another, perhaps related, deficiency in this chapter is the lack of any summary section on "margin of safety", a factor that is supposed to be explicitly considered in setting a NAAQS. This is an issue that is an especially troubling one for ozone, where the Staff Paper acknowledges that health effects that it judges to be adverse are expected to occur in large numbers of people living in the 12 MSAs who are considered to be susceptible, at least for the 74/4 and 70/4 options.

3) The section on Margin of Safety in the Agency's NAAQS proposal should also address the fact that the clinical laboratory exposures of healthy human volunteers provided much of the quantitative exposure-response information that guided the selection of the NAAQS options that were presented in the Jan. 2007 final draft, involved exposure to ozone alone.

4) While ozone is an appropriate indicator species for the Ozone and Photochemical NAAQS, it must be remembered that there is evidence, cited in the Staff Paper, from the childrens' camp studies and studies of workers and adults engaged in recreational exercise outdoors, that the ambient air mixtures produce greater responses than those seen in the studies of children and healthy adults in chambers with exposures to ozone alone. Thus, the chamber responses are likely to provide underestimates of the responses to ozone in ambient air mixtures.

5) For the reasons summarized above, I consider the effects that are estimated for the 74/4 level to be too high for a NAAQS that provides an acceptable degree of public health protection. I recognize that any limit lower than 70/4 is not technologically feasible for the U.S. in the near future, and that the costs of implementation for a still lower limit would likely exceed the public health benefits.

6) I believe that the issues that are raised above that deal with the adequacy of the protection that can be provided by the alternate NAAQS levels and the extent of a Margin of Safety, if any, at these levels, should be more thoroughly and explicitly addressed in the Federal Register proposal for a revised Ozone NAAQS than they were in the Final Draft of the Ozone Staff Paper.

Dr. Maria Morandi

Comments of Dr. Maria Morandi, March 4, 2007

The current version of the Staff Paper represents a significant improvement over the first draft. In general, the staff was responsive to the major concerns of the Panel, foremost among them the inconsistency between the scientific evidence for health effects of ozone observed at levels below the current primary standard that are described in the Final Ozone AQCD and summarized in the Final Ozone Staff Paper, and the recommendation for maintaining the current primary standard.

I have some concern with the description of the upper bound of the recommended range for a revised primary as a "…range of somewhat below 0.080 ppm .to 0.060 ppm…" in multiple areas of Chapter 6. Since the Staff Paper risk scenarios include the 0.074, 0.070, and 0.064 as representative levels of the recommended range it would strengthen the recommendation to provide a value for the upper bound of the range (say 0.074) as it is done for the lower bound (0.060 ppm).

Mr. Rich Poirot

Post-meeting comments on Chapters 7 & 8 of the January, 2007 OAQPS Ozone Staff Paper R. Poirot, VT DEC, March 19, 2007

My written comments prepared prior to the 3/5/07 Ozone Review Panel Teleconference on EPA's Final Ozone Staff Paper are pasted below. More recently, two important new papers by Sandy McLaughlin and others on environmental effects of ozone were published in the latest issue (April 2007) of *New Phytologist*. Clearly EPA staff can't continually revise completed Criteria Documents and Staff Papers as each new publication appears in the literature, but I would like to especially recommend these papers for staff consideration as they work with the Administrator to develop final proposals on revised (primary and) secondary standards for ozone. I'll also try to use some of these recent results to illustrate and emphasize several points raised in earlier CASAC ozone panel comments on the Staff Paper.

The first of these papers (McLaughlin et al., 2007a) shows current (2001-03) ozone levels causing 30 to 50% reductions in tree growth in mature trees in the southern Appalachian forests, while the second (McLaughlin et al., 2007b) shows how ozone induced reductions in the efficiency of water use by mature forest trees can lead to substantial reductions in soil moisture content (causing further indirect stress effects on under-story vegetation) and ultimately leading to reduced stream flow, especially under late season drought conditions, which are otherwise projected to become more common and/or severe in the future. This is the first demonstration I've seen that ozone effects on terrestrial ecosystems can lead directly to additional adverse effects on aquatic ecosystems. Thus the environmental effects of ozone at current levels of exposure are more intensive and extensive than we and staff had previously considered.

Ozone induced reductions in tree growth were noted in 9 of 10 tree species evaluated, with estimated seasonal growth reductions in the southern Appalachian study region of 33% during average ozone years (2001 and 2003), with further growth reductions of an additional 48% in a bad ozone year (2002) in that region. These large growth reductions were attributed not only to alterations in photosynthetic rates and carbon allocation but also to increased levels of water stress. The less efficient water usage by mature forest trees is attributed to reduced stomatal control, leading to increased water loss and increased ozone uptake, through increases in both daytime and nighttime stomatal conductance. Thus ozone exposures are increasingly relevant over more hours per day; ozone damage at one point in time predisposes trees to additional damage later in the growing season; and the effects on mature trees, as well as reductions in water availability for other components of forested terrestrial and aquatic ecosystems, are compounded over the entire growing season.

This evidence of increasing cumulative seasonal damage clearly illustrates why the current, short-term secondary standard needs to be revised to reflect longer-term seasonal effects. It can be noted that the cumulative ozone exposure metric employed in these studies, AOT60 (sum over the growing season of ozone in excess of 60 ppb), is similar to and well correlated with both the seasonal SUM06 and W126. However, the researchers in this case calculated their indices using all 24 hours of the day and over substantially longer growing seasons than the 12-hr, 3-

month aggregation proposed in the staff paper. Thus the staff recommendations to use only 12 daylight hours and only three summer months will tend to miss ozone effects during biologically important times of day and months of growing season in many sections of the country. The AOT60 for the Look Rock, TN site for 2001-2003 (calculated using all hours of day and aggregated over the period April 1 through October 30) from McLaughlin et al., 2007a,b are presented below in Table 1 along with my calculations of the 12-hr W126 aggregated over the maximum three contiguous summer months in each year (which is the way I'm guessing staff intends this metric to be calculated). Additional rows show the effect on the W126 of considering a longer 5-month growing season, or of considering ozone for 24 hours a day. If either longer growing seasons or more hours per day were considered, the seasonal W126 exposure could increase from 50% to 100% at this remote, southern, high elevation forest site.

	2001	2002	2003
AOT60, 24 hr, 7 month (McLaughlin et al., 2007a,b)	11.5 ppm h	24.0 ppm h	11.7 ppm
W126, 12-hr, 3 max contiguous summer months	20.0 ppm h	36.9 ppm h	17.9 ppm

W126, 12-hr, 5 month (4/15-9/15) growing season

W126, 24-hr, 3 max contiguous summer months

Table 1. Seasonal Ozone Metrics for Look Rock, TN, 2001-2003

h

h

29.9 ppm h50.5 ppm h28.3 ppm h37.9 ppm h69.2 ppm h35.0 ppm h

Note that the average 12-hr, 3-month W126 for the years 2001 & 2003 was about 19 ppm h. This is 10% lower than the level (21 ppm h) that staff had recommended as an upper bound for a seasonal W126 secondary standard. But McLaughlin et al. (2007a) estimate forest growth reductions of 33% for the 2001 & 2003 ozone seasons (compared to "control" conditions of no exposures > 60 ppb). So the staff-recommended upper range for a secondary standard (which has already been rejected in 1997 for not being sufficiently more protective than 0.084 primary standard) would allow more than a 33% reduction in tree growth (and associated reductions in soil moisture and stream flow).

Note also that the higher ozone year of 2002, for which an additional 48% growth reduction is estimated, had a 3-month W126 (or 7-month AOT60) that was about 50% higher than the 3-year 2001-2003 average. Thus if multi-year averaging is employed to promote a more "stable" standard (as opposed to more stable ecological health), the level of the standard should be reduced by at least 1/3 to assure that the intended threshold is not exceeded in individual years.

As indicated in pre-meeting comments below: staff recommendations for a seasonal cumulative W126 secondary standard are well justified, and the lower end of the proposed range (7.5 ppm h) is appropriate. The upper end of the proposed range (21 ppm h) is not protective and should be lowered. Consideration should also be given to inclusion of more hours/day and longer growing seasons, with a large downward adjustment to the level if multi-year averaging is used.

References

McLaughlin, S. B., M. Nosal, S. D. Wullschleger and G. Sun (2007a) Interactive effects of ozone and climate on tree growth and water use in a southern Appalachian forest in the USA, *New Phytologist* **174**: 109–124. <u>http://www.blackwell-synergy.com/doi/pdf/10.1111/j.1469-8137.2007.02018.x</u>

McLaughlin, S. B., S. D. Wullschleger, G. Sun and M. Nosal (2007b) Interactive effects of ozone and climate on water use, soil moisture content and streamflow in a southern Appalachian forest in the USA, *New Phytologist* **174**: 125–136. http://www.blackwell-synergy.com/doi/pdf/10.1111/j.1469-8137.2007.01970.x

Pre-meeting comments on Chapters 7 & 8 of the January, 2007 OAQPS Ozone Staff Paper R. Poirot, VT DEC, March 2, 2007

In the July 06 Second Draft Ozone Staff Paper, staff had proposed a secondary standard that differed substantially from the primary standard in averaging time, level and form. They recommended a seasonal index – SUM06 or W126 – limited to the 12 "daylight hours" accumulated over the three-month summer "growing season", within a range of 15 to 25 ppm-hrs for the SUM06, or a "comparable" range for the W126 metric (although there was some uncertainty in the calculation of an "equivalent W126", since some of the W126 values in that staff paper had been incorrectly calculated).

CASAC review comments (10/24/06) strongly supported the staff recommendations for a seasonal secondary standard that should be accumulated over <u>at least</u> the 12 daylight hours and <u>at least</u> the 3 maximum summer months. CASAC recommended that the range for a SUM06 indicator be lowered from the proposed 15 to 25 ppm-hrs to a more protective range of 10 to 20 ppm-hrs, and also advised that the W126, with no lower threshold, was conceptually preferable to the SUM06, and that a W126 range that was approximately <u>equivalent to</u> this SUM06 range would be preferable.

The current (January 07) Staff Paper revisions are directly responsive to most of the CASAC recommendations, providing an improved technical justification for a separate secondary standard, adding a more thorough analysis & discussion of uncertainties, and also in advocating the W126 as a preferable metric to the SUM06. Staff also concurred with CASAC suggestions to reduce the lower end of the range to a W126 of 7 ppm-hrs (estimated to be equivalent to a SUM06 at 10 ppm-hrs), but retained their original upper range of 21 ppm-hrs (a W126 level estimated to be equivalent to a SUM06 at 25 ppm-hrs – the same level staff had proposed in the 1997 review).

Overall, I think chapters 7 and 8 are much improved, although I would have preferred to see a lower, more protective upper end of the proposed range, closer to what CASAC recommended in the last review. There are still likely to be significant adverse environmental effects at a seasonal W126 level of 21 ppm-hrs, especially if the form of the standard is expressed as a 3-year average – thus allowing W126 levels substantially greater than 21 ppm-hrs in individual years. One potential problem with the currently proposed upper end of the level is that, if combined with a revised primary standard at (or below) the upper end of the proposed range of .070 ppm 4th highest 8-hour average, there are likely to be no locations where the secondary standard would be exceeded if the primary standard was not also exceeded (for example no points to the lower right of the intersecting 0.07 ppm 8-hr max and the 21 ppm-hrs W126 lines in Figure 7-1 on page 7-19 of the staff paper or in Figures 7B-1 or 7B-2 of the Appendices). Although it should be

cautioned that the relationships among various ozone indices are likely to change as progress is made toward reducing concentrations.

It's not required that a secondary standard be effectively more stringent than a primary standard, but as a practical matter, a secondary standard at a level equal to or less stringent than the primary standard has no function, since the primary is to be attained within 5 years, while the secondary has no time limit. However, a secondary standard that is more stringent than the primary extends the spatial extent and/or the relative degree of non-attainment, and so as a matter of policy, the Agency has tended to avoid setting separate secondary standards in the past. Indeed, when setting secondary standards (equal to primary standards) in the 1997 review for ozone, and more recently for fine particles in 2006, the Agency had first concurred with staff & CASAC that secondary standards with levels, forms and/or averaging times different from primary standards were clearly warranted, but then rationalized that the incremental benefits of achieving those alternative secondary standards – once the new primary standards had been attained - appeared to be small, and so the secondary standards were simply set equal to the primary. For this reason alone, seeing a proposed secondary standard which is less stringent than the upper range of the primary standard is a reason for concern. It looks like a set-up for a conclusion that a separate secondary standard is not needed. In fact the SUM06 equivalent (25 ppm-hrs) to a W126 at 21 ppm-hrs was considered in 1997 and discarded as not being a substantial improvement over the 8-hour maximum of 0.084 ppm. If staff proposes lowering the primary standard to (well) below 0.080 ppm, as is clearly warranted by the current health assessment, then to also recommend a secondary standard at a level that was discarded in 1997, for adding insufficient benefits to the 0.084 ppm primary standard, seems like a predetermination that a separate secondary standard will not be seriously considered once again.

Unquestionably a lowering (and attaining) of the primary daily 8-hour standard to the range of 0.060 to 0.070 ppm would have substantial beneficial reductions in the environmental effects of ozone. But if the Agency is also considering a secondary standard towards the upper end of the proposed range, I would strongly discourage the use of the "nearly covered by the primary standard" logic to avoid setting a separate secondary standard. The different averaging time is clearly warranted, there may well be changes in the relationship between daily maxima and seasonal indices (and growing seasons) in the future, there would be clear educational benefits in formalizing a separate environmental metric, and additional research would be encouraged to reduce current uncertainties and refine that environmental metric in future reviews.

Some additional reasons for reducing the upper end of the range – or for other possible more protective revisions to other aspects of the secondary standard metrics include the following:

• A reason for our previous recommendation to include "<u>at least</u>" 12 daylight hours in aggregating the W126 was the knowledge that not all the effects of ozone occur during daylight / photosynthesis (Musselman and Minnick, 2000). But the current staff argument (SP page 8-17) that "nocturnal stomatal conductance <u>varies widely</u> between species" (emphasis added) does not provide a compelling reason to discard the all the nighttime hours. The fact that some plant species are less sensitive than others to nocturnal ozone exposures is not a good reason to constrain the standard's applicability to disregard effects on those species which are sensitive. As a practical matter, most of the higher hourly ozone levels

contributing most to the seasonal index will occur during daylight hours in most low elevation agricultural areas. But this will not be the case for sensitive vegetation at higher elevations or near large water bodies, where a lengthening of the "daytime" window – even by a few hours - would result in a higher seasonal accumulation relative to a standard at any level, and especially for the W126 index. Even if the intent were to ignore species sensitive to nocturnal effects, the average length of "daylight" during the 3-month (or 4 or 5-month) "summer growing season" ranges from > 13 hours at southerly latitudes to > 14 hours at northerly latitudes (not 12 hours) across most of the continental US.

- In a similar way, CASAC advice to include "<u>at least</u>" the 3 maximum summer months was based on concerns that although high ozone and active plant growth would tend to co-occur most frequently and intensively during mid-summer, there are certainly regions or years when elevated ozone and vegetation damage can occur over longer "growing seasons". In my home town of Burlington, VT, just south of the 45th parallel and Canadian border, the "growing season" (time between last spring frost and first autumn frost) has not been shorter than 4 months during any of the past 50 years, and has been greater than 5 months in 90% of those years. Substantially longer "growing seasons" exist throughout most of the rest of the country, where both higher ozone levels and longer ozone seasons are likely. So limiting the period for W126 accumulation to only 3 months makes a seasonal standard at any level less stringent and/or protective than if a longer, more realistic growing season were used.
- The staff paper suggests (page 8-22) that a 3-year average form as is used for the primary standard should be considered "given the legitimate policy interest in having a more stable standard form." Again, as with the 12-hour daily and 3-month seasonal windows, this has the effect of making a seasonal standard at any level less protective than if an annual form were used. There's also an important conceptual distinction between a "stable" daily standard and a stable seasonal standard. The 8-hour daily standard depends on only 4 days or more precisely the level of the specific 8-hour maximum on the single 4th highest day. So an exceedance could be due to "a few anomalously bad days" (on which sensitive individuals may be able to take action to avoid maximum exposure). High levels of a seasonal index are not based on a few days but indicate cumulative effects over an entire "very bad summer" when substantial damage is likely to occur to sensitive vegetation. As the SP indicates (page 8-16) "Plants, unlike people, are exposed to ambient air 24 hours a day, every day for their entire life". So (standard-diluting) multi-year averaging is much less appropriate for a seasonal standard. If employed for "stability" purposes, the level of the standard should be adjusted downward to assure that the desired threshold is not exceeded in individual years.
- Another reason to lower the upper end of the proposed range relates to uncertainty in the "conversion factor" for relating a level of the seasonal SUM06 to an "equivalent" level of seasonal W126. As indicated on page 7B-2 of Appendix 7, "there is no standard method for calculating equivalent levels between metrics". The method employed here and described on the same page is based on equations for similar projected crop losses based on the NCLAN data. In the given example, 50% of crop cases were estimated to be protected from a relative yield loss of 10% at a SUM06 level of 25 ppm-hrs. A similar level of protection is estimated at a W126 level of 21 ppm-hrs, and thus a W126 of 21 ppm-hrs is considered equivalent to a SUM06 of 25 ppm-hrs. In a similar way a SUM06 of 15 ppm-hrs is estimated to be

equivalent to a W126 of 13 ppm-hrs. Note that these W126 levels – based on NCLAN data <u>collected in the 1980s</u> - are 84 to 87% of their "equivalent" SUM06 levels, respectively.

An alternative indication of "equivalency" is displayed in the Figure 7-4 scatter plot on page 7-29 of the Staff Paper. Based on much more recent ozone measurement data from 2001, the 2 indices are very highly correlated across all monitoring locations (R^2 =0.98) but the current slope is more like 0.75 (not 0.85). As shown in the box at lower left of this figure, a SUM06 of 25 ppm-hrs is – in recent years – "equivalent" to a W126 of 19 (not 21) ppm hrs. A reason for the differences in these calculations of equivalency may very well be a large (downward and broadening) shift in the distribution of ozone concentrations since the 1980s when the NCLAN studies were conducted. This shift in the relationship between ozone indices over time further emphasizes on the importance of establishing a separate secondary standard, and cautions against concluding that the relationship between primary and secondary standard metrics will remain constant in the future.

Thus if an upper SUM06 bound of 25 ppm-hrs is intended, the equivalent W126, based on the current US distribution of mid-summer ozone concentrations would be 19 ppm-hrs. If a multi-year form is being considered, this upper end of 19 ppm-hrs should be further reduced to assure it isn't substantially exceeded in individual years. If accommodations were also made to account for effects during hours of day or months of growing seasons which are not considered by the current proposal, then the upper bound level of the secondary W126 standard range could very well be adjusted downward from 19 toward 15 ppm-hrs – the approximate equivalent of the 20 ppm-hrs. upper bound SUM06 recommended in the last CASAC review.

Dr. Armistead (Ted) Russell

Review of the January 2007 OAQPS Ozone Staff Paper and the "Analysis of Uncertainty in Ozone Population Exposure Modeling"

Ted Russell

This version of the ozone Staff Paper (SP), is a definite improvement over the prior version, and integrates public comments, as well as CASAC's, in to the context of their recommendations on a change of the ozone NAAQS. Of most interest are the additions in Chapters 6, 7 and 8. Given that these are, presumably, final documents, the comments are aimed at how what is presented should be considered in the choice of a revised ozone NAAQS.

My main concern with Chapter 6 is that the analysis presented likely underestimates potential ozone exposure and risk reduction from tighter standards due to both biases in the current APEX application and the limited areas to which APEX was applied. I would not be surprised if such biases are relatively minor, but these biases should be stated quite explicitly and frequently so they are not forgotten. I would not suggest that they are calculated at this time as I think the analysis conducted so far provides ample evidence that the standard should be tightened, though if they were, it may be that Staff would not consider the 0.074/4 level. Their current analysis shows a large number of exposures of concern at that level as it is. That said, I found the tables presenting exposures at various levels of the standard illuminating and a good foundation for assessing possible levels/form of a revised Ozone NAAQS. A second concern with Chapter 6 is that it takes quite a while to get through it, but that is life as I am sure EPA staff want to be thorough in providing support for the changes suggested. A third concern with Chapter 6, as well as Chapter 2, is that the "other photochemical oxidants" are given short shrift and more attention should be paid to them in future assessments, and for further consideration in the choice of a revised NAAQS at this time.

In Chapter 7, they show, in Fig. 7-18, how W126 levels correlate with 8-hour levels and show the current and an alternative form of the primary standard with W126 levels. It is important to recognize that the relationship implied here may not be true given future controls. Thus, a 0.070 ppm primary NAAQS would not necessarily provide as much in terms of lowering W126 as might be taken away from this graph... though it actually may provide more. This provides increased support for a separate form for the secondary standard. In the future, they might look to provide an apportionment of uncertainty.

I was pleased with the report "Analysis of Uncertainty in Ozone Population Exposure Modeling," not because it was an extensive uncertainty analysis, but because it was an appropriate analysis given the resource/time constraints, and it provides the needed information upon which one can conclude that the uncertainties should not play a major role in the choice of future standard. In future assessments, calculating the contributions to uncertainty would be insightful.

Dr. James Ultman

Comments on the Final Draft of the Ozone Staff Paper James Ultman March 13, 2007

The staff is to be congratulated on producing a final document that is well-written and contains a logical risk analysis based on clearly justified health end points.

I strongly agree with staff's conclusion (3) on page 6-86 that the current scientific evidence provides strong support for consideration of a standard that would provide increased public health protection.

I disagree with staffs recommendation (3)(a) that consideration be given to a standard in the range of "somewhat below" 0.08 to 0.06. The phrase "somewhat below" is nebulous and allows the possibility of a standard that is "somewhat below" and yet essentially equivalent to the present standard of 0.08 ppm. I believe that there is sufficient scientific evidence, particularly with respect to hospital admissions and lung function decrements, to change the level of the standard to 0.07 ppm or lower.

The present staff paper is not adequately informed by scientific studies regarding the synergistic effects of other air pollutants in smog on the effects of ozone. As a result, staff had little choice but to conclude that ozone alone can still be considered an indicator of effects that occur in the presence of other photochemical oxidants (Conclusion (1) on page 6-85). There are also inadequate research results concerning the amplification of ozone-induced effects during lung development, a process that most likely is affected by ozone level as well as the time-history of exposure. It is imperative that research in these two orphaned areas be stimulated by the EPA.

Laboratory studies of compromised lung function at exposures below 0.08 ppm played an important role in staff's recommendation to lower the ozone standard, and yet, the available data is limited to small populations (see table 5.3). Clearly, additional measurements of this type are a high priority before the next review cycle of the ozone standard begins.

Dr. Sverre Vedal

March 2007 Critique of the Ozone OAQPS Staff Paper Sverre Vedal

Chapter 6 (Conclusions/Recommendations)

The chapter now reasonably summarizes the state of the science, draws overall defensible conclusions, and generally provides a credible basis for a addressing changes to the ozone NAAQS in light of the science. In most instances, appropriate caution is expressed when the data are not as strong as they might be. There are still a few persistent inconsistencies, which I will attempt to detail below. Also, while the opinions of the CASAC are almost always faithfully presented, this is not universally so. A few points:

1. Level of the standard.

The staff paper has now appropriately moved away from including the current standard (in essence, 0.084 ppm) in the range of recommended alternatives. The current recommendation, "within the range of somewhat below 0.080 ppm to 0.060 ppm," is more in keeping with the CASAC recommended range of 0.070 to 0.060 ppm. I commend the OAQPS staff in acknowledging the arguments made by the CASAC in this regard. I sense that "somewhat below 0.080 ppm" will leave open the possibility that the standard might be changed very little, which is not in line with CASAC recommendations.

2. CASAC opinions.

While most attributions to CASAC are correct, I don't believe it was a written opinion of CASAC that "more emphasis should be placed on numbers of subjects in controlled human exposure studies with FEV1 decrements greater than 10%, which can be clinically significant, rather than on the relatively small average decrements" (p.6-43). While this may have merit in some (or even many) situations, for example when noting that 26% of individuals had >10% FEV1 decrements at 0.08ppm (p. 5 of the CASAC letter), in other cases, such as the specific case of 0.060 or 0.040ppm exposures (Adams 2006), this approach amounts to attempting to find effects in a very few individuals when the statistical tests are not significant, which is a dangerous precedent – especially in this case where we are looking at small effects in 3 of 30 vs. 1 of 30, a pitiful number on which to attempt to base policy (see comment #6 below on future research needs).

3. Choice of alternative standards for risk assessment.

It may have been valuable to continue the risk assessment down to a 60/4 scenario instead of stopping at 64/4, but the trend seems clear.

4. Cardiovascular hospitalizations and mortality.

Evidence-based considerations (section 6.3.1.1) should have included a discussion of cardiovascular hospitalizations. The evidence for the absence of effects of ozone on cardiovascular hospitalizations has bearing on the plausibility of the mortality findings, which are dominated by cardiovascular, not respiratory, deaths. My review of the most recent findings

on hospitalizations (from 2006 and so not included in the CD) continues to show no evidence of ozone effects on cardiovascular hospitalizations. I therefore stand by my minority view that the mortality endpoints should not have been included in the risk assessment.

5. Inconsistencies.

There are a few inconsistencies. For example, "mortality is <u>likely associated</u> [my underline] with O_3 exposures" vs. "<u>possibly</u> [my underline] increased mortality" (p.6-47 last sentence mid-paragraph vs. top and bottom of page).

6. Future research.

It is appreciated that recommendations for future research are not a focus of the Staff Paper. Nevertheless, since they are included here, a few comments are appropriate.

(i) The very limited amount of human experimental data at concentrations lower than 80 ppb is astounding, especially in light of the importance of these data in the exposure estimates, the risk assessment and the recommendations. More prominence should be given to a recommendation to increase the number of subjects in such experiments, and to assess the reproducibility within individuals of the findings, much as has been done at concentrations of 0.08 ppm and above.

(ii) Regarding exposure work (recommendation #7, p.6-89), I would recommend adding the elderly with medical conditions as a group of great interest.

7. Figures 6-1 to 6-6.

I applaud the changes to figures 6-1 to 6-6 that includes comparison to current levels, even though this results in compression of some of the body of the plots by expanding the y-axis. Unfortunately, the figures are attempting to display information on too many issues.

Minor:

1. Appendix, Table 6 (p.6A-1) needs to be identified as such.

2. p.6-10, mid para. The wording suggests that lung function decrements following exposure to ozone are related to baseline level of lung function, whereas what is specifically described in the section referenced is that effects on <u>bronchial responsiveness</u> are related to baseline level. The experimental evidence that asthmatics have a greater lung function response to ozone than non-asthmatics remains very limited.

3. p.6-10. reference to CD p.8-80 is not the correct page.

4. p. 6-37, footnote. The correct Staff Paper tables are 5-16 and 5-17, not 5-10 and 5-11.

5. p.6-56. There is no evidence for "reduced lung function growth in children," just decrements

in lung function that likely have nothing to do with growth of either airways or lung parenchyma.
6. p.6-77. The continued reference to lung permeability effects as the most plausible explanation for cardiovascular effects of ozone is not recommended, especially when other effects of inflammation seem more credible.

7. p.6-79. I would add "estimated to line 10 when referring to reduction in mortality.

8. p.6-82. Reference should be to Appendix 6A not 6B in first paragraph.

Dr. James (Jim) Zidek

Comments on the Final Staff Report on NAAQS for Ozone James V Zidek, REVISED Mar, 2007

General: The final report is a substantial improvement over the original. Moreover, it summarizes well in Section 6.3.1.3 CASAC's discussion of on the need to tighten the NAAQS or ozone.

However, the proposed Staff upper limit of being somewhat below 0.080 is not only ambiguous but will, de facto, be taken as an upper limit of 0.080. Thus to two decimal places, it includes the current standard, something that runs against not only the letter of the CASAC recommendation but against is spirit as well as the spirit of the Staff's own position. A more practical alternative would have been 0.074, a level that has the well studied by Staff.

However, that still leaves the question of why Staff elected to go above the CASAC limit of 0.070 that I continue to support very strongly. Some rationale for that decision should have been provided in the report for the Administrator's consideration.

CHAPTER 3

Shephard et al (2005) cited in Section 3.4.2.1 is not in the bibliography at the end of Chap 3.

CHAPTER 4

The uncertainty analysis around Figures 4-4 to 4-6 is a valuable addition to the document and shows that the predictive point estimates of the percentage of children at given exposure levels are not susceptible to much uncertainty due to APEX output variability.

Page 4-22. The final report ignores the suggestion that LM=1 and LA =0 be used to avoid bias in estimating the exposures of individuals who work outside the study area. While that bias is likely to be small, running the model with those parameters as well as with both set to zero would have given some idea of its size.

Page 4-31 To repeat a point made about the Second Draft, tailoring APEX to fit the California situation assesses whether the model is ideally capable of accurately forecasting exposure. However, APEX as used to set National standards is a different model and it too should be assessed. It's AERs could well be higher than those in Sacramento in which case, it would not underestimate exposure like its tailored counterpart. The point is it could have been run with both sets of parameters to see if this made a meaningful difference.

ATTACHMENT: "Ozone population exposure analysis for selected urban areas".

For the record, the suggestions I made for clarification in this section were ignored for the most part. (Obviously they cannot be addressed now, as they are not mere errata.) More specifically: **Page 22:** No estimate has been given of the effect of using the school children's D and A as a surrogate for all individuals, in particular whether this choice is more liberal or conservative than drawing the sequence of daily time activity patterns at random from the population as a whole.

Page 54: The report does not explain how to interpret the person-day estimates, in relation to setting NAAQS, nor about how the aggregates were computed. In the case of person-days, was this done by: first calculating the expected number of days of exposure per person based on a number of APEX runs; and then multiplying by sub-population size? Some statement of the reliability of these estimates should have been given.

Page 79-80: APEX's underestimation of true exposure is of concern as is the use of weekly the aggregation of exposures because the impact on the latter of the ecologic effect (that is not addressed in the report).

The errata I pointed out were also ignored in the Jan 07 revision.

- **Page 21:** Clock hour "i" rather than "I" is correct, a result of the software's propensity to capitalize "i" whenever it appears alone without quotations around it.
- Page 40: Section 3.8.2 referred to on this page does not exist even in the final Staff report, so it was not clear what fractions were actually taken from Appendix A and used.

MEMORANDUM: "Analysis of uncertainty in ozone population exposure modeling" by John Langstaff

Page 8. The common practice of log transforming data from heavy tailed distributions leads naturally to GM = exp (AM) and GSD = exp (SD), and asymmetric 95% confidence intervals for both, (GM/GSD², GM*GSD²) for the GM for example. Therefore, I remain puzzled by the discussion of symmetric intervals on this page, a discussion that I commented about in the Draft.

Page 14. The final report repeats an earlier error, calling the cross-validation method the "jackknife."

CHAPTER 5

Page 5-18: The analysis in Section 5.3.1.3 is a major improvement over the Draft report. The concern for model uncertainty has been well addressed and honestly reported. The sensitivity to prior model probabilities shown in Figure 5-3 at low ozone concentrations correctly reflects the relevant lack of data at that end of the exposure spectrum and points to the need for more experiments in future work to better characterize that part of the exposure response curve.

Page 5-20: The rationale for selecting the 90/10, logistic/linear prior is not convincing. The completely uncertain shape of the true exposure response curve would make the 50/50 prior the natural choice. The analysis should then include a calculation of the posterior logistic/linear odds ratio to see to what extent the data prefer the latter. In fact, the Bayes factor, the ratio of the posterior to prior odds, is a common way of seeing to what degree the data do have a preference for one model over the other. Instead, the analysts have used the data and their impression of the logistic's superior fit to select the 90/10 even while conceding that the lack of data at lower exposure levels makes that choice tenuous.

Page 5-29: Section 4.5.6 referred to in the first bullet near the bottom of the page is about meteorological data, not air quality, suggesting an error.

CHAPTER 6

- **Page 6-31:** The errata list should correct citations made on this page to Table 5-6 and 5-7. As well, the citation of Section 5.3.2.5 seems incorrect. Should it be 5.3.1.3?
- **Page 6-21:** Here we learn that the choice of the prior odds in favor of the logistic model over the linear one does make a difference to assessment of risk for all school children when comparing the more stringent standards to the current standard. Since the 50/50 would have seemed the more natural choice, the effect of this change should be clearly spelled out. Would it have affected the Staff's recommendations had it been chosen?
- Page 6-24: I agree with the last sentence on this page: the variability of the degree of protection afforded by the standards across urban areas does seem an important in evaluating the current standard. That point is revisited on Page 6-50. However, it never emerges how Staff incorporated that factor in their recommendations. Should standards be based on the worst case?

Dr. Barbara Zielinska

Comments on the Ozone Final Staff Paper, Chapter 6: Staff Conclusions and Recommendations on the Primary O₃ NAAQS Barbara Zielinska

In my opinion, Chapter 6 of the Final Staff Paper, although very long, is well written, and adequately summarizes the pertinent scientific information. I have only a few comments regarding this chapter:

- 1. I think that the Staff recommendation for the new NAAQ ozone standard "within the range of somewhat below 0.080 ppm to 0.060 ppm" is rather vague as far as the upper limit of the standard is concerned and includes the possibility of changing the standard very little (0.079 ppm is also "somewhat" below 0.080). The first level below 0.080 ppm that has been shown in the Staff Paper as bringing substantial health benefits (Figures 6-1 to 6-6) was 0.074/4. However, the 0.070/4 option was even better and the trend continued to the 0.064/4 level (the last shown). For this reason, taking into account the data shown in the Staff Paper, I would consider the 0.074/4 option as an upper limit.
- 2. However, as stated in Section 6.3.2 (Indicator), ozone is only a surrogate for the larger group of photochemical oxidants, which health effect is largely unknown. Thus, it is possible, that acute exposure chamber studies that investigate the effect of ozone alone may underestimate the responses to ozone in ambient air mixtures. Taking into consideration that "measures leading to reductions in population exposures to O_3 are generally expected to lead to reductions in population exposures to other photochemical oxidants" (page 6-53), I support 0.070 ppm as the upper limit for the primary ozone standard.
- 3. I agree with comments of other panel members that the Chapter 6 does not adequately address the "margin of safety" issue in recommending the upper limit of the ozone standard as "somewhat" below 0.080 ppm. I also agree that the limiting the analysis of O₃ exposure to 12 major cities may underestimate its impact, as it has been shown that O₃ concentrations downwind of an urban area are often higher than within a city.
- 4. The Staff Paper method for estimating the Policy Relevant Background (PRB) is still not adequately justified and somewhat controversial. PRB may be relevant to a question if the considered NAAQS for ozone is attainable. Although it is possible that the proposed range of 0.070 to 0.060 ppm may overlap with extreme local values of PRB, it is rather unlikely that such overlap would occur frequently, especially for 8-hr average concentrations. As shown by Lefohn (2007), the diurnal O₃ concentrations that were measured in Trinidad Head, CA (background site), in April (the highest O₃ month) ranged from 0.030 to 0.050 ppm and the maximum hourly value reported was 0.066 ppm. In addition, the statistical form of the proposed ozone standard (annual third- to fifth-highest daily maximum 8-hr average concentration, averaged over three years) largely removes the influence of extreme events.

Reference: Lefohn, A. S. (2007) Major issues inadequately addressed in the final version of the EPA's Ozone Staff Paper. Comments on the EPA Staff Paper, submitted to EPA.

NOTICE

This report has been written as part of the activities of the U.S. Environmental Protection Agency's (EPA) Clean Air Scientific Advisory Committee (CASAC), a Federal advisory committee administratively located under the EPA Science Advisory Board (SAB) Staff Office that is chartered to provide extramural scientific information and advice to the Administrator and other officials of the EPA. The CASAC is structured to provide balanced, expert assessment of scientific matters related to issue and problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the EPA, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use. CASAC reports are posted on the SAB Web site at: http://www.epa.gov/sab.