

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

Preliminary Individual Comments on the Policy Assessment

For the Review of the Ozone NAAQS (Second Draft)

CASAC Ozone Review Panel

Updated March 21, 2014

Contents

George Allen	2
Ed Avol	7
Joe Brain	10
David Chock	13
Ana Diez Roux	15
David Grantz	19
Daniel J. Jacob	22
Steven Kleeberger	23
Fred Miller	24
Howard S. Neufeld	27
Armistead (Ted) Russell	31
James Ultman	33
Sverre Vedal	35
Peter Woodbury	37
Ronald E. Wyzga	46

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

George Allen

March 16, 2014

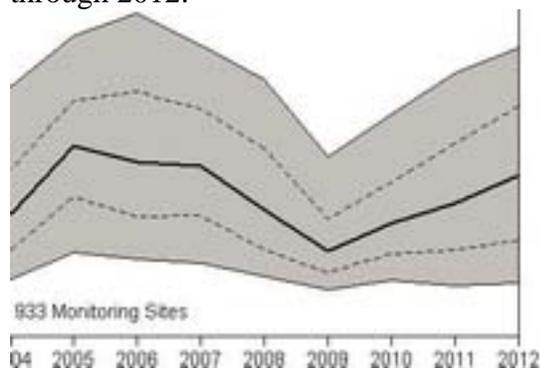
Preliminary Comments on Second Draft Policy Assessment Document for Ozone

These comments focus primarily on Chapter 2, Air Quality.

Charge Questions on O3 Monitoring and Air Quality (Chapter 2).

Ch. 2, Q #1. To what extent does the Panel agree that the most relevant information on monitoring (section 2.1), emissions and atmospheric chemistry (section 2.2), and common patterns of O3 concentrations (section 2.3) is presented, and to what extent is the information presented appropriately characterized and clearly communicated?

Section 2.1, Monitoring. National trends of annual 4th highest max 8-hour values are plotted in Figure 2-2, page 2-4. Section 2.1 appropriately notes the distinct drop between 2002 and 2004, consistent with the drop in summer NOx emissions due to the “NOx SIP call”, and notes the decreasing trend between 2000 and 2009. While that time period does appear to have a distinct downward trend, it is also informative to look at this same plot constrained to the period from 2004 through 2012:



This 9-year time period starting after the NOx SIP call drop in O3 shows no indication of a trend, and leads to a very different conclusion. While both this time window and EPA’s interpretation of O3 trends over 2000 through 2009 are valid, the latter is totally driven by a one-time intervention; since then there does not appear to be any progress in reducing O3 concentrations. Year to year variations in summer meteorological conditions can play a large role in “raw” trends of less than 15 to 20 years duration. In the past EPA has presented trend estimates that include adjustments for meteorology; it may be helpful to present such “adjusted trend” data to better assess progress since the NOx SIP call. 2013 O3-season data is now in AQS; even though those

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

data will not be “certified” for another 3 months, it would be informative to add that data for 2013 to this trend plot.

Section 2.2, Emissions and Atmospheric Chemistry. This section is a clearly written and concise summary of this topic. It makes the interesting point regarding the co-benefit from NO_x emission reductions for O₃, NO₂, and PM_{2.5}.

Section 2.3, Air Quality Concentrations. This section is a clearly written and concise summary of this topic. Footnote 7, page 2-10, makes the sometimes overlooked point that since O₃ is measured seasonally in most areas, the 4th highest day’s value is similar to the 98th percentile annual metric form used for some other criteria pollutants.

Section 2.4, Background O₃.

Ch. 2, Q #2. With regard to information on estimating O₃ concentrations associated with nonanthropogenic sources or “background O₃” (section 2.4), to what extent is this information appropriately characterized and clearly communicated?

This section is the core of this chapter. Estimates of background O₃ now play a minimal role in the REA document given the new approach to estimating risk under various emission reduction scenarios using the HDDM rollback method and total O₃ concentrations.

Background O₃ is still a factor in the Policy Assessment however, since a 2002 court decision allows EPA to consider background levels when evaluating risk for alternative (lower) standards (section 1.3.1, page 1-26, lines 17-19). But case law also states that “that attainability and technical feasibility are not relevant considerations in the setting of a NAAQS” (section 1.2.1, page 1-4 lines 19-21, API v. Costle, 1981). It is unclear how EPA might navigate between these two legal guidelines in terms of how background O₃ would be used in a policy and standard-setting context.

EPA performed new 2007 base “year” (7-months) zero-out and CAMx source apportionment modeling that is presented in this section. Section 2.4.2 (page 2-16, lines 6-14) introduces the concept of “apportionment-based US background” O₃ (AB-USB?) as the most relevant metric for estimation of a “fractional background” metric. Overall this chapter is difficult to follow. It seems the new modeling’s utility is to confirm earlier outcomes using these improved modeling approaches. It would be helpful if the chapter could better focus on these specific issues.

Section 2.4.3: The discussion on page 2-17, lines 1-12, is helpful in understanding the fractional contribution of background O₃ on days with elevated O₃.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

Figures 2-13 and 2-14 on page 2-19 could benefit from the addition of “N” (# of site-days) to each bin. Figure 2-13 is difficult to interpret without this information.

Section 2.4.4 presents background O₃ in the context of the 12 urban case study areas. Table 2-2 (page 2-21) seems to be the most relevant presentation, but is only for site-days > 60 ppb; it would be helpful to also include this information for site-days >65 and > 70.

Section 2.4.5 presents background O₃ in the context of a W126 secondary standard form for four locations (2 are large urban areas). Page 2-22 lines 10-12 refer to figure 2-7 (page 2-7) as showing high observed 2010-2012 W126 values for these four sites. These sites can not readily be identified on this map, so these values also need to be provided in a text form.

Other Comments.

Chapter 1, Section 1.2.2: This section is a useful summary of the court’s 7/23/2013 decision (reissued 12/11/13) regarding the 2008 O₃ NAAQS rule. While this ruling upheld the 2008 primary NAAQS of 75 ppb, it did so based on an unusual interpretation of CASAC’s intent in saying a range of 60 to 70 ppb was appropriate to consider. This may have implications on how future CASAC advisory reviews are written. Although this issue is not part of the PA review, it would be helpful if EPA staff could provide some guidance to CASAC on how to avoid future perceived ambiguity in its recommendations.

On page 1-10 lines 10-14, the court’s rationale for the 0.075 ppm not being inconsistent with CASAC advice is correctly explained. However it is informative to look more closely at the detailed wording of this argument, especially since it may require the CASAC to be more explicit in future letters regarding this issue.

The court decision is summarized at:

<http://www.lawandenvironment.com/2013/07/mississippi-v-epa-support-of-the-clean-air-science-advisory-committee-is-not-necessary-to-affirm-epas-naaqs/>

The decision itself:

<http://www.lawandenvironment.com/wp-content/uploads/2013/07/08-1200-1447980.pdf>

The essence of the decision, on page 41:

“...in order for EPA to explain adequately its reasons for disagreeing with CASAC, CASAC itself must be precise about the basis for its recommendations. Because in this case CASAC failed to specify whether the 0.070 ppm level it recommended as a maximum rested on a scientific conclusion about the existence of adverse health effects at that level, EPA’s invocation of

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

scientific uncertainty and more general public health policy considerations satisfies its obligations under the statute.”

Additional excerpts from the decision relevant to CASAC follow.

Pages 38-39:

EPA did not make such a specific scientific determination about the 0.070 ppm level that served as the ceiling of CASAC’s recommendation; instead, EPA referred generally to declining certainty below 0.075 ppm. Had CASAC reached a scientific conclusion that adverse health effects were likely to occur at the 0.070 ppm level, EPA’s failure to justify its uncertainty regarding the existence of adverse health effects at this level would be unacceptable. Indeed, it is a familiar principle that agencies may not “merely recite the terms ‘substantial uncertainty’ as a justification for [their] actions”; instead, they “must explain the evidence which is available, and must offer a rational connection between the facts found and the choice made.” *State Farm*, 463 U.S. at 52 (internal quotation marks omitted). In other words, EPA must explain why the evidence on which CASAC relied cannot support the degree of confidence CASAC placed in it. This is especially true given the added layer of stringency imposed by EPA’s obligations under section 307(d)(6).

But we are unable to determine whether CASAC reached any such scientific conclusion. Although CASAC stated that “overwhelming scientific evidence” supported its recommendation that the standard be set no higher than 0.070 ppm, Mar. 2007 CASAC Letter, at 2, it never explained whether this proposal was based on its scientific judgment that adverse health effects would occur at that level or instead based on its more qualitative judgment that the range it proposed would be appropriately protective of human health with an adequate margin of safety. Indeed, although CASAC concluded that “there is no longer significant scientific uncertainty regarding [its] conclusion that the current 8-hr primary NAAQS must be lowered,” given the “large body of data clearly demonstrat[ing] adverse human health effects at the current level,” CASAC recognized that “[s]cientific uncertainty does exist with regard to the lower level of ozone exposure that would be fully-protective of human health.” Oct. 2006 CASAC Letter, at 5.

To be sure, EPA’s statutory obligation to respond to CASAC does not evaporate whenever CASAC exercises judgment amidst scientific uncertainty. Quite to the contrary, had CASAC acknowledged uncertainty in the scientific evidence but explained that, based on its expert scientific judgment, it nonetheless believed adverse health effects were likely to occur at the 0.070 ppm level, then section 307(d)(6) would have required EPA to explain why it disagreed with this scientific conclusion. Put differently, to the extent that CASAC has exercised scientific judgment, EPA must respond in kind. But because CASAC never made clear the precise basis for its

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

recommendation, all we know for certain is this: both CASAC and EPA believed the existence of adverse health effects to be certain at the 0.08 ppm level and reached differing conclusions about what level below 0.08 ppm was requisite to protect the public health with an adequate margin of safety.

[end quote]

Page 41:

Absent a definitive scientific conclusion from CASAC that adverse health effects would occur at the 0.070 ppm level, we must assume that it too took these same considerations into account and simply exercised its judgment to recommend a standard set at a lower level. Although both CASAC and EPA must exercise public health policy judgment when confronted with scientific evidence that does not direct it to a specific outcome, it is to EPA's judgment that we must defer.

And (as noted earlier):

But in order for EPA to explain adequately its reasons for disagreeing with CASAC, CASAC itself must be precise about the basis for its recommendations. Because in this case CASAC failed to specify whether the 0.070 ppm level it recommended as a maximum rested on a scientific conclusion about the existence of adverse health effects at that level, EPA's invocation of scientific uncertainty and more general public health policy considerations satisfies its obligations under the statute.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

Ed Avol

Comments, 2nd Draft Ozone Policy Assessment (PA) January 2014

(As previously noted, I regrettably cannot attend the meeting in person, so I provide some limited comments for CASAC and Staff consideration)

CHAPTER 1 INTRODUCTION

1. P1-2, line 16 and Footnote 5: not clear that this footnote or caveat are needed; there could be other reasons, including substantive technical as well as basic grammatical or textual, reasons that might lead to a request for a 2nd draft document.
2. P1-14, line 4: With all due respect, there was considerable controversy over the Administrator's recommendation of a 0.075 ppm ozone standard. One cannot "know" what the Administrator "relied" on to make his determination. It would be more appropriate (and accurate) to say that "...the Administrator *was provided* the available scientific evidence...*He subsequently* revised the level of the 8-hour primary O3 standard..."
3. P1-14, line 21: We cannot know what "The Administrator *believed*..." This should be changed to something like "In the opinion of the Administrator..."
4. P1-19, Figure 1-1: A more accurate presentation of the review of the primary standard would suggest that the **Averaging Time** box in the figure be re-worded to allow for the possibility of either a longer *or shorter* -term averaging time.
5. P1-21, lines 8-12: This is a pretty convoluted and wordy sentence, almost obscuring the message. The point here is that based on available research, there is no evidence of a biological threshold for ozone health effects (...and that's a lot shorter and more understandable sentence!).
6. P1-27, lines 21 forward: Why is so much time and effort spent in this document discussing what a former Administrator did or did not do with regard to the last review? While it's appropriate to refer to this, it seems like there is an inordinate amount of text devoted to revisiting (or arguably, attempting to re-formulate) the historical record with regard to what a former Administrator did or did not rely on to make his prior determination. The issue before the current CASAC is NOT what the prior review did or did not decide; the issue before the current CASAC is the strength of the cumulative current evidence regarding ozone exposure and protection of the public's health, and the

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

clarity and appropriateness of proposed staff recommendations to the current Administrator.

7. P1-27, line29: We do not and cannot know to what extent the Administrator *carefully considered the public comments...or to what degree he further recognized that several additional lines of evidence had progressed sufficiently since the 1997 review to provide a more complete and coherent picture...* (p1-28, lines 1-3); this phrasing should be removed. The comments and information were provided, the Administrator had access to them, and he made a determination. (This PA is not the place to justify or re-interpret previous Administrator's actions, but rather to present current data and judgments).
8. (typographical error; p1-35, line 35, "evidence")
9. P1-40, lines 25 to 34: this is a useful paragraph describing the organization of the overall document, but it is completely out of place at the end of Chapter 1. This should be moved to the first few pages of Chapter 1, prior to the Background section, and an overview sentence could be added describing the presentation in Chapter 1.

CHAPTER 2 OZONE MONITORING AND AIR QUALITY

10. P2-8, line 13: This is an important point but is awkwardly phrased. Recommend re-wording to say, "...contributes to subsequent O₃ formation further downwind."
11. P2-9, line 7: replace "high" with "elevated", so that sentence reads "...result in a higher frequency and duration of days with elevated O₃ conditions."
12. P2-9, line16: replace "high" with "higher" and "low" with "lower"
13. P2-10, lines 26 to 27: The lower rates of chemical scavenging in downwind rural areas can often result in characteristically broader, more gradual hourly ambient O₃ concentrations, rather than the more"peaky" O₃ spikes often seen in urban areas with substantive rush-hour-type combustion NO contributions. This observation helps to clarify why locations such as Lake Arrowhead downwind of Los Angeles can exhibit elevated eight-hour levels compared to surrounding reporting locations.
14. P2-11 forward, Section 2.4Background O₃: Although I appreciate the figures, depth, and discussion regarding background ozone levels, this presentation seems to conflict with the prior determination that background levels are less important, since total ozone concentrations are being used in the current document to assess risk. This section might be valuable as a supplement or Appendix, but if total ozone is the perspective and approach being used, this whole section seems overly detailed, out of scope, and a

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

diversion from keeping the presentation focused and crisp. If staff were to consider every possible question that might be asked of them and seek to develop and provide as complete an answer to every other possible question, the resulting document would be several times larger than it already is and considerably less accessible to the Reader. In my opinion, this document should focus on the approach, implications, and process put into place by the related ISA and HREA, and not delve off into addressing every possible corollary or potential derivative consideration.

CHAPTER 4 CONSIDERATION OF ALTERNATIVE PRIMARY STANDARDS

(No specific comments on specific sections)

This chapter provides a useful and carefully documented assessment of alternative primary standards for ozone. Although I personally found it wordy and a bit indirect, it does provide a comprehensive evaluation of the anticipated health implications of alternative ozone standards in the 60 to 70ppb range. The figures and tabular summaries regarding assorted health indices should be of particular utility to the Administrator in her assessment.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

Joe Brain

O3 Monitoring and Air Quality (Chapter 2): This chapter provides a description of the current O3 monitoring network and recent concentrations, information on emissions and atmospheric chemistry, common patterns and variability in O3 concentrations, as well as, discussion of current information on estimating O3 concentrations associated with non-anthropogenic sources.

1. To what extent does the Panel agree that the most relevant information on monitoring (section 2.1), emissions and atmospheric chemistry (section 2.2), and common patterns of O3 concentrations (section 2.3) is presented, and to what extent is the information presented appropriately characterized and clearly communicated?

I believe that to a great extent, the most relevant information on monitoring, emissions, atmospheric chemistry, and resulting patterns of ozone concentration are presented in Chapter 2. A great deal of information is presented concisely. Especially the figures are helpful in understanding the geographic distribution of the network and the ozone concentrations that have been measured.

A key question is not answered. How does the information collected – the geographic distribution of monitoring stations – correlate with the distribution of humans throughout the United States. It's clear that information is more densely collected in the northeast and in coastal California. We know that that makes sense. But overall, if one simply designed a system of monitoring sites that was solely based on accurately measuring exposure of as many inhabitants as possible, would it be the same or would it be different?

For example, one can imagine that the monitoring sites were selected decades ago. To what extent does the current network operating today represent recent changes in population, such as dramatic declines in Detroit and growth in Las Vegas. There should be a paragraph or so defending the network or at least explaining the extent to

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

which it resembles an ideal, unbiased network. This same discussion should be made not only in relation to all people, but in relation to more responsive populations. What's the distribution of children? What's the distribution of people with preexisting disease and/or the elderly? To what extent do these distributions resemble the current ozone monitoring network?

Ozone, as we all know, is not a primary emission from cars, trucks, factories, or other anthropogenic sources. As we know, ozone comes from two primary precursors, oxides of nitrogen and volatile organic compounds. When they combine in the presence of sunlight, ozone is produced. Carbon monoxide and methane may modulate these chemical reactions.

Shouldn't we also have a map showing the distribution of sites that monitor these precursors or perhaps a map showing the relative quantitative importance of these precursor emissions? Should we then comment on the extent to which ozone creation is produced from local sources to ones that contribute because of long distance transport mechanisms? Of course, these issues are perhaps more related to control strategies than to the focused mandate of this report.

2. With regard to information on estimating O₃ concentrations associated with nonanthropogenic sources or "background O₃" (section 2.4), to what extent is this information appropriately characterized and clearly communicated?

I am delighted at the well-developed Section 2.4, which deals with background levels of ozone and their contributions from natural sources, as well as from anthropogenic emissions outside our borders. The PRB or the NAB (North American background) is important. (There is also the USB, US background.) The text and the figures are extremely useful, and clearly demonstrate that these background levels are appreciable.

Figures 2-8 through 2-10 include the phrase "zero-out modeling." The text, especially 2-12, has a thorough discussion of the limitations of this strategy. But what approaches to dealing with this background are rational and how have they

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

been incorporated into this document? This clearly affects the magnitude of attributable outcomes to ozone and to the nature of the dose-response curves at low and realistic levels. It also calls into question pivotal clinical studies. For example, when examining the responses of exercising human chamber subjects to 60, 70, 80, or 100 ppb ozone, should their measurements be compared to 0 ppb or is it more relevant and appropriate to compare that to background ozone levels? That has rarely been done, but would clearly diminish the magnitude of the changes reported. Again, I would be interested in variability in ozone levels in these geographic areas. The hypothesis that greater variability is associated with heightened responses, even if the average values are the same, is a hypothesis worth exploring. I also think there should be more discussion of co-exposures such as ozone and PM or ozone and heat stress.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

David Chock

RESPONSE TO CHARGE TO THE CASAC OZONE REVIEW PANEL ON THE SECOND EXTERNAL REVIEW DRAFT: POLICY ASSESSMENT FOR THE REVIEW OF THE OZONE NATIONAL AMBIENT AIR QUALITY STANDARDS

CHAPTER 2: OZONE MONITORING AND AIR QUALITY

Charge questions:

1. To what extent does the Panel agree that the most relevant information on monitoring (section 2.1), emissions and atmospheric chemistry (section 2.2), and common patterns of ozone concentrations (section 2.3) is presented, and to what extent is the information presented appropriately characterized and clearly communicated?
2. With regard to information on estimating ozone concentrations associated with non-anthropogenic sources or “background ozone” (section 2.4), to what extent is this information appropriately characterized and clearly communicated?

This Chapter provides a very clear and concise picture of the monitoring network, the recent observed ozone concentration trends, both spatially and temporally, and a very brief but relevant and credible description of the emissions and atmospheric chemistry. It also provides a clear description of the different definitions of background ozone concentrations. But the most outstanding feature of the Chapter is the very clear description of the source apportionment of background and anthropogenic emissions to the seasonal mean model-estimated MDA8 concentrations. Two approaches are discussed: the zero-out approach using CMAQ and the source-apportionment approach using CAMx coupled with the source-apportionment methodology. Both models are quite comparable in stand-alone performance, but coupled with the source-apportionment approach, the latter model results are most definitely more reliable scientifically. And this is the approach used in the Chapter to present the results on fractional contributions of US background emissions to the seasonal mean MDA8 in the 12 REA urban case study areas.

In the case of W126, the EPA uses a counterfactual assumption by determining the ozone concentrations by separately zeroing out different background emissions based on the definitions of NB, NAB and USB. The procedures are more complicated but are presented in the Appendix. The resulting estimates of background fractions for different definitions of background are generally consistent with but slightly lower than those for the MDA8. This is partly due to the definition of W126 which has a higher weighting for higher ozone concentrations.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

One very minor comment: Since seasonal means have been used quite extensively, it is better to incorporate the definition of season in the text rather than leaving it in the footnote (footnote 8 on p. 2-13).

Overall, this is an outstanding chapter in terms of clarity, conciseness, and scientific credibility. The authors should be congratulated for a job well done.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

Ana Diez Roux

Chapter 3. Adequacy of the Primary Standard

1. To what extent does section 3.1 (Evidence-based Considerations) capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA? To what extent is staff's consideration of the health effects evidence, including the adversity of reported respiratory effects and public health implications technically sound and clearly communicated at an appropriate level of detail? In the Panel's view has the information been appropriately interpreted for the purpose of assessing the adequacy of the current standard?

Overall section 3.1 appropriately describes key aspects of the evidence. I found the consideration of the evidence to be technically sound, and the information appropriately interpreted for the purpose of assessing the adequacy of the current standard. My main comment is that the section would benefit from synthesis and emphasis of the most important facts relevant to assessing the adequacy of the current standard. There is also some repetition within sections (for example the section on at risks populations repeats the key message several times).

2. With regard to the presentation of the exposure and risk information for the purpose of assessing the adequacy of the current standard, to what extent is the information, including associated limitations and uncertainties, sufficiently characterized, appropriately interpreted and clearly communicated?

Section 3.2 also contains abundant repetitions from the REA and could be synthesized.

The section refers to two important issues in estimating the health impact of alternative standards:

1. It is noted that the simulations used to estimate Ozone levels under alternative standards result in spatial patterns different than those observed in the epidemiologic studies on which the health effects measures are based. This would result in different health impacts than those predicted from the epidemiologic studies if one or both of the following conditions are met (a) factors associated with space modify the effects of ozone on health or (b) spatial mobility of persons within the area is a key driver of individual-level exposures. If we are confident that the impact of these two conditions is absent or negligible then we can be confident in the expected health benefits as predicted despite the change in the spatial pattern.
2. It is noted that based on the approach used to model ozone reductions under alternative standards, ozone levels may actually rise in some areas when meeting lower overall standards. This is because of the dynamics used to model ozone reductions. It should be noted that as a consequence the

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

estimates of the health effects are not precisely the health impacts of reducing ozone to a certain level, but rather the health impact of meeting an alternative standard *through a postulated set of changes to precursors* (some of which results in reductions and some of which result in increases in ozone). This is a subtle but important difference I think. It may be useful to at least note this. Also, is the approach used to model meeting alternative standards (which results in increases in some locations but decreases in others) realistic?

Pg 3-106 lines 23-28 suggest that since approximately 30-60% of the average daytime O₃ is attributable to US anthropogenic sources, then 30-60% of total O₃- associated health risks in the urban case studies is attributable to US anthropogenic sources. I don't think this statement is accurate: if the reductions in ozone exposure necessary to eliminate or sharply reduce ozone associated health effects can be achieved through reductions in US anthropogenic sources alone, then much more than 30-60% in health effects can be attributed to anthropogenic sources.

3. In the Panel's view, does the discussion in section 3.4 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that the current evidence and exposure/risk information call into question the adequacy of the current standard and that it is appropriate to consider revising the standard to achieve additional public health protection?

Overall I thought this section was adequate but could benefit from synthesis and emphasis.

Chapter 4. Consideration of Potential Alternative Primary Standards

- 1. In the Panel's view, has the evidence and exposure/risk information, including associated limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering potential alternative standards?*

Overall I found the chapter to be very well written and to the point. The point regarding ozone serving as an indicator for a standard meant to provide protection against photochemical oxidants is well taken. The discussion regarding averaging times is focused and supported by appropriate evidence. The discussion regarding the form was also very well written. The points supporting the use of an nth highest daily maximum (as opposed to an expected exceedance or percentile-based form) were well stated, however I found the justification of the 4th highest daily max (as opposed to the nth highest) incomplete.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

The section on controlled human exposures studies is an excellent summary although it loses focus in the latter part (pg 4-10 line 19 through pg 4-11 line 6). For example it is not clear why panel studies are discussed here as they are not controlled human exposures studies. The section on page 4-11 lines 6-20 should be consistent with and avoid repetitions with pg 4-10 lines 1-18.

The approach of summarizing associations in cities meeting various alternative standards may be informative but the point of this analysis is not stated clearly and the overall conclusion is not well stated (pg 4-13). What can we conclude then from table 4-1? If studies conducted in areas that have met lower standards do not show an effect do we conclude then that the standard produces appropriate health protection? But if they do does this suggest that an even lower standard is necessary? The logic of this analysis needs to be clarified.

The subsequent section (on associations below various cutpoints) is clearer but the conclusion could also be summarized more clearly. Is the key point that a standard of 60 ppb is protective whereas a standard of 65 or 70 is not because studies for which all exposures were below 65-70 still reported associations whereas those at levels below 60 did not? I also found Table 4-2 confusing. The main point needs to be summarized. The reference to the table in the text was confusing.

The section on protection from long term exposures is well done and convincing.

Section 4.4.2.1 would benefit from a final statement of the key conclusions derived from figure 4-1 to 4-4. The same applies to section 4.4.2.2. the bullets are useful but an overall summary statement of what we can conclude from these bullets taken together would be very helpful.

Section 4.4.2.3. The reason for the large difference in the % reduction in mortality associated with meeting a standard of 70 ppb for areas with area wide concentrations > 40ppb and >60ppb is not clear (the footnote does not help clarify). This also applies to other health outcomes. Also the rationale for reporting these two particular estimates is not presented. These types of estimates are repeated later in the chapter so their meaning needs to be clarified.

I'm not sure I would characterize a 9% reduction in ozone associated mortality as a "small " change (pg 4-41 , top of page). In any case it is larger than the effect observed with a standard of 70 ppb so it is not clear why it is considered small.

The chapter also does a reasonable job of grappling and acknowledging the complex issue of uncertainties.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

Minor comment: avoid using the word mortality (a rate) when you mean total number of deaths (as in Figure 4-10).

2. *In the Panel's view, does the discussion in section 4.6 provide an appropriate and sufficient rationale, supported by the discussions in sections 4.1 through 4.4, to support staff's preliminary conclusions regarding alternative primary standards (including the indicator, level, averaging time and form) that it is appropriate to consider?*

The section provides an appropriate and sufficient rationale. Overall the section is very well organized and the arguments are laid out in a clear and compelling way. A few clarifications, particularly of the data presented, would make this an outstanding chapter.

Tables 4-4 and 4-5 are clear but I found figure 4-13 cryptic. It is not clear exactly what is shown on the Y axis. Is it the ratio of deaths attributable to ozone for alternative standards compared to the 75 ppb standard? Maybe label the x axis : total ozone attributable deaths, ozone attributable deaths at ozone levels > 20, >40 and >60.

It is difficult to follow the calculations reported on page 4-51 lines 14-21. "For days with area wide concentrations at or above 20ppb a standard with a level of 70...". Is this derived from figure 4-13? But if so isn't this the reduction in deaths attributable to ozone above 20ppb (**not** on days with area wide concentrations at or above 20 ppb??)

3. *Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?*

No additional recommendations. Overall this is an excellent chapter. The final section in particular is very well done.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

David Grantz

Second Draft Policy Assessment for the Review of the Ozone NAAQS

Chapter 5. Adequacy of the Secondary Standard.

1. To what extent does the information in sections 5.1 through 5.5 capture and appropriately characterize the key aspects of the evidence for ozone welfare effects assessed and integrated in the ISA? To what extent does the information in section 5.1 (Nature of Effects and Biologically Relevant Exposure Metric) appropriately summarize the nature of ozone welfare effects and to what extent does it appropriately characterize the evidence with regard to biologically relevant exposures?

This chapter does a nice job off summarizing evidence for welfare effects of ozone exposure. The paragraph (page 1-37, lines 4-14) provides an excellent rationale for considering the range of available studies, and how they might be assessed. Similarly, lines 30-36 on page 1-37 provide an excellent rationale for emphasis on Class I and other protected areas.

The discussion of flux based metrics is useful and appropriate, concluding that potential benefit may eventually derive from such metrics but that excessive uncertainty remains at this time. The discussion regarding reduced uncertainty associated with OTC derived C-R relationships (page 5-10; page 5-31) is appropriate and clearly presented.

The reference to EPA 2013 (page 5-13, line 5) is curious. Meta-analysis has demonstrated that reduced carbon transport to roots is a generally observed phenomenon, though exceptions exist. This sentence needs to be reviewed, for accuracy and for syntax.

2. To what extent is staff's consideration of the welfare effects evidence, including the implications of reported vegetation effects with regard to adversity to public welfare technically sound and clearly communicated at an appropriate level of detail? In the Panel's view has the information been appropriately interpreted for the purpose of assessing the adequacy of the current standard?

The linkage of ecological effects to welfare effects is clearly and appropriately explained, and in sufficient detail.

The cottonwood data (Figures 5-1 and 5-3) receive too much emphasis. These data are clearly outliers, as already noted in the text (page 5-14, line 5) and require further confirmation.

The effort to monetize welfare impacts and benefits is appropriate, though techniques for this are not yet fully developed. Specifically, calculation of consumer and producer surplus data is a useful contribution to quantification of welfare effects. The interaction of agriculture and forestry as modeled by FASOM-GHG is mentioned in both the WREA and the PA but not adequately explained.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

3. With regard to the presentation of the exposure and risk information for the purpose of assessing the adequacy of the current standard, to what extent is the information, including associated limitations and uncertainties, sufficiently characterized, appropriately interpreted and clearly communicated?

Given that a W126 of 15 ppm hr is in many cases approximately equivalent to the current standard, and that injury is clearly observed below 15 ppm hr, the chapter demonstrates that the current standard is inadequate to protect against welfare effects due to ozone.

The consideration of uncertainty (page 5-22, line 23 on) represents an appropriate level of concern and level of interpretation. A similar tone should be adopted in the WREA. However, as in the WREA, the periodic consideration of uncertainty is again accumulated and repeated later (e.g. Page 5-27). Consolidation near the end of the chapter would enhance the impact of the evidence, reduce redundancy, and substantially shorten the document.

It is unclear why the information on foliar injury in four National Wildlife Refuges (Table 5-6) did not appear in the Risk Assessment.

The discussion at the top of page 5-55, related to economic losses due to bark beetles and to fire, perpetuates the questionable discussion in the WREA, confounding association with any evidence of causation. As stated these effects do not contribute much to the assessment of risk due to ozone nor to the adequacy of the current or alternative standards.

In Table 5-8 the ranges for Normal and Dry Palmer Z indices overlap. Is this intentional?

4. In the Panel's view, does the discussion in section 5.7 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that the current evidence and exposure/risk information call into question the adequacy of the current standard and that it is appropriate to consider revising the standard to achieve additional public welfare protection?

This section can be made more concise and impactful. It clearly demonstrates that ozone induced injury may occur in areas that meet the current standard. It systematically justifies the conclusion that the form of the standard should be reconsidered, and begins to build the case for levels that should be considered.

There is a wrong word/typographical error at page 5-62, line 2, which alters the meaning.

Chapter 6. Consideration of Potential Alternative Secondary Standards.

1. In the Panel's view, has the evidence and exposure/risk information, including associated limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering levels of protection and potential alternative standards?

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

It is well justified and consistent with previous CASAC judgment, that a cumulative, non-threshold metric, such as W126 is an appropriate form for the standard. Accumulation over the 08:00 – 20:00 daytime 12 hour period is an acceptable means of generalizing across latitudes and seasons. The compromises involved in this selection are clearly explained.

It is not convincing to argue that a multi-year averaging period is superior to a single year standard. Many cultivated and un-managed species are annuals, or cultivated as annuals. Perennials including trees may compound annual effects, but the effects are inherently single year impacts. Potential differences in soil moisture do not really bear on this question, as there are many factors that vary between years. The only significant reason provided in the chapter to consider a three year average is for increased statistical stability (page 6-11, lines 14-27). This may be sufficient reason, but this should be clearly stated. If a three year averaging period is implemented, it should be at a lower level than a single year standard to protect against single unusually damaging years that will be obscured in the average.

The key issue in the PA with respect to Welfare Effects is the level of the standard. It is surprising to find the statement at page 2-20, line 17-18, that “we are not able to identify a range of appropriate W126 index values”. If protection of the most sensitive members of the community is extended to components of ecosystems that impact public welfare, then several potential levels of the standard suggest themselves. Both visibility and seedling biomass exhibit identifiable thresholds at around 10 ppm hr (though visibility is more of a slope change than a decline to low injury level) and for relative biomass loss it is closer to 7 ppm hr. Crop loss appears to be less sensitive than these other indicators from the current analysis.

There is substantial redundancy in this chapter that could be consolidated for clarity and brevity.

2. In the Panel’s view, does the discussion in section 6.5 provide an appropriate and sufficient rationale, supported by the discussions in sections 6.1 through 6.4, to support staff’s preliminary conclusions regarding alternative secondary standards (including the indicator, level, averaging time and form) that it is appropriate to consider?

Given the apparent break points around 7-10 ppm hr for various endpoints, it is difficult to understand how staff comes to suggest a standard as high as 17 ppm hr. In many cases, 15 ppm hr is nearly equivalent to the current standard, which is considered here to be inadequate to protect against ozone induced welfare effects. If uncertainty is invoked to prevent over-protection, then 15 ppm hr is the highest justifiable level for the revised standard based on the internal logic of the WREA and PA. If, as seems more likely given patchy species and spatial data coverage, the uncertainty results in potential underestimation of risk, then a lower level should be considered.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

3. Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter? None.

Daniel J. Jacob

Comments on second draft PA for ozone

Introduction (Chapter 1):

1. Does the Panel find the introductory and background material (sections 1.1 and 1.2) to be appropriately characterized and clearly communicated?

Yes. My only confusion is in the use of “We” at various points in the text. It isn’t clear to me who “We” refers to.

On page 1-9 lines 3-4, “a causal relationship between O₃ and 8-hour exposures” doesn’t seem to make sense. Probably a typo.

2. In section 1.3, we describe the general approach for the review. This includes the key aspects of the approach employed in the last review in judging the adequacy of the then-existing standards and in selecting revised standards. Does the Panel find this description of the approach in the previous review adequate and clear? Does the summary of the approach in the current review appropriately describe important considerations in this review?

It is generally fine. I only have a few concerns:

1. Page 1-38: The choice of the W126 index as metric for the secondary standard is not revisited as part of the current review. Why is it not?
2. Page 1-40: It’s not clear if the analysis of the background contribution to ozone is to have solely a scientific purpose or also a policy purpose.
3. Page 1-40, lines 22-24: the notion that background ozone does not significantly impact the W126 index has been challenged by recent work, particularly for the Intermountain West where the background is high.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

Steven Kleeberger

PA Ch. 4:

1. In Panel's view, has the evidence and exposure/risk information, including associated limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering potential alternative standards?

I believe the information has been appropriated characterized and interpreted.

2. In the Panel's view, does the discussion in section 4.6 provide an appropriate and sufficient rationale, supported by the discussions in sections 4.1 through 4.4, to support staff's preliminary conclusions regarding alternative primary standards (including the indicator, level, averaging time and form) that it is appropriate to consider?

In my opinion, the rationale and discussion that lead to preliminary conclusions are appropriate. For more clear presentation, staff may wish to consider sub-headings for the consideration of 70, 65, and 60 ppb standard levels. Conclusions (p 4-57) are clearly stated, and the rationale for not considering levels below 60 ppb are appropriate.

3. Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?

I do not have additional interpretations or conclusions to add to the chapter.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

Fred Miller

Introduction (Chapter 1): This chapter provides context for the review, including the background of past reviews, as well as the scope and approach for the current review. This includes discussion of the basis for the current standard.

1. Does the Panel find the introductory and background material (sections 1.1 and 1.2) to be appropriately characterized and clearly communicated?
2. In section 1.3, we describe the general approach for the review. This includes the key aspects of the approach employed in the last review in judging the adequacy of the then-existing standards and in selecting revised standards. Does the Panel find this description of the approach in the previous review adequate and clear? Does the summary of the approach in the current review appropriately describe important considerations in this review?

Response: The introductory and background material provides the reader with a synopsis of the evolution of the NAAQS review process for photochemical oxidants together with insights into major litigation actions that have occurred over the last 30 years. The description of the approach in the previous review is clearly presented, and the summary of the current review approach captures the salient features of the review process.

O3 Monitoring and Air Quality (Chapter 2): This chapter provides a description of the current O3 monitoring network and recent concentrations, information on emissions and atmospheric chemistry, common patterns and variability in O3 concentrations, as well as, discussion of current information on estimating O3 concentrations associated with non-anthropogenic sources.

1. To what extent does the Panel agree that the most relevant information on monitoring (section 2.1), emissions and atmospheric chemistry (section 2.2), and common patterns of O3 concentrations (section 2.3) is presented, and to what extent is the information presented appropriately characterized and clearly communicated?
2. With regard to information on estimating O3 concentrations associated with nonanthropogenic sources or “background O3” (section 2.4), to what extent is this information appropriately characterized and clearly communicated?

Response: My comments address the layout of the figures and tables in this chapter and do not address the charge questions. The authors should consider a different color scheme for some of the figures -- it is hard for the reader to sometimes discern differences (e. g., Figure 2-1). Since figures and tables should stand alone, the legends sometimes need to be expanded so the reader does not have to refer to the text to interpret the table or figure (e. g., Figure 2-2).

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

Adequacy of the Primary Standard (Chapter 3): This chapter discusses key aspects of the health effects evidence and exposure/risk information, particularly relevant to consideration of adequacy of the current primary standard and specifically describes staff's consideration of this information in reaching preliminary conclusions about the adequacy of the current standard.

1. To what extent does section 3.1 (Evidence-based Considerations) capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA? To what extent is staff's consideration of the health effects evidence, including the adversity of reported respiratory effects and public health implications technically sound and clearly communicated at an appropriate level of detail? In the Panel's view has the information been appropriately interpreted for the purpose of assessing the adequacy of the current standard?

Response: This section captures the important studies discussed in the ISA and integrates them into a logical narrative of what the important findings were in each category of effect such as lung function decrements, pulmonary inflammation, respiratory symptoms, and respiratory mortality. The adversity of the effects and their implications for public health is discussed in a straightforward and clear manner that leads the reader through the body of data that has been amassed for this ubiquitous pollutant. The level of detail used is appropriate for the task at hand. Most importantly, the studies have been appropriately interpreted and discussed in Section 3.1.3 in the context of assessing the adequacy of the current standard. Section 3.1.3 presents the discussion of adversity in a manner that one might find in a legal briefing document, which speaks to the clarity of the points raised and supported by facts brought forward from the ISA and the HREA.

On page 3-15, the statement is made that the group mean decrements in various controlled human exposure studies at 60 ppb O₃ are not consistently statistically significant. While a correct statement, the authors should add that this is due to a lack of consistency in statistical power among the studies reflecting an inadequate number of subjects in some of the studies. There are places where paragraphs are duplicated almost verbatim on the same page, such as on page 72 for the first 2 paragraphs. On page 3-81, there is a reference to Table 3-12 but no such table appears in the chapter.

2. With regard to the presentation of the exposure and risk information for the purpose of assessing the adequacy of the current standard, to what extent is the information, including associated limitations and uncertainties, sufficiently characterized, appropriately interpreted and clearly communicated?

Response: The exposure and risk information pertinent to assessing the adequacy of the current standard is presented for 3 main categories: the adjusted air quality data, exposure-based considerations, and risk-based considerations. The salient points are clearly presented, and enough detail is provided so the reader can ascertain how much weight to assign to any limitations or

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

uncertainties. Major points being made are always supported by reference to studies or data presented either earlier in this draft of the PA or in the ISA or HREA, which leads one to conclude that the points have been appropriately interpreted.

Consideration might be given to having the Y-axis on each of Figures 3-7 to 3-10 all be from 0 to 30 percent. This would allow the reader to better understand the importance of the different points that are being made in this body of figures.

3. In the Panel's view, does the discussion in section 3.4 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that the current evidence and exposure/risk information call into question the adequacy of the current standard and that it is appropriate to consider revising the standard to achieve additional public health protection?

Response: Absolutely! – Section 3.4 is a “slam dunk”. This section, which is just slightly over 5 pages in length, clearly articulates the findings and points that underpin Staff's preliminary conclusion to call into question the adequacy of the current standard and the appropriateness of revising it.

Consideration of Potential Alternative Primary Standards (Chapter 4): This chapter discusses key aspects of the health effects evidence and exposure/risk information particularly relevant to consideration of potential alternative primary standards and specifically describes staff's consideration of this information in reaching preliminary conclusions on alternative standards appropriate to consider.

1. In the Panel's view, has the evidence and exposure/risk information, including associated limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering potential alternative standards?
2. In the Panel's view, does the discussion in section 4.6 provide an appropriate and sufficient rationale, supported by the discussions in sections 4.1 through 4.4, to support staff's preliminary conclusions regarding alternative primary standards (including the indicator, level, averaging time and form) that it is appropriate to consider?
3. Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?

Response: The evidence and exposure/risk information together with an acknowledgement of the inherent limitations and uncertainties is presented in a logical manner and the data have been appropriately interpreted. The discussion in section 4.6 is well constructed and the case for considering alternative standards is articulated clearly. However, the CASAC O₃ Panel should discussion meeting the summary paragraphs for the 3 alternative levels considered by staff as the

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

arguments/discussions presented in the PA have this reviewer inclined to want to revisit the upper level of 70 ppb based upon scientific body of evidence considerations and not on any policy recommendations.

Howard S. Neufeld

Comments on Policy Assessment – 2nd Revision

Chapter 1: Introduction

1. This chapter is an excellent introduction to the history of the standard setting process and the legal challenges to previous decisions and their outcomes. It also clearly outlines the goals of the PA. This was a well-written and well organized chapter.
2. Yes and yes. I have no other substantive comments.

Chapter 2: Monitoring and Air Quality

1. The graphs and explanations of the monitoring network and trends are clearly presented. However, the graphs call the 8-hr index values “*concentrations*” which they are not. Concentration is something like ppbv, nmol/mol, or ug/m³. Ozone indices are integrations of the concentrations over time and expressed as ppb*hrs which should properly be called just “*exposure or index values*”. One should not use the term “*concentration*” on either axes or titles. This same suggestion applies to any figures using ozone (e.g., Fig. 2.5).
2. The discussion on background ozone is satisfactory and clearly explains how staff is dealing with this concept.

Chapter 3: Adequacy of the Primary Standard

1. The analysis of the ISA conclusions is well done. The particular emphasis placed on studies on the low end of ozone concentrations is commendable. Staff has done a careful and thorough analysis of respiratory effects purportedly caused by ozone. The writing is clear and understandable to the general public.
2. I thought staff did an excellent job of translating the ISA and Risk Assessment results into a statement of adequacy with regards to the current standard. Their analysis of the

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

uncertainty and variability is both thorough and complete and serves to strengthen their conclusions reached about the adequacy of the current standard.

3. As noted above, staff has properly interpreted the new scientific studies and reached a logical conclusion that the current standard is not adequately protecting human health. This chapter was one of the strongest of all in the document: well synthesized, well justified, and with appropriate conclusions drawn from the analyses. I feel, therefore, that they are justified in proposing that the current standard should be revised.

Chapter 4: Consideration of Potential Alternative Primary Standards

1. The analyses of the various standard attributes (indicator, averaging time, form, and level) are well done. The conclusions that follow are appropriately stated and thoroughly justified.
2. I agree in all respects with the conclusions in section 4.6. I think the analyses preceding this section clearly justify the proposals in this section. I found nothing with which to disagree. In particular, staff's analysis of the difficulties in setting the standard too low are much appreciated and their detailed consideration of alternative metrics are to be commended. They clearly justify why the current indicator, averaging time and form of the standard should be retained, but that the level should be lowered.
3. I have no additional recommendations here.

Chapter 5: Adequacy of the Secondary Standard

1. Staff make a strong case (perhaps stronger than in any previous reviews) both that the current secondary standard fails to protect vegetation and ecosystem services from adverse effects, and that the form of the standard is inadequate to provide such protection. Sections 5.1 through 5.5 clearly lay out the argument for the impacts of ozone on ecological processes and ecosystem services. Their descriptions and analyses of the uncertainties are refreshingly clear and unbiased. Despite the paucity of data in certain areas, staff is still able to make statements of causality and risk with which to evaluate the adequacy of the current welfare standard.
2. Staff did an excellent job regarding technical soundness and providing clarity to the public. I might note that during the risk analysis, and also here, staff compares changes in seedling

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

growth under ozone exposure to adult tree changes in circumference, expressed as percent losses. However, circumference as a surrogate for growth is somewhat questionable since growth in diameter would imply an increase in area, which is related to changes in circumference by the square (and total growth, i.e. volume, would increase by the cube). A 10% reduction in circumference would translate into a 19% reduction in trunk area. How this might affect the conclusions drawn I don't know, but it suggests that using circumference underestimates the effects.

With regard to adequately interpreting the data for the purpose of assessing the adequacy of the current standard, I am satisfied with the analyses presented and agree with staff's interpretations.

3. The uncertainties are well laid out and explained and place the interpretations into proper perspective. It appears both in this section, and in the previous chapter, that staff has gone to great lengths to justify the conclusions reached from their analyses of the ISA and REA documents as well as making sure to follow the requirements of the Clean Air Act. I was very impressed with this aspect of the current PA.
4. I agree with most of the conclusions in section 5.7. I support moving from the 8-hr standard form to the cumulative W126 index, and I agree with using the maximum 3 month interval. I think a strong case can still be made that the timing should be for an individual year, rather than averaged over three years. I am concerned about the level and at what upper limit it should be set. Most of the analyses seemed to find effects below 15 ppm*hrs (many at 10 or even 7), so it would seem reasonable to set it lower than 15 ppm*hrs, and not as high as 17 ppm*hrs. Also, in many cases 15 ppm*hrs is approximately equivalent to the current standard, so keeping it that high would engender little benefit.

Chapter 6: Consideration of Alternative Secondary Standards

1. Staff make a very strong case for switching the secondary form to the W126 and for averaging it over three months and using the highest three month interval as the metric that is evaluated. The lack of an arbitrary threshold and the higher weightings for higher ozone concentrations are the appealing aspects of this ozone metric. I also support the use of daylight hours for this metric, from 8 am to 8 pm. There could be some quibbling about whether this time interval is shifted too late in the day, and misses some uptake early in the morning, but as staff notes, ozone at low elevations rarely rises to high values before 8 am.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

However, in mountain regions, ozone is high over a 24 hour period, and as such, starting the metric at 8 am instead of 7 am or even 6 am, may miss some aspects of the exposure impacts. However, given that only one time interval can be selected, and that most areas across the country are not at high elevations, I can support using the 8 am to 8 pm interval.

2. I am less convinced that the three year average form is better than a single year form. I fully understand staff's arguments about stability but remain to be convinced that this would provide superior protection (requisite protection) given the comments from CASAC on this topic from earlier reviews. And if the increased statistical stability is that important, then the level should be reduced in order to protect the most sensitive vegetation.

There seems little justification for allowing the increased flexibility of setting the level of the W126 above 15 ppm*hrs. See comments above in the Chapter 5 section. Most of the tree data show 2% annual growth losses at up to 14 ppm*hrs. It would seem prudent to take out the statement that the Administrator could consider exposure values above 15 ppm*hrs.

3. I have no further recommendations except one: the PA document contains many redundancies, which take away from its ability to clearly transmit its message to the public. This is especially so for Chapters 5 and 6. If there is any prudent way to shorten these chapters some, I think that would improve this document.

In conclusion, I would like to commend EPA Staff for their due diligence and hard work in putting these documents together. I was much impressed by the analyses and conclusions. They represent a real step forward from the first drafts.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

Armistead (Ted) Russell

Review of the Ozone PA

Overall, I found the PA informative and providing much of the information needed to inform the Administrator in regards to potentially modifying the ozone NAAQS. It generally has a good discussion on the adequacy of the current health and welfare standards, and potential revisions. Further, the preliminary revisions are in line with the evidence provided in the ISA and the analyses in the two REAs. The current presentation, for the most part, picks a reasonable balance between the desire to make the PA readable, concise and to the point, and providing sufficient information. The greatest need has to deal with issues involving the increases in lower levels of ozone in response to controls designed to reduce higher ozone levels. This issue impacts the risk and exposure assessments and the form of the standard.

In regards to the questions:

- To what extent is the most relevant information on monitoring, emissions and chemistry, and common patterns of ozone concentrations is presented, etc.:

The current Chapter 2 is very streamlined; too much so. At present, it focusses primarily on the issues involving background ozone, which is an appropriate discussion, but there is at least one larger issue that needs to be addressed here in some detail, that being the response of lower level ozone levels to controls. As shown in the Health REA this is a very important consideration, and should be discussed in more detail in Chapter 2 as it is an important consideration in the potential form of a standard, and the possible limitations of the current form. As such, the PA should provide a discussion of how the observed ozone levels at various percentiles have been found to be evolving, e.g., the decreases in higher levels and increases in lower levels. This should be augmented with results from the modeling. The PA should provide the Administrator with a firm understanding that controls oriented at reducing the peak levels of ozone (e.g., the 4th highest annual MDA8) may not be that effective at reducing more typical levels and may actually increase ozone levels on lower ozone levels and also increase 24 hour levels on a broader range of days. Chapter 2 needs an overall summary. What are the major take-home points for the Administrator (and others) from Chapter 2?

- Is the discussion of Background Ozone appropriately characterized and adequately communicated?

The discussion of background ozone is much more extensive than any other part of the air quality characterization. None-the-less, there are some missing pieces. First, the method by which the NB is calculated (e.g., models used) should be further described. The discussion of the source apportionment model estimates is much too minimal to really understand what is being done. Provide an extra sentence or two. The sentences beginning on 2-16, line 9 going to line 14 are not

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

clear.

The potential use of monitoring should be discussed.

I would also include a bit more on the range of controversy surrounding this issue. This should be recapped later on as well. In general, however, the discussion does provide a good and reasonably thorough assessment of the “background ozone” issue on setting a standard.

Page 2-16, line 16: It is not apparent that the difference between 66 and 59 is due to the definitional approach versus the difference in model .

2-17, 121-23: What exactly does this mean? In particular, does “but for” mean if background sources were not present, there would not be an exceedance, or does it mean, if only background sources were present, there would be an exceedance?

2-9, 134: When discussing specific metrics, be very careful as to what is being said as to not be ambiguous.

2-9 | 14. I think you mean “intrusions” not “inversions”

Chapter 4: Form of the health based standard. Given the potential for controls to increase lower levels of ozone, one might consider a different form of the standard that would be protective at lowering high levels of ozone and also decreasing mid and lower levels. This should at least be discussed at a level that could lead the Administrator/reader to confidently say that the current form is appropriate. Indeed, one might come to the conclusion that another form would be better. The PA could use a synthesis as well. The Synthesis should include how the health and welfare standards might work together. Further, it could identify the critical findings that would likely drive the decision to keep or revise the standards, including the characterization of the likely benefits of various choices of the standards and the uncertainties that are key. Maybe this will be included as part of the Executive Summary in the next draft. At present, the Executive Summary is a bit too short and weak. For example, it currently uses the phrase “call in to question”, which might be stated as finds that the current standard is inadequate to protect health, and provide the specific evidence to suggest so.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

James Ultman

Chapter 3. Adequacy of the Primary Standard

- To what extent does section 3.1 (Evidence-based Considerations) capture and appropriately

characterize the key aspects of the evidence assessed and integrated in the ISA? To what extent is staff's consideration of the health effects evidence, including the adversity of reported respiratory effects and public health implications technically sound and clearly communicated at an appropriate level of detail? In the Panel's view has the information been appropriately interpreted for the purpose of assessing the adequacy of the current standard?

The chapter does an excellent job of summarizing the current evidence-based considerations of O₃ health effects and placing them in the contexts of adversity to the individual as well as public health implications.

One minor comment concerning figure 3-1 (copied from figure 5-8 in the ISA): the mode-of-action pathways do not necessarily follow from the hierarchy of the figure. For example, inflammation and cell remodeling are both placed on the second level while epithelial metaplasia appears on the third level. I would argue that the proper sequence for the metaplastic changes that have been observed in toxicological studies should be: inflammation (second level)→cell remodeling (third level)→ metaplasia (fourth level not currently on figure). As it now stands, one must read appendix 3A to better appreciate how the components on the different levels of the figure are related.

Another minor comment: page 3-13 (line 6) gives a literal interpretation of the McDonnell and the Schelegle models in terms of a specific mechanism (i.e., oxidant stress). Although this is a reasonable hypothesis, one should recognize that both models are simply two-stage mathematical constructs that include a build-up of inhaled ozone dose by continuous inhalation in competition of a reduction in biologically-effect dose by some clearance or metabolic process.

- With regard to the presentation of the exposure and risk information for the purpose of assessing the adequacy of the current standard, to what extent is the information, including associated limitations and uncertainties, sufficiently characterized, appropriately interpreted and clearly communicated?

I think that the document is effective in presenting risk reduction between recent conditions and just meeting the current standard. It is much less effective in illustrating the risk reduction

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

between the current standard and alternative standards that is possible. Use of a figure such as 6-14 or a table such as 6-7 of the second draft REA are examples of how this could be done.

- In the Panel's view, does the discussion in section 3.4 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that the current evidence and exposure/risk information call into question the adequacy of the current standard and that it is appropriate to consider revising the standard to achieve additional public health protection?

As it now stands, this discussion primarily supports the conclusion that significant reductions in risk would occur with an improvement in air quality from recent conditions to just reaching the current standard. If the current standard is to be called into question, however, then more discussion is needed concerning the predicted risk reduction between the current and more stringent standards.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

Sverre Vedal

Ozone Policy Assessment

Ch. 3. Adequacy of the current standard

Adequacy of the Primary Standard (Chapter 3)

1. To what extent does section 3.1 (Evidence-based Considerations) capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA? To what extent is staff's consideration of the health effects evidence, including the adversity of reported respiratory effects and public health implications technically sound and clearly communicated at an appropriate level of detail? In the Panel's view has the information been appropriately interpreted for the purpose of assessing the adequacy of the current standard?

- Although there is some evidence from epi studies that anti-oxidants partially protect from lung function declines due to ozone exposure (3-15), the more direct evidence from human clinical studies does not support this.
- Toxicologic morphologic changes do not provide evidence of bronchial hyperresponsiveness – these changes occur at the level of the respiratory bronchiole and alveoli, which probably does not influence larger airways effects such as those in asthma. Perhaps there is some problem with the wording or intent here (3-40, lines 28-32).
- Observations on three endpoints (and conclusions on 3-119):
 - Long-term exposure effects on lung-function: valiant attempts are made to provide evidence for this using relatively weaker studies, whereas the best study (CHS) showed no effects.
 - Short-term exposure effects on symptoms in asthmatic children: arguments to justify not considering the two multi-city (multi-site, actually) studies that find no evidence of associations. I wonder if this same effort would have been made if these were the only two studies in which evidence for associations was found?
 - New onset asthma: argument is presented as to why the lack of a confirming main effect of long-term ozone exposure in the CHS is ok in light of the interesting gene polymorphism interaction analysis.
- In “Pulmonary Structure and Function” (3-44) there is no mention of the CHS study that provides the strongest evidence against long-term exposure effects of ozone on lung function.
- Does Section 3.1.3, Adversity of Effects, really require so much exposition? It's very repetitious of earlier material.
- Is compression of the ozone distribution due to model-based air quality adjustments realistic, i.e., decreases in high ozone concentrations and increases in low concentrations? (3-86)
- It is difficult to accept, if I'm understanding this correctly, that the percentage of children

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

experiencing lung function declines is approximately the same as the percentage of children exposed (Figures 3-7 through 3-14). For example, in Atlanta, 14% of children are estimated to experience at least one exposure of concern at or above 60 ppb (Fig. 3-7) and 17% of children are estimated to experience at least one day of >10% decline in FEV1 (Fig. 3-11).

- In addition to the sensitivity of epidemiologic-based risk on C-R functions due to choice of study region, e.g., large vs. small (3-114), there was also seeming substantial sensitivity to choice of regional vs. national C-R functions.
- Missing references detected: Rojas-Martinez 2007 (3-44, line 11), Joad 2006 (3-45, line 16), NRC 2008 (3-85), US EPA 2007 (3-98).
- [Refs to check: Kim 2011 AJRCCM re: inflamm at 60 ppb, Lin EHP 2008 on first asthma admission; Fanucchi 2006 infant rhesus]

2. With regard to the presentation of the exposure and risk information for the purpose of assessing the adequacy of the current standard, to what extent is the information, including associated limitations and uncertainties, sufficiently characterized, appropriately interpreted and clearly communicated?

I found this section to be among the best sections of Chapter 3.

3. In the Panel's view, does the discussion in section 3.4 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that the current evidence and exposure/risk information call into question the adequacy of the current standard and that it is appropriate to consider revising the standard to achieve additional public health protection?

Most definitely. It's well done.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

Peter Woodbury

Review of the Second Draft Policy Assessment for Ozone

10 March 2014

[NOTE: As of 10 March 2014, I have not completed my review of this document. I include fairly comprehensive comments for Chapter 6, a number of comments for Chapter 5, and some additional comments for other chapters below and will provide more as soon as I can]

Executive Summary

Introduction (Chapter 1): This chapter provides context for the review, including the background of past reviews, as well as the scope and approach for the current review. This includes discussion of the basis for the current standard.

1. Does the Panel find the introductory and background material (sections 1.1 and 1.2) to be appropriately characterized and clearly communicated?

Yes, this material is important and the coverage is appropriate.

2. In section 1.3, we describe the general approach for the review. This includes the key aspects of the approach employed in the last review in judging the adequacy of the then-existing standards and in selecting revised standards.

Does the Panel find this description of the approach in the previous review adequate and clear?

Yes, this material is important and the coverage is appropriate.

Does the summary of the approach in the current review appropriately describe important considerations in this review?

Overall, this summary is cogent and useful. However, regarding the secondary standard, certain important conclusions are misleading and require revision. For example, on page 1-27, lines 7-10 states that the “magnitude of the response becomes increasingly uncertain”. A similar statement is made on page 1-36, lines 24-27. This is somewhat misleading. Data such as the concentration-response functions for individual tree seedling species, supported by results from other methods such as FACE and naturally occurring gradients demonstrate that some species are very sensitive to ozone and show decreased growth at very low chronic exposure levels, while other species show little response to much higher levels. A similar result is found for crop species. Thus there is strong evidence of decreased growth and yield of some common tree and crop

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

species at very low ozone levels. The more important source of uncertainty at these low levels is determining what degree of growth decrement should be considered unacceptable to protect public welfare. This issue extends throughout the PA, and the PA could be strengthened by more specifically quantifying the spatial extent and degree of impact expected at current ozone exposures, the current standard, and at the alternate standards. For example, rather than focusing on the “median RBL”, quantify the number of counties containing sensitive tree species that are expected to have growth loss of greater than 1%, 2%, etc.

O3 Monitoring and Air Quality (Chapter 2): This chapter provides a description of the current O3 monitoring network and recent concentrations, information on emissions and atmospheric chemistry, common patterns and variability in O3 concentrations, as well as, discussion of current information on estimating O3 concentrations associated with non-anthropogenic sources.

1. To what extent does the Panel agree that the most relevant information on monitoring (section 2.1), emissions and atmospheric chemistry (section 2.2), and common patterns of O3 concentrations (section 2.3) is presented, and to what extent is the information presented appropriately characterized and clearly communicated?

2. With regard to information on estimating O3 concentrations associated with non-anthropogenic sources or “background O3” (section 2.4), to what extent is this information appropriately characterized and clearly communicated?

I’m not sure how to interpret the large difference in “counterfactual” vs “source apportionment” methods for estimating backgrounds, and the results are very different for W126 (p. 2-23 and elsewhere). But I have not yet spent enough time on this topic, so perhaps it will become clearer to me as I do so.

Adequacy of the Secondary Standard (Chapter 5): This chapter discusses key aspects of the welfare effects evidence and exposure/risk information, particularly relevant to consideration of adequacy of the current secondary standard and specifically describes staff’s consideration of this information in reaching preliminary conclusions about the adequacy of the current standard.

1. To what extent does the information in sections 5.1 through 5.5 capture and appropriately characterize the key aspects of the evidence for ozone welfare effects assessed and integrated in the ISA?

To what extent does the information in section 5.1 (Nature of Effects and Biologically Relevant Exposure Metric) appropriately summarize the nature of ozone welfare effects and to what extent does it appropriately characterize the evidence with regard to biologically relevant exposures?

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

2. To what extent is staff's consideration of the welfare effects evidence, including the implications of reported vegetation effects with regard to adversity to public welfare technically sound and clearly communicated at an appropriate level of detail?

In general, the draft is appropriate and substantially improved from the previous draft, with some caveats. First, it is important to appropriately address the fact that the sensitivity of most tree species and many crop species has not been quantified in terms of a C-R function. It should not be assumed that species of unknown sensitivity are not sensitive to ozone. For example, on page 5-18, lines 28-29, discusses "if present in these specially protected areas", referring to 7 of the 12 tree species for which C-R functions are available. More appropriately, it should state that "if ozone-sensitive species are present". This may sound like a minor point about language, but I believe it is actually an important point about how to apply the available scientific data to ecosystems, and it has large implications. For example, stating that "Half (6/12) of species with known C-R functions would have growth decreases greater than 5%, and of these species are representative of responses of unmeasured species, this degree of impact would occur in [state percentage of studied locations with this level of response]. In brief, it is important not to assume that unmeasured species are not sensitive to ozone, it is much more appropriate to assume that the sensitivity of species without C-R functions might be similar to the range of sensitivity for those species with C-R functions.

In the Panel's view has the information been appropriately interpreted for the purpose of assessing the adequacy of the current standard?

Please see comments above.

3. With regard to the presentation of the exposure and risk information for the purpose of assessing the adequacy of the current standard, to what extent is the information, including associated limitations and uncertainties, sufficiently characterized, appropriately interpreted and clearly communicated?

The choice of the word "paradigm" seems odd in question on p. 5-5, but O don't have a suggestion of a better term.

Make sure not to define "adverse" effects too narrowly (p. 5-6), loss of biomass growth could be important even if the species is not harvested for timber or fiber. This topic is mentioned elsewhere, and on Page 5-12 this issue is appropriately broadened, but perhaps on p. 5-6 some mention of other effects could be made, or a reference to other locations that address these broader impacts.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

p. 5-13, line 5 delete “although”

Figure 5-1 should be improved by moving the legend to the right of the main figure panel and arranging the legend species in the same order (top to bottom) as in the main figure panel.

p. 5-14, line 16 and elsewhere. As I mentioned in comments on the previous drafts, it is difficult to interpret a “median” response for both ozone-sensitive and relatively insensitive species. Instead, it makes sense to characterize the expected impacts on the sensitive species, and quantify the spatial extent and effect on biomass growth for (1) known sensitive species (i.e., those that are shown be particularly sensitive with their C-R functions, and (2) the same result assuming that the 12 species with known C-R functions represent all tree species. A more complex scheme could be developed to try to extrapolate known species to unknown species based on physiological characteristics, as was done for crops in the FASOM analysis, but there would be substantial uncertainty in such extrapolation.

p. 5-21. I think that the “modeling regions” in Table 5-4, are the 9 large US climate regions shown in Fig. 4-6, but this should be made explicit (the term “modeling region” doesn’t seem to be defined in the text currently).

p. 5-24. As in my comments on the first draft WREA and PA, and second draft WREA (Section 6.8) I still have a question about the RBL values weighted by basal area. Does the denominator basal area in the calculation include only the 12 species with C-R functions or does it include all species? If the latter, it is biased. If the former, the interpretation will vary depending on what fraction of the basal area is for species without C-R functions. Furthermore, if the goal is to assess ozone effects on total biomass growth of a mixed-species forest, then this value is not very informative because it will overestimate impacts in mixed species forests because of not including competition between sensitive and insensitive species (see previous comments on competition). If the purpose is to assess ozone impacts on sensitive species, this value is also not informative because it underestimates impacts on sensitive species for the same reason. A comparatively small growth decline in a sensitive species (e.g. 2%) based on a seedling study may translate into a larger effect at the stand scale.

Page 5-25. The method used with FASOM for forest growth is based on individual species C-R functions, but that is only appropriate for mono-specific stands. For mixed-species stands, overall forest growth will not be affected as much as would be implied by a weighted average of the growth rates (or yield losses) from individual C-R functions. This is because of competition among species with different sensitivity to ozone. This is a serious limitation in the approach for mixed-species forests that are common in many parts of the USA.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

I still don't agree about ignoring impacts on farmers and forest owners in high ozone areas just because national assessments include winners and losers. An example of such a calculation is presented on page 5-32, line 9-12 for soybean for 2 counties in Kansas. The number of counties in which yield loss is predicted to exceed 1, 2% or 5% could be tabulated for alternative standards. See comment for Chapter 6 of the WREA related to this topic. Summaries of county-scale information could be added to Table 6-4.

p. 5-30 line 31 etc. Clarify that NCLAN covered multiple locations in the USA and multiple crops, with multiple O₃ exposure levels using consistent methods – all of these factors are very important because they mean that the results are highly valuable for national risk assessments.

Check for occurrences of “PSDI”, should be “PDSI” throughout.

p. 5-41, line 6. Change “by of” to “by”.

Figure 5-5 (page 5-48). In figure legend, provide some information about the sites.

EPA should assure that uncertainties are not suggested or implied to always weaken the case for a more stringent standard. For example, the paucity of data on ozone sensitivity of most US plant species should be considered as “anticipated” that there are a large number of unidentified sensitive species, as well as of course many less sensitive species.

Page 5-62, replace “commiserate” with “commensurate”.

Page 5-63, beginning line 31. Rephrase the sentence on line 31 to be more definite (replace “might be” with “are”).

Page 5-65, lines 20-23. Replace “likelihood and magnitude of a response become increasingly uncertain” with “magnitude of effects become smaller”. As discussed above, the evidence is very strong for tree biomass loss and crop yield loss for sensitive species at W126 values of 5-10. It is the magnitude of the effect that is smaller. And for less sensitive species, there will be little or no biomass loss at low ozone exposure values. Again the important uncertainty is determining what magnitude of an effect is important for welfare, not whether there are any effects at lower ozone exposure levels. This is an important distinction.

4. In the Panel's view, does the discussion in section 5.7 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that the current evidence and exposure/risk information call into question the adequacy of the current standard and that it is appropriate to

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

consider revising the standard to achieve additional public welfare protection?

[PETER TO DO -- Address this question]

Consideration of Potential Alternative Secondary Standards (Chapter 6): This chapter discusses key aspects of the welfare effects evidence and exposure/risk information particularly relevant to consideration of potential alternative secondary standards and specifically describes staff's consideration of this information in reaching preliminary conclusions on alternative standards appropriate to consider.

1. In the Panel's view, has the evidence and exposure/risk information, including associated limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering levels of protection and potential alternative standards?

[PETER TO DO -- Address this question]

Page 6-8, line 4-5. Change to "extremely highly correlated metrics, with Pearson correlation coefficients of 0.99".

Page 6-9, line 16-17. I don't find that this conclusion is warranted – the data support an annual time frame. There should be some compelling reason to use a multi-year time frame. Note that the proposed form already includes a 3-month period, so it is not as sensitive as an hourly or 8-hour period to extreme events.

Page 6-9, lines 18-36. As in my comments in the previous 1st draft PA, it is not appropriate to assume that the only welfare effect of crop yield loss is total producer and consumer surpluses. I think that a goal of avoiding yield losses of sensitive crops of 5% or greater for each county would be appropriate to protect welfare. Farmers growing sensitive crops in high ozone locations can be considered a "sensitive population" for welfare impacts, and their crop yields should be protected. Furthermore, I do not find any support herein for the idea that the data do not support an annual time period for yield losses in annual crops.

Page 6-12. The argument that stability of compliance is of value is stated on this page. I agree with the previous CASAC statement (lines 26-29) that if a multi-year period is chosen for stability purposes, the level of the standard should be lowered to prevent exceedences of a threshold of impact. This is a very important point as it affects the choice of a level depending on the averaging time (1 versus 3 years).

Page 6-17 and 6-18. This discussion of individual species responses to different W126 levels is very helpful and informative, as is Table 6-1. However, I think Table 6-1 could be reformatted to make it easier to read by moving much of the text into column headings, and

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

increasing the number of columns. For example “ppm-hrs” should appear at the top of the first column, under the column heading rather than be repeated on every row. And “median species” could be a column heading for both tree seedlings and crops, as could “loss”. These changes would make it easier to see the actual values in the table. Also, it is not clear to me what “varying lower” means in the table.

Page 6-24, lines 10-24. See previous comments herein and for the first draft PA regarding a question with the weighted RBL scheme.

Page 6-25, line 14. Change “great” to “greater”.

Page 6-30, lines 14-18. It would be helpful to include here and elsewhere the fraction of US forests represented by the species with C-R functions (probably using basal area) as well as the fraction of US crop area covered by the crop species with C-R functions. This helps quantify the uncertainty, which is quite different for crops and forest tree species. This information is available in the REA and could be summarized here as well.

Beginning page 6-30 line 6 and onward. While it is useful to list the various uncertainties, it would be more helpful to give some idea of how the uncertainty might affect the interpretation. I realize that this is challenging, but my concern that it is important to communicate what is known with reasonable certainty versus what is really unknown. I commend the staff for accomplishing this challenging task well in the REA in Table 7-23. There is quite a lot of certainty in estimates of biomass loss for forest tree seedling species and crop species for which C-R functions have been developed. Because several dominant crop species have C-R functions, there is a quite a lot of certainty about impacts of ozone on crop yield across most annual cropland in the USA. But it is much more uncertain to extrapolate from the 12 forest tree species to all forest tree species in the US. For uncertainty in ozone exposure, while it is true that the sparseness of rural monitors means that in many regions there is uncertainty, there are large portions of the US where monitors are dense enough, and where there are not large mountains or other features that make interpolation more difficult, such that regional estimates of ozone exposure are pretty certain, even if there are somewhat larger uncertainties for individual locations.

Page 6-39, lines 29-31. This is a non-sequitur. The difficulty in determining the degree of impact that is important for welfare is not related to the question of averaging the standard across 1 or 3 years. Also, as quoted in the PA (page 6-36, line 19), the CASAC said “averaging across years in not recommended”.

Page 6-43, line 13-14. As for the tree species, crop results should focus on both a group (such as median) response and also individual species response. This is important because

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

sensitive species such as soybean are very widespread and important crops. Also, there is little attention given in the PA and WREA to non-crop annual species. The results for annual crops can be considered as also indicators for a very large number of annual non-crop species that may have many welfare values. While I appreciate the much greater attention to effects on crop yield in this second draft compared to the first draft, I still think a bit more attention to crops is warranted given the strength of the database on crop yield response to ozone.

Page 6-43, line 35 and elsewhere. While the EPA chose to focus on 2% biomass loss for forest species, greater acknowledgement should be made that CASAC recommended 1 to 2%. This is particularly important in conjunction with the decision by EPA to focus on a 3-year rather than annual averaging time as recommended by CASAC.

Page 6-44, line 21. I think it is worth discussing the implications of focusing on sensitive tree species in addition to the existing focus on median and majority species. I think it is misleading for example on line 14-15 to say “less than 9 or 10” without including that the 2 remaining species have much higher predicted biomass losses. I am not suggesting that these sensitive species should be the primary focus, but rather including them for consideration rather than not including them, as happens with the current emphasis. As for sensitive crop species, these sensitive tree species are ecologically important and widespread. Furthermore, they may also serve as indicators for the high likelihood that there are other sensitive tree species for which C-R functions have not been developed. As an example of how information on sensitive species might be included, the human health section of this PA includes estimates of the number of not just all children, but also asthmatics for example in Table 4-45, to better represent sensitive populations.

Page 6-45, lines 21-23. I don't understand why these lines are here. The EPA has selected a range of appropriate alternate values for the standard, and it is in accord with many previous CASAC recommendations. But this sentence says that the Administrator can reasonably choose a value beyond this range. This is a very open ended statement, and I don't understand what it is based on. If the EPA staff judge that a value above 15 ppm-hrs for W126 should be considered, then the analysis throughout the WREA and the PA should include a specific value above 15 ppm-hrs so that this suggestion can be reviewed by CASAC and others.

Page 6-45 lines 24-35. This is very helpful, pointing out the implications of choosing different values for the standard among the values put forward by EPA and by CASAC.

Page 6-46, lines 3-5 and 13-14. As mentioned above for the previous page, I don't understand the suggestion of values “somewhat above”. If the EPA staff judge that a value above 15 ppm-hrs for W126 should be considered, then the analysis throughout the WREA and the PA should include a specific value above 15 ppm-hrs so that this suggestion can be reviewed by

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

CASAC and others.

Page 6-48, lines 12-13. The only support that I find in the PA for a 3-consecutive-year time frame is stability of compliance among years. As discussed in the PA and in my prior comments, CASAC specifically recommends NOT averaging across years, so I think this recommendation should be reconsidered or at least further qualified.

Page 6-48, line 18, Again I find the usage of “somewhat above” to be vague and misleading and impossible to evaluate, see comments above.

2. In the Panel’s view, does the discussion in section 6.5 provide an appropriate and sufficient rationale, supported by the discussions in sections 6.1 through 6.4, to support staff’s preliminary conclusions regarding alternative secondary standards (including the indicator, level, averaging time and form) that it is appropriate to consider?

For the most part yes, except for the issue of mentioning values “somewhat above 15 ppm-hrs (see comments above). Also, I think more attention needs to be paid to suggesting a lower value for the standard if using a 3-year rather than a 1-year averaging time.

3. Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?

Please see comments above.

03-21-14 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel on the Policy Assessment (Second Draft). These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

Ronald E. Wyzga

Introduction (Chapter 1):

Charge questions:

1. Does the Panel find the introductory and background material (sections 1.1 and 1.2) to be appropriately characterized and clearly communicated?

I believe that these sections are extremely well-written. I especially commend the Agency's intent to provide a document "written to be understandable to a broad audience". With respect to the latter, there are a few places where jargon and/or technical terms have crept in that could be clarified for a more naïve audience. For example, p. 1-7, l. 19: "certiorari", p. 1-21: "Controlled Human Exposure Studies"; p. 1-36: "OTC", which I believe refers to open-topped chambers.

In other places legal references could be placed in a footnote as they are distracting from the text; e.g, p. 1-3, ll. 24-28.

2. In section 1.3, we describe the general approach for the review. This includes the key aspects of the approach employed in the last review in judging the adequacy of the then-existing standards and in selecting revised standards. Does the Panel find this description of the approach in the previous review adequate and clear? Does the summary of the approach in the current review appropriately describe important considerations in this review?

This is well-written and provides an important introduction. A minor comment is that some of the material in section 1.3.1.2.3 is repetitious of material in section 1.2.2.