Preliminary Individual Comments on the Policy Assessment for the Review of the Ozone NAAQS (First External Review Draft, August 2012)

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September 3, 2012

Preliminary Comments, O3 Policy Assessment First ERD

Charge Question, Chapter 1: Introduction

To what extent are the ambient O3 monitoring network, spatial and temporal patterns of ambient O3 concentrations, and background O3 concentrations (section 1.3) appropriately characterized and clearly communicated?

Section 1.3 briefly summarizes the ambient monitoring network and spatial and temporal patterns of O3, and includes appropriate references to more detail. A concise description of ozone chemistry is also included. Because of the importance of background O3 concentrations in all aspects of the standard setting process, this topic is covered in more detail, again with many references to chapter 3 of the ISA.

Comments from Mr. Ed Avol

1st Draft Policy Assessment Review for O3 31Aug2012

Chapter 4 Comments

General Comments:

In my opinion, this chapter does a generally excellent job as a first draft approach to outlining the considerations and deliberations ahead in taking ISA and REA findings to the policy level. There are several incomplete sections here, some appropriately awaiting final or more evolved version of the ISA and/or REA. It is encouraging to hear that the document authors are actively seeking input from CASAC regarding several issues, including the relative importance to assign to cut-point analyses by Bell et al, or to the relative confidence of exposure-response relationships over various parts of the O3 concentration continuum. However, based on the substantial efforts invested in the presented work, there surely must be perspectives emerging or logical preferences developed for several of the questions currently posed. Staff should move forward in the second draft and develop the policy assessment based on best judgment and experience. This can and should be guided in part by solicited comments from the public and CASAC. However, the next draft should not just be a mirror image of comments received, since the experience of working through these analyses and reviewing the compendium of data should rightly provide some logical guidance in its own right.

As a smaller editing issue, the writing style of the author(s) of this chapter lends itself to long complex sentences (often four to five lines in length), containing several often loosely-related ideas. This often makes it a challenge for the reader to fully understand the message in any given sentence. Whenever possible, shorter and clearer sentences should be used to make critical points.

Specific Comments:

1. Pg4-4, line 8: "…recognizing that a zero-risk standard is not required by the CAA." While this is a technically true statement, I believe this leaves a potentially unbalanced perception with the reader, so I recommend that a sentence reminding the reader that the CAA states that standards should be set that protect the public's health with "…an adequate margin of safety…", based on the best available evidence and the judgment of the Administrator, should be included here.
2. Pg4-5, Figure 4-1: change 2nd bullet under **Averaging Time** to read "Support for a different averaging time?", since there is no restriction to considering a shorter or longer time period.

3. Pg4-7, line 22: change "As discussed above…" to "As discussed previously…" since the reference is to comments made two chapters earlier, not in the above paragraph.
4. Pg4-8,lines18-22: this sentence is too convoluted, long, and somewhat self-apparent; suggest changing it to read something like the following: "We next consider the public health implications of controlled human exposure studies reporting O3-induced lung function decrements. While it is important to consider the statistical precision of <u>group</u> mean decrements when evaluating possible effects due to O3 exposures, it is also important to consider distribution of individual responses. This is critical, since some <u>individuals</u> may experience substantively larger decrements than the group average…" (The way it is currently written, aside from being too long a sentence, it says that some individuals may have values larger than the average…but that's what makes the *average* value the average (some values are larger while some are smaller!)
5. Pg4-8, lines 26-29: Two issues here: (1) use of the word "normal" to describe healthy or age/height/gender/race-specific adjusted lung function (in other words, what is normal?); (2) this is another drawn-out overly long sentence. These longer sentence structures diminish the clarity of the message. Suggest that this be broken into two sentences, as follows: "For individuals in relatively good health, a within-day change in FEV1 of 5% or greater has generally been accepted as clinically meaningful (Dryden et al 2010, ATS 2000). Changes of 10% or more among otherwise-healthy individuals has generally been characterized as a significant and abnormal response (Dryden et al 2010, ATS 2000).
6. Pg4-8, line29: remove the phrase "In addition,", and add a comma between standard and CASAC.
7. Pg4-9, line 5 : remove the phrase "With regard to this, we note that"
8. Pg4-9, line7: rephrase this line to read "…intermittent, moderate exertion with FEV1 decrements of 10% or more ranged from 3% to ..."
9. Pg4-9, line 22: delete entire line, and begin sentence in line 22, so that it reads,"The studies reporting O3-induced FEV1 decrements were generally conducted with healthy adults; individuals in at-risk groups could experience…"
10. Pg4-9, line 31: delete phrase "we note that"
11. Pg4-10, line 1: change "which includes" to "including"
12. Pg4-10, line 5: insert a comma between "study" and "Schelegle".
13. Pg4-10, lines 7 to 8: Revise this line to read "At lower exposure concentrations, Adams (2006) and Schelegle et al (2009) reported a tendency for…"
14. Pg4-23, line 2: Two significant figures for ozone concentrations in the ppb range ("…37.51 to 47.78 ppb…") overstates and mis-represents the precision with which these values were measured or known.
15. Pg4-27, lines 15 to 17: It is true that the current state of knowledge regarding ozone-related health outcomes lags behind the current level of confidence associated with respiratory outcomes. However, the observation that a broadening range of other

endpoints (cardiovascular, neurological, reproductive, developmental, and mortality) do appear to show effects is an important one. Causal relationships with ozone exposure may not have been established at the current time for these other outcomes. Nevertheless, the accrued weight of evidence regarding of the breadth of effects on other tissue and organ systems should reasonably have relevance and bearing on judgements about the adequacy of the current standard. The statement that "…they provide little additional information to inform a judgement…" seems overly strong and possibly erroneous. In fact, this statement is contradicted in the very next paragraph, which heralds the integrated consideration of new evidence in multiple organ systems for assorted health outcomes.

16. Pg4-29, lines 26 to 35: The tone of the presentation here seems defensive and tentative. There are unquestionably important and significant implications to concluding that the current ozone standard may not be adequate to protect public health. However, following an objective review and presentation of the available scientific evidence, if a determination is made that the current standard may be inadequate, so be it. An expressed purpose of this document is to lay out policy options for the Administrator to consider, based on the ISA and REA. This should be done in a clear and unambiguous manner.
17. P4-31, lines 11 and 12: change "8-hour average" to "(8-hour average concentrations)".
18. Pg4-31, lines 34 and 35: this is an incomplete sentence; suggest deleting the word "And" that begins this sentence.
19. Pg4-40, lines7 to10: I am not convinced that the potential for serious adverse responses to O3 exposure "…is likely related to the frequency of exposures…". Controlled human exposure studies addressing the issue of repeated exposures of individuals to O3, and the phenomenon of increased toleration (diminished response to similar dose, or adaptation, as it is sometimes described) have observed large initial responses, followed by lesser subsequent effects on the "macro-scale measurement" of lung function, in some individuals. The extent, duration, and impact of "micro-scale" changes is potentially a different matter, but the point is that single exposures to individuals who have not recently been previously exposed can and do elicit dramatic responses.
20. Pg4-47, line 6: "…consideration *may* also be given…to assessing...the effects of…alternative scenarios…(on) long-term O3 exposures." Under what circumstance would such consideration NOT be given? Since alternative scenarios to provide adequate protection from short-term O3 exposures will be explored in the 2nd draft, it would seem a logical inconsistency, and a document shortcoming, to not address whether the alternative scenarios would have any effects on the levels of protection afforded for long-term O3 exposures.
21. Pg4-49, line 4: for clarity, change this sentence to read "…long-term O3 metrics, the seasonal averages…"
22. Pg4-53, lines18 to 23: This section is a bit confusing. It's clear how long-range transport (from Asia and elsewhere) of O3, or precursors to O3 reasonably could (and presumably

do) affect background O3 levels. It seems more difficult to understand how long-range transport could be interpreted as “an exceptional event”, so that air monitoring data could be excluded. Moreover, earlier in this chapter, the decision to not remove the PRB O3 levels from consideration was invoked, based partly on prior CASAC recommendations. It seems appropriate that the conduct of risk and exposure analyses at any given level of O3, or in this instance, for alternative levels below 60ppb O3, can and should be a separate exercise from apportioning sources of ambient O3. In this passage, however, it seems that there is some equivocation about how the data will be treated and whether background O3 levels are germane to the analyses.

Comments from Dr. Michelle Bell

Chapter 2: Overview of the health evidence

1. To what extent does the presentation of the evidence appropriately reflect the assessment of the evidence, including the weight of evidence conclusions, in the third draft ISA?

The policy assessment appropriately reflects the weight of evidence conclusions in the draft ISA. The assessment is not very detailed in some respects, but I found that appropriate as this document should only present summary information.

2. To what extend is the presentation of the health effects evidence, including evidence for effects following short-term (Section 2.2) and long-term (Section 2.3) O3 exposures, technically sound, appropriately balanced, clearly communicated, and presented at an appropriate level of detail?

Overall, I find this section to be technically sound, appropriately balanced, and clearly communicated. There are a few places where the text is a bit unclear and would benefit from some rewording. An example is ton page 2-4 where the text notes that the more policy-relevant studies receive special focus, but it's not clear what this means as the other text implies that the overall body of evidence was considered. This is most likely not a problem with EPA's conceptual framework, but a wording issue. The approach to present the conclusions of the previous review (Air Quality Criteria Document 2006) and focus on the evidence since that time works well. The text does give some specifics about the additional studies (e.g., additional controlled human exposure studies evaluating ozone levels of 60 or 70 ppb), which is very helpful.

3. What are the views of the Panel on the appropriateness of staff's characterization of controlled human exposures studies, in particular those studies reporting respiratory effects following exposures to O3 concentrations below the level of the current O3 standard (Section 2.2.1)

I found the current draft to work well. In particular, the level of detail with some presentation of detailed results as examples works well.

4. What are the views of the Panel on the appropriateness of staff's discussion of key issues related to the interpretation of epidemiologic study results, including confounding by co-pollutants, effect modification, lag structure, the nature of concentration-response relationships, and the potential for thresholds (Sections 2.2.1.6, 2.2.1.7, and 2.2.2)?

The overall representation of the epidemiological studies is appropriate. It is appreciated that attention is given to the evidence from diverse populations, including sensitive subpopulations. It

is useful that the text highlights that terms such as vulnerability and susceptibility are used differently by different studies. The attention to confounders correctly notes studies that examined confounding and limitations such as the interpretation of biomarker levels and recall error in diaries for respiratory symptoms. It is appreciated that in addition to mentioning the limitations, the document highlights the implications of the limitation. An example is on page 2-16 where the impact of random error on effect estimates is discussed. To the degree possible, additional text on the implication of limitations, in addition to mention of the limitations, should be provided. There are a few places where the overall impact of the studies is a bit vague (e.g., "have generally reported positive associations" – most as in 51% or the vast majority?). However, EPA must balance the length and readability with the level of detail. The current structure with references to Figures and Tables elsewhere in the report is useful. When noting that single-city studies conducted in the US typically report associations that are positive but not statistically significant (page 2-18), it would be helpful to also note that multi-city studies (often for other health outcomes) that combine single-city estimates generally find non-statistically city-specific estimates that produce statistically significant overall effects. For Figure 2-1, note the ozone metric used for these results (e.g., 10 microgm/m3 in daily ozone), and highlight which studies were meta-analyses of previously conducted studies. The mention of confounding by $PM_{2.5}$ chemical components mentions some of the challenges of this issue such as the frequency of measurement for PM. Other challenges that should be mentioned are the frequency of measurement of ozone (often warm season only), spatial heterogeneity that may differ by pollutant meaning identical exposure methods may not be appropriate for the various pollutants, and detection limits, which may differ by $PM_{2.5}$ component. There are numerous other studies that did not find evidence of confounding of ozone associations by PM total mass beyond those mentioned (e.g., page 2-29 and 2-30). It is not necessary to list all of these, but the text should highlight that many other studies with consistent evidence have been conducted. The text on effect modification by pre-existing conditions (page 2-31) is potentially a bit misleading as it implies that pre-existing conditions do not modify ozone-health associations. Rather there is suggestive evidence that such effect modification exists, but the results are not consistent across the studies and the issue has not been sufficiently studied, so there is not a scientific consensus on which pre-existing conditions are most relevant.

5. What are the views of the Panel on the appropriateness and level of detail of the staff's characterization of the public health implications of the health evidence (Section 2.4) including the discussion of adversity, population-at-risk, averting behavior, and the size of populations at-risk from O3?

Overall, this text seems appropriate. The text on averting behavior (Section 2.4.3) is a bit vague. The summary basically says that several studies show evidence of averting behavior, but the summary is not specific enough in terms of the magnitude of the averting behavior and its driver (e.g., AQI). It would be appropriate to note that there is limited research on this topic and to recognize the unknowns in this area. The text on the size of at-risk population in the U.S. is appropriate.

Comments from Dr. David Chock

RESPONSE TO CHARGE TO THE CASAC OZONE REVIEW PANEL
ON THE FIRST DRAFT OF POLICY ASSESSMENT FOR OZONE

CHAPTER 1: INTRODUCTION

Charge Question 1: To what extent are the ambient O_3 monitoring network, spatial and temporal patterns of ambient O_3 concentrations, and background O_3 concentrations (section 1.3) appropriately characterized and clearly communicated?

This Chapter contains a concise and clear description of the historical background of the ozone NAAQS, the present ozone monitoring network, emissions, ozone chemistry and ambient concentrations. It also has a more extensive and clear description of the modeled North America background ozone concentrations. There are a few minor items described below that may help further improve the clarity of the Chapter.

On p. 1-11, lines 19 – 25, it would be helpful to include a statement on the ozone atmospheric lifetime in the troposphere (a few weeks) so that both the spatial and temporal scales of ozone transport can be better appreciated.

On p. 1-13, line 28, p. 1-17, line 26, etc. there is this phrase "total O_3" that is assumed to be well understood by the readers. But "total ozone" generally refers to the amount of ozone in a vertical column extended to the top of atmosphere. It may be clearer to simply change "total ozone" to "base-case ozone."

The title of Table 1-2 should include the 95th percentile.

On p. 1-18, line 35, p. 1-20, lines 6 and 14, p. 1-21, line 11, the words "base-case" should be added for the indicated ozone concentrations for clarity.

Comments from Dr. Ana Diez Roux
Chapter 4

1. What are the views of the Panel on how this chapter characterizes and considers the available health evidence and air quality information in reaching a preliminary staff conclusion on the adequacy of the current primary O3 standard (section 4.2)?

The chapter generally does a very good job of summarizing the available evidence. The review is complete and balanced.

In several places the chapter notes that selected epidemiologic studies that were conducted in cities that would not have met the current standard provide no insight into the appropriateness of the degree of public health protection provided by the current standard (tis statement is made several times in reference to both short term and long term exposure studies). This seems an overstatement. The informativeness of these studies depends on the actual distribution and range of ozone concentrations investigated rather than on whether the standard was or was not met. To the extent that these studies allow estimation of the dose-response gradient extending into the ozone exposure distribution that would be expected <u>even if the current standard were met</u>, they do indeed provide important evidence that can be used to determine the health benefit that could be expected if the standard were lowered even further.

2. Beyond the exposure and risk analyses of air quality adjusted to simulate just meeting the current standard in the first draft REA, what range of alternative O3 levels would be appropriate for further exposure and risk analyses in the second draft Health REA? To what extent does the information presented in section 4.3.1 help inform this consideration?

The abundant evidence of important health effects below the current standard reviewed in the various documents suggests that a range of alternative standards certainly as low as 60ppb should be explored.

Ideally, any comparison of the health impact of various standards (in terms of levels, form, or averaging time) should take into consideration (1) the expected change in <u>the continuous distribution of both short-term and long exposure levels</u> for the general population as well as for selected at risk groups; and (2) the expected health consequences of the shift in this whole distribution of short term and long term exposures <u>recognizing the continuous and approximately linear relation between ozone and various health conditions</u> supported by existing evidence. This can be summarized succinctly as (a) total number of cases prevented; and (b) percent of cases prevented for various population groups.

3. What are the views of the Panel on the preliminary approaches outlined in section 4.3.2 for considering air quality information from epidemiologic studies that characterized O3-related morbidity or mortality concentration-response relationships across the entire or restricted distributions of ambient O3 concentrations? What are the views of the Panel regarding how such air quality information can appropriately be considered in the context of drawing conclusions on potential alternative standards in the second draft Policy Assessment?

Whenever possible the epidemiologic studies should be used to draw inferences regarding the shape and magnitude of the causal or likely causal relation between ozone exposures (expressed in ways that are biologically meaningful) and various health outcomes. This allows utilizing information from various studies regardless of whether the way in which ozone was assessed directly matches the form or averaging period used in the standard. The purpose is to infer the general causal relation between actual exposure levels and risk of various outcomes.

This information should be combined with information on the impact of various standards on <u>the change in the continuous distribution of ozone exposures within the population</u> (using the metrics employed in the epidemiologic studies) in order to assess the health impact of a proposed change in the standard. Once the change in the exposure distribution under a proposed standard is established, the dose response estimates from the epidemiologic studies can be used to determine the expected change in risk. This kind of approach would not require transforming or forcing the exposure metrics used in the epidemiologic studies to match the various standards that want to be compared.

Comments from Dr. W. Michael Foster

Chapter 3: Overview of Health Exposure and Risk Assessments

1. To what extent are the assessment, interpretation, and presentation of the initial results of the exposure and risk analyses clearly communicated and appropriately focused to support consideration presented in chapter 4?

   This question seems to be principally directed to critiquing the exposure and risk analyses, and is outside of my area of expertise.

   Section 3.2.2 Risk Assessment Based on Controlled Human Exposure Studies (p. 3-14) is within my expertise and this section indicates that the "the risk assessment of ozone-induced lung function decrements will be released in parallel with this first draft Policy Assessment" and thus however are not part of this draft of the Policy Assessment. Accordingly, risk assessment from controlled human exposure studies, as indicated will be fully considered in the 2nd draft Policy Assessment, a topic more in line with my expertise.

2. To what extent does the Panel feel this chapter is useful for inclusion in the Policy Assessment, given the summary of the policy-relevant findings presented in the draft Health REA?

   Necessity of Chp. 3 in the Policy Assessment, from the standpoint that text information in Policy Assessment, Chp 4 (pg. 4-32 and 4-33) relevant to the risk of numbers and % of school-age children who experience at least one 8-h average ozone exposure above each benchmark (60, 70, 80 ppb) is *completely redundant* to text information of Chp. 3 (pg.3-7). Likewise text information on back ground of all-cause mortality (section 3.2.1.1, pg. 3-11 to 3-13) is *in part redundant* to the information of Chp. 4, section 4.2.2.3 Estimates of ozone-associated mortality and morbidity, pg.4-34, specifically the text as concerns *all cause mortality* on pgs. 4-37 to 4-39. The redundant sections listed above in Chp 3 could be excluded.

Comments from Dr. H. Christopher Frey
Charge Questions on Chapter 4: Staff's Preliminary Conclusions on the Primary O3 NAAQS

1. *What are the views of the Panel on how this chapter characterizes and considers the available health evidence and air quality information in reaching a preliminary staff conclusion on the adequacy of the current primary O3 standard (section 4.2)?*

Overall, the chapter provides adequate justification for the conclusion that the current standard is not adequate, and the term 'preliminary' can be deleted throughout. However, the rationale for the way in which epidemiologic studies are evaluated with respect to whether the air quality data that was part of the studies met the current standard is not articulated. The chapter has the flavor of 'here is some information' but does not provide a framework or motivation for what is discussed. For example, explain why it would be helpful if there were epidemiologic studies with statistically significant findings for which all air quality data was at concentrations below the current standard, and for which the frequency distribution of concentrations was stochastically dominated by the frequency distribution of actual concentrations in locations that just meet or exceed the standard. These evaluations are implied to be exclusion criteria for epidemiologic studies, although in reality there is no clear statement as to the significance or relevance of whether epidemiologic studies were in cities that met current standards. Furthermore, the chapter omits discussion of the importance of these two factors: (1) the frequency of ozone levels that are below the current standard; and (2) the statistical significance of concentration-response relationships inferred from epidemiologic studies at levels below the current standard. These latter points are relevant to the robustness of using concentration-response relationships from epidemiologic studies in risk assessment. It is important to set up the discussion with motivation and a framework before getting into the details of the discussion. Otherwise, it is not clear as to the point nor as to the finding.

2. *Beyond the exposure and risk analyses of air quality adjusted to simulate just meeting the current standard in the first draft REA, what range of alternative O3 levels would be appropriate for further exposure and risk analyses in the second draft Health REA? To what extent does the information presented in section 4.3.1 help inform this consideration?*

For short term (8-hour) averages, the draft policy assessment provides a strong rationale for including O3 levels of 60 ppb and 70 ppb. There is no need for further consideration of 80 ppb. The draft policy assessment also provides an underlying empirical basis for considering short

term levels lower than 60 ppm, such as 50 ppb or 55 ppb. The information presented is helpful to informing this consideration.

A preliminary conclusion is made that there is not a need to consider a long term average for a new standard; however, the rationale for this is not clear given that there is some scientific evidence that could motivate consideration of such a standard. It is reasonable to further evaluate the empirical relationship between air quality distributions that would just meet a short-term standard and their implications for long term exposures. However, consideration should be given to quantitative analysis of the long term risks or a better rational should be given for not proceeding in this direction.

3. *What are the views of the Panel on the preliminary approaches outlined in section 4.3.2 for considering air quality information from epidemiologic studies that characterized O3-related morbidity or mortality concentration-response relationships across the entire or restricted distributions of ambient O3 concentrations? What are the views of the Panel regarding how such air quality information can appropriately be considered in the context of drawing conclusions on potential alternative standards in the second draft Policy Assessment?*

Section 4.3.2 is generally reasonable. Key factors that should be taken into when considering the relevance of epidemiologic studies to evaluate concentration-response relationships for conditions below the current standard are the extent to which these studies are based on air quality data with levels below the standard (even if the cities from which the data were obtained may not have met the current standard) and the level of confidence in the concentration-response functions for concentrations in the range of interest, especially 50 to 75 ppm.

More detailed comments related to these charge questions and on other aspects of Chapter 4 are given below.

Specific Technical Comments:

Page	Lines	Comments
4-2	20	State what was the 'then-current standard' add "of 0.08 ppb (effectively, 0.084 ppb)

4-2	21-22	This statement assumes compliance with the standard. Given that about one-third of the U.S. population lives in areas that are not in attainment of the current standard, add 'if the standard was met'.
4-3	16-25	This is a very badly written paragraph. The ideas are not necessarily interconnected. The text is too verbose, repetitive, and not well-organized. The paragraph begins with a run-on sentence. The basic ideas here seem to be: • Based on the ISA, there is no ambient concentration threshold below which O3 effects do not occur, within the range of ambient concentrations observed during the ozone season • Then something is stated about uncertainties, but the text is so badly written that the point or its relevant to the point above is unclear. The need to take uncertainties into account is not limited to concentration-response functions. Thus, the paragraph should be rewritten or the content should be moved to other appropriate locations.
4-3	33-35	For clarity, should mention and discuss that the PA is based on hazard identification from the ISA and on exposure-response and concentration-response relationships from the REA.
4-4	9	If Figure 4-1 is central to the points made in the text, then it should be mentioned much earlier in the text. If it is really just an afterthought, as implied by not citing it until the end of all text that discusses the same points, then why have it at all? The figure should be cited earlier, and the text should systematically (clearly, concisely, in a well-organized manner) address the key points that also appear in the figure.
4-5	Figure	The Form of the current standard is not accurately summarized here. The form is the three year average of the annual 4th highest daily maximum 8-hour average concentrations based on the monitor reporting the highest such concentration. Even if it is not feasible to put all of this text into the box in the figure, there should be a footnote that explains this. The text should also address this point. The actual form of the standard is critical to much of the discussion later in this chapter, and the text seems to assume that a 4th highest value in one year is the 'form,' but this is not really the case.
4-6	9	Also mention that CASAC was asked to provide input regarding reconsideration of the 2008 standard. This is discussed later in the chapter, but should be mentioned here also for completeness.
4-6	20-21	Include a summary table of the endpoints and their causal determinations
4-9	7	"with FEV1 decrements of 10% or more" would be more clear than what is written here
4-10	7-10	"reported a tendency" is vague. Are there quantitative results. Also, this sentence could be must shorter… delete "With regard to lower exposure concentrations, we note that two studies,"
4-11	2-4	This point is important to the later discussion of averaging times and levels. If there were statistically significant effects for 1-hour averages at 60 ppb, what are the implications for the associated level of 8-hr averages? Presumably, the 8-hr average would have to be significantly lower than 60 ppb to be protective

		against a 1-hour period that averages 60 ppb.
4-15	6	At what time scale did these studies 'represent' potential health impacts
4-16	3-23	The text does not provide adequate motivation for why it is either necessary or appropriate to assess 'design values' for short-term epidemiologic studies. For example, if an epidemiologic study is based on the daily maximum 8-hr concentration, and if a concentration response function can be inferred with statistical significance that extends to a range of such concentrations that are below the level of the current standard, why does it matter as to what was the 'design value' during the time period of the epidemiologic study? The short-term concentration response functions are not applied to the 'design value', they are applied to a much shorter term form of concentration. Furthermore, strictly speaking, the design value is the 3-year average of the annual fourth-highest daily maximum 8-hour ozone concentration. It is not clear from the text in the PA that the 'design value' was actually used. Rather, it is implied that merely an annual fourth-highest daily maximum 8-hour ozone concentration for one year is treated as a 'design value.' If this is the case, it is not correct. It would be more relevant to decide on the relevance of an epidemiologic study based on the frequency distribution of daily maximum 8-hour values and the proportion of such values that are below the level of the current standard. Furthermore, it would be more relevant to evaluate the confidence interval in the concentration-response relationship as a function of concentration, to determine the statistical significance of the relationships for concentrations below the level of the current standard. Merely because cities included in a study may not have or did not meet the current standard does not mean, from a scientific perspective, that the dose-response relationships inferred from such studies are irrelevant to assessing a potentially more stringent standard.
4-18	Table	For Table 4-1, and also Tables 4-2 and 4-3, please consistently include data or information regarding the following attributes of the studies: what is the unit of the lag (days), what is the averaging time (be more clear – i.e. '8-h max' is the daily maximum 8-hour concentration), what percent of the averaging periods were at levels below the current standard, and over what time period was the study (how many years, months, days, etc., and what was the start and end time of the study). Furthermore, what is the three year time period for the so-called design value given in the last column, or is this the 4th highest value for only one year (if so, for what year)?
4-19	13-26	The PA must either provide a convincing rationale for this framing of how the conditions of epidemiological data should be compared to the standard, or take a different approach (or both). From a scientific perspective, this text fails to motivate why it matters that the epidemiologic studies are based on averaging of multiple monitors whereas the form of the standard is based on the monitor recording the highest concentration? From a scientific perspective, the issue

		seems to be whether exposures at levels below or up to the standard are associated with a significant frequency and severity of adverse effect. Epidemiologic studies that are based on data from areas that did not comply with the standard may nonetheless include data for which the concentrations were below the level of the standard. Thus, a more relevant question seems to be: what is the frequency of averaging periods in the study for which the concentration was below the level of the current standard, and can a concentration-response function be inferred that is statistically significant for concentrations below the level of the current standard? These questions are not posed nor addressed in this document. Furthermore, it seems inappropriate to compare an epidemiologic study to a design value, given that the design value is based on a three year average of the annual 4th highest values reported at the highest reporting monitor. There are no epidemiological studies that use three year averaging periods and the design value as the basis for developing a design value concentration – response function.
4-19	27-30	The type of information mentioned here is more useful for evaluating the relevance of an epidemiologic study to assess health impacts at levels below the current standard – i.e. it is useful to consider what proportion of averaging periods considered in the epidemiologic study had concentrations below the level of the current standard.
4-20	Figure 4-2	The caption is not clear. "Average" of what, exactly? (the maximum 8-hr concentrations reported from two or more monitors?) The finding here seems to be that the "maximum concentration" is, on average, about 8 percent higher than the 'average concentration.'
4-21	2-8	Similar to the analysis of the relevance of epidemiologic studies for short term effects, there is not really any fundamental rationale offered here as to why the conditions of the study must be only for locations that meet the current standard. From a scientific basis, isn't it sufficient that some portion of the averaging periods covered by the epidemiologic study are at levels below the current standard? Furthermore, isn't it sufficient that the concentration-response function inferred from the epidemiologic study is statistically significant at levels below that of the current standard. The concentration-response relationships are not based on design values. Therefore, comparison to design values should be the sole basis of a criterion for excluding an epidemiologic study from consideration.
4-21	Table 4-2	See also comments on Table 4-1. What is the time period of each study? Clearly state the averaging times of each study. Clearly state the time period upon which the design value is based.
4-22	1-2	The text is very unclear as to the basis of these so-called "50th percentiles." The range mentioned in the text is the full range shown in Table 4-2. However, it is never defined or explained that these are 50th percentile values. The notion of the median appears to apply to multi-city studies but not single city studies. However, as noted above, it is never explained as to why this comparison is either necessary or relevant.

4-22	11-13	The point made here is not sufficiently proven or justified. As stated, this statement seems to be false. Just because the design value during the time period of an epidemiologic study is above the level of the current standard does not mean that the epidemiologic study does not provide information useful to assess health effects at levels below the current standard. The more relevant considerations include: what is the averaging time of the study?; what is the range of average concentrations taken into account in the study?; is the concentration-response function from the study statistically significant at levels below those of the current standard? These questions are not posed nor addressed.
4-23	1-8	This text could be more clear as to the basis of the averaging times used in the epidemiologic studies – e.g., annual averages? Quarterly averages?
4-23	11-14	The planned analysis could be useful or informative. However, in addition, the answers should be provided to the questions posed above (e.g., see comments above).
4-23	Foot-note	Incorporate the footnote into the text. This material is important.
4-24	Table 4-3	See also comments on tables 4-1 and 4-2. Include the time period and other information to be consistent with information contained in each table.
4-24	13-18	The text should address whether the lack of significance is because of small sample sizes at these concentrations.
4-25	1-6	The text should address whether the lack of significance is because of small sample sizes at these concentrations.
4-26	1-3	So what? See comments above. From a scientific perspective, isn't it more relevant as to whether a concentration-response function can be established with statistical confidence and that can be applied to assess concentrations below the standard?
4-26		There is a lot of repetition on this page
4-27	5-11	Hasn't this already been stated/summarized?
4-28	6-22	From a scientific perspective, why does it matter if the study areas for epidemiologic studies did not meet the existing standard if they include data from which effects can be inferred at levels below the current standard? From a policy perspective, do the long term effects imply the need for a long-term averaging time for a new standard?
4-29	14-16	Yes! This is a key point, and one that should be treated more prominently and thoroughly throughout this chapter.
4-29	16-21	? This contradicts the previous statement and seems incorrect. The C-R functions from epidemiologic studies can be used in REAs to assess the health effects of other standards as long as the C-R is valid and statistically significant over a range of concentrations.
4-29	26	On this and other lines, the word "preliminary" can be removed.
4-31	34-35	I strongly agree with this statement – this is a very important point. Minor comment: do not start a sentence with "And"
4-32	21-36	Please make a table – all of this information can be summarized in a table,

		which would be easier to read than this text.
4-33	4-20	Please make a table – all of this information can be summarized in a table, which would be easier to read than this text.
4-33	22-23	"the results were similar in term of numbers" is not clear. Does this mean to say that the results were similar in terms of trends? In terms of the magnitude of exposure concentrations? The latter doesn't seem correct, but is what the text seems to be saying.
4-34	19-25	Later, statements are made that this approach of estimating effects only above background won't be used, which is good. However, in summarizing the previous approach, there should be some discussion to the effect that the human body is not sensitive to the origin of the ozone molecule.
4-34	33-35	This is good.
4-35	4-21	Neither the REA nor the PA give an adequate rationale or justification for why there should be any analyses based on LML. Perhaps there is a good rationale, but it is not articulated. It should be.
4-36	3-6	While the statement here is correct, it is out of context. Also discuss that the magnitude of the estimates are similar based on both studies.
4-36	20-23	Clarify – are these estimates on an annual basis?
4-36	23-25	Explain why LML-based estimates are lower. Is this because the implicit assumption is that the LML is a threshold, and that exposures below the LML cannot produce health effects? The interpretation of the LML-based analyses is not adequately given either here or in the REA.
4-37	11-12	Yes – agree.
4-37	14-37	Please create a table with these data.
4-38	1-7	Please create a table with these data.
4-38	16-42	Please create a table with these data.
4-39	1-13	Please create a table with these data.
4-39	31-36	The key statement here, that there were 'substantial decreases,' seems too strong and out of context. The 80 ppb benchmark is, frankly, completely irrelevant, and probably should be completely dropped. Thus, if the statement is based mainly on the 80 ppb benchmark, it is not relevant. Also, this text can be shorted by 2-3 lines without loss of content.
4-40	20	For clarity, should state that this is "for each of several cities" rather than for "some cities" to make clear that "up to hundreds" is on a per city basis, not aggregated over multiple cities.
4-41		Pages 4-41 to 4-43 seem to be a good summary of the prior CASAC advice
4-44	1-3	A statement like this should be in bold, since it is a key statement of the document.
4-44	8	Suggest delete "Staff believes that" from this sentence.
4-44	20	"uncertainties persist in the health evidence" should be replaced with "there are uncertainties regarding the magnitude of health effects, but there is far less uncertainty regarding the existence and causality of these effects" or something to this effect.
4-45	4-7	It is not clear that this is a valid statement. There is evidence reviewed earlier

		in the PA that indicates that there are long term effects that may be significant to public health. Even though there may not be existing epidemiologic studies that are based on air quality in compliance with the current standard, the concentration-response functions inferred by epidemiologic studies could be used in long-term risk assessments. It is worth further discussion as to whether there is adequate evidence to support consideration of an averaging time and level related to long term effects.
4-47	1-8	The statement that "the evidence… provides no basis to focus consideration on alternative forms of the primary O_3 standard at this time" is not well justified and seems to be too strong. There can be interactions between the form, level, and averaging time when making choices about a standard. For example, a standard based on a different form might need to be based on a different level to have the same stringency as the current standard, or to be more stringent than the current standard. While it may be correct to state that review of the scientific evidence does not provide a direct basis for choosing an alternative form, it seems incorrect to state that there is 'no basis' to consider alternative forms. From the distributions of ambient concentrations, it is clear that alternative forms could lead to more or less stringent standards for a given level and averaging time. The REA could be used to assess the implications of other forms. This does not mean that it is not reasonable for staff to reach a conclusion based on judgment that there is no need to change the current form for a short-term standard, but it is not correct to make such a decision on the false premise that there is no basis to consider other forms. However, left unanswered is whether consideration should be given to a long-term standard, in which case form must be considered.
4-48	7-10	While the statement here seems to be valid to the effect that the large majority of cities and time periods considered would not have met the current standard, the relevance of this statement is not clear. See earlier comments.
4-48	17-21	It is not entirely clear that this is a valid statement. There is not sufficient discussion to justify this conclusion. There does appear to evidence of long-term effects at concentrations lower than the level of the current standard. The paragraph goes on to point out that there is some correlation between short-term average concentration reductions and long term average concentration reductions, which is useful. The plan to conduct additional air quality analysis on this point is helpful.
4-49	1	Insert "number of" before '4th highest' for clarity.
4-49	8-10	This statement is vague. What about the plan will 'provide more relevant analysis' – i.e. in what way will the planned analyses be 'more relevant'? (i.e., it will be based on plausible emission reduction strategies and take into account the nonlinear interactions in emissions and ambient O3 concentration. Therefore, it will be more realistic.
4-49	Table 4-4	I recommend that the quantities given in a table be defined in table headers, and not in the table caption. I am not really sure what these numbers are. "Average Estimated Percent Decrease in Maximum and Seasonal O3

		Concentrations with Simulation of Just Meeting the Current Standard (2006-2008) Using Quadratic Rollback." A table header over the last three columns could be defined as "Average Estimated Percent Decrease Between Current Air Quality Versus Simulation of Air Quality that Just Meetings the Standard." What is 'seasonal average' – i.e. is this May through September for each year?
4-50	2-5	While it may be true that a short-term average standard could provide protection with respect to long-term exposures, there is nonetheless a need for analysis to support this claim. Furthermore, the adequacy of long-term exposure protection needs to be assessed.
4-50	8-10	This statement as written is probably not true. While it may be true that some O3 concentrations were above those allowed by the current standard, it is also true that some O3 concentrations were below those allowed by the current standard.
4-50	29-36	It would be useful to have a table that summarizes the information given here and on p. 4-51 lines 1-22.

Have a Technical Editor Carefully Edit This Chapter

This chapter needs to be carefully reviewed by a technical editor. Although there are few problems with syntax and grammar (except for some run-on sentences), the chapter is very poorly written in many places. The text is far too verbose and repetitive, which hinders the reader in trying to figure out the key points. Unless there is some statutory requirement for the text to be written in the first person, it should not be. Furthermore, there are far too many useless passive phrases ("we note that") that simply should be deleted every time they occur. Too many times, the intro of a paragraph includes 1-4 lines of text that summarize the previous paragraph, which the reader has just read.

As one example of the amount of unnecessary verbiage, the following is from Page 4-3, lines 16 to 22:

"In considering our approach in this review, we note that using the available scientific evidence and technical information to inform conclusions on the adequacy of the current primary O_3 standard and on potential alternative standards appropriate for consideration is complicated by the recognition that no population threshold, below which it can be concluded with confidence

that O_3-related effects do not occur, can be discerned within the range of O_3 concentrations commonly observed during the O_3 season in the U.S. (US EPA, 2012a, section

22 2.5.4.4)"

- Statements are made numerous times that 'scientific evidence and technical information' are considered or inform conclusions. Please state this just once in the introductory paragraph. Do NOT repeat this throughout the body of the chapter. Once it is stated, it is understood and need not be repeated.
- "we note that" – just delete this, everywhere. It wastes the reader's time.
- This is a run-on sentence.
- The first three lines repeat points already made and should be deleted.
- We already know that this report is about the U.S., so it is not necessary to state "in the U.S."
- Just please state the scientific finding without so many unnecessary words
- The revised version of this should be:

"There is no population threshold below which O_3-related effects do not occur, based on the range of O_3 concentrations observed during the O_3 season (US EPA, 2012a, section

2.5.4.4)"

The shorter version is clear and easy to read. The finding is already made in the ISA, so it is enough to cite the ISA for anyone who wants more detail. It is not necessary to defend this statement, since it is in the ISA.

The reason for going into detail for this example is to illustrate how useless so much of the text is, and what a waste of time it creates for the reader. Given that this document was prepared for review by a panel of very busy experts, it is surprising that it was not subject to editorial review to remove unnecessary text.

Some other examples (these are examples – there are many many more occurrences of completely unnecessary text, repetition, and run-on sentences):

Page	Lines	Comment
4-1	21-22	Delete: "In considering our approach to developing preliminary conclusions regarding the primary O_3 standard, we first note that"
4-1	28-29	Delete: "Therefore, in developing preliminary conclusions in this first draft PA, we are mindful that"
4-3	26-28	Delete: "In light of the above, staff's consideration of the adequacy of the current primary O_3 standard in this first draft PA and of potential alternative standards in the second draft PA recognizes that"
4-3	31	Delete: "Therefore, in considering the evidence and information"
4-6	20-22	Delete: "In first considering the strength of the evidence, we note the weight-of-evidence conclusions in the ISA. Specifically, as discussed above (section 2.1), we note" revise next words as "The ISA concludes…"
4-7	1	Delete: "which reflect the strength of the available evidence for different health endpoints,"
4-8	1-2	Delete "In first considering controlled human exposure" and "within the context of the current O_3 standard, we note that such studies"
4-8	9-10	Delete: "In considering these studies as a whole, we note that"
4-8	18-22	Replace the unreadable run-on text: "In further considering these controlled human exposure studies of O_3-induced lung function decrements, we note that while it is important to consider the statistical precision of group mean decrements when evaluating whether reported effects are due to O_3 exposures rather than chance alone, when considering the potential public health implications of study results it is also important to consider the potential for some individuals to experience larger decrements than average" with "The statistical precision of group mean decrements are considered when evaluating whether reported effects are due to O_3 exposures rather than chance alone. It is also important to consider the potential for some individuals to experience larger decrements than average"
4-9	1-3	Replace: "In light of the above, in considering the potential for some individuals to experience potentially adverse O_3-induced lung function decrements (as defined by CASAC in the last review) following exposures to O_3 concentrations below the level of the current standard" With "Therefore,"

Comments from Dr. David Grantz

Policy Assessment

Chapter 5
Questions 1-3.
The PA summarizes accurately conclusions that have been carried forward from the ISA through the REA to this document. Leaving aside questions as to whether all this repetition is necessary (a general concern), the material is well presented and in a roughly appropriate level of detail.

Question 4.
I felt that section 5.5 wandered a bit. It is not that useful to bring up the Essential Ecological Attributes from the Young and Sanzone report without further explanation. I found the mini-conclusion at the bottom of page 5-29 to be out of place—i.e. did not really follow nor summarize the preceding material.

In contrast, the separate sections on impacts (5.5. 2-6) did review nicely the array of evidence for ozone impacts. I think the level of detail may be excessive for a policy analysis, and more effort to aggregate results could achieve a greater economy of presentation. For example, model results are presented separately, then it is noted that they are essentially incompatible for various reasons, then they are amalgamated into the conclusion that they provide coherence. This could be accomplished in fewer steps.

Section 5.6 is a classic case of "burying the lead". The key point here is that EPA has moved to a paradigm of Ecosystem Services, that is intended to capture in a more meaningful way the adverse consequences of injury and damage previously described. The discussion of the Administrator's finding that end use and location can affect a determination of adversity can be made to follow directly from the Ecosystem Services approach.

The climate change and UVB aspects are nicely and succinctly presented.

Chapter 6
Question 1.
This chapter of the PA summarizes nicely the results of the REA. The question of propagation of uncertainty is more clearly stated in the PA than in the REA. Clearly a more meaningful review will be possible when the Second Draft REA and PA become available.

Question 2.
I think it is quite important to maintain the discussion of Ecosystem Services in the PA, with as many near-quantitative conclusions as possible. This both enhances the impact of the PA and lays out a marker for later analyses.

Question 3.

Interestingly, I think that much of Chapter 5 could be condensed or eliminated in the PA, but I think that this chapter is very important here.

Chapter 7.
Question 1.
I think this section does as good a job as possible in showing that the current standard is inadequate.

Question 2.
I think this chapter lays out a near-final conclusion regarding the importance of a cumulative and weighted standard.

The utility of the 3 month exposure period is demonstrated by correlation with another arbitrary period, 6 months, but as a practical matter 3 months is appropriate. The chapter notes that most experiments are of similar duration.

The exclusion of nocturnal exposures is appropriate at this time but remains a subject for further research. The probable low level of uptake at night in most ecosystems is well described. The conclusion (bottom page 7-21) that elevated nocturnal stomatal conductance, elevated ozone, and substantial atmospheric mixing may co-occur in southern California is probably too weak. Recent research suggests that this may be a significant exposure pathway, although smaller than in daylight.

The key issue to be resolved is the level of the standard (7.3.3). The summary of previous CASAC judgments on this issue is helpful. The remainder of the section, however, does not assist the reader in determining what level might be appropriate, despite its 5 pages in length. The section reviews a considerable number of general considerations including reference to new information which is not identified, but does not point to C-R curves or their surrogates that could be used to set the level of the standard.

As a separate matter I disagree strongly with exclusion of managed (agricultural; bottom page 7-25) ecosystems from consideration. First, we know the most about them. Second, while altered management can and does mitigate ozone impacts, these management strategies are themselves potentially costly. They include hidden cultivar development costs, as genotypes are excluded from breeding programs due to ozone-reduced yields, added fertilizer costs to recover yield and potentially inadvertently to provide protection against ozone, and use of marginal lands to compensate for reduced yields on existing arable lands.

Comments from Dr. Jack Harkema

Questions 1 and 2. Overall the presentation of the evidence in this chapter appropriately reflects the ISA. The emphasis, is clearly on the respiratory health effects of O3, as it should be. The chapter, however, is quite long and the narrative could be shortened by restricting the discussion to only the key studies that contribute most to the weight-of-evidence conclusions.

If the recent paper by Devlin et al. describing cardiovascular effects of a short-term controlled exposure in human subjects (Circulation. 2012 Jul 3;126(1):104-11) is added to the revised final draft of the ISA, it will be important to highlight the results of this study in the short-term cardiovascular effects section of this chapter. The implication of this study in the determination of the weight-of-evidence conclusion (e.g., suggestive of a causal relationship or likely to be a causal relationship for short-term O3 exposures and CV effects) will need to be addressed.

Ouestion 3. As stated above, emphasis of this section of the policy assessment should be on the adverse respiratory health effects that have been well documented to occur at low concentrations of ozone (e.g., O3-induced FEV1 decrements at or below 70 ppb in the controlled human exposure studies).

Comments from Dr. Daniel J. Jacob

Response to charge questions on chapter 1 of PA-1

Chapter 1: Introduction

1. To what extent are the ambient O3 monitoring network, spatial and temporal patterns of ambient O3 concentrations, and background O3 concentrations (section 1.3) appropriately characterized and clearly communicated?

There are some weaknesses in section 1.3 that I feel should be corrected. Itemized comments are below.

1. Page 10, lines 9-10: methane is a VOC.
2. Page 10, lines 15-17: the text doesn't do justice to the dominance of biogenic emissions as VOC sources over almost all of the US during the ozone season.
3. Page 10, lines 18-22: the statement that "distinction between natural and anthropogenic sources is often unclear" is unnecessarily muddling. The distinction is clear enough, and whether fires and vegetation sources are natural or not seems like a fine point. No need to breed confusion.
4. Page 10, line 24: "varying directly" is vague. How about simply saying that "The dependence of ozone on the emissions of its precursors is complicated and highly non-linear".
5. Page 10, line 30: not clear what "local valleys" refers to.
6. Page 11, lines 3-4: "increases of ozone to fill in the local valleys of low ozone". This is weird and seems wrong. I actually don't understand what it says.
7. Page 11, lines 4-6: text doesn't do justice to the fact that ozone production over most of the US during the ozone season is NOx-limited.
8. Page 11, line 22: replace "international/long-range" by "international and hemispheric"
9. Page 12, lines 6-9: this doesn't actually say anything about seasonal variability.
10. Page 13, line 4: I think that more discussion is needed of ozone levels at high-elevation sites, considering that they're so important when considering revisions of the NAAQS and the reader might not understand why ozone levels are so high there. Save for exceptional events this is not due to stratospheric intrusions, but simply to the increase in the ozone background with altitude due to increasing ozone lifetime (drier air) and lack of contact with the surface. In the same vein, it should be explained that ozone in the mid-latitudes background atmosphere (cf. ozonesondes) peaks in spring and is low in summer. In my experience this is not well understood by AQ managers but it is well understood by the global atmospheric chemistry community (cf. Monks Atm. Env. 2000 review).
11. Page 13, lines 6-9: I think that the text doesn't do justice to the fact that much of the NAAQS exceedences are in rural areas. In this overview of air quality concentrations I would expect more discussion of where/when the NAAQS is exceeded.

12. Page 14, line 7: Calculations of the NB as in Zhang et al. 2011 use pre-industrial levels of methane. This is a very important point since anthropogenic methane adds about 5 ppb to ozone.
13. Page 14, lines 13-14: this paragraph doesn't do justice to the low variability of the ozone background. One gets the impression from this paragraph that background ozone is largely an episodic phenomenon that could be addressed in part by the Exceptional Events Rule. In fact background ozone has remarkable uniformity. Except at high-elevation sites, it is extremely rare to see an ozone event associated with STE or intercontinental pollution.
14. Page 15, lines 21-22: model calculations of background do not express their results as contributions to ozone. This would be ill-posed for such a nonlinear problem.
15. Page 15, line 23: The text should point out a major weakness of models which is the inability to simulate high extrema in background (Zhang et al., AE 2011; Macdonald-Buller et al., EST 2011). This inability reflects numerical diffusion in a variable flow (Rastigeyev et al., JGR 2009) and cannot readily be fixed by increasing model resolution.
16. Page 15, line 35: there are a number of discernible differences between GEOS-Chem and CAMx including chemical mechanism, natural emissions, deposition…
17. Page 16, line 27: intercontinental pollution AND ANTHROPOGENIC METHANE.
18. Page 16, lines 28-30: again, the fundamental reason why the ozone background increases with altitude is because of the longer ozone lifetime and the lack of contact with the surface (deposition).
19. Page 16, lines 31-33: the mean ozone enhancement from Canada+Mexico pollution in that GEOS-Chem simulation is actually 3 ppb (see Figure 3-10 and page 3-62 of the 3rd draft ISA).
20. Page 17, lines 4-20: A lot of space is devoted to the effect of fires on the ozone background. I think that this is way overrated, although I can't deny that it is in the literature. But there are also a number of papers pointing out that fire plumes don't produce significant ozone (Singh et al., AE 2010; Alvarado et al., JGR 2010). It appears that models overestimate ozone production in fires, in part because they don't account for the fast conversion of NOx to PAN (Alvarado et al., JGR 2010) or for absorption of solar radiation in the concentrated smoke plume. Our ongoing analysis of the CASTNet data finds that fires make little contribution to ozone in the intermountain west and argues against the Jaffe et al. (2008) results. I know that the PA has to go with the published literature; but I would warn against overemphasizing the fires, as the current draft does.

Comments from Dr. Fred Miller

Chapter 4. Preliminary Staff Conclusions Regarding the Primary O_3 NAAQS

Pre-Meeting General Comments

This chapter is extremely well written, and the logic of the conclusions reached is very well documented. The organization of the chapter leads the reader by first asking a question, then providing the evidence from the ISA for the specific health endpoint being linked to O_3 exposure, and ending with the results of the exposure and risk assessment analyses for the endpoints being discussed.

This reviewer does not agree with the interpretation that the staff have taken relative to the suggestion by CASAC during the previous NAAQS review cycle where they state starting on page 4-34 "In taking this approach, the REA noted CASAC members, who recommended in the last review that EPA move away from using background in calculating risks (Henderson, 2007)". This reviewer believes staff misinterpreted CASAC's advice. The full paragraph from the Henderson (2007) memo is stated below.

> Finally, with respect to policy-relevant background (PRB), the Ozone Panel wishes to point out that the Final Ozone Staff Paper does not provide a sufficient base of evidence from the peer-reviewed literature to suggest that the current approach to determining a PRB is the best method to make this estimation. One reason is that part of the PRB is not controllable by EPA. It would require international cooperation beyond the bounds of North America. A better scientific understanding of the PRB and its relationship to intercontinental transport of air pollutants could serve as the basis for a more concerted effort to control its growth and preserve the gains in air quality achieved by control efforts within the U.S. In any case, there is no apparent need to define PRP in the context of establishing a health-based (primary) ozone NAAQS. The effects of inhaled ozone on decreases in respiratory function have been seen in healthy children exposed to ozone within ambient air mixtures in summer camps (1–6). Furthermore, the concentration-response functions above 40 ppb are either linear, or indistinguishable from linear. Thus, PRB is irrelevant to the discussion of where along the concentration-response function a NAAQS with an 8-hour averaging time that provides enhanced public health protection should be.

What CASAC was conveying was concerns about the state of knowledge of PRB levels at that time and that selecting the range to consider for setting the O_3 NAAQS based on the scientific evidence for health effects did not need to have the PRB level enter into the process. However, from a science policy and risk management judgment perspective, the Administrator must be made aware of the portion of the total risk for a given health endpoint that exists over which EPA regulatory action would not have any control – namely the portion of total risk from zero to the policy background level in order that she/he can execute their responsibilities under the Clean Air Act to set primary NAAQS that are neither more nor less stringent than necessary to protect public health with an adequate margin of safety.

Since the last review cycle, a great deal more of information about background levels of O_3 excluding anthropogenic sources has become available from a combination of measurements and atmospheric models. Moreover, there is a better understanding of how these levels vary during seasons of the year in different geographical regions. This translates into increased confidence in the Agency being able to incorporate adequately region specific background levels into their risk assessments and account for different cities in epidemiology studies having different background O_3 levels and, therefore, different reductions in risk values when considering alternative standard levels. Failure to do such invites litigation against the Administrator and the Agency.

Pre-Meeting Specific Comments

Page	**Comment**
4-3, 16	In light of the McDonnell et al. (2012) paper establishing a threshold for FEV_1 changes, this paragraph will need to be changed for the 2nd draft PA document. For this health endpoint, individual thresholds can be determined, which implies a population threshold can be found.
Figure 4-1	The last box in this figure should be modified to include "with an adequate margin of safety".
4-17, Footnote 7	This reviewer recommends that staff implement the analysis described in this footnote that could be done for the 2nd draft of the PA document.
4-26, Footnote 14	In addition to data density, the centrality of the data mean value also influences where the confidence limits widen.
4-40, 11	If there are currently no data to characterize the occurrence of repeated exposures above benchmark concentrations, why do staff indicate they will use such data if they become available. Do they know of such a study?
4-47, 3	This sentence conveys that the evidence continues to support the current O_3 indicator and provides no basis to focus consideration on alternative forms of the primary O_3 standard at this time. This reviewer has not seen any information in the ISA, HREA or PA documents that would prove that the statistical form of the standard does not need to be reevaluated. If one moves to lower levels for the primary standard, the statistical form (annual 4th highest daily maximum 8-hr concentration averaged over 3 years) should be re-examined to assess its robustness and sensitivity.

Comments from Dr. Howard Neufeld

August 30, 2012

Chapter 1: Introduction

1. To what extent are the ambient O3 monitoring network, spatial and temporal patterns of ambient O3 concentrations, and background O3 concentrations (section 1.3) appropriately characterized and clearly communicated?

This chapter is done well. I have no suggestions that would improve it.

Chapter 5: Consideration of the Welfare Evidence

1. To what extent does the presentation of the evidence appropriately reflect the assessment of the evidence, including the weight-of-evidence conclusions, in the third draft ISA?

I believe the PA does a good job of presenting the evidence.

2. To what extent is the presentation of the evidence related to mechanisms governing plant response to O3 (section 5.2) and on O3-related effects on vegetation (section 5.3) technically sound, appropriately balanced, clearly communicated, and presented at an appropriate level of detail?

The summaries of the topics in this question are all adequately presented, and with enough detail. When there are conflicting responses, they are discussed in a balanced manner. There were no technical problems that I saw.

3. What are the views of the Panel on the appropriateness of staff's discussions and conclusions on biologically relevant exposure metrics and staff's focus of the W126 form (section 5.4)?

The focus on the W126 is merited, and this should be the metric used. It is time to set a standard that makes biological sense.

4. While recognizing the lack of quantitative information on O3-related ecosystem effects, what are the Panel's views on the appropriateness of how this topic is addressed (section 5.5)?

Given the lack of data, I think the EPA did a good job of assessing the impacts and risks.

5. What are the views of the Panel on the considerations regarding adversity in the public welfare context as discussed in section 5.6?

This is a particularly well thought out and written section. The distinction between "injury" and "damage" is enlightening and the later section on expanding adverse effects to ecosystem level services is well described. I thought this section was most illuminating.

6. What are the views of the Panel on the considerations regarding other welfare effects as briefly summarized in section 5.7?

This section is done well. No major comments.

Chapter 6: Consideration of the Welfare Exposure and Risk Assessments

1. To what extent are the assessment, interpretation, and presentation of the initial results of the exposure and risk analyses clearly communicated and appropriately focused to support considerations presented in chapter 7?

This chapter is well written. The procedures for generating the response curves were well explained, and the rationale seems justified.

2. What are the views of the Panel on the appropriateness and usefulness of including a qualitative discussion of potential O3-related impacts on ecosystem services in this document?

Given the lack of quantitative data, I think it better to attempt qualitative analyses than to do nothing at all. We don't always have to have a mathematical relationship to discern that a pollutant is causing harm, and we don't always need a quantitative analysis to set some level of risk either. So this approach seems just fine with me.

3. To what extent does the Panel feel that this chapter is useful for inclusion in the Policy Assessment, given the summary of the policy-relevant findings presented in the draft Welfare REA?

I think it should be included, even if somewhat redundant. If this is a new approach, then reiterating it in several places is probably warranted.

Chapter 7: Staff's Preliminary Conclusions on the Secondary O3 NAAQS

1. What are the views of the Panel on how this chapter characterizes and considers the currently available vegetation evidence and the exposure and risk information from the first draft Welfare REA in reaching preliminary staff conclusions on the adequacy and appropriateness of the current secondary O3 standard (section 7.2)?

This is a well written chapter, and the conclusions draw logically from the conclusions in the Welfare REA. The justification for switching from an 8 hr average exposure index to a cumulative, weighted index (W126) is strong, and based on the evidence in the ISA and conclusions reached in the Welfare REA.

2. What are the views of the Panel on the elements and range of levels of a cumulative, seasonal standard identified in section 7.3 that would be appropriate for further analyses in the second draft Welfare REA? To what extent does the information presented in this section help inform this consideration?

The PA does a good job of justifying the range of levels for the secondary standard in order to adequately protect welfare attributes. The concise summaries and conclusions make this chapter easy to read and comprehend, and clearly establish a link between the scientific results and the policy recommendations.

Comments from Dr. Armistead (Ted) Russell

Review of Ozone PA 1st Draft.
I suspect that it is planned that the PA will have an Executive Summary and an Integrative Summary. The Integrative Summary should go in to detail about the relationship between the primary and secondary standards
Chapter 1:

1. The current organization of Chapter 1 does not make sense as an "Introduction." The section on O3 monitoring and air quality dominate. I would pull all of Section 1.3 and make that its own chapter. Note, even after that is done, the section on background levels dominate. While background is important, it is not balanced, and if it is going to have so much detail, the other parts of the PA should demonstrate how this detail is being used. In the new air quality chapter, additional details on observed ozone levels, distributions, trends, and responses to controls, are needed.
2. The new air quality chapter will need to provide information relevant to the form of the standard, e.g., fourth highest 8-hr MDA and an integrated metric for the secondary standard, and the current sections do not do this well.

Minor issues:
1-8, line 24 "se"?
1-10, l1: Should bring up the issue of high wintertime ozone now being found in some locations.
1-12, l3… I would suggest that ozone concentrations in many rural areas have a MUCH less pronounced afternoon peak… and may not have much of an afternoon peak at all depending upon transport considerations.
Chapter 4
You can tell this is a work in progress.

1. While
2. I would still have liked to see more of a scientific assessment of the rollback model that will be used in the REA. BenMAP and APEX will use some modeling results (or a fusion of data and various models). The ISA should assess the inputs to that modeling.

Minor issues:
4-22, line 26 Do you mean "median annual mean MDA 8-hr… "?
4-24, to- 4-26: Thanks for this nice analysis. It would be nice to take this a bit further to help assess uncertainty in response at low levels of the MDA 8-hr.
4-31, l14. Given your earlier discussion about uncertainty, where you note that some of the results were least uncertain at the middle levels, if there is less uncertainty at the higher levels. As written, it ultimately works, but at first it seems to contradict earlier discussions. You might want to be more clear about what is meant here.
4-31, l34. Sentence begins with "And" is awkward.
4-35, l18-21. It is worth explaining why the two approaches (down to zero vs. down to LML) are a reasonable bound.
4-36, l8-12. You might want to explain how a smaller % of total mortality (Bell et al.., study) corresponds to a higher number of O3-attributable deaths.
4-36, l21-29. You might want to use a table here.

4-49, l5-8. This result is tied to the use of the rollback method that does not have increases in the lowest ozone levels when controls are simulated.
4-53, l17-23. First, this is a long sentence, but more importantly, showing an exceptional event can be an arduous task, and if the high background just contributes to the exceedance, but is not the sole cause, how does this play in? The current sentence needs to be expanded to be more comprehensive about how extreme events would impact the "consideration of this information."

Comments from Dr. Helen Suh

Response to Charge Questions for Ozone Policy Assessment

Helen H. Suh

August 31, 2012

Chapter 3: Overview of Health Exposure and Risk Assessments

1. *To what extent are the assessment, interpretation, and presentation of the initial results of the exposure and risk analyses clearly communicated and appropriately focused to support considerations presented in chapter 4?*

The initial results of the exposure and risk analyses are clearly presented and summarized. The major findings and results from the ISA and the first draft REA are brought forward appropriately and are useful for considerations made in Chapter 4. Chapter 3, however, is really just a summary of findings and contains little in the way of interpretation of the REA results and how they pertain to considerations of level, averaging time, and form for the PA. Perhaps this is due to the fact that much of this interpretation follows in the next Chapter or that the draft does not incorporate results from the second draft REA. It is hopeful that later drafts of the PA will provide further interpretation (also see comments below to Question 2).

Other comments:

- Section 3.1.2, lines 15-16: The results were presented not only for school aged children but also the general population and asthmatic children.
- Section 3.8, lines 8-15: The sentences beginning with "When air quality was adjusted to simulate…" should be deleted. Earlier discussions in the PA as well in the REA stated that the APEX model is not proficient at modeling activity patterns that lead to repeated high ozone exposures, calling into question the validity of the repeated exposure estimates (See Page 3-6, lines 20-26). Thus, the observed estimates of repeated high ozone exposures should have no bearing exposure or risk assessments.
- Page 3-8, lines 17-18: "For some health endpoints, there is sufficient scientific evidence and information available to support the development of quantitative estimates of O3-related health risks." Although discussed in the REA, it would be helpful to redefine "sufficient" (e.g., was it based solely on the causality determinations?).
- Page 3-14, lines 6-19: The section discussing sources of variability and uncertainty is simply a listing of identified key sources and does not convey

relative importance of the various sources and if and how they affect risk estimates and subsequent policy assessments. For example, it may be useful to discuss how these variability and uncertainty sources may explain observed differences in the findings between cities or between studies (e.g., Zanobetti and Schwartz (2008) and Bell et al. (2004)).

2. *To what extent does the Panel feel that this chapter is useful for inclusion in the Policy Assessment, given the summary of the policy-relevant findings presented in the draft Health REA?*

The chapter does a good job of summarizing the material from the first draft REA, which was useful as a reminder to the reader. However, much of the summary is again included in the subsequent Chapter 4, which suggests that either Chapter 3 should be expanded to provide additional interpretation, that summaries included in Chapter 4 should be removed and replaced with references to Chapter 3, or that Chapter 3 should be deleted in favor of a larger Chapter 4.

Comments from Dr. James Ultman

Chapter 3. Assessment of O_3-Related Exposures and Risks

CHARGE QUESTION

1. To what extent are the assessment, interpretation, and presentation of the initial results of the exposure and risk analyses clearly communicated and appropriately focused to support considerations presented in chapter 4?

2. To what extent does the Panel feel that this chapter is useful for inclusion in the Policy Assessment, given the summary of the policy-relevant findings presented in the draft Health REA?

COMMENTS

1. This chapter provides a clear summary of the methodology and results of the exposure and epidemiologically-based risk assessments carried out in the first draft REA. It also indicates what additional assessments will be available in the next draft of the PA. I suggest two areas where improvements could be made:

- The use of flow diagrams as an aid in explaining the risk assessment methodology (e.g. a simplified form of figures 3-1 and 3-2 currently in the REA). Often the interactions between various inputs, outputs and processes are more evident from a figure than from the text.
- The use of simple tables in chapter 3 (as well as chapter 4) to present results of the risk assessments. It is usually easier to compare numerical results that appear side-by-side in a table than from the text. For example, the eight bullet items on page 3.7 and 3.8 could be replaced by a single table that might also contain corresponding results on asthmatic children.

2. This chapter provides a useful review of the methodology used for the risk assessments. There is, however, unnecessary redundancy between chapters 3 and 4 in stating the results of the risk assessments. For example, the eight bullet items on page 3-7 and 3-8 are the same as those on pages 4-32 and 4-33. I think it would be more logical to remove the “Key Observations” sections from chapter 3 and leave them in the “Exposure- and Risk-Based Consideration” section in chapter 4.

Comments from Dr. Peter Woodbury

Chapter 1: Introduction.

Comments for specific page and line numbers:

Page 1-11, lines 4. Change word "valley" to clarify meaning of low ozone area not topographical feature.

Chapter 5: Consideration of the Welfare Evidence

1. *To what extent does the presentation of the evidence appropriately reflect the assessment of the evidence, including the weight-of-evidence conclusions, in the third draft ISA?*

There is much good material in this chapter that reflects the ISA. However, the next draft should distinguish what is well known from what is not well known. While there is a lot that is not known about ozone effects on vegetation, there is also a lot that is known, and particularly in this document it is critical to distinguish what is well known from what is less well known. See detailed comments below for specific examples of both misleadingly vague language and good, clear language.

2. *To what extent is the presentation of the evidence related to mechanisms governing plant response to O_3 (section 5.2) and on O_3-related effects on vegetation (section 5.3) technically sound, appropriately balanced, clearly communicated, and presented at an appropriate level of detail?*

In general, this information is appropriate, but see specific comments below, and general comment above that more effort is required to clarify what is well known from what is not well known.

3. *What are the views of the Panel on the appropriateness of staff's discussions and conclusions on biologically relevant exposure metrics and staff's focus of the W126 form (section 5.4)?*

In general, this section is appropriate, but see specific comments below for suggested improvements.

4. *While recognizing the lack of quantitative information on O_3-related ecosystem effects, what are the Panel's views on the appropriateness of how this topic is addressed (section 5.5)?*

In general, this section is appropriate, but see specific comments below for suggested improvements. Note that some of the modeling studies cited do provide quantitative estimates of some effects at ecosystem scales.

5. *What are the views of the Panel on the considerations regarding adversity in the public welfare context as discussed in section 5.6?*

This section is helpful and should be retained. However, for this and other sections, consideration should be given to emphasizing information relevant to the conclusions of the document.

6. *What are the views of the Panel on the considerations regarding other welfare effects as briefly summarized in section 5.7?*

This section is helpful and should be retained. However, for this and other sections, consideration should be given to emphasizing information relevant to the conclusions of the document.

Comments for specific page and line numbers:

Page 5-1, lines 3-6. This chapter should focus on summarizing the whole body of knowledge of welfare effects, with an emphasis on new information.

Page 5-8, line 6. What is “salic” ? Salicylic?

Page 5-8, line 24. Spell out all abbreviations on their first occurrence e.g. “ROS”.

Page 5-13, line 2. Spell out all abbreviations on their first occurrence e.g. “OTC”.

Page 5-13, line 30. Change to “biomass energy”.

Page 5-15, para 2. Effects on soybean yield should be summarized here and in the WREA should be analyzed at the same level of detail as currently provided for individual tree species. See also comments for Chapters 6 and 7.

Page 5-17, para 1. More attention should be paid in this chapter to overall results, not so much to individual studies (new or old), such studies should be reviewed in the WREA. This comment, as mentioned in previous comments. Also, even if some individual studies are cited, I’m not sure that the Vollsnes et al. (2010) is critical, it is short term.

Page 5-18, para 2. This paragraph is accurate, but much too brief. As discussed in more detail in my comments elsewhere (Chapters 6 and 7), much more attention should be

paid in the PA and WREA to crop yield loss. As summarized here, there is strong evidence that common crops have substantial yield loss. Effects on sensitive crops such as soybean should be summarized here and analyzed in detail in the WREA should be analyzed at the same level of detail as currently provided for individual tree species. Lastly, at the end of this expanded section, it should be made clear that decades of evidence, and new confirming evidence clearly show that major crop and tree species experience growth and yield loss due to ambient ozone in many regions and years. However, the exact mechanisms of such losses are still being investigated (provides a transition to the next paragraph).

Page 5-18, lines 32-35. Clarify that robust data exist for yield losses at ambient ozone concentrations in many locations and years, because experiments have been conducted (or observations made) across a range of environmental conditions. Also, there is evidence for some types of interactions, such as drought decreasing ozone dose.

Page 5-19, line 26. Remove "space", it is not specific (plants don't really compete for space, they compete for light, water, etc.).

Page 5-20, para 1. Again, clarify that robust data exist for yield losses at ambient ozone concentrations in many locations and years, because experiments have been conducted (or observations made) across a range of environmental conditions.

Page 5-18, lines 32-35. Clarify that robust data exist for yield losses at ambient ozone concentrations in many locations and years, because experiments have been conducted (or observations made) across a range of environmental conditions. Also, there is evidence for some types of interactions, such as drought decreasing ozone dose.

Page 5-21, lines 29-32. Clarify that C3 and C4 plants are the vast majority for most regions and ecosystems of the USA.

Page 5-22, line 20. Change to "two to four months".

Page 5-22. A general comment – the next draft should better clarify what is known. While there is a lot that is not known about ozone effects on vegetation, there is also a lot that is known, and particularly in this document it is critical to distinguish what is well known from what is less well known. I have commented elsewhere (Chapter 7) on some examples of clear and unambiguous language as good examples for topics that are relatively well known. As written this chapter gives the impression that little is known about ozone effects on vegetation, which is not true.

Page 5-23, lines 24-27. This is an example of clear and unambiguous language, very useful as a summary sentence.

Page 5-27, line 9. Clarify that despite such issues, exposure-response models for important crop and tree species are robust because they were developed based on plants grown under realistic conditions in the field.

Page 5-27, line 15. Change "appear to be" to "are". This is an example of clarifying language for topics that are relatively well understood.

Page 5-27, line 27. Here and elsewhere change "food chain" to "food web".

Page 5-31, para 2. Use common names in this document, use scientific names in supporting documents (at least the first time).

Page 5-33, line 16. Spell out all abbreviations at first occurrence.

Page 5-39, line 25. Correct spelling of "t3o".

Chapter 6: Consideration of the Welfare Exposure and Risk Assessments

1 *To what extent are the assessment, interpretation, and presentation of the initial results of the exposure and risk analyses clearly communicated and appropriately focused to support considerations presented in chapter 7?*

While much of this chapter is useful, well written, and appropriate, there are serious deficiencies due to the narrow focus on Class 1 areas and on selected tree species. Correcting these deficiencies will require modest expansion of the WREA to include analysis of effects on the yields of sensitive crops in order to appropriately address adverse welfare effects. Such expansion can be done based on methods and analyses already completed. See detailed comments (by page number) below for further discussion of these important topics, as well as comments for Chapter 7.

2. *What are the views of the Panel on the appropriateness and usefulness of including a qualitative discussion of potential O_3-related impacts on ecosystem services in this document?*

In practical terms, ecosystem services are another way to classify effects, some of which (effects of crop yield, tree seedling growth, and some aspects of forest ecosystems) that have been analyzed in previous analyses in support of secondary ozone standards in the past. Additional analysis of effects on crop yield must be included, as discussed in my other comments on this chapter, Chapter 7, and elsewhere. Discussion of FASOM-GHG and i-Tree analyses should only be included if they are appropriate and robust, and should be reviewed by this panel. Page A-41 (WREA Appendix) indicates that ozone exposure-response functions for tree seedlings were used to calculate RYLs over their whole life span. Scaling effects from seedlings to mature trees is an important topic that has received substantial attention in

the literature as summarized in previous EPA documents for previous ozone standard reviews. Similarly, competition among tree species that differ in ozone sensitivity in mixed-species stands is expected to greatly alter how ozone affects the growth of an individual species. Page A-42 (WREA Appendix) indicates that yield is compared to a "clean air" background, and that relative yield gains of crops and trees is assumed to be zero at ambient ozone. It is not clear to me what this means, is it assumed that ambient ozone is not currently affecting crop and tree growth? This is not supported by the evidence. Furthermore apparently only sectoral net results are calculated for consumers and producers. As discussed further in my comments to Chapter 7, such analysis does not account for the individual producers some of whom will be winners and some of whom will be losers. The evidence strongly suggests that ambient ozone exposure in many locations and years is causing yield loss of sensitive crops and trees. In such locations, producers (and perhaps consumers) will be losing income due to ozone, and that is an adverse effect on them, even if producers in other regions are gaining income. If these issues are not addressed carefully, the results of the FASOM modeling will be neither appropriate nor robust.

3. *To what extent does the Panel feel that this chapter is useful for inclusion in the Policy Assessment, given the summary of the policy-relevant findings presented in the draft Welfare REA?*

This chapter is useful and should be retained, with revisions as suggested in other comments. The PA document must be "stand-alone" so that it can be read and understood separately from the other (supporting) documents (WREA and ISA). Thus it is inevitable to have some overlap between the PA and other documents, the WREA for this chapter. The PA should present the main conclusions of the supporting documents, including key figures and tables such that the strengths and limitations of the evidence for various adverse effects are clearly summarized. Obviously, most of the details must be presented in the supporting documents.

Comments for specific page and line numbers:

Page 6-1, line 4-5. Delete "including impacts on federal Class I case study areas".

Page 6-1, para 2. Replace "ecological" with "welfare".

Page 6-2, para 1. While the general approach of the quadratic rollback is appropriate, it does not address the potential for increases in ozone exposure in regions that meet current and proposed standards. Such increases could occur due to extractive industries or industrial or other development, or to changes in fire management, which could be considered anthropogenic. Consideration should be given to modeling potential increases in ozone exposure in the future due to such activities. Although challenging, it would be feasible to develop future scenarios based on current and past trends of development. Even if such future scenarios are not developed, consideration should be given to developing some approach to address the potential for increases

in ozone exposure in rural areas in the assessment. One way to do so would be to quantify adverse effects at the county level, divide the counties into bins based on degree of adverse effects, and discuss the implications if a larger number of counties fell into the higher bins in the future. Obviously these suggestions involve enhancements to the WREA to perform such analysis.

Page 6-6 and 6-7, Figures 6-2 and 6-3. For next draft, consider using bins related to proposed alternate standards, for example a bin beginning at the lowest proposed value for the standard. Also I suggest adding maps to show the incremental changes expected for each alternate standard option.

Page 6-8, para 1. In the WREA and elsewhere there should be additional separate causality analysis statements for annual crops and perhaps for perennial herbaceous crops as well as for trees. This is important because crop yield loss is an important assessment endpoint that has been omitted in this draft of the PA and WREA, and this omission should be rectified as discussed in my comments for Chapter 7 and elsewhere. Having separate causality statements for different types of vegetation would help to clarify that there are important adverse effects on different important types of vegetation.

Page 6-8, para 2. Crop production (food and feed) is a critically important provisioning service and substantial detailed analysis on ozone effects on crop yield must be included herein (as a new section comparable and parallel to the current section 6.2.2, including figures similar to 6-4 and 6-5 and Table 6-1) and in the WREA as discussed in my comments for Chapter 7 and elsewhere.

Pages 6-9 and 6-11, Figures 6-4 and 6-5. The independent axis of each graph should present percentages rather than ratios as it should be easier for the audience to understand and will be consistent with the text that discusses RBL as percentages. Also, it is potentially confusing to show biomass loss as a positive value, and it is important whether another approach would be less confusing to the audience. At a minimum this issue should be spelled out in each figure legend.

Page 6-10, para 1. Clarify what “maximum” means, is this averaged across the conterminous US, or the maximum for a region or a monitoring station or ??

Page 6-11, Figures 6-5. Remove slang of “Blow-Up” replace with the range of W126 or “selected portion of Figure 6-4” or something.

Page 6-11, para 1. How many species exceed 2% yield loss? 5% yield loss?

Chapter 7: Staff’s Preliminary Conclusions on the Secondary O_3 NAAQS

1. *What are the views of the Panel on how this chapter characterizes and considers the currently available vegetation evidence and the exposure and risk information from the first draft Welfare REA in reaching preliminary staff conclusions on the adequacy and*

appropriateness of the current secondary O_3 standard (section 7.2)?

While much of this chapter is useful, well written, and appropriate, there are serious deficiencies due to the narrow focus on Class 1 areas and on selected tree species. Effects on the yields of sensitive crops, effects on tree species in other regions, and other effects must also be included as a "primary" focus in order to appropriately address adverse welfare effects. See detailed comments (by page number) below for further discussion of these important topics.

2. *What are the views of the Panel on the elements and range of levels of a cumulative, seasonal standard identified in section 7.3 that would be appropriate for further analyses in the second draft Welfare REA? To what extent does the information presented in this section help inform this consideration?*

The focus on W126, on a 12-hour daytime period, and on a 3-month consecutive highest ozone exposure period are appropriate, and are well supported in this document, supporting documents, and previous EPA analyses. For the reasons presented in my detailed comments below, I suggest that estimates be made of values associated with 5% yield loss for individual species of ozone-sensitive crops and 1-2% yield los for individual species of ozone-sensitive tree seedlings be analyzed in the WREA for individual counties, and that this analysis be considered when selecting a range of potential secondary ozone standard values for further analysis herein.

Comments for specific page and line numbers:

Page 7-4, para 1. Yield loss of major crops must be discussed here, with a focus on crops that are sensitive to ozone and that are widespread, notably soybean. This is a critical gap in this document, the WREA and to some extent the ISA. Note however that the ISA does provide some relevant results in Figures 9.14 and 9.15 (note that I also suggest that these tables be expanded to include individual crops and also a threshold of 5% yield loss).

Page 7-5, para 3. Yield loss of major crops must be discussed here, with a focus on crops that are sensitive to ozone and that are widespread, notably soybean. To a lesser extent, effects on crop quality should also be addressed here.

Page 7-6, para 2. Yield loss of major crops must be discussed here, as noted above.

Page 7-8, para 2. Yield loss of major crops must be discussed here, as noted above. Specifically, the WREA should provide crop yield loss estimates for individual crops by county for current ambient ozone conditions for individual years, as well as projected ozone scenarios. Yield loss due to ozone is an adverse effect for an individual farmer. Such analysis would provide a firm basis for estimating adverse welfare effects. It is inadequate to analyze only sector-wide economic effects of reduced crop yield due to ozone, as is currently done using FASOM-GHG. The sector-wide approach is inadequate because it does not account for yield and income loss experienced by individual farmers in areas with elevated ozone. Such effects are real and cannot be "averaged out" by counting potential increases in the price of

soybean, because such increases will go primarily to farmers in low-ozone areas. In other words, even if there is no "net" effect of ozone on the price paid for soybeans in the USA overall, there is still an adverse effect on many farmers in areas with elevated ozone. Additionally, soybeans are a global commodity, and reduced yields in the US due to ozone decrease the competitiveness of US farmers compared to farmers in other countries with lower ozone levels.

Page 7-8, line 42. Change "often" to "usually" here and anywhere else where this phrase is used in this and other documents.

Page 7-11, para 2. Yield loss of major crops is important, is well studied, and must be discussed here, as noted above.

Page 7-11, para 3. The WREA should also quantify RBL for individual sensitive crop species as noted above.

Page 7-12, line 4. The Consensus Workshop actually said 1-2%, not 2%.

Page 7-12, para 1. The Consensus Workshop also focused on a 5% yield loss for crops and as noted above, crop yield impacts must be included herein. The Consensus Workshop in their final comments focused on 10% crop yield loss to account for uncertainties in estimating yield loss. However, more recent research has improved the ability to estimate yield losses of 5%, using the yield functions developed from NCLAN research. As noted in the WREA, these results have been greatly strengthened by more recent results from the Soy-FACE research, which found very similar yield losses as found previously in the NCLAN research using open-top chambers. Thus there is strong evidence to support quantifying the risk of a 5% yield loss for individual ozone-sensitive crops. As discussed above, I strongly suggest performing such assessment nationally at a resolution of individual counties (for counties where ozone-sensitive crops are grown).

Page 7-13, lines 19-23 **and** 7-14 lines 1-4. This language is very clear and unambiguous. I strongly recommend using such language elsewhere, while there is a lot that is not known about ozone effects on vegetation, there is also a lot that is known, and particularly in this document it is critical to distinguish what is well known from what is less well known.

Page 7-18, line 12. Change "clearly calls into question" to "does not support". See previous comment about using clear and unambiguous language when discussing topics that are well understood.

Page 7-18, line 14. Change "especially" to "including", see note below for reason.

Page 7-18, para 2. Crop yield loss must be discussed here. It is not adequate to leave such effects out of this document.

Page 7-24, para 1. It is important to quantify and discuss that the W126 used as proposed (3 month cumulative) already contains a good deal of integration through time, so it is inherently less affected by a few high hourly or daily ozone concentrations (upper tail of the distribution). This could be demonstrated by means of analysis of existing ozone monitoring data. Thus there is much less need to average across years in order to avoid excessive impact of a few high hourly or daily ozone values. Also, since ozone effects can be cumulative among years in perennial species, there is less justification for averaging effects among years – one high ozone year may have effects for many subsequent years, even if subsequent years have lower ozone exposure.

Page 7-25, para 1. I strongly disagree that the primary focus should be on Class 1 areas. These are undoubtedly important, but so are effects in other regions. Additionally, crop yield loss is quite important and must be included as a primary impact of ozone. The narrow "primary" focus is not appropriate, does not reflect the underlying science, and biases this document by leaving our important impacts over wide areas of the USA.

Page 7-25, para 2. I disagree in the strongest terms with this paragraph. As mentioned in previous comments, and as found in current and especially previous EPA analyses, there is very strong evidence for widespread yield loss for sensitive crops due to ozone during high ozone years. Additionally, the claim that management can eliminate ozone effects is not supported by the evidence. For example, the fact that results for soybean from the Soy-FACE experiment match so closely with those from NCLAN experiments from two decades previously indicate that current cultivars are equally sensitive to yield loss as old cultivars. Because the FACE experiment is larger and represents actual fields to a great degree, effects of management have clearly not eliminated effects of ozone on yield, they are still important. While such newer data are not available for most other crops, soybeans are sensitive to ozone, are grown widely, and are an extremely important crop in the USA.

Page 7-26, para 1. I disagree in the strongest terms with this paragraph, see previous comments.

Page 7-26, para 2. I disagree in the strongest terms with this paragraph, see previous comments.

Page 7-26, para 4. I disagree in the strongest terms with this paragraph, see previous comments. Such information is indeed critically important, but so are assessments of ozone effects for other regions and for a wider range of tree and crop species.

Page 7-27, para 4. While it is correct that documentation was not provided in the cited article, the exposure-response functions discussed in the ISA do provide support for the range of values cited. The focus in this document should be on the rationale in the cited document (preventing greater than a 5 or 10% loss of sensitive crops and preventing 1-2% growth decrease for sensitive tree species), combined with analysis from the ISA and WREA that support a range of values for the proposed W126 form.

Page 7-28, para 1. I strongly disagree that exposure response functions for sensitive crops should not be used. Also, allowing up to 10% biomass loss for sensitive crops may not protect against adverse welfare effects. Focusing on the median of studied trees and crops is not likely to protect against adverse welfare effects. Because there are sensitive species of both annual crops and trees that are widely grown, exposure response functions should be examined separately for these species.