



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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November 26, 2012

EPA-CASAC-13-003

The Honorable Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: CASAC Review of the EPA's *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (First External Review Draft – August 2012)*

Dear Administrator Jackson:

The Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel discussed the EPA's *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (First External Review Draft – August 2012)*, hereafter referred to as the PA, during a public meeting on September 13, 2012, and a public teleconference on November 5, 2012. The CASAC's consensus responses to the agency's charge questions and the individual review comments from the CASAC Ozone Review Panel are enclosed. The CASAC's key points are highlighted in this letter.

Overall, the CASAC finds that the PA needs substantial improvement, reflecting the still very preliminary first draft that was brought to the CASAC. The PA contains much information that is not directly relevant. Only key information and findings from the Integrated Science Assessment (ISA), Health Risk and Exposure Assessment (HREA), and Welfare Risk and Exposure Assessment (WREA) that will inform policy decisions should be included in the PA. This policy-relevant information should be presented in an appropriate summary format and a clear rationale for the inclusion of such information should be provided.

The PA fails to provide a clear description and definition of ozone background, to clearly discuss how background ozone may be considered in estimating the risk indicators for ozone (e.g., total risk and scenarios of reduced risk), and to discuss the role of background in developing options for the NAAQS.

The PA should more clearly highlight those studies that the ISA concludes contribute critical evidence for causal determinations. The presentation of the epidemiologic studies is well documented and balanced, but will be improved by indicating the most critical evidence for causal inference. The limited evidence on new-onset asthma should not contribute greatly to the consideration of the strength of evidence for respiratory-related effects. The CASAC does, however, support the overall designation of

respiratory effects as likely to be causal, based largely on the evidence from respiratory mortality findings.

The discussion of the primary ozone standard would be more effective if it focused on the key elements that led to the conclusion that the current standard needs to be reconsidered. It should avoid repetition of material already detailed in the ISA and HREA. Rather it should highlight the conclusions from these documents that are relevant to development of policy options. The PA provides a strong scientific rationale for consideration of ozone levels (8 hour averages) of 60 ppb to 70 ppb. If the EPA considers levels below 60 ppb, adequate justification should be provided.

The consideration of welfare impacts is not appropriately balanced. There is abundant scientific evidence regarding ozone impacts on crop species. This information is poorly represented in the PA. There should be more consideration of these substantial impacts, unless an adequate rationale can be provided to discount the scientific evidence. The discussions and conclusions on biologically relevant exposure metrics are clear and compelling and the focus on the W126 form is appropriate.

The discussion of ecosystem services should be enhanced with analysis and conclusions based upon more quantitative and semi-quantitative analyses. A rigorous discussion of ecosystem services will enhance the impact of the PA and will lay out an effective pathway for future analyses. Effects of ozone on the yield of sensitive crop species on a regional basis should be included using quantitative risk analyses, as discussed in the CASAC's review of the WREA.

In the draft PA, the EPA concludes that the current secondary standard is inadequate to protect vegetation and ecosystems. Although the conclusion is warranted, the foundation for the conclusion is too narrow because the analysis focuses on just Class I areas and on trees. Effects on sensitive crops, trees in regions outside of Class I areas, and additional ecosystem impacts should be included as major foci to assure that adverse welfare effects are fully considered. There is a strong justification made for using a cumulative and weighted exposure standard for welfare effects (i.e., the W126), and for the utility of using a 3-month daylight exposure metric. Averaging across years is not recommended because a single high exposure year could have lasting effects because of the perennial nature of many plants and the lag times associated with propagating effects through ecosystem trophic levels. Averaging would obscure such critical impacts and lead to inadequate protection against welfare effects.

There needs to be a better justification of the proposed level, or range of levels, to consider for a secondary standard. Options for levels should be based on factors including predicted 5% loss of crop yield and predicted 1-2% loss for trees. Greater emphasis should be placed on analyzing yield losses for a number of crops, especially those known to be sensitive to ozone and that are widely planted across the United States, such as soybean. The CASAC is unaware of robust scientific evidence that management practices eliminate adverse effects due to ozone. Furthermore, the CASAC does not concur with how the Forest and Agriculture Sector Optimization Model with Greenhouse Gases is currently applied to assess economic impacts.

The CASAC appreciates the opportunity to provide advice on the PA and looks forward to receiving the EPA's response and reviewing the second draft.

Sincerely,

/Signed/

Dr. H. Christopher Frey, Chair
Clean Air Scientific Advisory Committee

/Signed/

Dr. Jonathan M. Samet, Immediate Past Chair
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Enclosures

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**Consensus Responses to Charge Questions on
EPA's Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards
(First External Review Draft – August 2012)**

Chapter 1: Introduction

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

Chapter 1 is a well-written short account of the historical background of the ozone National Ambient Air Quality Standard (NAAQS) and a succinct description of the ozone monitoring network, spatial and temporal patterns of observed ambient and modeled North American (NA) background ozone concentrations. However, there are components of the chapter that would benefit from further expansion and clarification, and corrections for improved accuracy.

The Background section should be expanded to cover the evolution of the EPA's rationale for justifying the shifts in the choice of the form of the standard, the choice of metrics used for health risks and welfare risks, the choice of different types of non-domestic emission scenarios leading to different sets of ozone background concentrations and how these background concentrations may be used to assess the attainability of a proposed ozone NAAQS. The description of the evolution of the EPA's approach in response to public comment and litigation, and clarification on the use of the three different definitions of ozone backgrounds (presented by the EPA during the September 13, 2012 meeting), was particularly illuminating. It would be helpful to incorporate this material into this section in the second draft.

The chapter puts a great deal of emphasis on the metric, maximum daily 8-hour average (MDA8), used for the primary standard but little emphasis on a metric, such as W126, that would be relevant to the secondary standard. This emphasis reflects the past practice of making both standards equivalent. However, if a separate and independent secondary standard is to be promulgated, the relevant metric and its observed characteristics should be briefly described and compared with those of MDA8 in this chapter.

There are several inaccuracies and potential areas of confusion in the description of ozone chemistry and precursor emissions. Key points are highlighted below:

1. In the discussion of ozone chemistry, use of uncommon terms such as "local valley" can be confusing. It would be more straightforward to use "a localized decrease in ozone concentration compared to those in the surrounding areas." The notion of "increases of ozone to fill in the local valleys of low ozone" (p. 1-11, lines 3 – 4) can actually be inaccurate and confusing. It is simpler, clearer, and more accurate to state "increases of ozone concentrations in other areas."
2. The discussion of seasonal variability of ozone in U.S. cities actually does not address this variability (p. 1-12, lines 6-9). This needs to be addressed.

3. The chapter attributes the increased ozone concentrations at higher elevations to stratospheric intrusions (p. 1-13, lines 4 – 5 and p. 1-16, lines 29 – 30). However, other than the case of exceptional events, the observed increase is a result of higher ozone background with higher altitude due to increasing ozone lifetime (drier air) and lack of contact with the surface. Similarly, it should be explained that background ozone in the mid-latitudes atmosphere peaks in spring and is low in summer, primarily due to atmospheric chemistry rather than stratosphere-troposphere exchange (Monks, 2000; Li et al., 2002).
4. The chapter should provide a more informative discussion on where and when the primary ozone NAAQS is exceeded in a given time period, for example 2008-2010 (p. 1-13, lines 6-9). Displays of the tendency for high cumulative ozone exposures in rural areas based on the W126 metric would be relevant to the secondary NAAQS. This type of information is not readily available to policy makers or the public. Eastern U.S. monitor value maps make it clear that the annual 4th-highest 8-h mean ozone concentrations in recent years (2009 and 2012-preliminary data) can be highly variable. This variability has implications for the stability of the risk estimates based on the specific 3-year period chosen.
5. The description of the implication of nonlinear nature of ozone chemistry on p. 1-15, lines 19 – 23 is misleading. The nonlinear nature of ozone chemistry does not allow a meaningful attribution of ozone concentrations to given precursor emissions in the sense of additivity, let alone “approximating” the contributions from the emissions. Another important model limitation that needs to be included is the inability of models to simulate high concentration extremes due to numerical diffusion. It is also possible that models tend to overestimate the lower extremes and underestimate the upper extremes due to the incomplete characterization of the conditions under which extremes occur.
6. The chapter should accurately reflect the lack of general scientific agreement on the contribution of fires to background ozone. The evidence does not support the emphasis given to fires in the current draft.

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?

For the most part, the PA appropriately reflects the weight-of-evidence conclusions in the third draft of the *Integrated Science Assessment for Ozone and Related Photochemical Oxidants* (ISA). The assessment is not very detailed in some respects, but lack of detail in this context is appropriate, because this document should only present summary information. However, studies noted in the ISA that contributed most to the determination of the causality designation also should be highlighted in the PA. All significant revisions made to the final draft of the ISA that are relevant to the PA should be reflected in the revised PA.

Regarding the current weight-of-evidence assessment presented in the PA, the limited evidence on new-onset asthma should not contribute greatly to the consideration of the strength of evidence for

respiratory-related effects (see p. 2-3, line 27), as further explained in response to the next charge question. The overall designation of respiratory effects as likely to be causal is appropriate and is sufficiently supported based largely on the respiratory mortality finding from the American Cancer Society (ACS) cohort.

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

The document does a reasonable job of documenting the health effects evidence and providing an appropriate discussion about different effects and different time courses. Clinical studies are distinguished from epidemiologic studies, and outcomes, such as altered medication use, are put into context. Hospital admissions are also dealt with in a useful way. Key issues, such as co-pollutants and other outcomes, such as cardiovascular and reproductive outcomes, are also adequately discussed. One aspect which is not adequately discussed is the issue of adaptation. There is considerable literature on adaptation to oxidant injury. There is an extensive literature dealing with hyperoxia, and there is also strong evidence from ozone studies in animals. The same dose of inhaled ozone is much more toxic to naïve subjects than to those who have had repeated exposures to ozone. Thus, in risk models one must not only consider the ozone level, but the history of ozone exposures prior to a particular challenge. Two communities could have the same average ozone exposure during the year, but if in one city ozone levels are uniform, the effect is likely to be less than in another city where ozone levels are low most of the time, but with periodic higher levels. The pattern of ozone exposure is one that should be considered in the NAAQS review.

The evidence for new-onset asthma is described as providing “the strongest epidemiologic evidence for a relationship between long-term ozone exposure and respiratory effects” (p. 2-47, line 27 and repeated in the Integrated Discussion section, p. 2-74, line 33). The putatively “strong” evidence referred to is largely from the California Children’s Health Study (CHS) cohort based on one report that presents initial findings and another that is a gene-environment interaction study in which no ozone main effect was observed. The argument for “strong” evidence is predicated on interaction effects given the absence of a main effect, and on a small number of events in the study on outdoor sports. Therefore, it is difficult to argue that the evidence on new-onset asthma provides “the strongest epidemiologic evidence.” The association between respiratory mortality and long-term ozone exposure in the American Cancer Society (ACS) cohort provides strong evidence and is a more justifiable basis for a “likely to be causal” determination for the relationship between respiratory effects and long-term ozone exposure.

The PA states “that the epidemiological evidence clearly demonstrates that short-term ambient ozone exposure is associated with increases in respiratory symptoms and asthma medication use...” (p. 2-17, lines 6-7). However, the subsequent paragraphs in the text indicate that the evidence is more mixed. In the Integrated Discussion section, it is noted that “short-term ozone exposure was consistently associated with increases in respiratory symptoms and asthma medication use in asthmatic children” (p. 2-73, line 13). This is not so, given the findings of two multi-city studies, Schildcrout et al. (2006) and O’Connor et al. (2008).

Forced expiratory volume in 1 second (FEV₁) responses in asthmatics are not different from those in non-asthmatics, contrary to what is stated (p. 2- 61, line 18). The statement that reduced inspiratory

capacity, “in combination with mild bronchoconstriction, contributes to a decrease in FEV₁” (p. 2-53, line 29) suggests that both of these mechanisms are important in normal subjects in causing the reduction in FEV₁. Currently, the evidence does not support a meaningful role for bronchoconstriction in normal subjects. Other measures of airways function (e.g., airways resistance) show that asthmatics may experience bronchoconstriction following ozone exposure rather than just reduced inspiratory capacity (and reduced FEV₁ as a result), while in non-asthmatics, this bronchoconstrictive effect is very small. Bronchodilators do not prevent or reverse reduction in FEV₁ in non-asthmatics.

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

There should be further discussion of the context and interpretation of clinical exposure results, such as whether ozone-induced changes in pulmonary function should be referenced to the results of clean air exposure. This is particularly important at the lowest laboratory exposure of 40 ppm. As mentioned above, the interpretation of the role of bronchoconstriction in normal subjects and FEV₁ responses in asthmatics versus non-asthmatics needs to be revised.

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 copollutants, 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 epidemiologic studies is appropriate and well done. Clearly, the issue of confounding is an inherent potential limitation of epidemiologic studies. Additionally, the temporal relationship between exposure to ozone and responses is time-dependent and the lag period between exposure and outcome is dependent on the response measured. Thresholds may exist for some outcomes, but any thresholds may vary across populations and the typical heterogeneity of a population may obscure the existence of any threshold. Attention is given to the evidence from diverse populations, including sensitive subpopulations. The document should acknowledge the variation in terminology used across studies in referring to vulnerability and susceptibility.

The chapter draws attention to the potential limitations of the epidemiological evidence, giving consideration to confounding and measurement error. In addition to mentioning limitations, the document highlights some of their implications. For example, on page 2-16, the impact of random error on effect estimates is addressed. To the degree possible, additional text on the implication of limitations should be provided. There are a few places where the overall impact of the studies is vague (e.g., “have generally reported positive associations”). However, the EPA needs to balance length and readability with the level of detail. The current structure with references to Figures and Tables elsewhere in the report is useful.

The text on confounding by chemical components of fine particles (PM_{2.5}) draws attention to some of the challenges of this issue such as the frequency of measurements of particulate matter (PM). Other challenges should also be mentioned such as the frequency of measurement of ozone (often warm season only) and spatial heterogeneity that may differ by pollutants. In addition, there are numerous other studies, not mentioned in the text, providing evidence that there was not confounding of ozone

associations by PM total mass (e.g., page 2-29 and 2-30). Thus, the text should highlight that there are studies showing that PM is not a confounding factor.

The discussion on effect modification by pre-existing conditions (page 2-31) is 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. It is not clear 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 discussions of adversity, populations at-risk, averting behavior, and the size of populations at-risk from ozone?

The revised PA should be more concise and focused. The current draft is too lengthy and is not adequate for policy decisions. The discussion should provide specific alternative levels, alternative averaging times, and forms of the standard, and associated policy implications.

Section 2.4, *Public Health Implications*, seems more theoretical and philosophical, rather than actually laying out alternatives and their consequences. Tables 2-1 and 2-2 are useful supplements. Section 2.4.2, *At-Risk Populations*, is very important. As for most pollutants, the levels of protection needed are directly linked to those individuals who are most responsive because of increased probability of exposures or by increased responsiveness to the same levels. The chapter adequately addresses this topic but lacks consideration of specific levels.

The most important part of this chapter is clearly section 2.5, *Integrated Discussion of the Evidence*. However, the topics selected for discussion need a more explicit basis for inclusion and more complete discussion.

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 presentation of results from the exposure and risk analyses is appropriate, conveying essential findings that support policy assessment considerations. However, the revised draft should refine the presentation of findings to focus on risk estimates of exposure, morbidity, and hospital admissions, rather than revisiting conclusions already addressed or made previously in the REA.

The goal of the chapter should be to frame and interpret the findings from the REA that inform decisions as regards to the level, form, and averaging time of the ozone standard, taking into consideration the causal relationship between exposure to ozone (for school-age children, the general population, asthmatic children, workers, and other relevant subgroups) and adverse health effects. Consideration should be given to the use of tables or figures to convey key observations/summaries of exposures to ozone.

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 CASAC supports inclusion of this chapter, but suggests that it be reorganized to address considerations and questions that are posed in Chapter 4. Repetitive material in Chapters 3 and 4 should be avoided.

Chapter 4: Staff's Preliminary Conclusions on the Primary Ozone 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 ozone standard (section 4.2)?

Overall, the chapter provides an adequate summary of relevant evidence and justification for the conclusion that the current standard is not adequately protective of public health. However, the chapter would be more effective if it focused on the key elements that led staff to conclude that the standard needs to be reconsidered. It should avoid repetition of material already laid out in detail in the ISA and REA. Rather, it should highlight the key conclusions from these documents that are relevant to the policy decision. For example, it could identify key criteria important in determining whether the standard needs to be reconsidered and summarize the new evidence and conclusions from the ISA and REA relevant to each of these criteria. This would result in a more focused argument that avoids repetition.

The PA should be consistent with the ISA and the REA with regard to how epidemiologic evidence is considered and should provide a clear set of criteria by which the relevance of the epidemiologic studies should be judged. The PA would be improved by providing a framework useful in evaluating the relevance of the epidemiologic evidence that is explicit about: (a) why it is valuable to have epidemiologic studies based in cities that are in attainment of the current standard; and (b) why even studies conducted in cities that are not in attainment of the current standard can be informative regarding concentration-response relationships of relevance to risk and policy assessment. This chapter also should make reference to the ISA and REA documents that articulate how background was considered and provide a clear justification for this approach. Consistency and connection across these documents is crucial (see the CASAC's advice and recommendations on the REA).

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 ozone 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 PA provides a strong scientific rationale for consideration of ozone levels (8 hour averages) of 60 ppb to 70 ppb. There is no need for further consideration of 80 ppb. If the EPA considers levels below 60 ppb, adequate justification should be provided. The PA includes a preliminary conclusion that there is not a need to consider a long-term average for a new standard; however, the scientific evidence presented in the ISA and REA, suggest that such a standard may be needed. If the decision is made not to consider a long-term standard, the rationale for this needs to be better articulated.

Ideally, any comparison of the health impact of various standards (in terms of levels, statistical form, or averaging time) should include: the expected change in the continuous distribution of both short-term and long-term exposure levels for the general population, as well as for selected at-risk groups; and the expected health consequences of the shift in this whole distribution of short-term and long-term exposures, recognizing the continuous and approximately linear relationship between ozone and various health conditions 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 ozone-related morbidity or mortality concentration-response relationships across the entire or restricted distributions of ambient ozone 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?

The epidemiologic studies should be used to draw inferences regarding the shape and magnitude of the concentration-response functions between ozone exposures and various health outcomes across the full range of the ozone exposure distribution. An important consideration will be the level of confidence in the concentration-response functions for concentrations in the range of interest, especially 60 to 70 ppb and perhaps below 60 ppb. With this approach, the EPA can utilize 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 relationship (i.e., shape of and magnitude of the concentration-response function) between exposure levels and risk of various outcomes. As noted above, even studies performed in locations that did not meet the current standard may provide useful information on the relationship between ozone and health across the entire distribution of ozone.

Separately, modeling approaches described in the REA can be used to simulate the change in the distribution of ozone concentrations expected under various alternative standards at the finest temporal resolution possible. Expected exposure levels for individuals using varying averaging periods (e.g., 8-hour or 24-hour) matching those used in the epidemiologic studies can then be obtained from this “expected” concentration distribution. These can be used to estimate the health impact of ozone exposures directly using the concentration-response functions derived from the epidemiologic studies (with no need to back transform the metrics in the epidemiologic study to metrics analogous to the standard). In this way, the health impacts of various alternative standards can be compared. This kind of approach would not require transforming or forcing the exposure metrics used in the epidemiologic studies to match the form of various standards to be compared.

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?

The conclusions of the ISA have been carried through to this first draft of the PA. However, the document could more clearly indicate what is scientifically established versus what is not well known.

The U.S. EPA (2012) presentation “Review of the O3 NAAQS: First Draft Policy Assessment” to the CASAC provides an excellent example of such clarity (slides 11 and 12).

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

There is substantial detail that is repetitive with the ISA and REA. The CASAC recommends that EPA seek minimal redundancy, consistent with providing necessary information to support policy recommendations. The consideration of welfare impacts is not appropriately balanced, given that the abundant scientific evidence regarding ozone impacts on crop species is poorly represented in the current draft. This needs to be addressed in the next draft PA, either by clear exposition of reasons for discounting this abundant literature, or by greater consideration of these substantial impacts.

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)?

Section 5.4 is clear and compelling and the W126 form has a sufficient basis. This discussion should be replicated in the REA and used to explain the rationale for the difference in form between the primary and secondary standards.

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

The CASAC agrees with a focus on Ecosystem Services, as defined elsewhere in the Millennium Ecosystem Assessment (2005). Given the lack of quantitative studies on ecosystem effects, pointing to where ozone may have impacts is appropriate. However, this section needs to be sharpened.

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 adequate with the exception of the surprising omission of ozone effects on crop yields as one of the clearest examples of welfare effects. The scientific evidence is quite clear that ozone reduces crop yields. Ozone effects on crop yields should be considered, unless the EPA can provide a strong and compelling justification to the contrary.

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

Section 5.7 is clearly written and straight-forward in regard to the potential for climate and UV-B effects.

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?

Much of this chapter is useful, well written, and appropriate, as it nicely summarizes the results of the *Welfare Risk and Exposure Assessment for Ozone* (WREA). A more meaningful CASAC review will be possible when complete drafts of the WREA and PA become available. To address adverse welfare effects, the scope of the PA should be expanded to include regional yield losses of sensitive species of annual and perennial crops, as discussed in the CASAC's review of the WREA.

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

It is quite important to maintain the discussion of ecosystem services in the PA, with as many near-quantitative conclusions as possible. Such inclusion enhances the impact of the PA and lays out a productive pathway for future analyses. Effects of ozone on the yield of sensitive crop species on a regional basis should be included using quantitative risk analyses as discussed in the CASAC review of the WREA, and can be classified as a provisioning ecosystem service. Other topics that deserve attention include: (1) scaling effects from seedlings to mature trees; and (2) competition among tree species that differ in ozone sensitivity in mixed-species stands.

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 important and should be retained. Presentation of the main conclusions and citation of specific sections of the supporting documents for details is useful.

Chapter 7: Staff's Preliminary Conclusions on the Secondary Ozone 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 ozone standard (section 7.2)?

Chapter 7 documents that the current standard is inadequate to protect vegetation and ecosystems. However, the analysis is focused too narrowly on just Class I areas and on trees. Effects on sensitive crops, trees in regions outside of Class I areas, and additional ecosystem impacts should be included as major foci to adequately address adverse welfare effects.

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?

Chapter 7 offers a strong justification for using a cumulative and weighted exposure standard for welfare effects, i.e., the W126 index. Furthermore, it shows the utility of using a 3-month daylight exposure metric. However, averaging across years is not recommended because a single high year could have lasting effects on perennial plants, and because of time lags associated with propagating effects through ecosystem trophic levels. Averaging would obscure such important impacts and result in a failure to adequately protect welfare attributes. Excluding nocturnal exposures is appropriate at this time: although there are data suggesting appreciable uptake can occur at night, the uptake magnitude is no doubt much smaller than occurs during the day.

The chapter should better justify the proposed level, or range of levels, of a secondary standard. The CASAC recommends that the level(s) should be developed including a predicted 5% loss of crop yield and 1-2% tree loss. Although such small losses for trees seem inconsequential on a yearly basis, they compound over time and can result in substantial biomass losses over the decades-long lifespan of a tree.

Greater emphasis should be placed on analyzing yield losses for a number of crops, especially those known to be sensitive to ozone and that are widely planted across the United States, such as soybean, unless the EPA can provide a strong justification to the contrary. The CASAC is unaware of robust scientific evidence that management practices eliminate adverse effects due to ozone. Furthermore, the CASAC disagrees with how the Forest and Agriculture Sector Optimization Model with Greenhouse Gases is currently applied to assess economic impacts. Currently the model analyzes sector-wide effects but does not account for losses in areas affected by ozone. For example, it does not account for costs such as lowered income for farmers whose yields are reduced while farmers in low ozone areas profit more. Nor does it include hidden costs such as development of ozone-resistant cultivars, switching to crop species that are less sensitive to ozone, the use of additional fertilizer, or having to farm marginal lands to make up for ozone-induced yield losses.

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Appendix A

Compendium of Individual Comments by CASAC Ozone Review Panel Members on EPA's Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (First External Review Draft – August 2012)

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Mr. George A. Allen

Comment on Chapter 1 - Introduction

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

Section 1.3 briefly summarizes the ambient monitoring network and spatial and temporal patterns of ozone, and includes appropriate references to more detail. A concise description of ozone chemistry is also included. Because of the importance of background ozone 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.

Mr. Ed Avol

General Comments on Overall Document

The document seeks to summarize the basis for potential policy positions regarding the current ozone NAAQS, and possible alternatives to the existing standard, if and as warranted. The document (almost 300 pages in length) seems overly long and in some places, unnecessarily duplicative of sections of the ISA and REA that precede and/or accompany it. While a summary of the assembled information in the ISA is appropriate as the basis for positions presented in the PA, there is a lot of detail that might have been dealt with through citation or appendices, rather than direct inclusion in the body of the document. Even though currently incomplete, the PA seems large and somewhat unwieldy. Additional promised sections will likely make the overall document less accessible to those interested in understanding the potential options being considered.

As a smaller editing issue, the writing style of the author(s) 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:

Pg1-13, lines 5 to 6: The comments made regarding reasons for elevated rural O₃ concentrations are important, especially with respect to cumulative, longer-term O₃ exposures in rural or elevated locations removed from local sources of chemical scavenging. This could and should be more clearly stated by rephrasing the last line in the first paragraph on Pg 1-13, so that it reads, "As a result, multi-hour O₃ concentrations, and cumulative personal exposures, can be higher in some rural sites than those measured in ..."

Comments on Chapter 4

General Comments:

In my opinion, this chapter effectively outlines 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.

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, lines 18-22: 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 group 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 individuals 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, line 29: 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, line 7: 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 judgments about the adequacy of the current standard. The statement that “...they provide little additional information to inform a judgment...” 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, lines 7 to 10: 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 circumstances 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, lines 18 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 background 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.

Responses to Chapter 4 Charge Questions:

1. (views on how this chapter characterizes and considers available evidence in reaching conclusions on the adequacy of the current standard)
The chapter has many of the needed parts for a useful discussion, but there is too much detail, too much repetition, (and too much unfocused, even sloppy, writing). The PA should be a shorter, clearer application of the previous documents (the ISA data base, the REA applications) rather than a cut-and-paste compilation of the previous ISA and REA. The elements are largely in place here for a useful discussion, but it needs to be more focused and precise,
2. (range of alternative levels to be considered)
Based on the data presented in the ISA and estimates evaluated in the REA, it seems reasonable to consider the range of O₃ ambient levels between 50 and 75ppb (8hr exposures). This would overlap the previous CASAC recommendations, based on the previous science, and consider the newer information. In my opinion, the newer data provides a substantive basis for consideration of a standard at a range of lower levels than is currently the case.
3. (how to consider data from epi studies across entire or restricted O₃ concentration distributions)
As with much of the entire chapter, Section 4.3.2 provides a lot of useful information, but it also includes a lot of excess material that unnecessarily extends the presentation. A tighter and more focused (edited) summary of the position being taken, and the general reasons for them, would be appropriate (in other words, it shouldn't take 4+ pages to present what is said). I agree that there is data from recent epidemiological investigations on which to consider exposure distributions across the *entire* O₃ concentration range, and it would be informative to do so, and I do think there is interesting and important information to consider at ranges below the existing standard.

Dr. Michelle Bell

Comments on 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 extent 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 on 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.

Dr. Joseph D. Brain

Comments on Chapter 2 - Overview/Consideration of the Health Evidence

Preamble:

Again there should be uniformity among all specific pollutant assessment documents. [This comment probably relates to the introductory chapter.] Is there standard boilerplate which should be in every pollutant policy assessment which describes the process and defines key terms and common pathways which guide the agency?

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?

We believe that the evidence does reflect assessments made in the ISA, as now revised. Again, we point to the advisability of having widely accepted definitions for weight-of-evidence conclusions. There should be agreed upon definitions of all these levels of causality, which are defined in more detail. In this and in documents for other pollutants, this foundational document should be cited.

2. To what extent 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?

The document does a reasonable job of documenting health effects evidence and providing an appropriate commentary about different effects and different time courses. Clinical studies are distinguished from epidemiologic studies and outcomes, such as altered medication use are put into context. Hospital admissions are also dealt with in a useful way. Key issues, such as copollutants and other outcomes such as cardiovascular and reproductive outcomes, are also dealt with.

One aspect which is not adequately dealt with here or elsewhere in the ISA and REA is the issue of adaptation. There is considerable literature on adaptation to oxidant injury. There is an extensive literature dealing with hyperoxia, and there is also strong evidence from ozone studies in animals. The same dose of inhaled ozone is much more toxic to naïve subjects than to those who have had repeated exposures to lower levels of ozone. Thus, in risk models one must not only consider the ozone level, but the history of ozone exposures prior to a particular challenge. Two communities could have the same average ozone exposure during the year, but if in one city it was uniform, the effect is likely to be less than in another city where most of the time it's very low, but there are periodic higher levels. This pattern of ozone exposure is one that should be considered throughout the ozone regulatory process.

3. What are the views of the Panel on the appropriateness of staff's characterization of controlled human exposure 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)?

The interpretation and use of controlled human exposure studies at levels near to or below the current ozone standard are problematic in their design, execution, and interpretation. For example, on page 2-7,

is it correct to begin the sentence by saying that “prolonged exposure to 40 ppb ozone results in a small decrease in a group mean that is not statistically different...” If it’s really not statistically different, is it correct to say that it “results in a small decrease”? Some weight is given to other studies at higher levels of ozone, such as 60, 70, and 80 ppb and higher. Also absent in this discussion is the PRB. A question that should be asked and answered is whether data obtained at these low levels should be compared to zero ozone or to the PRB.

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 copollutants, 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 panel believes that EPA staff has done their best to deal with very problematic issues. Clearly, the issue of confounding is almost always present for epidemiologic studies. It is also the case that the intervals between exposure to ozone and responses are time dependent and that the lag period between exposure and outcome is dependent on the response measured. Yes, there may be a threshold for some effects, but that threshold is different for groups with different characteristics and thus with a mixed population thresholds may disappear.

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 discussions of adversity, populations at-risk, averting behavior, and the size of populations at-risk from O₃?

In total, I would expect that the policy assessment would be crisper and more focused. It seems lengthy and does not adequately set the stage for decisions which must be made by the administrator. Shouldn’t it focus more on specific alternative levels and the form of the regulation and thus relate to how that might alter outcomes?

Section 2.4, “Public Health Implications,” seems rather theoretical and philosophical rather than actually laying out alternatives and their consequences. Table 2-1 and 2-2 are useful supplements. Section 2.4.2, “At-Risk Populations,” is very important. As is true for most pollutants, the levels of protection needed are directly linked to those individuals who are most responsive by virtue of increased probability of exposures or by increased responsiveness to the same levels. The chapter does a good job in discussing this aspect, but links to specific levels are often absent.

The most important part of this chapter is clearly section 2.5, “Integrated Discussion of the Evidence.” Shouldn’t choices be more explicit and the positive and negative of these choices be more completely laid out.

Dr. David Chock

Comments on Chapter 1 - Introduction

Charge Question 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 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.

After hearing the EPA presentations to the Panel, I recommend that EPA incorporates the content of the presentation in this Chapter. Furthermore, it would be helpful if a description is included on the evolution of the EPA's thought processes in justifying the shifts in the choice of the form of the standard, the choice of the metrics used for health risks and welfare risks, the choice of different types of non-domestic emission scenarios leading to different sets of O₃ background concentrations and how these background concentrations may be used to assess the attainability of a proposed O₃ NAAQS.

The Chapter also needs to incorporate more information, including its definition, its observed property, etc., about the likely metric, W126, to be used in the secondary standard. This information is helpful even if it is determined that the secondary standard is to be identical to the primary standard.

There are some inaccurate statements in the description of ambient ozone concentrations. In particular, atmospheric chemistry rather than stratospheric ozone intrusion should have been given a more prominent role in explaining the observed high background ozone concentrations in spring and observed higher ozone concentrations at higher elevations.

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 O₃” 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.

Dr. Ana Diez-Roux

Comments on 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. However it needs to be more focused on the goal of the PA. The emphasis should be on key points crucial to revisiting the standard and what new evidence (relevant to these points) makes this revision compelling. The chapter should avoid revisiting conclusions previously arrived at, and should connect and refer back to prior documents. Of course some synthesis and restatement is important but this should not mean completely revising determinations made in prior documents.

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 (this 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 even if the current standard were met, 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. In this regard, the discussion of design values is probably not necessary.

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 (and even 50 or 55ppb for comparison purposes) 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 the continuous distribution of both short-term and long exposure levels 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 recognizing the continuous and approximately linear relation between ozone and various health conditions 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 (or concentration-response function) between actual exposure levels and risk of various outcomes.

In parallel, as is done in the REA, modeling approaches can be used to simulate the distribution of concentrations under various alternative standards. Exposure estimates that match those used in the epidemiologic studies can be derived from these distribution. These can be combined with the epidemiologic estimates of concentration response curves in order to estimate the health impact of the new distribution. This kind of approach would not require transforming or forcing the exposure metrics used in the epidemiologic studies to match the metrics of various standards that want to be compared as is currently attempted,

In summary the steps would be:

1. Obtain “best” estimate of concentration response function from epi studies based on whatever metric (averaging period) was used by the studies.
2. Simulate expected population distribution (at the lowest level of temporal resolution possible) under an alternative standard. Create summary measures from this distribution (e.g. 8 or 14 hour averages, or maximum values) analogous to those used in epidemiology studies
3. Combine the estimates in 2 with the concentration response function to estimate health impact of ozone under the new population distribution.

Dr. William Michael Foster

Comments on 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 Chapter 3 in the Policy Assessment, from the standpoint that text information in Policy Assessment, Chapter 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 Chapter 3 (pg.3-7). Likewise text information on background of all-cause mortality (section 3.2.1.1, pg. 3-11 to 3-13) is *in part redundant* to the information of Chapter 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 Chapter 3 could be excluded.

Dr. H. Christopher Frey

Comments 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 rationale 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: <ul style="list-style-type: none"> • 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 4 th 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 4 th 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	<p>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.</p> <p>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.</p> <p>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</p>

		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 4 th 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 4 th 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	The caption is not clear. “Average” of what, exactly? (the maximum 8-hr concentrations reported from two or more monitors?) The finding here seems

	4-2	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 “50 th 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 50 th 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 ‘4 th 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

		O ₃ concentrations were above those allowed by the current standard, it is also true that some O ₃ 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 O₃ 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 O₃-related effects do not occur, can be discerned within the range of O₃ concentrations commonly observed during the O₃ 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 O₃-related effects do not occur, based on the range of O₃ concentrations observed during the O₃ 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: <p>“In further considering these controlled human exposure studies of O₃-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 O₃ 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”</p> <p>with</p> <p>“The statistical precision of group mean decrements are considered when evaluating whether reported effects are due to O₃ exposures rather than chance alone. It is also important to consider the potential for some individuals to experience larger decrements than average”</p>
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,”
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Dr. David A. Grantz

Comments on 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.

Comments on 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.

Comments on 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.

Dr. Jack Harkema

Comments on Chapter 2

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.

Question 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).

Dr. Daniel Jacob

Comments on 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 NO_x-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 NO_x 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.

Dr. Frederick J. Miller

Comments on Chapter 4 - Staff's Preliminary Conclusions on the Primary O₃ NAAQS

Charge Questions

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)?*

Response: In the 1st draft of the Policy Assessment (PA) document, staff have done an excellent job of characterizing the nature of the available studies that support the conclusion drawn that the current primary O₃ standard is not adequate for the protection of public health. Over the last 20 years, this reviewer has read numerous 1st drafts of Criteria Documents and Staff Papers and now the 1st draft of the ISA, HREA, and PA documents, with this 1st draft of Chapter 4 of the PA document being one of the best chapters I have read from a “logic development” perspective.

While the narrative is sometimes not as concisely stated as it might be, there is an effective logical order to the chapter obtained by laying out the question to be addressed, presenting the studies that are most relevant to answering the question, and then explaining the reasoning that led to the conclusions reached. A legal “briefing document” could not have done a better job of describing the material in Section 4.2.1.

While Section 4.2.2 is concisely written, it deals with topics and issues that are not as easily summarized as those in Section 4.2.1 because the exposure and risk analyses for the epidemiology studies involve complex analyses. That being said, Section 4.2.2.4 (Integrated consideration of the exposure and risk information), while less than 2 pages in length, captures the salient points and clearly explains why the staff reached the preliminary conclusions that: (1) the 1st draft exposure and risk information support the available health evidence, and (2) at a minimum, the exposure and risk data support the reasonableness of considering a range of potential alternative standards that would increase public health protection against respiratory effects and mortality due to O₃ exposure.

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?*

Response: Staff present a strong case for why alternative levels in the range of 60 to 70 ppb should be considered in the 2nd drafts of the REA and the PA documents, and the material presented in section 4.3.1 makes it very obvious that this range should be considered. For this range, this reviewer would recommend 60, 65, and 70 ppb values be examined. Staff also convey the view that the new evidence when considered in the context of the evidence that was available during the previous NAAQS review cycle for O₃ provides support for considering levels somewhat below 60 ppb. The pros and cons of such a decision were discussed

at the September 11-13, 2012 meeting of the CASAC O₃ Panel, with no clear consensus view expressed by the Panel members. In the opinion of this reviewer, the scientific weight of the evidence is not sufficient to go below 60 ppb at this time given that: (1) the recent McDonnell et al. (2012) paper clearly establishes a threshold for changes in FEV1 responses to O₃ exposure, (2) there are only a few epidemiology studies where the design value is below the current standard and percentiles of the O₃ concentrations below 60 ppb are typically in the 20 to 25 % range or lower, and (3) the delta from background O₃ levels due to non-anthropogenic sources would probably become even more of an issue when examining percentage reduction of risk provided by alternative levels of the standard.

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?*

Response: The preliminary approaches outlined in Section 4.3.2 appear reasonable. An assumption of a linear non-threshold model relationship between various health endpoints examined in epidemiology studies and O₃ exposure has been widely used by various investigators and appears to be a reasonable assumption supported by various analyses examining alternative models; however, the ability to distinguish the difference between non-threshold and threshold models in epidemiology studies is problematic.

In some of the time series studies, the nature of the widening of the confidence interval above and below the range of about 30 to 50 ppb O₃ may well be due to the nature of the smoothing function used (e.g. a cubic spline function in Bell et al. (2005)). Staff correctly point out that the weight placed on the C-R relationship over different parts of the distribution of O₃ concentrations or the weight placed on the percentiles of air quality distributions for cut point analyses will influence the conclusions one can draw about alternative 8-hour O₃ standards.

One approach to consider is dividing the O₃ measurements into 5 ppb or 10 ppb intervals. Then use the variance of the air quality observations within the interval as a weighting function in the risk analysis employing the C-R relationship. For whatever weighting scenarios are used, the reasonableness of the approach can be checked using studies where the design criteria were below the level of the current standard (e.g., Mar and Koenig, 2009). One could compare the results of the overall risk estimates for such studies to the risk values obtained using the given weighting function. Also, staff could identify the fraction of total risk (i.e., from no cut off for O₃ level) that is captured by the alternative ppb level using any given weighting scheme. This would help put the alternative level into perspective compared to the current standard.

General Comments

This chapter is well written, and the logic of the conclusions reached is very well documented. The organization of the chapter first asks a question, then provides the evidence from the ISA for the specific

health endpoint being linked to O₃ exposure, and ends 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 apparently 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, and this reviewer does not recall that the advice was a consensus view. 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 PRB 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 O₃ 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 percentage reduction in risk for a given health endpoint that exists over which EPA regulatory action would not have any control. The need for this type of information introduces background O₃ levels into the picture and is needed 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 O₃ 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 O₃ levels and, therefore, different percentage reductions in risk values when considering alternative standard levels.

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 2 nd 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 2 nd 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 4 th highest daily maximum 8-hr concentration averaged over 3 years) should be re-examined to assess its robustness and sensitivity.

Dr. Howard Neufeld

Comments on 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.

Comments on 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.

Comments on 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.

Comments on 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.

Dr. Armistead (Ted) Russell

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

Comments on 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, 11: Should bring up the issue of high wintertime ozone now being found in some locations.

1-12, 13... 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.

Comments on Chapter 4

You can tell this is a work in progress.

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, 114. 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, 134. Sentence begins with “And” is awkward.

4-35, 118-21. It is worth explaining why the two approaches (down to zero vs. down to LML) are a reasonable bound.

4-36, 18-12. 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, 121-29. You might want to use a table here.

4-49, 15-8. 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, 117-23. 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.”

Dr. Helen Suh

Comments on 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 first draft REA are brought forward appropriately and are useful for considerations made in Chapter 4. Chapter 3, however, is just a summary of findings from the REA 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. However, for this chapter to be informative, the summary of results should be sharpened to target key questions that are important for later determinations in the PA (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)).

- 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, again raising questions about the need for Chapter 3. As discussed above, Chapter 3 should be revised to provide a targeted summary focused on key questions raised in Chapter 4, with careful consideration made to study summaries that will be useful for Chapter 4 and will eliminate the need for Chapter 4 to re-summarize findings.

Dr. James Ultman

Comments on Chapter 3 - Assessment of O₃-Related Exposures and Risks

Charge Questions

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?

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. 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?

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; similarly, the bullet items on page 3-11 is repeated on page 4-37. 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 on Chapter 4 - Assessment of O₃-Related Exposures and Risks

The next draft of the REA will probably use the McDonnell et. al. (2012) exposure-response model that has an x-intercept (threshold). The improved fit of this model at low levels of ozone exposure affords an opportunity to compute FEV1 decrements at background levels. I believe that this additional information would give policymakers a useful perspective from which to judge the lung function improvements predicted by lowering the ozone level.

Dr. Sverre Vedal

Comments on 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?

See response to #2 below regarding assessment of the evidence. Because this is dependent on the ISA presentation and summarization, the issues/problems raised in discussion of the ISA necessarily surface here as well. The presentation generally reflects the weight-of-evidence conclusions in the ISA. An exception: the weight-of-evidence conclusion regarding long-term exposure to ozone and respiratory health effects in ISA-3 is: “Taken together, the recent epidemiologic studies of respiratory health effects (including respiratory symptoms, new-onset asthma and respiratory mortality) combined with toxicological studies in rodents and nonhuman primates, provide biologically plausible evidence that there is likely to be a causal relationship between long-term exposure to O₃ and respiratory effects.” In the policy assessment draft, the weight-of-evidence conclusion for this is: “... which include *respiratory-related morbidity endpoints [my italics]*, including new-onset asthma, and respiratory mortality” (p. 2-3, line 27). The “respiratory-related morbidity endpoints” referred to are two (from the ISA): respiratory symptoms and new-onset asthma. My assessment of the evidence regarding new-onset asthma is summarized in my comments on Ch. 7 of the ISA and in 2.a, below – in short, I don’t believe the evidence on new-onset asthma should contribute to this category of causal designation. I do, however, support the overall designation of respiratory effects as likely to be causal, based largely on the respiratory mortality finding from the ACS study.

2. To what extent 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?

Generally fine, but exceptions:

a. New-onset asthma. Regarding new-onset asthma, this is described as providing “the strongest epidemiologic evidence for a relationship between long-term ozone exposure and respiratory effects” (p. 2-47, line 27 [taken from the ISA-3, p. 7-39, line 12] and repeated in the Integrated Discussion section, p. 2-74, line 33). The “strong” evidence referred to comes largely from the California Children’s Health Study (CHS) cohort. See my comments on ISA-3 on new-onset asthma. In light of the dependence on interaction effects to argue for an effect and the small pilot study on outdoor sports, it is difficult to argue that the evidence on new-onset asthma provides “the strongest epidemiologic evidence,” unless the remaining evidence is weak. The association between respiratory mortality and long-term ozone exposure in the ACS cohort provides arguably stronger evidence and in my opinion is a more justifiable basis for moving the relationship between respiratory effects and long-term ozone exposure from suggestive to likely to be causal.

b. Respiratory symptoms and medication use in asthmatic children. The epidemiological evidence on this is described as “clearly demonstrate[ing]s that ...” (p. 2-17, line 6), while the paragraphs in the text that follow paint the correct picture that this is anything but clear. See my comments on ISA-3 regarding

symptoms and med use in asthma. In the Integrated Discussion section, it is noted that “short-term ozone exposure was *consistently associated* [my italics] with increases in respiratory symptoms and asthma medication use in asthmatic children” (p. 2-73, line 13). This is not so given the findings of two recent multi-city studies (Schildcrout [2006] and O’Connor [2008]).

c. PFT responses in asthma vs. non-asthma. FEV₁ responses in asthmatics are not really different from those in non-asthmatics, contrary to what is stated (p. 2- 61, line 18). The statement that reduced inspiratory capacity, “in combination with mild bronchoconstriction, contributes to a decrease in FEV₁” (p. 2-53, line 29) suggests that these mechanisms are both important in normal subjects in causing the reduction in FEV₁. I don’t believe the evidence supports any meaningful role for bronchoconstriction in normal subjects. Other measures of airway function (eg, airways resistance) do show that asthmatics may show an effect of ozone on bronchoconstriction vs. just reduced inspiratory capacity (and reduced FEV₁ as a result), while in non-asthmatics, this bronchoconstrictive effect is a trivial effect (ie, bronchodilators do not prevent or reverse reduction in FEV₁ in non-asthmatics).

3. What are the views of the Panel on the appropriateness of staff’s characterization of controlled human exposure 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)?

Well characterized, except for that relating to the role of bronchoconstriction in normal subjects and FEV₁ responses in asthmatics vs. non-asthmatics. See my discussion in 2.c, above.

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 copollutants, 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)?

Well done.

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 discussions of adversity, populations at-risk, averting behavior, and the size of populations at-risk from O₃?

Grading of responses to short-term ozone exposure is presented in Table 2-1 and Table 2-2 pertaining to normal and diseased people, respectively. It is not clear why this gradation is identical in these two tables, apart from inclusion of the airways resistance, wheeze and treatment rows in Table 2-2 for diseased people.

Miscellaneous Comments

- p. 2-36, line 16. Why is there reference to a long-term exposure study in this section on short-term exposure effects?
- Chapter 4. Note the Wells reference (p. 4-57, line 3) is missing.

Dr. Kathleen Weathers

Comments on Chapter 5: Consideration of the Welfare Evidence

Overarching comment: It is very difficult to offer many suggestions on this document given how incomplete it is. Nonetheless, it is a good start.

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?

It does. The weight of evidence could be more clearly and succinctly stated, however.

The discussion about different kinds of evidence and their importance is an especially useful reminder that the most robust understanding comes when there is evidence from a variety of approaches, from experimental to theoretical. As a bit of an aside, I suggest having a look at S. R. Carpenter 1998 for an interesting framework in this regard.

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?

There is a fair bit of detail here that is repetitive with the other two documents, but it is probably necessary for a stand-alone document. I would suggest, however, that if there is to be repetition of information among documents, there be some consistency in the descriptions.

I still find awkward the use of “scale” and the implicit assumption that the ecosystem scale is larger.

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)?

I thought this was quite clear, compelling and that something like this text should be included in the other two documents.

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)?

The use of ecosystem services is good and pointing to where ozone may have impacts is the best that can be done at this time given the scientific information that is available. The below-ground biogeochemical processing inferences are still quite vague however.

Remember to stress what is known in the sea of unknowns (e.g. end of section 5.3).

The section “exposure factors that influence plant response” contains critically important information for understanding why the proposed form of the secondary standard is different from the primary. It should be highlighted.

The different terms ANPP, NPP, NEP should be defined and used consistently throughout the document.

Ecosystem effects, especially the influence of ozone on water cycling, might be fruitfully explored using a process model.

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

It is surprising that the effect of ozone on crop yield is not highlight or held up as a prime example of adverse effects.

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

See above in regard to crop yields.

Comments on 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 is a good chapter and mostly clearly communicated.

Describe, perhaps just in a phrase, what is meant by “fusing” data (see comments above).

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?

I think that this is a useful discussion and, as stated earlier, the focus on ecosystem services is a logical and appropriate choice.

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 that this is useful, too.

It is not entirely clear to me the justification for the lack of focus on crops (managed systems).

Including uncertainties is extremely important, as is determining a way to present them that does not undermine the significance of the results. Nothing is certain (taxes and death, notwithstanding).

Comments on 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)?

The characterization is good.

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?

The cumulative, seasonal standard is well supported and justified. And, while it is probably most sensible to exclude nighttime exposures, the lack of major diurnal oscillations and higher ozone concentrations at high elevation sites (e.g., some of the Class I and Wilderness areas in parks) suggests that nocturnal exposure may in fact be important in sensitive systems.

It seems that analyses that continue to focus on the difference in welfare effects between meeting the current (or proposed) primary standard and the proposed secondary standard are of great importance. Also, analysis, to the extent possible of further ecosystem effects using modeling efforts.

Dr. Peter Woodbury

Comments on 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.

Comments on 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 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?*

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 O₃-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. 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 at the same level of detail as is 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 5-19, 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 O₃-related impacts on ecosystem services in this document?*

In practical terms, ecosystem services are another way to classify effects, some of which have been analyzed in previous analyses in support of secondary ozone standards in the past, including effects of crop yield, tree seedling growth, and some aspects of forest ecosystems. 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 possibly 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. 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?

Comments on 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)?*

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 loss 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.