

Major Issues Inadequately Addressed in the Final Version of the EPA's Ozone Staff Paper

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S. Summary

1. There is serious concern that EPA has underestimated the PRB levels used in the Staff Paper for the 12 urban areas. The modeled PRB diurnal monthly concentrations are much lower at all of the 12 urban areas during the April to June period than the actual PRB concentrations measured at Trinidad Head, California.
2. The diurnal monthly PRB concentrations predicted by EPA are mostly in the 0.015 to 0.025 ppm range with few exceptions. Unlike the predicted PRB concentrations, the actual PRB diurnal concentrations experienced at Trinidad Head ranged from 0.050 ppm to approximately 0.030 ppm for the period April to June. Maximum PRB O₃ concentrations at the site are ≥ 0.050 ppm and have been experienced up to 0.066 ppm during the springtime.
3. Natural processes contribute in the springtime to O₃ concentrations measured at the surface in the United States at both high and low-elevation monitoring sites and hourly average concentration ≥ 0.05 ppm in the springtime can be attributed at times to these natural processes (Lefohn *et al.*, 2001; Cooper *et al.*, 2005).
4. Natural processes contribute to the replenishment of PRB across the entire United States and potentially play an important role during the springtime. Ludwig *et al.* (1977), by characterizing the behavior of radioactive debris injected into the stratosphere during nuclear weapons testing in the 1960s, noted that stratospheric O₃ appeared to make important contributions to surface O₃ concentrations in the Pacific Northwest, the eastern slopes of the Rocky Mountains, and the eastern United States during the January – June period.
5. The EPA's risk model is very sensitive to the choice of PRB. Using data from Appendix I from the Risk Assessment TSD (Abt Associates Inc, 2007), Figures 3 – 10 illustrate that the EPA's absolute incidences of O₃ non-accidental mortality estimates are extremely sensitive to the selection of PRB levels. For Los Angeles, using the 2002 air quality data, increasing the PRB by 5 ppb resulted in a 38% reduction in the estimates for absolute incidences of O₃ non-accidental mortality for

the “As Is” option. For the “84/4”, “74/4”, and “64/4” options, there was a 62%, 72%, and 86% reduction in the estimates when 5 ppb was added to PRB for the absolute incidences of O₃ non-accidental mortality, respectively. Similar percentage reductions occurred for Los Angeles using the 2004 air quality data.

6. Because the PRB monthly modeling estimates used to estimate risk were so low (i.e., almost flat diurnal PRB patterns mostly in the 0.015 to 0.025 ppm range with few exceptions), the percent reduction in estimates of absolute incidences of O₃ non-accidental mortality are more than likely greater than those calculated using the small 5 ppb increase in PRB applied in the Staff Paper.
7. The exposure-response function used for the lung function response analyses weights effects at concentrations below 0.04 ppm very low. Thus, adding 5 ppb to the base case assumption of diurnal PRB patterns mostly in the 0.015 to 0.025 ppm range (with few exceptions) would not be expected to affect lung function responses. The resulting PRB concentration increases to the 0.020 to 0.030 ppm range are much too small for PRB estimates. The occurrences of lung function responses would more than likely have shown a greater sensitivity to an increase in PRB if a more realistic range of PRB concentrations had been employed in the Staff Paper.
8. The EPA believes that the available epidemiological evidence neither supports nor refutes the existence of thresholds at the population level for effects such as increased hospital admissions and premature mortality. The no-threshold assumption has been central to the EPA approach for modeling mortality and morbidity effect estimates from O₃ ecologic epidemiology studies, most of which are time-series studies. The Staff Paper argues that potential thresholds from time-series studies, if they exist, may be at low concentrations or approaching background levels. The search for a “threshold” expends valuable creative energy in an arena that will probably bear no useful result. The Agency fails to realize that thresholds are only one example of a nonlinear exposure-response relationship. EPA ignores the evidence in the literature that the concentration-response functions for epidemiological studies are more than likely nonlinear, similar to the nonlinear results reported in controlled human health laboratory studies. Different risk results occur when applying a linear versus a nonlinear model and thus uncertainty exists about what the real effects are. To ignore nonlinearity in the C-R function is an unfortunate omission.
9. The PM Staff Paper (EPA, 2005) noted that a large degree of uncertainty in the human health risk assessments, using results from epidemiological studies, occurred when proportional and nonlinear concentration-response functions were applied in the Agency’s risk analyses. An important question is: what are the effects on risk estimates when applying nonlinear C-R functions in O₃ epidemiological studies? Similar to sensitivity testing using different PRB concentration levels, the uncertainty effects on risk estimates may also be great.
10. The value of the W126 and SUM06 cumulative exposure indices is correlated with the large number of hourly average concentrations ≥ 0.10 ppm (N100) that caused the

vegetation growth reductions observed in the NCLAN-type experiments. However, under ambient conditions, large numbers of hourly average concentrations ≥ 0.10 ppm (N100) are not experienced at most monitoring sites across the United States and the value of the ambient cumulative exposure index (e.g., W126) is not correlated with elevated hourly average concentrations. Because of this observation, neither the W126 nor the SUM06 metrics will provide *consistent* predictions under ambient conditions (i.e., higher values for the metrics do not necessarily imply a greater effect) and will not produce reliable predictions of vegetation effects without including the N100 index.

11. Recently, Davis and Orendovici (2006) have confirmed that under actual ambient field exposure conditions the use of the multi-component exposure index was required. Testing various models, the authors concluded that the model that used (1) plant species, (2) Palmer Drought Severity Index, and (3) the interaction of the W126 exposure index and the N100 index was superior in performance for establishing a statistically significant relationship between vegetation symptoms and O₃ exposure than models that did not use the combined W126 and N100 metrics.
12. By failing to seriously address the inconsistent predictive behavior of either the W126 or SUM06 indices, EPA will be following the identical route that was traveled when the AOT40 cumulative exposure index was applied in Europe. In the 1990s, areas of exceedance were mapped, but analyses at many exposure sites led to the conclusion that the AOT40 provided inadequate estimation of effects (Fuhrer *et al.*, 1997; Kärenlampi and Skärby, 1996). The W126 is a biologically based exposure index that reflects the importance of the elevated hourly average concentrations. However, the N100 index is required to make the W126 index more consistent in its ability to predict vegetation effects.
13. The EPA Staff Paper proposes the use of a 12-hour W126 exposure index instead of a 24-hour W126 index as a possible secondary O₃ standard. An extensive review of the literature reported that a large number of species had varying degrees of nocturnal stomatal conductance (Musselman and Minnick, 2000). Although EPA acknowledges that uptake of O₃ during the nighttime may be important, the Agency concludes that more research is needed. Ignoring nocturnal stomatal O₃ uptake will underestimate possible vegetation effects at some locations in the United States. This underestimate will not compensate for the inconsistent behavior of the W126 index when used without the N100 index.

1. Policy-Relevant Background Levels and Their Effects on Health Effects Risk Assessment

1.1 Introduction

The EPA's risk analyses are very sensitive to the selection of PRB levels. There is considerable uncertainty associated with the PRB modeling estimates made by the EPA. CASAC (Henderson, 2006) in its October 24, 2006 letter (CASAC Chapter-Specific Comments on EPA's 2nd Draft Ozone Staff Paper) to the EPA Administrator noted that the section on policy-relevant background (2.7) continued to have problems. CASAC believed that the section did not adequately address the uncertainties of the global GEOS-CHEM model, and how these uncertainties were reflected in the health risk analysis.

In the final version of the Ozone Staff Paper (EPA, 2007), the Agency failed to address the large degree of uncertainty associated with Policy-Relevant Background (PRB) that has been clearly documented in the Ozone Criteria Document (EPA, 2006), as well as during public written and oral testimony (e.g., Oltmans and Lefohn, 2005; Lefohn, 2006). The concerns that CASAC expressed in its October 24, 2006 letter (Henderson, 2006) concerning the large uncertainties with PRB still remain and this uncertainty affects the Agency's health risk estimates based on both the epidemiological and controlled human health exposure studies.

At the December 2005 CASAC meeting, Oltmans and Lefohn (2005) presented detailed scientific evidence that the empirical hourly average concentration data collected at Trinidad Head, CA were representative of PRB. Although the EPA's Ozone Criteria Document (EPA, 2006) concluded that PRB can be estimated only using chemical transport models (CTMs), the authors of the final version of the EPA's Staff Paper (EPA, 2007) appear to agree with Oltmans and Lefohn (2005) by noting "The comparisons at Trinidad Head are especially relevant because sources of the O₃ found there are often limited to those in the PRB definition" (page 2-54).

As indicated by Oltmans and Lefohn (2005) and the Staff Paper (EPA, 2007) the comparisons at Trinidad Head are especially relevant because sources of the O₃ found there are mostly associated with the PRB definition. Using published work by Goldstein *et al.* (2004), the Staff Paper (EPA, 2007) concludes “the observations, filtered to remove local influence, averaged 41 ± 5 ppbv, as compared to GEOS-CHEM predictions of 39 ± 5 ppbv, indicating no significant differences between the model predictions and observations for conditions suggestive of PRB.” These results, as reported in the Staff Paper (EPA, 2007), are described in Goldstein *et al.* (2004). However, the Staff Paper unfortunately omitted the discussion in Goldstein *et al.* (2004) pointing out that neither the GEOS-CHEM nor the MOZART models was successful in reproducing the hourly day-to-day temporal structure in the 4-week (April 19 – May 22, 2002) study-period observations. The use of short 4-week study-period averages mentioned in the Staff Paper (2007) “smoothed” the actual temporal differences that occurred between the modeling predictions and the empirical data and significant uncertainties exist between the measurements made at the Trinidad Head PRB monitoring site and the predictions originating from the GEOS-CHEM model.

Although the predictions originating from the GEOS-CHEM model were unable to match the Trinidad Head PRB data, the Staff Paper (EPA, 2007) has applied the PRB GEOS-CHEM modeling results that indicated that “O₃ concentrations at the surface are generally predicted to be in the range of 0.015 to 0.035 ppm in the afternoon” and “...40 ppb is likely to be too high for the mean PRB O₃ concentration” (page 2-55). The exposure and health risk analyses described in Chapters 4 and 5 use estimates of PRB based on runs of the GEOS-CHEM model applied for the 2001 warm season (i.e., April to September). These data were used to create monthly average diurnal profiles, which were fixed for each month during the O₃ season. The PRB estimates from

the grid nearest each of the 12 urban areas (Atlanta, Boston, Chicago, Cleveland, Detroit, Houston, Los Angeles, New York City, Philadelphia, Sacramento, St. Louis, and Washington, D.C.) included in the exposure and risk analyses were used to estimate PRB in each of these areas.

The PRB monitoring site at Trinidad Head experiences a significant diurnal variation in O₃ mixing ratios with minimum values in the early morning and highest amounts throughout the afternoon (Oltmans and Lefohn, 2005). The diurnal signal in O₃ at Trinidad Head is not, however, driven by the diurnal pattern of photochemical O₃ production but by the pattern of onshore and offshore flow regimes. During the day, the measurement site is well ventilated by air coming directly off the Pacific Ocean. During the early morning and evening, air that has passed over heavily vegetated terrain to the east of the sampling site and is *depleted* in O₃ by deposition often reaches the measurement location (Oltmans and Lefohn, 2005). If the air were to come off the Pacific Ocean over a 24-hour period, the actual PRB concentrations at Trinidad Head would exhibit a diurnal pattern that would be fairly flat. For estimating PRB at Trinidad Head, the O₃ concentrations currently observed in the diurnal pattern during the early morning and evening periods would actually be greater than those currently measured at the monitoring site. For comparison of the PRB concentrations measured at Trinidad Head with the EPA's estimates of PRB, I have used the actual data at Trinidad Head and have not corrected for what the pattern would appear to be if the air were coming off the Pacific Ocean over a 24-hour period.

The diurnal monthly concentrations derived from the modeled PRB predictions are much lower at all of the 12 urban areas during the springtime period than the actual PRB

concentrations reported at Trinidad Head. Figure 1 illustrates the comparison for the month of April between predicted PRB diurnal concentrations for the 12 cities and the diurnal pattern for

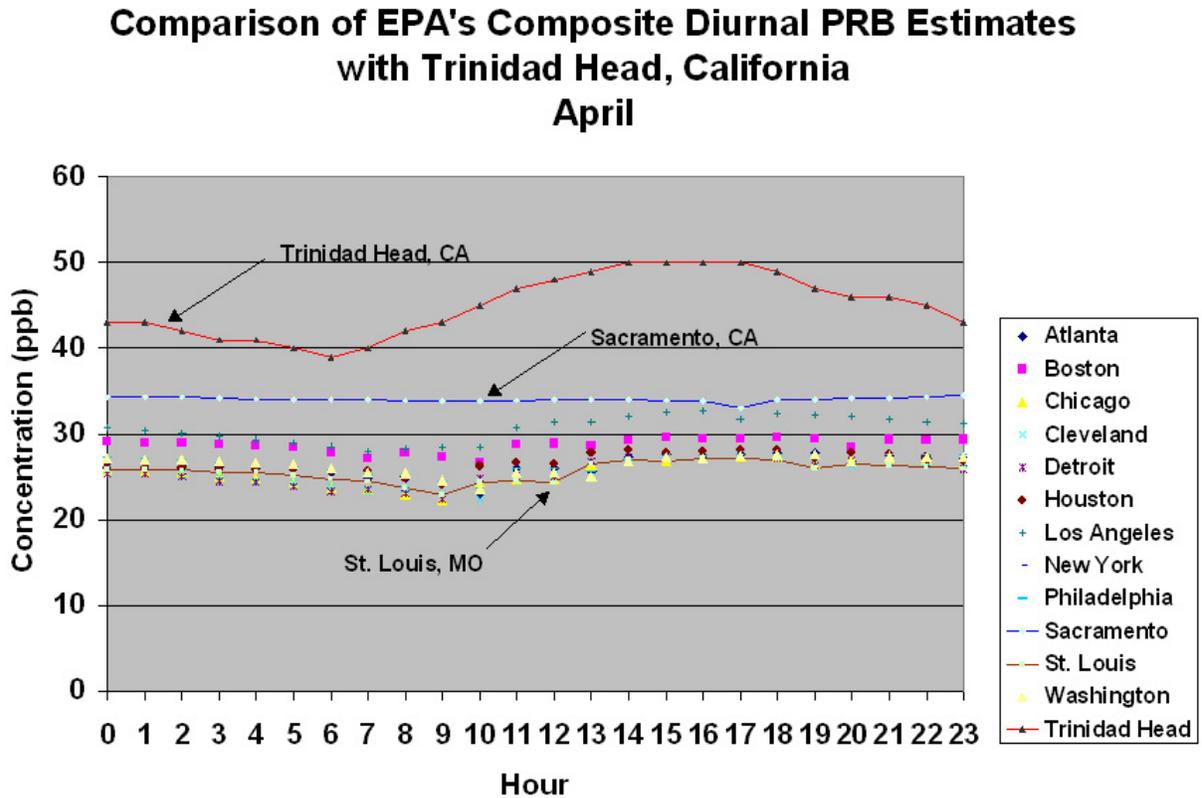


Figure 1. Comparison of EPA’s composite diurnal PRB O₃ estimates with Trinidad Head, CA for April. Source: Oltmans and Lefohn (2005).

Trinidad Head. For the month, the maximum monthly diurnal average at Trinidad Head was 0.050 ppm and the minimum diurnal average was 0.039 ppm. In comparing the diurnal patterns for the months of April through July, it is not until July that the diurnal PRB pattern for Trinidad Head is equivalent to the predicted PRB hourly average concentrations predicted by the GEOS-CHEM model for the 12 cities (Lefohn, 2006). The PRB concentrations predicted by EPA are mostly in the 0.015 to 0.025 ppm range with few exceptions (see Appendix 2A of the Staff Paper). The PRB averaged diurnal concentrations at Trinidad Head ranged from 0.050 ppm to

approximately 0.030 ppm for the period April to June. Maximum PRB O₃ concentrations at the site are ≥ 0.050 ppm and have been experienced up to 0.066 ppm during the springtime.

During the CASAC deliberations at the August 24-25, 2006 CASAC meeting, a discussion occurred that hypothesized that the empirical PRB data at Trinidad Head did not represent PRB at other locations except for areas along the west coast of the United States. It was the opinion of some of the discussants that the PRB O₃ concentrations measured at Trinidad Head were lower at monitoring sites east of the California site because NO_x scavenged PRB O₃ concentrations as they were transported across the United States. It appeared that some of the discussants assumed that the replenishment by natural processes was minimal at all times during the year. Even if this assumption were correct, which I do not believe, the EPA's predictions for PRB O₃ concentrations for the two western United States' sites (i.e., Los Angeles and Sacramento) should have been comparable to the PRB O₃ concentrations measured at Trinidad Head, California, which they were not.

Natural processes contribute in the springtime to O₃ concentrations measured at the surface in the United States at both high and low-elevation monitoring sites and hourly average concentration ≥ 0.05 ppm in the springtime can be attributed at times to these natural processes (Lefohn *et al.*, 2001; Cooper *et al.*, 2005). Measurements of radioactive debris transported downward from the stratosphere, as the result of nuclear testing during the 1960s, show clear patterns of transported stratospheric O₃ during the springtime at both high- and low-elevation surface monitoring sites (Ludwig *et al.*, 1977). Ludwig *et al.* (1977) examined the behavior of a surrogate for stratospheric O₃ by characterizing the behavior of radioactive debris injected into the stratosphere during nuclear weapons testing in the 1960s. The transfer of this debris from the stratosphere to the troposphere, and downward to the surface was used to trace the transfer

processes that would move stratospheric O₃ over the same route. Using ⁹⁰Sr, Ludwig *et al.* (1977) concluded that a significant stratospheric contribution to seasonally averaged, ground level O₃ concentrations in the middle latitudes of the Northern Hemisphere, with a maximum occurring in the springtime, was evident. Ludwig *et al.* (1977) reported that stratospheric O₃ appeared to make important contributions to surface O₃ concentrations in the Pacific Northwest, the eastern slopes of the Rocky Mountains, and the eastern United States during the January – June period.

Natural processes contribute to the replenishment of PRB and potentially play an important role during the springtime. The key issue is the frequency of stratospheric O₃ transported down to the surface during the springtime and the absolute value of the contribution. Stohl *et al.* (2003) point out that during pre-industrial times, when tropospheric O₃ concentrations were lower than today's levels, stratospheric-tropospheric exchange processes made the major contribution to surface O₃. Using the Schönbein method, Bojkov (1986) concluded that the average daily maximum of the surface O₃ partial pressure in the Great Lakes area of North America was approximately 0.019 ppm between the 1870s and 1903. Although there is difficulty, because of uncertainties in using some of the earlier methods in quantifying the differences between surface O₃ concentrations measured in the last half of the 19th century with those currently monitored at remote locations in the world, the actual patterns of exposure (e.g., springtime maximum concentrations) reported are of particular interest. Figure 2 from Bojkov (1986) paper is shown. Note that the highest daily maximum O₃ concentrations occurred during the April – May period. Data from Bojkov (1986) for 19th century O₃ concentrations measured in the United States (Bojkov, 1986) showed that spring peak O₃ partial pressures were about 4 ± 1 mPa (30-50 ppb) in the Midwestern United States. In his study, Bojkov (1986)

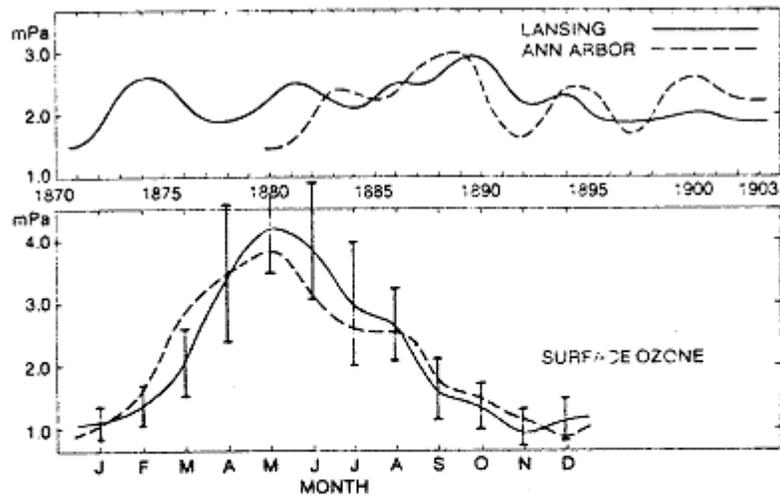


FIG. 2. Surface ozone partial pressures at Lansing (1871-1903), and Ann Arbor (1880-1903), Michigan. Upper panel: long-term course smoothed by $b' = (a + 2b + c)/4$ filter; Lower panel: annual cycle of the daily maximum values with vertical bars representing 2σ for each monthly average at Lansing (the standard deviation is nearly identical at Ann Arbor). See text for discussion.

Source: Bojkov (1986)

Figure 2. Surface ozone partial pressures measured at Lansing (1871-1903) and Ann Arbor (1880-1903), Michigan. (Source: Bojkov, 1986).

determined the daily maximum O_3 values by identifying the maximum of the 7-hour average values of the daytime (0700-1400 h) or nighttime (2100-0700 h) periods. Although the absolute values for the daily maximum 7-h average concentrations may be uncertain, the springtime pattern of higher O_3 values observed by Bojkov (1986) during the pre-industrial period appears to match the current seasonal pattern and concentration levels observed at the PRB site at Trinidad Head.

1.2 The Results of Altering Policy-Relevant Background Levels on Risk Estimates

As indicated in the Introduction (Section 1.1), there is serious concern that EPA has underestimated the PRB levels used in the Staff Paper for the 12 urban areas. In the Staff Paper,

EPA (2007) selected three locations (Atlanta, Los Angeles, and New York) for a sensitivity analysis for lung function responses, and calculated lung function responses using (1) the original PRB estimates, (2) lower PRB estimates for each location, and (3) higher PRB estimates for each location. EPA's staff also conducted a sensitivity analysis for non-accidental mortality associated with O₃ exposure for all 12 urban areas. For all of the urban areas, except Atlanta, the lower PRB estimates were calculated by subtracting 5 ppb from the original PRB estimates; for Atlanta, the lower PRB estimates were calculated by subtracting 10 ppb from the original PRB estimates. In all locations, the higher PRB estimates were calculated by adding 5 ppb to the original PRB estimates.

Results of the PRB sensitivity analysis for non-accidental mortality associated with O₃ exposures expressed in terms of absolute estimates were presented for 2002 and 2004 for recent air quality and air quality adjusted to just meet the current (0.084 ppm, 4th daily maximum) and two alternative standards (0.074 ppm, 4th daily maximum and 0.064 ppm, 4th daily maximum) (see Risk Assessment TSD, Section 4.3 and Appendix I). Appendix I presents the results using incidence and incidence per 100,000 relevant population.

Because it appears that EPA has underestimated PRB concentrations, the focus on the remaining part of this section is on the decreases in estimated risk associated with *adding* 5 ppb to the original PRB estimates for the 12 cities. Although EPA has added 5 ppb to its PRB estimates, it is my opinion that because the PRB estimates were so low to begin with (i.e., 15 - 25 ppb), the decreases in risk are even greater than those estimated in the Staff Paper. In the sensitivity analyses, higher assumed PRB levels generally resulted in decreased estimates in the incidence of mortality. Estimates assuming higher PRB levels result in decreased estimates of

non-accidental mortality incidence per 100,000 that were 50% or greater less than the base case estimates. On page 5-82 of the Staff Paper (EPA, 2007), EPA concludes:

...changing the estimates of PRB tended to have progressively greater impacts on the estimates of mortality risk as progressively more stringent standards were considered....

Using the data set identified in Figures 6-5 and 6-6 (i.e., Bell *et al.*, 2004 – 95 U.S. Cities) of the Staff Paper (pages 6-71 and 6-72), I have quantified the differences in the absolute incidences of O₃ non-accidental mortality between the baseline PRB and baseline PRB+5 ppb. The actual data used in my analyses were obtained from Appendix I from the Risk Assessment TSD (Abt Associates Inc, 2007). Figures 3 – 10 illustrate the results of comparing the O₃-related non-accidental mortality incidences for the current and alternative standards when PRB estimates are increased 5 ppb using 2002 and 2004 air quality data. The blue bars represent the baseline PRB incidence estimates and the maroon bars represent the PRB + 5 ppb incidences. The percentages above the bars represent the percent decrease changes in incidences as PRB was increased by 5 ppb.

Figures 3 – 10 illustrate that the EPA’s absolute incidences of O₃ non-accidental mortality estimates are extremely sensitive to the selection of PRB levels. For example, increasing the PRB by 5 ppb over the PRB baseline for Los Angeles in 2002 resulted in a 38% reduction in the estimates for absolute incidences of O₃ non-accidental mortality for the “As Is” option. For the “84/4”, “74/4”, and “64/4” options, there was a 62%, 72%, and 86% reduction in the estimates when 5 ppb was added to PRB for the absolute incidences of O₃ non-accidental mortality, respectively. Similar percentage reductions occurred for Los Angeles using the 2004 air quality data. Because the PRB modeling estimates used to estimate risk were so low (i.e., almost flat diurnal PRB patterns mostly in the 0.015 to 0.025 ppm range with few exceptions), the percent reduction in estimates of absolute incidences of O₃ non-accidental mortality are more

Comparison of Ozone-Related Non-Accidental Mortality Incidences for "As Is" When PRB Estimates are Increased 5 ppb - 2002 Air Quality Data

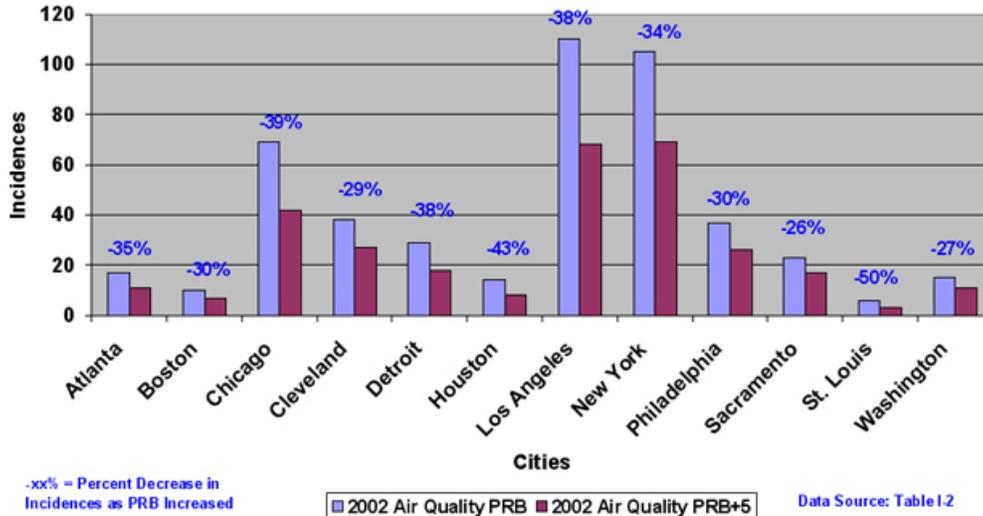


Figure 3. Comparison of ozone-related non-accidental mortality incidences “As Is” when PRB estimates are increased 5 ppb – 2002 air quality data.

Comparison of Ozone-Related Non-Accidental Mortality Incidences for "84/4" When PRB Estimates are Increased 5 ppb - 2002 Air Quality Data

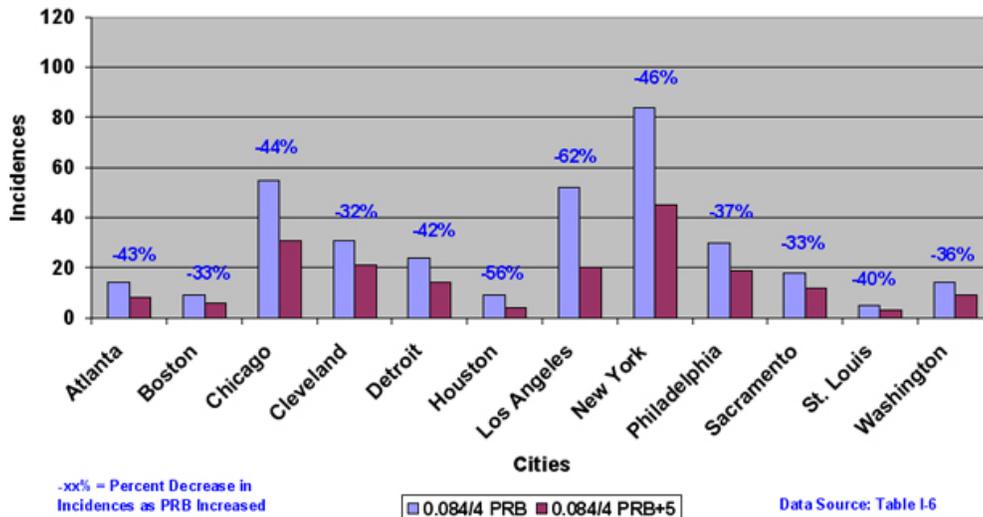


Figure 4. Comparison of ozone-related non-accidental mortality incidences “84/4” when PRB estimates are increased 5 ppb – 2002 air quality data.

Comparison of Ozone-Related Non-Accidental Mortality Incidences for "74/4" When PRB Estimates are Increased 5 ppb - 2002 Air Quality Data

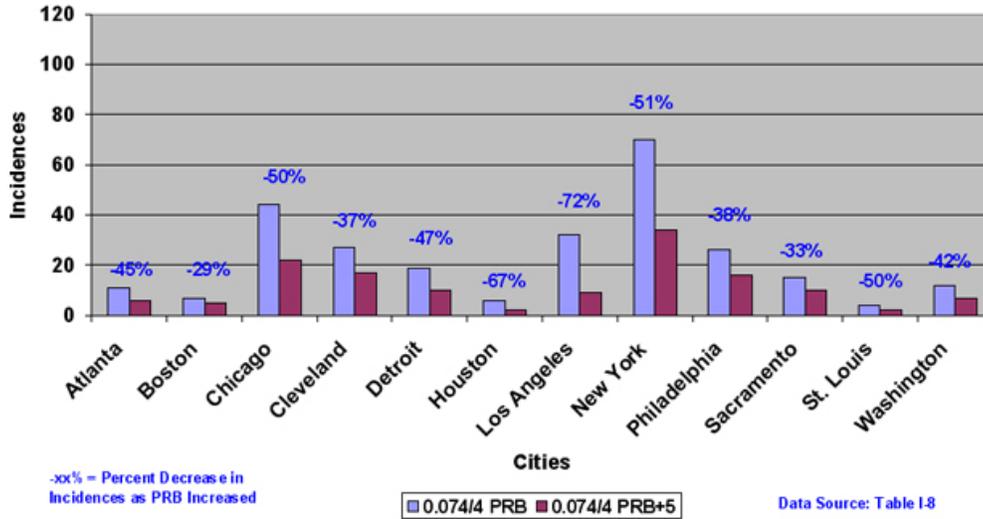


Figure 5. Comparison of ozone-related non-accidental mortality incidences “74/4” when PRB estimates are increased 5 ppb – 2002 air quality data.

Comparison of Ozone-Related Non-Accidental Mortality Incidences for "64/4" When PRB Estimates are Increased 5 ppb - 2002 Air Quality Data

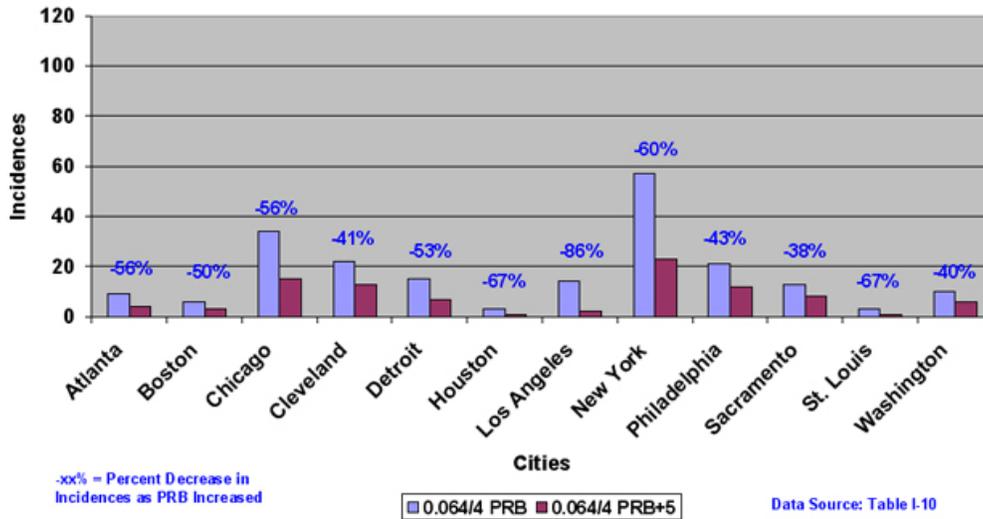


Figure 6. Comparison of ozone-related non-accidental mortality incidences “64/4” when PRB estimates are increased 5 ppb – 2002 air quality data.

Comparison of Ozone-Related Non-Accidental Mortality Incidences for "As Is" When PRB Estimates are Increased 5 ppb - 2004 Air Quality Data

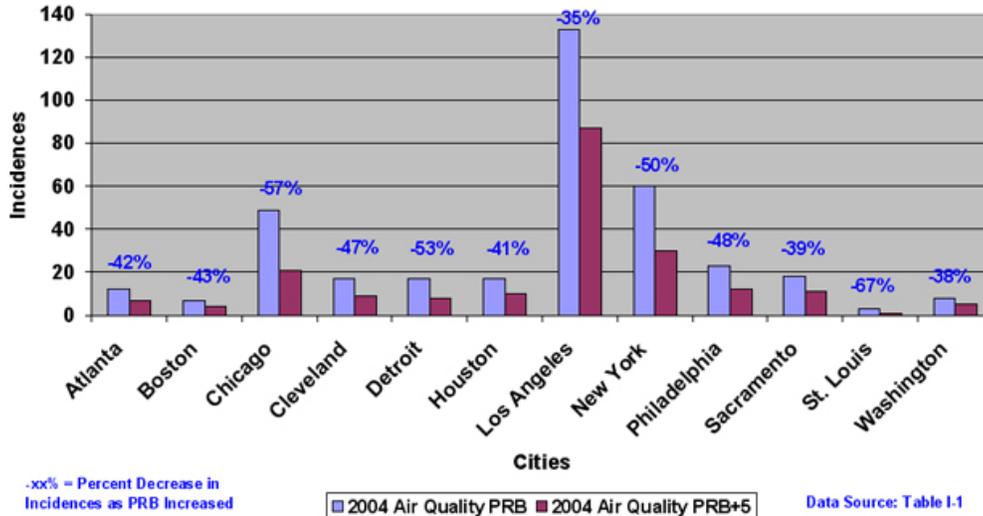


Figure 7. Comparison of ozone-related non-accidental mortality incidences “As Is” when PRB estimates are increased 5 ppb – 2004 air quality data.

Comparison of Ozone-Related Non-Accidental Mortality Incidences for "84/4" When PRB Estimates are Increased 5 ppb - 2004 Air Quality Data

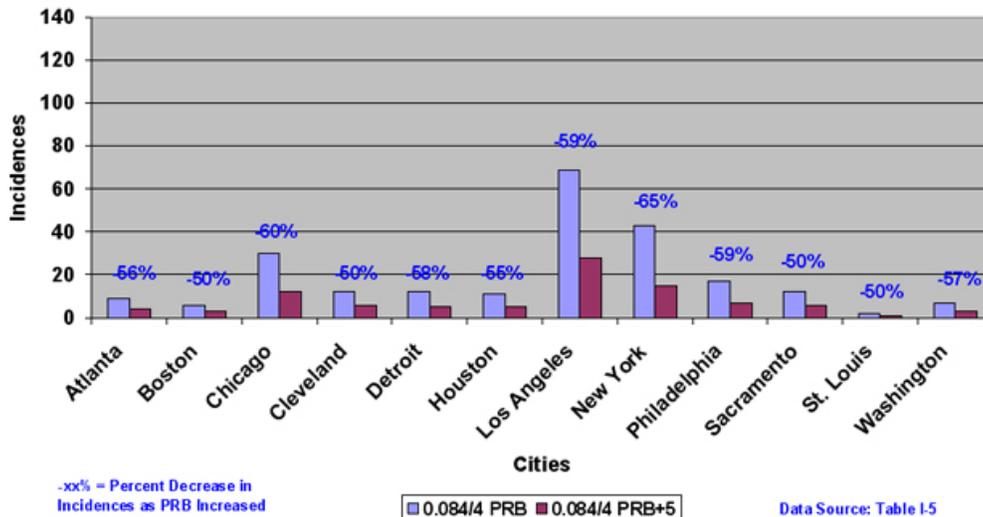


Figure 8. Comparison of ozone-related non-accidental mortality incidences “84/4” when PRB estimates are increased 5 ppb – 2004 air quality data.

Comparison of Ozone-Related Non-Accidental Mortality Incidences for "74/4" When PRB Estimates are Increased 5 ppb - 2004 Air Quality Data

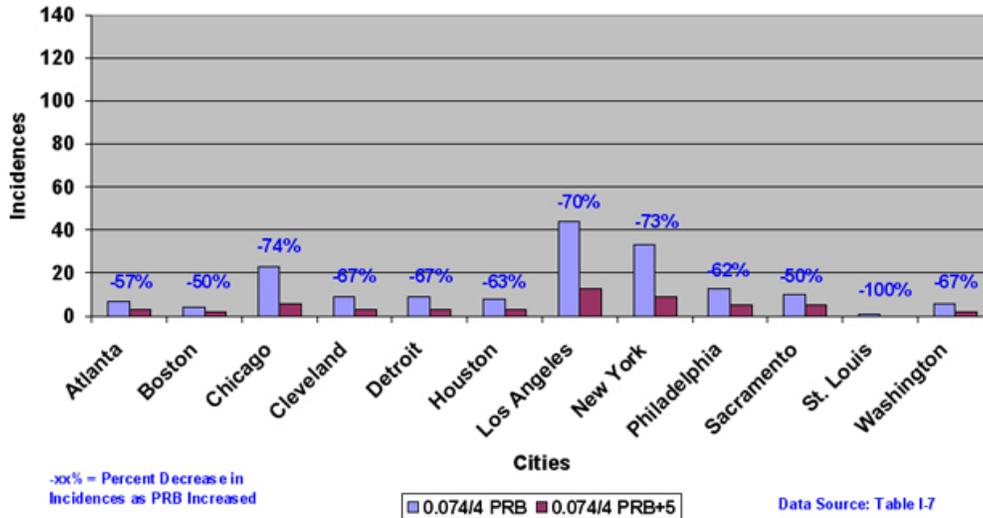


Figure 9. Comparison of ozone-related non-accidental mortality incidences “74/4” when PRB estimates are increased 5 ppb – 2004 air quality data.

Comparison of Ozone-Related Non-Accidental Mortality Incidences for "64/4" When PRB Estimates are Increased 5 ppb - 2004 Air Quality Data

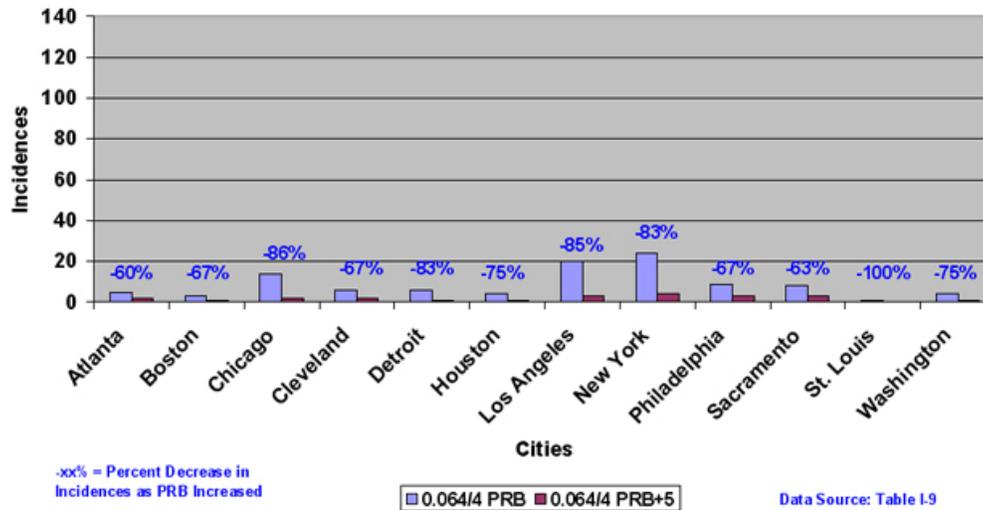


Figure 10. Comparison of ozone-related non-accidental mortality incidences “64/4” when PRB estimates are increased 5 ppb – 2004 air quality data.

than likely greater than those calculated using the small 5 ppb increase in PRB applied in the Staff Paper.

When I evaluated the data in the various tables in the Staff Paper (EPA, 2007), I noticed that the information in the “Percent of Total Incidence” column in Tables 5-16 and 5-17 appeared to be overestimated by a factor of two. Dividing the information in the column entitled “Incidence per 100,000 Relevant Population” by the baseline mortality rates provided in Table 5-6 and multiplying by 100 can confirm this. Although this apparent error did not affect my calculations, they might affect policy decisions that would be based on this column of information.

As indicated earlier, in the PRB sensitivity analysis for lung function responses, EPA selected three locations (Atlanta, Los Angeles, and New York), and calculated lung function responses using (1) the original PRB estimates, (2) lower PRB estimates for each location, and (3) higher PRB estimates for each location. The Staff Paper noted that the impact of alternative lower and higher assumed PRB levels on lung function responses in all school age children (with responses defined as a decrement in FEV1 > 15%,) was relatively small, generally much less than $\pm 3\%$. In terms of total occurrences of moderate lung function responses, the Staff Paper (2007) reported that different assumptions about PRB had a somewhat larger impact, but the impact was still generally less than about $\pm 10\%$ relative to the base case assumption for PRB. It is important to note that the exposure-response function used for the analyses weights effects associated with the EPA estimated PRB concentrations very low. Figure 11, reproduced from page 5-26 of the Staff Paper (EPA, 2007), illustrates that PRB concentrations below 0.04 ppm have minimum impact on lung function response. The figure shows that adding 5 ppb to the base case assumption of diurnal PRB patterns mostly in the 0.015 to 0.025 ppm range (with few

exceptions) would not be expected to affect lung function responses. A PRB range of 0.020 to 0.030 ppm range is much too small for PRB estimates. The occurrences of lung function responses would more than likely show a greater sensitivity to increases in PRB if a more realistic range of PRB concentrations had been employed in the Staff Paper.

Figure 5-4. Median Exposure-Response Functions Using Three Different Combinations of Logistic and Linear (Hockeystick) Models

Figure 5-4a. FEV₁ Decrements $\geq 10\%$

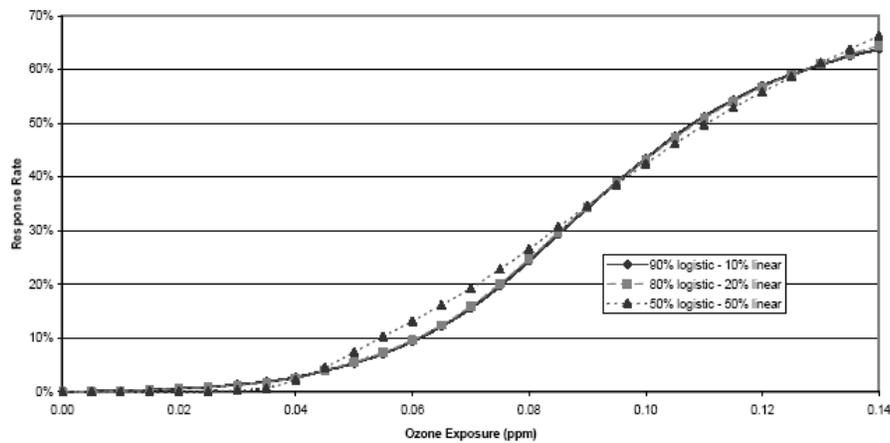


Figure 5-4b. FEV₁ Decrements $\geq 15\%$

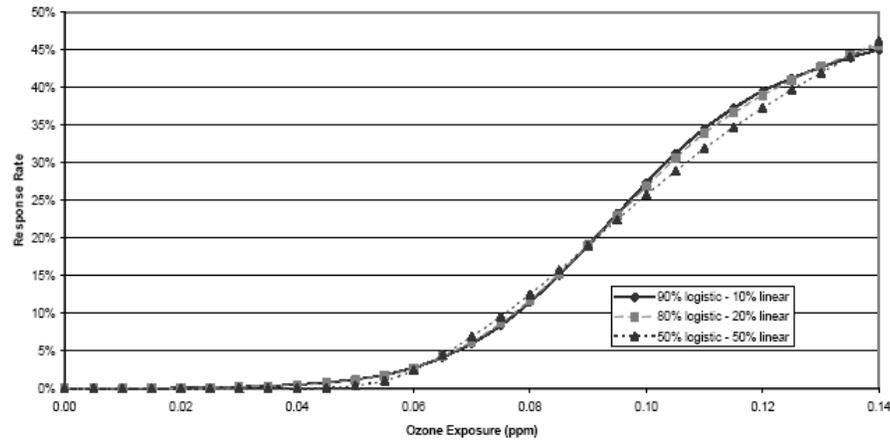


Figure 11. Median exposure-response function.

2. Threshold versus Nonlinearity for Epidemiologic Risk Estimates

On Page 3-48 of the Staff Paper (EPA, 2007), the authors note that the available evidence from epidemiological studies suggest that no clear conclusion can be reached with regard to possible threshold levels for O₃-related effects. The EPA believes that the available epidemiological evidence neither supports nor refutes the existence of thresholds at the population level for effects such as increased hospital admissions and premature mortality. The no-threshold assumption has been central to the EPA approach for modeling mortality and morbidity effect estimates from ozone ecologic epidemiology studies, most of which are time-series studies. The Staff Paper argues that potential thresholds from time-series studies, if they exist, may be at low concentrations or approaching background levels. The search for a “threshold” expends valuable creative energy in an arena that will probably bear no useful result. The Agency fails to realize that thresholds are only one example of a nonlinear exposure-response relationship. EPA ignores the evidence in the literature that the concentration-response functions for epidemiological studies are more than likely nonlinear, similar to the nonlinear results reported in controlled human health laboratory studies. Obviously, the choice of the C-R function greatly affects the magnitude of the predicted human health risk. Different risk results occur when applying a linear versus a nonlinear model and thus uncertainty exists about what the real effects are. To ignore nonlinearity in the C-R function is an unfortunate omission.

While EPA staff continues to search for the existence of a threshold for use in the C-R function using time-series results, vegetation researchers, which include EPA scientists, have focused their attention on exploring nonlinearity in the exposure-response functions associated with the effects of vegetation growth reduction and O₃ exposures. The recommendation by CASAC and the authors of the Staff Paper (EPA, 2007) to adopt the W126 cumulative exposure

index as a possible secondary O₃ standard reflects the realization that nonlinear relationships are important. CASAC and the authors of the Staff Paper (EPA, 2007) note that a vegetation threshold-based exposure index, such as the SUM06, is not as biologically relevant as the continuously weighted sigmoid W126 exposure index because thresholds have not been identified for vegetation effects. The PM Staff Paper (EPA, 2005) noted that a large degree of uncertainty in the human health risk assessments, using results from epidemiological studies, occurred when proportional and nonlinear concentration-response functions were applied in the Agency's risk analyses. An important question is what are the effects on risk estimates when applying nonlinear C-R functions in O₃ epidemiological studies? Similar to sensitivity testing using different PRB concentration levels, the uncertainty effects on risk estimates may also be great.

3. The Use of the W126 Exposure Cumulative Exposure Index as a Secondary O₃ Standard

In 1985, as a participant of the National Crop Loss Assessment Network (NCLAN) research group, I proposed the use of the W126 exposure index as a biologically based metric for predicting vegetation effects from O₃ exposures. The cumulative exposure W126 exposure index uses a sigmoidally weighted function as described by Lefohn and Runeckles (1987) and Lefohn *et al.* (1988). As described in the Ozone CD (EPA, 2006) and Staff Paper (EPA, 2007), the W126 index focuses on the higher hourly average concentrations, while retaining the mid- and lower-level values and avoids applying a non-biologically based artificial threshold.

3.1 The Inconsistency of Exposure Indices in Predicting Vegetation Effects

Based on analyzing the NCLAN data, Lefohn and Foley (1992) noted that in order for the W126 to perform adequately *under ambient conditions* as an exposure metric that predicts vegetation effects, the number of hourly average concentrations ≥ 0.10 ppm (N100) had to be coupled with the W126 index. This was because the exposure-response relationships developed for the W126 exposure index were based on the NCLAN fumigation protocol, which resulted in large numbers of hourly average concentrations ≥ 0.10 ppm. In other words, the exposure-response relationships are tightly linked to the artificially high number of elevated O₃ concentrations that originated in the NCLAN experiments. The elevated hourly average concentrations observed in the NCLAN experiments were responsible for causing the reduction in observed yields. In turn, the elevated hourly average concentrations were highly correlated with the value of the cumulative exposure index (i.e., W126 or SUM06) calculated. Under ambient conditions, large numbers of hourly average concentrations ≥ 0.10 ppm are not experienced at most monitoring sites across the United States and the value of the cumulative exposure index (e.g., W126) is no longer correlated with the elevated hourly average concentrations that caused the growth reductions observed in the NCLAN-type experiments. Because of this observation, both the W126 and SUM06 metrics are not *consistent* (i.e., higher values for the metrics do not necessarily imply a greater effect) under ambient conditions and will not produce reliable predictions of vegetation effects without including the N100 index. Yun and Laurence (1999) showed that the *same* SUM06 value resulted in very different foliar injury when exposure regimes with different numbers of high concentrations were applied. The authors concluded that the SUM06 might not be a good predictor of injury. Additional concerns have been raised in the literature (e.g., Lefohn and Foley, 1992; Lefohn *et al.*, 1997; Edwards *et al.*,

1994; FLAG, 2000; Musselman *et al.*, 2006) about the use of only the W126 or SUM06 exposure-response relationships for predicting vegetation effects if the relationships were derived using NCLAN-type experimental data. Lefohn (1998) and Lefohn *et al.* (1997) have provided examples of the application of a multi-component index (i.e., W126 and N100) using data derived from NCLAN fumigation protocols. The authors believed that the multi-component index addressed the problem of the inconsistency of the W126 and SUM06 cumulative exposure indices.

Recently, Davis and Orendovici (2006) confirmed that under actual ambient field exposure conditions, the use of the multi-component exposure index was required. Testing various models, the authors concluded that the model that used (1) plant species, (2) Palmer Drought Severity Index, and (3) the interaction of the W126 exposure index and the N100 index was superior in performance for establishing a statistically significant relationship between vegetation symptoms and O₃ exposure than models that did not use the combined W126 and N100 metrics. The authors reported that the incidence of O₃ symptoms was most related to the O₃ metrics W126 index coupled to the N100 index.

Although the concern was raised by Lefohn and Foley (1992) and recently noted by Musselman *et al.* (2006) in a critical review of the use of exposure- and flux-based indices in assessing vegetation effects, the Staff Paper (EPA, 2007) ignored this important consideration except for describing the concern. On page 8-20, the authors state, “Specifically, a few commenters (sic) were of the view that a W126 (or SUM06) was not sufficient in and of itself but should be combined with a measure of the number of peaks above 100 ppb (N100).”

An example of what happens when only the W126 cumulative exposure index is used to predict vegetation effects is discussed in the following pages. Figure 12 (from page 7-28 of the

Staff Paper) illustrates the estimated 12-hour, 3-month W126 cumulative exposure for 2001 for the United States. Adjusting the hourly average concentrations downward by 10% resulted in applying “corrected” W126 values to estimate black cherry biomass loss. Figure 13 (from page 7H-3 in the Appendix to the Staff Paper) illustrates the predicted losses for black cherry in 2001. Between 20 to 30% biomass loss was estimated for black cherry for 2001 for the Allegheny National Forest in Pennsylvania.

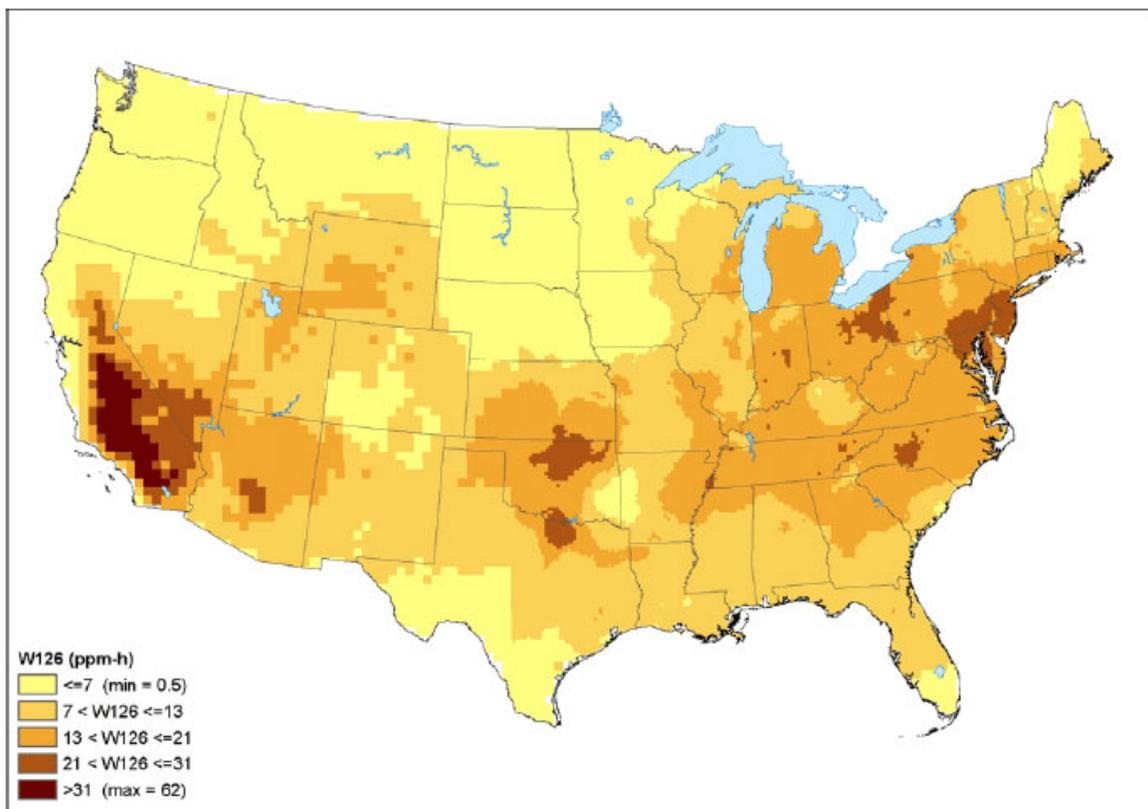


Figure 12. 12-hour, 3-month W126 cumulative exposure for 2001. Source: EPA (2007).

Unfortunately, there is little or no ground truth associated with the biomass loss predictions and thus, EPA is unable to confirm any of the loss estimates. Thus, at best, the exposure-response models used in the Staff Paper (EPA, 2007) are theoretical models used to “estimate” vegetation effects; information about the uncertainty associated with the predictions is

lacking. Given the large biomass loss estimated for black cherry for 2001, I have reviewed the U.S. Department of Agriculture Forest Service's bioindicator surveys to explore whether some indication exists for large biomass losses for black cherry for the 2001 growth season.

Morin *et al.* (2006) reported on the O₃ bioindicator survey results conducted for the Allegheny National Forest for the period 1998 and 2001 for both black cherry and pin cherry for each year. The amount of symptoms exhibited (an indicator of a physiological response)

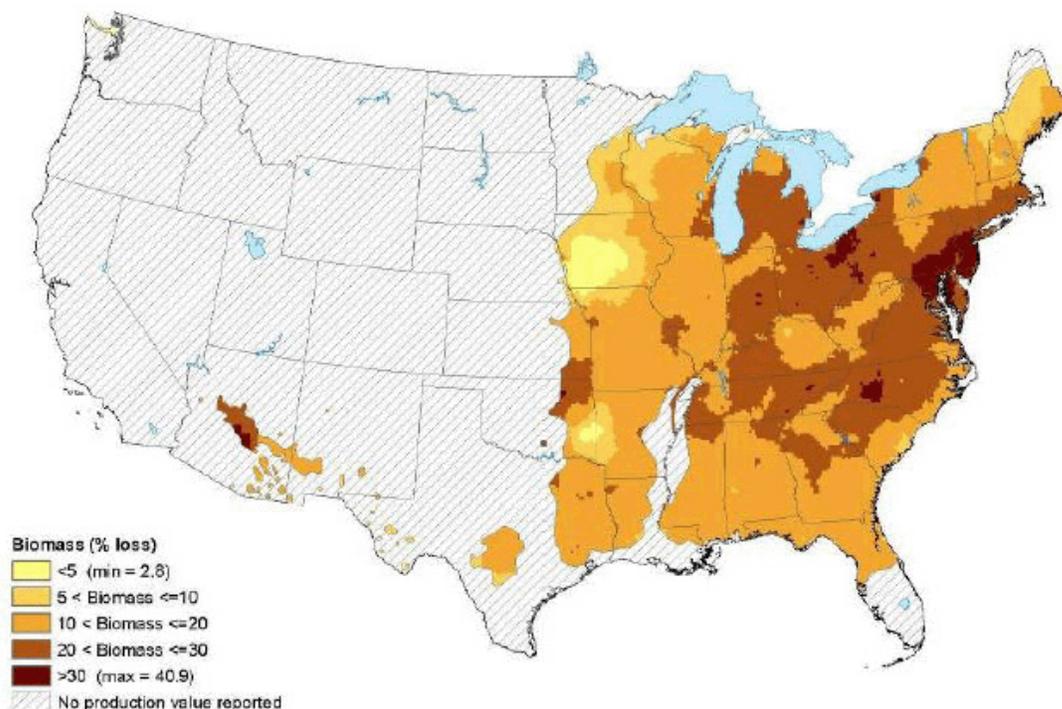


Figure 13. Estimated black cherry annual biomass loss based on interpolated 2001 maximum 3-month 12-hour W126 with a 10% downward adjustment of hourly O₃ concentrations. Source: Appendix to Staff Paper (EPA, 2007).

on the black cherry was less for the years when the Palmer Hydrologic Index was the lowest (i.e., 1999 and 2001) (<http://www1.ncdc.noaa.gov/pub/data/cirs/>). Morin *et al.* (2006) also reported survey results from 173 plots on the Allegheny National Forest. The authors recorded observations on the health of black cherry trees between 1998 and 2001. Observations were

made of the following forest health indicators: crown dieback, crown density, crown ratio, foliage transparency, the types of tree damage, and the amount of standing dead trees. None of the results for the forest health indicators showed any concerns for the health of the population of black cherry in the Allegheny National Forest. If O₃ exposures were significantly impacting the carbohydrate production or causing the trees to utilize carbohydrate reserves, there could be an increase in the amount of crown dieback or mortality. Some crown dieback was observed on black cherry, but this was associated with areas which were defoliated by cherry scalloped moth and/or elm spanworm. Mortality of black cherry was greatest in the smallest diameter class, which the authors reported "... likely was due to self-thinning of this shade-intolerant species."

Figure 14 illustrates the 24-hour, 6-month (April – September) W126 kriged exposure values for 2001 for the United States. The kriged values used in the figure were presented in Chapter 3 of the Ozone CD (EPA, 2006). In contrast to the W126 exposure values, Figure 15 illustrates the number of hourly average concentrations ≥ 0.10 ppm (N100) for the same period. Note that most of the United States experiences infrequent occurrences of N100 values. Areas of concern are located in California, Texas, parts of the Midwest, South, and East. An entirely different picture of potential vegetation impacts exists when one compares Figures 14 and 15. Based on published experimental results, the addition of the N100 provides a more realistic picture of the potential for vegetation effects based on the concept that the higher hourly average concentrations should be provided greater weight than the mid- and low-level concentrations.

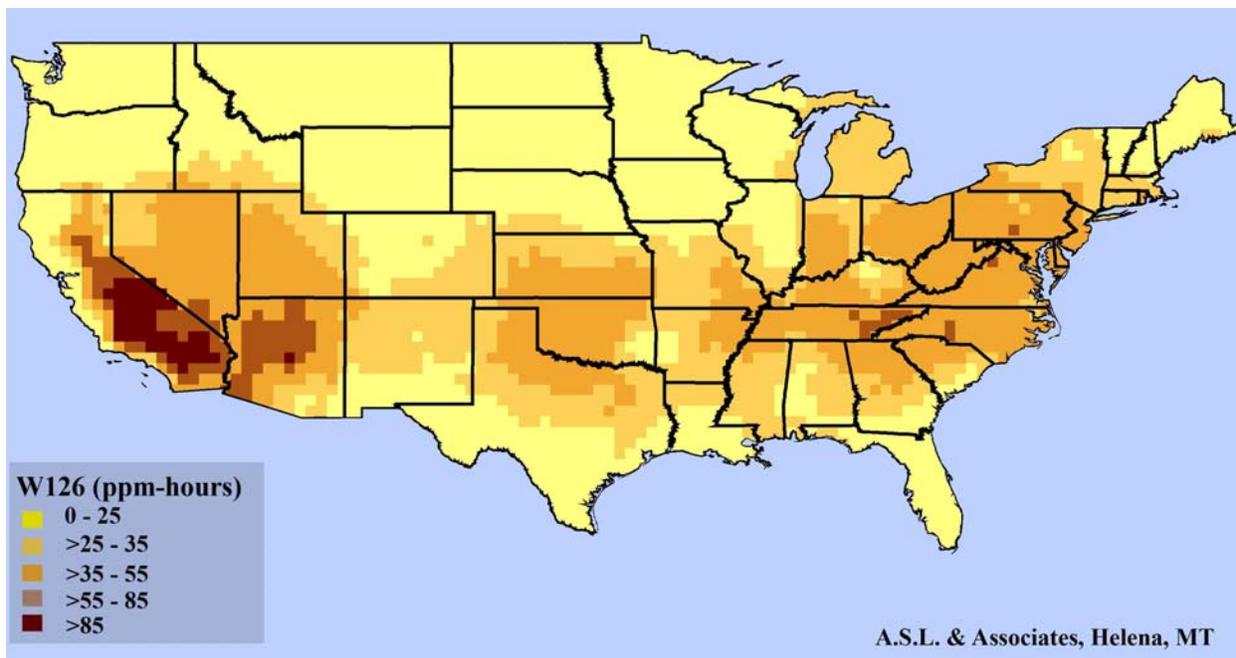


Figure 14. 24-hour, 6-month (April – September) W126 cumulative exposure for 2001. Data Source: EPA (2006).

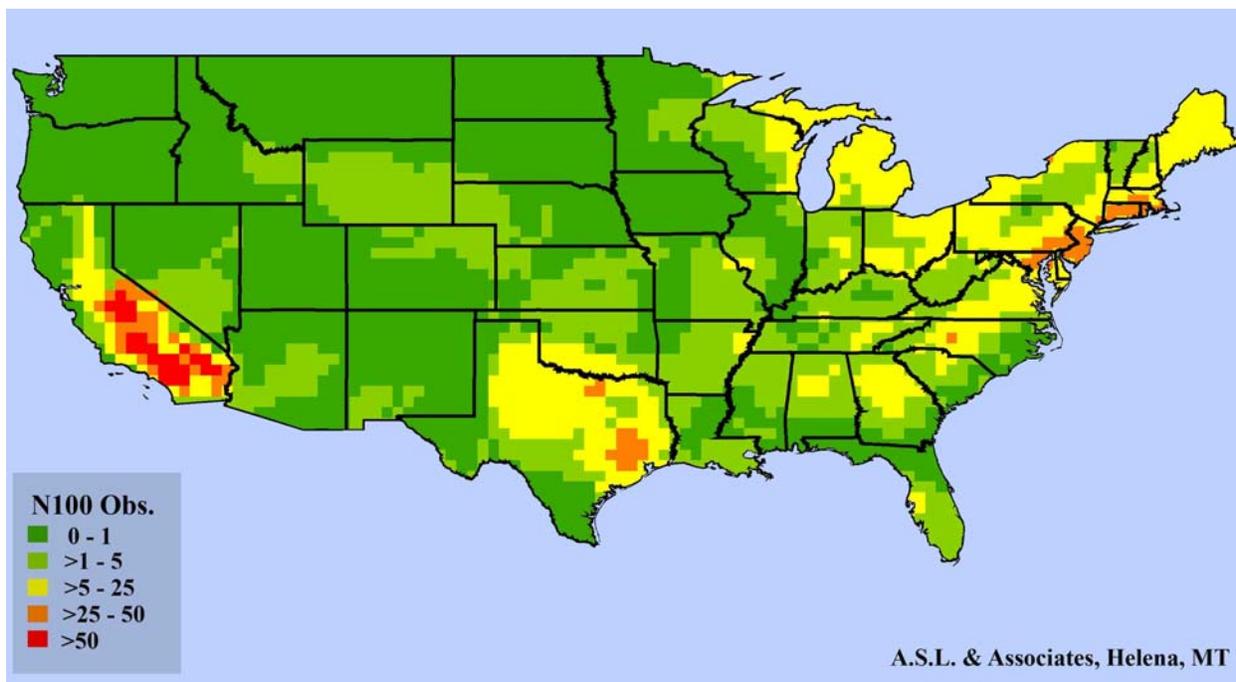


Figure 15. 24-hour, 6-month (April – September) N100 values for 2001. Data Source: EPA (2006).

By failing to seriously address the issue, the inconsistent predictive behavior of either the W126 or SUM06 indices will be similar to the predictive behavior experienced when the AOT40 cumulative exposure index was applied in Europe. In the 1990s, areas of exceedance were mapped, but analyses at many exposure sites led to the conclusion that the AOT40 provided inadequate estimations of effects (Fuhrer *et al.*, 1997; Kärenlampi and Skärby, 1996). The W126 is a biologically based exposure index that reflects the importance of the elevated hourly average concentrations. However, the N100 index is required to make the W126 index more consistent in its ability to predict vegetation effects.

3.2 The Importance of Nighttime Exposures

The EPA Staff Paper (EPA, 2007) proposes the use of a 12-hour W126 exposure index as a possible secondary O₃ standard. An extensive review of the literature reported that a large number of species had varying degrees of nocturnal stomatal conductance (Musselman and Minnick, 2000). Although EPA acknowledges that uptake of O₃ during the nighttime may be important, the Agency states on page 8-17,

“...staff concludes that it remains unclear to what extent nocturnal uptake contributes to the vegetation effects of yield loss, biomass loss or visible foliar injury. Due to the many species- and site-specific variables that influence the potential for and significance of nocturnal uptake, staff concludes that additional research needs to be done before considering whether this component of vegetation exposure should be addressed with a different averaging time.”

Nocturnal O₃ flux depends on the level of turbulence that intermittently occurs at night. Massman (2004) suggested that nocturnal stomatal O₃ uptake accounted for about 15% of the cumulative daily effective O₃ dose that was related to predicted injury. Similarly, Grulke *et al.* (2004) showed that the stomatal conductance at night for Ponderosa pine in the San Bernardino National Forest (CA) ranged from one tenth to one fourth that of maximum daytime gas

exchange. Ignoring nocturnal stomatal O₃ uptake will underestimate the vegetation effects at some locations in the United States. This underestimate will not compensate for the inconsistent behavior of the W126 index when used without the N100 index.

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Major Issues Inadequately Addressed in the Final Version of the EPA's Ozone Staff Paper

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PRB Underestimated by EPA

- The modeled PRB diurnal monthly concentrations are much lower at all of the 12 urban areas than the actual PRB concentrations measured at Trinidad Head, California;
- The diurnal monthly PRB concentrations predicted by EPA are mostly in the 0.015 to 0.025 ppm range with few exceptions. The actual PRB diurnal concentrations experienced at Trinidad Head ranged from 0.050 ppm to approximately 0.030 ppm for April to June. Maximum PRB O₃ concentrations at the site are as high as 0.066 ppm;

Natural Processes are Important

- Natural processes contribute in the springtime to O₃ concentrations measured at the surface in the United States at both high and low-elevation monitoring sites and hourly average concentration ≥ 0.05 ppm in the springtime can be attributed at times to these natural processes (Lefohn *et al.*, 2001; Cooper *et al.*, 2005);
- Natural processes contribute to the replenishment of PRB across the entire United States;

Risk Model is Very Sensitive to the Choice of PRB

- For Los Angeles for the “As Is”, “84/4”, “74/4”, and “64/4” options, there was a 38%, 62%, 72%, and 86% reduction in the non-accidental mortality estimates, respectively, when 5 ppb was added to PRB 2002 air quality data;
- Because the PRB monthly modeling estimates used to estimate risk were so low (i.e., mostly in the 0.015 to 0.025 ppm range), the percent reduction in estimates of absolute incidences of O₃ non-accidental mortality are more than likely greater than those calculated using the small 5 ppb increase in PRB applied in the Staff Paper;

Lung Function Responses Are Sensitive to Choice of PRB

- The exposure-response function used for the lung function response analyses weights effects at concentrations below 0.04 ppm very low. The occurrences of lung function responses would more than likely have shown a greater sensitivity to an increase in PRB if a more realistic range of PRB concentrations had been employed in the Staff Paper;

Thresholds Are Only One Example of Nonlinearity

- The Agency fails to realize that thresholds are only one example of a nonlinear exposure-response relationship;
- EPA ignores the evidence in the literature that the concentration-response functions for epidemiological studies are more than likely nonlinear, similar to the nonlinear results reported in controlled human health laboratory studies;
- An important question is: what are the effects on risk estimates when applying nonlinear C-R functions in O₃ epidemiological studies? Similar to sensitivity testing using different PRB concentration levels, the uncertainty effects on risk estimates may also be great;

Exposure Indices Will Not Provide *Consistent* Predictions

- Neither the W126 nor the SUM06 metrics will provide *consistent* predictions under ambient conditions and will not produce reliable predictions of vegetation effects without including the N100 index; and
- EPA appears to be following the identical route that was traveled when the AOT40 cumulative exposure index was applied in Europe. In the 1990s, areas of exceedance were mapped, but analyses at many exposure sites led to the conclusion that the AOT40 provided inadequate estimation of effects (Fuhrer *et al.*, 1997; Kärenlampi and Skärby, 1996).