Oral Comments on the Health Risk and Exposure Assessment for Ozone (Second External Review Draft)

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Good morning, my name is Sonja Sax from Gradient. I provided some written comments to Dr Stallworth on March 13. I hope you had an opportunity to review them. I want to highlight a couple of points I raised in those comments. Specifically, my comments today relate to the epidemiology-based risk assessment presented in Section 7 of the *Health Risk and Exposure Assessment for Ozone Second External Review Draft* (REA). It is important that the Clean Air Scientific Advisory Committee (CASAC) consider recommending a clear and more balanced approach regarding the assessment methods and the presentation and interpretation of results as posed by the United States Environmental Protection Agency's (EPA) charge question for this section of the REA.

EPA's risk assessment approach is a vast improvement over the approach in the first draft REA. However, instead of evaluating mortality and respiratory morbidity risks down to a zero ozone concentration, EPA should only evaluate risks above ozone threshold levels. There are several valid reasons for doing this: One reason is that there is significant uncertainty at very low levels of ozone because there are no data for risks at those levels. Also, there are background levels of ozone that cannot be regulated; therefore, for policy determinations, it is important to understand risks associated with ozone levels that could potentially be regulated. My last point on this topic is that the ozone mode of action indicates that there are thresholds for ozone effects, and these are considered in the lung function risk assessment. There is no reason to believe that a threshold would not also be associated with other health impacts, particularly more serious ones.

Also regarding EPA's approach, there are instances where EPA selected to include certain model options for the core results and alternative options for the sensitivity analyses. In this regard, we believe that EPA should have selected alternative assumptions for the core analysis. For example, EPA should have included the monitor areas specified in the epidemiology studies and concentration-response function (CRFs) based on regional-priors and inclusive of PM_{10}. In doing so, EPA would be presenting the most appropriate risk estimates.

In terms of selecting the appropriate air quality zone, EPA used an expanded area that includes monitors that were not included in the underlying epidemiology studies. This resulted in a significant mismatch between the estimated ozone concentrations in the risk analysis *vs*. what was estimated in the epidemiology studies, and it introduced a significant amount of unnecessary uncertainty. EPA also selected for its core analysis a CRF based on national-priors, but due to known variability in regional estimates, the regional-priors are a better option. Finally, as EPA did for the long-term risk analysis, it should include the CRF based on a two-pollutant model to account for potential confounding in the core analysis. Alternative assumptions should be relegated to sensitivity analyses.

EPA provided confidence bounds for mortality estimates that incorporate some of the known uncertainty. These were presented only in tables in the draft REA but should be included in all the figures. I show an example here today for a select number of studies (Figure 1). As you can see from this figure, by presenting risk estimates together with confidence bounds, you can clearly tell that any reductions in mortality from the current ozone standard to alternative levels of the standard are not only very small, but

well within the confidence bounds. This indicates that there is likely no statistical difference in risks, and therefore no identified benefit from reducing the level of ozone standard. EPA acknowledged this uncertainty but did not highlight it throughout the REA.

Overall, the EPA approach could be improved if the REA presented risk estimates above a threshold ozone concentration based on either background levels or health-specific thresholds. The analysis would also be improved by including in the core results estimates based on assumptions that best reflect the science, as opposed to relegating this to appendices. Based on the current results, however, it is clear that there is no difference in the risks associated with the current level of the ozone standard and alternative levels when considering model uncertainty. Baserd on the risk assessment results, I urge the Clean Air Scientific Advisory Committee (CASAC) to suggest that EPA retain the current level of the standard, or at least presenting this as an option to the Administrator.

Thank you for your consideration of these comments on behalf of myself and American Petroleum Institute

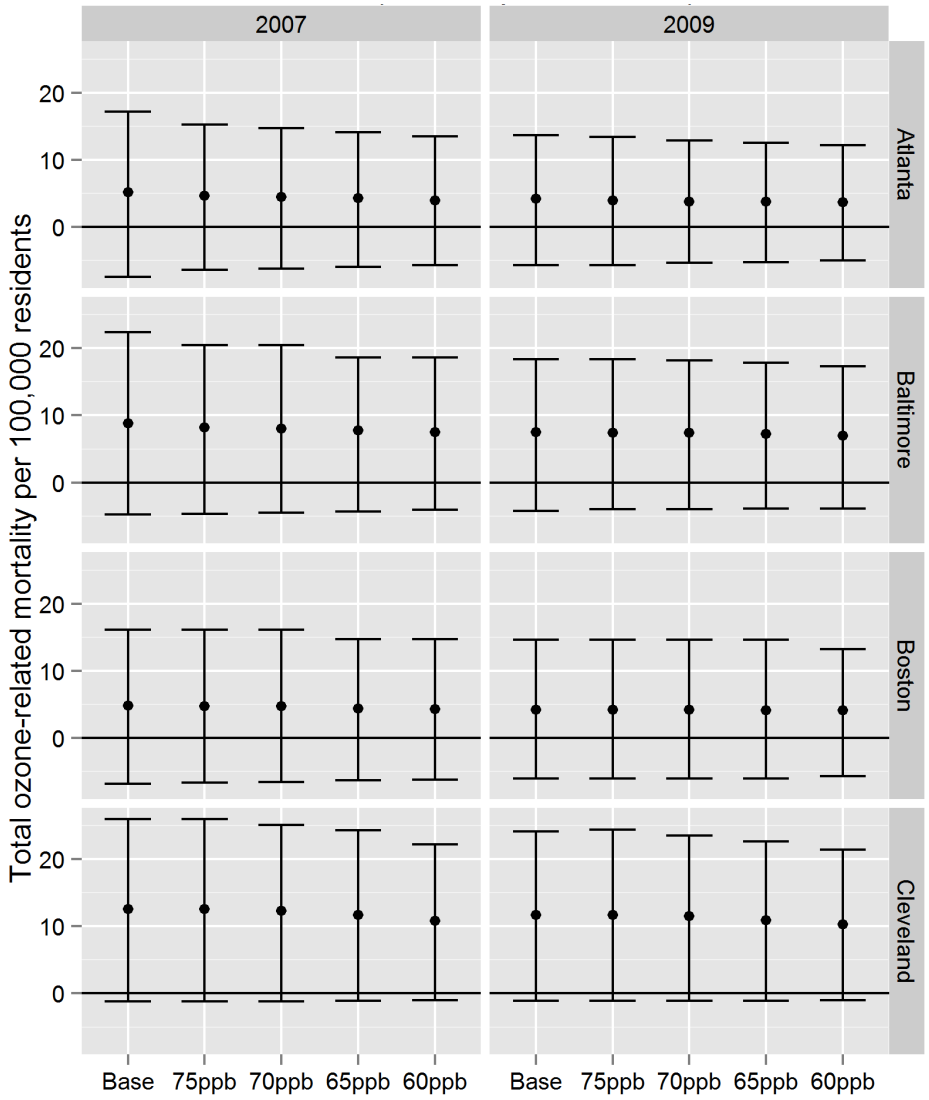

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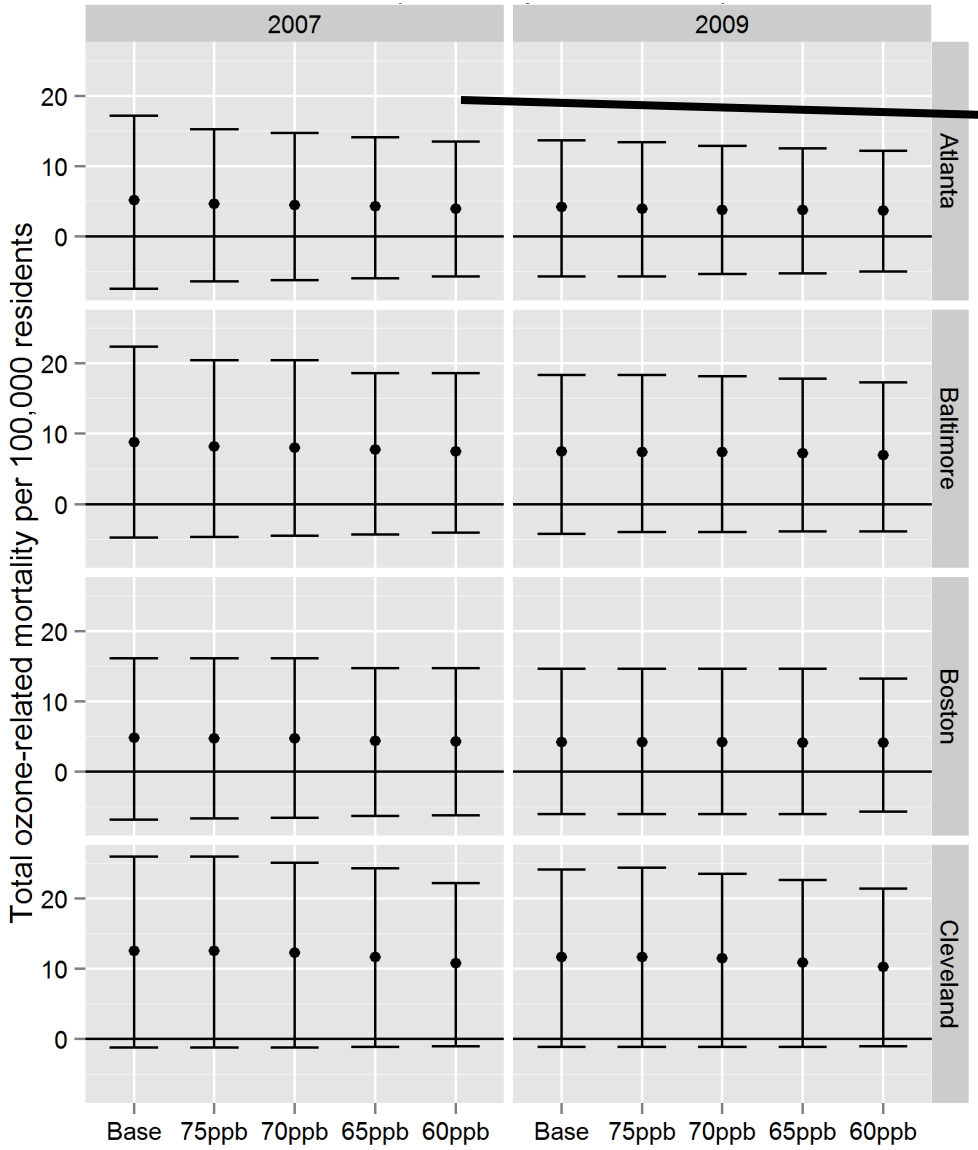
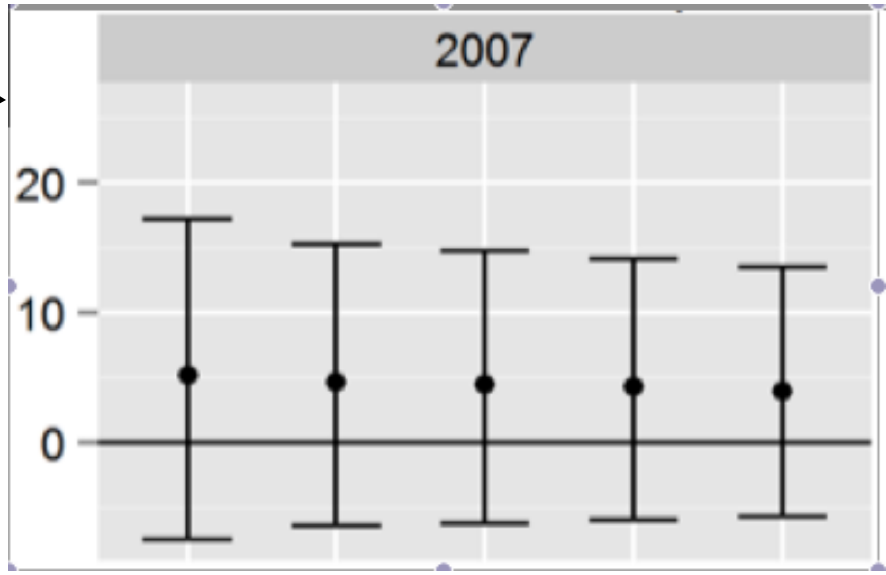
Figure 1 All-cause Mortality Rates (per 100,000 people) with 95% Confidence Intervals. Mortality rates estimated for air quality meeting current and or alternative ozone standard standards in Atlanta, Baltimore, Boston, and Cleveland in 2007 and 2009. Based on data in Table 7-7 in US EPA (2014).

Comments on the Health REA
Sonja Sax, ScD

- Approach
  - Should evaluate risks above a threshold level
    - Uncertainty at low levels of ozone
    - Ozone mode of action and controlled studies indicate a threshold
    - Need to understand risks above background levels
  - Core analysis should be based on :
    - Model areas in epidemiology studies, regional-prior estimates, and co-pollutant model
- Presentation
  - Confidence intervals should be included in figures (see Figure 1)
- Interpretation
  - Results show no significant benefit from lower standards





- Risk reductions are low
- Risk reductions within uncertainty
- No benefit from lower standards

Figure 1 All-cause Mortality Rates (per 100,000 people) with 95% Confidence Intervals.
Mortality rates estimated for air quality meeting current and or alternative ozone standard standards in Atlanta, Baltimore, Boston, and Cleveland in 2007 and 2009. Based on data in Table 7-7 in EPA REA.