Oral Comments on the Policy Assessment for Ozone (Second External Review Draft)

Sonja N. Sax, ScD
Gradient
March 25, 2014

Good afternoon, I am 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, on issues with the way the United States Environmental Protection Agency (EPA) presented the exposure and risk assessment estimates in Sections 3.2 and 4.4.2 of the second draft *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards* (PA). We urge CASAC to consider these comments in answering charge questions for this section of the PA.

Regarding the lung function exposure and risk assessment, EPA did not specify the conservative nature of the assessment or present uncertainty bounds for the exposure and risk estimates that it highlighted in the PA, which implies that estimates are higher and more certain than they actually are. With regard to the mortality and morbidity risk assessment, in the *Health Risk and Exposure Assessment for Ozone Second External Review Draft* (REA), EPA concluded that lower ozone standards had very little impact on these risk estimates, but this conclusion is not evident in the PA.

In the REA, EPA applied a number of conservative assumptions at every level of the exposure and lung function risk assessment that yielded overstated and unrealistic risk estimates, particularly at the lowest exposures and for the smallest decrements in forced expiratory volume in one second (FEV_1). For example, EPA focused on what it considers to be "higher-risk" individuals, such as children engaged in moderate to heavy exercise outdoors. These simulated children were modeled to have the highest overall ozone exposures, although it is uncertain if this accurately reflects today's children. In addition, EPA evaluated benchmark levels of ozone down to 60 ppb and lung function decrements in excess of 10%, even though evidence does not support adverse health impacts at these levels. Finally, EPA highlighted single occurrences of exposures above benchmarks or lung function decrements above a threshold, where multiple occurrences are more likely to be associated with adverse health effects. All of these factors alone would yield conservative estimates, but together they compound to yield unrealistic scenarios. Although appropriate analyses are provided by EPA in the REA (often in the appendices), by highlighting results based on these highly conservative scenarios in the PA, EPA overestimated and overstated exposures and risks.

One only needs to look at more reasonable, but still conservative, exposure benchmarks or lung function decrements to see a completely different picture emerging from that which EPA presented in the PA. For example, based on a health protective level of 70 ppb, and looking at two exceedances in a year, a very small fraction of children (the most highly exposed individuals) would exceed this benchmark − less than 1%. Similar results are observed for lung function risk estimates when considering multiple occurrences and FEV_1 decrements > 15%.

EPA also provided no confidence bounds to account for the uncertainty in model estimates. This limits the usefulness of exposure and risk estimates because one cannot determine whether lowering the ozone standard results in statistically significant changes in exposures or lung function risks.

With regard to the mortality and morbidity risk assessment based on epidemiology studies, EPA did present confidence bounds for risk estimates. These confidence bounds show that risk estimates for scenarios of just meeting the current ozone standard are not likely to be statistically different from estimates for alternative lower standards (see Figure 1). In the REA, EPA acknowledged uncertainty by concluding that "[m]ortality from short- and long-term [ozone] exposures and respiratory hospitalization risk is not greatly affected by meeting lower standards" (US EPA, 2014, p. 9-46)[1]. This conclusion was not presented in the PA. Also, in the PA, there was no consideration of the uncertainty bounds and what this means in terms of whether there are statistically significant risk reductions with alternative ozone standards. Overall, the exposure and risk assessments do not support lowering the ozone standard, and this should be reflected in the PA.

Thank you for the opportunity to speak on behalf of myself and the American Petroleum Institute.

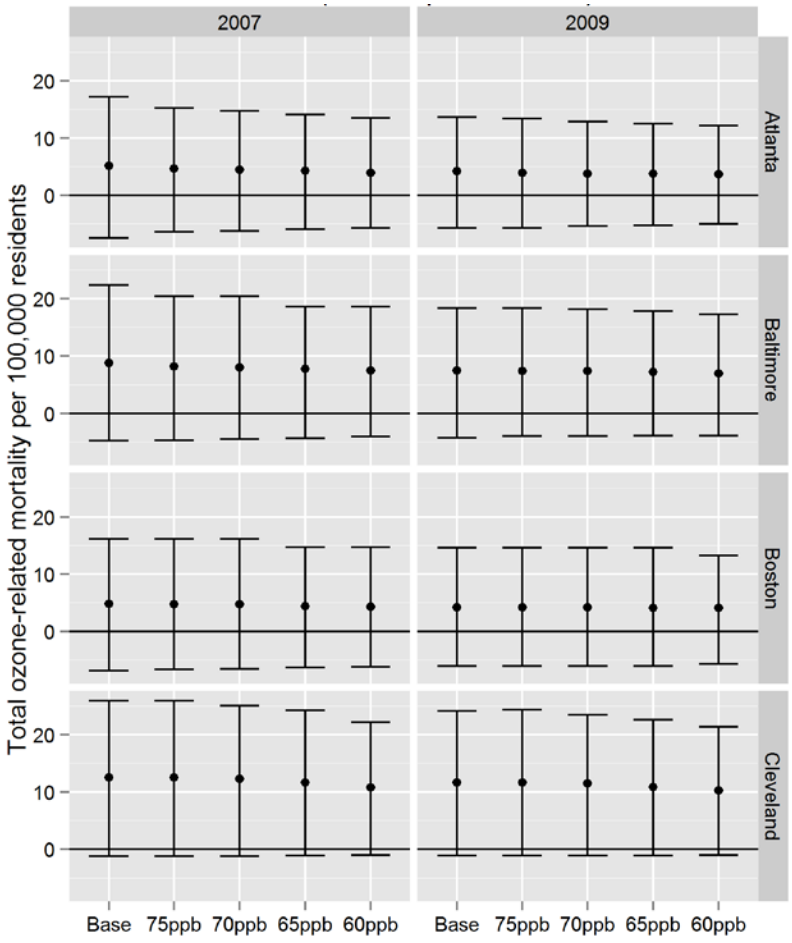


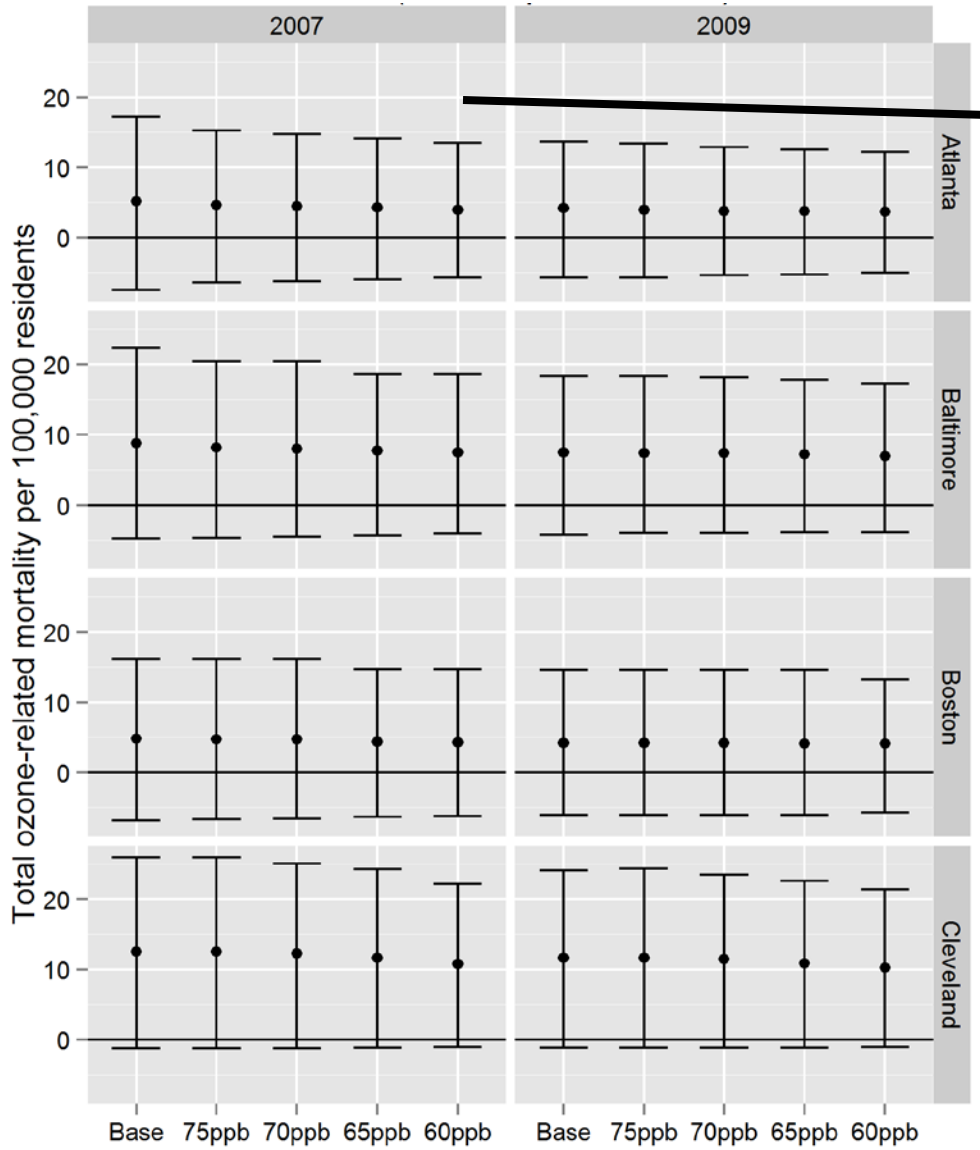
Figure 1 All-cause Mortality Rates (per 100,000 people) with 95% Confidence Intervals. Mortality rates estimated for air quality meeting current and or alternative ozone standard standards in Atlanta, Baltimore, Boston, and Cleveland in 2007 and 2009. Based on data in Table 7-7 in US EPA (2014).

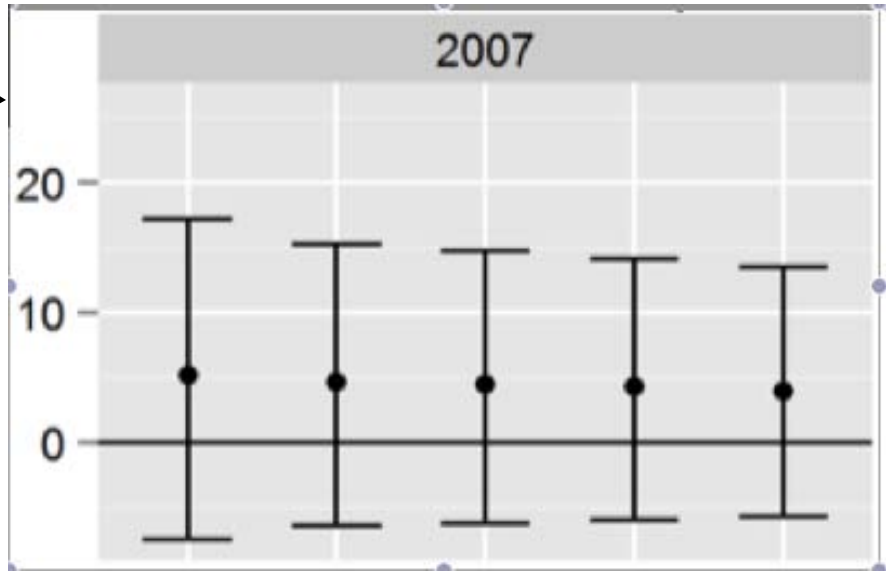
[1] US EPA. 2014. "Health Risk and Exposure Assessment for Ozone (Second External Review Draft)." EPA-452/P-14-004a

Comments on the Policy Assessment
Sonja Sax, ScD

- Lung function risk estimates – highly conservative approach
  - Highlight "higher-risk" individuals
  - Focus on single exceedance of 60 ppb benchmark
  - Focus on single FEV_1 decrements >10%
  - No confidence intervals for exposure and risk estimates
- Mortality and morbidity estimates
  - Confidence intervals indicate no statistical difference between current and alternative standards (see Figure 1)
  - Conclusion needs to be carried forward in PA

Copyright Gradient 2014





- 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.

Copyright Gradient 2014
GRADIENT