

# Clarifying Comments

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Gradient has commented extensively on the importance of considering a threshold in risk assessments based on epidemiology evidence. Ozone's mode of action (MoA) clearly indicates a threshold for ozone effects, and a threshold model was used by Jerrett *et al.* (2009) study. Given ozone's MoA and the availability of a threshold model, the US Environmental Protection Agency (EPA) should have relied on this model for its core long-term mortality risk estimates, but it did not. Previously, the Clean Air Scientific Advisory Committee (CASAC) requested that this analysis be included in the final Health Risk and Exposure Assessment (REA) as a sensitivity analysis. However, given the significant impact this analysis would have on long-term mortality estimates, Dr. Miller raised concerns during the May 28, 2014, teleconference about relegating consideration of a threshold to a sensitivity analysis. In contrast, Dr. Diez-Roux noted that the threshold was below the alternative standards being considered, implying that it should not significantly impact overall conclusions. Dr. Vedal correctly stated that one needs to consider how the Jerrett *et al.* (2009) findings relate to the form of the standard.

We strongly agree with Drs. Miller. and Vedal. The analysis conducted by Dr. Anne Smith, presented in her written and oral comments during the May 28 call, clearly shows that there would be no mortality risk in 10 of the 12 urban areas EPA included in its risk analysis for a scenario meeting the current standard of 75 parts per billion (ppb). Denver and Los Angeles would be the only cities where there would be any observed mortality risk, but the results for these cities are questionable. Specifically, as EPA noted in the Health REA, risk estimates for Los Angeles are likely to be unreliable because of the significant nitrogen oxide reductions needed to achieve current and alternative standards. Background sources of ozone are a significant contributor to overall ozone concentrations in Denver, making it difficult to attain even the current ozone standard in that city.

Similarly, if a threshold were considered in the short-term analysis for mortality and morbidity ozone effects, there would likely be a similar finding of no mortality risk above threshold concentrations. For example, in heat maps presented in Figures 7-2 and 7-3 of the Health REA, the large majority of mortality risks are observed at ozone concentrations below 60 ppb with a scenario of just meeting the current ozone standard; this is also the range in which the greatest benefits are observed for lower ozone standards. If a threshold model were used for the short-term mortality assessment, the results would likely show little to no mortality risk from ozone exposure above this threshold and likely no benefit from lowering the standard. This is an important analysis currently missing in EPA's second draft of the Health REA.

EPA should place more emphasis on using a threshold model for assessing risks from both long- and short-term mortality before closing comment on the second draft Health REA. It is also critical that CASAC review and understand these threshold-based risk results prior to making recommendations to the Administrator, necessitating review of a third draft REA.

## Reference

Jerrett, M; Burnett, RT; Pope, CA; Ito, K; Thurston, G; Krewski, D; Shi, Y; Calle, E; Thun, M. 2009. "Long-term ozone exposure and mortality." *N. Engl. J. Med.* 360(11):1085-1095.