The Exposure and Risk Assessment Results Do Not Support Lowering the Ozone NAAQS

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Thank you for the opportunity to speak today. In the Proposed Rule (PR), the US EPA Administrator concludes that new evidence indicates that the ozone NAAQS should be lowered to a level between 0.065 and 0.070 ppm (US EPA, 2014a). The Administrator is relying, in part, on the results from the Health Risk and Exposure Assessment (HREA, US EPA, 2014b). Specifically, in the PR, the Administrator concludes that the exposure and risk estimates indicate that lowering the ozone NAAQS would reduce exposures and prevent lung function decrements. As I will discuss today, US EPA did not specify the conservative nature of these assessments or quantify the model uncertainty, which makes the exposure and risk estimates appear higher and more certain than they actually are. When accounting for these factors, there appear to be marginal, if any, benefits from a lower ozone standard.

The exposure and lung function risk assessments rely on the APEX model, which simulates exposures and related health risks for different population groups. The model results are a function of the inputs and assumptions used, and alternative assumptions can impact these results significantly. Our independent evaluation of the APEX modeling that US EPA conducted indicates that US EPA applied conservative assumptions at every level of the exposure and lung function risk assessment, and therefore it presented unrealistic exposures and overstated risks.

For example, US EPA focused on what it considers to be "higher-risk" individuals, such as children. In addition it assumed that the modeled children spent more time outdoors and had "moderate or greater exertion level at the time of exposure" (US EPA, 2014b), although it is uncertain if this accurately reflects today's children. In fact, one of the limitations of the APEX model is that it relies on time-activity information for children that is quite dated and is not necessarily supported by more recent studies that, for example, reported a significant decline in physical activity from childhood to adolescence, with the rate of decline increasing in recent years (Dumith *et al*., 2011). Active children would also naturally have higher ventilation rates than non-active children, and US EPA acknowledges in the HREA that the ventilation rates used in the APEX modeling are greater than recently published measurements.

Another feature of the APEX analysis that likely overestimated risks is that an individual's lung function decrement is calculated over 1- to 60-minute periods. This approach yields a higher estimated number of individuals experiencing these short-term lung function decrements compared to an approach that considers an 8-hr average exposure. This issue is highlighted by the findings from the exposure and lung function risk assessments, which suggest a much higher percentage of children with lung function decrements than would be expected based on the results from the exposure assessment and from the finding in controlled exposure studies (*e.g.*, Schelegle *et al*., 2009). In addition, the risk assessment findings are inconsistent with EPA's conclusion in the PR, which noted that "the interindividual variability in responsiveness following exposures of concern means that only a subset of individuals who are exposed at and above a given benchmark concentration would actually be expected to experience

respiratory effects." (US EPA, 2014a). This also calls into question their applicabilty to the current form of the standard which is based on an 8-hr average.

All of the factors I discuss here would individually yield conservative estimates, but together they compound to give unrealistic results. Although some sensitivity analyses were conducted by US EPA in the HREA in order to evaluate how many of these assumptions impacted the findings, the results that are presented in the PR are for these highly conservative findings only.

In addition to the assumptions that yield estimates of exposure and lung function risks that are overestimated, there is considerable uncertainty in these estimates that is not quantified, and only briefly discussed in the PR. Given the time constraints, I will only mention one of them: US EPA assumes that children are as responsive as the most responsive 18-year old subjects in chamber studies. It justifies this assumption by citing results from summer camp studies (*e.g.*, Kinney *et al*., 1996) and a single chamber study of children 8-11 years old (McDonnell *et al.* 1985). These studies, however, suggest that children are no more responsive to the effects of ozone than adults, and that they may even be less so. Therefore, based on these limited data, US EPA should assume that children are as responsive as an average adult, rather than the most responsive adults. The current assumption only adds another conservative layer to an already highly conservative analysis.

Despite being overly conservative, the exposure and risk results suggest that only a small percentage of the most highly exposed and "at-risk" population would have exposures and lung function risks considered to be adverse at the current level of the standard (US EPA, 2014b). This means that under a more realistic scenario, an even smaller percentage of the general population is likely to be affected. In the HREA, US EPA compares these risk estimates to risks associated with modeled estimates for meeting alternative standards. The results show marginal reductions with alternative standards, with the largest reductions generally achieved by just meeting the current standard (US EPA, 2014b). Importantly, these marginal reductions are likely well within the model uncertainty, and thus not statistically signficant. This is not considered in the US EPA analysis. Overall, our evaluation of the exposure and risk assessments results indicates that lowering the ozone NAAQS will not result in a significant reduction in lung function risks.

References

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