

The Scientific Evidence Does Not Support the Administrator's Proposed Conclusion That the Primary Ozone NAAQS Should Be between 0.065 and 0.070 ppm

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Thank you for the opportunity to speak on behalf of the American Wood Council. The American Wood Council (AWC) is the voice of North American wood products manufacturing, representing over 75 percent of an industry that provides approximately 400,000 men and women with family-wage jobs. AWC members make products that are essential to everyday life from a renewable resource that absorbs and sequesters carbon. Staff experts develop state-of-the-art engineering data, technology, and standards for wood products to assure their safe and efficient design, as well as provide information on wood design, green building, and environmental regulations. AWC also advocates for balanced government policies that affect wood products.

The US EPA Administrator concluded that new evidence indicates that the ozone NAAQS should be between 0.065 and 0.070 ppm (US EPA, 2014). However, new health effects evidence cited in the Proposed Rule is no stronger than evidence cited in previous reviews, and does not support lowering the primary NAAQS below 0.075 ppm. This is true for all realms of evidence, including that from controlled exposure, epidemiology, and mode-of-action studies, but today, I am focusing on controlled exposure studies.

The Proposed Rule concluded that two new controlled exposure studies, by Kim *et al.* (2011) and Schelegle *et al.* (2009), support lowering the ozone standard. Kim *et al.* (2011) observed statistically significant lung function decrements and airway inflammation at 0.06 ppm. However, the mean decrements they reported across the study population were so small (1.71% and 1.19% for FEV₁ and FVC, respectively) that they indicate normal variability and are not clinically significant. Also, the severity of symptoms for ozone-exposed subjects was similar to control subjects, indicating that ozone exposure did not cause noticeable effects (reviewed by Goodman *et al.*, 2014). These clinically insignificant data do not provide a basis for lowering the standard.

In the second study, Schelegle *et al.* (2009) reported lung function decrements and respiratory symptoms at 0.072 ppm, but lung function was restored to baseline



conditions between one and four hours after exposure ended. Because ozone has an acrid odor, the participants most likely knew when they were being exposed to ozone vs. filtered air, and therefore may have been more likely to report symptoms after ozone exposure.

Despite this, in an independent analysis, my colleagues and I found no correlation between symptoms and the magnitude of lung function decrements in these individuals. Also, Schelegle *et al.* (2009) focused on decrements greater than 10% and, while US EPA considers a 10% cutoff reasonable for moderate lung function decrements, in healthy populations, a 10% decrement, and possibly even a 15% decrement, would not be noticeable (Bieke, 2007). Moreover, studies have shown that acute lung function decrements even after higher ozone exposures (~0.2 ppm) are not predictive of, or causally associated with, ozone-induced inflammation or subsequent lung injury (*e.g.*, Blomberg *et al.*, 1999).

It is also notable that in the Schelegle *et al.* (2009) study, the time period between the 0.072 ppm exposure and the control exposure was 55 days on average (ranging from 13 to 302 days). Co-exposures, seasonal changes in lung function, and the physical conditioning of subjects could have changed over this time, making it difficult to interpret results (OSHA, 2013; Pellegrino *et al.*, 2005). In addition, Schelegle *et al.* (2009) used a triangular exposure profile, where exposure is increased step-wise and then decreased step-wise to achieve a target average exposure concentration. While a triangular exposure profile is more reflective of ambient ozone fluctuations compared to a constant exposure pattern, the specific patterns chosen by Schelegle *et al.* (2009) do not reflect diurnal patterns in most cities (Lefohn and Hazucha, 2005). Taken together, all of these issues with the Schelegle *et al.* (2009) study indicate that it does not provide a basis for lowering the standard.

The Proposed Rule suggests that susceptible populations, such as asthmatics, would be more responsive to acute ozone exposure than healthy adults, but there is no evidence to support this (*e.g.*, Kehrl *et al.*, 1985; Linn *et al.*, 1983; Mudway *et al.*, 2001, as cited US EPA, 2013). Moreover, the exercise level maintained in these and other controlled ozone exposure studies is likely more strenuous and of a longer duration (*i.e.*, up to 6.6 hours) than most of the general US population experience, with the exception of some outdoor workers. These scenarios are especially unrealistic for the most sensitive populations, whose conditions would likely prevent them from performing exercise at the duration and ventilation rate required to produce these small decrements in lung function.

Finally, results of these and other controlled exposure studies cannot be directly extrapolated to the US population. These studies only evaluated a small number of people (fewer than 60), and only three subjects were ozone responders (*i.e.*, had an FEV₁ decrement over 10%) in each study.



These studies involved people performing quasi-continuous exercise for an extended period of time at an intensity not likely achievable by sensitive individuals, such as asthmatics, and under exposure profiles that likely represent worst-case scenarios. It is not appropriate to base a standard to protect over 300 million people on reported effects in a few individuals under controlled experimental conditions.

The ultimate goal of the NAAQS is to protect the health of the general population, including sensitive groups, and not necessarily people who are able to perform quasi-continuous strenuous exercise for six hours or more while constantly exposed to outdoor ozone levels. It is unclear how chamber studies relate to more typical exposure conditions, even for sensitive individuals. EPA should conclude that these durations of exposure and near-continuous exercise levels limit the extrapolation of these results to the averaging time and numerical levels of the NAAQS. Perhaps more importantly, because compliance with the NAAQS is conservatively based on the single highest monitor in each urban area, EPA should conclude that the current 0.075 ppm standard provides adequate population protection from daily ambient exposures of 0.060 ppm and above (US EPA, 2014). Taken together, the new evidence indicates that the current standard is protective and should be retained, and that alternative proposed standards will not provide additional public health protection.

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