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

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Thank you for the opportunity to speak on behalf of the Treated Wood Council.

The United States Environmental Protection Agency (EPA) concluded that a lower ozone standard would lead to fewer people exposed above benchmarks of 60, 70, and 80 ppb and be more public-health protective than the current standard. This conclusion is primarily based on exposure estimates from the Air Pollutants Exposure (APEX) model and the risk assessment based on controlled human exposure studies of lung function deficits. Today, I will discuss how the current standard of 75 ppb is health protective, and that evidence does not indicate that lowering the standard will lead to additional health benefits.

There are two primary reasons for this: the first is the layers of conservatism that compound in EPA's analysis, and the second is that EPA has not shown that benefits from lower ozone standards are greater than those attained with the current standard.

Regarding the conservatism, in the exposure assessment, EPA mainly focused on exercising children (who have the highest exposures), benchmarks down to 60 ppb, and one-day exceedances of these benchmarks. There is no evidence that one-day exceedances above these low benchmarks will affect health or, as my colleagues and I discussed in a 2013 paper in *Inhalation Toxicology*, that ozone causes adverse effects below 80 ppb (Goodman *et al*., 2013). EPA should not emphasize a benchmark of 60 ppb, but should instead focus on analyses of higher benchmarks and for multiple-day exceedances.

In a similar vein, in its risk assessment, EPA highlighted the risks of a child having a forced expiratory volume in one second (FEV_1) decrement of $\geq$ 10% on a single day in a year or ozone season. EPA modeled responses in children to be higher than adults, even though controlled exposure studies indicate that this is not the case. Also, as described in detail by Pellegrino *et al*. (2005), there is a large amount of variability in FEV_1 across time in healthy adults, and even more so in adults with chronic obstructive pulmonary disease (COPD), and a single exceedance of 10% is not clinically significant. Pellegrino *et al.* (2005) also noted that most authorities agree that only a 12-15% change is meaningful.

Any of these factors alone would result in a worst-case scenario; together, they compound and contribute to unrealistic estimates of ozone exposures and risks.

Regarding the benefits from lower alternative standards, EPA acknowledged many uncertainties in the REA, but did not quantify them. Sources of uncertainty include air quality estimates based on ambient monitor concentrations, adjustments of air quality to simulate meeting current and alternative standards, APEX exposure estimates, activity profiles, physiological parameters, and exposure-response functions. These uncertainties can be large and, if quantified, together would likely contribute to large confidence bounds around risk estimates. Also, the exposure and lung function risk assessment reported very small

incremental benefits from lower standards, and it is quite likely that these estimated benefits are well within model uncertainty. This indicates that the evidence does not support additional benefits from alternative standards. EPA should update its approach to include confidence bounds around exposure and risk estimates and conduct statistical tests to determine whether health benefits differ with current *vs.* proposed alternative standards.

Before I conclude, I want to bring up a point about the presentation of results in the REA. In several cases, results were presented in a misleading fashion. For example, a 50% decrease is much more substantial if going from 200 to 100 *vs.* 2 to 1. Also, instead of highlighting results from unrealistic exposure and risk scenarios, EPA should consider more realistic scenarios in its core analyses and present the associated exposure and risk estimates with confidence bounds in the body of the report, not the appendices.

In conclusion, before the REA is finalized, EPA should focus on more realistic exposures and risks and should use statistical tests to determine whether there are actual additional benefits from lowering the current standard of 75 ppb to somewhere between 60 and 70 ppb. I believe if this were done, it would be clear that the evidence does not indicate that proposed alternative standards offer additional health benefits over the current standard.

References

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