

Comments on the Policy 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. Today I would like to address the United States Environmental Protection Agency's (EPA's) question to the Clean Air Scientific Advisory Committee (CASAC) regarding the extent to which section 3.1 in the *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards* (PA) captures and appropriately characterizes the key aspects of the evidence assessed and integrated in the Integrated Science Assessment (ISA; US EPA, 2013).

EPA's approach to the consideration of scientific evidence for ozone-related health effects is based on the causal framework used in the ISA (US EPA, 2013), which has serious limitations (Goodman *et al.*, 2013a). The framework does not include specific guidance for several aspects that are critical for a rigorous weight-of-evidence (WoE) evaluation, and that omission led to an inconsistent evaluation of the evidence. The ISA should have evaluated all relevant studies in a consistent manner using well-specified criteria and determined whether, as a whole, they constitute evidence for causation or are more likely indicative of an alternative hypothesis. Based on the inadequate evaluation of evidence in the ISA, the PA cannot soundly conclude that there is sufficient evidence for any causal relationships at ozone exposures below the current standard.

In its consideration of the available evidence regarding potential modes of action by which ozone could cause health effects, EPA should evaluate mechanistic and biomarker studies using a WoE approach to adequately assess the consistency and coherence of results within and across disciplines in relation to respiratory and extrapulmonary effects of ozone. In addition, the PA should include a discussion of the clinical relevance of biomarkers and their relation to adverse apical effects to support their usefulness.

The PA considers the evidence for respiratory effects associated with short- and long-term ozone exposure. Regarding short-term ozone exposure and respiratory effects, the key epidemiology studies on which EPA relied in the ISA to support its causality determinations reported small changes in respiratory function and have numerous limitations that undermine many of the results. These limitations were also present in studies evaluated in previous ozone reviews, and the evidence for respiratory-related effects of ozone is not strengthened by the availability of more recent evidence. A critical evaluation of controlled human exposure studies demonstrated that lung function effects in humans exposed to ozone at concentrations below 72 ppb were independent and not statistically different in participants exposed to filtered air, indicating a lack of causation (Goodman *et al.*, 2013b). In addition, broadly recognized clinical guidelines do not consider reported lung function effects at ozone concentrations below 88 ppb to be adverse (Goodman *et al.*, 2013b). The PA should acknowledge that the currently available evidence does not support a causal relationship between short-term ozone exposure at concentrations below the current standard and adverse respiratory effects.

With regard to respiratory effects associated with long-term ozone exposure, EPA's classification of a likely to be causal relationship is unsubstantiated. The recent evidence EPA cited to support this classification did not demonstrate any consistent associations with ozone exposure, and EPA did not adequately address the limitations of the available studies. Importantly, the evidence is no more compelling than for other health outcomes for which EPA determined evidence was only "suggestive" of a causal relationship. The same uncertainties remain since the last review of the respiratory effects associated with long-term ozone exposure (US EPA, 2006), and this should be reflected in the PA.

The consideration of the evidence for total mortality associated with short-term ozone exposure in the PA does not take into account the numerous inconsistencies across recent multi-city studies, including those that use similar datasets and modeling assumptions. The risk estimates reported in these studies are likely heavily biased as a result of unresolved between-city heterogeneity and numerous uncertainties associated with confounding effects, model selection, and the shape of the ozone-mortality concentration-response function (CRF). EPA should discuss these considerations in the PA, and it should eliminate statements describing the evidence as "consistent." The results for cardiovascular (CV)- and respiratory-related mortality are even less consistent, with most studies reporting results that are not statistically significant. Overall, the available data do not support a causal relationship between short-term ozone exposure and mortality at exposures equal to or below the current National Ambient Air Quality Standards for ozone, and this should be reflected in the PA.

Finally, many new studies of the potential effects of short-term ozone exposure on the CV system have become available since the last ozone review (US EPA, 2006), which concluded that the body of evidence for CV effects of ozone was limited. A systematic WoE analysis of the available evidence indicated that these studies do not provide stronger evidence of a causal relationship (Goodman *et al.*, 2014); this should be reflected in the PA.

Overall, section 3.1 of the PA does not capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA.

References

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