

# Texas Commission on Environmental Quality Comments to the CASAC on the Integrated Science Assessment for Ozone and Related Photochemical Oxidants

September 11, 2012

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Good morning. I am Dr. Stephanie Shirley, a toxicologist with the Texas Commission on Environmental Quality. The TCEQ is charged with protecting our state's human and natural resources consistent with sustainable economic development<sup>1</sup>.

I'd like to touch on several issues concerning the ozone ISA on behalf of the TCEQ<sup>2</sup>.

First, is the use of observational epidemiology to support the ozone NAAQS. The current proposed standard is based largely on observational epidemiology studies. However, these studies are exploratory in nature, designed to look for correlations (which are distinct from causation), and are not rigorous enough to utilize as the basis for such important policy decisions. In requiring national air quality standards for criteria pollutants, the Clean Air Act treats these six pollutants differently than all other pollutants by not allowing cost and technological feasibility to be taken into account. Therefore, the risk management options left to state regulators are severely limited or absent. In our mind, that raises the bar for the scientific basis of standards regulating the criteria pollutants.

Second is the discrepancy between ambient concentrations of ozone and personal exposures to ozone. It is widely recognized that eight-hour ambient ozone concentrations from central monitoring stations do not accurately reflect personal exposure to ozone. Most individuals spend the majority of their time indoors, and indoor concentrations of ozone are dramatically lower than outdoor concentrations (Sarnat et al. 2006). Moreover, TCEQ analysis shows that eight-hour ozone concentrations can easily vary 30% geospatially within a county. Therefore, assigning exposure concentrations to a cohort is problematic.

Third, the effect sizes reported as relative risks or hazard ratios in the available literature are quite modest and may be indicative of confounding. Indeed, it has been reported that such studies are more prone to residual confounding than previously recognized (Janes *et al.* 2007, Smith et al. 2009, Greven *et al.* 2011). Multiple agencies have cautioned against over interpreting such small relative risks<sup>3</sup>.

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<sup>1</sup> Our goal is sensible regulation that addresses real environmental risks, while being based on sound science and compliance with state and federal statutes. In every case where Texas disagrees with EPA action, it is because these actions are not consistent with these principles

<sup>2</sup> Many of these same issues have been raised previously by multiple groups – see McClellan et al. 2009

<sup>3</sup> <http://benchmarks.cancer.gov/2002/07/epidemiology-in-a-nutshell/> “Relative risks or odds ratios less than 2.00 are viewed with caution.” WHO/IARC: Breslow and Day (1980). *Statistical methods in cancer research. Vol. 1. The analysis of case control studies.* IARC Sci. Publ. No. 32, Lyon, p. 36. “Relative risks of less than 2.0 may readily reflect some unperceived bias or confounding factor, those over 5.0 are unlikely to do so.” WHO: Craun and Calderon. *How to interpret Epidemiological Associations.* “an increased risk of less than 50% (RR=1.0-1.5)...is considered by many epidemiologists to be either a weak association or no association.” In addition to such scientific guidance, legal precedence also indicates that relative risks below 2 should not be considered to support a hypothesized relationship The Federal Judicial Center Reference Manual on Scientific Evidence Third Edition (2011)<sup>3</sup> provides the following guidance: “The higher the relative risk, the stronger the association and the lower the chance that the effect is spurious... because epidemiology is sufficiently imprecise to accurately measure small increases in risk, in general, studies that find a relative risk less than 2.0 should not be sufficient for causation. The concern is

Forth, the definition of an “adverse effect” with regard to exposure to ambient ozone remains ambiguous and subject to interpretation. Clinical studies examining respiratory effects of low concentrations of ozone have shown only slight, reversible effects that are, largely not clinically significant. For example, the FEV<sub>1</sub> decreases found in the Adams *et al.* 2006 study are within normal daily variation according to the Medarov *et al.* 2008 study<sup>4</sup>.

Fifth, there is a lack of consistency within and between studies. There appears to be little critical evaluation of the consistency of findings within and among studies, and often positive associations are overemphasized, without regard to their statistical or biological significance. The current weight of evidence approach lacks methods for critically evaluating such factors.

Finally, it is difficult to discern the effect of ozone on health endpoints given the presence of confounding factors. Few studies fully account for simultaneous exposure to multiple pollutants, which obscures the association between health effects and ozone exposure (Franklin and Schwartz 2008 and Jerrett *et al.* 2009). Furthermore, it has been repeatedly demonstrated that these associations are confounded by temperature, relative humidity, and population characteristics such as age, socioeconomic status, and exercise.

Overall, the TCEQ encourages a more rigorous and transparent weight of evidence approach that devotes more attention to the limitations of the existing studies with respect to consistency, reproducibility, bias, control for confounders, and shortcomings in methodology.

Regarding the secondary standards for ozone:

- The TCEQ questions the need for a separate secondary standard that is different in form and level from the primary standard.
- There is inadequate research and analysis of the comparative protectiveness of a secondary ozone NAAQS in a form different from the form and level of the primary standard to justify its promulgation.
- Establishing a separate form for the secondary standard would at the very least cause the state to expend resources on analysis, public education, SIP documentation requirements, and computer resources that could be better directed towards attaining the primary ozone standard, which would benefit the health of both the public and the ecosystem.

In closing, the TCEQ’s expectation is that regulations, especially health-based standards, be based on sound science, be justifiable, and realize true public health benefits.

Thank you for the opportunity to provide comment and for your attention.

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*not with specific causation but with general causation and the likelihood that an association less than 2.0 is noise rather than reflecting a true causal relationship.”*

<sup>4</sup> See also Pellegrino *et al.* 2005 for guidance interpreting pulmonary function tests.

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