

Oral Statement to CASAC Review Panel on the Integrated Review Plan for Particulate Matter May 23, 2016

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Good afternoon, my name is Lindsey Jones, and I am a Senior Toxicologist with the Texas Commission on Environmental Quality (TCEQ). I appreciate the opportunity to speak to you today about the EPA's draft Integrated Review Plan (IRP) for Particulate Matter (PM). The TCEQ understands the difficulty facing this committee and the EPA in reviewing the PM NAAQS. Because of the abundant and complex literature, and the far-reaching impacts of a new PM standard, we strongly encourage CASAC and the EPA to conduct the high quality, thorough, balanced, and objective review and synthesis of information that is necessary for a meaningful, protective standard.

My comments this afternoon are focused on uncertainties identified in the draft IRP. The TCEQ encourages a robust, quantitative consideration of uncertainty, as recommended by the NRC, and accurate communication of all such information through use of uncertainty bounds on point risk estimates. We encourage CASAC to give particularly thorough consideration to the following four key areas in the IRP and in subsequent documents.

1. Particulate matter composition

PM is highly heterogeneous, varying in composition and across cities, regions, and seasons. Whenever possible, the TCEQ urges CASAC to determine how PM component data informs biological plausibility and mode of action, rather than reverting to the simple conclusion that all PM species are equally toxic. PM component data should be used quantitatively as much as possible when evaluating associations provided in epidemiology studies.

2. Causality

The TCEQ strongly encourages CASAC to reevaluate the strength and methods of the EPA's existing causal framework. Of particular concern is whether a single, positive result is adequate to make the determination of "suggestive of causality," as is currently done. This bar is very low and does not seem to consider the entire weight of available evidence. CASAC and EPA should consider a number of recent publications that propose improved methods for assessing causality from a body of evidence. These methods would significantly improve the causality assessment and help ensure that selected health endpoints are truly capable of being protected by a standard.

3. Shape of the particulate matter dose-response curve

For those health effects with enough data for a likely-causal link, CASAC and the EPA should discuss at length the shape of the dose-response curve. Equal consideration

should be given to all potential shapes of the curve, not just whether the curve is linear or non-linear, and departures from linearity at concentrations below existing standards should consider all lines of evidence, including clinical and toxicological results. Epidemiology studies with errors and biases that are known to obscure thresholds (e.g. multi-city studies, confounding) should not be used as the primary basis for choosing the shape of the dose-response curve. Fully understanding the shape of the curve and its associated uncertainty is especially critical in evaluating potential effects at low concentrations.

4. Exposure measurement error

The TCEQ highly recommends that CASAC and the EPA use adjustment factors or other quantitative methods to better account for the exposure measurement error uncertainties in available epidemiology literature. We caution against the temptation to simplify the results to say that exposure measurement error always biases risk estimates toward the null when evidence suggests that the relationship is actually far more complex. The TCEQ also strongly encourages the EPA to give close consideration to the differences between monitored and modeled PM data.

Thank you, again, for the opportunity to provide these comments.