Oral Statement to CASAC Review Panel on the Integrated Review Plan for Particulate Matter August 9, 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 again about the Environmental Protection Agency's (EPA's) draft Integrated Review Plan (IRP) for Particulate Matter (PM). My comments this afternoon are focused on the literature review that the EPA will use in its upcoming Integrated Science Assessment (ISA).

In the May 23, 2016 CASAC meeting and in written member comments, several CASAC members deliberated on the importance of the study selection process for the upcoming ISA. Our own search of the scientific literature revealed over 7,000 peer-reviewed articles related to PM inhalation. Over 1,800 of these articles were published within the last five years. Although not all of these articles could or should be included in the EPA's assessment, failure to have well-articulated review criteria may bias study inclusion. We applaud and agree with the suggestion made by CASAC members that a more thorough discussion from the EPA on appropriate study inclusion criteria is imperative and necessary. We are further encouraged by the CASAC discussion suggesting that included studies be further critically reviewed for study quality and risk of bias. This is especially important in these types of assessments because of inherent limitations in the different streams of evidence from human, animal, and mechanistic studies that ultimately need to be integrated. Looking at statistical significance apart from limitations and bias can drastically affect the strength of the final PM NAAQS.

Having an established, *a priori* method for systematically choosing studies that will form the foundation of the evaluation is not a novel concept. Systematic reviews have been used in several scientific disciplines since the late-1970s and 1980s. The EPA itself has already begun implementing such a process in its Integrated Risk Information System (IRIS) chemical risk assessments to, in their words, "increase the transparency and clarity related to identifying and evaluating evidence and drawing conclusions in ongoing and future assessments."

However, it was clear from the June PM ISA Workshop that the EPA has not yet determined search strings it feels confident with, even though the ISA has already been drafted and disseminated to the experts participating in the workshop. This casts an unfortunate shadow on the confidence and transparency of the literature review process. It is crucial that the PM literature be reviewed thoroughly and objectively. Reductions in particle pollution have been the basis of numerous, expensive regulations in the last decade. Even small changes to the level of the existing PM NAAQS will have large implications to the entire country.

For these reasons, we strongly encourage CASAC to provide clear guidance to the EPA on this matter, particularly because of the weight that study quality will bear in subsequent assessment documents. The EPA has already shown that it will change course in its analysis to comply with strong CASAC feedback. Adjusting the EPA's literature review process now through firm guidance will provide much-needed consistency and transparency to the ISA and the subsequent assessment documents that are developed as the PM NAAQS is reviewed in the coming years.

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