# TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

*Protecting Texas by Reducing and Preventing Pollution*

June 15, 2006

Dr. Nancy Beck
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
New Executive Office Building, Room 10201
Washington, DC 20503

Re: Federal Register, Vol. 71, No. 10, January 17, 2006, Proposed Risk Assessment Bulletin

Dear Dr. Beck:

The Texas Commission on Environmental Quality (TCEQ) has reviewed the Office of Management and Budget Proposed Risk Assessment Bulletin (Bulletin). The TCEQ supports the improvement of the risk assessment process, but has concerns regarding the potential far-reaching implications of the Bulletin and some of the proposed requirements. We appreciate the opportunity to provide the enclosed comments.

If you have questions regarding our comments, please contact Joseph T. Haney, Jr., Toxicology Section, at (512) 239-5691, or jhaney@tceq.state.tx.us.

Sincerely,

D.C. Schanbacher

David C. Schanbacher, P.E.
Chief Engineer

Enclosure

**Texas Commission on Environmental Quality (TCEQ) Comments on the Office of Management and Budget Proposed Risk Assessment Bulletin Federal Register, Vol. 71, No. 10, January 17, 2006**

Section headings in the comments below correspond to those contained in the document.

*Section I: Definitions*

Risk assessment is defined in this section of the Bulletin as "a scientific and/or technical document that assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety, or the environment." This section also indicates that this definition applies to documents that could be used for risk assessment purposes (e.g., exposure assessment) and those that evaluate risk mitigation activities. As interpreted by the Bulletin, this definition may be too broad as it may be construed to include documents which are not considered "risk assessments" by the scientific community but are only ancillary in nature (e.g., analytical chemistry reports). The *Types of Risk Assessments* section confirms that "risk assessment" as used in the Bulletin is a broad term that encompasses a variety of different analytical techniques and disciplines, from toxicology to social science. As such, this document has far-reaching implications across regulatory programs (e.g., Superfund), regulatory guidance (e.g., cancer guidelines, Risk Assessment Guidance for Superfund (RAGS)), and disciplines (e.g., toxicology, epidemiology, economics, medicine, chemistry, engineering). The potential effects and far-reaching implications of the Bulletin, which are not evaluated and may not be fully understood, deserve a detailed evaluation across potentially affected disciplines and programs.

*Section IV: General Risk Assessment and Reporting Standards*

*3. Standards Related to Characterization of Risk*

This section of the Bulletin indicates that every quantitative risk estimate should provide a range of plausible risk estimates when there is scientific uncertainty or variability. Because of the broad definition of "risk assessment" in the Bulletin and because there is always scientific uncertainty or variability (e.g., toxicity factors, exposure assessment), this seems to require a risk estimate range for every risk assessment (i.e., influential and non-influential, screening level assessments) and ranges for many of the inputs into remediation risk assessments, such as toxicity factors from USEPA's Integrated Risk Information System (IRIS) database (e.g., RfDs, URFs), exposure factors (e.g., incidental soil ingestion rates, exposure frequency), representative media exposure concentrations, etc. Calculating multiple estimates of risk based on possible combinations of these ranges to provide a risk range, if required by the final Bulletin, may be burdensome and should be commensurate with necessity and the importance of the risk assessment. For example, where a conservative estimate indicates that risk is acceptable, additional analyses to provide a risk range are both burdensome and unnecessary for regulatory risk management decisions. On the other hand, where a conservative point estimate or central estimate would indicate that action is required to mitigate risk, the low end of a plausible risk

range meeting risk-based criteria (e.g., superfund sites) should not be considered *carte blanche* for inaction.

This section of the Bulletin also indicates that where feasible, a document made available to the public in support of a regulation should identify peer-reviewed studies known to the agency that support, are directly relevant to, or fail to support any estimates of risk of adverse health effects, and the methodology used to reconcile inconsistencies in the scientific data. It could be argued that it is feasible, although burdensome, to reference the numerous studies which may support a toxicity factor (e.g., RfD) used to estimate risk, and the many studies which would not necessarily support the risk estimate as they did not identify the critical effect. However, a reference in a risk assessment to the USEPA IRIS substance file, for example, should be considered to satisfy this requirement.

*5. Standards Related to Critical Assumptions*

This section indicates that the range of scientific opinions regarding the likelihood of plausible alternative assumptions, the direction and magnitude of any resulting changes if key assumptions were to be changed, and the basis and rationale for combining the assumptions utilized should be discussed for both influential and non-influential risk assessments. Additionally, whenever possible, a quantitative evaluation of reasonable alternative assumptions should be provided. As there is a range of scientific opinions on many of the parameters often used in risk assessment which can have a significant effects on key findings (e.g., exposure parameters, toxicity factors), these requirements may be burdensome and require that risk estimates be calculated using every possible combination of alternative assumptions, when a reasonable maximum estimate or central estimate may suffice for risk manager decision-making. Instead of a requirement being applied indiscriminately, the level of effort should be commensurate with necessity and the importance of the risk assessment.

*7. Standards Related to Regulatory Analysis*

The basis for a central risk estimate should not be limited to methods involving calculating multiple estimates of risk or a distribution of multiple estimates of risk and should allow for a central estimate based on assumptions judged to be representative of central tendency (e.g., $50^{th}$ percentile exposure factors, average exposure point concentrations).