Oral clarifying comments presented to the EPA CAAC reviewing the draft EPA IRIS Toxicological Assessments of ETBE and TBA, June 6, 2018.

James S. Bus, Exponent, Inc., on behalf of LyondellBasell

The draft SAB CAAC Letter to the Administrator (EPA CAAC 2/21/2018) states that the SAB "agrees that noncancer toxicity at sites other than kidney should not be used as the basis for deriving an oral reference dose (RfD) or inhalation reference concentrations (RfC) for ETBE or tBA." This recommendation appears to directly conflict with subsequent text indicating a lack of SAB consensus regarding confidence in the human relevance of the kidney toxicity of ETBE and tBA. Given the lack of consensus of the SAB on the risk relevance of kidney toxicity, the SAB CAAC should recommend that EPA develop alternative RfD/RfC values for all potentially human-relevant endpoints for which suitable dose-response data are available for RfD/RfC derivations. Such a recommendation would be consistent with current EPA practice and policy to develop RfC/RfD values from all appropriate endpoint data (NAS, 2018), rather than restrict the focus only to the endpoint producing toxicity at the lowest NOAEL dose.

The rationale for developing RfD/RfC values from multiple endpoints is of particular importance and value for ETBE and tBA IRIS documentation in that:

1) The SAB could not reach consensus on the kidney endpoint due to disagreement of whether this endpoint is qualitatively relevant to human risk; and
2) If subsequent science and/or evaluations further inform the kidney endpoint as not human relevant, the availability of high quality RfD/RfC values derived from alternative endpoints within the IRIS assessments for ETBE and tBA will make these assessments of continuing relevance for informing human non-cancer health risks.

Reference:

NAS (National Academy of Sciences). 2018. Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation. National Academies Press. Available at http://nap.edu/25086. See p. 88.