Integrated Risk Information System (IRIS) Public Science Meeting June 30, 2016 *tert*-Butyl Alcohol

Session 7: Public Comment Session on the draft *tert*-Butyl Alcohol assessment

Marcy I. Banton, DVM, PhD, DABVT

LyondellBasell

Literature Search Strategy and Evidence Tables

Thanks to EPA for addressing some of our comments submitted on the 2013 tert-butyl alcohol (TBA) Preliminary Materials, however a number of issues we had identified remain in the draft TBA assessment:

- Literature Search Strategy
  - Information on how the primary references were selected for “Sources of Health Effects Data” versus “Supporting Studies” and consistent application of decision criteria.
  - Increased clarity regarding which circumstances data were used from “Supporting Studies” references and when data were not used.
  - Consistent reporting of negative data.
  - Inclusion of mechanistic study data in evaluating TBA health effects.

Literature Search Strategy and Evidence Tables

- Evidence Tables
  - Clarification on what determined the endpoints selected for inclusion in evidence tables.
  - Exclusion of mechanistic key events in evidence tables (e.g. hyaline droplet accumulation) is not consistent with the intent of the EPA IRIS program and does not lead to the development of useful hazard evaluation.
  - Incomplete reporting of study data for multiple key references Errors in reported study findings were determined by reviewers, but were not incorporated into the evidence tables in the supplemental material
  - Studies with poor quality, as identified by the reviewers through Klimisch scoring, should be excluded from evidence tables.
  - It is unclear when mechanistic data were included in the assessment and when data were not, and inclusion is inconsistent throughout. Inclusion/exclusion criteria should be made and implemented for mechanistic data.
  - Inclusion of relevant endpoints showing no effects associated with TBA.
  - Inclusion of study limitations when relevant.

Background Information

Some of the background information on TBA is out-dated. More recent information on environmental occurrence and chemical properties is available and should be used in the TBA assessment.

- Environmental occurrence – the draft assessment reports TRI numbers for 2012. The numbers for 2013 and 2014 are available and would likely be different than the values.
- Physicochemical properties – the draft assessment reports old mostly handbook values. For some of the properties, newer experimental data is available (cited on ECHA dissemination website).

Effects other than cancer

- Rat kidney effects do not appear relevant to human health but provide a conservative systemic effects endpoint for toxicity assessment. Other organ findings are insufficient to base human health assessments.
- The proposed RfD and RfC values for TBA are similar to values developed in Europe (DNELs, Derived No Effect Levels):

	EPA RfC/RfD	EU REACH DNELs (General Population, Systemic Effects, Long-Term)
Inhalation	0.9 mg/m^3	0.5 mg/m^3
Oral	0.1 mg/kg bw-day	0.3 mg/kg bw-day