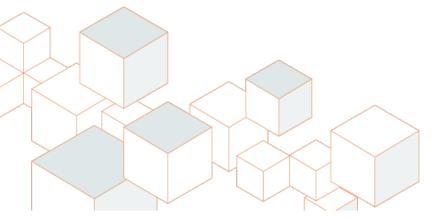


October 26, 2016

COMMENTS FOR EPA'S PUBLIC SCIENCE MEETING: ETHYL TERTIARY BUTYL ETHER (ETBE)

Kimberly White, PhD Senior Director, ACC





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Improvements and Clarification Needed

Cross-Cutting Issues

- Coordination and incorporation of relevant information on tert-Butanol
 - Applicability of preamble to the approaches used in the draft ETBE IRIS assessment
 - 3 Criteria for evaluating study quality
 - Clarity on new undefined terminology
 - 5 Peer review of suggestive cancer endpoint
- 6 Presentation of uncertainty information

Coordination and incorporation of relevant information on tert-Butanol

Charge document states the draft ETBE IRIS assessment is being developed "in tandem" with tert-butanol

Preface of the draft ETBE IRIS assessment notes there are issues relevant to both; however, none of the June 2016 discussions, nor any of the public comments, are incorporated into the current ETBE draft

- Revise draft ETBE IRIS assessment with all relevant comments and changes incorporated and then release for public comment and discussion before a version is sent to the CAAC
- Revise the charge to the CAAC to ensure that the CAAC responds to public comments

Applicability of preamble to the approaches used in the draft ETBE IRIS assessment

- Multiple comments previously submitted on the preamble in other assessments (i.e. Ammonia, TMB) and its utility
- Relevance of the preamble is not clear for the draft ETBE IRIS assessment

- ☐ The beginning of the draft ETBE IRIS assessment preamble should clearly note what is relevant and what practices are still "under development"
- A charge question regarding the relevance of the preamble to the draft ETBE IRIS assessment should be added to the CAAC charge
- Separate from any specific IRIS assessment, the preamble should undergo peerreview by the CAAC

Criteria for evaluating study quality

Draft includes a listing of general "considerations"

- ➤ In draft ETBE IRIS assessment most of the studies are GLP
- For diverse datasets, this approach will not be sufficiently transparent

- □ Draft ETBE IRIS assessment should clearly articulate the study quality criteria
- □ All evidence tables should have a column noting the study quality

Clarity on new undefined terminology

The draft ETBE IRIS assessment introduces terminology that has not been defined

- > Kidney effects were identified as a potential human hazard"
- ➤ Evidence is *suggestive* that liver toxicity follows ETBE exposure"

- The draft ETBE IRIS assessment should clearly define these new terms
- ☐ If a new non-cancer framework has been developed, it should undergo public comment and peer review

Peer review of suggestive cancer endpoint

- □ Consistent with the cancer guidelines, suggestive cancer values may be only appropriate for certain uses
- ☐ Lack of documentation for the appropriate uses for the cancer values

- The draft ETBE IRIS assessment should appropriately characterize how the derived value should be used
- The CAAC charge question should be revised to ask if the science supports the proposed uses

Presentation of uncertainty information

- □Limited value in only delineating the uncertainties in a table
- □ Uncertainty presented for cancer only

- □ Provide uncertainty information for both cancer and noncancer endpoints
- Add a charge question for the CAAC to provide comments and suggestions to improve the utility of the uncertainty characterization
- ☐ Consider use of different approaches for addressing uncertainty information (e.g. <u>Beck et al 2016</u>)