



October 26, 2016

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

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# Improvements and Clarification Needed

## Cross-Cutting Issues

1

Coordination and incorporation of relevant information on tert-Butanol

2

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

3

Criteria for evaluating study quality

4

Clarity on new undefined terminology

5

Peer review of suggestive cancer endpoint

6

Presentation of uncertainty information

# CROSS-CUTTING ISSUE #1

## 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

## Recommendations for Improvement

- ☐ 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

# CROSS-CUTTING ISSUE #2

## 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

## Recommendations for Improvement

- ❑ 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 peer-review by the CAAC

# CROSS-CUTTING ISSUE #3

## 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

## Recommendations for Improvement

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

# CROSS-CUTTING ISSUE #4

## 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"

## Recommendations for Improvement

- ❑ 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

# CROSS-CUTTING ISSUE #5

## 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

## Recommendations for Improvement

- ☐ 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



# CROSS-CUTTING ISSUE #6

## Presentation of uncertainty information

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

## Recommendations for Improvement

- ❑ Provide uncertainty information for both cancer and non-cancer 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. [Beck et al 2016](#))