

IRIS Bimonthly Meeting  
Arlington, VA  
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*Advocacy: the voice of small business in government*

# Small Business and IRIS

IRIS has implications for  
regulations and regulatory  
policy

# NRC Recommendations (2011)

- *Establish Standard Protocols for Evidence Identification*
- *Establish Clear Guidelines for Study Selection*
- *Standardize Presentation of Studies to Capture Study Characteristics, WOE and Utility for Deriving Unit Risks*
- *Standardize Approach for WOE*

# IRIS Enhancements – July 2013

- Step 1 Chemicals
  - *Publicly releases literature search, literature search strategy, critical study selection criteria, evidence tables for critical studies, and exposure-response figures*
  - *Convenes public meeting to discuss literature search, evidence tables, exposure-response figures and key issues*

# Missing Information

- *Critical Study Selection Criteria*
- *Identification of Critical Studies and Rationale for Selection*
- *Evidence Tables Presenting the Critical Studies*
- *Identification and Application of WOE Factors*
- *Identification of Key Issues*

# NRC (2011) Implementation

- *July 2013 IRIS enhanced procedures were designed to implement the NRC recommendations*
- *EPA adopted strategy of robust early input to avoid low quality IRIS assessments*
- *Proper implementation of enhanced procedures is critical to small business input*

# Industry Comments

*Previous commenters, including trade associations representing small businesses, found that EPA generally did not fully implement the Step 1 procedures regarding study quality, identification of critical studies and weight-of-evidence (WOE) criteria for both step 1 and step 4 chemicals.*

# Conclusions

- *Step 1 Chemicals*
  - *EPA Should Supplement Step 1 Materials with Study Quality Criteria and Identification of Critical Studies*
  - *EPA Should Identify Key Issues*
  - *EPA Should Convene New Step 1 Public Meeting in Accordance with Enhanced IRIS Procedures*



# Conclusions

- *Step 4 Chemicals*
  - *EPA Should Modify Assessment to Address Inadequacies*
  - *EPA Should Improve Peer Review Questions*

# Additional Comments

*EPA Needs to Set Aside Adequate  
Time for Step 1 and Step 4  
Meetings to Ensure Robust  
Dialogue Among Scientists*

# Additional Comments

*Chemical Specific*

*CAAC Review Committees Need to  
Include Diversity of Viewpoints  
(Not Solely Government and  
Academic)*

# Contact Information

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