



December 12 - 13, 2013

COMMENTS FOR THE DECEMBER EPA BI-MONTHLY MEETING: ETHYLENE OXIDE

Kimberly Wise, PhD

ACC Center for Advancing Risk Assessment Science and Policy (ARASP)



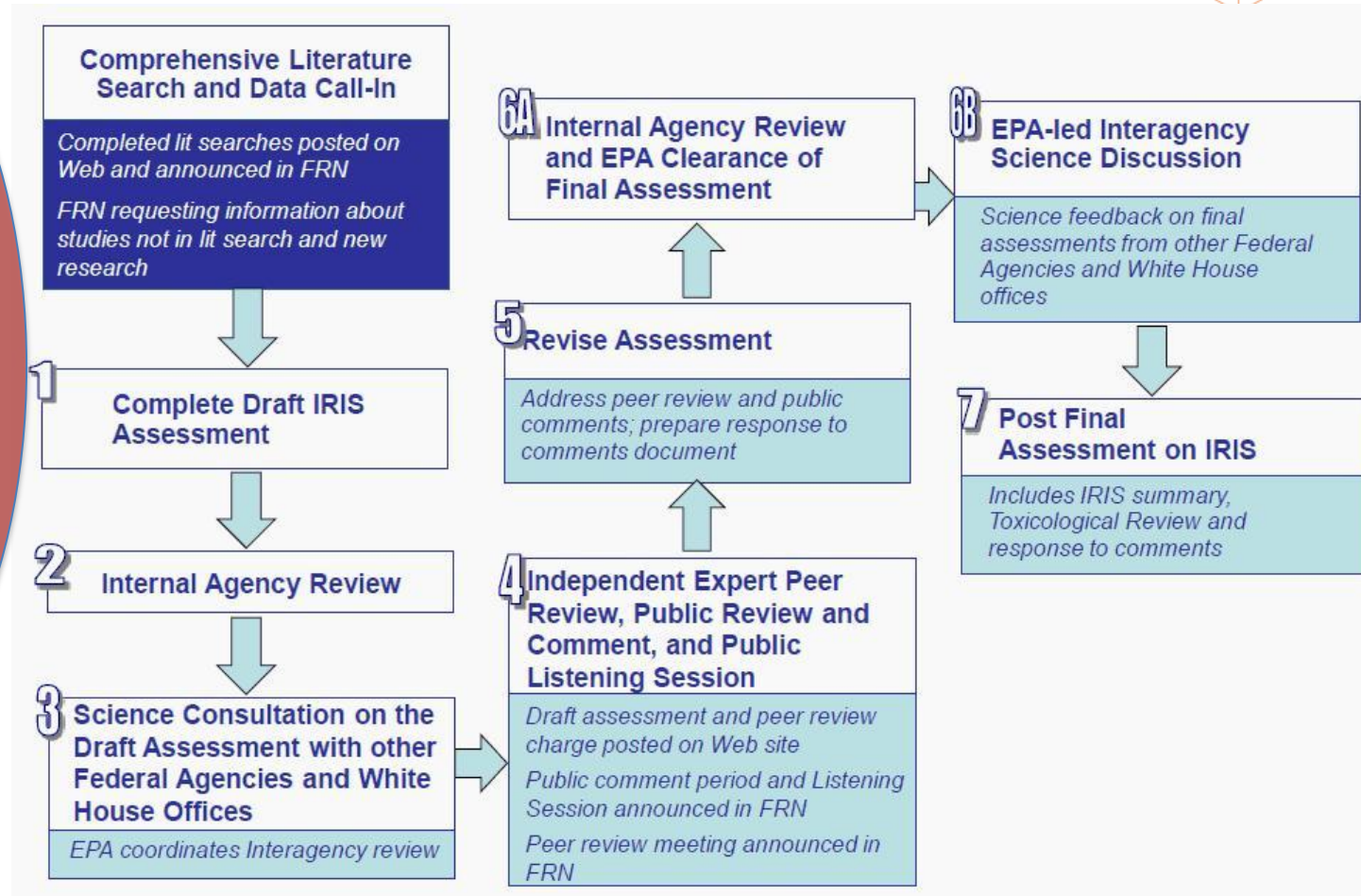
Promotes

- Development and Application of Scientifically Sound Methods
- Transparent and Explicit Data Evaluation Criteria
- Adoption of Policies and Practices that Use Best Available and Relevant Science
- Use of Mode of Action (MOA) Information

IRIS in 2013 Program

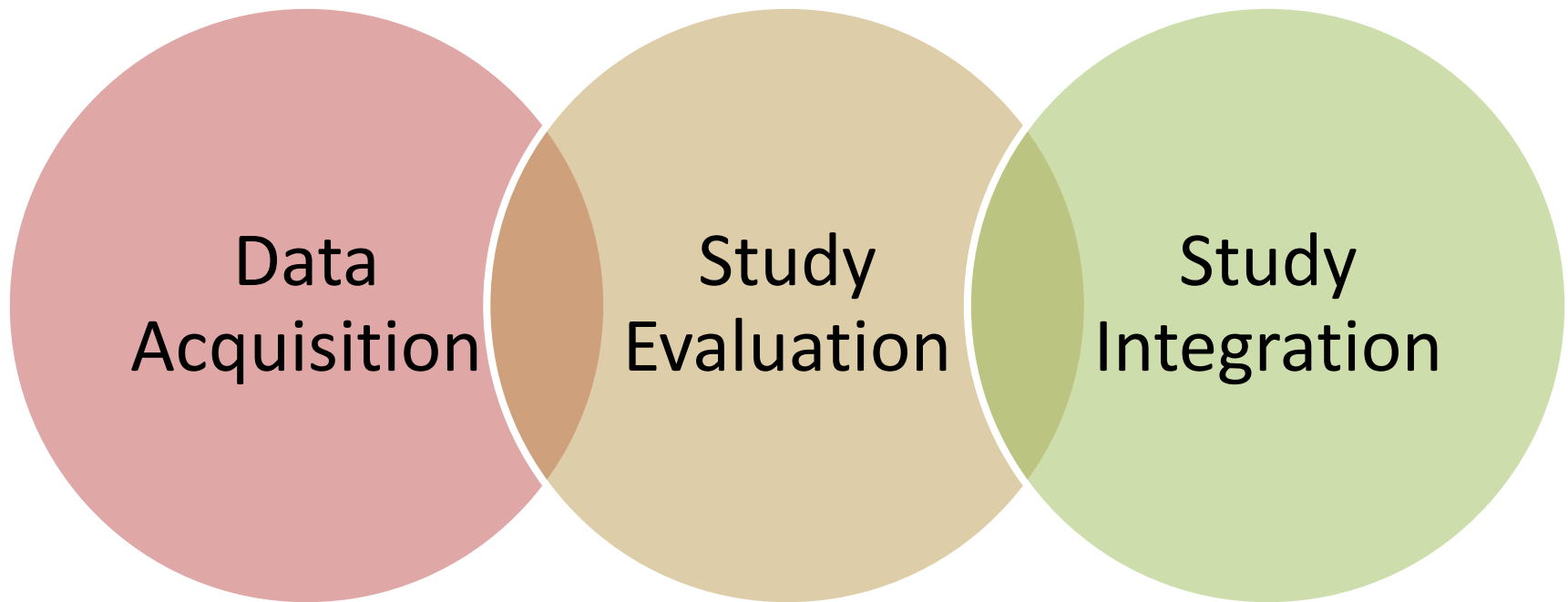
Enhancements Announced

- ❑ Scoping and Problem formulation
- ❑ Release of Lit Search and Evidence Tables
- ❑ Early ID of Science Issues
- ❑ Stopping Rules



Continual Improvement of IRIS

- ❖ Increasing Transparency, Objectivity, and Consistency
- ❖ Timely Implementation of All NRC Recommendations



Improving Ethylene Oxide Assessment



Complete Data Quality Evaluations

- Provide the criteria for evaluating the quality of epidemiology, toxicology and mechanistic studies
- Provide suitable definitions for what constitutes a determination of “high-quality”
- Describe the elements of the study that have increased or decreased its quality

Revise Evidence Tables

- Align studies and data in the order deemed most relevant to supporting the weight of evidence conclusions
- Add column which identifies the quality determination of the study

Improving Ethylene Oxide Assessment



Address Endogenous Exposures

- Include discussion of ambient EtO exposure levels in relation to the derived unit risk
- Include discussion of homeostatic mechanisms that exist at typical EtO endogenous exposure levels

Robust Peer Review

- Present both linear and non-linear models in the assessment and develop relevant risk estimates based on each model.
- Identify an “honest broker” to ensure the disposition of public comments and peer review recommendations



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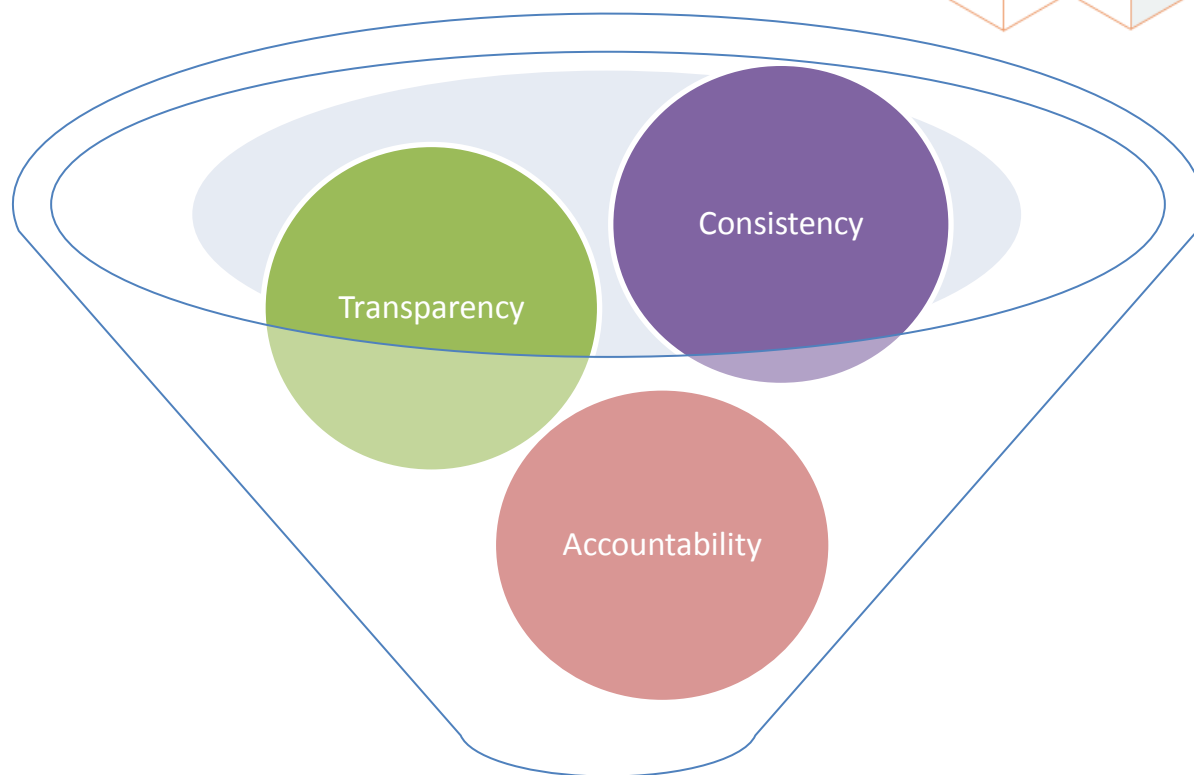
COMMENTS FOR THE DECEMBER EPA BI-MONTHLY MEETING: BENZO(A)PYRENE

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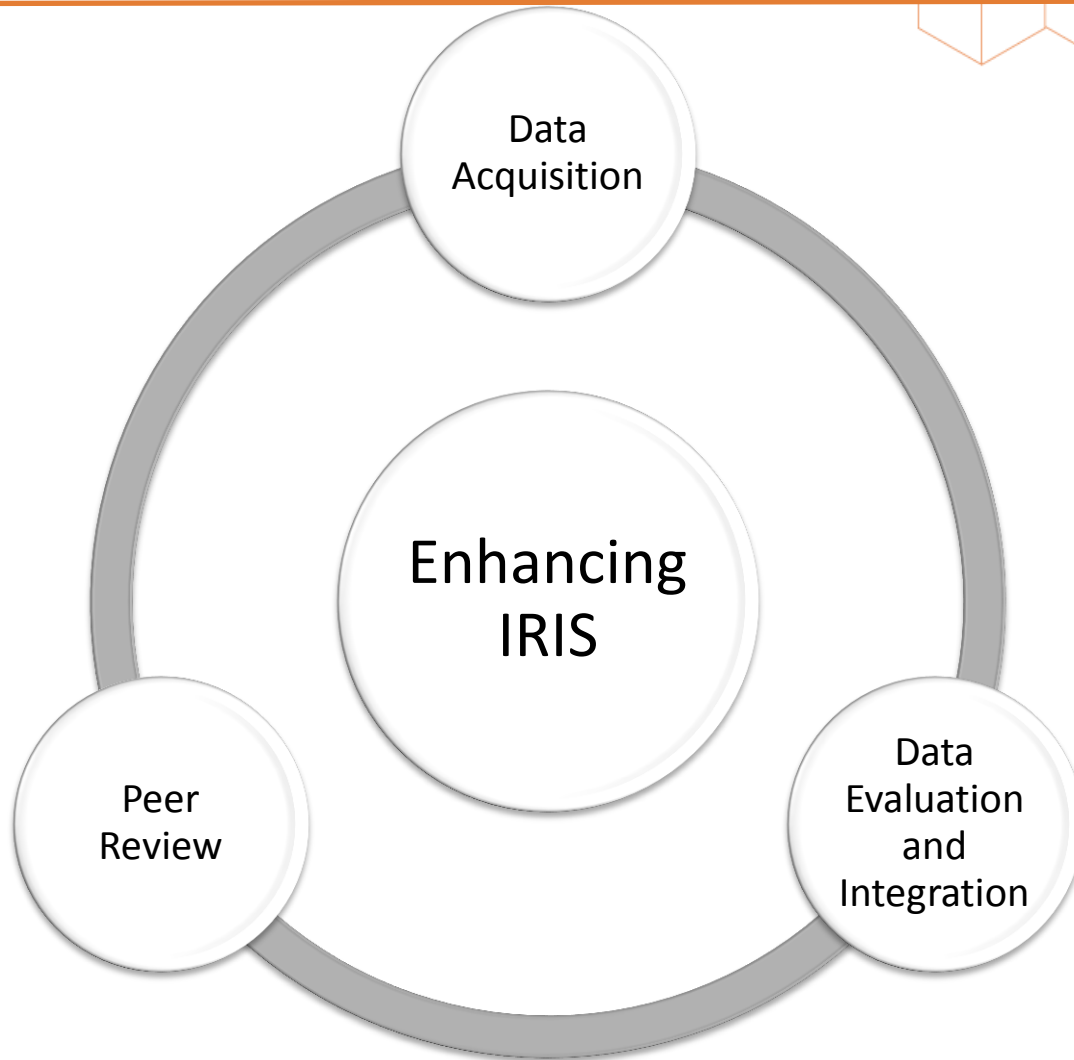


Improving IRIS



High Quality Chemical Assessments

Key Areas for Enhancement



Improving Benzo[a]pyrene Assessment



Conduct Problem Formulation

- Identify the goals and scope of a BaP assessment
- Discuss the potential areas of concern for human health associated with relevant BaP exposure levels

Complete Data Quality Evaluations

- Clearly identify whether EPA considers the study to be of high, medium or low quality.
- Clearly identify study quality characteristics and describe how each of the studies meets, or does not meet, these criteria (e.g. for animal data, such criteria could include a clear evaluation of study design, sample size, statistical power, and the dose-response and exposure characterization)
- Include discussion of how the quality evaluation influenced a study's use in the weight of evidence evaluation

Improving Benzo[a]pyrene Assessment



Revise Evidence Tables

- Present all the data, positive and negative, equally within the evidence table

Improve Systematic Review

- Include all relevant information (e.g. studies involving exposure to BaP via the use of coal tar pharmaceuticals)
- Integrate all the information and explain why a decrease in anxiety, as measured in animal models, should be considered an adverse effect
- Provide a realistic timeline for completing and fully implementing all of the NRC recommendations

Robust Peer Review

- Include experts in dermal dosimetry on the peer review panel to evaluate the EPA's dermal slope factor and associated methodology



Summary

Path-forward

