

Recommendations from:  
Workshop on Overcoming Challenges of Incorporating  
Higher-Tier Data in ERA and Risk Management of  
Pesticides

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# Four Questions Generated Feedback in Breakouts

1. What are the characteristics of higher tier studies that make them useful in a risk assessment?
2. How can the tiered risk assessment process, with respect to the use of higher-tier studies, be improved?
3. What are the characteristics of higher-tier studies that make them useful for risk management decision making?
4. What are the barriers to evaluating and effectively utilizing higher-tier studies in regulatory decision making to achieve protection goals?

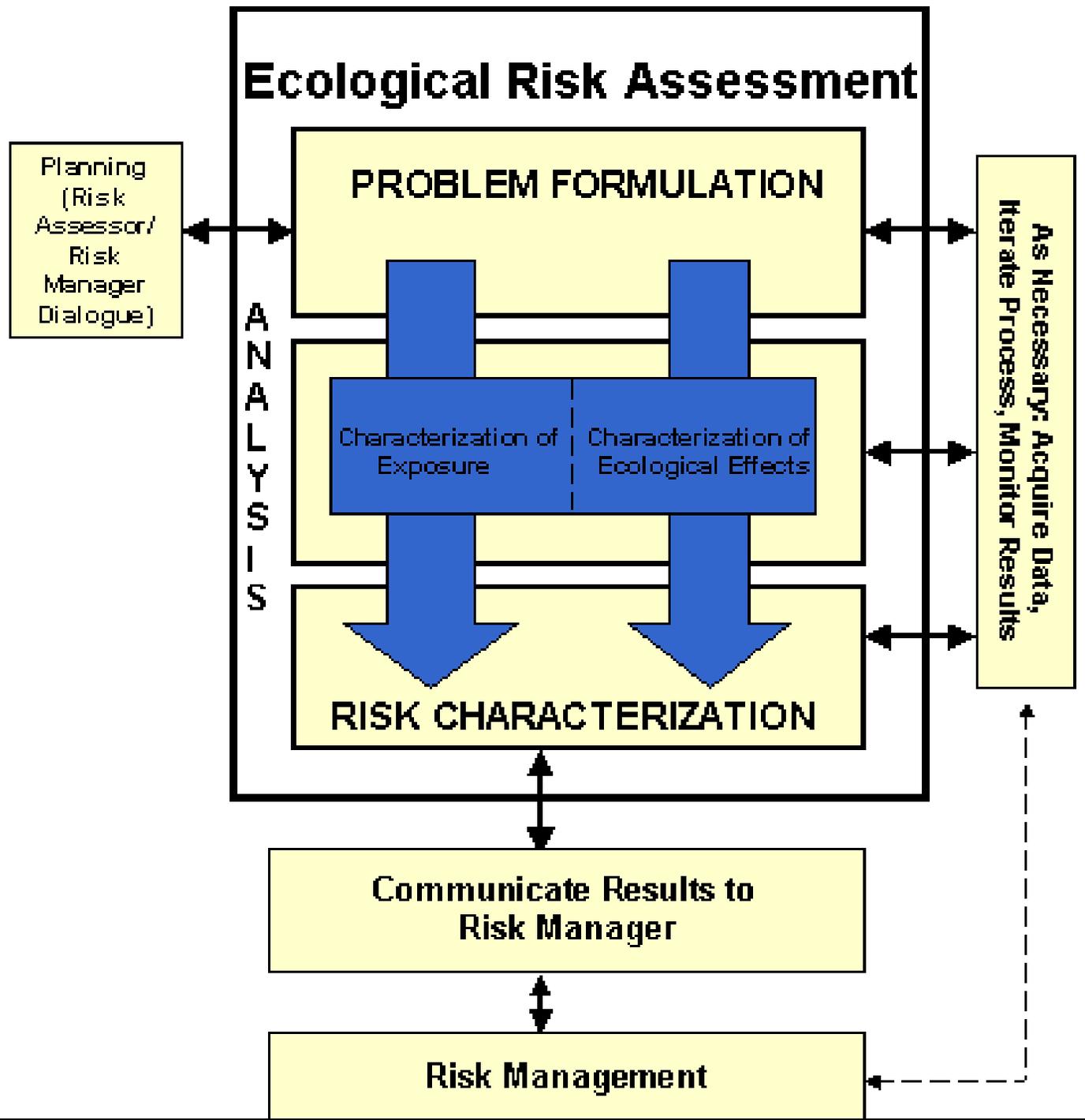


More effective and open communication among registrants, risk assessors and risk managers to clarify protection goals and address issues of concern earlier in the registration and reg-review processes.

Registrants should confer with EPA early in the process to discuss regulatory goals and assessment objectives to reach an understanding of areas needing attention for decision making.

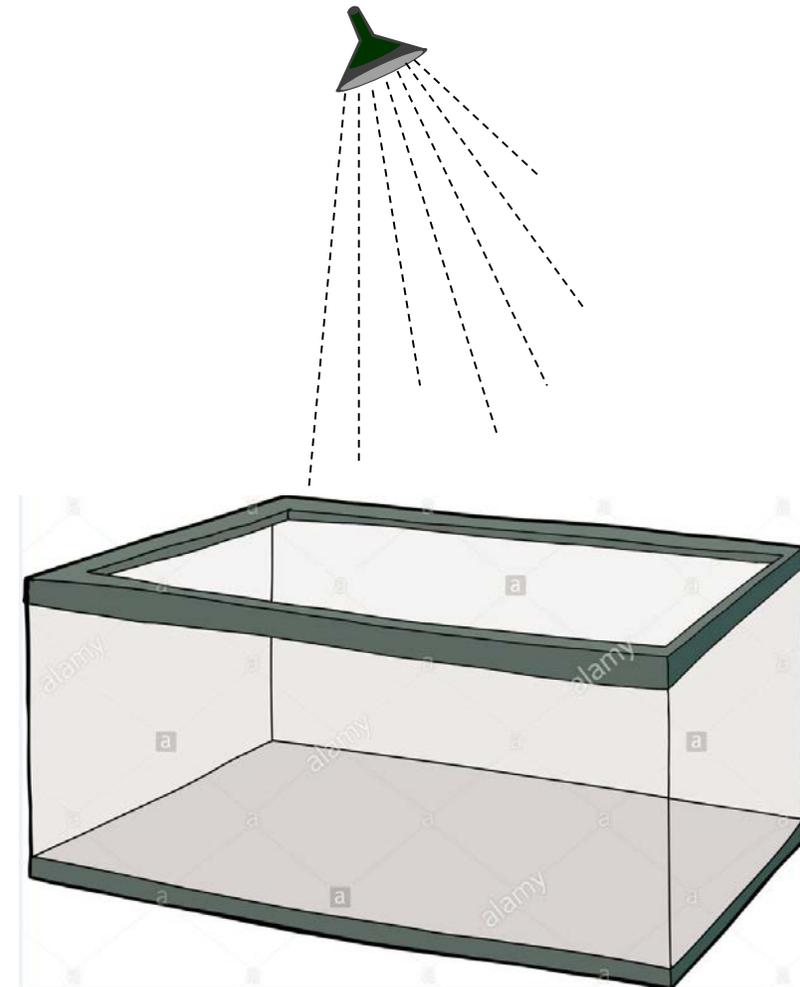
- EPA and registrants need to have a common understanding of specific and actionable protection goals and assessment endpoints before initiating a higher tier study.
- EPA and registrants should prioritize studies that focus on the most significant issues.
- The assessment should be refined iteratively to address issues of concern (adaptive management framework).





# Study design should be carefully considered to minimize complexity and to provide high value to the risk assessment and risk management process.

- When a screening level assessment indicates exceedances, risk assessors should incorporate higher-tier data, as appropriate, into a refined risk characterization to better inform risk assessment and risk management decisions.
- Higher-tier studies should be designed to address specific risk assessment questions or should address uncertainty in the context of a risk management goal.
- Approach the design of higher tier studies in a step-wise process (simple → complex) following EPA's Data Quality Objectives Process / guidance.
- Flexibility is needed for the design of higher-tier studies but they should be designed, analyzed and interpreted in accordance with EPA's established Data Quality Objectives Process.
- Decision criteria regarding higher-tier testing and assessment in some cases do not exist and would benefit from:
  - Developing or revising additional guidance
  - Developing Standard Evaluation Procedures (SEPs) for commonly requested higher-tier studies.



Improved transparency is needed relative to risk-benefit assessments and other critical inputs to risk management decisions.



- The Agency should provide more complete summaries of the data and information that was used to come to a risk management decision.
- A weight of evidence approach and data quality criteria should be used to evaluate study reliability and relevance and to guide which studies to utilize in regulatory decision making.

Retrospective analyses of success-failure learnings on higher-tier studies would be useful to inform registrant assessments and improve study quality and relevance.



- Recommendation: Conduct a retrospective review of situations where higher-tiered studies were conducted and clearly helped to inform risk assessment/risk management decisions.
- Recommendation: Conduct a post-mortem on pyrethroid risk assessment process, summarizing what worked in terms of higher-tier testing and what needs improvement.

# Additional resources may be required to overcome challenges.

Resource limitations are a serious constraint in the development, review, and application of higher-tier data for risk assessment.

- If complex issues are addressed late in the process, getting higher-tier data as a “surprise” can be challenging for EPA to meet required time lines.
- EPA OPP would benefit from a research budget and internal grant process to address areas that improve testing and assessment.



# Status of Workshop Proceedings

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- Manuscript highlighting and giving context to workshop recommendations is nearing completion.
- The manuscript will be reviewed by the workshop attendees for consensus and general content.
- Manuscript will be submitted in May – June time-frame to IEAM - SETAC for publication.