US EPA ARCHIVE DOCUMENT

Endangered Species Act Update

Pesticide Program Dialogue Committee

Thursday, May 3

Session VIII

Topics

- National Academy of Sciences Review
- Usage Pilot Project
- Registration Review: Process Changes Affecting Endangered Species Work

National Academy of Sciences Review

- EPA, Department of Commerce, Department of Interior and the US Department of Agriculture have requested the National Research Council of the National Academy of Sciences undertake an independent review of science issues related to:
  - Best Available Data
  - Mixtures – in the product, tank, or field
  - Sublethal Effects
  - Inert Ingredients
  - Geographic Data Sources and Information

National Academy of Sciences Review

- Specifically we are asking the NRC to explore:
  - What constitutes best available scientific data and information?
  - What are the best scientific methods available for projecting sublethal, indirect and cumulative effects?
  - What methods could be used to assess the effects of mixtures in formulated products or in the environment?
  - What methodology might be used to project effects of inert ingredients?
  - What protocols might be used in the development of assumptions associated with model inputs and the use of sensitivity analyses to evaluate the impact of multiple assumptions on interpretation of results?
  - How might the federal government employ uncertainty factors to account for formulation toxicity, synergy, additivity, etc. ?
  - What constitutes authoritative geospatial information – including spatial and temporal scales that most appropriately delineate habitat of the species and duration of potential effects?

National Academy of Sciences Review

- Review initiated in spring 2011
- To review scientific and technical issues related to Ecological Risk Assessment under FIFRA and ESA
- 18-month process + 3 months for report = 21 months
  - Report in early 2013
- 17 committee members
- Three public meetings
  - 1st meeting on November 3, 2011 – Washington, DC
  - 2nd meeting on January 31, 2012 – Seattle, WA
  - 3rd meeting on April 4, 2012 – Washington, DC

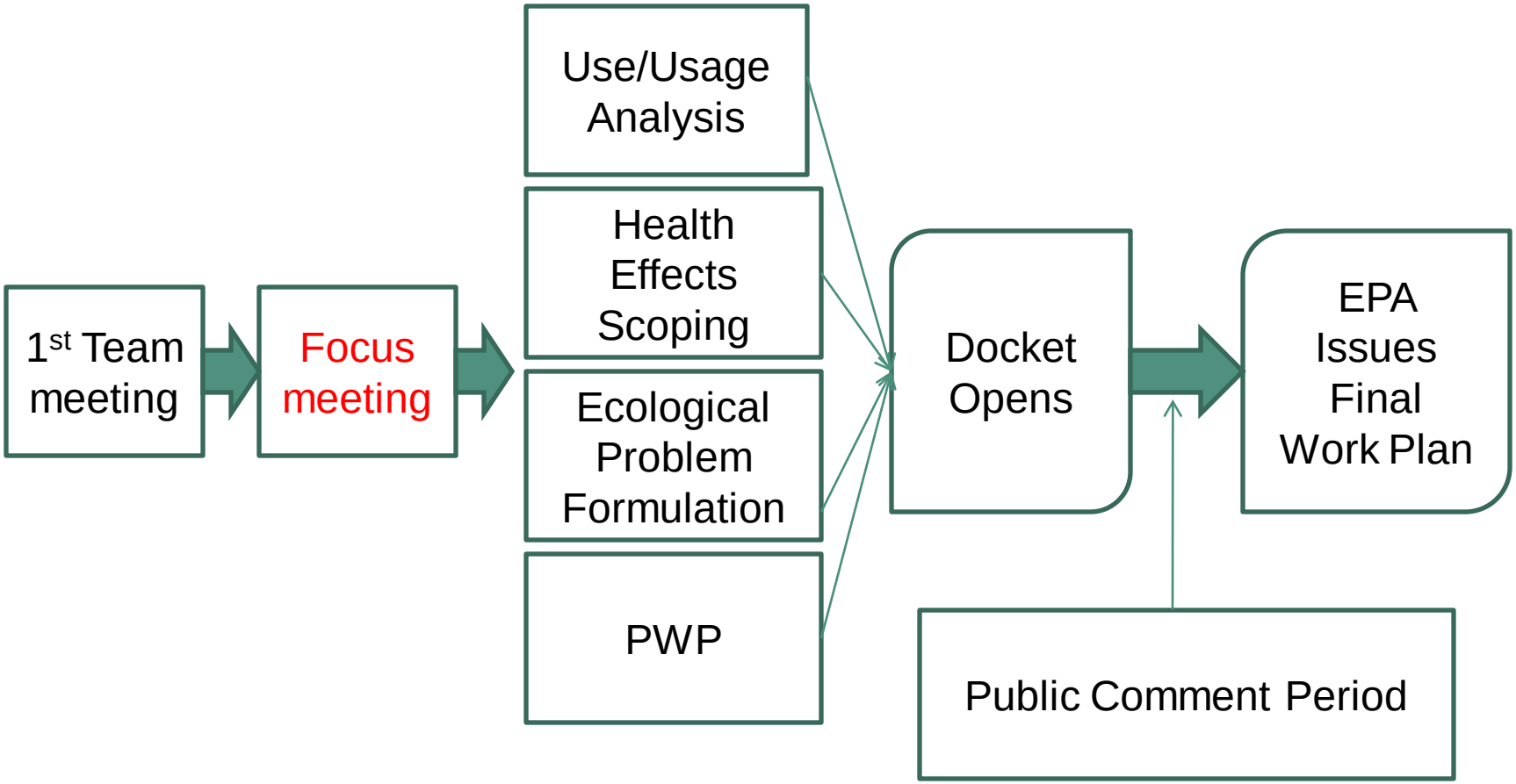
Usage Pilot Project

- Cooperative USDA, EPA, and NMFS project
- Goal: Determine effect of incorporating how pesticides are actually used (vs. labeled max) on the RPAs that are developed
- Information on rate, timing, and frequency of applications being developed by crop and county
  - Oryzalin and Diflubenzuron
  - California's Pesticide Use Reporting (PUR) database
  - Information on mean, 90th, 95th, and 99th percentiles

Registration Review Process & ESA Consultations

- Since the April 2011 PPDC, EPA met with the PPDC PRIA Workgroup twice, once in July 2011 and again in September 2011, to discuss issues related to ESA consultations under Registration Review and process changes needed to address them.
- EPA is making the following process changes to increase efficiencies and to address the issue of "obtaining the best information available to inform its preliminary ESA work under Registration Review"

Registration Review Process & ESA Consultations - Obtaining the Best Information



What Is a Focus Meeting?

- A meeting to discuss a specific Registration Review chemical/case
- Focus on needs identified by OPP Registration Review team early in the process
- Initiated by OPP
- Typically with OPP staff and affected registrants.

Purposes

- Initiate dialogue early in the process to focus on areas that make a difference.
- Use the best information early in process
- Minimize rework
- Focus on areas with potential risks
- Minimize work on negligible risks
- Save OPP and registrant resources in the longer term

Potential Topics

- Data needs
- Label clarity
- Understanding atypical uses
- Discuss likely risk concerns
- Early mitigation

Desired Outcomes

- Clear understanding of supported uses
  - Ideally master label
- Agreement on submitted data
- Discuss available data that might address outstanding data needs
- Begin meaningful dialogue for clarifying labels
- General agreement/understanding of the scope of the risk assessments that OPP will conduct under Registration Review

Benefits

- Initiate dialogue early in review process
- Streamline data needs
- Focus risk assessments on potential risk areas
- Get in front of ESA
- Save Resources

Timing/Number

- Number of meetings can vary from multiple to none
- Typically between 1st team meeting and commencement of problem formulation
- Teams will be encouraged to try different timing approaches

Next Steps

- Pilot Approach
- Encouraging Flexibility
  - Need for meeting
  - Number of meetings
  - Timing of meeting(s)
  - Content of meeting(s)
  - Attendance
- All meeting minutes will be publically available shortly after meeting.

Summary

- Enhance transparency
- Early involvement
- Focus on areas with the greatest concern
- Flexibility