US ERA ARCHIVE DOCUMENT



Registration Review Update

Presentation to the Pesticide Program Dialogue Committee

November 2012



Topics to be Covered

- Accomplishments to Date
- Focus Meetings
- Preliminary Risk Assessments



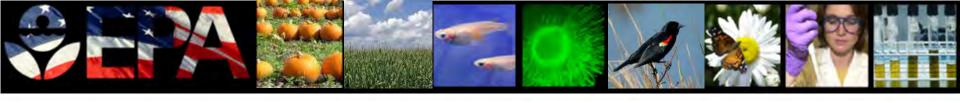
Registration Review

- FIFRA provision requires periodic review of each pesticide's registration
- Covers all pesticides
- 15-year review cycle
- Flexible, transparent, open process
- Includes public participation
- Ensures continuity in protecting human health and the environment



Registration Review Program Implementation

- Began implementation in 2007
- Over 1100 active ingredients
- Includes:
 - National ESA assessments
 - Endocrine disruptor screening program
- First round to be completed by October 2022



Accomplishments to Date

• 370 cases opened

• 320 cases past the final work plan stage

35 Final decisions issued

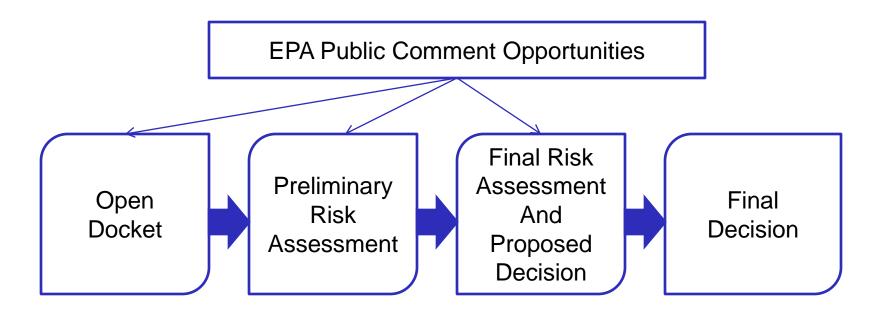


What Is a Focus Meeting?

- 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.

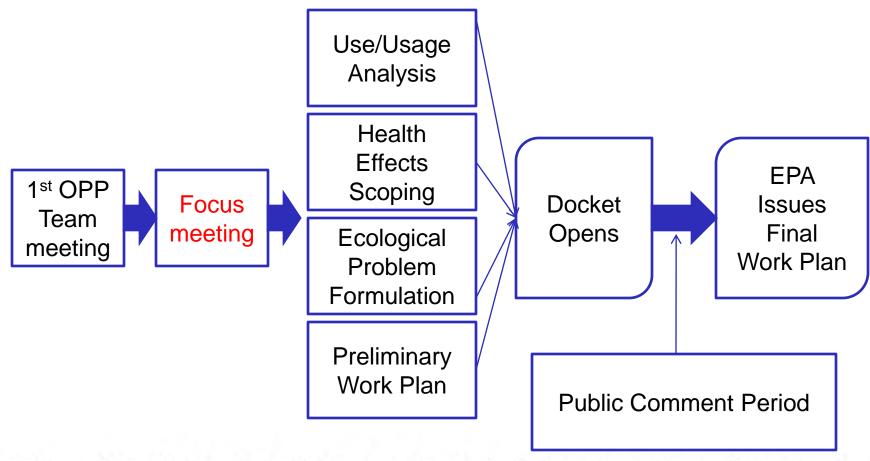


Overview of the Process





Adding Focus Meetings to the Process





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
- Assumptions and uncertainties
- Coordination with registration actions
- Data generated for registration in other countries



Desired Outcomes

- Understanding of supported uses and use patterns
- Agreement on data to be submitted
- If necessary, information regarding data waivers
- Discuss available data that might address outstanding data needs
- Begin meaningful dialogue for clarifying labels
- Begin dialogue and information exchange to fulfill data needs



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 OPP 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

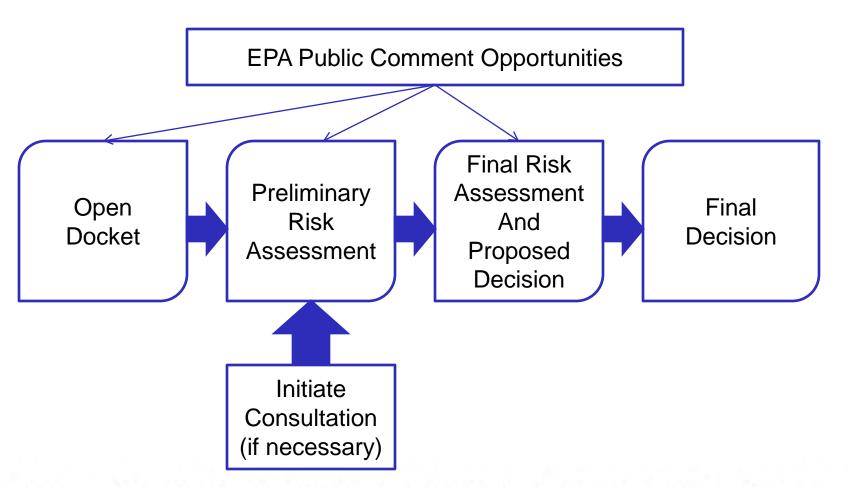


Preliminary Risk Assessments

- Several preliminary risk assessments will be issued for public comment
- Scope will change

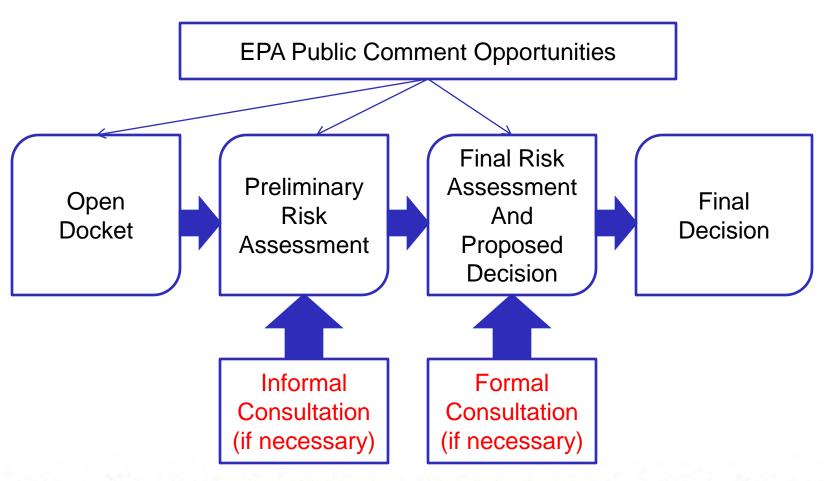


Original Vision of the Process





Revised Vision of the Process





Refined Risk Assessments

- Future effects determinations based on further refinement
 - Species-specific biological data
 - More detailed and accurate info on use patterns
 - Sub-county-level spatial proximity data for cooccurrence of potential effects areas with listed species and critical habitat



Why Make These Changes

- Ensures that we have correctly captured the uses to be supported for re-evaluation
- Provides an opportunity to obtain appropriate geospatial data for supported uses
- Better utilization of resources for the Agency and the Services



For More Information

Registration Review

www.epa.gov/oppsrrd1/registration_review/

- Schedule for Beginning Reviews
 - http://www.epa.gov/oppsrrd1/registration_review/schedule.htm
- Pesticide Registration Review Status

http://www.epa.gov/oppsrrd1/registration_review/reg_review_status.htm