

US EPA ARCHIVE DOCUMENT

The FIFRA Registration Review Process and ESA Consultations: Suggestions for Improved Inputs

PPDC

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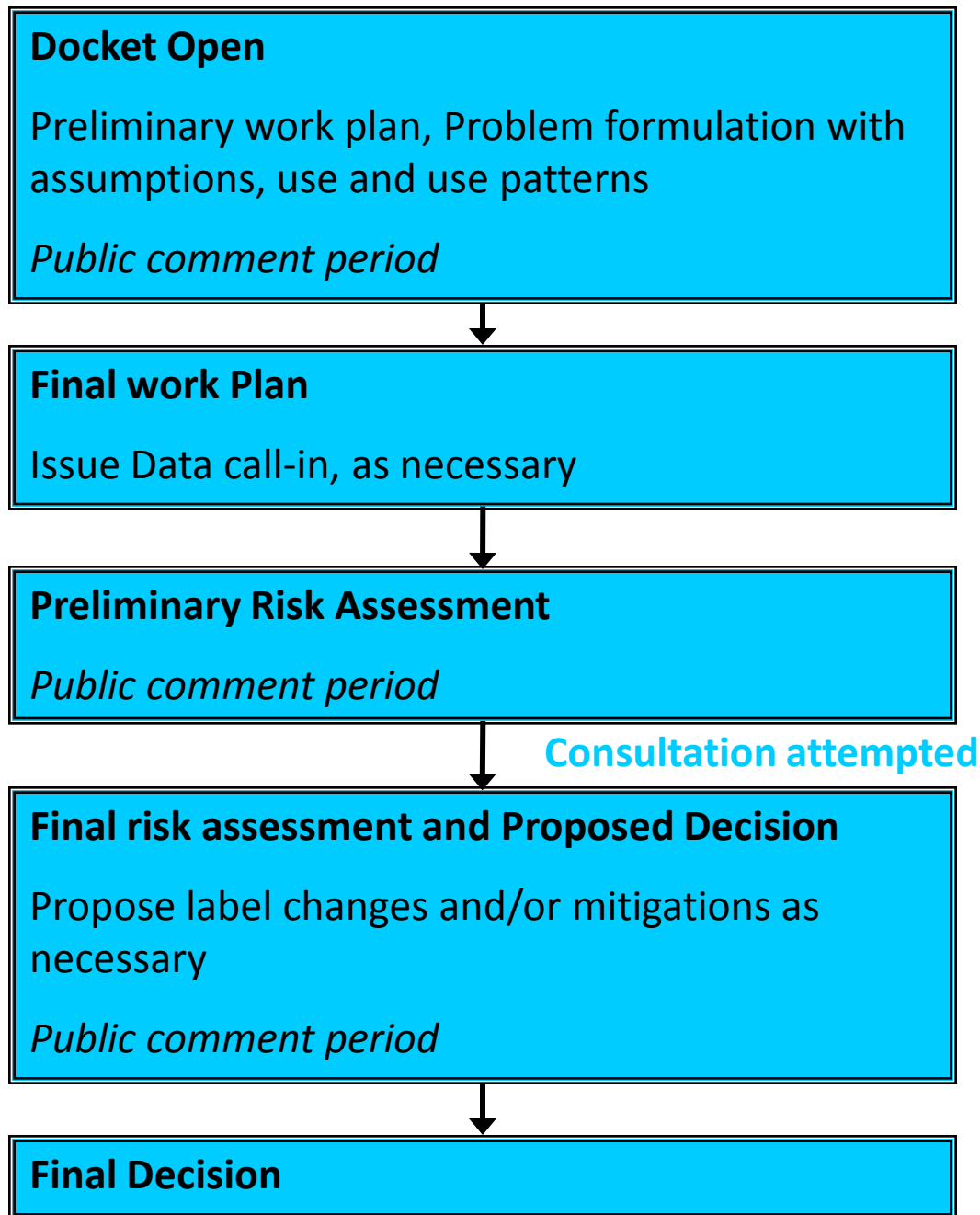


Goals

- o Predictable process with clear opportunities and adequate time for stakeholder involvement
- o Comprehensive assessment and transparent, well documented risk management decisions at the end of Registration Review
- o Predictable participation in consultation process open to all affected stakeholders
- o Balanced implementation that protects species and minimizes potential impact on agriculture

Registration Review

Current General Process



Comments

Docket Open

Preliminary work plan, Problem formulation with assumptions, use and use patterns

Public comment period

Final work Plan

Issue Data call-in, as necessary

Preliminary Risk Assessment

Public comment period

Final risk assessment and Proposed Decision

Propose label changes and/or mitigations as necessary

Public comment period

Final Decision

Mechanism/Meeting for registrant to supply information on current and pending registered uses before problem formulation

Clear mechanism and statement for stakeholders to supply information and timing of submission (States, USDA, local FWS and NOAA fisheries, others)

Identify potential interactions with Services during the process

After first public comment period, option for registrant to request meeting with EPA for clarification and/or to discuss what other relevant data may be available

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Final Decision

Restatement of potential data needs from stakeholders and timing of submission (especially information relevant to endangered species assessment)

- with and without DCI
- allows timely and relevant, up-to date information prior to initiation of preliminary risk assessment

Statement of endangered species data requirements

Comments

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Final Decision

Increased communication with States (and other stakeholders) on importance of local information and how it will be used in the process

EPA enters dialogue with stakeholders on assumptions in risk assessment that are driving the outcome

Relevant stakeholders may include: registrant, USDA, growers, crop experts, nozzle manufacturers, aerial applicators, state and local programs (including Services), etc.

Comments

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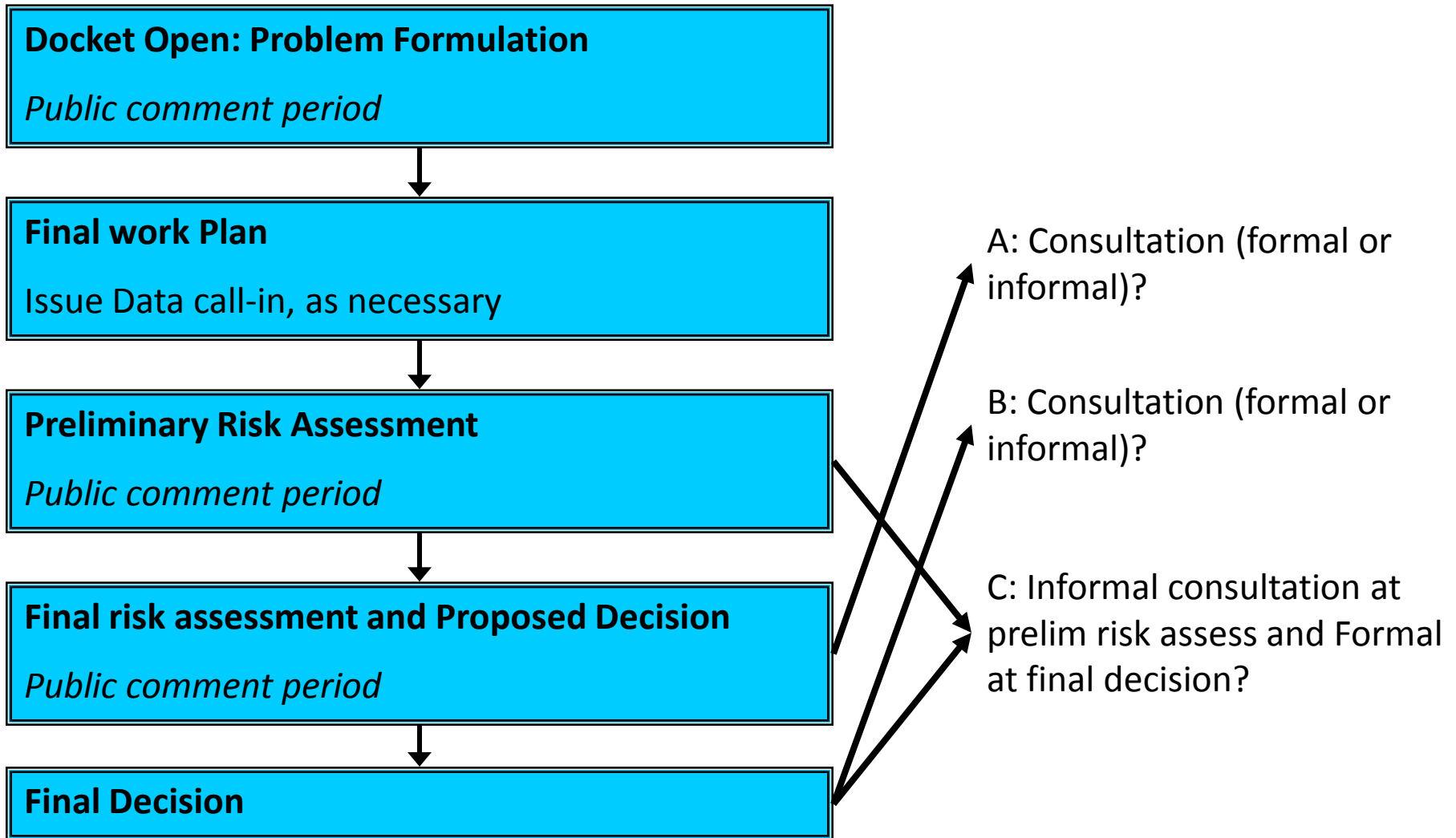
Public comment period

Final Decision

Dialogue with relevant stakeholders on mitigation options

After the comment period for the preliminary risk assessment, EPA revises and/or refines the risk assessment, and documents risk management decisions

EPA Proposed Options for Consultation



Consultation Options/Recommendations

- o Where consultation occurs (formal or informal), the registrants need to be identified as the applicants prior to initiation of discussion
 - Registrant/Applicant provides Services (via EPA) with assessment or other relevant information / data, as appropriate
- o EPA and the Services interact throughout the process (as needed), early and often
 - To obtain and exchange relevant information
 - For example, outreach on species location or other information may be needed
 - Interagency interactions should be part of normal operations (e.g., MOU)

Consultation Options/Recommendations

- o EPA makes maximum use of the Counterpart Regulations (2004)
 - Alternative consultation process for highly complex assessments and perhaps during the period of the NAS study/project
 - Section 402.46 of the counterparts survived the court challenges. This section allows EPA to:
 - Make an “effects determination.”
 - Make jeopardy, ITS, RPA and RPM judgments
 - But all subject to Services review
- o Use informal and formal consultations as needed for regulatory decisions

Consultation Options/Recommendations

Consultation Goal

- **If consultation is required it should be conducted on complete effects determinations/biological assessments and only for the decisions that need consultation, which allows for:**
 - Stakeholder comments to be considered and addressed
 - Most informed, refined assessment
 - Full documentation of risk management decisions
 - Clear identification of species not at risk (no effect or not likely to adversely affect) and species at risk and in need of formal consultation (may affect, likely to adversely affect)
 - Best use of Services resources
- Alternative options may be needed, especially during the next couple of years

Registration Review and Consultation

Other Topics for Discussion

o Registration Review Decisions

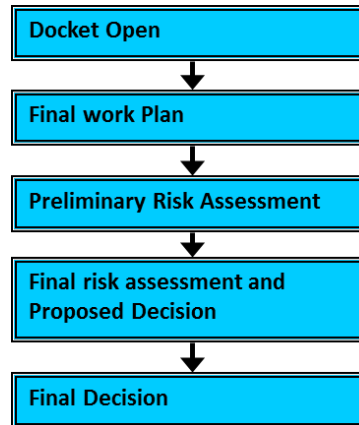
- The current registration review process includes proposed decision with the preliminary risk assessment and then a final decision
- Are other options needed?
- Final Decisions and Interim Decisions?

Process Improvements

- Early registrant interactions with EPA
 - Pre- and post-problem formulation, etc.
- Increased communication with other stakeholders
- Better understanding of data needs and submission
- EPA and Services “early and often” interactions
 - Possible MOU to clarify roles of agencies
- Consultation
 - Registrant clearly identified as applicant
 - Use of Counterpart Regulations
 - Formal on completed effects determination
- Consideration of final vs. interim decisions?
 - Needs further evaluation

Potential Benefits

- Thoroughly understood uses and use patterns
- Increased understanding of data and information needs and submission opportunities
- Integration of local information and best available data
- Full consideration of mitigation options
- Clearly defined and fully informed risk assessment assumptions
- Efficient and targeted interactions with Services



Conclusions

- o A more open and transparent registration review process will benefit all
 - Mechanism for registrant and other stakeholders to provide information, inputs at key steps in the process
 - Early and often Interactions with Services for information and data exchange
 - Information and input by the Services during the process is required, especially in timely provision of relevant species information
 - Final decision and document that is open, transparent and with defensible risk management decisions
- o Better utilization of counterpart regulations for consultation
- o Consultation goal: If consultation is required it should be conducted on complete effects determinations/biological assessments and only for the decisions that need consultation

Appreciate the opportunity to present

Other process steps in need of discussion

Look forward to the continued dialogue within
the Process Improvement Workgroup

Thank You