

US EPA ARCHIVE DOCUMENT

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

PRIA Process Improvement
Workgroup

September 2011



Goals

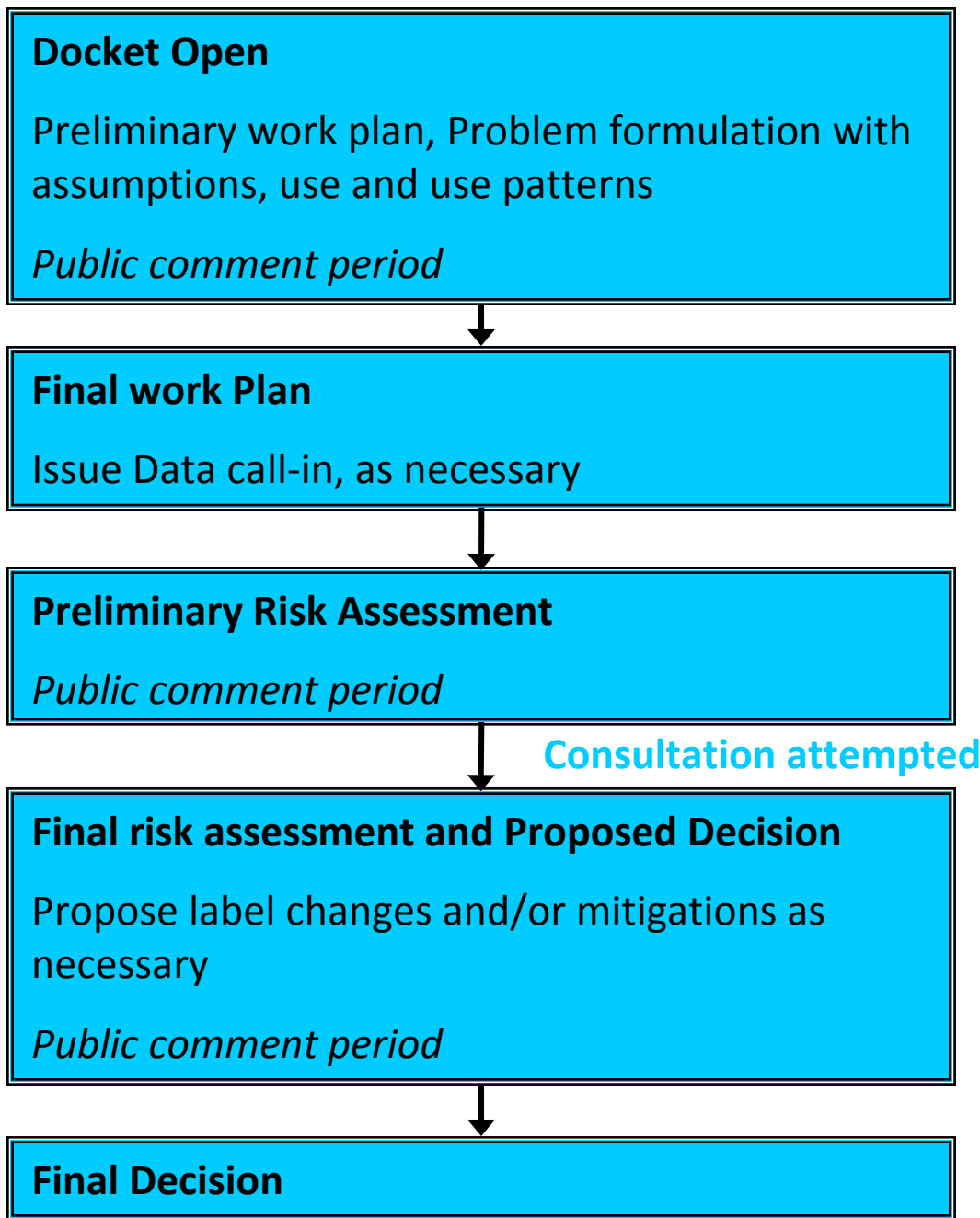
- o Predictable process with clear opportunities and adequate time for stakeholder involvement
- o Comprehensive assessment and transparent, well documented risk management decisions at the end of Registration Review
- o Predictable participation in consultation process open to all affected stakeholders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

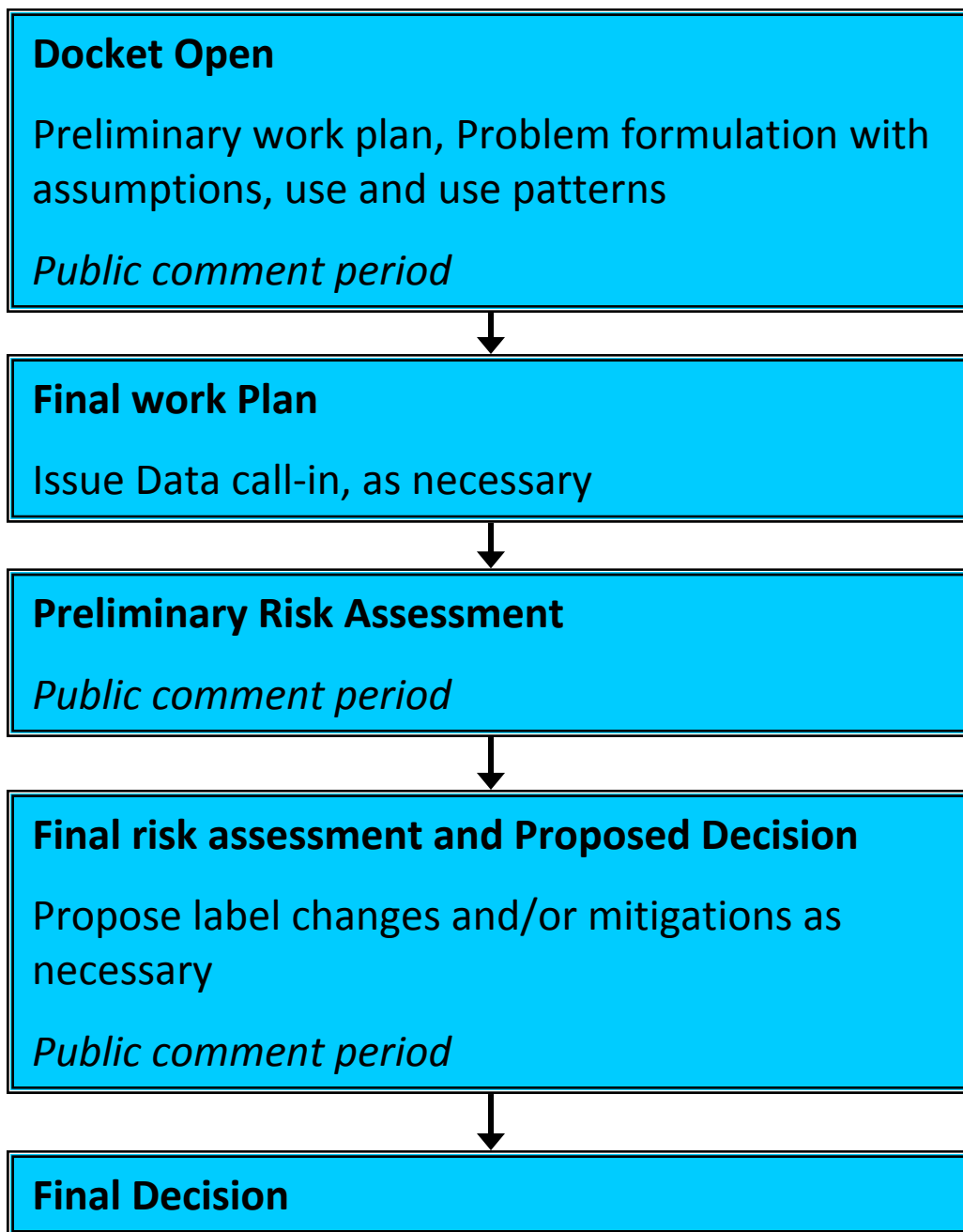
Benefits of CLA Recommendations

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

Registration Review

Current General Process





Comments

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

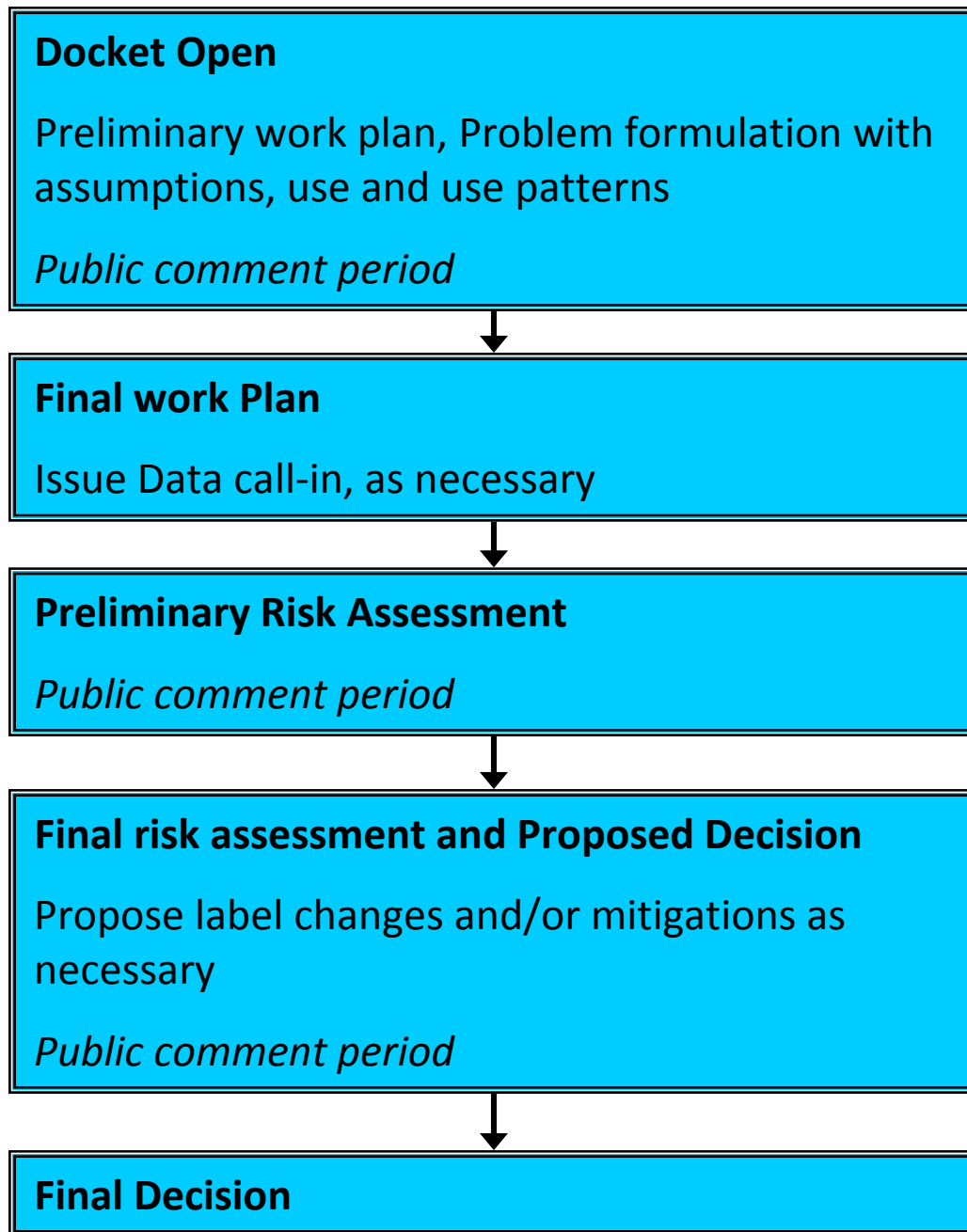
Clear mechanism and statement for stakeholders to supply information and timing of submission (States, USDA, local FWS and NOAA fisheries, others)

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



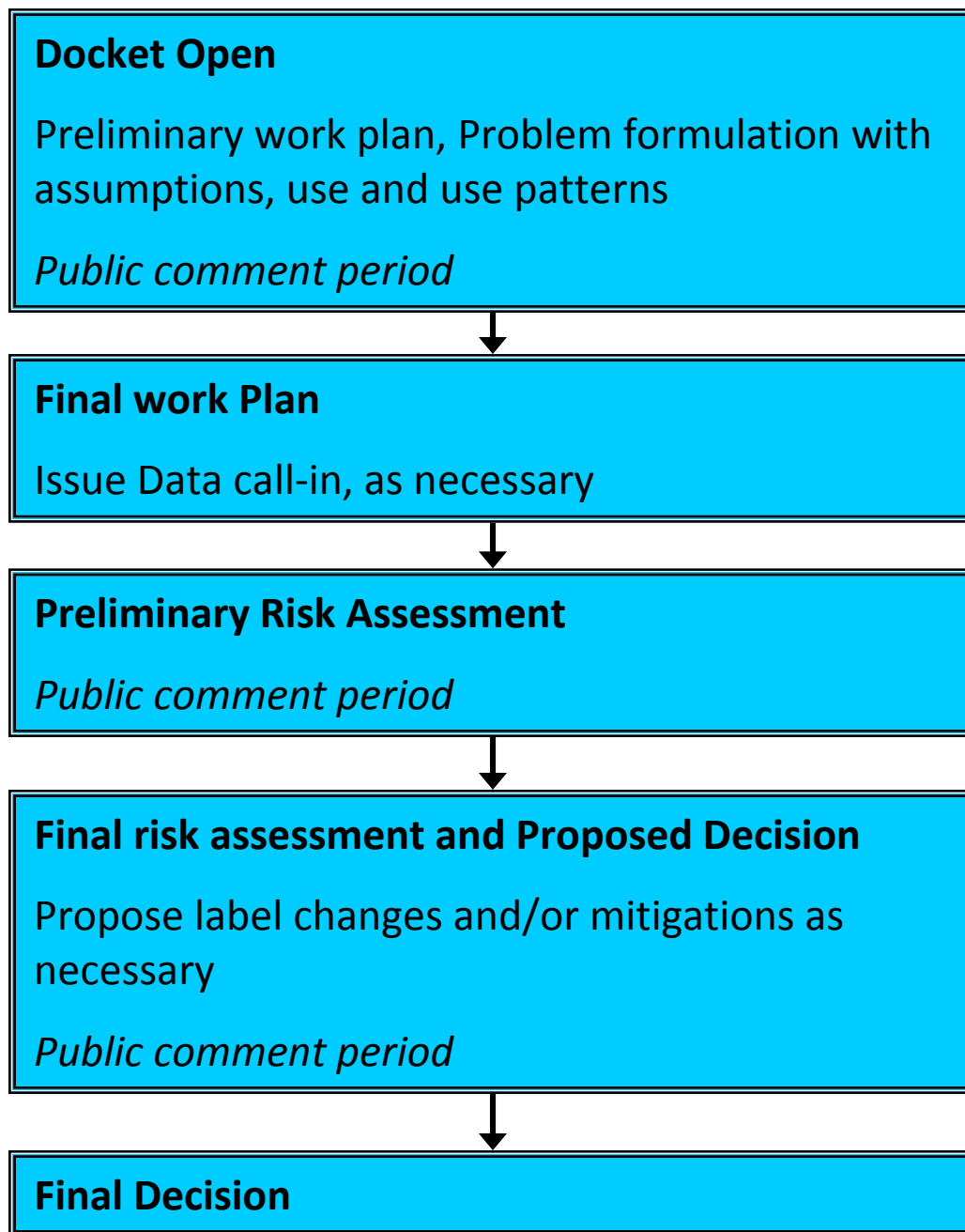
Comments



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



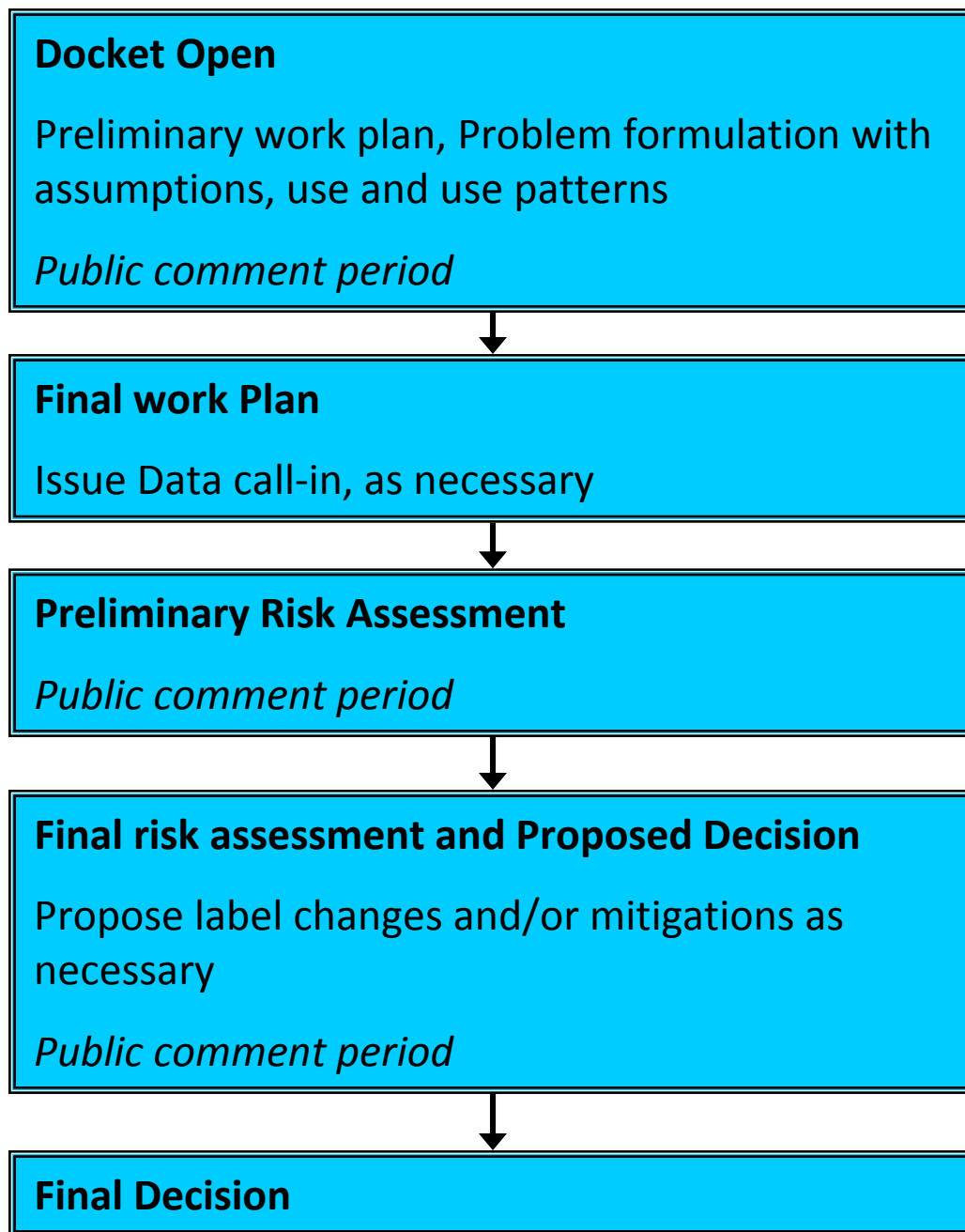
Comments

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.



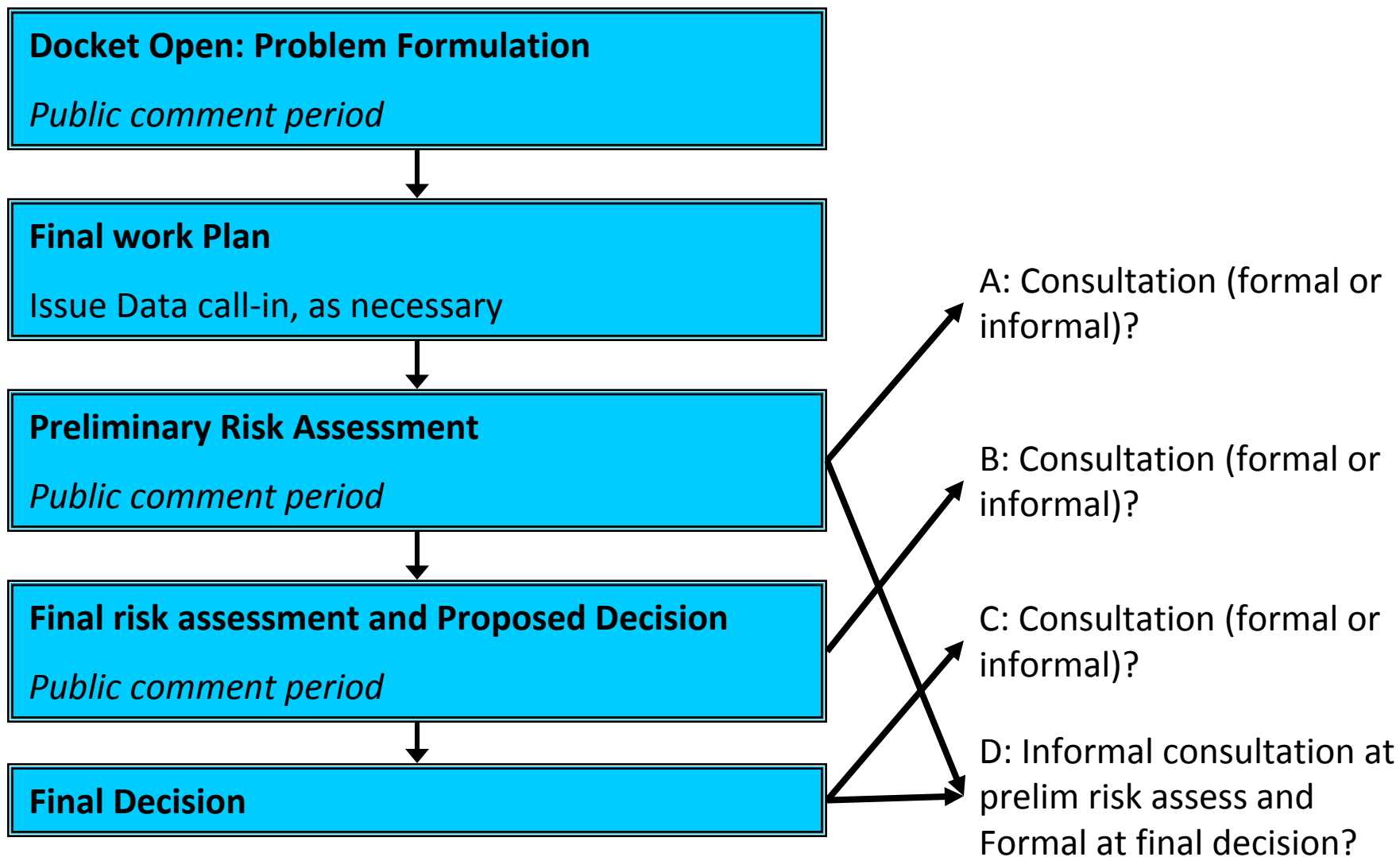


Comments

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 discussions
 - Registrant/Applicant provides Services (via EPA) with assessment or other relevant information / data, as appropriate
- o Consultation should be conducted on complete effects determinations/biological assessment, which allows for:
 - Stakeholder comments 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)
 - Best use of Services resources

Consultation Options/Recommendations

- o EPA and the Services interact throughout the process, early and often
 - Interagency interactions should be part of normal operations (e.g., MOU)
 - Need to obtain and exchange relevant information
- o Use informal and formal consultations as needed for regulatory decisions
 - Outreach on species location, other information particularly needed during public comment period for EPA Preliminary Risk Assessment

Consultation Options/Recommendations

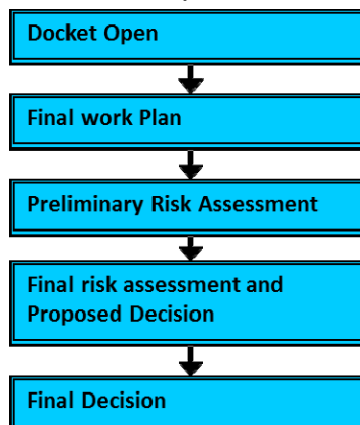
- o EPA makes maximum use of the Counterpart Regulations (2004)
 - Alternative consultation process for highly complex assessments and perhaps during the period of the NAS study/project
 - Section 402.46 of the counterparts survived the court challenges. This section allows EPA to:
 - Make an “effects determination.”
 - Make jeopardy, ITS, RPA and RPM judgments
 - But all subject to Services review
- o **Formal Consultation (if needed) should be at/near the end of the registration review process (Option C) - long term goal**
 - Important to consider all stakeholder input and decisions
 - Alternative options may be needed, especially during the next couple of years

Suggested 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

Benefits Suggestions Bring

- Thoroughly understood uses and use patterns
- Clearly defined and fully informed risk assessment assumptions
- Increased understanding of data and information needs and submission opportunities
- Integration of local information and best available data
- Full consideration of mitigation options
- 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
 - 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 formal consultation needed, it should be at or near end of the effects determination to ensure most complete assessment is considered, focus on the species of concern, maximize efficiency and utilization of resources
 - Information and input by the Services during the process is required, especially in timely provision of relevant species information

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