



Process and criteria for efficient assessment of pesticide risk to endangered species

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Developments in the ES assessment process for pesticides since last year's SETAC meeting

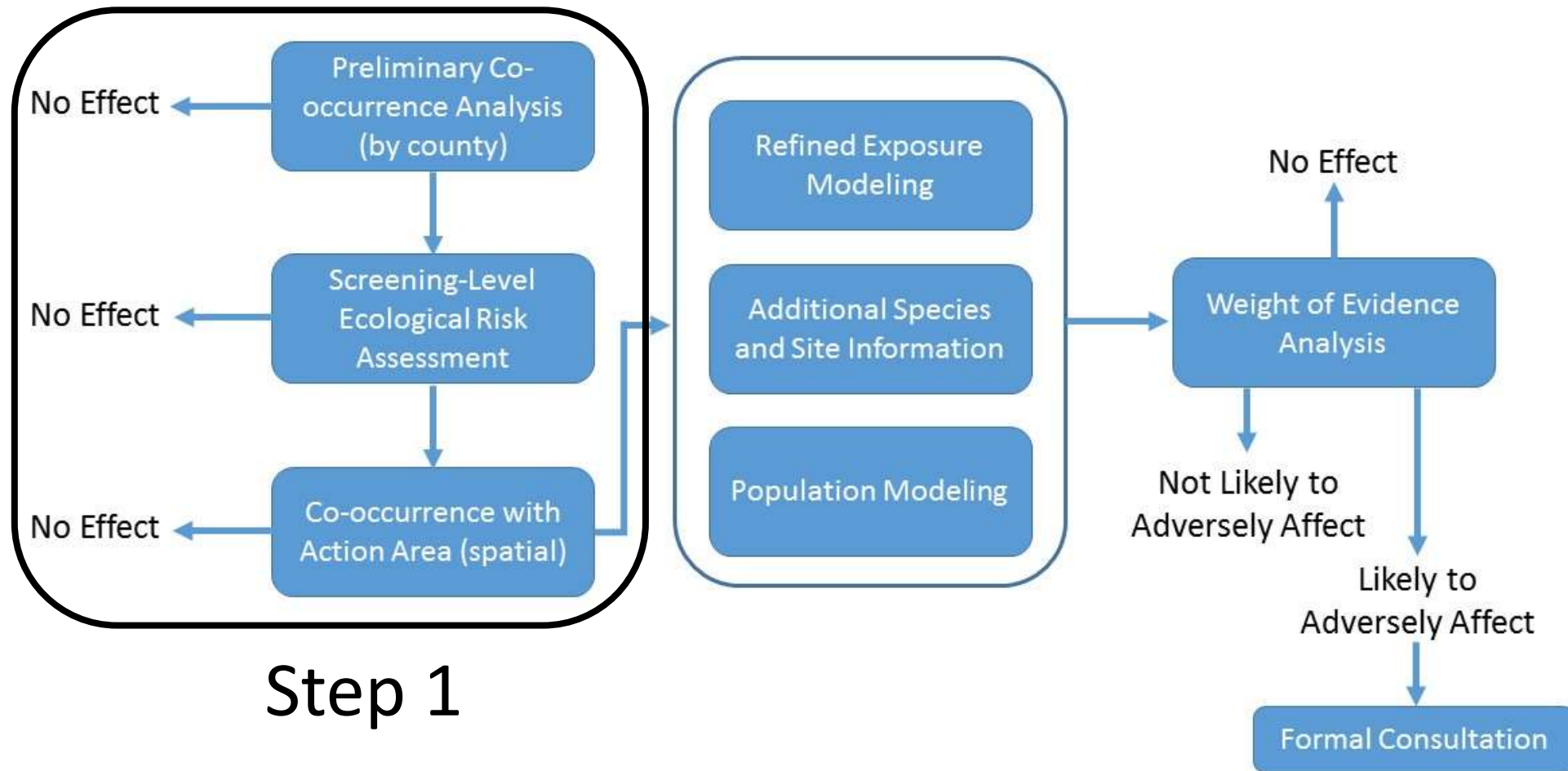
- Nov 2015 – SETAC presentations from agencies and registrants on OP assessments
- Dec 2015 – EPA releases preliminary OP BE (Biological Evaluation) documents
- April 2016 – EPA releases complete draft OP BE documents
- June 2016 – BE comment period ends
- June – November 2016: National discussion about Interim Approach as seen in OP BEs
 - ESA stakeholder workshop
 - CLA efforts
 - And now SETAC 2016!

NAS Panel (2013) suggested 3 steps in the ESA assessment and decision process

Process Step	Assessment Focus	Decisions
Step 1	Spatial co-occurrence of species with action area	No Effect (if no co-occurrence)
Step 2	Risk characterization based on effects endpoints, exposure estimates, and other information	No Effect, Not Likely to Adversely Affect, Likely to Adversely Affect (based on weight of evidence)
Step 3	Risk to populations	Jeopardy; mitigations

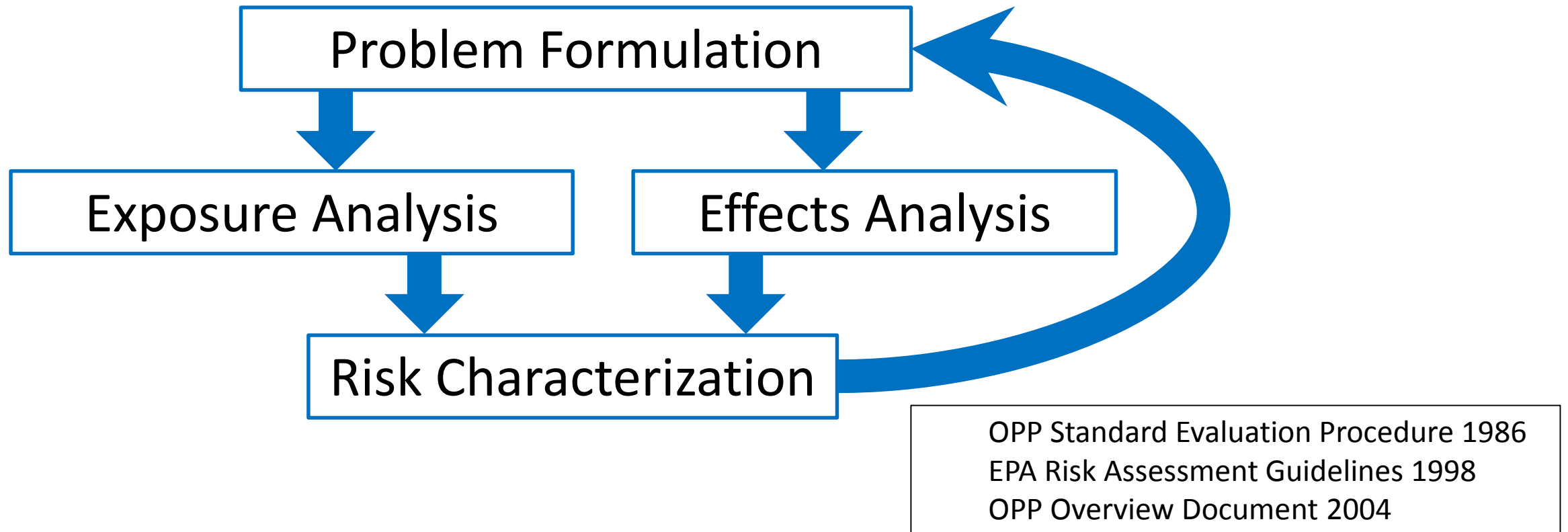
Policy needed: protection goals and risk criteria

Overview of the endangered species assessment process



Screening-level ecological risk assessment (SLERA)

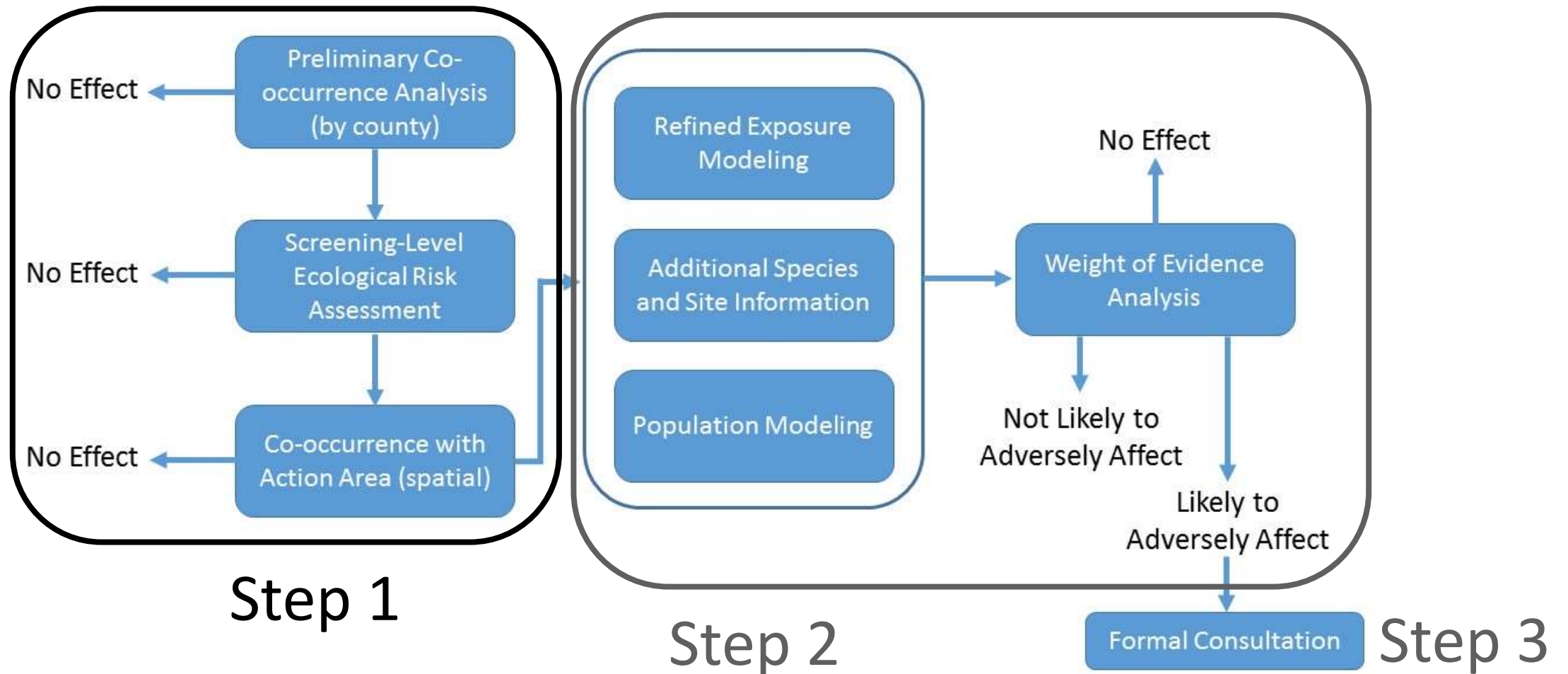
Functionally equivalent to standard FIFRA ecological risk assessment



Screening-level ecological risk assessment (SLERA)

- Effects analysis
 - Effects thresholds: 1-in-a-million mortality? Something else?
 - Surrogate species: closest taxonomic match between listed and tested species
- Exposure estimates (EECs)
 - EECs from standard EPA environmental fate models and application scenarios
 - What likelihood of occurrence do the standard models and scenarios represent? Typical? Reasonable worst-case? Extremely rare?
 - Standard scenarios for many uses represent extremely unusual situations, > 99th percentile
 - What is an acceptable likelihood of exposure?
 - Policy is needed on intended threshold for likelihood of EEC exceedance

Overview of the endangered species assessment process



Weight of evidence analysis blends information from multiple sources into a scaled decision metric.



The settings can be tuned to generate the most useful output – to maximize the ability to discriminate degrees of risk.

Weight of evidence analysis should generate a gradation of risk findings across species.

- Objective: accurately and efficiently distinguish species at greatest risk from those at less risk.
- ES assessment process should produce a gradation of findings so resources can be directed toward species at greatest risk.
- Only an extremely potent pesticide might be expected to pose a high risk to virtually all plants and animals, yet that was the finding of the 3 OP BEs.
- For proper use of resources, and for species protection, it is necessary to define a threshold for a reasonable expectation of harm versus a level not of concern – a policy issue.

Messages

- Assessment of pesticide risk to listed species on a national scale is a **conceptual and logistical challenge**.
- Because risk can never be entirely precluded, explicit **protection goals and objective scientific criteria** are a critical foundation for regulatory decisions.
- Risk criteria should address both **magnitude and likelihood** of potential exposure and effects.

Messages (continued)

- The process for assessing risk to listed species is more efficient if the first step includes an explicit **screening-level ecological risk assessment** based on standard approaches that have been used for decades to make pesticide registration decisions.
- The weight of evidence analysis must **discriminate levels of risk** efficiently across a large number of listed species so that resources can focus on species for which pesticide use is most likely to harm individuals and populations.

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COMMENTS, PLEASE?