Considerations for listed species within EPA's ecological risk assessment process

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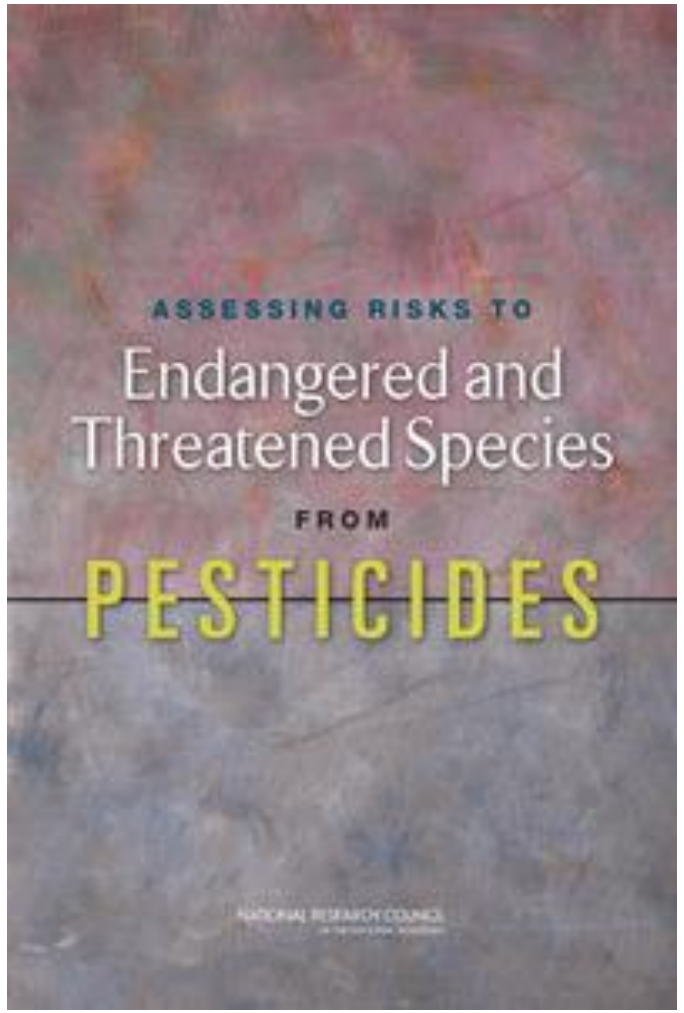
Regulatory Authority

- Endangered Species Act of 1973 (ESA, Section 7(a)(2)) requires *all Federal agencies to ensure that the discretionary actions they authorize, fund, and carry out are not likely to jeopardize federally listed threatened or endangered (listed) species or destroy or adversely modify designated critical habitat of such species*
- Consultation with U.S. Fish and Wildlife Service (USFWS) and NOAA National Marine Fisheries Service (NMFS), herein "the Services"
- EPA must ensure their actions will not jeopardize threatened or endangered (listed) species.
  - Federal Insecticide, Fungicide, Rodenticide Act (FIFRA)
  - Clean Water Act (CWA)
  - Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA/Superfund)
  - Resource Conservation and Recovery Act (RCRA)

NASEM 2013 Pesticide ESA Review

- Sponsored by EPA, FWS, NOAA, & US Department of Agriculture (USDA)
- Scope of review: Examine scientific and technical issues related to determining risks to species that are listed under the ESA posed by pesticides that are registered under FIFRA.
- Inter-Agency workshops (2013-2016) to develop interim methods to address review findings
  - Focus on 3-step process
  - Consistency across EPA Program Offices & the Services
  - Transparency of new methodologies
  - Pilot chemicals: chlorpyrifos, malathion, diazinon

- EPA Biological Evaluation methodology: https://www3.epa.gov/pesticides/nas/revised/revised-method-march2020.pdf



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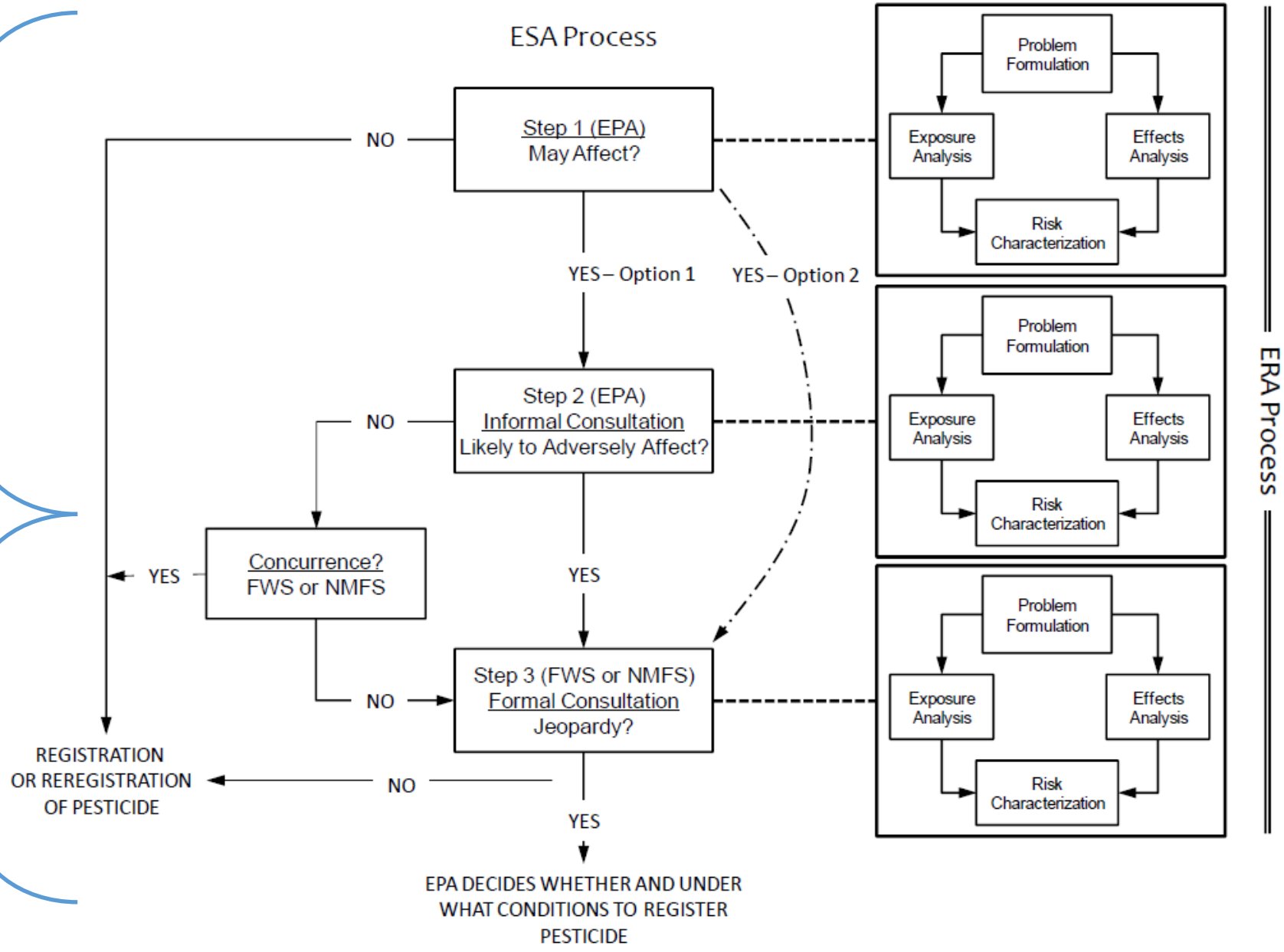
NAS 2013 ESA review – Focal Areas

- Develop a common approach used by all parties
- Assessments conducted using the best available data available
  - Document strategies for data search and retrieval
  - Quality
  - Transparency
  - Relevance
- Exposure: where, when
- Effects: sublethal, indirect, cumulative
- Risk characterization: integration of exposure and effects

3-Step ESA Risk Assessment Process

Biological Evaluation (BE): Conducted by EPA OPP, OW, Regions

Biological Opinion (BioOp/BO): Conducted by Services



NAS 2013 ESA Review: Exposure

- Includes breakdown products of toxicological significance
- Estimate concentrations to which species might be exposed
- Chemical fate and transport models heavily relied upon
  - Recognize limitations and apply in appropriate context
  - Lack of models for open ocean
- Focus shifts with different Steps
  - Step 1 (EPA): Do the areas where the chemical will be used overlap spatially with the habitats of any listed species?
  - Step 2 (EPA): What are the relevant environmental compartments (e.g., water, soil), associated characteristics, locations (offsite transport?) and times/seasons in which exposure concentrations need to be estimated (time- and space- varying)?
  - Step 3 (Services): Develop quantitative estimates of pesticide concentrations and their associated distributions for the particular listed species and their habitats (site-specific, time-sensitive life stages).
- Additional considerations: reliable geospatial data and habitat delineation

NAS 2013 ESA Review: Effects

- Sublethal
  - Step 2: identify sublethal effects, concentration-response
  - Step 3: show how sublethal effects change survival or reproduction of the listed species, population viability analyses
- Indirect
  - E.g., impacts to prey, habitat
  - Challenge to quantify, often require complex models
- Cumulative
  - interact or accumulate over time and space
- Extrapolation
  - Interspecies
  - Across life stages
  - Endpoints (sub-organism/adverse outcome pathways -> populations)
- Species sensitivity ranges/distributions

NAS 2013 ESA Review: Risk Characterization

Risk: the probability of an adverse effect

- Risk Quotient (RQ) = exposure estimate/effects estimate
  - Does not estimate risk
  - Relies on a large margin between exposure and effects concentrations
  - NAS concluded: RQs are NOT scientifically defensible for listed species

- Probabilistic risk
  - Integrates uncertainties of exposure and effects
  - Probability distributions to quantify uncertainty
    - Sampling variability
    - Lack of knowledge
    - Measurement/model error
  - Risk is presented as a probability with associated uncertainty
  - Methodologies not standardized

Considerations under CWA

National Ambient Water Quality Criteria (AWQC) – US EPA Office of Water (OW)

- Listed species not explicitly considered for national aquatic life criteria (ALC)
- National criteria adopted by the states or used as starting point
- Chronic criteria historically based on EC20

Biological Evaluations under CWA

- EPA Regions develop BEs to evaluate proposed state or tribal water quality standards and lead consultation
  - OW supports technical development of effects assessment
  - Acute & chronic low effect thresholds (e.g., LC5, EC5) for listed species, compare to criteria
- If LAA, EPA may:
  - Conduct a refined exposure assessment to evaluate the assumption listed species will be continually exposed to criteria levels
  - Work with a state/tribe to revise the proposed water quality standard to be based on the sensitive listed species EC5.
  - Formally conclude LAA and submit the BE to the Services (formal consultation)
    - Services determine if the proposed action will jeopardize the continued existence of listed species
    - No jeopardy may be found based on limited exposure or because effects do not result in population-level effects

Considerations under CWA

- OW has been developing effect assessments following a working draft internal methodology that follows the fundamentals described in the 2013 NAS ESA Report.
- Biggest challenges
  - Exposure duration and concentrations
    - Assumptions of continuous exposure, which is typically not the case
  - Surrogate species representativeness for data limited chemicals
  - Estimation tools do not provide chronic effects
    - Chronic criteria drives “on the ground” impacts

Considerations for NASEM Committee

- Direct exposure to listed species/geographic overlap
- Evaluation of surrogate effects data
- Degradation of critical habitat
- Indirect effects
- Uncertainties
- Imperiled groups*: e.g., coral, amphibians, freshwater mussels

*Imperiled taxonomic groups may have multiple species listed under ESA and the group as a whole experience widespread declines, even if not all species are officially listed

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Questions?