ESA Update

Anita Pease, EPA
Craig Aubrey, FWS
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Today’s Topics

- Status of ESA-related Activities
- April 2015 ESA Stakeholder Meeting
- Challenges and Perspectives
National Academy of Sciences Report

- Released on April 30, 2013
- Developed in response to a joint request by EPA, NMFS, FWS, and USDA
- Recommended 3-step process that integrates ecological risk assessment methods with ESA Section 7 consultations
3-Step Approach: ESA Consultation and Ecological Risk Assessment

**Step 1**
- May Affect?
  - No
  - Yes

  **Step 2**
  - Likely to Adversely Affect?
    - No
    - Yes
      - Concurrence?
        - Yes
        - Registration or reregistration of pesticide
          - EPA decides whether and under what conditions to register pesticide
        - No
          - No
            - Exposure Analysis
              - Risk Characterization
                - Problem formulation
                  - Exposure Analysis
                    - Response Analysis
                      - Risk Characterization
                        - Problem formulation
                          - Exposure Analysis
                            - Response Analysis
                              - Risk Characterization
                                - Problem formulation
                                  - Exposure Analysis
                                    - Response Analysis
                                      - Risk Characterization
                                        - Problem formulation
                                          - Exposure Analysis
                                            - Response Analysis
                                              - Risk Characterization
                                                - EPA [BE]

    - No
      - Yes
        - FWS and NOAA [BiOp]
Goal: unified interagency approach with agreement on process across all phases

“Shared” agency approaches

All agencies open to change in risk assessment methodologies

Once vetted, day-forward and iterative approach based on real-world experience

Streamlined process
ESA Timeline

- April 2013: NAS report released
- Three interagency workshops:
  - August 2013, May 2014, and November 2014
- Four stakeholder workshops:
  - April 2014: Feedback on interim approaches
  - October 2014: Interagency presentations and more stakeholder feedback
- Settlement agreements on ESA-litigation
- Multiple stakeholder presentations
Status of Ongoing Work

- First national-level pesticide consultations
- Collaborative effort among EPA, NMFS, FWS, and USDA
- Consistent with interim approaches based on the NAS report recommendations
- The three pilot chemicals are:
  - Chlorpyrifos
  - Diazinon
  - Malathion
- Draft Biological Evaluations (BEs) for three pilots in Fall of 2015
- Final Biological Opinions (BiOps) for three pilots in December of 2017
April 2015 Stakeholder Workshop

- Update on the Problem Formulation (PF) for the three ESA pilot chemicals
- Geospatial data on pesticide use patterns and listed species range maps
- Risk hypothesis and weight-of-evidence (WOE) approach
- Step 2 analysis:
  - Aquatic analysis: shortnose sturgeon
  - Terrestrial analysis: Kirtland’s warbler
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- Update of the PF for three ESA pilots
  - Description of the Federal Action under ESA
    - Product labels of all pesticide products containing the pesticide being assessed
    - Seeking label clarification of use sites that can be anywhere
  - Pesticide Active Ingredient Information
    - Mode and mechanism of action, fate overview and degradates of concern
  - Conceptual models
  - Analysis plan
    - Step 1 - “May affect” or “no effect” - based on co-occurrence of species range with pesticide use
    - Step 2 - NLAA or LAA
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- Geospatial data
  - Needed for Steps 1-3 of the analysis

- Pesticide Use Sites:
  - Agricultural uses: Cropland Data Layer (CDL) and National Agricultural Statistic Service (NASS) census levels
  - Non-ag uses: forestry, nurseries, mosquitocides

- Listed Species Range Maps:
  - NMFS species provided to EPA (~100 species)
  - FWS using phased approach to refine and deliver data
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- Risk Hypothesis (RH) and WOE Approach
  - RH = is it likely that fitness of an individual of a listed species and/or the primary and biological features (PBFs) of designated critical habitat will be adversely affected by pesticide x according to registered labels?
  - Various lines of evidence are assigned weights based on confidence in data using criteria
    - Exposure data: relevance and robustness
    - Effects data: biological relevance, species surrogacy, and robustness
  - Compare exposure concentration data with effects data to establish overlap
  - Interagency teams are currently developing the WOE process
    - Approach to be applied and revised based on lessons learned from the pilot BEs
Challenges and Perspectives

- Aquatic modeling
  - ~2000 - 8000 modeling runs per chemical

- Terrestrial modeling
  - Need to account for 3 different sets of units (mg/kg diet, mg/kg BW, and lbs a.i./A)
  - Need to integrate existing terrestrial tools (T-REX, T-HERPs, AgDrift, and TerrPlant)

- Number of LAA/NLAA calls - 1,850 listed species, approx. 800 of which have designated critical habitat (CH)
Challenges and Perspectives

- Each Agency implements its statute, regulation, and policies
  - This is not a “culture”
  - Each organization is expected and required to carry out their mandates
- NAS report provided the roadmap
  - Gray areas require interpretation and judgement
- It’s a lot of work
  - It’s not one and done; additional analyses will be routine
  - Conclusions will change
Questions?