Update on Problem Formulations for the Three ESA Pilot Chemicals: Description and Scope of the Federal Action

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ESA Pilots

- Brief Background
- Description of the Action
- Summary of the Draft Problem Formulation

Brief Background

- First national-level pesticide consultations
- Collaborative effort among EPA, NMFS, FWS, and USDA
- Following the recommendations of the 2013 NAS (NRC) report
- The three pilot chemicals are:
  - Chlorpyrifos
  - Diazinon
  - Malathion

Brief Background

- ESA pesticide consultations will be conducted as part of registration review
- Registration Review – the EPA periodically reviews all pesticides to ensure they meet current standards for human health and environmental safety

Brief Background

- The consultation process involves:
  - EPA's risk assessment (*i.e.*, the Biological Evaluation) that serves as the basis for the Services' Biological Opinion






Brief Background

- The Biological Evaluation (BE) determines whether registered pesticides adversely affect individuals of listed species and their designated critical habitats
    - **Step 1** ["No Effect/May Effect" Determination]
    - **Step 2** ["Not Likely to Adversely Affect (NLAA)/Likely to Adversely Affect (LAA) Determination]

- The Biological Opinion (BiOp) determines whether registered pesticides result in 'jeopardy' for a listed species or 'adverse modification' of designated critical habitat
    - **Step 3** ["Jeopardy/No Jeopardy" Determination and "Adverse Modification/No Adverse Modification" Determination]

Description of the Federal Action

- The Federal Action under the ESA – encompasses the EPA's registration of the uses, as described by product labels, of all pesticide products containing the pesticide being assessed
- The Federal Action includes products registered under Section 3 (national labels), Section 24c (Special local need labels) and Section 18 (emergency exemptions)

Description of the Federal Action

- Label clarification(s)
  - For use sites that could be anywhere (*e.g.*, mosquito adulticide uses)
  - For annual application rates, minimum application intervals, and maximum number of annual applications allowed
  - Clarification of use site terms. (*e.g.*, fencerows/hedgerows; ‘wide area’)
  - Master use table

Description of the Federal Action

- Mitigation to minimize non-target, off-site exposure
  - Does the registrant plan to support all of the current uses?
  - Are there mitigation measures that can be implemented?
    - Drift reduction technology
    - Conservation practices
    - Rate reductions
    - Timing restrictions
    - Geographic restrictions
    - Buffers
    - Use restrictions

Description of the Federal Action

- Consideration of Existing Biological Opinions
- Usage Data
  - Usage data can inform risk characterization and exploration of mitigation options
    - What are the pesticide's major uses and in what areas?
    - What are typical application practices?

Description of the Federal Action

Mitigation measures and label clarifications are discussed and/or negotiated prior to and after the risk assessment phase with registrants during the registration review process

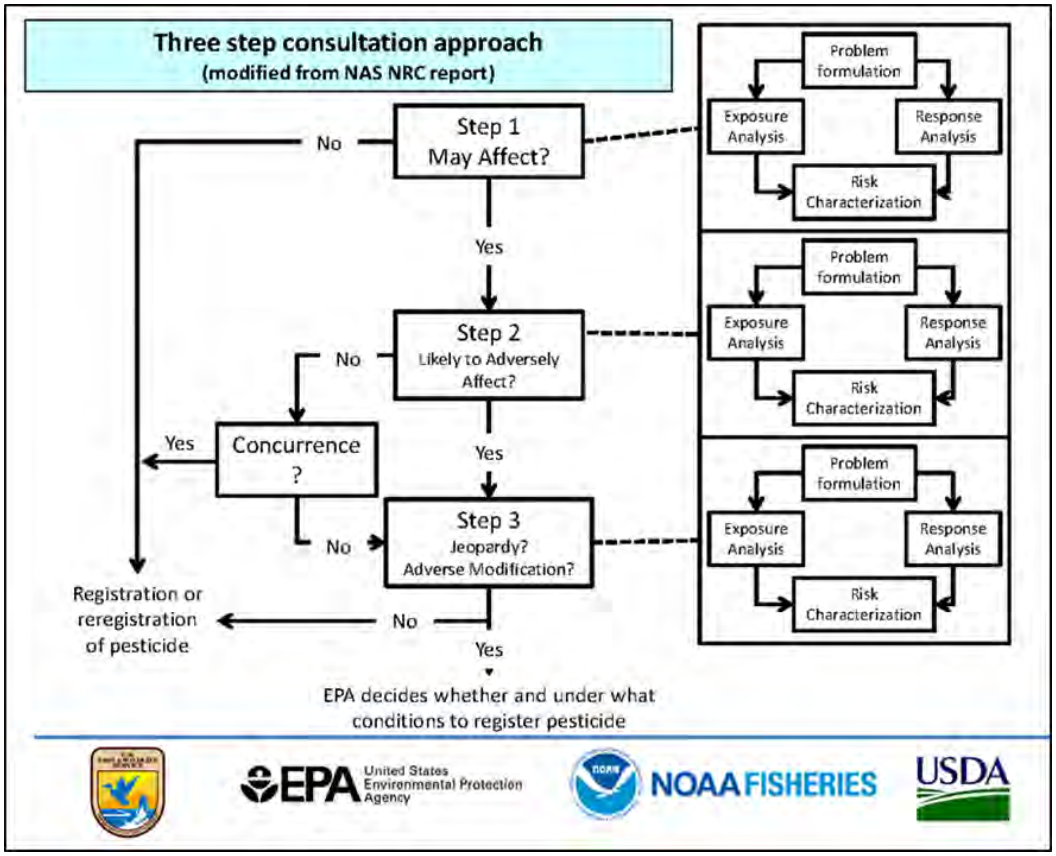
- Commitment letters to amend the labels enable the evaluation to include the mitigation measures
- Implementation of mitigation measures is achieved through label amendments subject to EPA approval

Description of the Federal Action

The Description of the Action is part of the Problem Formulation

Problem Formulation

- Purpose of the Problem Formulation (PF) – to outline the strategic framework and analysis plan for evaluating risk posed by the stressors of the action to listed species and their critical habitats



Problem Formulation (for the BE)

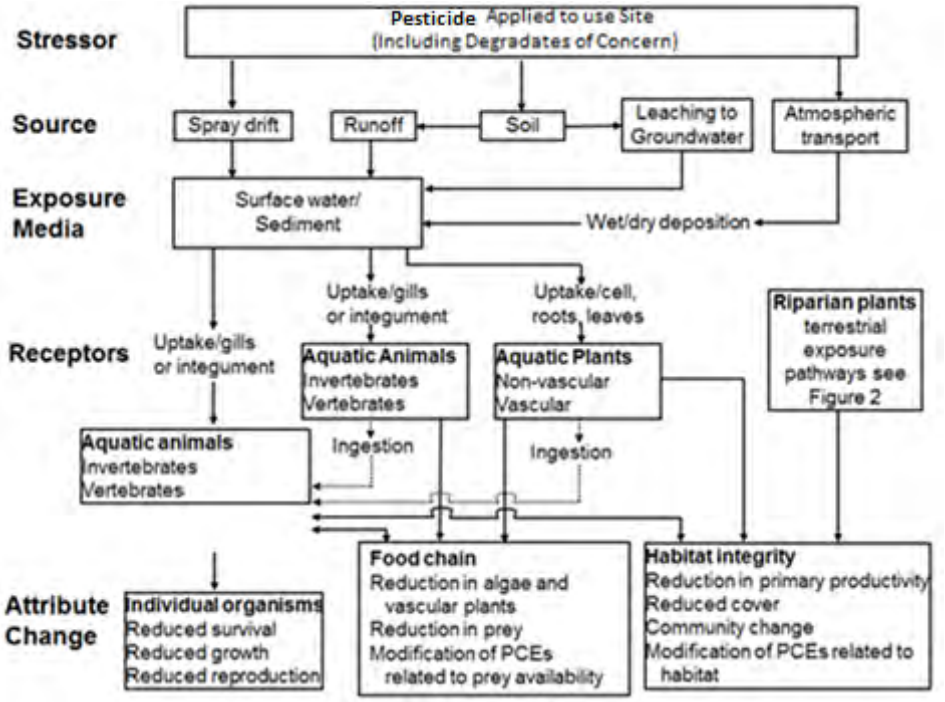
- Description of the Federal Action
- Pesticide Active Ingredient Information
- Conceptual Models
- Analysis Plan

Pesticide Active Ingredient Properties

- Mode and mechanism of action
  - Including the Adverse Outcome Pathway (AOP) if available
- Fate overview
  - General description of fate and transport characteristics
- Degradates of concern

Conceptual Models

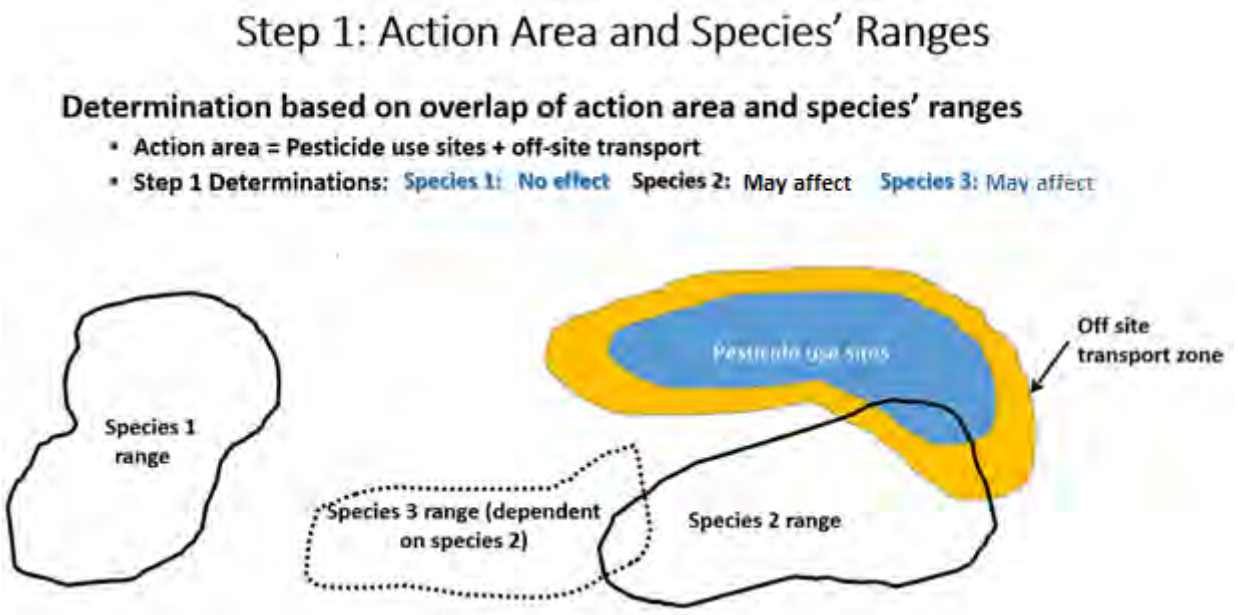
- Conceptual models for potential exposure routes
- Risk hypotheses
  - These will be discussed in a later presentation



Example conceptual model for aquatic organisms

Analysis Plan (Step 1)

- Step 1
  - "May Affect' determination will be made for any listed species and/or designated critical habitat that overlaps with the action area
  - Action area – "…all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action" (50 CFR §402.2)



The 'use footprint', the determination of the off-site transport, and the species range data will be discussed in later presentations.

Analysis Plan (Step 1)

- The action area is based on the lowest toxicity value for the most sensitive species in the environment that results in the farthest distance from the use site(s):
  - **Animals**:
    - Mortality - concentration that results in a 1-in-a-million chance of mortality [based on HC_{05} of SSD or most sensitive LC_{50}/LD_{50} (if an SSD cannot be derived)]
    - Sublethal Effects – concentration equal to the lowest NOAEC/NOAEL/EC_x value for an effect relatable to survival, growth, or reproduction and environmentally relevant exposure routes
  - **Plants**:
    - Concentration equal to the lowest NOAEC or EC_{05} value

Analysis Plan (Step 2)

- Weight-of-evidence approach
- Lines of evidence
- Estimating exposures (in aquatic and terrestrial habitats)
- Effects thresholds (direct and indirect effects)
- Effects arrays
- Incident data
- Mixture analysis
- Consideration of biotic and/or abiotic effects on toxicity

These will be discussed in later presentations (including the terrestrial and aquatic examples)

Thank You

Questions?