Interagency Approach for Implementation of National Academy of Sciences Report: Assessing Risks to Endangered and Threatened Species from Pesticides

NOAA FISHERIES

United States
Environmental Protection
Agency

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Agenda

- Background
- Process for addressing recommendations of National Academy of Sciences
- Interim approach
- Future work

Background

- USEPA, USFWS, NMFS and USDA requested that National Academy of Sciences (NAS) review existing methods for assessing risks of pesticides to listed species
- NAS Report (2013)
  - "Assessing risks to endangered and threatened species from pesticides"
    (http://www.nap.edu/catalog.php?record_id=18344)
  - Provided recommendations
    - Common approach
    - Best available data
    - Uncertainty
    - Exposure analysis
    - Effects analysis
    - Risk characterization

Process for addressing NAS recommendations

Multi-stage process involving interim approaches

1. Review NAS recommendations and identify methods that can be implemented in short (now), mid (6 months – 1 year), and long term (1+ years)
   - Overall, agencies agree with recommendations
2. Establish initial interim approach
   - Identifies overall approach for conducting listed species assessments for pesticides
3. Conduct current risk assessments using interim approach
   - Details of implementing interim approach will be worked out with initial risk assessments
4. Evaluate methods that may be applied to mid and long term activities
5. Revise risk assessment method based on lessons learned from application of scientific approaches

Process for addressing NAS recommendations

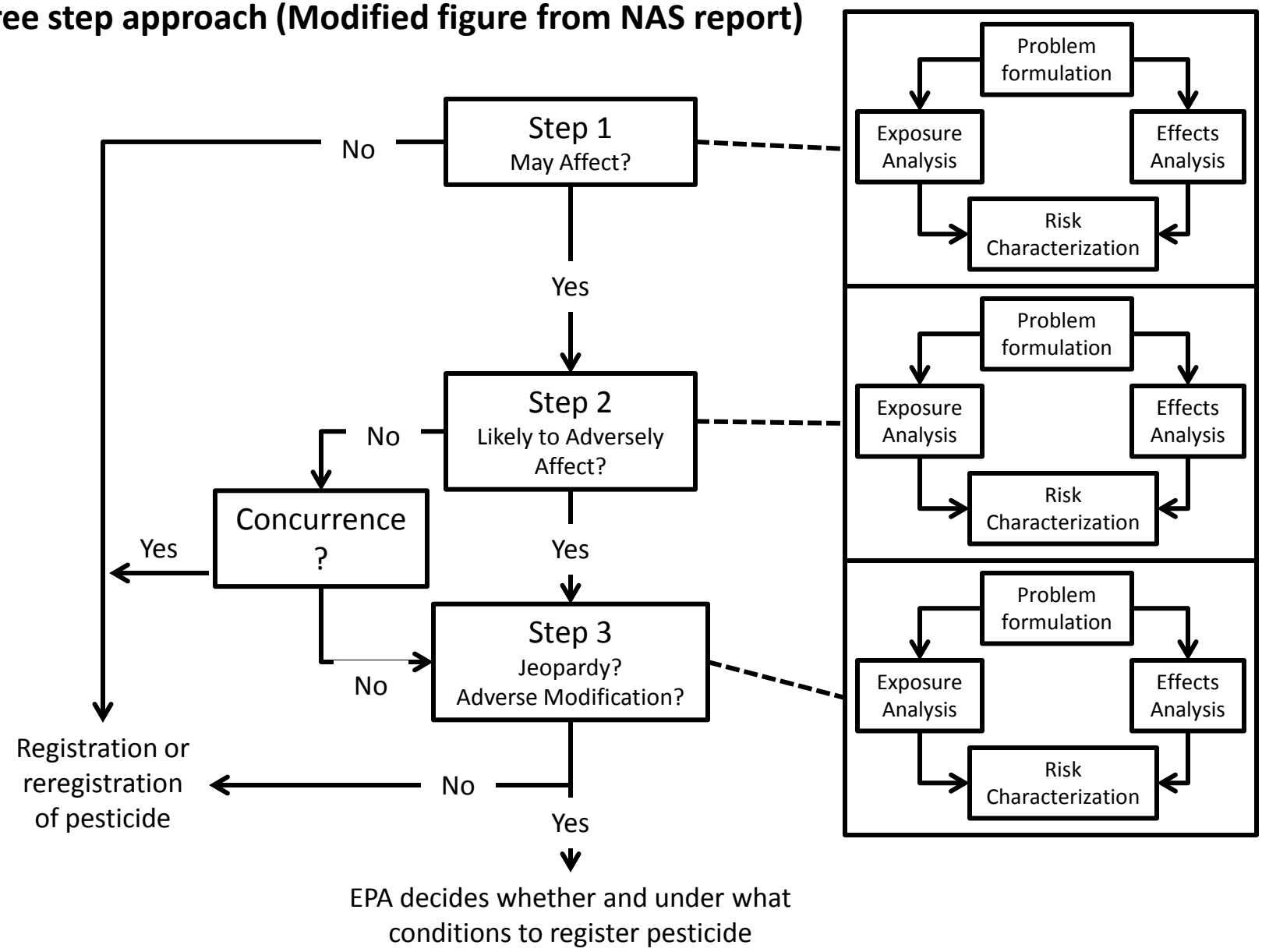
Interim Approach

- Incorporates many of the NAS recommendations
- Intended to be partnership among all agencies
- Agencies will communicate throughout process
- In the future, the process may change as we gain experience
- Develop streamlined process

Guiding principles for Interim Approaches

1. Quantitative when possible
2. Role of quantitative and qualitative data used will be explained
3. Agencies will develop systematic approach for using data (qualitative and quantitative)
4. Conclusions will be based on weight-of-evidence
5. Robust quantitative data will have priority in weight-of-evidence
6. Agencies will share draft findings and provide feedback

Three step approach (Modified figure from NAS report)



Interim Approach: Step 1

- Purpose: to determine whether use of a pesticide “may affect” a listed species
- Requires 2 sets of geospatial information
  - Species range (including critical habitat location)
  - Action area (Pesticide exposure area)
- Determination
  - “May Affect” if there is an overlap
  - “No Effect” if there is no overlap
- Based on NAS recommendation
  - “Step 1 would determine whether pesticide use and off-site transport areas overlap geographically with listed species ranges and their critical habitats”

Interim Approach: Step 1

Establishment of Action Area Map

- Pesticide Labels
  - Define use sites (e.g., cotton, residential, forestry, etc.)
  - Define application rates and methods for determining extent of off site transport
- Use site maps based on best available land cover data
  - National Land Cover Dataset (NLCD)
  - Crop Data Layer (CDL)
  - National Agricultural Statistics Service (NASS) information
- Off site transport area of concern
  - Maps established using exposure models and toxicity thresholds

Interim Approach: Step 1

Interagency approach: Establishing extent of off-site transport zone

Develop methods to identify the lowest concentration below which there are no biological effects of the pesticide. The lowest concentration will be used to determine the maximum extent of off-site transport.

The agencies will collaborate to produce an array of all best available toxicity information from available studies, using ECOTOX (http://cfpub.epa.gov/ecotox/) and other information made known to the agencies

Interim Approach: Step 1

Establishment of Action Area

- Off-site transport area of concern (continued)
  - Exposure off of the treated area is estimated using existing models
    - Terrestrial: AgDRIFT, T-REX, TerrPlant
    - Aquatic: PRZM/EXAMS
  - The farthest distance from the edge of the field where risks extend is based on the most conservative endpoints
    - Animals
      - Concentration (or dose) that would result in a chance of 1 in a million of causing mortality to an individual. This is calculated by using HC_{05} of species sensitivity distribution (SSD) of LC_{50} or EC_{50} values for taxa and representative slope. If SSD cannot be derived, most sensitive LC_{50} or EC_{50} will be used.
      - Concentration equal to NOAEC from chronic toxicity study. Endpoint may be based on growth, reproduction or other sublethal effect
    - Plants - Lowest of NOAEC or EC_{05}

Interim Approach: Step 1

Sublethal Effects Thresholds

- Animals - Lowest available NOEC or other scientifically defensible effect thresholds (ECx)
  - Endpoints generally from in vivo studies with whole organisms and linked to environmentally relevant exposures
  - Effects levels other than NOEC levels involve consideration of power of the concurrent NOEC and whether dose response information can establish a different threshold with a reasonable degree of confidence
  - Thresholds for a given taxa may, when supported by professional judgment, be based on sub-organism toxicity studies provided there is a linkage to environmentally relevant exposures that can influence survival, growth and reproduction

Interim Approach: Step 1

Differences between previous approach and interim approach

- The lowest toxicity value from agreed upon methods will be used to define the action area
- Services will provide EPA with maps of listed species ranges
- EPA will provide Services a map of all projected pesticide use areas
- Thresholds for establishing action area have changed
  - No longer based on RQs and LOCs
- Previous determinations did not systematically consider sublethal effects (besides growth and reproduction)
- Agencies will work together to establish action area

Interim Approach: Step 2

Purpose:

To determine whether uses of a pesticide (as allowed on labels) are “likely to adversely affect” (LAA) or “not likely to adversely affect” (NLAA) a listed species or their designated critical habitats

Interim Approach: Step 2

Exposure characterization

- Agencies will coordinate to develop exposure estimates
  - Use existing models (PRZM/EXAMS, TerrPlant, AgDRIFT and T-REX)
  - Assuming generic aquatic habitats relevant to groups of listed species
- General (ambient monitoring) will not be used to estimate exposure or assess models
- Targeted (field-scale) monitoring may be used if available

Interim Approach: Step 2

Effects characterization

- Construct risk hypotheses using species and toxicity information to evaluate impacts to listed species and habitat
- Assign direct and indirect toxicity information to appropriate risk hypotheses for listed species
  - Builds on dataset used for Step 1
  - thresholds for mortality, growth and reproduction and other sublethal effects, e.g., essential behaviors
  - Based on surrogate species
- Develop species sensitivity distributions when possible
- EPA's ECOTOX database and other sources will be used for toxicity data
- Develop arrays of toxicity data on a concentration gradient

Interim Approach: Step 2

Effects characterization (continued)

- Thresholds for direct effects and obligate relationships
  - Animals
    - Concentration (or dose) that would result in a chance of 1 in a million of causing mortality to an individual. This is calculated by using HC_{05} of species sensitivity distribution (SSD) of LC_{50} or EC_{50} values for taxa and representative slope. If SSD cannot be derived, most sensitive LC_{50} or EC_{50} will be used.
    - Sublethal effects
      - Direct effects based on NOAEC or ECx linked to survival or reproduction
      - Indirect effects based on LOAEC or other scientifically defensible effect thresholds (ECx) for growth or reproduction
  - Plants
    - Lowest of NOAEC or EC_{05}

Interim Approach: Step 2

Effects characterization (continued)

- Thresholds for indirect effects
  - Animals
    - Concentration (or dose) that would result in a decrease of 10% of individuals. This is calculated by using HC_{05} of SSD of LC_{50} or EC_{50} values and representative slope. If SSD cannot be derived, most sensitive LC_{50} or EC_{50} will be used.
    - LOAEC or other scientifically defensible effect thresholds (ECx) for growth or reproduction
  - Plants
    - Lowest of LOAEC or EC_{25}

Interim Approach: Step 2

Risk characterization: NLAA/LAA determinations

- Determinations will utilize a weight-of-evidence approach that will consider multiple lines of evidence including:
  - exceedance of agreed upon effect thresholds
  - exposure that may impair an individual's survival or reproduction
    - Sublethal effects linked to survival or reproduction (*e.g.,* growth and essential behaviors)
    - Indirect and habitat effects
  - exposure and response to mixtures (qualitative analysis)
  - frequency, magnitude, duration, and likelihood of exposure
  - Incident reports
  - Available mixture data
  - Species life histories

Interim Approach: Step 2

Differences between previous approach and interim approach

- Exposure:
  - Generic aquatic habitats (not just farm ponds)
  - Concentration over time (not just point estimates)
- Additional effects data will be considered
  - Additional effects considered in weight-of-evidence (previous assessments relied primarily upon most sensitive endpoints)
  - Previous determinations did not systematically consider sublethal effects (besides growth and reproduction)
  - Species sensitivity distributions will be created when possible
- Life histories of listed species will be considered
- Previous approach relied heavily upon RQs and LOCs
  - Based on survival, growth and reproduction (apical endpoints)
  - New approach will be based on thresholds (not RQs)

Interim Approach: Step 3

Purpose:

To determine if pesticide labels for an active ingredient do not cause jeopardy to listed species and their designated critical habitats are not modified

Interim Approach: Step 3

Considerations

- Weight-of-evidence
- Builds on information provided in step 2
- Population effects (using models when appropriate)
- Species Sensitivity Distributions
- Dose-response slopes

Future work: details to be worked out during the initial consultations

Step 1

- Need to compile species range maps in GIS format
- Need to develop approach for modeling off-site transport
- Need to select appropriate database(s)
- Need to address all use sites
  - *e.g.,* forests, rights of way, urban/residential
- Need to work out model parameterization

Future work: details to be worked out during the initial consultations

Step 2

- Exposure modeling
  - Need to establish “generic” habitats
  - Agencies need to developed specific approach for model inputs and assumptions and procedures for generating time and space varying estimates
- Effects characterization
  - Need to develop SSD methodology
  - Need to develop weight of evidence approach

Future work: details to be worked out during the initial consultations

Step 3

- Need to develop weight-of-evidence approach to evaluate population level responses
- Develop population models where appropriate information is available

Questions/Comments