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

November 15, 2013

Agenda

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

Background

- Agencies developed separate approaches for evaluating risks of pesticides
  - Different responsibilities, institutional cultures and expertise
- Previous attempts at resolving differences did not reach consensus

Background

USEPA, USFWS, NMFS and USDA requested that National Academy of Sciences (NAS) review existing methods for assessing risks of pesticides to listed species and provide recommendations for improving approach

Background

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

- 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

Shared Values

- Transparent
- Seamless and streamlined
- Replicable and predictable
- Protective of species and habitats
- Effective, efficient and engaging for all stakeholders

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

Process for addressing NAS recommendations: Public engagement

- Present Interim Approaches to Public
  - Share progress
  - Solicit feedback during the meeting
- Implement the Interim Approaches
  - Implement the interim approaches for biological evaluations, and use the public engagement process finalized in March 2013 to collect feedback from stakeholders (http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0442-0038)
- Manage Adaptively and Improve
  - Improve the interim approaches over time through experience and feedback until we reach our goal – final shared methods & streamlining consultation process

NAS Recommendations: Overarching themes

- The ecological risk assessment framework provides a common, scientifically credible approach that can form the basis for the consultation process

- The assessments completed by the agencies should build upon each other

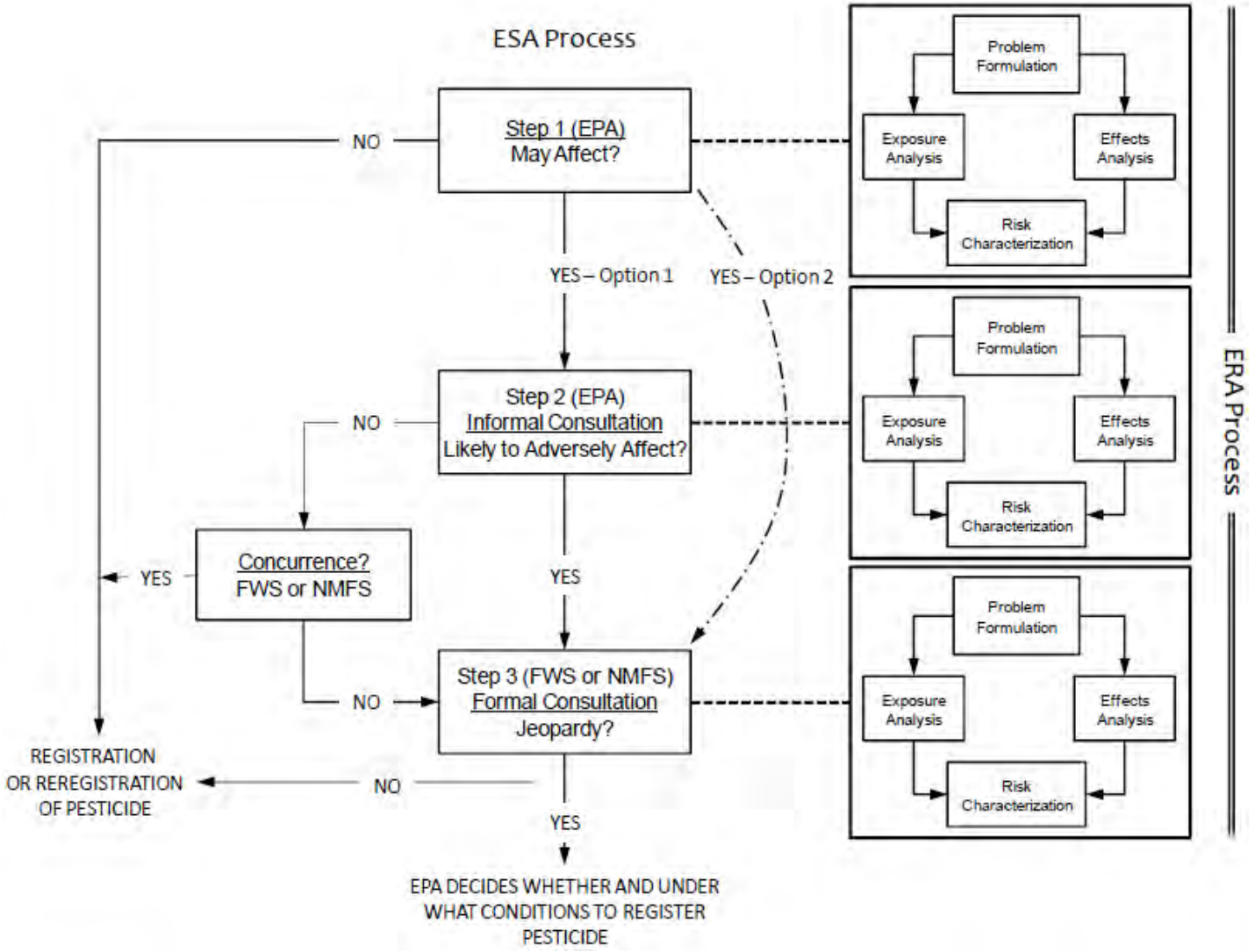
- Explicitly addressing uncertainty throughout the risk assessment is necessary

NAS Recommendations: common approach

- Risk assessment paradigm should be used by all agencies (problem formulation, exposure and effects analysis, risk characterization)
- Process should include 3 steps:
  1) May Affect/No effect,
  2) LAA/NLAA,
  3) Jeopardy/No jeopardy

  (note that scope is different for each step)
- Agencies should coordinate early, ideally at problem formulation stage

Three step approach (figure from NAS report)



NAS Recommendations: Risk Characterization

- Steps 2 and 3 should be based on probabilistic methods
- Risk quotients and uncertainty factors should not be used
- Uncertainty should be explicitly and quantitatively considered in exposure and effects analyses

NAS Recommendations: Exposure Analysis (modeling practices)

- Exposure analysis would vary with each step
  - Step 1 based on overlap of use site and species range
  - Step 2 based on pesticide concentrations over time and space in generic habitats
  - Step 3 based on refined models more specific to listed species
- Screening level models should not be used in Steps 2 and 3
- General monitoring studies should not be used to estimate pesticide exposure or to evaluate model performance
- Key processes need to be identified and parameter values well defined

NAS Recommendations: Exposure Analysis (geospatial data)

- Quantifiable ranges of species can be determined
- Existing data are sufficient for quantitative exposure analyses (landcover, topography, hydrography, meteorology, solar radiation, soils and geology)
- National Spatial Data Infrastructure compliant data can increase transparency and repeatability and reduce uncertainty.

NAS Recommendations: Exposure Analysis (uncertainties)

- Impact of inerts on active ingredient fate should be considered (qualitatively at least; quantitatively at best). QSARs may be used.
- When impact of environmental mixtures can not be quantified, they should be qualitatively described. Monitoring data may be useful in identifying relevant mixtures.
- Modeling estimates should be evaluated with targeted field studies
- More data are needed to characterize sorption and biodegredation

NAS Recommendations: Effects Analysis (sublethal, indirect and cumulative effects)

- Pesticide effects require quantification of effects to survival and reproduction of the species in the wild
- For Step 2, broad search should be conducted to identify sublethal effects data
- For Step 3, impacts of sublethal effects on survival and reproduction should be part of a population viability analysis. If this is not possible, a qualitative discussion of uncertainty should be included.
- Quantitative indirect effects should be included

NAS Recommendations: Effects Analysis (effects models)

- Spatial structure, temporal variability and density dependence should be incorporated into population models (probabilistic). When not possible, generic and deterministic approaches can be used.
- Effects to a population should be modeled using a range of concentrations reasonably encountered by the population
- Threshold levels (e.g., NOAEC and LC50) do not provide enough information for population-level risk assessments

NAS Recommendations: Effects Analysis (mixtures)

- Quantitative assessment of risks associated with mixtures requires extensive data. When these data are absent, a quantitative assessment cannot be conducted. Potential effects of mixtures should be characterized.
- Other chemicals are relevant when they modify the toxicity of the active ingredient when considering endpoints relevant to the assessed species
- Additivity can be assumed when assessing effects of mixtures
- Concentration addition may be used when chemicals have a common mode of action
- Synergistic interactions need to be considered when a synergist is as relevant concentrations

NAS Recommendations: Effects Analysis (Uncertainties)

- A range of sensitivities could be defined as an alternative to a single surrogate species
- Interspecies correlation analysis and species sensitivity distributions can be used
- Life histories of listed species should be considered

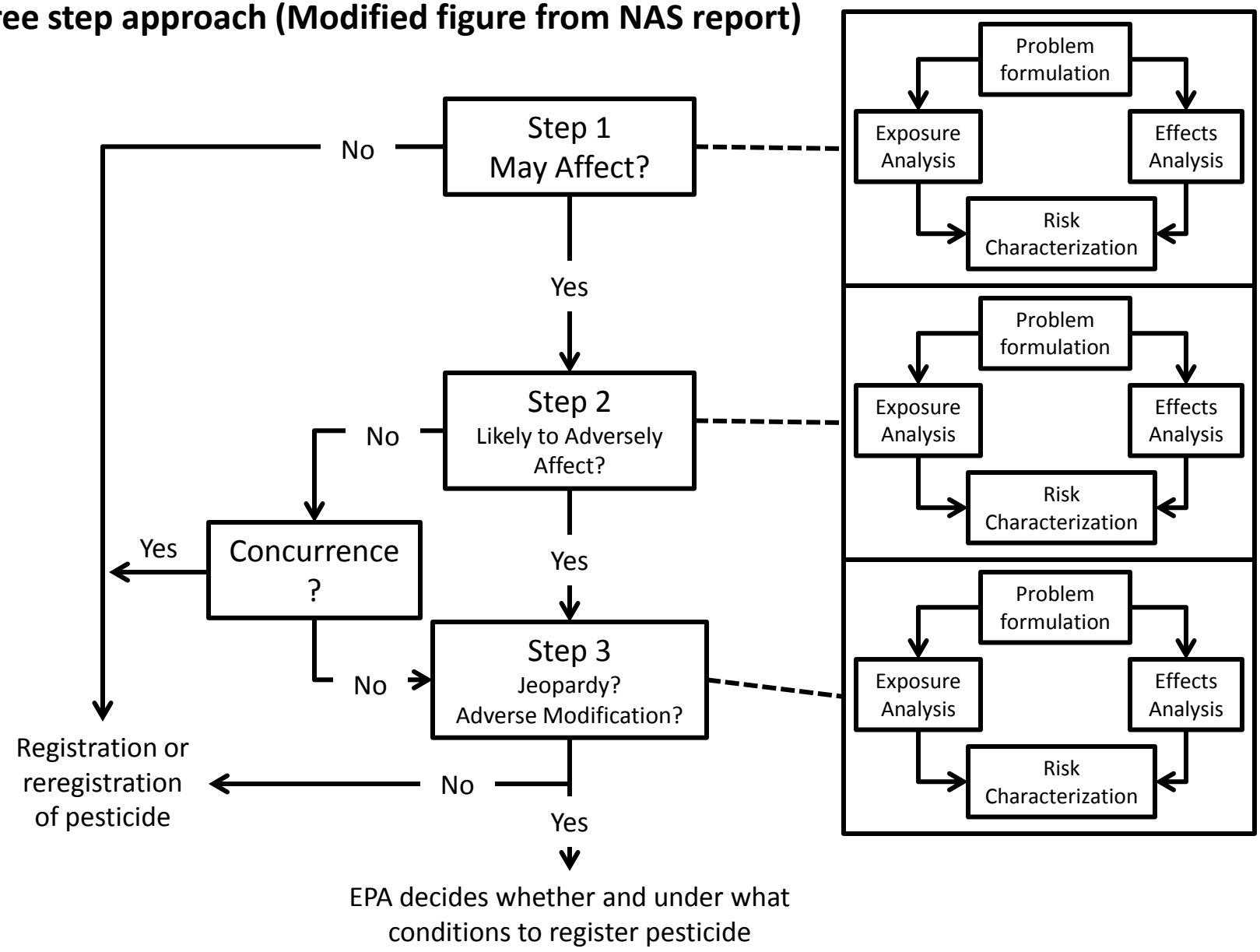
NAS Recommendations: Best Available Data

- Broad search should be conducted at beginning of process. Search should be documented
- Stakeholders should be included early in the risk assessment process so that they can contribute data
- Data should be screened for relevance and reviewed according to OMB criteria (objectivity, utility and integrity)
- Reviews should be documented in the risk assessment

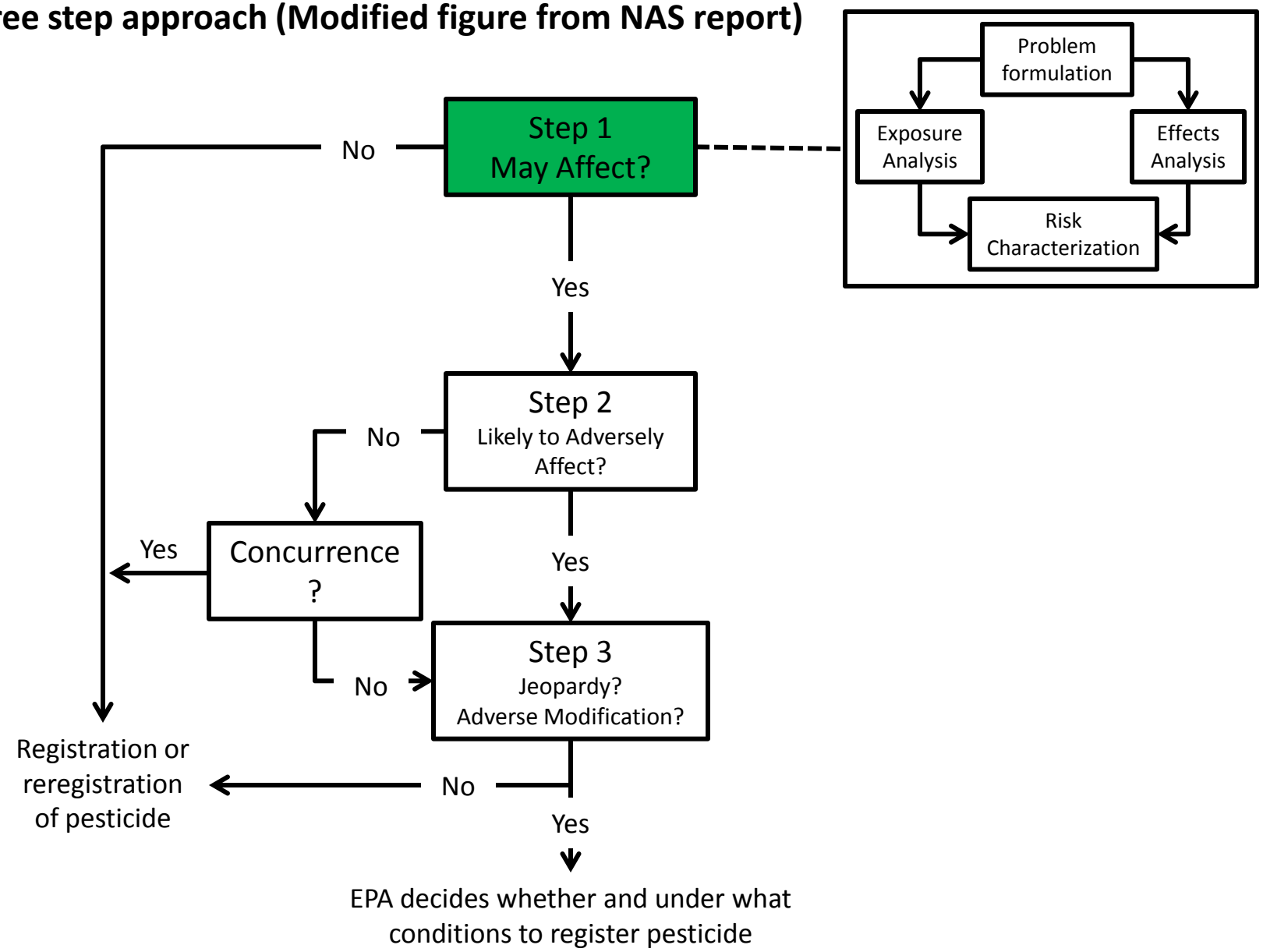
Interim Approach

- Three step process
- Immediately implements NAS recommendations relative to common approach
  - Three steps will build upon each other
  - Each step is based on risk assessment framework

Three step approach (Modified figure from NAS report)



Three step approach (Modified figure from NAS report)



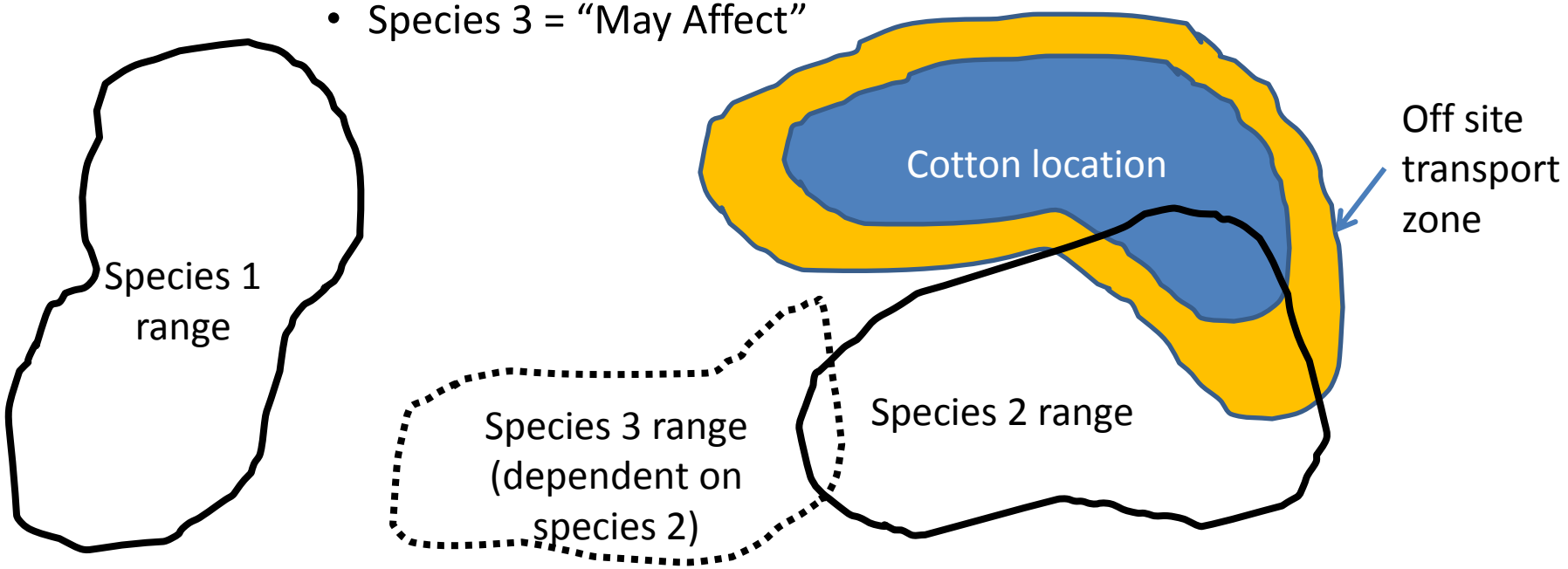
Interim Approach: Step 1

- 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

Example:

- Action = use of Pesticide x on cotton
- Determinations
  - Species 1 = “No Effect”
  - Species 2 = “May Affect”
  - Species 3 = “May Affect”



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.

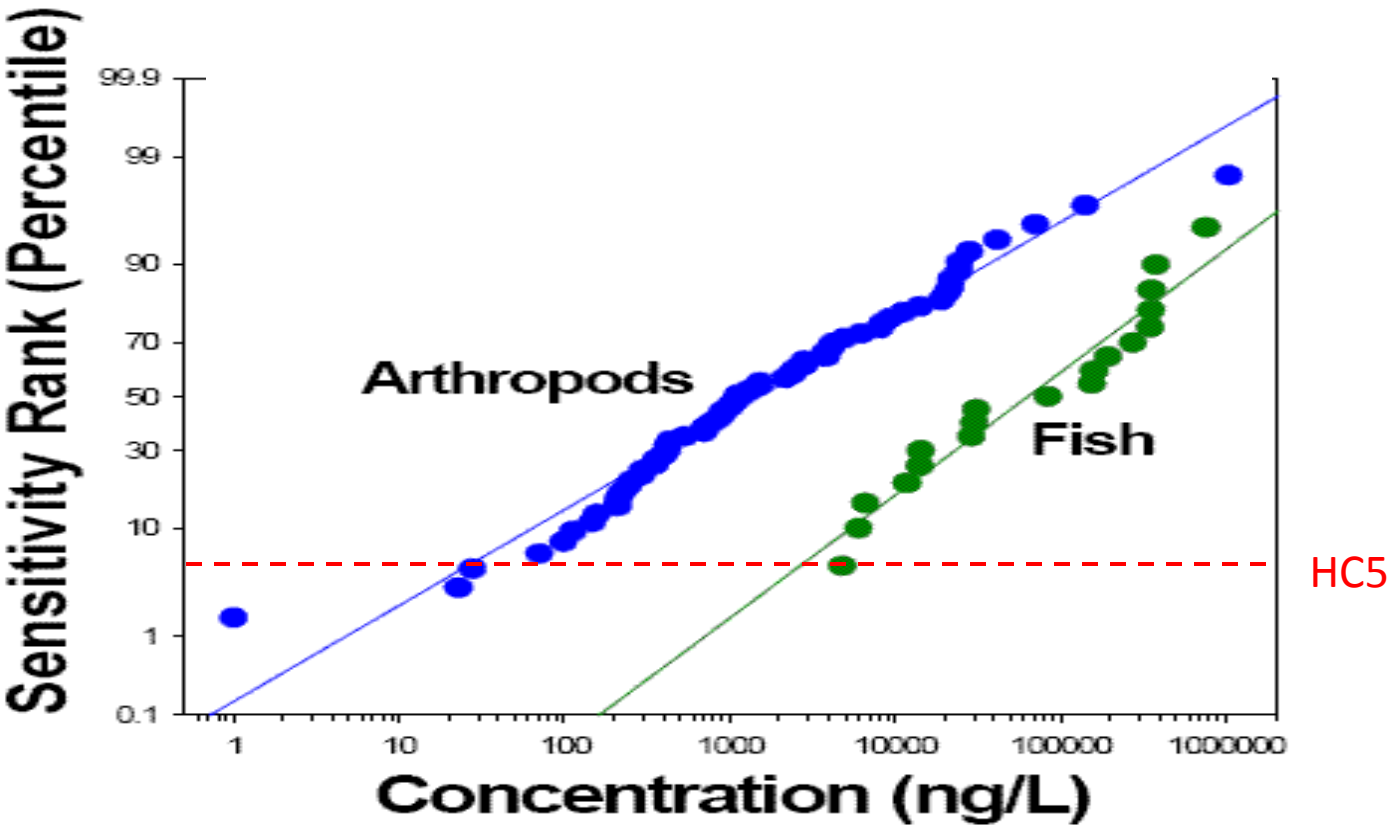
The agencies will collaborate to produce an array of all best available toxicity information from available studies, using ECOTOX (http://cfpub.epa.gov/ecotox/) and other information made known to the agencies

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



Species sensitivity distributions for aquatic arthropods and fish. Distributions composed of LC50 values.

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

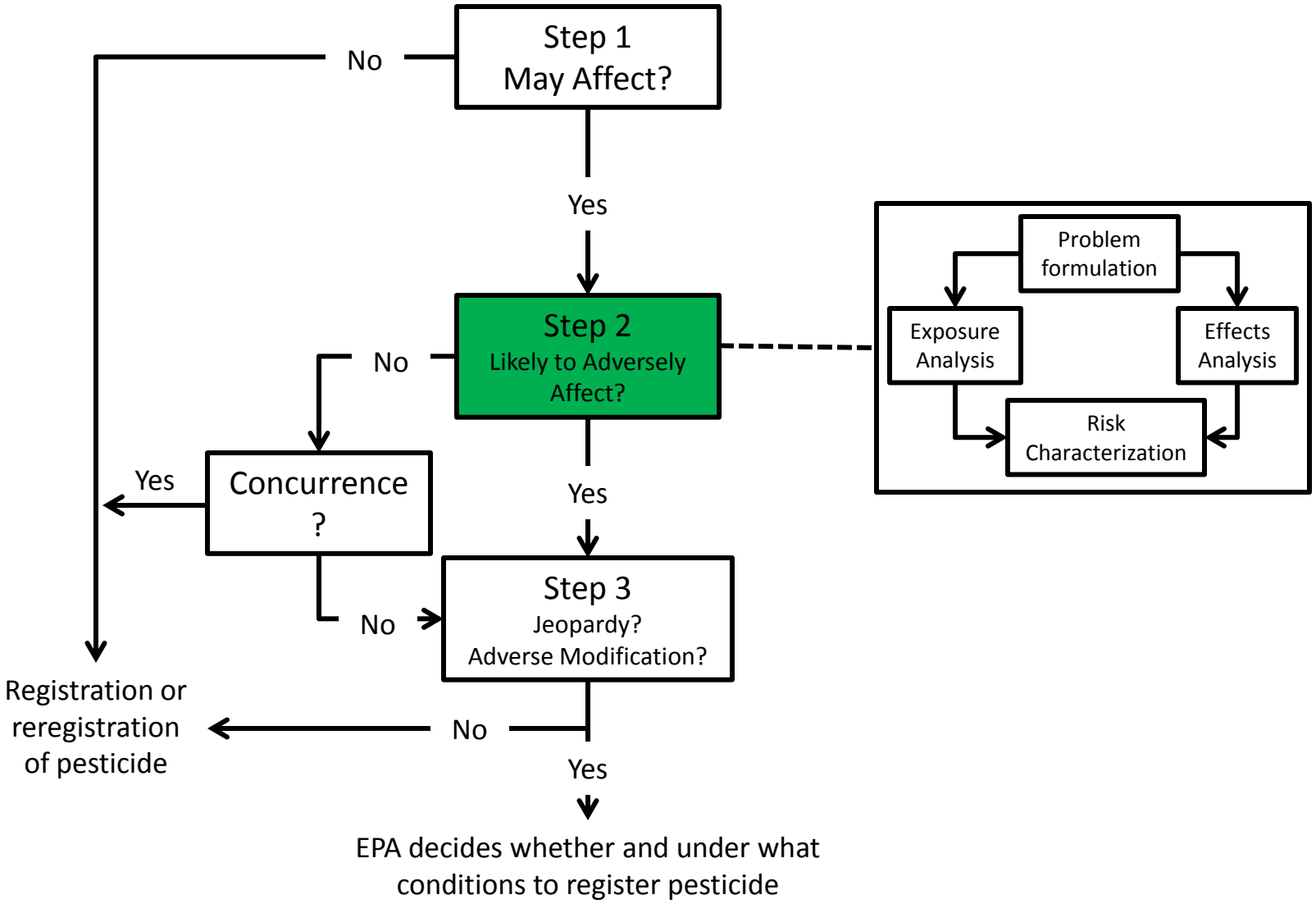
- The lowest toxicity value from agreed upon methods will be used to define the action area
- Services will provide EPA with maps of listed species ranges
- EPA will provide Services a map of all projected pesticide use areas
- Thresholds for establishing action area have changed
  - No longer based 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 1

Challenges

- Difficult to predict changes in land use that may affect future pesticide use
- Not all species ranges are available in GIS format
- Sub-county level location data are not practical or available for all listed species
- Some pesticide use sites are not well represented with existing geospatial data (e.g., rights-of-way)
- Difficult to consider qualitative data when establishing pesticide exposure area (e.g., mixtures)
- Toxicity of chemical mixtures not considered

Three step approach (Modified figure from NAS report)



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.
  - 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

Effects characterization (continued)

- Thresholds for sublethal effects (NLAA/LAA)
  - Animals
    - Direct effects based on NOAEC or ECx linked to survival or reproduction
    - Indirect effects based on LOEC or other scientifically defensible effect thresholds (ECx) for growth or reproduction

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 impairs an individual's survival or reproduction
    - Direct measures of survival and reproduction
    - Sublethal effects linked to survival and reproduction (e.g., growth, and essential behaviors identified through problem formulation)
    - Indirect and habitat effects
  - exposure and response to mixtures (qualitative analysis)
  - frequency, magnitude, duration, and likelihood of exposure

Interim Approach: Step 2

Risk Characterization

- Additional information evaluated in weight-of-evidence
  - Incident reports
  - Sublethal effects
    - In vivo and sub-organism level data considered in context of environmentally relavent exposure
  - Mixtures
    - Ambient monitoring data
    - Formulations (including adjuvants, other active and inert ingredients)
    - Tank mixtures
    - Environmental mixtures

Interim Approach: Step 2

Species-specific characteristics considered

- Direct effects to birds, mammals, terrestrial-phase amphibians and reptiles will account for diet and body weight in estimating exposure (T-REX model)
- Indirect effects based on
  - Diet
  - Relevant habitat (aquatic, terrestrial or wetland)

Interim Approach: Step 2

Addresses several NAS recommendations

- Risk Characterization
  - Approach is probabilistic when possible
  - RQs not used
  - Uncertainties associated with exposure and effects included
- Exposure Characterization
  - Exposure estimates for generic habitats based on modeling of authorized uses
  - Estimates account for variability in time and space (not simple point estimates)
  - Targeted monitoring data considered
- Effects Characterization
  - Survival, growth, and reproduction quantitatively assessed
  - Sublethal effects included
  - Surrogate species uncertainties explored when possible (SSDs)
- Best available data

Interim Approach: Step 2

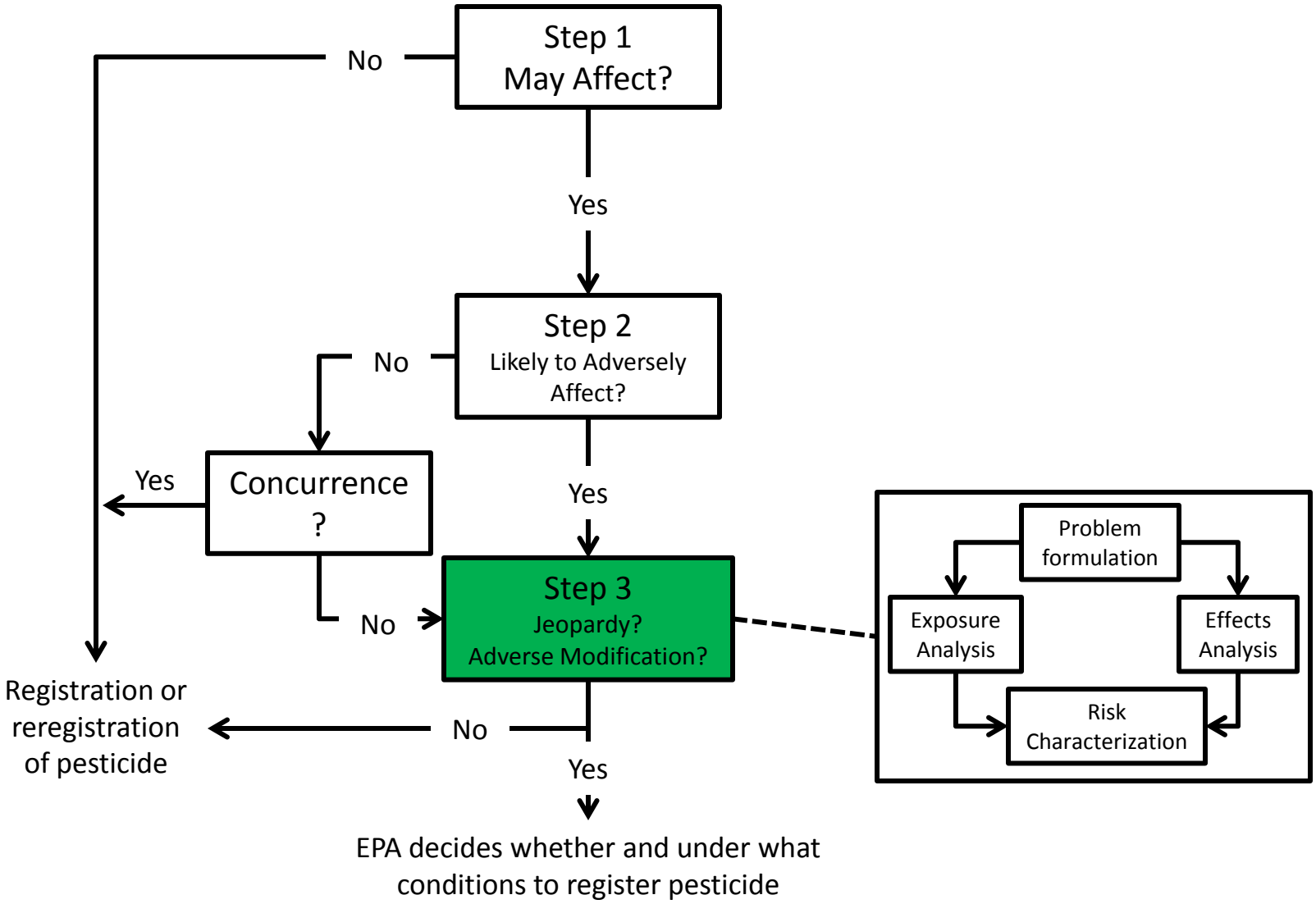
Differences between previous approach and interim approach

- 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 2

- Challenges
  - Exposure models not available for some application methods and transport pathways, e.g. animal application, runoff from residential/urban
  - Probabilistic methods not fully incorporated at this time
  - Spatially explicit modeling tools not yet available for regulatory use (e.g., Spatial Aquatic Model)
  - Linkages not yet established between all sublethal effects and survival, growth and reproduction
  - Areas of uncertainty not yet addressed
    - Exposure and response to mixtures
    - Surrogate species

Three step approach (Modified figure from NAS report)



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

Interim Approach: Step 3

- Differences between previous approach and interim approach
  - Previous approach included work of all 3 steps
  - New approach will build upon previous analyses (Steps 1 and 2)

- Challenge
  - Population models not available (at this time) for all species

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

Step 1

- Species Ranges
  - Need to compile species range maps in GIS format
  - Need to develop approach for modeling off-site transport
- Action area
  - Need to select appropriate database(s)
  - Need to address all use sites e.g., forests, rights of way, urban/residential, etc.
  - 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

Future work: mid term

- Common approach
  - Goal is to develop streamlined process for moving between steps
- Exposure modeling
  - Spatially explicitly modeling
- Increase understanding of relative sensitivity of test and listed species
  - Evaluate WebICE
- Sublethal effects
  - Need to identify effects that impact apical endpoints and make qualitative and quantitative linkages
- Refine geospatial data layers representing pesticide use sites
- Populate listed species database with biological information
  - e.g., diet, habitat, reproductive timing
- Determine if some pesticide uses are not of concern
- Ongoing documentation of evolving approaches

Future work: long term

- Develop database of species range information
  - Need to be sub-county resolution (when practical)
- Establish quantitative approach for assessing risks of mixtures
- Develop probabilistic risk assessment methods
- Create population models
  - Generic and specific

Questions/Comments